Patient agreement to systemic anti-cancer therapy (SACT)

AIDA (All- transretinoic acid and Idarubicin)

Hospital/NHS Trust/NHS Board:

_____

_____

Responsible consultant:

Name: _____

Job title: _____

Patient details

Patient's surname/family name:

_____

Patient's first name(s): _____

_____

Date of birth: _____

NHS number: _____
(or other identifier)

Special requirements:
(eg other language/other communication method)

_____

_____

_____

_____

Name of proposed course of treatment (include brief explanation if medical term not clear)

☐ AIDA - ATRA (All-transretinoic acid) or Tretinoin and Idarubicin chemotherapy for the treatment of acute promyelocytic leukaemia (APML).
☐ INDUCTION: ATRA taken orally on day 1 until haematologic complete response or for a maximum of 60 days. Idarubicin given intravenously on days 1,3, 5 & 7.
☐ 1st CONSOLIDATION: ATRA orally days 1-15. Idarubicin intravenously days 1- 4.
☐ 2nd CONSOLIDATION: ATRA orally days 1-15. Mitoxantrone intravenously days 1-5.
☐ 3rd CONSOLIDATION: ATRA orally days 1-15. Idarubicin intravenously only day 1.

Where will I have treatment?

☐ Outpatient ☐ Day unit/case ☐ Inpatient ☐ Other: _____

Statement of health professional

(to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in the hospital/Trust/NHS board's consent policy)

☑ Tick all relevant boxes

☐ I confirm the patient has capacity to give consent.

☐ I have explained the course of treatment and intended benefit to the patient.

The intended benefits (there are no guarantees about outcome)

☐ Prolong survival.

☐ Control symptoms, reduce transfusion needs and improve quality of life.

☐ Induction – therapy given in the acute state of the disease, aiming to shrink the tumour.

☐ Curative – to give you the best possible chance of being cured.

☐ Maintenance – therapy given on continuing basis, aiming to prevent disease flaring up and to control the symptoms.

☐ Disease control / Palliative – the aim is not to cure but to control the disease and reduce the symptoms. The aim is to improve both quality and quantity of life.

Statement of health professional

Patient identifier/label

You may have one or more of the side effects listed

Common side effects:

Affecting more than 10 in every 100 (>10%) people

- ☐ An increased risk of getting an infection from a drop in white blood cells – this makes it harder to fight infections and you can become very ill.
- ☐ **If you have a severe infection this can be life-threatening. Contact your doctor or hospital straight away if:**
  - **your temperature goes over 37.5°C or over 38°C, depending on the advice given by your chemotherapy team**
  - **you suddenly feel unwell (even with a normal temperature)**
- ☐ Thinning of the hair or hair loss, nausea (feeling sick), vomiting (being sick), dry nose, dry mouth, reduced appetite, sore mouth and ulcers, abdominal (tummy pain), diarrhoea, constipation, feeling tired and weak (fatigue).
- ☐ Vision and hearing problems including hearing loss, headaches, dizziness, rash, itching, pins and needles in hands and feet, chills, red colour urine (resolves 1-2 days after).
- ☐ Fast heart rate, breathlessness or breathing changes, pain (chest, bone), increased sweating, flushing, mood changes, feeling anxious, sad and confused, difficulty sleeping (insomnia), weight loss.
- ☐ Anaemia (low red blood cells), bruising or bleeding (low platelets); this may be prolonged and you may need a transfusion.
- ☐ Raised cholesterol and fat (triglycerides) levels, changes in liver, kidney function (monitored), inflammation of lips, pancreas.
- ☐ Tretinoin (ATRA) can cause increase pressure in the head. Symptoms may include double or loss of vision, feeling or being sick, dizziness, headaches, ringing in your ears and altered consciousness. Please contact your doctor or nurse.

Occasional side effects:

Affecting between 1-10 in every 100 (1-10%) people

- ☐ Heart problems (changes in the way the heart works with fluid build-up, shortness of breath, risk of a heart attack), changes in heart rates (low or high). You may need an ECG (electrocardiogram).
- ☐ Pain, redness, inflammation at the site of injection.
- ☐ Bleeding from the gut.
- ☐ Tretinoin (ATRA) can cause differentiation syndrome in the first month of treatment which can be life-threatening. Symptoms include:

Occasional side effects continued:

temperature, shortness of breath, rapid breathing, build up of fluid with weight gain. You may be treated with steroids and tretinoin withheld or discontinued.

Other risks:

- ☐ Idarubicin may leak out of the vein while it is being given (extravasation) and can damage the tissue around the vein. Tell the nurse straight away if you have any stinging, pain, redness or swelling around the vein. It's uncommon but important to deal with quickly.
- ☐ Increased risk of tumour lysis syndrome in some patients (when treatment destroys cancer cells too quickly for the kidneys to cope and leads to changes in blood tests). Rarely, dialysis may be needed. You may be prescribed medicines for prevention/ treatment.
- ☐ Before treatment you may have blood tests to check for viruses (Hepatitis B or C, HIV, or unusual infections). Treatment may weaken your natural defence (immune) system so infections like this may worsen or become active if you've had them before. You may have medicines to prevent or treat infection.
- ☐ Growth factors (GCSF) will be prescribed to maintain number of white cells to prevent infection. You may experience bone pain, headaches, red and itchy skin around the injection site.
- ☐ Late effects include a rare chance of a second cancer (years later) and problems with your heart (months later).
- ☐ Side effects of anti-sickness medication include diarrhoea, constipation, headaches.
- ☐ Changes in your memory, concentration or ability to think clearly. There can be many causes including your treatment, diagnosis or both.
- ☐ Cancer and its treatment can increase your risk of developing a blood clot (thrombosis), causing pain, redness and swelling in an arm or leg, breathlessness, chest pain. Tell your doctor straight away if you have any symptoms.
- ☐ Some anti-cancer medicines can damage ovaries and sperm. This may lead to infertility and/or early menopause (hot flushes, vaginal dryness).

Continue on to the next page

Statement of health professional

Patient identifier/label

Other risks continued:

- ☐ Some anti-cancer medicines may damage the development of a baby in the womb. It is important not to become pregnant or make someone else pregnant during treatment and for up to 7 months afterwards**.** Women of child bearing age will be tested for pregnancy before and during treatment. Use effective contraception throughout. Speak to your doctor or nurse.
- ☐ Complications of treatment can very occasionally be life-threatening and may result in death. The risks are different for every individual. Potentially life-threatening complications include those listed on this form, but other exceedingly rare side effects may also be life-threatening.

Statement of health professional

Patient identifier/label

Any other risks and information:

_____

_____

☐ I have discussed the intended benefit and risks of the recommended treatment, and of any available alternative treatments (including no treatment).

☐ I have discussed the side effects of the recommended treatment, which could affect the patient straight away or in the future, and that there may be some side effects not listed because they are rare or have not yet been reported. Each patient may experience side effects differently.

☐ I have discussed what the treatment is likely to involve (including inpatient/outpatient treatment, timing of the treatment, blood and any additional tests, follow-up appointments etc) and location.

☐ I have explained to the patient, that they have the right to stop this treatment at any time and should contact the responsible consultant or team if they wish to do so.

☐ I have discussed concerns of particular importance to the patient in regard to treatment

(please write details here): _____

_____

Clinical management guideline/Protocol compliant (please tick):

☐ Yes ☐ No ☐ Not available If No please document reason here:

_____

The following written information has been provided:

☐ Information leaflet for Tretinoin (ATRA), Idarubicin and Mitoxantrone

☐ 24 hour alert card or SACT advice service contact details

☐ SACT treatment record (cruk.org/treatment-record)

☐ Other, please state: _____

_____

Health professional details:

Signed: _____

Date: _____

Name (PRINT): _____

_____

Job title: _____

_____

Statement of interpreter **(where appropriate)**

Interpreter booking reference (if applicable):

I have interpreted the information above to the patient to the best of my ability and in a way in which I believe they can understand.

Signed: _____ Date: _____

Name (PRINT): _____ Job title: _____

Statement of patient

Patient identifier/label

Please read this form carefully. If your treatment has been planned in advance, you should already have your own copy of the form which describes the benefits and risks of the proposed treatment. If not, you will be offered a copy now. If you have any further questions, do ask – we are here to help you. You have the right to change your mind at any time, including after you have signed this form.

☐ I have had enough time to consider my options and make a decision about treatment.

☐ I agree to the course of treatment described on this form.

A witness should sign below if the patient is unable to sign but has indicated their consent. A person with parental responsibility will be asked to sign for young people under the age of 16 years.

Patient's signature: _____

Name (PRINT): _____ Date: _____

Person with parental responsibility/witness' signature: _____

Name (PRINT): _____ Date: _____

Copy accepted by patient: yes / no (please circle)

Confirmation of consent

(health professional to complete when the patient attends for treatment, if the patient has signed the form in advance)

On behalf of the team treating the patient, I have confirmed that the patient has no further questions and wishes the course of treatment/procedures to go ahead.

Signed: _____

Date: _____

Name (PRINT): _____

Job title: _____

Important notes: (tick if applicable)

☐ See also advance decision to refuse treatment

☐ Patient has withdrawn consent (ask patient to sign and date here)

Signed: _____

Date: _____

Further information for patients

Contact details (if patient wishes to discuss options later):

_____

Contact your hospital team if you have any questions about cancer and its treatment.

Cancer Research UK can also help answer your questions about cancer and treatment. If you want to talk in confidence, call our information nurses on freephone 0808 800 4040, Monday to Friday, 9am to 5pm. Alternatively visit cruk.org for more information.

These forms have been produced by Guy's and St. Thomas' NHS Foundation Trust as part of a national project to support clinicians in ensuring all patients are fully informed when consenting to SACT.

The project is supported by Cancer Research UK. This does not mean you are taking part in a clinical trial.

CANCER RESEARCH UK

Guidance for health professionals

(to be read in conjunction with the hospital's consent policy)

Patient identifier/label

What a consent form is for

This form documents the patient's agreement to go ahead with the treatment you have proposed. It is not a legal waiver – if patients, for example, do not receive enough information on which to base their decision, then the consent may not be valid, even though the form has been signed. Patients are also entitled to change their mind after signing the form, if they retain capacity to do so. The form should act as an aide-memoir to health professionals and patients, by providing a checklist of the kind of information patients should be offered, and by enabling the patient to have a written record of the main points discussed. In no way should the written information provided for the patient be regarded as a substitute for face-to-face discussions with the patient.

The law on consent

See the following publications for a comprehensive summary of the law on consent. Consent: Patients and doctors making decisions together, GMC 2020 (gmc-uk.org/guidance). Reference guide to consent for examination or treatment, Department of Health, 2nd edition 2009 (doh.gov.uk).

Who can give consent

Everyone aged 16 or over is presumed to have the capacity to give consent for themselves, unless the opposite is demonstrated. For young people, it is good practice to involve those with parental responsibility in the consent discussions, unless specifically asked not to. A person with parental responsibility must sign this form for a child or young person under the age of 16. Such patients should be given the opportunity to 'assent' to treatment if they wish. If a patient has the capacity to give consent but is physically unable to sign a form, you should complete this form as usual and ask an independent witness to confirm that the patient has given consent orally or non-verbally.

When NOT to use this form

If the patient lacks the capacity to give consent, you should use an alternative form available for this purpose (dependent on patient age). A patient lacks capacity if they have an impairment or disturbance of the brain, affecting the way their mind works. For example, if they cannot do one of the following:

- understand information about the decision to be made
- retain that information in their mind
- use or weigh this information as a part of their decision making process, or
- communicate their decision (by talking, using sign language or any other means)

You should always take all reasonable steps (for example involving more specialist colleagues) to support a patient in making their own decision, before concluding that they are unable to do so. Relatives cannot be asked to sign a form on behalf of an adult who lacks capacity to consent for themselves, unless they have been given the authority to do so under a Lasting Power of Attorney or as a court deputy.

Information

Information about what the treatment will involve, its benefits and risks (including side-effects and complications) and alternatives to the particular procedure proposed, is crucial for patients when making up their minds. The courts have stated that patients should be told about 'significant risks which would affect the judgement of a reasonable patient'. 'Significant' has not been legally defined, but the GMC requires doctors to tell patients about 'significant, unavoidable or frequently occurring' risks. If patients make clear they have particular concerns about certain kinds of risk, you should ensure that they are informed about these risks, even if very small or rare. You should always answer questions honestly. Sometimes, patients may make it clear that they do not want to have any information about the options, but want you to decide on their behalf. In such circumstances, you should do your best to ensure that the patient receives at least very basic information about what is proposed. Where information is refused, you should document this on the consent form or in the patient's notes.

NHS Scotland

NHS Scotland staff should refer to Healthcare Improvement Scotland. Guidance on consent for SACT and local NHS Board guidance on consent aligned to the Scottish legal framework.

References

1. Summary of Product Characteristics for individual drugs: medicines.org.uk/emc
2. Cancer Research UK: cruk.org/about-cancer/treatment/drugs
3. Macmillan Cancer Support: macmillan.org.uk/cancer-information-and-support/treatments-and-drugs
4. Guy's and St. Thomas' NHS Foundation Trust, Chemotherapy consent form

Patient agreement to systemic anti-cancer therapy (SACT)

ATRA (All-transretinoic acid)

Hospital/NHS Trust/NHS Board:

_____

_____

Responsible consultant:

Name: _____

Job title: _____

Patient details

Patient's surname/family name:

_____

Patient's first name(s): _____

_____

Date of birth: _____

NHS number: _____
(or other identifier)

Special requirements:
(eg other language/other communication method)

_____

_____

_____

_____

Name of proposed course of treatment (include brief explanation if medical term not clear)

☐ ATRA (All-transretinoic acid) /Tretinoin in combination with chemotherapy for the treatment of acute promyelocytic leukaemia (APML).
☐ Tretinoin (ATRA) is taken orally twice each day for up to 1 week until diagnosis of APML is confirmed.
☐ Once diagnosis of APML is confirmed, continue with ATRA and add in chemotherapy.
☐ Tretinoin (ATRA) is continued until haematologic complete response or for a maximum of 60 days. A separate consent form must be used for chemotherapy.
☐ A separate form must be used for chemotherapy.

Where will I have treatment?

☐ Outpatient ☐ Day unit/case ☐ Inpatient ☐ Other: _____

Statement of health professional

(to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in the hospital/Trust/NHS board's consent policy)

☑ Tick all relevant boxes

☐ I confirm the patient has capacity to give consent.

☐ I have explained the course of treatment and intended benefit to the patient.

The intended benefits (there are no guarantees about outcome)

☐ Prolong survival.

☐ Control symptoms, reduce transfusion needs and improve quality of life.

☐ Induction – therapy given in the acute state of the disease, aiming to shrink the tumour.

☐ Curative – to give you the best possible chance of being cured.

☐ Maintenance – therapy given on continuing basis, aiming to prevent disease flaring up and to control the symptoms

☐ Disease control / Palliative – the aim is not to cure but to control the disease and reduce the symptoms. The aim is to improve both quality and quantity of life.

Statement of health professional

Patient identifier/label

You may have one or more of the side effects listed

Common side effects:

Affecting more than 10 in every 100 (>10%) people

- ☐ An increased risk of getting an infection from a drop in white blood cells – this makes it harder to fight infections and you can become very ill.
- ☐ **If you have a severe infection this can be life- threatening. Contact your doctor or hospital straight away if:**
  - **your temperature goes over 37.5°C or over 38°C, depending on the advice given by your chemotherapy team**
  - **you suddenly feel unwell (even with a normal temperature)**
- ☐ Thinning of the hair or hair loss, nausea (feeling sick), vomiting (being sick), dry nose, dry mouth, reduced appetite, abdominal (tummy pain), diarrhoea, constipation, feeling tired and weak (fatigue).
- ☐ Vision and hearing problems including hearing loss, headaches, dizziness, rash, itching, pins and needles in hands and feet.
- ☐ Fast heart rate, breathlessness or breathing changes, pain (chest, bone), increased sweating, flushing, mood changes, feeling anxious, sad, confused, difficulty sleeping (insomnia).
- ☐ Raised cholesterol and fat (triglycerides) levels, changes in liver and kidney function (monitored), inflammation of lips, inflammation of the pancreas.
- ☐ Tretinoin (ATRA) can cause increase pressure in the head. Symptoms may include double or loss of vision, feeling or being sick, dizziness, headaches, ringing in your ears and altered consciousness. Please contact your doctor or nurse.

Occasional side effects:

Affecting between 1-10 in every 100 (1-10%) people

- ☐ Tretinoin (ATRA) can cause differentiation syndrome in the first month of treatment which can be life-threatening. Symptoms include temperature, shortness of breath, rapid breathing, build up of fluid with weight gain. You may be treated with steroids and tretinoin withheld or discontinued.

Other risks:

- ☐ Increased risk of tumour lysis syndrome in some patients (when treatment destroys cancer cells too quickly for the kidneys to cope and leads to changes in blood tests). Rarely, dialysis may be needed. You may be prescribed medicines for prevention/ treatment.
- ☐ Before treatment you may have blood tests to check for viruses (Hepatitis B or C, HIV, or unusual infections). Treatment may weaken your natural defence (immune) system so infections like this may worsen or become active if you've had them before. You may have medicines to prevent or treat infection.
- ☐ Side effects of anti-sickness medication include diarrhoea, constipation, headaches.
- ☐ Changes in your memory, concentration or ability to think clearly. There can be many causes including your treatment, diagnosis, or both.
- ☐ Cancer and its treatment can increase your risk of developing a blood clot (thrombosis), causing pain, redness and swelling in an arm or leg, breathlessness, chest pain. Tell your doctor straight away if you have any symptoms.
- ☐ Some anti-cancer medicines can damage ovaries and sperm. This may lead to infertility and/or early menopause (hot flushes, vaginal dryness).
- ☐ Some anti-cancer medicines may damage the development of a baby in the womb. It is important not to become pregnant or make someone else pregnant during treatment and for at least 1 month after Tretinoin. May be longer depending on the chemotherapy. Women of child bearing age will be tested for pregnancy before and during treatment. Use effective contraception throughout. You can talk to your doctor or nurse about this.
- ☐ Complications of treatment can very occasionally be life-threatening and may result in death. The risks are different for every individual. Potentially life-threatening complications include those listed on this form, but other exceedingly rare side effects may also be life-threatening.

Statement of health professional

Patient identifier/label

Any other risks and information:

_____

_____

☐ I have discussed the intended benefit and risks of the recommended treatment, and of any available alternative treatments (including no treatment).

☐ I have discussed the side effects of the recommended treatment, which could affect the patient straight away or in the future, and that there may be some side effects not listed because they are rare or have not yet been reported. Each patient may experience side effects differently.

☐ I have discussed what the treatment is likely to involve (including inpatient/outpatient treatment, timing of the treatment, blood and any additional tests, follow-up appointments etc) and location.

☐ I have explained to the patient, that they have the right to stop this treatment at any time and should contact the responsible consultant or team if they wish to do so.

☐ I have discussed concerns of particular importance to the patient in regard to treatment

(please write details here): _____

_____

Clinical management guideline/Protocol compliant (please tick):

☐ Yes ☐ No ☐ Not available If No please document reason here:

_____

The following written information has been provided:

☐ Information leaflet for ATRA (All-transretinoic acid)

☐ 24 hour alert card or SACT advice service contact details

☐ SACT treatment record (cruk.org/treatment-record)

☐ Other, please state: _____

_____

Health professional details:

Signed: _____

Date: _____

Name (PRINT): _____

_____

Job title: _____

_____

Statement of interpreter **(where appropriate)**

Interpreter booking reference (if applicable):

I have interpreted the information above to the patient to the best of my ability and in a way in which I believe they can understand.

Signed: _____ Date: _____

Name (PRINT): _____ Job title: _____

Statement of patient

Patient identifier/label

Please read this form carefully. If your treatment has been planned in advance, you should already have your own copy of the form which describes the benefits and risks of the proposed treatment. If not, you will be offered a copy now. If you have any further questions, do ask – we are here to help you. You have the right to change your mind at any time, including after you have signed this form.

☐ I have had enough time to consider my options and make a decision about treatment.

☐ I agree to the course of treatment described on this form.

A witness should sign below if the patient is unable to sign but has indicated their consent. A person with parental responsibility will be asked to sign for young people under the age of 16 years.

Patient's signature: _____

Name (PRINT): _____ Date: _____

Person with parental responsibility/witness' signature: _____

Name (PRINT): _____ Date: _____

Copy accepted by patient: yes / no (please circle)

Confirmation of consent

(health professional to complete when the patient attends for treatment, if the patient has signed the form in advance)

On behalf of the team treating the patient, I have confirmed that the patient has no further questions and wishes the course of treatment/procedures to go ahead.

Signed: _____

Date: _____

Name (PRINT): _____

Job title: _____

Important notes: (tick if applicable)

☐ See also advance decision to refuse treatment

☐ Patient has withdrawn consent (ask patient to sign and date here)

Signed: _____

Date: _____

Further information for patients

Contact details (if patient wishes to discuss options later):

_____

Contact your hospital team if you have any questions about cancer and its treatment.

Cancer Research UK can also help answer your questions about cancer and treatment. If you want to talk in confidence, call our information nurses on freephone 0808 800 4040, Monday to Friday, 9am to 5pm. Alternatively visit cruk.org for more information.

These forms have been produced by Guy's and St. Thomas' NHS Foundation Trust as part of a national project to support clinicians in ensuring all patients are fully informed when consenting to SACT.

The project is supported by Cancer Research UK. This does not mean you are taking part in a clinical trial.

Guidance for health professionals

(to be read in conjunction with the hospital's consent policy)

Patient identifier/label

What a consent form is for

This form documents the patient's agreement to go ahead with the treatment you have proposed. It is not a legal waiver – if patients, for example, do not receive enough information on which to base their decision, then the consent may not be valid, even though the form has been signed. Patients are also entitled to change their mind after signing the form, if they retain capacity to do so. The form should act as an aide-memoir to health professionals and patients, by providing a checklist of the kind of information patients should be offered, and by enabling the patient to have a written record of the main points discussed. In no way should the written information provided for the patient be regarded as a substitute for face-to-face discussions with the patient.

The law on consent

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Who can give consent

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When NOT to use this form

If the patient lacks the capacity to give consent, you should use an alternative form available for this purpose (dependent on patient age). A patient lacks capacity if they have an impairment or disturbance of the brain, affecting the way their mind works. For example, if they cannot do one of the following:

- understand information about the decision to be made
- retain that information in their mind
- use or weigh this information as a part of their decision making process, or
- communicate their decision (by talking, using sign language or any other means)

You should always take all reasonable steps (for example involving more specialist colleagues) to support a patient in making their own decision, before concluding that they are unable to do so. Relatives cannot be asked to sign a form on behalf of an adult who lacks capacity to consent for themselves, unless they have been given the authority to do so under a Lasting Power of Attorney or as a court deputy.

Information

Information about what the treatment will involve, its benefits and risks (including side-effects and complications) and alternatives to the particular procedure proposed, is crucial for patients when making up their minds. The courts have stated that patients should be told about 'significant risks which would affect the judgement of a reasonable patient'. 'Significant' has not been legally defined, but the GMC requires doctors to tell patients about 'significant, unavoidable or frequently occurring' risks. If patients make clear they have particular concerns about certain kinds of risk, you should ensure that they are informed about these risks, even if very small or rare. You should always answer questions honestly. Sometimes, patients may make it clear that they do not want to have any information about the options, but want you to decide on their behalf. In such circumstances, you should do your best to ensure that the patient receives at least very basic information about what is proposed. Where information is refused, you should document this on the consent form or in the patient's notes.

NHS Scotland

NHS Scotland staff should refer to Healthcare Improvement Scotland. Guidance on consent for SACT and local NHS Board guidance on consent aligned to the Scottish legal framework.

References

1. Summary of Product Characteristics for individual drugs: medicines.org.uk/emc
2. Cancer Research UK: cruk.org/about-cancer/treatment/drugs
3. Macmillan Cancer Support: macmillan.org.uk/cancer-information-and-support/treatments-and-drugs
4. Guy's and St. Thomas' NHS Foundation Trust, Chemotherapy consent form

Patient agreement to systemic anti-cancer therapy (SACT)

ATRA (All-transretinoic acid) - ATO (Arsenic trioxide)

Hospital/NHS Trust/NHS Board:

_____

_____

Responsible consultant:

Name: _____

Job title: _____

Patient details

Patient's surname/family name:

_____

Patient's first name(s): _____

_____

Date of birth: _____

NHS number: _____
(or other identifier)

Special requirements:
(eg other language/other communication method)

_____

_____

_____

_____

Name of proposed course of treatment (include brief explanation if medical term not clear)

☐ ATRA (all-transretinoic acid) or Tretinoin - ATO (arsenic trioxide) for the treatment of acute promyelocytic leukaemia (APML).

☐ INDUCTION: ATRA orally on day 1, twice a day, until haematologic complete response or for a maximum of 60 days. Week 1: ATO intravenously on days 1 to 5. Weeks 2 - 8: ATO intravenously twice a week only (usually Mondays and Thursdays) for 1 cycle.

☐ CONSOLIDATION (with ATRA): Weeks 1 and 2: ATRA orally twice each day. Week 3 & 4: No treatment. Repeat every 28 days for 7 cycles. This is given together with ATO (see below).

☐ CONSOLIDATION (with ATO): Week 1: ATO intravenously daily for 5 days. Weeks 2,3 & 4: ATO intravenously twice a week. Weeks 5,6,7 & 8: No treatment. Repeat every 56 days (8 weeks) for 4 cycles.

Where will I have treatment?

☐ Outpatient ☐ Day unit/case ☐ Inpatient ☐ Other: _____

Statement of health professional

(to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in the hospital/Trust/NHS board's consent policy)

☑ Tick all relevant boxes

☐ I confirm the patient has capacity to give consent.

☐ I have explained the course of treatment and intended benefit to the patient.

The intended benefits (there are no guarantees about outcome)

☐ Prolong survival.

☐ Control symptoms, reduce transfusion needs and improve quality of life.

☐ Induction – therapy given in the acute state of the disease, aiming to shrink the tumour

☐ Curative – to give you the best possible chance of being cured.

☐ Maintenance – therapy given on continuing basis, aiming to prevent disease flaring up and to control the symptoms.

☐ Disease control / Palliative – the aim is not to cure but to control the disease and reduce the symptoms. The aim is to improve both quality and quantity of life

Statement of health professional

Patient identifier/label

You may have one or more of the side effects listed

Common side effects:

Affecting more than 10 in every 100 (>10%) people

- ☐ An increased risk of getting an infection from a drop in white blood cells – this makes it harder to fight infections and you can become very ill.
- ☐ **If you have a severe infection this can be life-threatening. Contact your doctor or hospital straight away if:**
  - **your temperature goes over 37.5°C or over 38°C, depending on the advice given by your chemotherapy team**
  - **you suddenly feel unwell (even with a normal temperature)**
- ☐ Thinning of the hair or hair loss, nausea (feeling sick), vomiting (being sick), dry nose, dry mouth, reduced appetite, abdominal (tummy pain), diarrhoea, constipation, feeling tired and weak (fatigue).
- ☐ Vision and hearing changes including hearing loss, headaches, dizziness, rash, itching, pins and needles in hands and feet.
- ☐ Fast heart rate, breathlessness or breathing changes, shortness of breath, pain (muscle, chest, bone), increased sweating, flushing, mood changes, feeling anxious, sad, confused, difficulty sleeping (insomnia).
- ☐ Raised cholesterol and fat (triglycerides) levels, low potassium, low magnesium, changes in liver, kidney function (monitored), inflammation of lips, inflammation of the pancreas.
- ☐ Arsenic can raise your blood sugar. This usually goes back to normal after treatment. If you have diabetes, it may lead to higher blood sugar levels. Please ask your doctor/nurse/GP if concerned.
- ☐ Tretinoin (ATRA) can cause increase pressure in the head. Symptoms may include double or loss of vision, feeling or being sick, dizziness, headaches, ringing in your ears and altered consciousness. Please contact your doctor or nurse.
- ☐ This treatment can cause differentiation syndrome in the first month which can be life-threatening. Symptoms include temperature, shortness of breath, rapid breathing, build up of fluid with weight gain. You may be treated with steroids and treatment withheld or discontinued.

Occasional side effects:

Affecting between 1-10 in every 100 (1-10%) people

- ☐ Low blood pressure, anaemia (low red blood cells) and bruising or bleeding (low platelets). This can be prolonged and you may need a transfusion.
- ☐ Build-up of fluid between the heart and lungs, seizures, swelling in the face, blurry vision.
- ☐ Inflammation of the blood vessels (vasculitis). This can affect different parts of the body causing weight loss, temperature, muscle and joint pains, feeling tired and general illness.

Other risks:

- ☐ Arsenic may leak out of the vein while it is being given (extravasation) and can damage the tissue around the vein. Tell the nurse straight away if you have any stinging, pain, redness or swelling around the vein. It's uncommon but important to deal with quickly.
- ☐ Increased risk of tumour lysis syndrome in some patients (when treatment destroys cancer cells too quickly for the kidneys to cope and leads to changes in blood tests). Rarely, dialysis may be needed. You may be prescribed medicines for prevention/ treatment.
- ☐ Before treatment you may have blood tests to check for viruses (Hepatitis B or C, HIV, or unusual infections). Treatment may weaken your natural defence (immune) system so infections like this may worsen or become active if you've had them before. You may have medicines to prevent or treat infection.
- ☐ Side effects of anti-sickness medication include diarrhoea, constipation, headaches.
- ☐ Changes in your memory, concentration or ability to think clearly. There can be many causes including your treatment, diagnosis, or both.
- ☐ Late effects include a rare chance of a second cancer (years later) and problems with your heart.
- ☐ Growth factors (GCSF) may be prescribed to maintain number of white cells to prevent infection. You may experience bone pain, headaches, red and itchy skin around the injection site.

Continue to the next page

Patient identifier/label

Statement of health professional

Other risks continued:

- ☐ Cancer and its treatment can increase your risk of developing a blood clot (thrombosis), causing pain, redness and swelling in an arm or leg, breathlessness, chest pain. Tell your doctor straight away if you have any symptoms.
- ☐ Some anti-cancer medicines can damage ovaries and sperm. This may lead to infertility and/or early menopause (hot flushes, vaginal dryness).
- ☐ Some anti-cancer medicines may damage the development of a baby in the womb. It is important not to become pregnant or make someone else pregnant during treatment and for at least 6 months. Women of child bearing age will be tested for pregnancy before and during treatment. Use effective contraception. You can talk to your doctor or nurse about this
- ☐ Complications of treatment can very occasionally be life-threatening and may result in death. The risks are different for every individual. Potentially life-threatening complications include those listed on this form, but other exceedingly rare side effects may also be life-threatening.

Statement of health professional

Patient identifier/label

Any other risks and information:

_____

_____

☐ I have discussed the intended benefit and risks of the recommended treatment, and of any available alternative treatments (including no treatment).

☐ I have discussed the side effects of the recommended treatment, which could affect the patient straight away or in the future, and that there may be some side effects not listed because they are rare or have not yet been reported. Each patient may experience side effects differently.

☐ I have discussed what the treatment is likely to involve (including inpatient/outpatient treatment, timing of the treatment, blood and any additional tests, follow-up appointments etc) and location.

☐ I have explained to the patient, that they have the right to stop this treatment at any time and should contact the responsible consultant or team if they wish to do so.

☐ I have discussed concerns of particular importance to the patient in regard to treatment

(please write details here): _____

_____

Clinical management guideline/Protocol compliant (please tick):

☐ Yes ☐ No ☐ Not available If No please document reason here:

_____

The following written information has been provided:

☐ Information leaflet for ATRA (All-transretinoic acid) - ATO (Arsenic trioxide)

☐ 24 hour alert card or SACT advice service contact details

☐ SACT treatment record (cruk.org/treatment-record)

☐ Other, please state: _____

_____

Health professional details:

Signed: _____

Date: _____

Name (PRINT): _____

_____

Job title: _____

_____

Statement of interpreter **(where appropriate)**

Interpreter booking reference (if applicable):

I have interpreted the information above to the patient to the best of my ability and in a way in which I believe they can understand.

Signed: _____ Date: _____

Name (PRINT): _____ Job title: _____

Statement of patient

Patient identifier/label

Please read this form carefully. If your treatment has been planned in advance, you should already have your own copy of the form which describes the benefits and risks of the proposed treatment. If not, you will be offered a copy now. If you have any further questions, do ask – we are here to help you. You have the right to change your mind at any time, including after you have signed this form.

☐ I have had enough time to consider my options and make a decision about treatment.

☐ I agree to the course of treatment described on this form.

A witness should sign below if the patient is unable to sign but has indicated their consent. A person with parental responsibility will be asked to sign for young people under the age of 16 years.

Patient's signature: _____

Name (PRINT): _____ Date: _____

Person with parental responsibility/witness' signature: _____

Name (PRINT): _____ Date: _____

Copy accepted by patient: yes / no (please circle)

Confirmation of consent

(health professional to complete when the patient attends for treatment, if the patient has signed the form in advance)

On behalf of the team treating the patient, I have confirmed that the patient has no further questions and wishes the course of treatment/procedures to go ahead.

Signed: _____

Date: _____

Name (PRINT): _____

Job title: _____

Important notes: (tick if applicable)

☐ See also advance decision to refuse treatment

☐ Patient has withdrawn consent (ask patient to sign and date here)

Signed: _____

Date: _____

Further information for patients

Contact details (if patient wishes to discuss options later):

_____

Contact your hospital team if you have any questions about cancer and its treatment.

Cancer Research UK can also help answer your questions about cancer and treatment. If you want to talk in confidence, call our information nurses on freephone 0808 800 4040, Monday to Friday, 9am to 5pm. Alternatively visit cruk.org for more information.

These forms have been produced by Guy's and St. Thomas' NHS Foundation Trust as part of a national project to support clinicians in ensuring all patients are fully informed when consenting to SACT.

The project is supported by Cancer Research UK. This does not mean you are taking part in a clinical trial.

Guidance for health professionals

(to be read in conjunction with the hospital's consent policy)

Patient identifier/label

What a consent form is for

This form documents the patient's agreement to go ahead with the treatment you have proposed. It is not a legal waiver – if patients, for example, do not receive enough information on which to base their decision, then the consent may not be valid, even though the form has been signed. Patients are also entitled to change their mind after signing the form, if they retain capacity to do so. The form should act as an aide-memoir to health professionals and patients, by providing a checklist of the kind of information patients should be offered, and by enabling the patient to have a written record of the main points discussed. In no way should the written information provided for the patient be regarded as a substitute for face-to-face discussions with the patient.

The law on consent

See the following publications for a comprehensive summary of the law on consent. Consent: Patients and doctors making decisions together, GMC 2020 (gmc-uk.org/guidance). Reference guide to consent for examination or treatment, Department of Health, 2nd edition 2009 (doh.gov.uk).

Who can give consent

Everyone aged 16 or over is presumed to have the capacity to give consent for themselves, unless the opposite is demonstrated. For young people, it is good practice to involve those with parental responsibility in the consent discussions, unless specifically asked not to. A person with parental responsibility must sign this form for a child or young person under the age of 16. Such patients should be given the opportunity to 'assent' to treatment if they wish. If a patient has the capacity to give consent but is physically unable to sign a form, you should complete this form as usual and ask an independent witness to confirm that the patient has given consent orally or non-verbally.

When NOT to use this form

If the patient lacks the capacity to give consent, you should use an alternative form available for this purpose (dependent on patient age). A patient lacks capacity if they have an impairment or disturbance of the brain, affecting the way their mind works. For example, if they cannot do one of the following:

- understand information about the decision to be made
- retain that information in their mind
- use or weigh this information as a part of their decision making process, or
- communicate their decision (by talking, using sign language or any other means)

You should always take all reasonable steps (for example involving more specialist colleagues) to support a patient in making their own decision, before concluding that they are unable to do so. Relatives cannot be asked to sign a form on behalf of an adult who lacks capacity to consent for themselves, unless they have been given the authority to do so under a Lasting Power of Attorney or as a court deputy.

Information

Information about what the treatment will involve, its benefits and risks (including side-effects and complications) and alternatives to the particular procedure proposed, is crucial for patients when making up their minds. The courts have stated that patients should be told about 'significant risks which would affect the judgement of a reasonable patient'. 'Significant' has not been legally defined, but the GMC requires doctors to tell patients about 'significant, unavoidable or frequently occurring' risks. If patients make clear they have particular concerns about certain kinds of risk, you should ensure that they are informed about these risks, even if very small or rare. You should always answer questions honestly. Sometimes, patients may make it clear that they do not want to have any information about the options, but want you to decide on their behalf. In such circumstances, you should do your best to ensure that the patient receives at least very basic information about what is proposed. Where information is refused, you should document this on the consent form or in the patient's notes.

NHS Scotland

NHS Scotland staff should refer to Healthcare Improvement Scotland. Guidance on consent for SACT and local NHS Board guidance on consent aligned to the Scottish legal framework.

References

1. Summary of Product Characteristics for individual drugs: medicines.org.uk/emc
2. Cancer Research UK: cruk.org/about-cancer/treatment/drugs
3. Macmillan Cancer Support: macmillan.org.uk/cancer-information-and-support/treatments-and-drugs
4. Guy's and St. Thomas' NHS Foundation Trust, Chemotherapy consent form

Patient agreement to systemic anti-cancer therapy (SACT)

Azacitidine

Hospital/NHS Trust/NHS Board:

_____

_____

Responsible consultant:

Name: _____

Job title: _____

Patient details

Patient's surname/family name:

_____

Patient's first name(s): _____

_____

Date of birth: _____

NHS number: _____
(or other identifier)

Special requirements:
(eg other language/other communication method)

_____

_____

_____

_____

Name of proposed course of treatment (include brief explanation if medical term not clear)

☐ Azacitidine for the treatment of Acute Myeloid Leukaemia (AML) OR Myelodysplastic Syndrome (MDS) OR Chronic Myelomonocytic Leukaemia (CMML).

☐ Azacitidine given subcutaneously on days 1 to 7* OR on days 1 to 5 and 8 to 9* (*delete as appropriate). OR

☐ AML maintenance only: Azacitidine taken orally once each day on days 1 to 14 (followed by a 14 day rest period). If required, this may be extended to once each day on days 1 to 21 (followed by a 7 day rest period). Your doctor will tell you if this is the case.

☐ Each treatment cycle lasts for 28 days. Treatment is continued until disease progression or unacceptable side effects.

Where will I have treatment?

☐ Outpatient ☐ Day unit/case ☐ Inpatient ☐ Other: _____

Statement of health professional

(to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in the hospital/Trust/NHS board's consent policy)

☑ Tick all relevant boxes

☐ I confirm the patient has capacity to give consent.

☐ I have explained the course of treatment and intended benefit to the patient.

The intended benefits (there are no guarantees about outcome)

☐ Prolong survival.

☐ Control symptoms, reduce transfusion needs and improve quality of life.

☐ Induction – therapy given in the acute stage of the disease, aiming to shrink the tumour.

☐ Curative – to give you the best possible chance of being cured.

☐ Maintenance – therapy on a continuous basis, to prevent disease flare up and control symptoms.

☐ Disease control/palliative – aim is not to cure, but to control/shrink the disease, improve quality of life and survival.

Statement of health professional

Patient identifier/label

You may have one or more of the side effects listed

Common side effects:

Affecting more than 10 in every 100 (>10%) people

- ☐ An increased risk of getting an infection from a drop in white blood cells – this makes it harder to fight infections and you can become very ill.
- ☐ **If you have a severe infection this can be life-threatening. Contact your doctor or hospital straight away if:**
  - **your temperature goes over 37.5°C or over 38°C, depending on the advice given by your chemotherapy team**
  - **you suddenly feel unwell (even with a normal temperature)**
- ☐ Nausea (feeling sick) and vomiting (being sick).
- ☐ Abdominal (tummy) pain, diarrhoea or constipation.
- ☐ Appetite loss, weight loss.
- ☐ Fatigue (feeling tired).
- ☐ If you are having Azacitidine by subcutaneous injection, you may notice pain, redness, itching, bruising and swelling where the injection is given.
- ☐ Anaemia (low number of red blood cells) and bruising or bleeding caused by low number of platelets. This can be prolonged and you may need a transfusion.
- ☐ Shortness of breath, chest pain.
- ☐ Difficulty sleeping (insomnia), headaches, dizziness.
- ☐ Itching, rash.
- ☐ Pain in the muscles and joints.

Occasional side effects:

Affecting between 1-10 in every 100 (1-10%) people

- ☐ Thinning of the hair or hair loss.
- ☐ Feeling generally unwell.
- ☐ Drowsiness.
- ☐ Oral fungal infection (white coating inside your mouth).
- ☐ Blood shot eyes.
- ☐ Sore mouth and ulcers, bleeding gums.
- ☐ Indigestion.
- ☐ Blood in the urine.
- ☐ Changes in kidney function (picked up in blood tests.
- ☐ High blood pressure.

Other risks:

- ☐ There may be increased risk of tumour lysis syndrome in some patients. This occurs when the treatment destroys cancer cells too quickly for the kidneys to cope and leads to changes in the blood tests. Rarely, dialysis may be needed. High risk patients will be prescribed medicines for prevention.
- ☐ Before treatment you may have blood tests to check for viruses (Hepatitis B or C, HIV, or unusual infections). Treatment may weaken your natural defence (immune) system so infections like this may worsen or become active if you've had them before. You may have medicines to prevent or treat infection.
- ☐ Late effects include problems with your heart (risk is higher in patients with a history of heart problems).
- ☐ Potential side effects with the anti-sickness medication may include: constipation, diarrhoea, headaches.
- ☐ Cancer and treatment for cancer can increase your risk of developing a blood clot (thrombosis). A blood clot may cause pain, redness and swelling in a leg or arm, or breathlessness and chest pain. Tell your doctor straight away if you have these symptoms
- ☐ You may notice changes in your memory, concentration, or your ability to think clearly. There can be many causes of this, including your treatment, diagnosis, or both.
- ☐ Some anti-cancer medicines can damage ovaries and sperm. This may lead to infertility and/or early menopause. Early menopause may cause symptoms of hot flushes and vaginal dryness.
- ☐ Some anti-cancer medicines may damage the development of a baby in the womb. It is important not to become pregnant or make someone else pregnant during treatment and for at least 6 months afterwards. Women of child bearing age will be tested for pregnancy before and during treatment. Use effective contraception. You can talk to your doctor or nurse about this.
- ☐ Complications of treatment can very occasionally be life-threatening and may result in death. The risks are different for every individual. Potentially life-threatening complications include those listed on this form, but other exceedingly rare side effects may also be life-threatening.

Statement of health professional

Patient identifier/label

Any other risks and information:

_____

_____

☐ I have discussed the intended benefit and risks of the recommended treatment, and of any available alternative treatments (including no treatment).

☐ I have discussed the side effects of the recommended treatment, which could affect the patient straight away or in the future, and that there may be some side effects not listed because they are rare or have not yet been reported. Each patient may experience side effects differently.

☐ I have discussed what the treatment is likely to involve (including inpatient/outpatient treatment, timing of the treatment, blood and any additional tests, follow-up appointments etc) and location.

☐ I have explained to the patient, that they have the right to stop this treatment at any time and should contact the responsible consultant or team if they wish to do so.

☐ I have discussed concerns of particular importance to the patient in regard to treatment

(please write details here): _____

_____

Clinical management guideline/Protocol compliant (please tick):

☐ Yes ☐ No ☐ Not available If No please document reason here:

_____

The following written information has been provided:

☐ Information leaflet for Azacitidine

☐ 24 hour alert card or SACT advice service contact details

☐ SACT treatment record (cruk.org/treatment-record)

☐ Other, please state: _____

_____

Health professional details:

Signed: _____

Date: _____

Name (PRINT): _____

_____

Job title: _____

_____

Statement of interpreter **(where appropriate)**

Interpreter booking reference (if applicable):

I have interpreted the information above to the patient to the best of my ability and in a way in which I believe they can understand.

Signed: _____ Date: _____

Name (PRINT): _____ Job title: _____

Statement of patient

Patient identifier/label

Please read this form carefully. If your treatment has been planned in advance, you should already have your own copy of the form which describes the benefits and risks of the proposed treatment. If not, you will be offered a copy now. If you have any further questions, do ask – we are here to help you. You have the right to change your mind at any time, including after you have signed this form.

☐ I have had enough time to consider my options and make a decision about treatment.

☐ I agree to the course of treatment described on this form.

A witness should sign below if the patient is unable to sign but has indicated their consent. A person with parental responsibility will be asked to sign for young people under the age of 16 years.

Patient's signature: _____

Name (PRINT): _____ Date: _____

Person with parental responsibility/witness' signature: _____

Name (PRINT): _____ Date: _____

Copy accepted by patient: yes / no (please circle)

Confirmation of consent

(health professional to complete when the patient attends for treatment, if the patient has signed the form in advance)

On behalf of the team treating the patient, I have confirmed that the patient has no further questions and wishes the course of treatment/procedures to go ahead.

Signed: _____

Date: _____

Name (PRINT): _____

Job title: _____

Important notes: (tick if applicable)

☐ See also advance decision to refuse treatment

☐ Patient has withdrawn consent (ask patient to sign and date here)

Signed: _____

Date: _____

Further information for patients

Contact details (if patient wishes to discuss options later):

_____

Contact your hospital team if you have any questions about cancer and its treatment.

Cancer Research UK can also help answer your questions about cancer and treatment. If you want to talk in confidence, call our information nurses on freephone 0808 800 4040, Monday to Friday, 9am to 5pm. Alternatively visit cruk.org for more information.

These forms have been produced by Guy's and St. Thomas' NHS Foundation Trust as part of a national project to support clinicians in ensuring all patients are fully informed when consenting to SACT.

The project is supported by Cancer Research UK. This does not mean you are taking part in a clinical trial.

Guidance for health professionals

(to be read in conjunction with the hospital's consent policy)

Patient identifier/label

What a consent form is for

This form documents the patient's agreement to go ahead with the treatment you have proposed. It is not a legal waiver – if patients, for example, do not receive enough information on which to base their decision, then the consent may not be valid, even though the form has been signed. Patients are also entitled to change their mind after signing the form, if they retain capacity to do so. The form should act as an aide-memoir to health professionals and patients, by providing a checklist of the kind of information patients should be offered, and by enabling the patient to have a written record of the main points discussed. In no way should the written information provided for the patient be regarded as a substitute for face-to-face discussions with the patient.

The law on consent

See the following publications for a comprehensive summary of the law on consent. Consent: Patients and doctors making decisions together, GMC 2020 (gmc-uk.org/guidance). Reference guide to consent for examination or treatment, Department of Health, 2nd edition 2009 (doh.gov.uk).

Who can give consent

Everyone aged 16 or over is presumed to have the capacity to give consent for themselves, unless the opposite is demonstrated. For young people, it is good practice to involve those with parental responsibility in the consent discussions, unless specifically asked not to. A person with parental responsibility must sign this form for a child or young person under the age of 16. Such patients should be given the opportunity to 'assent' to treatment if they wish. If a patient has the capacity to give consent but is physically unable to sign a form, you should complete this form as usual and ask an independent witness to confirm that the patient has given consent orally or non-verbally.

When NOT to use this form

If the patient lacks the capacity to give consent, you should use an alternative form available for this purpose (dependent on patient age). A patient lacks capacity if they have an impairment or disturbance of the brain, affecting the way their mind works. For example, if they cannot do one of the following:

- understand information about the decision to be made
- retain that information in their mind
- use or weigh this information as a part of their decision making process, or
- communicate their decision (by talking, using sign language or any other means)

You should always take all reasonable steps (for example involving more specialist colleagues) to support a patient in making their own decision, before concluding that they are unable to do so. Relatives cannot be asked to sign a form on behalf of an adult who lacks capacity to consent for themselves, unless they have been given the authority to do so under a Lasting Power of Attorney or as a court deputy.

Information

Information about what the treatment will involve, its benefits and risks (including side-effects and complications) and alternatives to the particular procedure proposed, is crucial for patients when making up their minds. The courts have stated that patients should be told about 'significant risks which would affect the judgement of a reasonable patient'. 'Significant' has not been legally defined, but the GMC requires doctors to tell patients about 'significant, unavoidable or frequently occurring' risks. If patients make clear they have particular concerns about certain kinds of risk, you should ensure that they are informed about these risks, even if very small or rare. You should always answer questions honestly. Sometimes, patients may make it clear that they do not want to have any information about the options, but want you to decide on their behalf. In such circumstances, you should do your best to ensure that the patient receives at least very basic information about what is proposed. Where information is refused, you should document this on the consent form or in the patient's notes.

NHS Scotland

NHS Scotland staff should refer to Healthcare Improvement Scotland. Guidance on consent for SACT and local NHS Board guidance on consent aligned to the Scottish legal framework.

References

1. Summary of Product Characteristics for individual drugs: medicines.org.uk/emc
2. Cancer Research UK: cruk.org/about-cancer/treatment/drugs
3. Macmillan Cancer Support: macmillan.org.uk/cancer-information-and-support/treatments-and-drugs
4. Guy's and St. Thomas' NHS Foundation Trust, Chemotherapy consent form

Patient agreement to systemic anti-cancer therapy (SACT)

Azacitidine + Venetoclax

Hospital/NHS Trust/NHS Board:

_____

_____

Responsible consultant:

Name: _____

Job title: _____

Patient details

Patient's surname/family name:

_____

Patient's first name(s): _____

_____

Date of birth: _____

NHS number: _____
(or other identifier)

Special requirements:
(eg other language/other communication method)

_____

_____

_____

_____

Name of proposed course of treatment (include brief explanation if medical term not clear)

☐ Azacitidine and venetoclax chemotherapy for the treatment of acute myeloid leukaemia (AML).

☐ Cycle 1: Azacitidine is given subcutaneously on days 1 to 5 and 8 and 9 every 28 days* OR given subcutaneously on days 1 to 7 every 28 days* (*delete as appropriate). Venetoclax is taken orally from days 1-28.

☐ Cycle 2: Azacitidine is given subcutaneously on days 1 to 5 and 8 and 9 every 28 days* OR given subcutaneously on days 1 to 7 every 28 days* (*delete as appropriate). Venetoclax is taken orally from days 1-28. Your doctor will adjust the number of days, depending on your blood results.

☐ Treatment is continued until disease progression or unacceptable side effects.

Where will I have treatment?

☐ Outpatient ☐ Day unit/case ☐ Inpatient ☐ Other: _____

Statement of health professional

(to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in the hospital/Trust/NHS board's consent policy)

☑ Tick all relevant boxes

☐ I confirm the patient has capacity to give consent.

☐ I have explained the course of treatment and intended benefit to the patient.

The intended benefits (there are no guarantees about outcome)

☐ Prolong survival.

☐ Control symptoms, reduce transfusion needs and improve quality of life.

☐ Induction – therapy given in the acute state of the disease, aiming to shrink the tumour.

☐ Curative – to give you the best possible chance of being cured.

☐ Maintenance – therapy given on continuing basis, aiming to prevent disease flaring up and to control the symptoms.

☐ Disease control / Palliative – the aim is not to cure but to control the disease and reduce the symptoms. The aim is to improve both quality and quantity of life.

Statement of health professional

Patient identifier/label

You may have one or more of the side effects listed

Common side effects:

Affecting more than 10 in every 100 (>10%) people

- ☐ An increased risk of getting an infection from a drop in white blood cells – this makes it harder to fight infections and you can become very ill.
- ☐ If you have a severe infection this can be life-threatening. Contact your doctor or hospital straight away if:
  - **your temperature goes over 37.5°C or over 38°C, depending on the advice given by your chemotherapy team**
  - **you suddenly feel unwell (even with a normal temperature)**
- ☐ Nausea (feeling sick), vomiting (being sick), abdominal (tummy) pain, diarrhoea or constipation, lack of appetite, weight loss, sore mouth and ulcers,
- ☐ Fatigue (feeling tired), difficulty sleeping (insomnia), headaches, dizziness, feeling drowsy.
- ☐ Anaemia (due to low red blood cells) and bruising or bleeding (due to low platelets). This can be prolonged and you may need a transfusion.
- ☐ Low potassium, changes in liver function (monitored).
- ☐ Low blood pressure.
- ☐ Itching, rash.
- ☐ Shortness of breath, chest pain.
- ☐ Pain in the muscle and joints.
- ☐ If you are having Azacitidine by subcutaneous injection, you may notice pain, redness, itching, bruising and swelling where the injection is given.

Occasional side effects:

Affecting between 1-10 in every 100 (1-10%) people

- ☐ There may be increased risk of tumour lysis syndrome in some patients. This occurs when the treatment destroys cancer cells too quickly for the kidneys to cope and leads to changes in the blood tests. Rarely, dialysis may be needed. High risk patients will be prescribed medicines for prevention.
- ☐ Thinning of the hair or hair loss, feeling generally unwell, blood shot eyes, indigestion, high blood pressure.
- ☐ Changes in kidney function (monitored), development of gall stones, inflammation of the gall bladder, blood in the urine.

Occasional side effects continued:

- ☐ Oral fungal infection (white coating inside your mouth), bleeding gums.

Other risks:

- ☐ Before treatment you may have blood tests to check for viruses (Hepatitis B or C, HIV, or unusual infections). Treatment may weaken your natural defence (immune) system so infections like this may worsen or become active if you've had them before. You may have medicines to prevent or treat infection.
- ☐ Side effects of anti-sickness medication include diarrhoea, constipation, headaches.
- ☐ Late effects include problems with your heart (risk is higher in patients with a history of heart problems).
- ☐ Growth factors (GCSF) may be prescribed to maintain number of white cells to prevent infection. You may experience bone pain, headaches, red and itchy skin around the injection site.
- ☐ Changes in your memory, concentration or ability to think clearly. There can be many causes including your treatment, diagnosis, or both.
- ☐ Cancer and its treatment can increase your risk of developing a blood clot (thrombosis), causing pain, redness and swelling in an arm or leg, breathlessness, chest pain. Tell your doctor straight away if you have any symptoms.
- ☐ Some anti-cancer medicines can damage ovaries and sperm. This may lead to infertility and/or early menopause (hot flushes, vaginal dryness).
- ☐ Some anti-cancer medicines may damage the development of a baby in the womb. It is important not to become pregnant or make someone else pregnant during treatment and for at least 6 months afterwards. Women of child bearing age will be tested for pregnancy before and during treatment. Use effective contraception. You can talk to your doctor or nurse about this
- ☐ Complications of treatment can very occasionally be life-threatening and may result in death. The risks are different for every individual. Potentially life-threatening complications include those listed on this form, but other exceedingly rare side effects may also be life-threatening.

Statement of health professional

Patient identifier/label

Any other risks and information:

_____

_____

☐ I have discussed the intended benefit and risks of the recommended treatment, and of any available alternative treatments (including no treatment).

☐ I have discussed the side effects of the recommended treatment, which could affect the patient straight away or in the future, and that there may be some side effects not listed because they are rare or have not yet been reported. Each patient may experience side effects differently.

☐ I have discussed what the treatment is likely to involve (including inpatient/outpatient treatment, timing of the treatment, blood and any additional tests, follow-up appointments etc) and location.

☐ I have explained to the patient, that they have the right to stop this treatment at any time and should contact the responsible consultant or team if they wish to do so.

☐ I have discussed concerns of particular importance to the patient in regard to treatment

(please write details here): _____

_____

Clinical management guideline/Protocol compliant (please tick):

☐ Yes ☐ No ☐ Not available If No please document reason here:

_____

The following written information has been provided:

☐ Information leaflet for Azacitidine and Venetoclax

☐ 24 hour alert card or SACT advice service contact details

☐ SACT treatment record (cruk.org/treatment-record)

☐ Other, please state: _____

Health professional details:

Signed: _____

Date: _____

Name (PRINT): _____

_____

Job title: _____

_____

Statement of interpreter **(where appropriate)**

Interpreter booking reference (if applicable):

I have interpreted the information above to the patient to the best of my ability and in a way in which I believe they can understand.

Signed: _____ Date: _____

Name (PRINT): _____ Job title: _____

Statement of patient

Patient identifier/label

Please read this form carefully. If your treatment has been planned in advance, you should already have your own copy of the form which describes the benefits and risks of the proposed treatment. If not, you will be offered a copy now. If you have any further questions, do ask – we are here to help you. You have the right to change your mind at any time, including after you have signed this form.

☐ I have had enough time to consider my options and make a decision about treatment.

☐ I agree to the course of treatment described on this form.

A witness should sign below if the patient is unable to sign but has indicated their consent. A person with parental responsibility will be asked to sign for young people under the age of 16 years.

Patient's signature: _____

Name (PRINT): _____ Date: _____

Person with parental responsibility/witness' signature: _____

Name (PRINT): _____ Date: _____

Copy accepted by patient: yes / no (please circle)

Confirmation of consent

(health professional to complete when the patient attends for treatment, if the patient has signed the form in advance)

On behalf of the team treating the patient, I have confirmed that the patient has no further questions and wishes the course of treatment/procedures to go ahead.

Signed: _____

Date: _____

Name (PRINT): _____

Job title: _____

Important notes: (tick if applicable)

☐ See also advance decision to refuse treatment

☐ Patient has withdrawn consent (ask patient to sign and date here)

Signed: _____

Date: _____

Further information for patients

Contact details (if patient wishes to discuss options later):

_____

Contact your hospital team if you have any questions about cancer and its treatment.

Cancer Research UK can also help answer your questions about cancer and treatment. If you want to talk in confidence, call our information nurses on freephone 0808 800 4040, Monday to Friday, 9am to 5pm. Alternatively visit cruk.org for more information.

These forms have been produced by Guy's and St. Thomas' NHS Foundation Trust as part of a national project to support clinicians in ensuring all patients are fully informed when consenting to SACT.

The project is supported by Cancer Research UK. This does not mean you are taking part in a clinical trial.

Guidance for health professionals

(to be read in conjunction with the hospital's consent policy)

Patient identifier/label

What a consent form is for

This form documents the patient's agreement to go ahead with the treatment you have proposed. It is not a legal waiver – if patients, for example, do not receive enough information on which to base their decision, then the consent may not be valid, even though the form has been signed. Patients are also entitled to change their mind after signing the form, if they retain capacity to do so. The form should act as an aide-memoir to health professionals and patients, by providing a checklist of the kind of information patients should be offered, and by enabling the patient to have a written record of the main points discussed. In no way should the written information provided for the patient be regarded as a substitute for face-to-face discussions with the patient.

The law on consent

See the following publications for a comprehensive summary of the law on consent. Consent: Patients and doctors making decisions together, GMC 2020 (gmc-uk.org/guidance). Reference guide to consent for examination or treatment, Department of Health, 2nd edition 2009 (doh.gov.uk).

Who can give consent

Everyone aged 16 or over is presumed to have the capacity to give consent for themselves, unless the opposite is demonstrated. For young people, it is good practice to involve those with parental responsibility in the consent discussions, unless specifically asked not to. A person with parental responsibility must sign this form for a child or young person under the age of 16. Such patients should be given the opportunity to 'assent' to treatment if they wish. If a patient has the capacity to give consent but is physically unable to sign a form, you should complete this form as usual and ask an independent witness to confirm that the patient has given consent orally or non-verbally.

When NOT to use this form

If the patient lacks the capacity to give consent, you should use an alternative form available for this purpose (dependent on patient age). A patient lacks capacity if they have an impairment or disturbance of the brain, affecting the way their mind works. For example, if they cannot do one of the following:

- understand information about the decision to be made
- retain that information in their mind
- use or weigh this information as a part of their decision making process, or
- communicate their decision (by talking, using sign language or any other means)

You should always take all reasonable steps (for example involving more specialist colleagues) to support a patient in making their own decision, before concluding that they are unable to do so. Relatives cannot be asked to sign a form on behalf of an adult who lacks capacity to consent for themselves, unless they have been given the authority to do so under a Lasting Power of Attorney or as a court deputy.

Information

Information about what the treatment will involve, its benefits and risks (including side-effects and complications) and alternatives to the particular procedure proposed, is crucial for patients when making up their minds. The courts have stated that patients should be told about 'significant risks which would affect the judgement of a reasonable patient'. 'Significant' has not been legally defined, but the GMC requires doctors to tell patients about 'significant, unavoidable or frequently occurring' risks. If patients make clear they have particular concerns about certain kinds of risk, you should ensure that they are informed about these risks, even if very small or rare. You should always answer questions honestly. Sometimes, patients may make it clear that they do not want to have any information about the options, but want you to decide on their behalf. In such circumstances, you should do your best to ensure that the patient receives at least very basic information about what is proposed. Where information is refused, you should document this on the consent form or in the patient's notes.

NHS Scotland

NHS Scotland staff should refer to Healthcare Improvement Scotland. Guidance on consent for SACT and local NHS Board guidance on consent aligned to the Scottish legal framework.

References

1. Summary of Product Characteristics for individual drugs: medicines.org.uk/emc
2. Cancer Research UK: cruk.org/about-cancer/treatment/drugs
3. Macmillan Cancer Support: macmillan.org.uk/cancer-information-and-support/treatments-and-drugs
4. Guy's and St. Thomas' NHS Foundation Trust, Chemotherapy consent form

Patient agreement to systemic anti-cancer therapy (SACT)

DA (Daunorubicin and Cytarabine)

Hospital/NHS Trust/NHS Board:

_____

_____

Responsible consultant:

Name: _____

Job title: _____

Patient details

Patient's surname/family name:

_____

Patient's first name(s): _____

_____

Date of birth: _____

NHS number: _____
(or other identifier)

Special requirements:
(eg other language/other communication method)

_____

_____

_____

_____

Name of proposed course of treatment (include brief explanation if medical term not clear)

☐ DA (Daunorubicin and Cytarabine) chemotherapy for the treatment of acute myeloid leukaemia (AML) **OR** high risk myelodysplastic syndrome (MDS).

☐ DA 3+10: Daunorubicin intravenously on days 1, 3 and 5 and Cytarabine intravenously twice each day on days 1 to 10. Usually followed by DA 3+8: Daunorubicin on days 1, 3 and 5 and Cytarabine twice a day on days 1 to 8 **OR**

☐ DA 2+5: Daunorubicin intravenously on days 1 and 3, Cytarabine intravenously twice each day on days 1 to 5 **OR**

☐ DA 3+7: Daunorubicin intravenously on days 1, 3 and 5, Cytarabine intravenously over 24 hours on days 1 to 7.

Where will I have treatment?

☐ Outpatient ☐ Day unit/case ☐ Inpatient ☐ Other: _____

Statement of health professional

(to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in the hospital/Trust/NHS board's consent policy)

☑ Tick all relevant boxes

☐ I confirm the patient has capacity to give consent.

☐ I have explained the course of treatment and intended benefit to the patient.

The intended benefits (there are no guarantees about outcome)

☐ Prolong survival

☐ Control symptoms, reduce transfusion needs and improve quality of life.

☐ Induction – therapy given in the acute state of the disease, aiming to shrink the tumour.

☐ Curative – to give you the best possible chance of being cured.

☐ Maintenance – therapy given on continuing basis, aiming to prevent disease flaring up and to control the symptoms.

☐ Disease control / Palliative – the aim is not to cure but to control the disease and reduce the symptoms. The aim is to improve both quality and quantity of life.

Statement of health professional

Patient identifier/label

You may have one or more of the side effects listed

Common side effects:

Affecting more than 10 in every 100 (>10%) people

- ☐ An increased risk of getting an infection from a drop in white blood cells – this makes it harder to fight infections and you can become very ill.
- ☐ If you have a severe infection this can be life-threatening. Contact your doctor or hospital straight away if:
  - **your temperature goes over 37.5°C or over 38°C, depending on the advice given by your chemotherapy team**
  - **you suddenly feel unwell (even with a normal temperature)**
- ☐ Nausea (feeling sick), vomiting (being sick), sore mouth and ulcers, difficulty swallowing, taste changes, loss of appetite, abdominal (tummy) pain, diarrhoea.
- ☐ Thinning of the hair or hair loss, skin changes (itching, rash, darkening), change in nail colour.
- ☐ Anaemia (due to low red blood cells) and bruising or bleeding (due to low platelets); this can be prolonged requiring a transfusion.
- ☐ Changes in liver and kidney function (monitored), red colour urine for 1-2 days after treatment (due to Daunorubicin).
- ☐ Cytarabine syndrome can occur 6 to 12 hours after receiving Cytarabine. Symptoms include a high temperature or chills, rash, pain in the eyes, bones, tummy and chest. Inform your doctor or nurse.

Occasional side effects:

Affecting between 1-10 in every 100 (1-10%) people

- ☐ Skin changes (severe symptoms with redness, itching, blisters), changes in eye sight (reversible).
- ☐ High uric acid levels, weight loss.
- ☐ Inflammation and ulcers at the opening end of the bowel (anus).
- ☐ Heart problems with changes in the way your heart works including abnormal heart rhythms (fast heart rate) and risk of a heart attack.

Other risks:

- ☐ This treatment may leak out of the vein while it is being given (extravasation) and can damage the tissue around the vein. Tell the nurse straight away if you have any stinging, pain, redness or swelling around the vein. It's uncommon but important to deal with quickly.
- ☐ Late effects include a rare chance of a second cancer (years later) and heart problems.
- ☐ A condition called posterior reversible encephalopathy syndrome (PRES) is a rare side effect. Symptoms include headaches, feeling confused, vision problems (including blindness), fits. Contact your doctor or nurse.
- ☐ This treatment rarely causes other nervous system side effects, such as drowsiness, unsteadiness or mood changes.
- ☐ There may be an increased risk of tumour lysis syndrome in some patients (when treatment destroys cancer cells too quickly for the kidneys to cope and leads to changes in the blood tests). Rarely, dialysis may be needed. You may be prescribed medicines for prevention or treatment.
- ☐ Side effects of anti-sickness medication include diarrhoea, constipation, headaches.
- ☐ Growth factors (GCSF) may be prescribed to maintain number of white cells to prevent infection. You may experience bone pain, headaches, red and itchy skin around the injection site.
- ☐ Before treatment you may have blood tests to check for viruses (Hepatitis B or C, HIV, or unusual infections). Treatment may weaken your natural defence (immune) system so infections like this may worsen or become active if you've had them before. You may have medicines to prevent or treat infection.
- ☐ Changes in your memory, concentration or ability to think clearly.
- ☐ Cancer and its treatment can increase your risk of developing a blood clot (thrombosis), causing pain, redness and swelling in an arm or leg, breathlessness, chest pain. Tell your doctor straight away if you have any symptoms.
- ☐ Some anti-cancer medicines can damage ovaries and sperm. This may lead to infertility and/or early menopause (hot flushes, vaginal dryness).
- ☐ Some anti-cancer medicines may damage the development of a baby in the womb. It is important not to become pregnant or make someone else pregnant during treatment and for at least 6 months afterwards. Use effective contraception.
- ☐ Complications of treatment can very occasionally be life-threatening and may result in death. The risks are different for every individual. Potentially life-threatening complications include those listed on this form, but other exceedingly rare side effects may also be life-threatening.

Statement of health professional

Patient identifier/label

Any other risks and information:

_____

_____

☐ I have discussed the intended benefit and risks of the recommended treatment, and of any available alternative treatments (including no treatment).

☐ I have discussed the side effects of the recommended treatment, which could affect the patient straight away or in the future, and that there may be some side effects not listed because they are rare or have not yet been reported. Each patient may experience side effects differently.

☐ I have discussed what the treatment is likely to involve (including inpatient/outpatient treatment, timing of the treatment, blood and any additional tests, follow-up appointments etc) and location.

☐ I have explained to the patient, that they have the right to stop this treatment at any time and should contact the responsible consultant or team if they wish to do so.

☐ I have discussed concerns of particular importance to the patient in regard to treatment

(please write details here): _____

_____

Clinical management guideline/Protocol compliant (please tick):

☐ Yes ☐ No ☐ Not available If No please document reason here:

_____

The following written information has been provided:

☐ Information leaflet for Daunorubicin and Cytarabine

☐ 24 hour alert card or SACT advice service contact details

☐ SACT treatment record (cruk.org/treatment-record)

☐ Other, please state: _____

_____

Health professional details:

Signed: _____

Date: _____

Name (PRINT): _____

_____

Job title: _____

_____

Statement of interpreter **(where appropriate)**

Interpreter booking reference (if applicable):

I have interpreted the information above to the patient to the best of my ability and in a way in which I believe they can understand.

Signed: _____ Date: _____

Name (PRINT): _____ Job title: _____

Statement of patient

Patient identifier/label

Please read this form carefully. If your treatment has been planned in advance, you should already have your own copy of the form which describes the benefits and risks of the proposed treatment. If not, you will be offered a copy now. If you have any further questions, do ask – we are here to help you. You have the right to change your mind at any time, including after you have signed this form.

☐ I have had enough time to consider my options and make a decision about treatment.

☐ I agree to the course of treatment described on this form.

A witness should sign below if the patient is unable to sign but has indicated their consent. A person with parental responsibility will be asked to sign for young people under the age of 16 years.

Patient's signature: _____

Name (PRINT): _____ Date: _____

Person with parental responsibility/witness' signature: _____

Name (PRINT): _____ Date: _____

Copy accepted by patient: yes / no (please circle)

Confirmation of consent

(health professional to complete when the patient attends for treatment, if the patient has signed the form in advance)

On behalf of the team treating the patient, I have confirmed that the patient has no further questions and wishes the course of treatment/procedures to go ahead.

Signed: _____

Date: _____

Name (PRINT): _____

Job title: _____

Important notes: (tick if applicable)

☐ See also advance decision to refuse treatment

☐ Patient has withdrawn consent (ask patient to sign and date here)

Signed: _____

Date: _____

Further information for patients

Contact details (if patient wishes to discuss options later):

_____

Contact your hospital team if you have any questions about cancer and its treatment.

Cancer Research UK can also help answer your questions about cancer and treatment. If you want to talk in confidence, call our information nurses on freephone 0808 800 4040, Monday to Friday, 9am to 5pm. Alternatively visit cruk.org for more information.

These forms have been produced by Guy's and St. Thomas' NHS Foundation Trust as part of a national project to support clinicians in ensuring all patients are fully informed when consenting to SACT.

The project is supported by Cancer Research UK. This does not mean you are taking part in a clinical trial.

Guidance for health professionals

(to be read in conjunction with the hospital's consent policy)

Patient identifier/label

What a consent form is for

This form documents the patient's agreement to go ahead with the treatment you have proposed. It is not a legal waiver – if patients, for example, do not receive enough information on which to base their decision, then the consent may not be valid, even though the form has been signed. Patients are also entitled to change their mind after signing the form, if they retain capacity to do so. The form should act as an aide-memoir to health professionals and patients, by providing a checklist of the kind of information patients should be offered, and by enabling the patient to have a written record of the main points discussed. In no way should the written information provided for the patient be regarded as a substitute for face-to-face discussions with the patient.

The law on consent

See the following publications for a comprehensive summary of the law on consent. Consent: Patients and doctors making decisions together, GMC 2020 (gmc-uk.org/guidance). Reference guide to consent for examination or treatment, Department of Health, 2nd edition 2009 (doh.gov.uk).

Who can give consent

Everyone aged 16 or over is presumed to have the capacity to give consent for themselves, unless the opposite is demonstrated. For young people, it is good practice to involve those with parental responsibility in the consent discussions, unless specifically asked not to. A person with parental responsibility must sign this form for a child or young person under the age of 16. Such patients should be given the opportunity to 'assent' to treatment if they wish. If a patient has the capacity to give consent but is physically unable to sign a form, you should complete this form as usual and ask an independent witness to confirm that the patient has given consent orally or non-verbally.

When NOT to use this form

If the patient lacks the capacity to give consent, you should use an alternative form available for this purpose (dependent on patient age). A patient lacks capacity if they have an impairment or disturbance of the brain, affecting the way their mind works. For example, if they cannot do one of the following:

- understand information about the decision to be made
- retain that information in their mind
- use or weigh this information as a part of their decision making process, or
- communicate their decision (by talking, using sign language or any other means)

You should always take all reasonable steps (for example involving more specialist colleagues) to support a patient in making their own decision, before concluding that they are unable to do so. Relatives cannot be asked to sign a form on behalf of an adult who lacks capacity to consent for themselves, unless they have been given the authority to do so under a Lasting Power of Attorney or as a court deputy.

Information

Information about what the treatment will involve, its benefits and risks (including side-effects and complications) and alternatives to the particular procedure proposed, is crucial for patients when making up their minds. The courts have stated that patients should be told about 'significant risks which would affect the judgement of a reasonable patient'. 'Significant' has not been legally defined, but the GMC requires doctors to tell patients about 'significant, unavoidable or frequently occurring' risks. If patients make clear they have particular concerns about certain kinds of risk, you should ensure that they are informed about these risks, even if very small or rare. You should always answer questions honestly. Sometimes, patients may make it clear that they do not want to have any information about the options, but want you to decide on their behalf. In such circumstances, you should do your best to ensure that the patient receives at least very basic information about what is proposed. Where information is refused, you should document this on the consent form or in the patient's notes.

NHS Scotland

NHS Scotland staff should refer to Healthcare Improvement Scotland. Guidance on consent for SACT and local NHS Board guidance on consent aligned to the Scottish legal framework.

References

1. Summary of Product Characteristics for individual drugs: medicines.org.uk/emc
2. Cancer Research UK: cruk.org/about-cancer/treatment/drugs
3. Macmillan Cancer Support: macmillan.org.uk/cancer-information-and-support/treatments-and-drugs
4. Guy's and St. Thomas' NHS Foundation Trust, Chemotherapy consent form

Patient agreement to systemic anti-cancer therapy (SACT)

Etoposide (Oral)

Hospital/NHS Trust/NHS Board:

_____

_____

Responsible consultant:

Name: _____

Job title: _____

Patient details

Patient's surname/family name:

_____

Patient's first name(s): _____

_____

Date of birth: _____

NHS number: _____
(or other identifier)

Special requirements:
(eg other language/other communication method)

_____

_____

_____

_____

Name of proposed course of treatment (include brief explanation if medical term not clear)

☐ Etoposide as palliative chemotherapy for the treatment of acute myeloid leukaemia (AML).

☐ Etoposide is taken orally once a day three times a week* or on alternate days* (*delete as appropriate).

☐ The dose is reviewed regularly and will be adjusted by your doctor depending on your blood results.

☐ Treatment is continued until disease progression or unacceptable side effects.

Where will I have treatment?

☐ Outpatient ☐ Day unit/case ☐ Inpatient ☐ Other: _____

Statement of health professional

(to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in the hospital/Trust/NHS board's consent policy)

☑ Tick all relevant boxes

☐ I confirm the patient has capacity to give consent.

☐ I have explained the course of treatment and intended benefit to the patient.

The intended benefits (there are no guarantees about outcome)

☐ Prolong survival.
☐ Control symptoms, reduce transfusion needs and improve quality of life.
☐ Induction – therapy given in the acute state of the disease, aiming to shrink the tumour
☐ Curative – to give you the best possible chance of being cured.
☐ Maintenance – therapy given on continuing basis, aiming to prevent disease flaring up and to control the symptoms.
☐ Disease control / Palliative – the aim is not to cure but to control the disease and reduce the symptoms. The aim is to improve both quality and quantity of life.

Statement of health professional

Patient identifier/label

You may have one or more of the side effects listed

Common side effects:

Affecting more than 10 in every 100 (>10%) people

- ☐ An increased risk of getting an infection from a drop in white blood cells – this makes it harder to fight infections and you can become very ill.
- ☐ **If you have a severe infection this can be life-threatening. Contact your doctor or hospital straight away if:**
  - **your temperature goes over 37.5°C or over 38°C, depending on the advice given by your chemotherapy team**
  - **you suddenly feel unwell (even with a normal temperature)**
- ☐ Feeling sick (nausea) and being sick (vomiting), abdominal (tummy) pain, weight loss, constipation.
- ☐ Tiredness and feeling weak (fatigue).
- ☐ Thinning of the hair or hair loss.
- ☐ Change in skin colour.
- ☐ Anaemia (due to low red blood cells) and bruising or bleeding (due to low platelets); this can be prolonged and you may need a transfusion.
- ☐ Changes in liver function tests (monitored).

Occasional side effects:

Affecting between 1-10 in every 100 (1-10%) people

- ☐ Sore mouth and ulcers,
- ☐ Diarrhoea, feeling dizzy.
- ☐ Rash and/or itching of the skin.
- ☐ Changes in heart rhythm, high blood pressure.
- ☐ Etoposide can increase the risk of developing a second cancer (acute leukaemia), years after treatment.

Other risks:

- ☐ Side effects of anti-sickness medication include diarrhoea, constipation, headaches.
- ☐ Before treatment you may have blood tests to check for viruses (Hepatitis B or C, HIV, or unusual infections). Treatment may weaken your natural defence (immune) system so infections like this may worsen or become active if you've had them before. You may have medicines to prevent or treat infection.
- ☐ Changes in your memory, concentration or ability to think clearly. There can be many causes including your treatment, diagnosis, or both.
- ☐ Cancer and its treatment can increase your risk of developing a blood clot (thrombosis), causing pain, redness and swelling in an arm or leg, breathlessness, chest pain. Tell your doctor straight away if you have any symptoms.
- ☐ Some anti-cancer medicines can damage ovaries and sperm. This may lead to infertility and/or early menopause (hot flushes, vaginal dryness).
- ☐ Some anti-cancer medicines may damage the development of a baby in the womb. It is important not to become pregnant or make someone else pregnant during treatment and for up to 6 months afterwards. Women of child bearing age will be tested for pregnancy before and during treatment. Use effective contraception throughout. Speak to your doctor or nurse.
- ☐ Complications of treatment can very occasionally be life-threatening and may result in death. The risks are different for every individual. Potentially life-threatening complications include those listed on this form, but other, exceedingly rare side effects may also be life-threatening.

Statement of health professional

Patient identifier/label

Any other risks and information:

_____

_____

☐ I have discussed the intended benefit and risks of the recommended treatment, and of any available alternative treatments (including no treatment).

☐ I have discussed the side effects of the recommended treatment, which could affect the patient straight away or in the future, and that there may be some side effects not listed because they are rare or have not yet been reported. Each patient may experience side effects differently.

☐ I have discussed what the treatment is likely to involve (including inpatient/outpatient treatment, timing of the treatment, blood and any additional tests, follow-up appointments etc) and location.

☐ I have explained to the patient, that they have the right to stop this treatment at any time and should contact the responsible consultant or team if they wish to do so.

☐ I have discussed concerns of particular importance to the patient in regard to treatment

(please write details here): _____

_____

Clinical management guideline/Protocol compliant (please tick):

☐ Yes ☐ No ☐ Not available If No please document reason here:

_____

The following written information has been provided:

☐ Information leaflet for Etoposide (oral)

☐ 24 hour alert card or SACT advice service contact details

☐ SACT treatment record (cruk.org/treatment-record)

☐ Other, please state: _____

_____

Health professional details:

Signed: _____

Date: _____

Name (PRINT): _____

_____

Job title: _____

_____

Statement of interpreter **(where appropriate)**

Interpreter booking reference (if applicable):

I have interpreted the information above to the patient to the best of my ability and in a way in which I believe they can understand.

Signed: _____ Date: _____

Name (PRINT): _____ Job title: _____

Statement of patient

Patient identifier/label

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☐ I have had enough time to consider my options and make a decision about treatment.

☐ I agree to the course of treatment described on this form.

A witness should sign below if the patient is unable to sign but has indicated their consent. A person with parental responsibility will be asked to sign for young people under the age of 16 years.

Patient's signature: _____

Name (PRINT): _____ Date: _____

Person with parental responsibility/witness' signature: _____

Name (PRINT): _____ Date: _____

Copy accepted by patient: yes / no (please circle)

Confirmation of consent

(health professional to complete when the patient attends for treatment, if the patient has signed the form in advance)

On behalf of the team treating the patient, I have confirmed that the patient has no further questions and wishes the course of treatment/procedures to go ahead.

Signed: _____

Date: _____

Name (PRINT): _____

Job title: _____

Important notes: (tick if applicable)

☐ See also advance decision to refuse treatment

☐ Patient has withdrawn consent (ask patient to sign and date here)

Signed: _____

Date: _____

Further information for patients

Contact details (if patient wishes to discuss options later):

_____

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The project is supported by Cancer Research UK. This does not mean you are taking part in a clinical trial.

Guidance for health professionals

(to be read in conjunction with the hospital's consent policy)

Patient identifier/label

What a consent form is for

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The law on consent

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Who can give consent

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When NOT to use this form

If the patient lacks the capacity to give consent, you should use an alternative form available for this purpose (dependent on patient age). A patient lacks capacity if they have an impairment or disturbance of the brain, affecting the way their mind works. For example, if they cannot do one of the following:

- understand information about the decision to be made
- retain that information in their mind
- use or weigh this information as a part of their decision making process, or
- communicate their decision (by talking, using sign language or any other means)

You should always take all reasonable steps (for example involving more specialist colleagues) to support a patient in making their own decision, before concluding that they are unable to do so. Relatives cannot be asked to sign a form on behalf of an adult who lacks capacity to consent for themselves, unless they have been given the authority to do so under a Lasting Power of Attorney or as a court deputy.

Information

Information about what the treatment will involve, its benefits and risks (including side-effects and complications) and alternatives to the particular procedure proposed, is crucial for patients when making up their minds. The courts have stated that patients should be told about 'significant risks which would affect the judgement of a reasonable patient'. 'Significant' has not been legally defined, but the GMC requires doctors to tell patients about 'significant, unavoidable or frequently occurring' risks. If patients make clear they have particular concerns about certain kinds of risk, you should ensure that they are informed about these risks, even if very small or rare. You should always answer questions honestly. Sometimes, patients may make it clear that they do not want to have any information about the options, but want you to decide on their behalf. In such circumstances, you should do your best to ensure that the patient receives at least very basic information about what is proposed. Where information is refused, you should document this on the consent form or in the patient's notes.

NHS Scotland

NHS Scotland staff should refer to Healthcare Improvement Scotland. Guidance on consent for SACT and local NHS Board guidance on consent aligned to the Scottish legal framework.

References

1. Summary of Product Characteristics for individual drugs: medicines.org.uk/emc
2. Cancer Research UK: cruk.org/about-cancer/treatment/drugs
3. Macmillan Cancer Support: macmillan.org.uk/cancer-information-and-support/treatments-and-drugs
4. Guy's and St. Thomas' NHS Foundation Trust, Chemotherapy consent form

Patient agreement to systemic anti-cancer therapy (SACT)

Gemtuzumab ozogamicin + chemotherapy

Hospital/NHS Trust/NHS Board:

_____

_____

Responsible consultant:

Name: _____

Job title: _____

Patient details

Patient's surname/family name:

_____

Patient's first name(s): _____

_____

Date of birth: _____

NHS number: _____
(or other identifier)

Special requirements:
(eg other language/other communication method)

_____

_____

_____

_____

Name of proposed course of treatment (include brief explanation if medical term not clear)

☐ Gemtuzumab ozogamicin as part of chemotherapy for CD33 positive acute myeloid leukaemia (AML).

☐ Gemtuzumab is given intravenously in combination with chemotherapy as part of induction and consolidation.

☐ A separate consent form must be completed for the chemotherapy regimen.

Where will I have treatment?

☐ Outpatient ☐ Day unit/case ☐ Inpatient ☐ Other: _____

Statement of health professional

(to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in the hospital/Trust/NHS board's consent policy)

☑ Tick all relevant boxes

☐ I confirm the patient has capacity to give consent.

☐ I have explained the course of treatment and intended benefit to the patient.

The intended benefits (there are no guarantees about outcome)

☐ Prolong survival.
☐ Control symptoms, reduce transfusion needs and improve quality of life.
☐ Induction – therapy given in the acute state of the disease, aiming to shrink the tumour.
☐ Curative – to give you the best possible chance of being cured.
☐ Maintenance – therapy given on continuing basis, aiming to prevent disease flaring up and to control the symptoms.
☐ Disease control / Palliative – the aim is not to cure but to control the disease and reduce the symptoms. The aim is to improve both quality and quantity of life.

Statement of health professional

Patient identifier/label

You may have one or more of the side effects listed

Common side effects:

Affecting more than 10 in every 100 (>10%) people

- ☐ An increased risk of getting an infection from a drop in white blood cells – this makes it harder to fight infections and you can become very ill.
- ☐ **If you have a severe infection this can be life-threatening. Contact your doctor or hospital straight away if:**
  - **your temperature goes over 37.5°C or over 38°C, depending on the advice given by your chemotherapy team**
  - **you suddenly feel unwell (even with a normal temperature)**
- ☐ Nausea (feeling sick), vomiting (being sick), abdominal (tummy) pain, indigestion, constipation, diarrhoea.
- ☐ Sore mouth and ulcers, loss of appetite, feeling weak and tired (fatigue).
- ☐ Anaemia (due to low red blood cells) and bruising or bleeding (due to low platelets); this can be prolonged and you may need a transfusion, changes in liver function (monitored).
- ☐ You may have nose bleeds, bleeding gums, blood in the urine, stools or tiny red, brown or purple spots that may look like a rash.
- ☐ Headache, fluid build-up in hands and feet, rash.
- ☐ High or low blood pressure, high heart rate, shortness of breath, chills.
- ☐ This treatment can raise your blood sugar. If you have diabetes, it may lead to higher blood sugar levels.

Occasional side effects:

Affecting between 1-10 in every 100 (1-10%) people

- ☐ Liver related side effects from minor through to veno-occlusive disease which can be potentially life-threatening. Let your doctor or nurse know if you experience rapid weight gain, pain in the upper right side of your belly, jaundice (yellow skin), build-up of fluid around your tummy.
- ☐ Infusion related side effects may occur during or shortly after the infusion. Symptoms include fast heart rate, wheezing, face swelling, difficulty breathing, fluctuating blood pressure and rash.
- ☐ There may be an increased risk of tumour lysis syndrome in some patients (when treatment destroys cancer cells too quickly for the kidneys to cope and leads to changes in blood tests. Rarely, dialysis may be needed. You may be prescribed medicines for prevention or treatment.
- ☐ Itching and redness of the skin.
- ☐ One or more of your organs may not work properly (this can be life-threatening).

Other risks:

- ☐ Gemtuzumab ozogamicin may leak out of the vein while it is being given (extravasation) and can damage the tissue around the vein. Tell the nurse straight away if you have any stinging, pain, redness or swelling around the vein. It's uncommon but important to deal with quickly.
- ☐ Side effects with the anti-sickness medication may include: constipation, diarrhoea, headaches.
- ☐ Before treatment you may have blood tests to check for viruses (Hepatitis B or C, HIV, or unusual infections). Treatment may weaken your natural defence (immune) system so infections like this may worsen or become active if you've had them before. You may have medicines to prevent or treat infection.
- ☐ Growth factors (GCSF) may be prescribed to maintain number of white cells to prevent infection. You may experience bone pain, headaches, red and itchy skin around the injection site.
- ☐ Late effects include a very rare chance of a second cancer (years later) and problems with your heart.
- ☐ Changes in your memory, concentration or ability to think clearly. There can be many causes including your treatment, diagnosis, or both.
- ☐ Cancer and its treatment can increase your risk of developing a blood clot (thrombosis), causing pain, redness and swelling in an arm or leg, breathlessness, chest pain. Tell your doctor straight away if you have any symptoms.
- ☐ Some anti-cancer medicines can damage ovaries and sperm. This may lead to infertility and/or early menopause (hot flushes, vaginal dryness).

Continue on to the next page

Patient identifier/label

Statement of health professional

Other risks continued

- ☐ Some anti-cancer medicines may damage the development of a baby in the womb. It is important not to become pregnant or make someone else pregnant during treatment and for up to 7 months following last dose of Gemtuzumab ozogamicin. Use effective contraception throughout. It is advisable to use 2 methods of effective contraception during treatment with Gemtuzumab ozogamicin. Women of child bearing age will be tested for pregnancy before and during treatment.Speak to your doctor or nurse.
- ☐ Complications of treatment can very occasionally be life-threatening and may result in death. The risks are different for every individual. Potentially life-threatening complications include those listed on this form, but other exceedingly rare side effects may also be life-threatening.

Statement of health professional

Patient identifier/label

Any other risks and information:

_____

_____

☐ I have discussed the intended benefit and risks of the recommended treatment, and of any available alternative treatments (including no treatment).

☐ I have discussed the side effects of the recommended treatment, which could affect the patient straight away or in the future, and that there may be some side effects not listed because they are rare or have not yet been reported. Each patient may experience side effects differently.

☐ I have discussed what the treatment is likely to involve (including inpatient/outpatient treatment, timing of the treatment, blood and any additional tests, follow-up appointments etc) and location.

☐ I have explained to the patient, that they have the right to stop this treatment at any time and should contact the responsible consultant or team if they wish to do so.

☐ I have discussed concerns of particular importance to the patient in regard to treatment

(please write details here): _____

_____

Clinical management guideline/Protocol compliant (please tick):

☐ Yes ☐ No ☐ Not available If No please document reason here:

_____

The following written information has been provided:

☐ Information leaflets for Gemtuzumab ozogamicin and chemotherapy

☐ 24 hour alert card or SACT advice service contact details

☐ SACT treatment record (cruk.org/treatment-record)

☐ Other, please state: _____

Health professional details:

Signed: _____

Date: _____

Name (PRINT): _____

_____

Job title: _____

_____

Statement of interpreter **(where appropriate)**

Interpreter booking reference (if applicable):

I have interpreted the information above to the patient to the best of my ability and in a way in which I believe they can understand.

Signed: _____ Date: _____

Name (PRINT): _____ Job title: _____

Statement of patient

Patient identifier/label

Please read this form carefully. If your treatment has been planned in advance, you should already have your own copy of the form which describes the benefits and risks of the proposed treatment. If not, you will be offered a copy now. If you have any further questions, do ask – we are here to help you. You have the right to change your mind at any time, including after you have signed this form.

☐ I have had enough time to consider my options and make a decision about treatment.

☐ I agree to the course of treatment described on this form.

A witness should sign below if the patient is unable to sign but has indicated their consent. A person with parental responsibility will be asked to sign for young people under the age of 16 years.

Patient's signature: _____

Name (PRINT): _____ Date: _____

Person with parental responsibility/witness' signature: _____

Name (PRINT): _____ Date: _____

Copy accepted by patient: yes / no (please circle)

Confirmation of consent

(health professional to complete when the patient attends for treatment, if the patient has signed the form in advance)

On behalf of the team treating the patient, I have confirmed that the patient has no further questions and wishes the course of treatment/procedures to go ahead.

Signed: _____

Date: _____

Name (PRINT): _____

Job title: _____

Important notes: (tick if applicable)

☐ See also advance decision to refuse treatment

☐ Patient has withdrawn consent (ask patient to sign and date here)

Signed: _____

Date: _____

Further information for patients

Contact details (if patient wishes to discuss options later):

_____

Contact your hospital team if you have any questions about cancer and its treatment.

Cancer Research UK can also help answer your questions about cancer and treatment. If you want to talk in confidence, call our information nurses on freephone 0808 800 4040, Monday to Friday, 9am to 5pm. Alternatively visit cruk.org for more information.

These forms have been produced by Guy's and St. Thomas' NHS Foundation Trust as part of a national project to support clinicians in ensuring all patients are fully informed when consenting to SACT.

The project is supported by Cancer Research UK. This does not mean you are taking part in a clinical trial.

Guidance for health professionals

(to be read in conjunction with the hospital's consent policy)

Patient identifier/label

What a consent form is for

This form documents the patient's agreement to go ahead with the treatment you have proposed. It is not a legal waiver – if patients, for example, do not receive enough information on which to base their decision, then the consent may not be valid, even though the form has been signed. Patients are also entitled to change their mind after signing the form, if they retain capacity to do so. The form should act as an aide-memoir to health professionals and patients, by providing a checklist of the kind of information patients should be offered, and by enabling the patient to have a written record of the main points discussed. In no way should the written information provided for the patient be regarded as a substitute for face-to-face discussions with the patient.

The law on consent

See the following publications for a comprehensive summary of the law on consent. Consent: Patients and doctors making decisions together, GMC 2020 (gmc-uk.org/guidance). Reference guide to consent for examination or treatment, Department of Health, 2nd edition 2009 (doh.gov.uk).

Who can give consent

Everyone aged 16 or over is presumed to have the capacity to give consent for themselves, unless the opposite is demonstrated. For young people, it is good practice to involve those with parental responsibility in the consent discussions, unless specifically asked not to. A person with parental responsibility must sign this form for a child or young person under the age of 16. Such patients should be given the opportunity to 'assent' to treatment if they wish. If a patient has the capacity to give consent but is physically unable to sign a form, you should complete this form as usual and ask an independent witness to confirm that the patient has given consent orally or non-verbally.

When NOT to use this form

If the patient lacks the capacity to give consent, you should use an alternative form available for this purpose (dependent on patient age). A patient lacks capacity if they have an impairment or disturbance of the brain, affecting the way their mind works. For example, if they cannot do one of the following:

- understand information about the decision to be made
- retain that information in their mind
- use or weigh this information as a part of their decision making process, or
- communicate their decision (by talking, using sign language or any other means)

You should always take all reasonable steps (for example involving more specialist colleagues) to support a patient in making their own decision, before concluding that they are unable to do so. Relatives cannot be asked to sign a form on behalf of an adult who lacks capacity to consent for themselves, unless they have been given the authority to do so under a Lasting Power of Attorney or as a court deputy.

Information

Information about what the treatment will involve, its benefits and risks (including side-effects and complications) and alternatives to the particular procedure proposed, is crucial for patients when making up their minds. The courts have stated that patients should be told about 'significant risks which would affect the judgement of a reasonable patient'. 'Significant' has not been legally defined, but the GMC requires doctors to tell patients about 'significant, unavoidable or frequently occurring' risks. If patients make clear they have particular concerns about certain kinds of risk, you should ensure that they are informed about these risks, even if very small or rare. You should always answer questions honestly. Sometimes, patients may make it clear that they do not want to have any information about the options, but want you to decide on their behalf. In such circumstances, you should do your best to ensure that the patient receives at least very basic information about what is proposed. Where information is refused, you should document this on the consent form or in the patient's notes.

NHS Scotland

NHS Scotland staff should refer to Healthcare Improvement Scotland. Guidance on consent for SACT and local NHS Board guidance on consent aligned to the Scottish legal framework.

References

1. Summary of Product Characteristics for individual drugs: medicines.org.uk/emc
2. Cancer Research UK: cruk.org/about-cancer/treatment/drugs
3. Macmillan Cancer Support: macmillan.org.uk/cancer-information-and-support/treatments-and-drugs
4. Guy's and St. Thomas' NHS Foundation Trust, Chemotherapy consent form

Patient agreement to systemic anti-cancer therapy (SACT)

Gemtuzumab ozogamicin with Daunorubicin and Cytarabine

Hospital/NHS Trust/NHS Board:

_____

_____

Responsible consultant:

Name: _____

Job title: _____

Patient details

Patient's surname/family name:

_____

Patient's first name(s): _____

_____

Date of birth: _____

NHS number: _____
(or other identifier)

Special requirements:
(eg other language/other communication method)

_____

_____

_____

_____

Name of proposed course of treatment (include brief explanation if medical term not clear)

☐ Gemtuzumab, Daunorubicin and Cytarabine for the treatment of CD33 positive acute myeloid leukaemia (AML).

☐ Induction 1: Gemtuzumab given intravenously on days 1,4 &7, Daunorubicin intravenously on days 1 to 3, Cytarabine intravenously on days 1 to 7.

☐ Induction 2 (only if needed): Daunorubicin on days 1 & 2. Cytarabine on days 1 to 3.

☐ Consolidation 1: Gemtuzumab on day 1, Daunorubicin on day 1, Cytarabine on days 1 to 4.

☐ Consolidation 2: Gemtuzumab on day 1, Daunorubicin on days 1 & 2, Cytarabine on days 1 to 4.

Where will I have treatment?

☐ Outpatient ☐ Day unit/case ☐ Inpatient ☐ Other: _____

Statement of health professional

(to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in the hospital/Trust/NHS board's consent policy)

☑ Tick all relevant boxes

☐ I confirm the patient has capacity to give consent.

☐ I have explained the course of treatment and intended benefit to the patient.

The intended benefits (there are no guarantees about outcome)

☐ Prolong survival.

☐ Control symptoms, reduce transfusion needs and improve quality of life.

☐ Induction – therapy given in the acute state of the disease, aiming to shrink the tumour.

☐ Curative – to give you the best possible chance of being cured.

☐ Maintenance – therapy given on continuing basis, aiming to prevent disease flaring up and to control the symptoms.

☐ Disease control / Palliative – the aim is not to cure but to control the disease and reduce the symptoms. The aim is to improve both quality and quantity of life

Statement of health professional

Patient identifier/label

You may have one or more of the side effects listed

Common side effects:

Affecting more than 10 in every 100 (>10%) people

- ☐ An increased risk of getting an infection from a drop in white blood cells – this makes it harder to fight infections and you can become very ill.
- ☐ **If you have a severe infection this can be life-threatening. Contact your doctor or hospital straight away if:**
  - **your temperature goes over 37.5°C or over 38°C, depending on the advice given by your chemotherapy team**
  - **you suddenly feel unwell (even with a normal temperature)**
- ☐ Nausea (feeling sick), vomiting (being sick), abdominal (tummy) pain, indigestion, constipation, diarrhoea.
- ☐ Sore mouth and ulcers, loss of appetite, difficulty swallowing, taste changes, feeling weak and tired (fatigue).
- ☐ Thinning of the hair or hair loss, skin changes (itching, rash, darkening), change in nail colour.
- ☐ Anaemia (due to low red blood cells) and bruising or bleeding (due to low platelets); this can be prolonged and you may need a transfusion, changes in liver and kidney function (monitored).
- ☐ You may have nose bleeds, bleeding gums, blood in the urine, stools or tiny red, brown or purple spots that may look like a rash.
- ☐ Red colour urine for 1-2 days after treatment (due to daunorubicin).
- ☐ Headache, fluid build-up in hands and feet, rash, high or low blood pressure, high heart rate, shortness of breath, chills.
- ☐ Inflammation of the lining of the eye lids (conjunctiva) making eyes feel sore, red and itchy (this is temporary). Steroid eye drops during and for 3 days after Cytarabine to prevent this will be given.
- ☐ Gemtuzumab ozogamicin can raise your blood sugar. If you have diabetes, it may lead to higher blood sugar levels.
- ☐ Cytarabine syndrome can occur 6 to 12 hours after receiving Cytarabine. Symptoms include a high temperature or chills, rash, pain in the eyes, bones, tummy and chest. Inform your doctor or nurse.

Occasional side effects:

Affecting between 1-10 in every 100 (1-10%) people

- ☐ Liver related side effects from minor through to veno-occlusive disease which can be potentially life-threatening. Let your doctor or nurse know if you experience rapid weight gain, pain in the upper right side of your belly, jaundice (yellow skin), build-up of fluid around your tummy.
- ☐ Infusion related side effects may occur during or shortly after the infusion. Symptoms include fast heart rate, wheezing, face swelling, difficulty breathing, fluctuating blood pressure and rash.
- ☐ Inflammation and ulcers at the opening end of the bowel (anus), which can be severe leading to infections.
- ☐ Heart problems with changes in the way your heart works including abnormal heart rhythm (fast heart rate) and risk of a heart attack.
- ☐ Severe skin changes (redness, itching sometimes blisters), acid reflux, weight loss.
- ☐ Eye sight changes (reversible), high uric acid levels.
- ☐ One or more of your organs may not work properly (this can be life-threatening).
- ☐ High dose Cytarabine can cause temporary or occasionally permanent changes to the nervous system. Symptoms include seizures (fits), drowsiness, unsteadiness and mood changes.
- ☐ There may be an increased risk of tumour lysis syndrome in some patients (when treatment destroys cancer cells too quickly for the kidneys to cope and leads to changes in blood tests. Rarely, dialysis may be needed. You may be prescribed medicines for prevention or treatment.

Other risks:

- ☐ All intravenous drugs may leak out of the vein while it is being given (extravasation) and can damage the tissue around the vein. Tell the nurse straight away if you have any stinging, pain, redness or swelling around the vein. It's uncommon but important to deal with quickly.
- ☐ Also, rarely high dose Cytarabine can cause changes in the lungs with shortness of breath, wheeezing, cough or a fever. Please inform your doctor or nurse if you notice these symptoms.
- ☐ Side effects with the anti-sickness medication may include: constipation, diarrhoea, headaches.

Continue on to the next page

Statement of health professional

Patient identifier/label

Other risks continued:

- ☐ Before treatment you may have blood tests to check for viruses (Hepatitis B or C, HIV, or unusual infections). Treatment may weaken your natural defence (immune) system so infections like this may worsen or become active if you've had them before. You may have medicines to prevent or treat infection.
- ☐ Growth factors (GCSF) may be prescribed to maintain number of white cells to prevent infection. You may experience bone pain, headaches, red and itchy skin around the injection site.
- ☐ Late effects include a rare chance of a second cancer (years later) and problems with your heart.
- ☐ Changes in your memory, concentration or ability to think clearly. There can be many causes including your treatment, diagnosis, or both.
- ☐ Cancer and its treatment can increase your risk of developing a blood clot (thrombosis), causing pain, redness and swelling in an arm or leg, breathlessness, chest pain. Tell your doctor straight away if you have any symptoms.
- ☐ Some anti-cancer medicines can damage ovaries and sperm. This may lead to infertility and/or early menopause (hot flushes, vaginal dryness).
- ☐ Some anti-cancer medicines may damage the development of a baby in the womb. It is important not to become pregnant or make someone else pregnant during treatment and for up to 7 months afterwards. It is advisable to use 2 methods of effective contraception during treatment with Gemtuzumab ozogamicin. Women of child bearing age will be tested for pregnancy before and during treatment. Use effective contraception throughout. Speak to your doctor or nurse.
- ☐ Complications of treatment can very occasionally be life-threatening and may result in death. The risks are different for every individual. Potentially life-threatening complications include those listed on this form, but other exceedingly rare side effects may also be life-threatening.

Statement of health professional

Patient identifier/label

Any other risks and information:

_____

_____

☐ I have discussed the intended benefit and risks of the recommended treatment, and of any available alternative treatments (including no treatment).

☐ I have discussed the side effects of the recommended treatment, which could affect the patient straight away or in the future, and that there may be some side effects not listed because they are rare or have not yet been reported. Each patient may experience side effects differently.

☐ I have discussed what the treatment is likely to involve (including inpatient/outpatient treatment, timing of the treatment, blood and any additional tests, follow-up appointments etc) and location.

☐ I have explained to the patient, that they have the right to stop this treatment at any time and should contact the responsible consultant or team if they wish to do so.

☐ I have discussed concerns of particular importance to the patient in regard to treatment

(please write details here): _____

_____

Clinical management guideline/Protocol compliant (please tick):

☐ Yes ☐ No ☐ Not available If No please document reason here:

_____

The following written information has been provided:

☐ Information leaflet for Gemtuzumab ozogamicin, Daunorubicin and Cytarabine

☐ 24 hour alert card or SACT advice service contact details

☐ SACT treatment record (cruk.org/treatment-record)

☐ Other, please state: _____

_____

Health professional details:

Signed: _____

Date: _____

Name (PRINT): _____

_____

Job title: _____

_____

Statement of interpreter **(where appropriate)**

Interpreter booking reference (if applicable):

I have interpreted the information above to the patient to the best of my ability and in a way in which I believe they can understand.

Signed: _____ Date: _____

Name (PRINT): _____ Job title: _____

Statement of patient

Patient identifier/label

Please read this form carefully. If your treatment has been planned in advance, you should already have your own copy of the form which describes the benefits and risks of the proposed treatment. If not, you will be offered a copy now. If you have any further questions, do ask – we are here to help you. You have the right to change your mind at any time, including after you have signed this form.

☐ I have had enough time to consider my options and make a decision about treatment.

☐ I agree to the course of treatment described on this form.

A witness should sign below if the patient is unable to sign but has indicated their consent. A person with parental responsibility will be asked to sign for young people under the age of 16 years.

Patient's signature: _____

Name (PRINT): _____ Date: _____

Person with parental responsibility/witness' signature: _____

Name (PRINT): _____ Date: _____

Copy accepted by patient: yes / no (please circle)

Confirmation of consent

(health professional to complete when the patient attends for treatment, if the patient has signed the form in advance)

On behalf of the team treating the patient, I have confirmed that the patient has no further questions and wishes the course of treatment/procedures to go ahead.

Signed: _____

Date: _____

Name (PRINT): _____

Job title: _____

Important notes: (tick if applicable)

☐ See also advance decision to refuse treatment

☐ Patient has withdrawn consent (ask patient to sign and date here)

Signed: _____

Date: _____

Further information for patients

Contact details (if patient wishes to discuss options later):

_____

Contact your hospital team if you have any questions about cancer and its treatment.

Cancer Research UK can also help answer your questions about cancer and treatment. If you want to talk in confidence, call our information nurses on freephone 0808 800 4040, Monday to Friday, 9am to 5pm. Alternatively visit cruk.org for more information.

These forms have been produced by Guy's and St. Thomas' NHS Foundation Trust as part of a national project to support clinicians in ensuring all patients are fully informed when consenting to SACT.

The project is supported by Cancer Research UK. This does not mean you are taking part in a clinical trial.



Guidance for health professionals

(to be read in conjunction with the hospital's consent policy)

Patient identifier/label

What a consent form is for

This form documents the patient's agreement to go ahead with the treatment you have proposed. It is not a legal waiver – if patients, for example, do not receive enough information on which to base their decision, then the consent may not be valid, even though the form has been signed. Patients are also entitled to change their mind after signing the form, if they retain capacity to do so. The form should act as an aide-memoir to health professionals and patients, by providing a checklist of the kind of information patients should be offered, and by enabling the patient to have a written record of the main points discussed. In no way should the written information provided for the patient be regarded as a substitute for face-to-face discussions with the patient.

The law on consent

See the following publications for a comprehensive summary of the law on consent. Consent: Patients and doctors making decisions together, GMC 2020 (gmc-uk.org/guidance). Reference guide to consent for examination or treatment, Department of Health, 2nd edition 2009 (doh.gov.uk).

Who can give consent

Everyone aged 16 or over is presumed to have the capacity to give consent for themselves, unless the opposite is demonstrated. For young people, it is good practice to involve those with parental responsibility in the consent discussions, unless specifically asked not to. A person with parental responsibility must sign this form for a child or young person under the age of 16. Such patients should be given the opportunity to 'assent' to treatment if they wish. If a patient has the capacity to give consent but is physically unable to sign a form, you should complete this form as usual and ask an independent witness to confirm that the patient has given consent orally or non-verbally.

When NOT to use this form

If the patient lacks the capacity to give consent, you should use an alternative form available for this purpose (dependent on patient age). A patient lacks capacity if they have an impairment or disturbance of the brain, affecting the way their mind works. For example, if they cannot do one of the following:

- understand information about the decision to be made
- retain that information in their mind
- use or weigh this information as a part of their decision making process, or
- communicate their decision (by talking, using sign language or any other means)

You should always take all reasonable steps (for example involving more specialist colleagues) to support a patient in making their own decision, before concluding that they are unable to do so. Relatives cannot be asked to sign a form on behalf of an adult who lacks capacity to consent for themselves, unless they have been given the authority to do so under a Lasting Power of Attorney or as a court deputy.

Information

Information about what the treatment will involve, its benefits and risks (including side-effects and complications) and alternatives to the particular procedure proposed, is crucial for patients when making up their minds. The courts have stated that patients should be told about 'significant risks which would affect the judgement of a reasonable patient'. 'Significant' has not been legally defined, but the GMC requires doctors to tell patients about 'significant, unavoidable or frequently occurring' risks. If patients make clear they have particular concerns about certain kinds of risk, you should ensure that they are informed about these risks, even if very small or rare. You should always answer questions honestly. Sometimes, patients may make it clear that they do not want to have any information about the options, but want you to decide on their behalf. In such circumstances, you should do your best to ensure that the patient receives at least very basic information about what is proposed. Where information is refused, you should document this on the consent form or in the patient's notes.

NHS Scotland

NHS Scotland staff should refer to Healthcare Improvement Scotland. Guidance on consent for SACT and local NHS Board guidance on consent aligned to the Scottish legal framework.

References

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3. Macmillan Cancer Support: macmillan.org.uk/cancer-information-and-support/treatments-and-drugs
4. Guy's and St. Thomas' NHS Foundation Trust, Chemotherapy consent form

Patient agreement to systemic anti-cancer therapy (SACT)

FLAG

Hospital/NHS Trust/NHS Board:

_____

_____

Responsible consultant:

Name: _____

Job title: _____

Patient details

Patient's surname/family name:

_____

Patient's first name(s): _____

_____

Date of birth: _____

NHS number: _____
(or other identifier)

Special requirements:
(eg other language/other communication method)

_____

_____

_____

_____

Name of proposed course of treatment (include brief explanation if medical term not clear)

☐ FLAG (Fludarabine, Cytarabine, GCSF) chemotherapy for the treatment of acute myeloid leukaemia (AML).
☐ G-CSF (granulocyte colony-stimulating factor) is given subcutaneously on days 1 to 7 (starting the day before chemotherapy for 7 days in total). Local policy may vary.
☐ Fludarabine given intravenously on days 2 to 6 followed by Cytarabine. Cytarabine given intravenously on days 2 to 6. Total of 5 doses each.
☐ This is given for a maximum of 2 cycles depending on blood counts.

Where will I have treatment?

☐ Outpatient ☐ Day unit/case ☐ Inpatient ☐ Other: _____

Statement of health professional

(to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in the hospital/Trust/NHS board's consent policy)

☑ Tick all relevant boxes

☐ I confirm the patient has capacity to give consent.

☐ I have explained the course of treatment and intended benefit to the patient.

The intended benefits (there are no guarantees about outcome)

☐ Prolong survival.

☐ Control symptoms, reduce transfusion needs and improve quality of life.

☐ Induction – therapy given in the acute state of the disease, aiming to shrink the tumour.

☐ Curative – to give you the best possible chance of being cured.

☐ Maintenance – therapy given on continuing basis, aiming to prevent disease flaring up and to control the symptoms.

☐ Disease control / Palliative – the aim is not to cure but to control the disease and reduce the symptoms. The aim is to improve both quality and quantity of life.

Statement of health professional

Patient identifier/label

You may have one or more of the side effects listed

Common side effects:

Affecting more than 10 in every 100 (>10%) people

- ☐ An increased risk of getting an infection from a drop in white blood cells – this makes it harder to fight infections and you can become very ill.
- ☐ **If you have a severe infection this can be life-threatening. Contact your doctor or hospital straight away if:**
  - **your temperature goes over 37.5°C or over 38°C, depending on the advice given by your chemotherapy team**
  - **you suddenly feel unwell (even with a normal temperature)**
- ☐ Nausea (feeling sick) and vomiting (being sick), abdominal (tummy) pain, diarrhoea.
- ☐ Sore mouth and ulcers, weight loss, feeling tired and weak (fatigue).
- ☐ Thinning of hair or hair loss, cough.
- ☐ Anaemia (due to low red blood cells) and bruising or bleeding (due to low platelets); this can be prolonged and you may need a transfusion.
- ☐ Changes in liver and kidney function (monitored).
- ☐ Cytarabine syndrome can occur 6 to 12 hours after receiving Cytarabine. Symptoms include fever or chills, rash, pain in the eyes, bones, tummy and chest.
- ☐ Inflammation of the lining of the eye lids (conjunctiva) making eyes feel sore, red and itchy (this is temporary). Steroid eye drops during and for 3 days after Cytarabine to prevent this will be given.

Occasional side effects:

Affecting between 1-10 in every 100 (1-10%) people

- ☐ Inflammation and ulcers at the opening end of the bowel (anus), sometimes can be severe leading to infections.
- ☐ Numbness and tingling in hands and feet, skin changes (redness, itching, sometimes blisters).
- ☐ Eye sight changes (reversible), weight loss, high uric acid levels.
- ☐ This treatment increases the risk of temporary or occasionally permanent changes to the nervous system. Symptoms include fits, drowsiness, unsteadiness, irritability and mood changes. Inform your doctor or nurse.
- ☐ Blood pressure changes.
- ☐ Recovery of blood counts may be very slow and in rare cases recovery may be incomplete.

Other risks:

- ☐ Cytarabine, Fludarabine may leak out of the vein while it is being given (extravasation) and can damage the tissue around the vein. Tell the nurse straight away if you have any stinging, pain, redness or swelling around the vein. It's uncommon but important to deal with quickly.
- ☐ Growth factors (GCSF) will be prescribed to maintain number of white cells to prevent infection. You may experience bone pain, headaches, red and itchy skin around the injection site.
- ☐ Late effects include a rare chance of a second cancer (years later) and problems with your heart.
- ☐ Fludarabine depletes a certain type of cell in your blood (T-cells) and therefore you will require irradiated blood products if transfused.
- ☐ Rarely, this treatment can cause changes in the lungs with shortness of breath, wheezing, cough or a fever. Please inform your doctor or nurse if you notice these symptoms.
- ☐ There is an increased risk of tumour lysis syndrome in some patients when treatment destroys cancer cells too quickly for the kidneys to cope and leads to changes in blood tests. Rarely, dialysis may be needed. You may be prescribed medicines for prevention or treatment.
- ☐ Before treatment you may have blood tests to check for viruses (Hepatitis B or C, HIV, or unusual infections). Treatment may weaken your natural defence (immune) system so infections like this may worsen or become active if you've had them before. You may have medicines to prevent or treat infection.
- ☐ Side effects of anti-sickness medication include diarrhoea, constipation, headaches.
- ☐ Changes in your memory, concentration or ability to think clearly. There can be many causes including your treatment, diagnosis, or both.
- ☐ Cancer and its treatment can increase your risk of developing a blood clot (thrombosis), causing pain, redness and swelling in an arm or leg, breathlessness, chest pain. Tell your doctor straight away if you have any symptoms.

Continue on to the next page

Patient identifier/label

Statement of health professional

Other risks continued:

- ☐ Some anti-cancer medicines can damage ovaries and sperm. This may lead to infertility and/or early menopause (hot flushes, vaginal dryness).
- ☐ Some anti-cancer medicines may damage the development of a baby in the womb. It is important not to become pregnant or make someone else pregnant during treatment and for up to 6 months afterwards. Women of child bearing age will be tested for pregnancy before and during treatment. Use effective contraception throughout. Speak to your doctor or nurse.
- ☐ Complications of treatment can very occasionally be life-threatening and may result in death. The risks are different for every individual. Potentially life-threatening complications include those listed on this form, but other exceedingly rare side effects may also be life-threatening.

Statement of health professional

Patient identifier/label

Any other risks and information:

_____

_____

☐ I have discussed the intended benefit and risks of the recommended treatment, and of any available alternative treatments (including no treatment).

☐ I have discussed the side effects of the recommended treatment, which could affect the patient straight away or in the future, and that there may be some side effects not listed because they are rare or have not yet been reported. Each patient may experience side effects differently.

☐ I have discussed what the treatment is likely to involve (including inpatient/outpatient treatment, timing of the treatment, blood and any additional tests, follow-up appointments etc) and location.

☐ I have explained to the patient, that they have the right to stop this treatment at any time and should contact the responsible consultant or team if they wish to do so.

☐ I have discussed concerns of particular importance to the patient in regard to treatment

(please write details here): _____

_____

Clinical management guideline/Protocol compliant (please tick):

☐ Yes ☐ No ☐ Not available If No please document reason here:

_____

The following written information has been provided:

☐ Information leaflet for Fludarabine, Cytarabine and GCSF

☐ 24 hour alert card or SACT advice service contact details

☐ SACT treatment record (cruk.org/treatment-record)

☐ Other, please state: _____

_____

Health professional details:

Signed: _____

Date: _____

Name (PRINT): _____

_____

Job title: _____

_____

Statement of interpreter **(where appropriate)**

Interpreter booking reference (if applicable):

I have interpreted the information above to the patient to the best of my ability and in a way in which I believe they can understand.

Signed: _____ Date: _____

Name (PRINT): _____ Job title: _____

Statement of patient

Patient identifier/label

Please read this form carefully. If your treatment has been planned in advance, you should already have your own copy of the form which describes the benefits and risks of the proposed treatment. If not, you will be offered a copy now. If you have any further questions, do ask – we are here to help you. You have the right to change your mind at any time, including after you have signed this form.

☐ I have had enough time to consider my options and make a decision about treatment.

☐ I agree to the course of treatment described on this form.

A witness should sign below if the patient is unable to sign but has indicated their consent. A person with parental responsibility will be asked to sign for young people under the age of 16 years.

Patient's signature: _____

Name (PRINT): _____ Date: _____

Person with parental responsibility/witness' signature: _____

Name (PRINT): _____ Date: _____

Copy accepted by patient: yes / no (please circle)

Confirmation of consent

(health professional to complete when the patient attends for treatment, if the patient has signed the form in advance)

On behalf of the team treating the patient, I have confirmed that the patient has no further questions and wishes the course of treatment/procedures to go ahead.

Signed: _____

Date: _____

Name (PRINT): _____

Job title: _____

Important notes: (tick if applicable)

☐ See also advance decision to refuse treatment

☐ Patient has withdrawn consent (ask patient to sign and date here)

Signed: _____

Date: _____

Further information for patients

Contact details (if patient wishes to discuss options later):

_____

Contact your hospital team if you have any questions about cancer and its treatment.

Cancer Research UK can also help answer your questions about cancer and treatment. If you want to talk in confidence, call our information nurses on freephone 0808 800 4040, Monday to Friday, 9am to 5pm. Alternatively visit cruk.org for more information.

These forms have been produced by Guy's and St. Thomas' NHS Foundation Trust as part of a national project to support clinicians in ensuring all patients are fully informed when consenting to SACT.

The project is supported by Cancer Research UK. This does not mean you are taking part in a clinical trial.

Guidance for health professionals

(to be read in conjunction with the hospital's consent policy)

Patient identifier/label

What a consent form is for

This form documents the patient's agreement to go ahead with the treatment you have proposed. It is not a legal waiver – if patients, for example, do not receive enough information on which to base their decision, then the consent may not be valid, even though the form has been signed. Patients are also entitled to change their mind after signing the form, if they retain capacity to do so. The form should act as an aide-memoir to health professionals and patients, by providing a checklist of the kind of information patients should be offered, and by enabling the patient to have a written record of the main points discussed. In no way should the written information provided for the patient be regarded as a substitute for face-to-face discussions with the patient.

The law on consent

See the following publications for a comprehensive summary of the law on consent. Consent: Patients and doctors making decisions together, GMC 2020 (gmc-uk.org/guidance). Reference guide to consent for examination or treatment, Department of Health, 2nd edition 2009 (doh.gov.uk).

Who can give consent

Everyone aged 16 or over is presumed to have the capacity to give consent for themselves, unless the opposite is demonstrated. For young people, it is good practice to involve those with parental responsibility in the consent discussions, unless specifically asked not to. A person with parental responsibility must sign this form for a child or young person under the age of 16. Such patients should be given the opportunity to 'assent' to treatment if they wish. If a patient has the capacity to give consent but is physically unable to sign a form, you should complete this form as usual and ask an independent witness to confirm that the patient has given consent orally or non-verbally.

When NOT to use this form

If the patient lacks the capacity to give consent, you should use an alternative form available for this purpose (dependent on patient age). A patient lacks capacity if they have an impairment or disturbance of the brain, affecting the way their mind works. For example, if they cannot do one of the following:

- understand information about the decision to be made
- retain that information in their mind
- use or weigh this information as a part of their decision making process, or
- communicate their decision (by talking, using sign language or any other means)

You should always take all reasonable steps (for example involving more specialist colleagues) to support a patient in making their own decision, before concluding that they are unable to do so. Relatives cannot be asked to sign a form on behalf of an adult who lacks capacity to consent for themselves, unless they have been given the authority to do so under a Lasting Power of Attorney or as a court deputy.

Information

Information about what the treatment will involve, its benefits and risks (including side-effects and complications) and alternatives to the particular procedure proposed, is crucial for patients when making up their minds. The courts have stated that patients should be told about 'significant risks which would affect the judgement of a reasonable patient'. 'Significant' has not been legally defined, but the GMC requires doctors to tell patients about 'significant, unavoidable or frequently occurring' risks. If patients make clear they have particular concerns about certain kinds of risk, you should ensure that they are informed about these risks, even if very small or rare. You should always answer questions honestly. Sometimes, patients may make it clear that they do not want to have any information about the options, but want you to decide on their behalf. In such circumstances, you should do your best to ensure that the patient receives at least very basic information about what is proposed. Where information is refused, you should document this on the consent form or in the patient's notes.

NHS Scotland

NHS Scotland staff should refer to Healthcare Improvement Scotland. Guidance on consent for SACT and local NHS Board guidance on consent aligned to the Scottish legal framework.

References

1. Summary of Product Characteristics for individual drugs: medicines.org.uk/emc
2. Cancer Research UK: cruk.org/about-cancer/treatment/drugs
3. Macmillan Cancer Support: macmillan.org.uk/cancer-information-and-support/treatments-and-drugs
4. Guy's and St. Thomas' NHS Foundation Trust, Chemotherapy consent form

Patient agreement to systemic anti-cancer therapy (SACT)

FLAG + Idarubicin

Hospital/NHS Trust/NHS Board:

_____

_____

Responsible consultant:

Name: _____

Job title: _____

Patient details

Patient's surname/family name:

_____

Patient's first name(s): _____

_____

Date of birth: _____

NHS number: _____
(or other identifier)

Special requirements:
(eg other language/other communication method)

_____

_____

_____

_____

Name of proposed course of treatment (include brief explanation if medical term not clear)

☐ FLAG (Fludarabine, Cytarabine, GCSF) & Idarubicin chemotherapy for the treatment of acute myeloid leukaemia (AML) or high risk Myelodysplastic Syndrome (MDS).

☐ G-CSF (granulocyte colony-stimulating factor) given subcutaneously on days 1 to 7 (starting the day before chemotherapy for 7 days in total). Local policy may vary.

☐ Fludarabine given intravenously on days 2 to 6 followed by Cytarabine. Cytarabine given intravenously on days 2 to 6. Total of 5 doses.

☐ Idarubicin is given intravenously on days 4, 5 and 6. Total of 3 doses or less.

☐ This is guven for a maximum of 2 cycles depending on blood counts.

Where will I have treatment?

☐ Outpatient ☐ Day unit/case ☐ Inpatient ☐ Other: _____

Statement of health professional

(to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in the hospital/Trust/NHS board's consent policy)

☑ Tick all relevant boxes

☐ I confirm the patient has capacity to give consent.

☐ I have explained the course of treatment and intended benefit to the patient.

The intended benefits (there are no guarantees about outcome)

☐ Prolong survival.

☐ Control symptoms, reduce transfusion needs and improve quality of life.

☐ Induction – therapy given in the acute state of the disease, aiming to shrink the tumour.

☐ Curative – to give you the best possible chance of being cured.

☐ Maintenance – therapy given on continuing basis, aiming to prevent disease flaring up and to control the symptoms.

☐ Disease control / Palliative – the aim is not to cure but to control the disease and reduce the symptoms. The aim is to improve both quality and quantity of life.

Statement of health professional

Patient identifier/label

You may have one or more of the side effects listed

Common side effects:

Affecting more than 10 in every 100 (>10%) people

- ☐ An increased risk of getting an infection from a drop in white blood cells – this makes it harder to fight infections and you can become very ill.
- ☐ **If you have a severe infection this can be life-threatening. Contact your doctor or hospital straight away if:**
  - **your temperature goes over 37.5°C or over 38°C, depending on the advice given by your chemotherapy team**
  - **you suddenly feel unwell (even with a normal temperature)**
- ☐ Nausea (feeling sick), vomiting (being sick), abdominal (tummy) pain, diarrhoea, weight loss.
- ☐ Thinning of hair or hair loss, cough.
- ☐ Sore mouth and ulcers, weight loss, feeling tired and weak (fatigue), headache, chills, red colour urine for 1-2 days following treatment with Idarubicin.
- ☐ Anaemia (due to low red blood cells) and bruising or bleeding (due to low platelets); this can be prolonged and you may need a transfusion.
- ☐ Changes in liver and kidney fuction (monitored).
- ☐ Cytarabine syndrome can occur 6 to 12 hours after receiving Cytarabine. Symptoms include fever or chills, rash, pain in the eyes, bones, tummy and chest.
- ☐ Inflammation of the lining of the eye lids (conjunctiva) making eyes feel sore, red and itchy (this is temporary). Steroid eye drops during and for 3 days after Cytarabine to prevent this will be given.

Occasional side effects:

Affecting between 1-10 in every 100 (1-10%) people

- ☐ Inflammation and ulcers of the opening at the end of the bowel (anus), sometimes can cause bleeding leading to severe infections.
- ☐ Numbness and tingling in hands and feet, skin changes (redness, itching sometimes blisters).
- ☐ Changes in eye sight (reversible), high uric acid levels.
- ☐ Rapid changes in heart rates (high or low), changes in the way the heart works with fluid build-up, shortness of breath, fast heart beat. Such symptoms can occur early on or within 2-3 months after treatment.
- ☐ Recovery of blood counts may be very slow and in rare cases recovery may be incomplete.

Occasional side effects continued:

- ☐ This treatment increases the risk of temporary or occasionally permanent changes to the nervous system. Symptoms include fits, drowsiness, unsteadiness and mood changes. Inform your doctor or nurse.
- ☐ Pain, redness and inflammation at the site of injection.

Other risks:

- ☐ Cytarabine, Fludarabine, Idarubicin may leak out of the vein while it is being given (extravasation) and can damage the tissue around the vein. Tell the nurse straight away if you have any stinging, pain, redness or swelling around the vein. It's uncommon but important to deal with quickly.
- ☐ Growth factors (GCSF) will be prescribed to maintain number of white cells to prevent infection. You may experience bone pain, headaches, red and itchy skin around the injection site.
- ☐ Late effects include a rare chance of a second cancer (years later) and problems with your heart.
- ☐ Fludarabine depletes a certain type of cell in your blood (T-cells) and therefore you will require irradiated blood products if transfused.
- ☐ Rarely, this treatment can cause changes in the lungs with shortness of breath, wheezing, cough or a fever. Please inform your doctor or nurse if you notice these symptoms.
- ☐ There is an increased risk of tumour lysis syndrome in some patients when treatment destroys cancer cells too quickly for the kidneys to cope and leads to changes in blood tests. Rarely, dialysis may be needed. You may be prescribed medicines for prevention or treatment.
- ☐ Before treatment you may have blood tests to check for viruses (Hepatitis B or C, HIV, or unusual infections). Treatment may weaken your natural defence (immune) system so infections like this may worsen or become active if you've had them before. You may have medicines to prevent or treat infection.
- ☐ Side effects of anti-sickness medication include diarrhoea, constipation, headaches.

Continue on to the next page

Patient identifier/label

Statement of health professional

Other risks continued:

- ☐ Changes in your memory, concentration or ability to think clearly. There can be many causes including your treatment, diagnosis, or both.
- ☐ Cancer and its treatment can increase your risk of developing a blood clot (thrombosis), causing pain, redness and swelling in an arm or leg, breathlessness, chest pain. Tell your doctor straight away if you have any symptoms.
- ☐ Some anti-cancer medicines can damage ovaries and sperm. This may lead to infertility and/or early menopause (hot flushes, vaginal dryness).
- ☐ Some anti-cancer medicines may damage the development of a baby in the womb. It is important not to become pregnant or make someone elase pregnant during treatment and for up to 7 months afterwards. Women of child bearing age will be tested for pregnancy before and during treatment. Use effective contraception throughout. Speak to your doctor or nurse.
- ☐ Complications of treatment can very occasionally be life-threatening and may result in death. The risks are different for every individual. Potentially life-threatening complications include those listed on this form, but other exceedingly rare side effects may also be life-threatening.

Statement of health professional

Patient identifier/label

Any other risks and information:

_____

_____

☐ I have discussed the intended benefit and risks of the recommended treatment, and of any available alternative treatments (including no treatment).

☐ I have discussed the side effects of the recommended treatment, which could affect the patient straight away or in the future, and that there may be some side effects not listed because they are rare or have not yet been reported. Each patient may experience side effects differently.

☐ I have discussed what the treatment is likely to involve (including inpatient/outpatient treatment, timing of the treatment, blood and any additional tests, follow-up appointments etc) and location.

☐ I have explained to the patient, that they have the right to stop this treatment at any time and should contact the responsible consultant or team if they wish to do so.

☐ I have discussed concerns of particular importance to the patient in regard to treatment

(please write details here): _____

_____

Clinical management guideline/Protocol compliant (please tick):

☐ Yes ☐ No ☐ Not available If No please document reason here:

_____

The following written information has been provided:

☐ Information leaflet for Fludarabine, Cytarabine, GCSF and Idarubicin

☐ 24 hour alert card or SACT advice service contact details

☐ SACT treatment record (cruk.org/treatment-record)

☐ Other, please state: _____

_____

Health professional details:

Signed: _____

Date: _____

Name (PRINT): _____

_____

Job title: _____

_____

Statement of interpreter **(where appropriate)**

Interpreter booking reference (if applicable):

I have interpreted the information above to the patient to the best of my ability and in a way in which I believe they can understand.

Signed: _____ Date: _____

Name (PRINT): _____ Job title: _____

Statement of patient

Patient identifier/label

Please read this form carefully. If your treatment has been planned in advance, you should already have your own copy of the form which describes the benefits and risks of the proposed treatment. If not, you will be offered a copy now. If you have any further questions, do ask – we are here to help you. You have the right to change your mind at any time, including after you have signed this form.

☐ I have had enough time to consider my options and make a decision about treatment.

☐ I agree to the course of treatment described on this form.

A witness should sign below if the patient is unable to sign but has indicated their consent. A person with parental responsibility will be asked to sign for young people under the age of 16 years.

Patient's signature: _____

Name (PRINT): _____ Date: _____

Person with parental responsibility/witness' signature: _____

Name (PRINT): _____ Date: _____

Copy accepted by patient: yes / no (please circle)

Confirmation of consent

(health professional to complete when the patient attends for treatment, if the patient has signed the form in advance)

On behalf of the team treating the patient, I have confirmed that the patient has no further questions and wishes the course of treatment/procedures to go ahead.

Signed: _____

Date: _____

Name (PRINT): _____

Job title: _____

Important notes: (tick if applicable)

☐ See also advance decision to refuse treatment

☐ Patient has withdrawn consent (ask patient to sign and date here)

Signed: _____

Date: _____

Further information for patients

Contact details (if patient wishes to discuss options later):

_____

Contact your hospital team if you have any questions about cancer and its treatment.

Cancer Research UK can also help answer your questions about cancer and treatment. If you want to talk in confidence, call our information nurses on freephone 0808 800 4040, Monday to Friday, 9am to 5pm. Alternatively visit cruk.org for more information.

These forms have been produced by Guy's and St. Thomas' NHS Foundation Trust as part of a national project to support clinicians in ensuring all patients are fully informed when consenting to SACT.

The project is supported by Cancer Research UK. This does not mean you are taking part in a clinical trial.



Guidance for health professionals

(to be read in conjunction with the hospital's consent policy)

Patient identifier/label

What a consent form is for

This form documents the patient's agreement to go ahead with the treatment you have proposed. It is not a legal waiver – if patients, for example, do not receive enough information on which to base their decision, then the consent may not be valid, even though the form has been signed. Patients are also entitled to change their mind after signing the form, if they retain capacity to do so. The form should act as an aide-memoir to health professionals and patients, by providing a checklist of the kind of information patients should be offered, and by enabling the patient to have a written record of the main points discussed. In no way should the written information provided for the patient be regarded as a substitute for face-to-face discussions with the patient.

The law on consent

See the following publications for a comprehensive summary of the law on consent. Consent: Patients and doctors making decisions together, GMC 2020 (gmc-uk.org/guidance). Reference guide to consent for examination or treatment, Department of Health, 2nd edition 2009 (doh.gov.uk).

Who can give consent

Everyone aged 16 or over is presumed to have the capacity to give consent for themselves, unless the opposite is demonstrated. For young people, it is good practice to involve those with parental responsibility in the consent discussions, unless specifically asked not to. A person with parental responsibility must sign this form for a child or young person under the age of 16. Such patients should be given the opportunity to 'assent' to treatment if they wish. If a patient has the capacity to give consent but is physically unable to sign a form, you should complete this form as usual and ask an independent witness to confirm that the patient has given consent orally or non-verbally.

When NOT to use this form

If the patient lacks the capacity to give consent, you should use an alternative form available for this purpose (dependent on patient age). A patient lacks capacity if they have an impairment or disturbance of the brain, affecting the way their mind works. For example, if they cannot do one of the following:

- understand information about the decision to be made
- retain that information in their mind
- use or weigh this information as a part of their decision making process, or
- communicate their decision (by talking, using sign language or any other means)

You should always take all reasonable steps (for example involving more specialist colleagues) to support a patient in making their own decision, before concluding that they are unable to do so. Relatives cannot be asked to sign a form on behalf of an adult who lacks capacity to consent for themselves, unless they have been given the authority to do so under a Lasting Power of Attorney or as a court deputy.

Information

Information about what the treatment will involve, its benefits and risks (including side-effects and complications) and alternatives to the particular procedure proposed, is crucial for patients when making up their minds. The courts have stated that patients should be told about 'significant risks which would affect the judgement of a reasonable patient'. 'Significant' has not been legally defined, but the GMC requires doctors to tell patients about 'significant, unavoidable or frequently occurring' risks. If patients make clear they have particular concerns about certain kinds of risk, you should ensure that they are informed about these risks, even if very small or rare. You should always answer questions honestly. Sometimes, patients may make it clear that they do not want to have any information about the options, but want you to decide on their behalf. In such circumstances, you should do your best to ensure that the patient receives at least very basic information about what is proposed. Where information is refused, you should document this on the consent form or in the patient's notes.

NHS Scotland

NHS Scotland staff should refer to Healthcare Improvement Scotland. Guidance on consent for SACT and local NHS Board guidance on consent aligned to the Scottish legal framework.

References

1. Summary of Product Characteristics for individual drugs: medicines.org.uk/emc
2. Cancer Research UK: cruk.org/about-cancer/treatment/drugs
3. Macmillan Cancer Support: macmillan.org.uk/cancer-information-and-support/treatments-and-drugs
4. Guy's and St. Thomas' NHS Foundation Trust, Chemotherapy consent form

Patient agreement to systemic anti-cancer therapy (SACT)

Gilteritinib (single agent)

Hospital/NHS Trust/NHS Board:

_____

_____

Responsible consultant:

Name: _____

Job title: _____

Patient details

Patient's surname/family name:

_____

Patient's first name(s): _____

_____

Date of birth: _____

NHS number: _____
(or other identifier)

Special requirements:
(eg other language/other communication method)

_____

_____

_____

_____

Name of proposed course of treatment (include brief explanation if medical term not clear)

☐ Gilteritinib for the treatment of FLT3 mutation positive relapsed/resistant acute myeloid leukaemia (AML).

☐ Gilteritinib is taken orally once a day, treatment is supplied every 28 days (one cycle).

☐ Treatment is continued until disease progression or unacceptable side effects.

Where will I have treatment?

☐ Outpatient ☐ Day unit/case ☐ Inpatient ☐ Other: _____

Statement of health professional

(to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in the hospital/Trust/NHS board's consent policy)

☑ Tick all relevant boxes

☐ I confirm the patient has capacity to give consent.

☐ I have explained the course of treatment and intended benefit to the patient.

The intended benefits (there are no guarantees about outcome)

☐ Prolong survival.

☐ Control symptoms, reduce transfusion needs and improve quality of life.

☐ Induction – therapy given in the acute state of the disease, aiming to shrink the tumour.

☐ Curative – to give you the best possible chance of being cured.

☐ Maintenance – therapy given on continuing basis, aiming to prevent disease flaring up and to control the symptoms.

☐ Disease control / Palliative – the aim is not to cure but to control the disease and reduce the symptoms. The aim is to improve both quality and quantity of life.

Statement of health professional

Patient identifier/label

You may have one or more of the side effects listed

Common side effects:

Affecting more than 10 in every 100 (>10%) people

- ☐ An increased risk of getting an infection from a drop in white blood cells – this makes it harder to fight infections and you can become very ill.
- ☐ **If you have a severe infection this can be life-threatening. Contact your doctor or hospital straight away if:**
  - **your temperature goes over 37.5°C or over 38°C, depending on the advice given by your chemotherapy team**
  - **you suddenly feel unwell (even with a normal temperature)**
- ☐ Nausea (feeling sick), diarrhoea and/or constipation, feeling weak and tired (fatigue).
- ☐ Feeling dizzy, low blood pressure.
- ☐ Shortness of breath and/or cough, pain in muscle and joints, pain and fluid build-up in hands and feet.
- ☐ Changes in liver function tests (monitored).
- ☐ High level of creatine kinase in the blood (a type of protein present in blood if abnormal muscle and heart function).

Occasional side effects:

Affecting between 1-10 in every 100 (1-10%) people

- ☐ Generally feeling unwell, allergic reactiions, muscle stiffness.
- ☐ Changes in kidney function causing less urine to pass, swelling in the legs.
- ☐ Changes in the way the heart works, abnormal heart rhythms (QT prolongation). Contact your doctor if you have changes in your heartbeat, or if you feel dizzy, lightheaded, or faint. You may need an ECG (electrocardiogram).
- ☐ Gilteritinib can cause a condition called differentiation syndrome, which can be life-threatening. Symptoms include temperature, shortness of breath, rapid breathing, build-up of fluid. You may be treated with steroids.

Other risks:

- ☐ A condition called posterior reversible encephalopathy syndrome (PRES) is a rare side effect. Symptoms include headaches, feeling confused, vision problems (including blindness), fits. Contact your doctor or nurse.
- ☐ Side effects with the anti-sickness medication may include: constipation, diarrhoea, headaches.

Occasional side effects continued:

- ☐ Growth factors (GCSF) may be prescribed to maintain number of white cells to prevent infection. You may experience bone pain, headaches, red and itchy skin around the injection site.
- ☐ There may be an increased risk of tumour lysis syndrome in some patients when treatment destroys cancer cells too quickly for the kidneys to cope and leads to changes in blood tests. Rarely, dialysis may be needed. You may be prescribed medicines for prevention or treatment.
- ☐ Before treatment you may have blood tests to check for viruses (Hepatitis B or C, HIV, or unusual infections). Treatment may weaken your natural defence (immune) system so infections like this may worsen or become active if you've had them before. You may have medicines to prevent or treat infection.
- ☐ Changes in your memory, concentration or ability to think clearly. There can be many causes including your treatment, diagnosis, or both.
- ☐ Cancer and its treatment can increase your risk of developing a blood clot (thrombosis), causing pain, redness and swelling in an arm or leg, breathlessness, chest pain. Tell your doctor straight away if you have any symptoms.
- ☐ Some anti-cancer medicines can damage ovaries and sperm. This may lead to infertility and/or early menopause (hot flushes, vaginal dryness).
- ☐ Some anti-cancer medicines may damage the development of a baby in the womb. It is important not to become pregnant or make someone else pregnant during treatment and for up to 6 months afterwards. Women of child bearing age will be tested for pregnancy before and during treatment. Use effective contraception throughout. Speak to your doctor or nurse.
- ☐ Complications of treatment can very occasionally be life-threatening and may result in death. The risks are different for every individual. Potentially life-threatening complications include those listed on this form, but other exceedingly rare side effects may also be life-threatening.

Statement of health professional

Patient identifier/label

Any other risks and information:

_____

_____

☐ I have discussed the intended benefit and risks of the recommended treatment, and of any available alternative treatments (including no treatment).

☐ I have discussed the side effects of the recommended treatment, which could affect the patient straight away or in the future, and that there may be some side effects not listed because they are rare or have not yet been reported. Each patient may experience side effects differently.

☐ I have discussed what the treatment is likely to involve (including inpatient/outpatient treatment, timing of the treatment, blood and any additional tests, follow-up appointments etc) and location.

☐ I have explained to the patient, that they have the right to stop this treatment at any time and should contact the responsible consultant or team if they wish to do so.

☐ I have discussed concerns of particular importance to the patient in regard to treatment

(please write details here): _____

_____

Clinical management guideline/Protocol compliant (please tick):

☐ Yes ☐ No ☐ Not available If No please document reason here:

_____

The following written information has been provided:

☐ Information leaflet for Gilteritinib

☐ 24 hour alert card or SACT advice service contact details

☐ SACT treatment record (cruk.org/treatment-record)

☐ Other, please state: _____

_____

Health professional details:

Signed: _____

Date: _____

Name (PRINT): _____

_____

Job title: _____

_____

Statement of interpreter **(where appropriate)**

Interpreter booking reference (if applicable):

I have interpreted the information above to the patient to the best of my ability and in a way in which I believe they can understand.

Signed: _____ Date: _____

Name (PRINT): _____ Job title: _____

Statement of patient

Patient identifier/label

Please read this form carefully. If your treatment has been planned in advance, you should already have your own copy of the form which describes the benefits and risks of the proposed treatment. If not, you will be offered a copy now. If you have any further questions, do ask – we are here to help you. You have the right to change your mind at any time, including after you have signed this form.

☐ I have had enough time to consider my options and make a decision about treatment.

☐ I agree to the course of treatment described on this form.

A witness should sign below if the patient is unable to sign but has indicated their consent. A person with parental responsibility will be asked to sign for young people under the age of 16 years.

Patient's signature: _____

Name (PRINT): _____ Date: _____

Person with parental responsibility/witness' signature: _____

Name (PRINT): _____ Date: _____

Copy accepted by patient: yes / no (please circle)

Confirmation of consent

(health professional to complete when the patient attends for treatment, if the patient has signed the form in advance)

On behalf of the team treating the patient, I have confirmed that the patient has no further questions and wishes the course of treatment/procedures to go ahead.

Signed: _____

Date: _____

Name (PRINT): _____

Job title: _____

Important notes: (tick if applicable)

☐ See also advance decision to refuse treatment

☐ Patient has withdrawn consent (ask patient to sign and date here)

Signed: _____

Date: _____

Further information for patients

Contact details (if patient wishes to discuss options later):

_____

Contact your hospital team if you have any questions about cancer and its treatment.

Cancer Research UK can also help answer your questions about cancer and treatment. If you want to talk in confidence, call our information nurses on freephone 0808 800 4040, Monday to Friday, 9am to 5pm. Alternatively visit cruk.org for more information.

These forms have been produced by Guy's and St. Thomas' NHS Foundation Trust as part of a national project to support clinicians in ensuring all patients are fully informed when consenting to SACT.

The project is supported by Cancer Research UK. This does not mean you are taking part in a clinical trial.



Guidance for health professionals

(to be read in conjunction with the hospital's consent policy)

Patient identifier/label

What a consent form is for

This form documents the patient's agreement to go ahead with the treatment you have proposed. It is not a legal waiver – if patients, for example, do not receive enough information on which to base their decision, then the consent may not be valid, even though the form has been signed. Patients are also entitled to change their mind after signing the form, if they retain capacity to do so. The form should act as an aide-memoir to health professionals and patients, by providing a checklist of the kind of information patients should be offered, and by enabling the patient to have a written record of the main points discussed. In no way should the written information provided for the patient be regarded as a substitute for face-to-face discussions with the patient.

The law on consent

See the following publications for a comprehensive summary of the law on consent. Consent: Patients and doctors making decisions together, GMC 2020 (gmc-uk.org/guidance). Reference guide to consent for examination or treatment, Department of Health, 2nd edition 2009 (doh.gov.uk).

Who can give consent

Everyone aged 16 or over is presumed to have the capacity to give consent for themselves, unless the opposite is demonstrated. For young people, it is good practice to involve those with parental responsibility in the consent discussions, unless specifically asked not to. A person with parental responsibility must sign this form for a child or young person under the age of 16. Such patients should be given the opportunity to 'assent' to treatment if they wish. If a patient has the capacity to give consent but is physically unable to sign a form, you should complete this form as usual and ask an independent witness to confirm that the patient has given consent orally or non-verbally.

When NOT to use this form

If the patient lacks the capacity to give consent, you should use an alternative form available for this purpose (dependent on patient age). A patient lacks capacity if they have an impairment or disturbance of the brain, affecting the way their mind works. For example, if they cannot do one of the following:

- understand information about the decision to be made
- retain that information in their mind
- use or weigh this information as a part of their decision making process, or
- communicate their decision (by talking, using sign language or any other means)

You should always take all reasonable steps (for example involving more specialist colleagues) to support a patient in making their own decision, before concluding that they are unable to do so. Relatives cannot be asked to sign a form on behalf of an adult who lacks capacity to consent for themselves, unless they have been given the authority to do so under a Lasting Power of Attorney or as a court deputy.

Information

Information about what the treatment will involve, its benefits and risks (including side-effects and complications) and alternatives to the particular procedure proposed, is crucial for patients when making up their minds. The courts have stated that patients should be told about 'significant risks which would affect the judgement of a reasonable patient'. 'Significant' has not been legally defined, but the GMC requires doctors to tell patients about 'significant, unavoidable or frequently occurring' risks. If patients make clear they have particular concerns about certain kinds of risk, you should ensure that they are informed about these risks, even if very small or rare. You should always answer questions honestly. Sometimes, patients may make it clear that they do not want to have any information about the options, but want you to decide on their behalf. In such circumstances, you should do your best to ensure that the patient receives at least very basic information about what is proposed. Where information is refused, you should document this on the consent form or in the patient's notes.

NHS Scotland

NHS Scotland staff should refer to Healthcare Improvement Scotland. Guidance on consent for SACT and local NHS Board guidance on consent aligned to the Scottish legal framework.

References

1. Summary of Product Characteristics for individual drugs: medicines.org.uk/emc
2. Cancer Research UK: cruk.org/about-cancer/treatment/drugs
3. Macmillan Cancer Support: macmillan.org.uk/cancer-information-and-support/treatments-and-drugs
4. Guy's and St. Thomas' NHS Foundation Trust, Chemotherapy consent form

Patient agreement to systemic anti-cancer therapy (SACT)

High dose Cytarabine (Ara C)

Hospital/NHS Trust/NHS Board:

_____

_____

Responsible consultant:

Name: _____

Job title: _____

Patient details

Patient's surname/family name:

_____

Patient's first name(s): _____

_____

Date of birth: _____

NHS number: _____
(or other identifier)

Special requirements:
(eg other language/other communication method)

_____

_____

_____

_____

Name of proposed course of treatment (include brief explanation if medical term not clear)

☐ High dose Cytarabine (Ara C) chemotherapy for the treatment of acute myeloid leukaemia (AML).

☐ Cytarabine is given intravenously twice each day on days 1, 3 and 5.

☐ Treatment is given for 1 or 2 cycles depending on blood counts.

☐ Lower doses may be considered for older patients and patients with underlying conditions at the discretion of the clinical team.

Where will I have treatment?

☐ Outpatient ☐ Day unit/case ☐ Inpatient ☐ Other: _____

Statement of health professional

(to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in the hospital/Trust/NHS board's consent policy)

☑ Tick all relevant boxes

☐ I confirm the patient has capacity to give consent.

☐ I have explained the course of treatment and intended benefit to the patient.

The intended benefits (there are no guarantees about outcome)

☐ Prolong survival.

☐ Control symptoms, reduce transfusion needs and improve quality of life.

☐ Induction – therapy given in the acute state of the disease, aiming to shrink the tumour.

☐ Curative – to give you the best possible chance of being cured.

☐ Maintenance – therapy given on continuing basis, aiming to prevent disease flaring up and to control the symptoms.

☐ Disease control / Palliative – the aim is not to cure but to control the disease and reduce the symptoms. The aim is to improve both quality and quantity of life.

Statement of health professional

Patient identifier/label

You may have one or more of the side effects listed

Common side effects:

Affecting more than 10 in every 100 (>10%) people

- ☐ An increased risk of getting an infection from a drop in white blood cells – this makes it harder to fight infections and you can become very ill.
- ☐ **If you have a severe infection this can be life-threatening. Contact your doctor or hospital straight away if:**
  - **your temperature goes over 37.5°C or over 38°C, depending on the advice given by your chemotherapy team**
  - **you suddenly feel unwell (even with a normal temperature)**
- ☐ Nausea (feeling sick), vomiting (being sick), abdominal (tummy) pain, diarrhoea, sore mouth and ulcers, difficulty swallowing, thinning of hair or hair loss.
- ☐ Anaemia (due to low red blood cells) and bruising or bleeding (due to low platelets); this can be prolonged and you may need a transfusion.
- ☐ Cytarabine syndrome can occur 6 to 12 hours after receiving Cytarabine. Symptoms include a high temperature or chills, rash, pain in the eyes, bones, tummy and chest. Inform your doctor or nurse.
- ☐ Inflammation of the lining of the eye lids (conjunctiva) making eyes feel sore, red and itchy (this is temporary). Steroid eye drops during and for 3 days after Cytarabine to prevent this will be given.

Occasional side effects:

- ☐ Inflammation and ulcers at the opening of the bowel (anus), sometimes can be severe leading to infections, skin changes (redness, itching sometimes blisters).
- ☐ Changes in eye sight (reversible), weight loss.
- ☐ Changes in liver, kidney function (monitored).
- ☐ High dose Cytarabine can cause temporary or occasionally permanent changes to the nervous system. Symptoms include seizures (fits), drowsiness, unsteadiness, mood changes. Inform your doctor or nurse.

Other risks:

- ☐ Cytarabine may leak out of the vein while it is being given (extravasation) and can damage the tissue around the vein. Tell the nurse straight away if you have any stinging, pain, redness or swelling around the vein. It's uncommon but important to deal with quickly.
- ☐ Also, this treatment can cause changes in the lungs with shortness of breath, wheezing, cough or a fever. Please inform your doctor or nurse if you notice these symptoms.
- ☐ There is a risk of tumour lysis syndrome in some patients when treatment destroys cancer cells too quickly for the kidneys to cope and leads to changes in blood tests. Rarely, dialysis may be needed. You may be prescribed medicines for prevention or treatment.
- ☐ Before treatment you may have blood tests to check for viruses (Hepatitis B or C, HIV, or unusual infections). Treatment may weaken your natural defence (immune) system so infections like this may worsen or become active if you've had them before. You may have medicines to prevent or treat infection.
- ☐ Late effects include a very rare chance of a second cancer (years later) and problems with your heart.
- ☐ Growth factors (GCSF) may be prescribed to maintain number of white cells to prevent infection. You may experience bone pain, headaches, red and itchy skin around the injection site.
- ☐ Side effects of anti-sickness medication include diarrhoea, constipation, headache.
- ☐ Changes in your memory, concentration or ability to think clearly. There can be many causes including your treatment, diagnosis, or both.
- ☐ Cancer and its treatment can increase your risk of developing a blood clot (thrombosis), causing pain, redness and swelling in an arm or leg, breathlessness, chest pain. Tell your doctor straight away if you have any symptoms.
- ☐ Some anti-cancer medicines can damage ovaries and sperm. This may lead to infertility and/or early menopause (hot flushes, vaginal dryness).

Continue on to the next page

Patient identifier/label

Statement of health professional

Other risks continued:

☐ Some anti-cancer medicines may damage the development of a baby in the womb. It is important not to become pregnant or make someone else pregnant up to 12 months afterwards. Women of child bearing age will be tested for pregnancy before and during treatment. Use effective contraception throughout.

☐ Complications of treatment can very occasionally be life-threatening and may result in death.The risks are different for every individual. Potentially life-threatening complications include those listed on this form, but other exceedingly rare side effects may also be life-threatening.

Statement of health professional

Patient identifier/label

Any other risks and information:

_____

_____

☐ I have discussed the intended benefit and risks of the recommended treatment, and of any available alternative treatments (including no treatment).

☐ I have discussed the side effects of the recommended treatment, which could affect the patient straight away or in the future, and that there may be some side effects not listed because they are rare or have not yet been reported. Each patient may experience side effects differently.

☐ I have discussed what the treatment is likely to involve (including inpatient/outpatient treatment, timing of the treatment, blood and any additional tests, follow-up appointments etc) and location.

☐ I have explained to the patient, that they have the right to stop this treatment at any time and should contact the responsible consultant or team if they wish to do so.

☐ I have discussed concerns of particular importance to the patient in regard to treatment

(please write details here): _____

_____

Clinical management guideline/Protocol compliant (please tick):

☐ Yes ☐ No ☐ Not available If No please document reason here:

_____

The following written information has been provided:

☐ Information leaflet for high dose Cytarabine

☐ 24 hour alert card or SACT advice service contact details

☐ SACT treatment record (cruk.org/treatment-record)

☐ Other, please state: _____

_____

Health professional details:

Signed: _____

Date: _____

Name (PRINT): _____

_____

Job title: _____

_____

Statement of interpreter **(where appropriate)**

Interpreter booking reference (if applicable):

I have interpreted the information above to the patient to the best of my ability and in a way in which I believe they can understand.

Signed: _____ Date: _____

Name (PRINT): _____ Job title: _____

Statement of patient

Patient identifier/label

Please read this form carefully. If your treatment has been planned in advance, you should already have your own copy of the form which describes the benefits and risks of the proposed treatment. If not, you will be offered a copy now. If you have any further questions, do ask – we are here to help you. You have the right to change your mind at any time, including after you have signed this form.

☐ I have had enough time to consider my options and make a decision about treatment.

☐ I agree to the course of treatment described on this form.

A witness should sign below if the patient is unable to sign but has indicated their consent. A person with parental responsibility will be asked to sign for young people under the age of 16 years.

Patient's signature: _____

Name (PRINT): _____ Date: _____

Person with parental responsibility/witness' signature: _____

Name (PRINT): _____ Date: _____

Copy accepted by patient: yes / no (please circle)

Confirmation of consent

(health professional to complete when the patient attends for treatment, if the patient has signed the form in advance)

On behalf of the team treating the patient, I have confirmed that the patient has no further questions and wishes the course of treatment/procedures to go ahead.

Signed: _____

Date: _____

Name (PRINT): _____

Job title: _____

Important notes: (tick if applicable)

☐ See also advance decision to refuse treatment

☐ Patient has withdrawn consent (ask patient to sign and date here)

Signed: _____

Date: _____

Further information for patients

Contact details (if patient wishes to discuss options later):

_____

Contact your hospital team if you have any questions about cancer and its treatment.

Cancer Research UK can also help answer your questions about cancer and treatment. If you want to talk in confidence, call our information nurses on freephone 0808 800 4040, Monday to Friday, 9am to 5pm. Alternatively visit cruk.org for more information.

These forms have been produced by Guy's and St. Thomas' NHS Foundation Trust as part of a national project to support clinicians in ensuring all patients are fully informed when consenting to SACT.

The project is supported by Cancer Research UK. This does not mean you are taking part in a clinical trial.



Guidance for health professionals

(to be read in conjunction with the hospital's consent policy)

Patient identifier/label

What a consent form is for

This form documents the patient's agreement to go ahead with the treatment you have proposed. It is not a legal waiver – if patients, for example, do not receive enough information on which to base their decision, then the consent may not be valid, even though the form has been signed. Patients are also entitled to change their mind after signing the form, if they retain capacity to do so. The form should act as an aide-memoir to health professionals and patients, by providing a checklist of the kind of information patients should be offered, and by enabling the patient to have a written record of the main points discussed. In no way should the written information provided for the patient be regarded as a substitute for face-to-face discussions with the patient.

The law on consent

See the following publications for a comprehensive summary of the law on consent. Consent: Patients and doctors making decisions together, GMC 2020 (gmc-uk.org/guidance). Reference guide to consent for examination or treatment, Department of Health, 2nd edition 2009 (doh.gov.uk).

Who can give consent

Everyone aged 16 or over is presumed to have the capacity to give consent for themselves, unless the opposite is demonstrated. For young people, it is good practice to involve those with parental responsibility in the consent discussions, unless specifically asked not to. A person with parental responsibility must sign this form for a child or young person under the age of 16. Such patients should be given the opportunity to 'assent' to treatment if they wish. If a patient has the capacity to give consent but is physically unable to sign a form, you should complete this form as usual and ask an independent witness to confirm that the patient has given consent orally or non-verbally.

When NOT to use this form

If the patient lacks the capacity to give consent, you should use an alternative form available for this purpose (dependent on patient age). A patient lacks capacity if they have an impairment or disturbance of the brain, affecting the way their mind works. For example, if they cannot do one of the following:

- understand information about the decision to be made
- retain that information in their mind
- use or weigh this information as a part of their decision making process, or
- communicate their decision (by talking, using sign language or any other means)

You should always take all reasonable steps (for example involving more specialist colleagues) to support a patient in making their own decision, before concluding that they are unable to do so. Relatives cannot be asked to sign a form on behalf of an adult who lacks capacity to consent for themselves, unless they have been given the authority to do so under a Lasting Power of Attorney or as a court deputy.

Information

Information about what the treatment will involve, its benefits and risks (including side-effects and complications) and alternatives to the particular procedure proposed, is crucial for patients when making up their minds. The courts have stated that patients should be told about 'significant risks which would affect the judgement of a reasonable patient'. 'Significant' has not been legally defined, but the GMC requires doctors to tell patients about 'significant, unavoidable or frequently occurring' risks. If patients make clear they have particular concerns about certain kinds of risk, you should ensure that they are informed about these risks, even if very small or rare. You should always answer questions honestly. Sometimes, patients may make it clear that they do not want to have any information about the options, but want you to decide on their behalf. In such circumstances, you should do your best to ensure that the patient receives at least very basic information about what is proposed. Where information is refused, you should document this on the consent form or in the patient's notes.

NHS Scotland

NHS Scotland staff should refer to Healthcare Improvement Scotland. Guidance on consent for SACT and local NHS Board guidance on consent aligned to the Scottish legal framework.

References

1. Summary of Product Characteristics for individual drugs: medicines.org.uk/emc
2. Cancer Research UK: cruk.org/about-cancer/treatment/drugs
3. Macmillan Cancer Support: macmillan.org.uk/cancer-information-and-support/treatments-and-drugs
4. Guy's and St. Thomas' NHS Foundation Trust, Chemotherapy consent form

Patient agreement to systemic anti-cancer therapy (SACT)

High dose Cytarabine (Ara C) and Amsacrine

Hospital/NHS Trust/NHS Board:

_____

_____

Responsible consultant:

Name: _____

Job title: _____

Patient details

Patient's surname/family name:

_____

Patient's first name(s): _____

_____

Date of birth: _____

NHS number: _____
(or other identifier)

Special requirements:
(eg other language/other communication method)

_____

_____

_____

_____

Name of proposed course of treatment (include brief explanation if medical term not clear)

☐ High dose Cytarabine (Ara C) and Amsacrine chemotherapy for salvage therapy in relapsed or resistant acute myeloid leukaemia (AML).

☐ High dose Cytarabine (Ara C) is given intravenously on days 1 to 5 and Amsacrine is given intravenously on days 1 to 3.

☐ A minimum of 1 course is given. Consideration for subsequent courses requires a consultant decision.

Where will I have treatment?

☐ Outpatient ☐ Day unit/case ☐ Inpatient ☐ Other: _____

Statement of health professional

(to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in the hospital/Trust/NHS board's consent policy)

☑ Tick all relevant boxes

☐ I confirm the patient has capacity to give consent.

☐ I have explained the course of treatment and intended benefit to the patient.

The intended benefits (there are no guarantees about outcome)

☐ Prolong survival.

☐ Control symptoms, reduce transfusion needs and improve quality of life.

☐ Induction – therapy given in the acute state of the disease, aiming to shrink the tumour.

☐ Curative – to give you the best possible chance of being cured.

☐ Maintenance – therapy given on continuing basis, aiming to prevent disease flaring up and to control the symptoms.

☐ Disease control / Palliative – the aim is not to cure but to control the disease and reduce the symptoms. The aim is to improve both quality and quantity of life.

Statement of health professional

Patient identifier/label

You may have one or more of the side effects listed

Common side effects:

Affecting more than 10 in every 100 (>10%) people

- ☐ An increased risk of getting an infection (including COVID-19) from a drop in white blood cells – this makes it harder to fight infections and you can become very ill.
- ☐ If you have a severe infection this can be life-threatening. Contact your doctor or hospital straight away if:
  - **your temperature goes over 37.5°C or over 38°C, depending on the advice given by your chemotherapy team**
  - **you suddenly feel unwell (even with a normal temperature)**
- ☐ Nausea (feeling sick) and vomiting (being sick), abdominal (tummy) pain, diarrhoea, sore mouth and ulcers.
- ☐ Thinning of the hair or hair loss, red or brown spots on the skin (purpura).
- ☐ Low blood pressure.
- ☐ Anaemia (due to low red blood cells) and bruising or bleeding (due to low platelets); this can be prolonged and you may need a transfusion.
- ☐ Changes in liver and kidney function (monitored).
- ☐ Cytarabine syndrome can occur 6 to 12 hours after receiving Cytarabine. Symptoms include a high temperature or chills, rash, pain in the eyes, bones, tummy and chest. Inform your doctor or nurse.
- ☐ Inflammation of the lining of the eye lids (conjunctiva) making eyes feel sore, red and itchy (this is temporary). Steroid eye drops during and for 3 days after Cytarabine to prevent this will be given.

Occasional side effects:

Affecting between 1-10 in every 100 (1-10%) people

- ☐ Inflammation and ulcers of the opening at the end of the bowel (anus), which can be severe leading to infections.
- ☐ Skin changes (redness, itching sometimes blisters).
- ☐ Changes in eye sight (reversible).
- ☐ Changes in the way the heart works with symptoms of fluid build-up and shortness of breath, abnormal heart rhythm (fast heart rate).

Occasional side effects continued:

- ☐ Sudden frequent mood swings, blood in the urine, low potassium levels, shortness of breath, weight loss.
- ☐ High dose Cytarabine can cause temporary or occasionally permanent changes to the nervous system. Symptoms include seizures (fits), drowsiness, unsteadiness and mood changes. Inform your doctor or nurse.

Other risks:

- ☐ All intravenous drugs may leak out of the vein while it is being given (extravasation) and can damage the tissue around the vein. Tell the nurse straight away if you have any stinging, pain, redness or swelling around the vein. It's uncommon but important to deal with quickly.
- ☐ There may be an increased risk of tumour lysis syndrome in some patients (when treatment destroys cancer cells too quickly for the kidneys to cope and leads to changes in blood tests). Rarely, dialysis may be needed. You may be prescribed medicines for prevention or treatment.
- ☐ Rarely, high dose Cytarabine can cause changes in the lungs with shortness of breath, wheezing, cough or a fever. Please contact your doctor or nurse if you notice these symptoms.
- ☐ Side effects of anti-sickness medication include diarrhoea, constipation, headache.
- ☐ Before treatment you may have blood tests to check for viruses (Hepatitis B or C, HIV, or unusual infections). Treatment may weaken your natural defence (immune) system so infections like this may worsen or become active if you've had them before. You may have medicines to prevent or treat infection.
- ☐ Late effects include a very rare chance of a second cancer (years later) and problems with your heart.
- ☐ Growth factors (GCSF) may be prescribed to maintain number of white cells to prevent infection. You may experience bone pain, headaches, red and itchy skin around the injection site.
- ☐ Changes in your memory, concentration or ability to think clearly. There can be many causes including your treatment, diagnosis, or both.

Continue on to the next page

Patient identifier/label

Statement of health professional

Other risks continued:

- ☐ Cancer and its treatment can increase your risk of developing a blood clot (thrombosis), causing pain, redness and swelling in an arm or leg, breathlessness, chest pain. Tell your doctor straight away if you have any symptoms.
- ☐ Some anti-cancer medicines can damage ovaries and sperm. This may lead to infertility and/or early menopause (hot flushes, vaginal dryness).
- ☐ Some anti-cancer medicines may damage the development of a baby in the womb. It is important not to become pregnant or make someone else pregnant during treatment and for up to 6 months afterwards. Women of child bearing age will be tested for pregnancy before and during treatment. Use effective contraception throughout. Speak to your doctor or nurse.
- ☐ Complications of treatment can very occasionally be life-threatening and may result in death. The risks are different for every individual. Potentially life-threatening complications include those listed on this form, but other exceedingly rare side effects may also be life-threatening.

Statement of health professional

Patient identifier/label

Any other risks and information:

_____

_____

☐ I have discussed the intended benefit and risks of the recommended treatment, and of any available alternative treatments (including no treatment).

☐ I have discussed the side effects of the recommended treatment, which could affect the patient straight away or in the future, and that there may be some side effects not listed because they are rare or have not yet been reported. Each patient may experience side effects differently.

☐ I have discussed what the treatment is likely to involve (including inpatient/outpatient treatment, timing of the treatment, blood and any additional tests, follow-up appointments etc) and location.

☐ I have explained to the patient, that they have the right to stop this treatment at any time and should contact the responsible consultant or team if they wish to do so.

☐ I have discussed concerns of particular importance to the patient in regard to treatment

(please write details here): _____

_____

Clinical management guideline/Protocol compliant (please tick):

☐ Yes ☐ No ☐ Not available If No please document reason here:

_____

The following written information has been provided:

☐ Information leafet for high dose Cytarabine and Amsacrine

☐ 24 hour alert card or SACT advice service contact details

☐ SACT treatment record (cruk.org/treatment-record)

☐ Other, please state: _____

_____

Health professional details:

Signed: _____

Date: _____

Name (PRINT): _____

_____

Job title: _____

_____

Statement of interpreter **(where appropriate)**

Interpreter booking reference (if applicable):

I have interpreted the information above to the patient to the best of my ability and in a way in which I believe they can understand.

Signed: _____ Date: _____

Name (PRINT): _____ Job title: _____

Statement of patient

Patient identifier/label

Please read this form carefully. If your treatment has been planned in advance, you should already have your own copy of the form which describes the benefits and risks of the proposed treatment. If not, you will be offered a copy now. If you have any further questions, do ask – we are here to help you. You have the right to change your mind at any time, including after you have signed this form.

☐ I have had enough time to consider my options and make a decision about treatment.

☐ I agree to the course of treatment described on this form.

A witness should sign below if the patient is unable to sign but has indicated their consent. A person with parental responsibility will be asked to sign for young people under the age of 16 years.

Patient's signature: _____

Name (PRINT): _____ Date: _____

Person with parental responsibility/witness' signature: _____

Name (PRINT): _____ Date: _____

Copy accepted by patient: yes / no (please circle)

Confirmation of consent

(health professional to complete when the patient attends for treatment, if the patient has signed the form in advance)

On behalf of the team treating the patient, I have confirmed that the patient has no further questions and wishes the course of treatment/procedures to go ahead.

Signed: _____

Date: _____

Name (PRINT): _____

Job title: _____

Important notes: (tick if applicable)

☐ See also advance decision to refuse treatment

☐ Patient has withdrawn consent (ask patient to sign and date here)

Signed: _____

Date: _____

Further information for patients

Contact details (if patient wishes to discuss options later):

_____

Contact your hospital team if you have any questions about cancer and its treatment.

Cancer Research UK can also help answer your questions about cancer and treatment. If you want to talk in confidence, call our information nurses on freephone 0808 800 4040, Monday to Friday, 9am to 5pm. Alternatively visit cruk.org for more information.

These forms have been produced by Guy's and St. Thomas' NHS Foundation Trust as part of a national project to support clinicians in ensuring all patients are fully informed when consenting to SACT.

The project is supported by Cancer Research UK. This does not mean you are taking part in a clinical trial.



Guidance for health professionals

(to be read in conjunction with the hospital's consent policy)

Patient identifier/label

What a consent form is for

This form documents the patient's agreement to go ahead with the treatment you have proposed. It is not a legal waiver – if patients, for example, do not receive enough information on which to base their decision, then the consent may not be valid, even though the form has been signed. Patients are also entitled to change their mind after signing the form, if they retain capacity to do so. The form should act as an aide-memoir to health professionals and patients, by providing a checklist of the kind of information patients should be offered, and by enabling the patient to have a written record of the main points discussed. In no way should the written information provided for the patient be regarded as a substitute for face-to-face discussions with the patient.

The law on consent

See the following publications for a comprehensive summary of the law on consent. Consent: Patients and doctors making decisions together, GMC 2020 (gmc-uk.org/guidance). Reference guide to consent for examination or treatment, Department of Health, 2nd edition 2009 (doh.gov.uk).

Who can give consent

Everyone aged 16 or over is presumed to have the capacity to give consent for themselves, unless the opposite is demonstrated. For young people, it is good practice to involve those with parental responsibility in the consent discussions, unless specifically asked not to. A person with parental responsibility must sign this form for a child or young person under the age of 16. Such patients should be given the opportunity to 'assent' to treatment if they wish. If a patient has the capacity to give consent but is physically unable to sign a form, you should complete this form as usual and ask an independent witness to confirm that the patient has given consent orally or non-verbally.

When NOT to use this form

If the patient lacks the capacity to give consent, you should use an alternative form available for this purpose (dependent on patient age). A patient lacks capacity if they have an impairment or disturbance of the brain, affecting the way their mind works. For example, if they cannot do one of the following:

- understand information about the decision to be made
- retain that information in their mind
- use or weigh this information as a part of their decision making process, or
- communicate their decision (by talking, using sign language or any other means)

You should always take all reasonable steps (for example involving more specialist colleagues) to support a patient in making their own decision, before concluding that they are unable to do so. Relatives cannot be asked to sign a form on behalf of an adult who lacks capacity to consent for themselves, unless they have been given the authority to do so under a Lasting Power of Attorney or as a court deputy.

Information

Information about what the treatment will involve, its benefits and risks (including side-effects and complications) and alternatives to the particular procedure proposed, is crucial for patients when making up their minds. The courts have stated that patients should be told about 'significant risks which would affect the judgement of a reasonable patient'. 'Significant' has not been legally defined, but the GMC requires doctors to tell patients about 'significant, unavoidable or frequently occurring' risks. If patients make clear they have particular concerns about certain kinds of risk, you should ensure that they are informed about these risks, even if very small or rare. You should always answer questions honestly. Sometimes, patients may make it clear that they do not want to have any information about the options, but want you to decide on their behalf. In such circumstances, you should do your best to ensure that the patient receives at least very basic information about what is proposed. Where information is refused, you should document this on the consent form or in the patient's notes.

NHS Scotland

NHS Scotland staff should refer to Healthcare Improvement Scotland. Guidance on consent for SACT and local NHS Board guidance on consent aligned to the Scottish legal framework.

References

1. Summary of Product Characteristics for individual drugs: medicines.org.uk/emc
2. Cancer Research UK: cruk.org/about-cancer/treatment/drugs
3. Macmillan Cancer Support: macmillan.org.uk/cancer-information-and-support/treatments-and-drugs
4. Guy's and St. Thomas' NHS Foundation Trust, Chemotherapy consent form

Patient agreement to systemic anti-cancer therapy (SACT)

Hydroxycarbamide

Hospital/NHS Trust/NHS Board:

_____

_____

Responsible consultant:

Name: _____

Job title: _____

Patient details

Patient's surname/family name:

_____

Patient's first name(s): _____

_____

Date of birth: _____

NHS number: _____
(or other identifier)

Special requirements:
(eg other language/other communication method)

_____

_____

_____

_____

Name of proposed course of treatment (include brief explanation if medical term not clear)

☐ Hydroxycarbamide as palliative chemotherapy* or cytoreduction* (*delete as appropriate) for the treatment of acute myeloid leukaemia (AML).

☐ Hydroxycarbamide is taken orally each day.

☐ Treatment is continued until disease progression or unacceptable side effects.

Where will I have treatment?

☐ Outpatient ☐ Day unit/case ☐ Inpatient ☐ Other: _____

Statement of health professional

(to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in the hospital/Trust/NHS board's consent policy)

☑ Tick all relevant boxes

☐ I confirm the patient has capacity to give consent.

☐ I have explained the course of treatment and intended benefit to the patient.

The intended benefits (there are no guarantees about outcome)

☐ Prolong survival.

☐ Control symptoms, reduce transfusion needs and improve quality of life.

☐ Induction – therapy given in the acute state of the disease, aiming to shrink the tumour.

☐ Curative – to give you the best possible chance of being cured.

☐ Maintenance – therapy given on continuing basis, aiming to prevent disease flaring up and to control the symptoms.

☐ Disease control / Palliative – the aim is not to cure but to control the disease and reduce the symptoms. The aim is to improve both quality and quantity of life.

Statement of health professional

Patient identifier/label

You may have one or more of the side effects listed

Common side effects:

Affecting more than 10 in every 100 (>10%) people

- ☐ An increased risk of getting an infection from a drop in white blood cells – this makes it harder to fight infections and you can become very ill.
- ☐ **If you have a severe infection this can be life-threatening. Contact your doctor or hospital straight away if:**
  - **your temperature goes over 37.5°C or over 38°C, depending on the advice given by your chemotherapy team**
  - **you suddenly feel unwell (even with a normal temperature)**
- ☐ Nausea (feeling sick), vomiting (being sick), indigestion, abdominal (tummy) pain, diarrhoea, constipation, dark stools.
- ☐ Sore mouth and ulcers, weight loss, feeling tired and weak (fatigue).
- ☐ Thinning of the hair or hair loss.
- ☐ Skin changes (redness, rash, darkening, peeling, raised patches), skin ulcers (this is usually on the lower legs and feet).
- ☐ Nail changes (change in colour, thicker, thinner or brittle).
- ☐ Anaemia (due to low red blood cells) and bruising or bleeding (due to low platelets); this can be prolonged and you may need a transfusion.
- ☐ Pain when passing urine, changes in kidney function (monitored).

Occasional side effects:

Affecting between 1-10 in every 100 (1-10%) people

- ☐ Changes in lungs function causing shortness of breath, cough.
- ☐ Hallucinations, feeing disoriented.
- ☐ Feeling drowsy, dizziness, headache, fits.
- ☐ Changes in liver function (monitored).

Other risks:

- ☐ Increased risk of skin cancers if taking Hydroxycarbamide long term. Protect your skin from sun exposure and check your skin for any changes in appearance, new growths, or lesions (that may look like a wart), or change in the size or colour of a mole. Inform your doctor or nurse if you are worried about any new/enlarging skin growths or lesions.
- ☐ Changes in your memory, concentration or ability to think clearly. There can be many causes including your treatment, diagnosis, or both.
- ☐ Cancer and its treatment can increase your risk of developing a blood clot (thrombosis), causing pain, redness and swelling in an arm or leg, breathlessness, chest pain. Tell your doctor straight away if you have any symptoms.
- ☐ Growth factors (GCSF) may be prescribed to maintain number of white cells to prevent infection. You may experience bone pain, headaches, red and itchy skin around the injection site.
- ☐ Before treatment you may have blood tests to check for viruses (Hepatitis B or C, HIV, or unusual infections). Treatment may weaken your natural defence (immune) system so infections like this may worsen or become active if you've had them before. You may have medicines to prevent or treat infection.
- ☐ Hydroxycarbamide can damage ovaries and sperm. This may lead to infertility and/or early menopause (hot flushes, vaginal dryness).
- ☐ Hydroxycarbamide may damage the development of a baby in the womb. It is important not to become pregnant or make someone else pregnant during treatment or for several months afterwards. Women of child bearing age will be tested for pregnancy before and during treatment. Use effective contraception during this time. You can talk to your doctor or nurse about this.
- ☐ Complications of treatment can very occasionally be life-threatening and may result in death. The risks are different for every individual. Potentially life-threatening complications include those listed on this form, but other exceedingly rare side effects may also be life-threatening.

Statement of health professional

Patient identifier/label

Any other risks and information:

_____

_____

☐ I have discussed the intended benefit and risks of the recommended treatment, and of any available alternative treatments (including no treatment).

☐ I have discussed the side effects of the recommended treatment, which could affect the patient straight away or in the future, and that there may be some side effects not listed because they are rare or have not yet been reported. Each patient may experience side effects differently.

☐ I have discussed what the treatment is likely to involve (including inpatient/outpatient treatment, timing of the treatment, blood and any additional tests, follow-up appointments etc) and location.

☐ I have explained to the patient, that they have the right to stop this treatment at any time and should contact the responsible consultant or team if they wish to do so.

☐ I have discussed concerns of particular importance to the patient in regard to treatment

(please write details here): _____

_____

Clinical management guideline/Protocol compliant (please tick):

☐ Yes ☐ No ☐ Not available If No please document reason here:

_____

The following written information has been provided:

☐ Information leaflet for Hydroxycarbamide

☐ 24 hour alert card or SACT advice service contact details

☐ SACT treatment record (cruk.org/treatment-record)

☐ Other, please state: _____

_____

Health professional details:

Signed: _____

Date: _____

Name (PRINT): _____

_____

Job title: _____

_____

Statement of interpreter **(where appropriate)**

Interpreter booking reference (if applicable):

I have interpreted the information above to the patient to the best of my ability and in a way in which I believe they can understand.

Signed: _____ Date: _____

Name (PRINT): _____ Job title: _____

Statement of patient

Patient identifier/label

Please read this form carefully. If your treatment has been planned in advance, you should already have your own copy of the form which describes the benefits and risks of the proposed treatment. If not, you will be offered a copy now. If you have any further questions, do ask – we are here to help you. You have the right to change your mind at any time, including after you have signed this form.

☐ I have had enough time to consider my options and make a decision about treatment.

☐ I agree to the course of treatment described on this form.

A witness should sign below if the patient is unable to sign but has indicated their consent. A person with parental responsibility will be asked to sign for young people under the age of 16 years.

Patient's signature: _____

Name (PRINT): _____ Date: _____

Person with parental responsibility/witness' signature: _____

Name (PRINT): _____ Date: _____

Copy accepted by patient: yes / no (please circle)

Confirmation of consent

(health professional to complete when the patient attends for treatment, if the patient has signed the form in advance)

On behalf of the team treating the patient, I have confirmed that the patient has no further questions and wishes the course of treatment/procedures to go ahead.

Signed: _____

Date: _____

Name (PRINT): _____

Job title: _____

Important notes: (tick if applicable)

☐ See also advance decision to refuse treatment

☐ Patient has withdrawn consent (ask patient to sign and date here)

Signed: _____

Date: _____

Further information for patients

Contact details (if patient wishes to discuss options later):

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Contact your hospital team if you have any questions about cancer and its treatment.

Cancer Research UK can also help answer your questions about cancer and treatment. If you want to talk in confidence, call our information nurses on freephone 0808 800 4040, Monday to Friday, 9am to 5pm. Alternatively visit cruk.org for more information.

These forms have been produced by Guy's and St. Thomas' NHS Foundation Trust as part of a national project to support clinicians in ensuring all patients are fully informed when consenting to SACT.

The project is supported by Cancer Research UK. This does not mean you are taking part in a clinical trial.



Guidance for health professionals

(to be read in conjunction with the hospital's consent policy)

Patient identifier/label

What a consent form is for

This form documents the patient's agreement to go ahead with the treatment you have proposed. It is not a legal waiver – if patients, for example, do not receive enough information on which to base their decision, then the consent may not be valid, even though the form has been signed. Patients are also entitled to change their mind after signing the form, if they retain capacity to do so. The form should act as an aide-memoir to health professionals and patients, by providing a checklist of the kind of information patients should be offered, and by enabling the patient to have a written record of the main points discussed. In no way should the written information provided for the patient be regarded as a substitute for face-to-face discussions with the patient.

The law on consent

See the following publications for a comprehensive summary of the law on consent. Consent: Patients and doctors making decisions together, GMC 2020 (gmc-uk.org/guidance). Reference guide to consent for examination or treatment, Department of Health, 2nd edition 2009 (doh.gov.uk).

Who can give consent

Everyone aged 16 or over is presumed to have the capacity to give consent for themselves, unless the opposite is demonstrated. For young people, it is good practice to involve those with parental responsibility in the consent discussions, unless specifically asked not to. A person with parental responsibility must sign this form for a child or young person under the age of 16. Such patients should be given the opportunity to 'assent' to treatment if they wish. If a patient has the capacity to give consent but is physically unable to sign a form, you should complete this form as usual and ask an independent witness to confirm that the patient has given consent orally or non-verbally.

When NOT to use this form

If the patient lacks the capacity to give consent, you should use an alternative form available for this purpose (dependent on patient age). A patient lacks capacity if they have an impairment or disturbance of the brain, affecting the way their mind works. For example, if they cannot do one of the following:

- understand information about the decision to be made
- retain that information in their mind
- use or weigh this information as a part of their decision making process, or
- communicate their decision (by talking, using sign language or any other means)

You should always take all reasonable steps (for example involving more specialist colleagues) to support a patient in making their own decision, before concluding that they are unable to do so. Relatives cannot be asked to sign a form on behalf of an adult who lacks capacity to consent for themselves, unless they have been given the authority to do so under a Lasting Power of Attorney or as a court deputy.

Information

Information about what the treatment will involve, its benefits and risks (including side-effects and complications) and alternatives to the particular procedure proposed, is crucial for patients when making up their minds. The courts have stated that patients should be told about 'significant risks which would affect the judgement of a reasonable patient'. 'Significant' has not been legally defined, but the GMC requires doctors to tell patients about 'significant, unavoidable or frequently occurring' risks. If patients make clear they have particular concerns about certain kinds of risk, you should ensure that they are informed about these risks, even if very small or rare. You should always answer questions honestly. Sometimes, patients may make it clear that they do not want to have any information about the options, but want you to decide on their behalf. In such circumstances, you should do your best to ensure that the patient receives at least very basic information about what is proposed. Where information is refused, you should document this on the consent form or in the patient's notes.

NHS Scotland

NHS Scotland staff should refer to Healthcare Improvement Scotland. Guidance on consent for SACT and local NHS Board guidance on consent aligned to the Scottish legal framework.

References

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2. Cancer Research UK: cruk.org/about-cancer/treatment/drugs
3. Macmillan Cancer Support: macmillan.org.uk/cancer-information-and-support/treatments-and-drugs
4. Guy's and St. Thomas' NHS Foundation Trust, Chemotherapy consent form

Patient agreement to systemic anti-cancer therapy (SACT)

Ivosidenib and Azacitidine

Hospital/NHS Trust/NHS Board:

_____

_____

Responsible consultant:

Name: _____

Job title: _____

Patient details

Patient's surname/family name:

_____

Patient's first name(s): _____

_____

Date of birth: _____

NHS number: _____
(or other identifier)

Special requirements:
(eg other language/other communication method)

_____

_____

_____

_____

Name of proposed course of treatment (include brief explanation if medical term not clear)

☐ Ivosidenib and azacitidine chemotherapy for the treatment of acute myeloid leukaemia (AML).
☐ Ivosidenib is taken orally once a day for 28 days. Azacitidine is given subcutaneously once a day on days 1 -7.
☐ Each treatment cycle lasts for 28 days. Treatment is continued until disease progression or unacceptable side effects.
☐ Response may be assessed by regular blood counts and possibly a bone marrow aspirate and biopsy.

Where will I have treatment?

☐ Outpatient ☐ Day unit/case ☐ Inpatient ☐ Other: _____

Statement of health professional

(to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in the hospital/Trust/NHS board's consent policy)

☑ Tick all relevant boxes

☐ I confirm the patient has capacity to give consent.

☐ I have explained the course of treatment and intended benefit to the patient.

The intended benefits (there are no guarantees about outcome)

☐ Prolong survival.

☐ Control symptoms, reduce transfusion needs and improve quality of life.

☐ Induction – therapy given in the acute state of the disease, aiming to shrink the tumour.

☐ Curative – to give you the best possible chance of being cured.

☐ Maintenance – therapy given on continuing basis, aiming to prevent disease flaring up and to control the symptoms.

☐ Disease control / Palliative – the aim is not to cure but to control the disease and reduce the symptoms. The aim is to improve both quality and quantity of life.

Statement of health professional

Patient identifier/label

You may have one or more of the side effects listed

Common side effects:

Affecting more than 10 in every 100 (>10%) people

- ☐ An increased risk of getting an infection from a drop in white blood cells – this makes it harder to fight infections and you can become very ill.
- ☐ If you have a severe infection this can be life-threatening. Contact your doctor or hospital straight away if:
  - **your temperature goes over 37.5°C or over 38°C, depending on the advice given by your chemotherapy team**
  - **you suddenly feel unwell (even with a normal temperature)**
- ☐ Vomiting (being sick).
- ☐ Headache, dizziness.
- ☐ Difficulty sleeping (insomnia).
- ☐ Pain in hands and feet, muscles and joints and back.
- ☐ Anaemia (due to low red blood cells) and bruising or bleeding caused by low number of platelets. This can be prolonged and you may need a transfusion.
- ☐ Ivosidenib can cause differentiation syndrome which can be life-threatening. Symptoms include temperature, shortness of breath, rapid breathing, build-up of fluid with weight gain. You may be treated with steroids and Ivodesinib withheld or discontinued.
- ☐ Ivodesinib can cause changes in heart rhythm. Contact your doctor if you have a change in your heart beat, feel dizzy, lighheaded or faint.
- ☐ With Azacitidine injection, you may notice pain, redness, itching, bruising and swelling.

Occasional side effects:

Affecting between 1-10 in every 100 (1-10%) people

- ☐ Numbness and tingling in hands and feet.
- ☐ Pain in the throat, mouth area.

Other risks:

- ☐ There may be an increased risk of tumour lysis syndrome in some patients when treatment destroys cancer cells too quickly for the kidneys to cope and leads to changes in blood tests. Rarely, dialysis may be needed. You may be prescribed medicines for prevention or treatment.
- ☐ Before treatment you may have blood tests to check for viruses (Hepatitis B or C, HIV, or unusual infections). Treatment may weaken your natural defence (immune) system so infections like this may worsen or become active if you've had them before. You may have medicines to prevent or treat infection.
- ☐ Side effects of anti-sickness medication include diarrhoea, constipation, headache.
- ☐ Late effects include a very rare chance of a second cancer (years later) and problems with your heart.
- ☐ Cancer and its treatment can increase your risk of developing a blood clot (thrombosis), causing pain, redness and swelling in an arm or leg, breathlessness, chest pain. Tell your doctor straight away if you have any symptoms.
- ☐ Changes in your memory, concentration or ability to think clearly. There can be many causes including your treatment, diagnosis, or both.
- ☐ Some anti-cancer medicines can damage ovaries and sperm. This may lead to infertility and/or early menopause (hot flushes, vaginal dryness).
- ☐ Some anti-cancer medicines may damage the development of a baby in the womb. It is important not to become pregnant or make someone else pregnant during treatment and for up to 1 month after Ivodesinib and 6 months after Azacitidine. Women of child bearing age will be tested for pregnancy before and during treatment. Use effective contraception throughout. Speak to your doctor or nurse.
- ☐ Complications of treatment can very occasionally be life-threatening and may result in death. The risks are different for every individual. Potentially life-threatening complications include those listed on this form, but other exceedingly rare side effects may also be life-threatening.

Statement of health professional

Patient identifier/label

Any other risks and information:

_____

_____

☐ I have discussed the intended benefit and risks of the recommended treatment, and of any available alternative treatments (including no treatment).

☐ I have discussed the side effects of the recommended treatment, which could affect the patient straight away or in the future, and that there may be some side effects not listed because they are rare or have not yet been reported. Each patient may experience side effects differently.

☐ I have discussed what the treatment is likely to involve (including inpatient/outpatient treatment, timing of the treatment, blood and any additional tests, follow-up appointments etc) and location.

☐ I have explained to the patient, that they have the right to stop this treatment at any time and should contact the responsible consultant or team if they wish to do so.

☐ I have discussed concerns of particular importance to the patient in regard to treatment

(please write details here): _____

_____

Clinical management guideline/Protocol compliant (please tick):

☐ Yes ☐ No ☐ Not available If No please document reason here:

_____

The following written information has been provided:

☐ Information leaflet for Ivosidenib and Azacitidine

☐ 24 hour alert card or SACT advice service contact details

☐ SACT treatment record (cruk.org/treatment-record)

☐ Other, please state: _____

_____

Health professional details:

Signed: _____

Date: _____

Name (PRINT): _____

_____

Job title: _____

_____

Statement of interpreter **(where appropriate)**

Interpreter booking reference (if applicable):

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Signed: _____ Date: _____

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A witness should sign below if the patient is unable to sign but has indicated their consent. A person with parental responsibility will be asked to sign for young people under the age of 16 years.

Patient's signature: _____

Name (PRINT): _____ Date: _____

Person with parental responsibility/witness' signature: _____

Name (PRINT): _____ Date: _____

Copy accepted by patient: yes / no (please circle)

Confirmation of consent

(health professional to complete when the patient attends for treatment, if the patient has signed the form in advance)

On behalf of the team treating the patient, I have confirmed that the patient has no further questions and wishes the course of treatment/procedures to go ahead.

Signed: _____

Date: _____

Name (PRINT): _____

Job title: _____

Important notes: (tick if applicable)

☐ See also advance decision to refuse treatment

☐ Patient has withdrawn consent (ask patient to sign and date here)

Signed: _____

Date: _____

Further information for patients

Contact details (if patient wishes to discuss options later):

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Guidance for health professionals

(to be read in conjunction with the hospital's consent policy)

Patient identifier/label

What a consent form is for

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When NOT to use this form

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- understand information about the decision to be made
- retain that information in their mind
- use or weigh this information as a part of their decision making process, or
- communicate their decision (by talking, using sign language or any other means)

You should always take all reasonable steps (for example involving more specialist colleagues) to support a patient in making their own decision, before concluding that they are unable to do so. Relatives cannot be asked to sign a form on behalf of an adult who lacks capacity to consent for themselves, unless they have been given the authority to do so under a Lasting Power of Attorney or as a court deputy.

Information

Information about what the treatment will involve, its benefits and risks (including side-effects and complications) and alternatives to the particular procedure proposed, is crucial for patients when making up their minds. The courts have stated that patients should be told about 'significant risks which would affect the judgement of a reasonable patient'. 'Significant' has not been legally defined, but the GMC requires doctors to tell patients about 'significant, unavoidable or frequently occurring' risks. If patients make clear they have particular concerns about certain kinds of risk, you should ensure that they are informed about these risks, even if very small or rare. You should always answer questions honestly. Sometimes, patients may make it clear that they do not want to have any information about the options, but want you to decide on their behalf. In such circumstances, you should do your best to ensure that the patient receives at least very basic information about what is proposed. Where information is refused, you should document this on the consent form or in the patient's notes.

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1. Summary of Product Characteristics for individual drugs: medicines.org.uk/emc
2. Cancer Research UK: cruk.org/about-cancer/treatment/drugs
3. Macmillan Cancer Support: macmillan.org.uk/cancer-information-and-support/treatments-and-drugs
4. Guy's and St. Thomas' NHS Foundation Trust, Chemotherapy consent form

Patient agreement to systemic anti-cancer therapy (SACT)

Liposomal Daunorubicin and Cytarabine (Vyxeos)

Hospital/NHS Trust/NHS Board:

_____

_____

Responsible consultant:

Name: _____

Job title: _____

Patient details

Patient's surname/family name:

_____

Patient's first name(s): _____

_____

Date of birth: _____

NHS number: _____
(or other identifier)

Special requirements:
(eg other language/other communication method)

_____

_____

_____

_____

Name of proposed course of treatment (include brief explanation if medical term not clear)

☐ Liposomal Daunorubicin and Cytarabine (Vyxeos) chemotherapy for the treatment of newly diagnosed acute myeloid leukaemia (AML).
☐ INDUCTION 1: Liposomal Daunorubicin and Cytarabine (Vyxeos) is given intravenously on days 1, 3 and 5.
☐ INDUCTION 2: Liposomal Daunorubicin and Cytarabine (Vyxeos) is given intravenously on days 1 and 3, if needed.
☐ CONSOLIDATION : Liposomal Daunorubicin and Cytarabine (Vyxeos) is given intravenously on days 1 and 3.

Where will I have treatment?

☐ Outpatient ☐ Day unit/case ☐ Inpatient ☐ Other: _____

Statement of health professional

(to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in the hospital/Trust/NHS board's consent policy)

☑ Tick all relevant boxes
☐ I confirm the patient has capacity to give consent.
☐ I have explained the course of treatment and intended benefit to the patient.

The intended benefits (there are no guarantees about outcome)

☐ Prolong survival.
☐ Control symptoms, reduce transfusion needs and improve quality of life.
☐ Induction – therapy given in the acute state of the disease, aiming to shrink the tumour.
☐ Curative – to give you the best possible chance of being cured.
☐ Maintenance – therapy given on continuing basis, aiming to prevent disease flaring up and to control the symptoms.
☐ Disease control / Palliative – the aim is not to cure but to control the disease and reduce the symptoms. The aim is to improve both quality and quantity of life.

Statement of health professional

Patient identifier/label

You may have one or more of the side effects listed

Common side effects:

Affecting more than 10 in every 100 (>10%) people

- ☐ An increased risk of getting an infection from a drop in white blood cells – this makes it harder to fight infections and you can become very ill.
- ☐ **If you have a severe infection this can be life-threatening. Contact your doctor or hospital straight away if:**
  - **your temperature goes over 37.5°C or over 38°C, depending on the advice given by your chemotherapy team**
  - **you suddenly feel unwell (even with a normal temperature)**
- ☐ Nausea (feeling sick), vomiting (being sick), sore mouth and ulcers, reduced appetite, abdominal (tummy) pain, diarrhoea, constipation.
- ☐ Allergic reactions (including rash), shortness of breath, cough, fluid in the lungs, generalised swelling with swelling in your arms and legs.
- ☐ Itching, excessive sweating, feeling tired and weak (fatigue), pain in muscle and joints, changes in eye sight.
- ☐ Headache, dizziness, difficulty sleeping, feeling anxious and confused with reduced awareness of environment.
- ☐ Changes in the way the heart works, abnormal heart rhythm (fast heart rate), chest pain, low or high blood pressure.
- ☐ Changes in kidney function (monitored), bleeding (most commonly nose bleed).

Occasional side effects:

Affecting between 1-10 in every 100 (1-10%) people

- ☐ Anaemia (due to low red blood cells) and bruising or bleeding (due to low platelets); this can be prolonged and may require transfusion.
- ☐ Thinning of the hair or hair loss, night sweats, indigestion.
- ☐ There is an increased risk of tumour lysis syndrome in some patients when treatment destroys cancer cells too quickly for the kidneys to cope and leads to changes in blood tests. Rarely, dialysis may be needed. You may be prescribed medicines for prevention or treatment.

Other risks:

- ☐ This treatment may leak out of the vein while it is being given (extravasation) and can damage the tissue around the vein. Tell the nurse straight away if you have any stinging, pain, redness or swelling around the vein. It's uncommon but important to deal with quickly.
- ☐ Before treatment you may have blood tests to check for viruses (Hepatitis B or C, HIV, or unusual infections). Treatment may weaken your natural defence (immune) system so infections like this may worsen or become active if you've had them before. You may have medicines to prevent or treat infection.
- ☐ Recovery of blood counts may be very slow and in rare cases recovery may be incomplete.
- ☐ Late effects include a very rare chance of a second cancer (years later) and problems with your heart.
- ☐ Side effects of anti-sickness medication include diarrhoea, constipation, headache.
- ☐ Growth factors (GCSF) may be prescribed to maintain number of white cells to prevent infection. You may experience bone pain, headaches, red and itchy skin around the injection site.
- ☐ Changes in your memory, concentration or ability to think clearly. There can be many causes including your treatment, diagnosis, or both.
- ☐ Cancer and its treatment can increase your risk of developing a blood clot (thrombosis), causing pain, redness and swelling in an arm or leg, breathlessness, chest pain. Tell your doctor straight away if you have any symptoms.
- ☐ Some anti-cancer medicines can damage ovaries and sperm. This may lead to infertility and/or early menopause (hot flushes, vaginal dryness).
- ☐ Some anti-cancer medicines may damage the development of a baby in the womb. It is important not to become pregnant or make someone else pregnant during treatment and for atleast 6 months afterwards.Women of child bearing age will be tested for pregnancy before and during treatment. Use effective contraception throughout. Speak to your doctor or nurse.
- ☐ Complications of treatment can very occasionally be life-threatening and may result in death. The risks are different for every individual. Potentially life-threatening complications include those listed on this form, but other exceedingly rare side effects may also be life-threatening.

Statement of health professional

Patient identifier/label

Any other risks and information:

_____

_____

☐ I have discussed the intended benefit and risks of the recommended treatment, and of any available alternative treatments (including no treatment).

☐ I have discussed the side effects of the recommended treatment, which could affect the patient straight away or in the future, and that there may be some side effects not listed because they are rare or have not yet been reported. Each patient may experience side effects differently.

☐ I have discussed what the treatment is likely to involve (including inpatient/outpatient treatment, timing of the treatment, blood and any additional tests, follow-up appointments etc) and location.

☐ I have explained to the patient, that they have the right to stop this treatment at any time and should contact the responsible consultant or team if they wish to do so.

☐ I have discussed concerns of particular importance to the patient in regard to treatment

(please write details here): _____

_____

Clinical management guideline/Protocol compliant (please tick):

☐ Yes ☐ No ☐ Not available If No please document reason here:

_____

The following written information has been provided:

☐ Information leaflet for Liposomal Daunorubicin and Cytarabine (Vyxeous)

☐ 24 hour alert card or SACT advice service contact details

☐ SACT treatment record (cruk.org/treatment-record)

☐ Other, please state: _____

Health professional details:

Signed: _____

Date: _____

Name (PRINT): _____

_____

Job title: _____

_____

Statement of interpreter **(where appropriate)**

Interpreter booking reference (if applicable):

I have interpreted the information above to the patient to the best of my ability and in a way in which I believe they can understand.

Signed: _____ Date: _____

Name (PRINT): _____ Job title: _____

Statement of patient

Patient identifier/label

Please read this form carefully. If your treatment has been planned in advance, you should already have your own copy of the form which describes the benefits and risks of the proposed treatment. If not, you will be offered a copy now. If you have any further questions, do ask – we are here to help you. You have the right to change your mind at any time, including after you have signed this form.

☐ I have had enough time to consider my options and make a decision about treatment.

☐ I agree to the course of treatment described on this form.

A witness should sign below if the patient is unable to sign but has indicated their consent. A person with parental responsibility will be asked to sign for young people under the age of 16 years.

Patient's signature: _____

Name (PRINT): _____ Date: _____

Person with parental responsibility/witness' signature: _____

Name (PRINT): _____ Date: _____

Copy accepted by patient: yes / no (please circle)

Confirmation of consent

(health professional to complete when the patient attends for treatment, if the patient has signed the form in advance)

On behalf of the team treating the patient, I have confirmed that the patient has no further questions and wishes the course of treatment/procedures to go ahead.

Signed: _____

Date: _____

Name (PRINT): _____

Job title: _____

Important notes: (tick if applicable)

☐ See also advance decision to refuse treatment

☐ Patient has withdrawn consent (ask patient to sign and date here)

Signed: _____

Date: _____

Further information for patients

Contact details (if patient wishes to discuss options later):

_____

Contact your hospital team if you have any questions about cancer and its treatment.

Cancer Research UK can also help answer your questions about cancer and treatment. If you want to talk in confidence, call our information nurses on freephone 0808 800 4040, Monday to Friday, 9am to 5pm. Alternatively visit cruk.org for more information.

These forms have been produced by Guy's and St. Thomas' NHS Foundation Trust as part of a national project to support clinicians in ensuring all patients are fully informed when consenting to SACT.

The project is supported by Cancer Research UK. This does not mean you are taking part in a clinical trial.



Guidance for health professionals

(to be read in conjunction with the hospital's consent policy)

Patient identifier/label

What a consent form is for

This form documents the patient's agreement to go ahead with the treatment you have proposed. It is not a legal waiver – if patients, for example, do not receive enough information on which to base their decision, then the consent may not be valid, even though the form has been signed. Patients are also entitled to change their mind after signing the form, if they retain capacity to do so. The form should act as an aide-memoir to health professionals and patients, by providing a checklist of the kind of information patients should be offered, and by enabling the patient to have a written record of the main points discussed. In no way should the written information provided for the patient be regarded as a substitute for face-to-face discussions with the patient.

The law on consent

See the following publications for a comprehensive summary of the law on consent. Consent: Patients and doctors making decisions together, GMC 2020 (gmc-uk.org/guidance). Reference guide to consent for examination or treatment, Department of Health, 2nd edition 2009 (doh.gov.uk).

Who can give consent

Everyone aged 16 or over is presumed to have the capacity to give consent for themselves, unless the opposite is demonstrated. For young people, it is good practice to involve those with parental responsibility in the consent discussions, unless specifically asked not to. A person with parental responsibility must sign this form for a child or young person under the age of 16. Such patients should be given the opportunity to 'assent' to treatment if they wish. If a patient has the capacity to give consent but is physically unable to sign a form, you should complete this form as usual and ask an independent witness to confirm that the patient has given consent orally or non-verbally.

When NOT to use this form

If the patient lacks the capacity to give consent, you should use an alternative form available for this purpose (dependent on patient age). A patient lacks capacity if they have an impairment or disturbance of the brain, affecting the way their mind works. For example, if they cannot do one of the following:

- understand information about the decision to be made
- retain that information in their mind
- use or weigh this information as a part of their decision making process, or
- communicate their decision (by talking, using sign language or any other means)

You should always take all reasonable steps (for example involving more specialist colleagues) to support a patient in making their own decision, before concluding that they are unable to do so. Relatives cannot be asked to sign a form on behalf of an adult who lacks capacity to consent for themselves, unless they have been given the authority to do so under a Lasting Power of Attorney or as a court deputy.

Information

Information about what the treatment will involve, its benefits and risks (including side-effects and complications) and alternatives to the particular procedure proposed, is crucial for patients when making up their minds. The courts have stated that patients should be told about 'significant risks which would affect the judgement of a reasonable patient'. 'Significant' has not been legally defined, but the GMC requires doctors to tell patients about 'significant, unavoidable or frequently occurring' risks. If patients make clear they have particular concerns about certain kinds of risk, you should ensure that they are informed about these risks, even if very small or rare. You should always answer questions honestly. Sometimes, patients may make it clear that they do not want to have any information about the options, but want you to decide on their behalf. In such circumstances, you should do your best to ensure that the patient receives at least very basic information about what is proposed. Where information is refused, you should document this on the consent form or in the patient's notes.

NHS Scotland

NHS Scotland staff should refer to Healthcare Improvement Scotland. Guidance on consent for SACT and local NHS Board guidance on consent aligned to the Scottish legal framework.

References

1. Summary of Product Characteristics for individual drugs: medicines.org.uk/emc
2. Cancer Research UK: cruk.org/about-cancer/treatment/drugs
3. Macmillan Cancer Support: macmillan.org.uk/cancer-information-and-support/treatments-and-drugs
4. Guy's and St. Thomas' NHS Foundation Trust, Chemotherapy consent form

Patient agreement to systemic anti-cancer therapy (SACT)

Low dose Cytarabine (Ara C)

Hospital/NHS Trust/NHS Board:

_____

_____

Responsible consultant:

Name: _____

Job title: _____

Patient details

Patient's surname/family name:

_____

Patient's first name(s): _____

_____

Date of birth: _____

NHS number: _____
(or other identifier)

Special requirements:
(eg other language/other communication method)

_____

_____

_____

_____

Name of proposed course of treatment (include brief explanation if medical term not clear)

☐ Low dose Cytarabine (Ara C) is used as non-curative/palliative chemotherapy for AML* or MDS (intermediate, high risk disease)* or CMML-2 * (*delete as appropriate).

☐ Cytarabine (Ara C) given subcutaneously twice each day* or once a day* (*delete as appropriate) on days 1 -10. This is given every 28 to 42 days.

☐ If tolerated, a minimum of 4 cycles is given. There is no maximum cycle number OR

☐ This may be given as continuous intravenous infusion depending on local policy.

Where will I have treatment?

☐ Outpatient ☐ Day unit/case ☐ Inpatient ☐ Other: _____

Statement of health professional

(to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in the hospital/Trust/NHS board's consent policy)

☑ Tick all relevant boxes

☐ I confirm the patient has capacity to give consent.

☐ I have explained the course of treatment and intended benefit to the patient.

The intended benefits (there are no guarantees about outcome)

☐ Prolong survival.

☐ Control symptoms, reduce transfusion needs and improve quality of life.

☐ Induction – therapy given in the acute state of the disease, aiming to shrink the tumour.

☐ Curative – to give you the best possible chance of being cured.

☐ Maintenance – therapy given on continuing basis, aiming to prevent disease flaring up and to control the symptoms.

☐ Disease control / Palliative – the aim is not to cure but to control the disease and reduce the symptoms. The aim is to improve both quality and quantity of life.

Statement of health professional

Patient identifier/label

You may have one or more of the side effects listed

Common side effects:

Affecting more than 10 in every 100 (>10%) people

- ☐ An increased risk of getting an infection from a drop in white blood cells – this makes it harder to fight infections and you can become very ill.
- ☐ **If you have a severe infection this can be life-threatening. Contact your doctor or hospital straight away if:**
  - **your temperature goes over 37.5°C or over 38°C, depending on the advice given by your chemotherapy team**
  - **you suddenly feel unwell (even with a normal temperature)**
- ☐ Nausea (feeling sick), vomiting (being sick), abdominal (tummy) pain, diarrhoea, difficulty swallowing.
- ☐ Sore mouth and ulcers, skin rash.
- ☐ Thinning of the hair or hair loss.
- ☐ Anaemia (due to low red blood cells) and bruising or bleeding (due to low platelets); this can be prolonged and you may need a transfusion.
- ☐ Pain, swelling and redness at the injection site.

Occasional side effects:

Affecting between 1-10 in every 100 (1-10%) people

- ☐ More severe skin changes (redness, itching sometimes blisters).
- ☐ Weight loss.
- ☐ Inflammation and ulcers of the opening at the end of the bowel (anus).
- ☐ Changes in kidney and liver function (monitored).

Other risks:

- ☐ There is an increased risk of tumour lysis syndrome in some patients when treatment destroys cancer cells too quickly for the kidneys to cope and leads to changes in blood tests. Rarely, dialysis may be needed. You may be prescribed medicines for prevention or treatment.
- ☐ Before treatment you may have blood tests to check for viruses (Hepatitis B or C, HIV, or unusual infections). Treatment may weaken your natural defence (immune) system so infections like this may worsen or become active if you've had them before. You may have medicines to prevent or treat infection.
- ☐ Side effects of anti-sickness medication include diarrhoea, constipation, headache.
- ☐ Changes in your memory, concentration or ability to think clearly. There can be many causes including your treatment, diagnosis, or both.
- ☐ Late effects include a very rare chance of a second cancer (years later) and problems with your heart.
- ☐ Rarely, Cytarabine can cause changes in the lungs with shortness of breath, wheezing, cough or fever. Please inform your doctor or nurse if you notice these symptoms.
- ☐ Cancer and its treatment can increase your risk of developing a blood clot (thrombosis), causing pain, redness and swelling in an arm or leg, breathlessness, chest pain. Tell your doctor straight away if you have any symptoms.
- ☐ Some anti-cancer medicines can damage ovaries and sperm. This may lead to infertility and/or early menopause (hot flushes, vaginal dryness).
- ☐ Some anti-cancer medicines may damage the development of a baby in the womb. It is important not to become pregnant or make someone else pregnant during treatment and for up to 6 months afterwards. Use effective contraception throughout. Speak to your doctor or nurse.
- ☐ Complications of treatment can very occasionally be life-threatening and may result in death. The risks are different for every individual. Potentially life-threatening complications include those listed on this form, but other exceedingly rare side effects may also be life-threatening.

Statement of health professional

Patient identifier/label

Any other risks and information:

_____

_____

☐ I have discussed the intended benefit and risks of the recommended treatment, and of any available alternative treatments (including no treatment).

☐ I have discussed the side effects of the recommended treatment, which could affect the patient straight away or in the future, and that there may be some side effects not listed because they are rare or have not yet been reported. Each patient may experience side effects differently.

☐ I have discussed what the treatment is likely to involve (including inpatient/outpatient treatment, timing of the treatment, blood and any additional tests, follow-up appointments etc) and location.

☐ I have explained to the patient, that they have the right to stop this treatment at any time and should contact the responsible consultant or team if they wish to do so.

☐ I have discussed concerns of particular importance to the patient in regard to treatment

(please write details here): _____

_____

Clinical management guideline/Protocol compliant (please tick):

☐ Yes ☐ No ☐ Not available If No please document reason here:

_____

The following written information has been provided:

☐ Information leaflet for Low dose Cytarabine (Ara C)

☐ 24 hour alert card or SACT advice service contact details

☐ SACT treatment record (cruk.org/treatment-record)

☐ Other, please state: _____

Health professional details:

Signed: _____

Date: _____

Name (PRINT): _____

_____

Job title: _____

_____

Statement of interpreter **(where appropriate)**

Interpreter booking reference (if applicable):

I have interpreted the information above to the patient to the best of my ability and in a way in which I believe they can understand.

Signed: _____ Date: _____

Name (PRINT): _____ Job title: _____

Statement of patient

Patient identifier/label

Please read this form carefully. If your treatment has been planned in advance, you should already have your own copy of the form which describes the benefits and risks of the proposed treatment. If not, you will be offered a copy now. If you have any further questions, do ask – we are here to help you. You have the right to change your mind at any time, including after you have signed this form.

☐ I have had enough time to consider my options and make a decision about treatment.

☐ I agree to the course of treatment described on this form.

A witness should sign below if the patient is unable to sign but has indicated their consent. A person with parental responsibility will be asked to sign for young people under the age of 16 years.

Patient's signature: _____

Name (PRINT): _____ Date: _____

Person with parental responsibility/witness' signature: _____

Name (PRINT): _____ Date: _____

Copy accepted by patient: yes / no (please circle)

Confirmation of consent

(health professional to complete when the patient attends for treatment, if the patient has signed the form in advance)

On behalf of the team treating the patient, I have confirmed that the patient has no further questions and wishes the course of treatment/procedures to go ahead.

Signed: _____

Date: _____

Name (PRINT): _____

Job title: _____

Important notes: (tick if applicable)

☐ See also advance decision to refuse treatment

☐ Patient has withdrawn consent (ask patient to sign and date here)

Signed: _____

Date: _____

Further information for patients

Contact details (if patient wishes to discuss options later):

_____

Contact your hospital team if you have any questions about cancer and its treatment.

Cancer Research UK can also help answer your questions about cancer and treatment. If you want to talk in confidence, call our information nurses on freephone 0808 800 4040, Monday to Friday, 9am to 5pm. Alternatively visit cruk.org for more information.

These forms have been produced by Guy's and St. Thomas' NHS Foundation Trust as part of a national project to support clinicians in ensuring all patients are fully informed when consenting to SACT.

The project is supported by Cancer Research UK. This does not mean you are taking part in a clinical trial.

Guidance for health professionals

(to be read in conjunction with the hospital's consent policy)

Patient identifier/label

What a consent form is for

This form documents the patient's agreement to go ahead with the treatment you have proposed. It is not a legal waiver – if patients, for example, do not receive enough information on which to base their decision, then the consent may not be valid, even though the form has been signed. Patients are also entitled to change their mind after signing the form, if they retain capacity to do so. The form should act as an aide-memoir to health professionals and patients, by providing a checklist of the kind of information patients should be offered, and by enabling the patient to have a written record of the main points discussed. In no way should the written information provided for the patient be regarded as a substitute for face-to-face discussions with the patient.

The law on consent

See the following publications for a comprehensive summary of the law on consent. Consent: Patients and doctors making decisions together, GMC 2020 (gmc-uk.org/guidance). Reference guide to consent for examination or treatment, Department of Health, 2nd edition 2009 (doh.gov.uk).

Who can give consent

Everyone aged 16 or over is presumed to have the capacity to give consent for themselves, unless the opposite is demonstrated. For young people, it is good practice to involve those with parental responsibility in the consent discussions, unless specifically asked not to. A person with parental responsibility must sign this form for a child or young person under the age of 16. Such patients should be given the opportunity to 'assent' to treatment if they wish. If a patient has the capacity to give consent but is physically unable to sign a form, you should complete this form as usual and ask an independent witness to confirm that the patient has given consent orally or non-verbally.

When NOT to use this form

If the patient lacks the capacity to give consent, you should use an alternative form available for this purpose (dependent on patient age). A patient lacks capacity if they have an impairment or disturbance of the brain, affecting the way their mind works. For example, if they cannot do one of the following:

- understand information about the decision to be made
- retain that information in their mind
- use or weigh this information as a part of their decision making process, or
- communicate their decision (by talking, using sign language or any other means)

You should always take all reasonable steps (for example involving more specialist colleagues) to support a patient in making their own decision, before concluding that they are unable to do so. Relatives cannot be asked to sign a form on behalf of an adult who lacks capacity to consent for themselves, unless they have been given the authority to do so under a Lasting Power of Attorney or as a court deputy.

Information

Information about what the treatment will involve, its benefits and risks (including side-effects and complications) and alternatives to the particular procedure proposed, is crucial for patients when making up their minds. The courts have stated that patients should be told about 'significant risks which would affect the judgement of a reasonable patient'. 'Significant' has not been legally defined, but the GMC requires doctors to tell patients about 'significant, unavoidable or frequently occurring' risks. If patients make clear they have particular concerns about certain kinds of risk, you should ensure that they are informed about these risks, even if very small or rare. You should always answer questions honestly. Sometimes, patients may make it clear that they do not want to have any information about the options, but want you to decide on their behalf. In such circumstances, you should do your best to ensure that the patient receives at least very basic information about what is proposed. Where information is refused, you should document this on the consent form or in the patient's notes.

NHS Scotland

NHS Scotland staff should refer to Healthcare Improvement Scotland. Guidance on consent for SACT and local NHS Board guidance on consent aligned to the Scottish legal framework.

References

1. Summary of Product Characteristics for individual drugs: medicines.org.uk/emc
2. Cancer Research UK: cruk.org/about-cancer/treatment/drugs
3. Macmillan Cancer Support: macmillan.org.uk/cancer-information-and-support/treatments-and-drugs
4. Guy's and St. Thomas' NHS Foundation Trust, Chemotherapy consent form

Patient agreement to systemic anti-cancer therapy (SACT)

Low dose Cytarabine (Ara C) and Venetoclax

Hospital/NHS Trust/NHS Board:

_____

_____

Responsible consultant:

Name: _____

Job title: _____

Patient details

Patient's surname/family name:

_____

Patient's first name(s): _____

_____

Date of birth: _____

NHS number: _____
(or other identifier)

Special requirements:
(eg other language/other communication method)

_____

_____

_____

_____

Name of proposed course of treatment (include brief explanation if medical term not clear)

☐ Low dose Cytarabine (Ara C) and Venetoclax for the treatment of acute myeloid leukaemia (AML).
☐ Cycle 1: Cytarabine (Ara C) is given subcutaneously once a day on days 1 -10. Venetoclax is taken orally from days 1 to 28.
☐ Cycle 2: Cytarabine is given subcutaneously once daily on days 1-10. Venetoclax is taken orally from days 1 to 28. Your doctor may adjust the number of days, depending on your blood results.
☐ Treatment is continued until disease progression or unacceptable side effects.

Where will I have treatment?

☐ Outpatient ☐ Day unit/case ☐ Inpatient ☐ Other: _____

Statement of health professional

(to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in the hospital/Trust/NHS board's consent policy)

☑ Tick all relevant boxes

☐ I confirm the patient has capacity to give consent.

☐ I have explained the course of treatment and intended benefit to the patient.

The intended benefits (there are no guarantees about outcome)

☐ Prolong survival.

☐ Control symptoms, reduce transfusion needs and improve quality of life.

☐ Induction – therapy given in the acute state of the disease, aiming to shrink the tumour.

☐ Curative – to give you the best possible chance of being cured.

☐ Maintenance – therapy given on continuing basis, aiming to prevent disease flaring up and to control the symptoms.

☐ Disease control / Palliative – the aim is not to cure but to control the disease and reduce the symptoms. The aim is to improve both quality and quantity of life.

Statement of health professional

Patient identifier/label

You may have one or more of the side effects listed

Common side effects:

Affecting more than 10 in every 100 (>10%) people

- ☐ An increased risk of getting an infection from a drop in white blood cells – this makes it harder to fight infections and you can become very ill.
- ☐ **If you have a severe infection this can be life-threatening. Contact your doctor or hospital straight away if:**
  - **your temperature goes over 37.5°C or over 38°C, depending on the advice given by your chemotherapy team**
  - **you suddenly feel unwell (even with a normal temperature)**
- ☐ Nausea (feeling sick), vomiting (being sick), abdominal (tummy) pain, diarrhoea, constipation.
- ☐ Sore mouth and ulcers, feeling tired and weak (fatigue), thinning of the hair or hair loss.
- ☐ Anaemia (due to low red blood cells) and bruising or bleeding (due to low platelets); this can be prolonged and you may need a transfusion.
- ☐ High potassium, high phosphate, low calcium levels, high bilirubin, changes in liver function – Picked up in blood tests and monitored.
- ☐ Inflammation and ulcers of the opening end of the bowel (anus).
- ☐ Pain, swelling and redness at the injection site, skin rash, dizziness, low blood pressure, shortness of breath, joint pain.

Occasional side effects:

Affecting between 1-10 in every 100 (1-10%) people

- ☐ More severe skin changes (redness, itching sometimes blisters).
- ☐ There may be an increased risk of tumour lysis syndrome in some patients (when treatment destroys cancer cells too quickly for the kidneys to cope and leads to changes in blood tests). Rarely, dialysis may be needed. You may be prescribed medicines for prevention or treatment.
- ☐ Weight loss.
- ☐ Changes in kidney function (monitored).
- ☐ Development of gall stones, inflammation of the gall bladder.

Other risks:

- ☐ Before treatment you may have blood tests to check for viruses (Hepatitis B or C, HIV, or unusual infections). Treatment may weaken your natural defence (immune) system so infections like this may worsen or become active if you've had them before. You may have medicines to prevent or treat infection.
- ☐ Side effects of anti-sickness medication include diarrhoea, constipation, headache.
- ☐ Late effects include a very rare chance of a second cancer (years later) and problems with your heart.
- ☐ Growth factors (GCSF) may be prescribed to maintain number of white cells to prevent infection. You may experience bone pain, headaches, red and itchy skin around the injection site.
- ☐ Changes in your memory, concentration or ability to think clearly. There can be many causes including your treatment, diagnosis, or both.
- ☐ Rarely, Cytarabine can cause changes in the lungs with shortness of breath, wheezing, cough or fever. Please inform your doctor or nurse if you notice these symptoms.
- ☐ Cancer and its treatment can increase your risk of developing a blood clot (thrombosis), causing pain, redness and swelling in an arm or leg, breathlessness, chest pain. Tell your doctor straight away if you have any symptoms.
- ☐ Some anti-cancer medicines can damage ovaries and sperm. This may lead to infertility and/or early menopause (hot flushes, vaginal dryness).
- ☐ Some anti-cancer medicines may damage the development of a baby in the womb. It is important not to become pregnant or make someone else pregnant during treatment and for up to 6 months afterwards. .Women of child bearing age will be tested for pregnancy before and during treatment. Use effective contraception throughout. Speak to your doctor or nurse.
- ☐ Complications of treatment can very occasionally be life-threatening and may result in death. The risks are different for every individual. Potentially life-threatening complications include those listed on this form, but other exceedingly rare side effects may also be life-threatening.

Statement of health professional

Patient identifier/label

Any other risks and information:

_____

_____

☐ I have discussed the intended benefit and risks of the recommended treatment, and of any available alternative treatments (including no treatment).

☐ I have discussed the side effects of the recommended treatment, which could affect the patient straight away or in the future, and that there may be some side effects not listed because they are rare or have not yet been reported. Each patient may experience side effects differently.

☐ I have discussed what the treatment is likely to involve (including inpatient/outpatient treatment, timing of the treatment, blood and any additional tests, follow-up appointments etc) and location.

☐ I have explained to the patient, that they have the right to stop this treatment at any time and should contact the responsible consultant or team if they wish to do so.

☐ I have discussed concerns of particular importance to the patient in regard to treatment

(please write details here): _____

_____

Clinical management guideline/Protocol compliant (please tick):

☐ Yes ☐ No ☐ Not available If No please document reason here:

_____

The following written information has been provided:

☐ Information leaflet for Low dose Cytarabine (Ara C) and Venetoclax

☐ 24 hour alert card or SACT advice service contact details

☐ SACT treatment record (cruk.org/treatment-record)

☐ Other, please state: _____

_____

Health professional details:

Signed: _____

Date: _____

Name (PRINT): _____

_____

Job title: _____

_____

Statement of interpreter **(where appropriate)**

Interpreter booking reference (if applicable):

I have interpreted the information above to the patient to the best of my ability and in a way in which I believe they can understand.

Signed: _____ Date: _____

Name (PRINT): _____ Job title: _____

Statement of patient

Patient identifier/label

Please read this form carefully. If your treatment has been planned in advance, you should already have your own copy of the form which describes the benefits and risks of the proposed treatment. If not, you will be offered a copy now. If you have any further questions, do ask – we are here to help you. You have the right to change your mind at any time, including after you have signed this form.

☐ I have had enough time to consider my options and make a decision about treatment.

☐ I agree to the course of treatment described on this form.

A witness should sign below if the patient is unable to sign but has indicated their consent. A person with parental responsibility will be asked to sign for young people under the age of 16 years.

Patient's signature: _____

Name (PRINT): _____ Date: _____

Person with parental responsibility/witness' signature: _____

Name (PRINT): _____ Date: _____

Copy accepted by patient: yes / no (please circle)

Confirmation of consent

(health professional to complete when the patient attends for treatment, if the patient has signed the form in advance)

On behalf of the team treating the patient, I have confirmed that the patient has no further questions and wishes the course of treatment/procedures to go ahead.

Signed: _____

Date: _____

Name (PRINT): _____

Job title: _____

Important notes: (tick if applicable)

☐ See also advance decision to refuse treatment

☐ Patient has withdrawn consent (ask patient to sign and date here)

Signed: _____

Date: _____

Further information for patients

Contact details (if patient wishes to discuss options later):

_____

Contact your hospital team if you have any questions about cancer and its treatment.

Cancer Research UK can also help answer your questions about cancer and treatment. If you want to talk in confidence, call our information nurses on freephone 0808 800 4040, Monday to Friday, 9am to 5pm. Alternatively visit cruk.org for more information.

These forms have been produced by Guy's and St. Thomas' NHS Foundation Trust as part of a national project to support clinicians in ensuring all patients are fully informed when consenting to SACT.

The project is supported by Cancer Research UK. This does not mean you are taking part in a clinical trial.

CANCER RESEARCH UK

Guidance for health professionals

(to be read in conjunction with the hospital's consent policy)

Patient identifier/label

What a consent form is for

This form documents the patient's agreement to go ahead with the treatment you have proposed. It is not a legal waiver – if patients, for example, do not receive enough information on which to base their decision, then the consent may not be valid, even though the form has been signed. Patients are also entitled to change their mind after signing the form, if they retain capacity to do so. The form should act as an aide-memoir to health professionals and patients, by providing a checklist of the kind of information patients should be offered, and by enabling the patient to have a written record of the main points discussed. In no way should the written information provided for the patient be regarded as a substitute for face-to-face discussions with the patient.

The law on consent

See the following publications for a comprehensive summary of the law on consent. Consent: Patients and doctors making decisions together, GMC 2020 (gmc-uk.org/guidance). Reference guide to consent for examination or treatment, Department of Health, 2nd edition 2009 (doh.gov.uk).

Who can give consent

Everyone aged 16 or over is presumed to have the capacity to give consent for themselves, unless the opposite is demonstrated. For young people, it is good practice to involve those with parental responsibility in the consent discussions, unless specifically asked not to. A person with parental responsibility must sign this form for a child or young person under the age of 16. Such patients should be given the opportunity to 'assent' to treatment if they wish. If a patient has the capacity to give consent but is physically unable to sign a form, you should complete this form as usual and ask an independent witness to confirm that the patient has given consent orally or non-verbally.

When NOT to use this form

If the patient lacks the capacity to give consent, you should use an alternative form available for this purpose (dependent on patient age). A patient lacks capacity if they have an impairment or disturbance of the brain, affecting the way their mind works. For example, if they cannot do one of the following:

- understand information about the decision to be made
- retain that information in their mind
- use or weigh this information as a part of their decision making process, or
- communicate their decision (by talking, using sign language or any other means)

You should always take all reasonable steps (for example involving more specialist colleagues) to support a patient in making their own decision, before concluding that they are unable to do so. Relatives cannot be asked to sign a form on behalf of an adult who lacks capacity to consent for themselves, unless they have been given the authority to do so under a Lasting Power of Attorney or as a court deputy.

Information

Information about what the treatment will involve, its benefits and risks (including side-effects and complications) and alternatives to the particular procedure proposed, is crucial for patients when making up their minds. The courts have stated that patients should be told about 'significant risks which would affect the judgement of a reasonable patient'. 'Significant' has not been legally defined, but the GMC requires doctors to tell patients about 'significant, unavoidable or frequently occurring' risks. If patients make clear they have particular concerns about certain kinds of risk, you should ensure that they are informed about these risks, even if very small or rare. You should always answer questions honestly. Sometimes, patients may make it clear that they do not want to have any information about the options, but want you to decide on their behalf. In such circumstances, you should do your best to ensure that the patient receives at least very basic information about what is proposed. Where information is refused, you should document this on the consent form or in the patient's notes.

NHS Scotland

NHS Scotland staff should refer to Healthcare Improvement Scotland. Guidance on consent for SACT and local NHS Board guidance on consent aligned to the Scottish legal framework.

References

1. Summary of Product Characteristics for individual drugs: medicines.org.uk/emc
2. Cancer Research UK: cruk.org/about-cancer/treatment/drugs
3. Macmillan Cancer Support: macmillan.org.uk/cancer-information-and-support/treatments-and-drugs
4. Guy's and St. Thomas' NHS Foundation Trust, Chemotherapy consent form

Patient agreement to systemic anti-cancer therapy (SACT)

MACE (Amsacrine, Cytarabine, Etoposide)

Hospital/NHS Trust/NHS Board:

_____

_____

Responsible consultant:

Name: _____

Job title: _____

Patient details

Patient's surname/family name:

_____

Patient's first name(s): _____

_____

Date of birth: _____

NHS number: _____
(or other identifier)

Special requirements:
(eg other language/other communication method)

_____

_____

_____

_____

Name of proposed course of treatment (include brief explanation if medical term not clear)

☐ MACE (Amsacrine, Cytarabine and Etoposide) chemotherapy for acute myeloid leukaemia (AML).

☐ Amsacrine, Cytarabine and Etoposide are given intravenously on days 1 to 5 (total of 5 doses).

☐ MACE is usually given for 1 cycle only

Where will I have treatment?

☐ Outpatient ☐ Day unit/case ☐ Inpatient ☐ Other: _____

Statement of health professional

(to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in the hospital/Trust/NHS board's consent policy)

☑ Tick all relevant boxes

☐ I confirm the patient has capacity to give consent.

☐ I have explained the course of treatment and intended benefit to the patient.

The intended benefits (there are no guarantees about outcome)

☐ Prolong survival.

☐ Control symptoms, reduce transfusion needs and improve quality of life.

☐ Induction – therapy given in the acute state of the disease, aiming to shrink the tumour.

☐ Curative – to give you the best possible chance of being cured.

☐ Maintenance – therapy given on continuing basis, aiming to prevent disease flaring up and to control the symptoms.

☐ Disease control / Palliative – the aim is not to cure but to control the disease and reduce the symptoms. The aim is to improve both quality and quantity of life.

Statement of health professional

Patient identifier/label

You may have one or more of the side effects listed

Common side effects:

Affecting more than 10 in every 100 (>10%) people

- ☐ An increased risk of getting an infection from a drop in white blood cells – this makes it harder to fight infections and you can become very ill.
- ☐ If you have a severe infection this can be life-threatening. Contact your doctor or hospital straight away if:
  - **your temperature goes over 37.5°C or over 38°C, depending on the advice given by your chemotherapy team**
  - **you suddenly feel unwell (even with a normal temperature)**
- ☐ Nausea (feeling sick), vomiting (being sick), abdominal (tummy) pain, constipation, diarrhoea, weight loss.
- ☐ Thinning of the hair or hair loss, sore mouth and ulcers, tiredness and feeling weak (fatigue), skin changes (change in colour, red or brown spots, rash).
- ☐ Anaemia (low number of red blood cells) and bruising or bleeding (low number of platelets); this can be prolonged and you may need a transfusion.
- ☐ Changes in liver and kidney function (monitored).
- ☐ Low blood pressure, pain, redness, swelling at the injection of site.
- ☐ Cytarabine syndrome can occur 6 to 12 hours after receiving cytarabine. Symptoms include a high temperature or chills, rash, pain in the eyes, bones, tummy and chest. Inform your doctor or nurse.

Occasional side effects:

Affecting between 1-10 in every 100 (1-10%) people

- ☐ Allergic reactions to etoposide. This can be severe and can occur immediately or a few hours later. Symptoms include difficulty in breathing, rapid heart rate, sweating, temperature, high or low blood pressure, feeling sick and being sick, rash or itching affecting the whole body, occasionally swelling of the face.
- ☐ Heart problems including changes in heart rhythm, risk of a heart attack, risk of heart failure with symptoms of fluid build-up and shortness of breath, high blood pressure.
- ☐ Blood pressure may drop if intravenous etoposide given to quickly.

Occasional side effects continued:

- ☐ Inflammation and ulcers of the opening at the end of the bowel (anus).
- ☐ Severe skin changes (redness, itching sometimes blisters), dizziness, shortness of breath.
- ☐ Sudden frequent mood swings, blood in the urine, low potassium levels.

Other risks:

- ☐ All intravenous drugs may leak out of the vein while it is being given (extravasation) and can damage the tissue around the vein. Tell the nurse straight away if you have any stinging, pain, redness or swelling around the vein. It's uncommon but important to deal with quickly.
- ☐ There may be an increased risk of tumour lysis syndrome in some patients (when treatment destroys cancer cells too quickly for the kidneys to cope and leads to changes in blood tests). Rarely, dialysis may be needed. You may be prescribed medicines for prevention or treatment.
- ☐ Late effects include a very rare chance of a second cancer (years later) and problems with your heart.
- ☐ Side effects of anti-sickness medication include diarrhoea, constipation, headache.
- ☐ Before treatment you may have blood tests to check for viruses (Hepatitis B or C, HIV, or unusual infections). Treatment may weaken your natural defence (immune) system so infections like this may worsen or become active if you've had them before. You may be given medicines to prevent infecion.
- ☐ Growth factors (GCSF) may be prescribed to maintain number of white cells to prevent infection. You may experience bone pain, headaches, red and itchy skin around the injection site.
- ☐ Changes in your memory, concentration or ability to think clearly. There can be many causes including your treatment, diagnosis, or both.
- ☐ Rarely, Cytarabine can cause changes in the lungs with shortness of breath, wheezing, cough or fever. Please inform your doctor or nurse if you notice these symptoms.

Continue on to the next page

Patient identifier/label

Statement of health professional

Other risks continued:

- ☐ Cancer and its treatment can increase your risk of developing a blood clot (thrombosis), causing pain, redness and swelling in an arm or leg, breathlessness, chest pain. Tell your doctor straight away if you have any symptoms.
- ☐ Some anti-cancer medicines can damage ovaries and sperm. This may lead to infertility and/or early menopause (hot flushes, vaginal dryness).
- ☐ Some anti-cancer medicines may damage the development of a baby in the womb. It is important not to become pregnant or make someone else pregnant during treatment and for up to 6 months afterwards. Women of child bearing age will be tested for pregnancy before and during treatment. Use effective contraception throughout. Speak to your doctor or nurse.
- ☐ Complications of treatment can very occasionally be life-threatening and may result in death. The risks are different for every individual. Potentially life-threatening complications include those listed on this form, but other exceedingly rare side effects may also be life-threatening.

Statement of health professional

Patient identifier/label

Any other risks and information:

_____

_____

☐ I have discussed the intended benefit and risks of the recommended treatment, and of any available alternative treatments (including no treatment).

☐ I have discussed the side effects of the recommended treatment, which could affect the patient straight away or in the future, and that there may be some side effects not listed because they are rare or have not yet been reported. Each patient may experience side effects differently.

☐ I have discussed what the treatment is likely to involve (including inpatient/outpatient treatment, timing of the treatment, blood and any additional tests, follow-up appointments etc) and location.

☐ I have explained to the patient, that they have the right to stop this treatment at any time and should contact the responsible consultant or team if they wish to do so.

☐ I have discussed concerns of particular importance to the patient in regard to treatment

(please write details here): _____

_____

Clinical management guideline/Protocol compliant (please tick):

☐ Yes ☐ No ☐ Not available If No please document reason here:

_____

The following written information has been provided:

☐ Information leaflet for MACE (Amsacrine, Cytarabine and Etoposide)

☐ 24 hour alert card or SACT advice service contact details

☐ SACT treatment record (cruk.org/treatment-record)

☐ Other, please state: _____

_____

Health professional details:

Signed: _____

Date: _____

Name (PRINT): _____

_____

Job title: _____

_____

Statement of interpreter **(where appropriate)**

Interpreter booking reference (if applicable):

I have interpreted the information above to the patient to the best of my ability and in a way in which I believe they can understand.

Signed: _____ Date: _____

Name (PRINT): _____ Job title: _____

Statement of patient

Patient identifier/label

Please read this form carefully. If your treatment has been planned in advance, you should already have your own copy of the form which describes the benefits and risks of the proposed treatment. If not, you will be offered a copy now. If you have any further questions, do ask – we are here to help you. You have the right to change your mind at any time, including after you have signed this form.

☐ I have had enough time to consider my options and make a decision about treatment.

☐ I agree to the course of treatment described on this form.

A witness should sign below if the patient is unable to sign but has indicated their consent. A person with parental responsibility will be asked to sign for young people under the age of 16 years.

Patient's signature: _____

Name (PRINT): _____ Date: _____

Person with parental responsibility/witness' signature: _____

Name (PRINT): _____ Date: _____

Copy accepted by patient: yes / no (please circle)

Confirmation of consent

(health professional to complete when the patient attends for treatment, if the patient has signed the form in advance)

On behalf of the team treating the patient, I have confirmed that the patient has no further questions and wishes the course of treatment/procedures to go ahead.

Signed: _____

Date: _____

Name (PRINT): _____

Job title: _____

Important notes: (tick if applicable)

☐ See also advance decision to refuse treatment

☐ Patient has withdrawn consent (ask patient to sign and date here)

Signed: _____

Date: _____

Further information for patients

Contact details (if patient wishes to discuss options later):

_____

Contact your hospital team if you have any questions about cancer and its treatment.

Cancer Research UK can also help answer your questions about cancer and treatment. If you want to talk in confidence, call our information nurses on freephone 0808 800 4040, Monday to Friday, 9am to 5pm. Alternatively visit cruk.org for more information.

These forms have been produced by Guy's and St. Thomas' NHS Foundation Trust as part of a national project to support clinicians in ensuring all patients are fully informed when consenting to SACT.

The project is supported by Cancer Research UK. This does not mean you are taking part in a clinical trial.

Guidance for health professionals

(to be read in conjunction with the hospital's consent policy)

Patient identifier/label

What a consent form is for

This form documents the patient's agreement to go ahead with the treatment you have proposed. It is not a legal waiver – if patients, for example, do not receive enough information on which to base their decision, then the consent may not be valid, even though the form has been signed. Patients are also entitled to change their mind after signing the form, if they retain capacity to do so. The form should act as an aide-memoir to health professionals and patients, by providing a checklist of the kind of information patients should be offered, and by enabling the patient to have a written record of the main points discussed. In no way should the written information provided for the patient be regarded as a substitute for face-to-face discussions with the patient.

The law on consent

See the following publications for a comprehensive summary of the law on consent. Consent: Patients and doctors making decisions together, GMC 2020 (gmc-uk.org/guidance). Reference guide to consent for examination or treatment, Department of Health, 2nd edition 2009 (doh.gov.uk).

Who can give consent

Everyone aged 16 or over is presumed to have the capacity to give consent for themselves, unless the opposite is demonstrated. For young people, it is good practice to involve those with parental responsibility in the consent discussions, unless specifically asked not to. A person with parental responsibility must sign this form for a child or young person under the age of 16. Such patients should be given the opportunity to 'assent' to treatment if they wish. If a patient has the capacity to give consent but is physically unable to sign a form, you should complete this form as usual and ask an independent witness to confirm that the patient has given consent orally or non-verbally.

When NOT to use this form

If the patient lacks the capacity to give consent, you should use an alternative form available for this purpose (dependent on patient age). A patient lacks capacity if they have an impairment or disturbance of the brain, affecting the way their mind works. For example, if they cannot do one of the following:

- understand information about the decision to be made
- retain that information in their mind
- use or weigh this information as a part of their decision making process, or
- communicate their decision (by talking, using sign language or any other means)

You should always take all reasonable steps (for example involving more specialist colleagues) to support a patient in making their own decision, before concluding that they are unable to do so. Relatives cannot be asked to sign a form on behalf of an adult who lacks capacity to consent for themselves, unless they have been given the authority to do so under a Lasting Power of Attorney or as a court deputy.

Information

Information about what the treatment will involve, its benefits and risks (including side-effects and complications) and alternatives to the particular procedure proposed, is crucial for patients when making up their minds. The courts have stated that patients should be told about 'significant risks which would affect the judgement of a reasonable patient'. 'Significant' has not been legally defined, but the GMC requires doctors to tell patients about 'significant, unavoidable or frequently occurring' risks. If patients make clear they have particular concerns about certain kinds of risk, you should ensure that they are informed about these risks, even if very small or rare. You should always answer questions honestly. Sometimes, patients may make it clear that they do not want to have any information about the options, but want you to decide on their behalf. In such circumstances, you should do your best to ensure that the patient receives at least very basic information about what is proposed. Where information is refused, you should document this on the consent form or in the patient's notes.

NHS Scotland

NHS Scotland staff should refer to Healthcare Improvement Scotland. Guidance on consent for SACT and local NHS Board guidance on consent aligned to the Scottish legal framework.

References

1. Summary of Product Characteristics for individual drugs: medicines.org.uk/emc
2. Cancer Research UK: cruk.org/about-cancer/treatment/drugs
3. Macmillan Cancer Support: macmillan.org.uk/cancer-information-and-support/treatments-and-drugs
4. Guy's and St. Thomas' NHS Foundation Trust, Chemotherapy consent form

Patient agreement to systemic anti-cancer therapy (SACT)

MEC (Mitoxantrone, Etoposide and Cytarabine)

Hospital/NHS Trust/NHS Board:

_____

_____

Responsible consultant:

Name: _____

Job title: _____

Patient details

Patient's surname/family name:

_____

Patient's first name(s): _____

_____

Date of birth: _____

NHS number: _____
(or other identifier)

Special requirements:
(eg other language/other communication method)

_____

_____

_____

_____

Name of proposed course of treatment (include brief explanation if medical term not clear)

☐ MEC (Mitoxantrone, Etoposide and Cytarabine) for the treatment of acute myeloid leukemia (AML).

☐ Mitoxantrone, Etoposide and Cytarabine are given intravenously on days 1 to 5 (total of 5 doses each).

☐ MEC is usually given for 1 or 2 cycles.

Where will I have treatment?

☐ Outpatient ☐ Day unit/case ☐ Inpatient ☐ Other: _____

Statement of health professional

(to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in the hospital/Trust/NHS board's consent policy)

☑ Tick all relevant boxes

☐ I confirm the patient has capacity to give consent.

☐ I have explained the course of treatment and intended benefit to the patient.

The intended benefits (there are no guarantees about outcome)

☐ Prolong survival.

☐ Control symptoms, reduce transfusion needs and improve quality of life.

☐ Induction – therapy given in the acute state of the disease, aiming to shrink the tumour.

☐ Curative – to give you the best possible chance of being cured.

☐ Maintenance – therapy given on continuing basis, aiming to prevent disease flaring up and to control the symptoms.

☐ Disease control / Palliative – the aim is not to cure but to control the disease and reduce the symptoms. The aim is to improve both quality and quantity of life.

Statement of health professional

Patient identifier/label

You may have one or more of the side effects listed

Common side effects:

Affecting more than 10 in every 100 (>10%) people

- ☐ An increased risk of getting an infection from a drop in white blood cells – this makes it harder to fight infections and you can become very ill.
- ☐ **If you have a severe infection this can be life-threatening. Contact your doctor or hospital straight away if:**
  - **your temperature goes over 37.5°C or over 38°C, depending on the advice given by your chemotherapy team**
  - **you suddenly feel unwell (even with a normal temperature)**
- ☐ Thinning of the hair or hair loss, nausea (feeling sick), vomiting (being sick), constipation, diarrhoea, sore mouth and ulcers, difficulty swallowing, weight loss, tiredness and feeling weak (fatigue), abdominal (tummy) pain, change in skin colour.
- ☐ Anaemia (low number of red blood cells), bruising or bleeding (low number of platelets); this can be prolonged and you may need a transfusion.
- ☐ Changes in liver function and kidney function (monitored).
- ☐ Cytarabine syndrome can occur 6 to 12 hours after receiving Cytarabine. Symptoms include a high temperature or chills, rash, pain in the eyes, bones, tummy and chest. Inform your doctor or nurse.
- ☐ Cytarabine can cause inflammation of the lining of the eye lids (conjunctiva) making eyes feel sore, red and itchy (this is temporary). Steroid eye drops during and for 3 days after Cytarabine to prevent this will be given.

Occasional side effects:

Affecting between 1-10 in every 100 (1-10%) people

- ☐ Allergic reactions to Etoposide. This can be severe and can occur immediately or a few hours later. Symptoms include difficulty in breathing, increase in heart rate, sweating, temperature, high or low blood pressure, feeling sick and being sick, rash or itching affecting the whole body, occasionally swelling of the face.
- ☐ Heart problems with changes in the way your heart works with symptoms of fluid build-up and shortness of breath (heart failure), risk of a heart attack, abnormal heart rhythm (fast heart rate).

Occasional side effects continued:

- ☐ Inflammation and ulcers at the opening end of the bowel (anus), sometimes can be severe leading to infections.
- ☐ Blood pressure may drop if intravenous Etoposide given to quickly.
- ☐ Severe skin changes (redness, itching sometimes blisters), eye sight changes (reversible).
- ☐ Change in colour of the eyes, nails and urine, shortness of breath.
- ☐ High dose Cytarabine can cause temporary or occasionally permanent changes to the nervous system. Symptoms include seizures (fits), drowsiness, unsteadiness and mood changes.

Other risks:

- ☐ All intravenous drugs may leak out of the vein while it is being given (extravasation) and can damage the tissue around the vein. Tell the nurse straight away if you have any stinging, pain, redness or swelling around the vein. It's uncommon but important to deal with quickly.
- ☐ Also, rarely high dose Cytarabine can cause changes in the lungs with shortness of breath, wheeezing, cough or a fever. Please inform your doctor or nurse if you notice these symptoms.
- ☐ There may be an increased risk of tumour lysis syndrome in some patients when treatment destroys cancer cells too quickly for the kidneys to cope and leads to changes in blood tests. Rarely, dialysis may be needed. You may be prescribed medicines for prevention or treatment.
- ☐ Late effects include a very rare chance of a second cancer (years later) and problems with your heart.
- ☐ Side effects of anti-sickness medication include diarrhoea, constipation, headache.
- ☐ Before treatment you may have blood tests to check for viruses (Hepatitis B or C, HIV, or unusual infections). Treatment may weaken your natural defence (immune) system so infections like this may worsen or become active if you've had them before. You may be given medication to prevent infection.

Continue on to the next page

Patient identifier/label

Statement of health professional continued

Other risks continued:

- ☐ Growth factors (GCSF) may be prescribed to maintain number of white cells to prevent infection. You may experience bone pain, headaches, red and itchy skin around the injection site.
- ☐ Changes in your memory, concentration or ability to think clearly. There can be many causes including your treatment, diagnosis, or both.
- ☐ Cancer and its treatment can increase your risk of developing a blood clot (thrombosis), causing pain, redness and swelling in an arm or leg, breathlessness, chest pain. Tell your doctor straight away if you have any symptoms.
- ☐ Some anti-cancer medicines can damage ovaries and sperm. This may lead to infertility and/or early menopause (hot flushes, vaginal dryness).
- ☐ Some anti-cancer medicines may damage the development of a baby in the womb. It is important not to become pregnant or make someone else pregnant during treatment and for up to 6 months afterwards. Women of child bearing age will be tested for pregnancy before and during treatment. Use effective contraception throughout. Speak to your doctor or nurse.
- ☐ Complications of treatment can very occasionally be life-threatening and may result in death. The risks are different for every individual. Potentially life-threatening complications include those listed on this form, but other exceedingly rare side effects may also be life-threatening.

Statement of health professional

Patient identifier/label

Any other risks and information:

_____

_____

☐ I have discussed the intended benefit and risks of the recommended treatment, and of any available alternative treatments (including no treatment).

☐ I have discussed the side effects of the recommended treatment, which could affect the patient straight away or in the future, and that there may be some side effects not listed because they are rare or have not yet been reported. Each patient may experience side effects differently.

☐ I have discussed what the treatment is likely to involve (including inpatient/outpatient treatment, timing of the treatment, blood and any additional tests, follow-up appointments etc) and location.

☐ I have explained to the patient, that they have the right to stop this treatment at any time and should contact the responsible consultant or team if they wish to do so.

☐ I have discussed concerns of particular importance to the patient in regard to treatment

(please write details here): _____

_____

Clinical management guideline/Protocol compliant (please tick):

☐ Yes ☐ No ☐ Not available If No please document reason here:

_____

The following written information has been provided:

☐ Information leaflet for MEC (Mitoxantrone, Etoposide and Cytarabine)

☐ 24 hour alert card or SACT advice service contact details

☐ SACT treatment record (cruk.org/treatment-record)

☐ Other, please state: _____

_____

Health professional details:

Signed: _____

Date: _____

Name (PRINT): _____

_____

Job title: _____

_____

Statement of interpreter **(where appropriate)**

Interpreter booking reference (if applicable):

I have interpreted the information above to the patient to the best of my ability and in a way in which I believe they can understand.

Signed: _____ Date: _____

Name (PRINT): _____ Job title: _____

Statement of patient

Patient identifier/label

Please read this form carefully. If your treatment has been planned in advance, you should already have your own copy of the form which describes the benefits and risks of the proposed treatment. If not, you will be offered a copy now. If you have any further questions, do ask – we are here to help you. You have the right to change your mind at any time, including after you have signed this form.

☐ I have had enough time to consider my options and make a decision about treatment.

☐ I agree to the course of treatment described on this form.

A witness should sign below if the patient is unable to sign but has indicated their consent. A person with parental responsibility will be asked to sign for young people under the age of 16 years.

Patient's signature: _____

Name (PRINT): _____ Date: _____

Person with parental responsibility/witness' signature: _____

Name (PRINT): _____ Date: _____

Copy accepted by patient: yes / no (please circle)

Confirmation of consent

(health professional to complete when the patient attends for treatment, if the patient has signed the form in advance)

On behalf of the team treating the patient, I have confirmed that the patient has no further questions and wishes the course of treatment/procedures to go ahead.

Signed: _____

Date: _____

Name (PRINT): _____

Job title: _____

Important notes: (tick if applicable)

☐ See also advance decision to refuse treatment

☐ Patient has withdrawn consent (ask patient to sign and date here)

Signed: _____

Date: _____

Further information for patients

Contact details (if patient wishes to discuss options later):

_____

Contact your hospital team if you have any questions about cancer and its treatment.

Cancer Research UK can also help answer your questions about cancer and treatment. If you want to talk in confidence, call our information nurses on freephone 0808 800 4040, Monday to Friday, 9am to 5pm. Alternatively visit cruk.org for more information.

These forms have been produced by Guy's and St. Thomas' NHS Foundation Trust as part of a national project to support clinicians in ensuring all patients are fully informed when consenting to SACT.

The project is supported by Cancer Research UK. This does not mean you are taking part in a clinical trial.



Guidance for health professionals

(to be read in conjunction with the hospital's consent policy)

Patient identifier/label

What a consent form is for

This form documents the patient's agreement to go ahead with the treatment you have proposed. It is not a legal waiver – if patients, for example, do not receive enough information on which to base their decision, then the consent may not be valid, even though the form has been signed. Patients are also entitled to change their mind after signing the form, if they retain capacity to do so. The form should act as an aide-memoir to health professionals and patients, by providing a checklist of the kind of information patients should be offered, and by enabling the patient to have a written record of the main points discussed. In no way should the written information provided for the patient be regarded as a substitute for face-to-face discussions with the patient.

The law on consent

See the following publications for a comprehensive summary of the law on consent. Consent: Patients and doctors making decisions together, GMC 2020 (gmc-uk.org/guidance). Reference guide to consent for examination or treatment, Department of Health, 2nd edition 2009 (doh.gov.uk).

Who can give consent

Everyone aged 16 or over is presumed to have the capacity to give consent for themselves, unless the opposite is demonstrated. For young people, it is good practice to involve those with parental responsibility in the consent discussions, unless specifically asked not to. A person with parental responsibility must sign this form for a child or young person under the age of 16. Such patients should be given the opportunity to 'assent' to treatment if they wish. If a patient has the capacity to give consent but is physically unable to sign a form, you should complete this form as usual and ask an independent witness to confirm that the patient has given consent orally or non-verbally.

When NOT to use this form

If the patient lacks the capacity to give consent, you should use an alternative form available for this purpose (dependent on patient age). A patient lacks capacity if they have an impairment or disturbance of the brain, affecting the way their mind works. For example, if they cannot do one of the following:

- understand information about the decision to be made
- retain that information in their mind
- use or weigh this information as a part of their decision making process, or
- communicate their decision (by talking, using sign language or any other means)

You should always take all reasonable steps (for example involving more specialist colleagues) to support a patient in making their own decision, before concluding that they are unable to do so. Relatives cannot be asked to sign a form on behalf of an adult who lacks capacity to consent for themselves, unless they have been given the authority to do so under a Lasting Power of Attorney or as a court deputy.

Information

Information about what the treatment will involve, its benefits and risks (including side-effects and complications) and alternatives to the particular procedure proposed, is crucial for patients when making up their minds. The courts have stated that patients should be told about 'significant risks which would affect the judgement of a reasonable patient'. 'Significant' has not been legally defined, but the GMC requires doctors to tell patients about 'significant, unavoidable or frequently occurring' risks. If patients make clear they have particular concerns about certain kinds of risk, you should ensure that they are informed about these risks, even if very small or rare. You should always answer questions honestly. Sometimes, patients may make it clear that they do not want to have any information about the options, but want you to decide on their behalf. In such circumstances, you should do your best to ensure that the patient receives at least very basic information about what is proposed. Where information is refused, you should document this on the consent form or in the patient's notes.

NHS Scotland

NHS Scotland staff should refer to Healthcare Improvement Scotland. Guidance on consent for SACT and local NHS Board guidance on consent aligned to the Scottish legal framework.

References

1. Summary of Product Characteristics for individual drugs: medicines.org.uk/emc
2. Cancer Research UK: cruk.org/about-cancer/treatment/drugs
3. Macmillan Cancer Support: macmillan.org.uk/cancer-information-and-support/treatments-and-drugs
4. Guy's and St. Thomas' NHS Foundation Trust, Chemotherapy consent form

Patient agreement to systemic anti-cancer therapy (SACT)

MidAC (Mitoxantrone and Cytarabine)

Hospital/NHS Trust/NHS Board:

_____

_____

Responsible consultant:

Name: _____

Job title: _____

Patient details

Patient's surname/family name:

_____

Patient's first name(s): _____

_____

Date of birth: _____

NHS number: _____
(or other identifier)

Special requirements:
(eg other language/other communication method)

_____

_____

_____

_____

Name of proposed course of treatment (include brief explanation if medical term not clear)

☐ MidAC (Mitoxantrone and Cytarabine) chemotherapy for the treatment of acute myeloid leukaemia (AML).

☐ Mitoxantrone is given intravenously on days 1 to 5 (total of 5 doses) and Cytarabine given intravenously twice each on days 1 to 3 (total of 6 doses).

☐ MidAC is usually given once only .

☐ Where will I have treatment?

☐ Outpatient ☐ Day unit/case ☐ Inpatient ☐ Other: _____

Statement of health professional

(to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in the hospital/Trust/NHS board's consent policy)

☑ Tick all relevant boxes

☐ I confirm the patient has capacity to give consent.

☐ I have explained the course of treatment and intended benefit to the patient.

The intended benefits (there are no guarantees about outcome)

☐ Prolong survival.

☐ Control symptoms, reduce transfusion needs and improve quality of life.

☐ Induction – therapy given in the acute state of the disease, aiming to shrink the tumour.

☐ Curative – to give you the best possible chance of being cured.

☐ Maintenance – therapy given on continuing basis, aiming to prevent disease flaring up and to control the symptoms.

☐ Disease control / Palliative – the aim is not to cure but to control the disease and reduce the symptoms. The aim is to improve both quality and quantity of life.

Statement of health professional

Patient identifier/label

You may have one or more of the side effects listed

Common side effects:

Affecting more than 10 in every 100 (>10%) people

- ☐ An increased risk of getting an infection (from a drop in white blood cells – this makes it harder to fight infections and you can become very ill.
- ☐ If you have a severe infection this can be life-threatening. Contact your doctor or hospital straight away if:
  - **your temperature goes over 37.5°C or over 38°C, depending on the advice given by your chemotherapy team**
  - **you suddenly feel unwell (even with a normal temperature)**
- ☐ Nausea (feeling sick), vomiting (being sick), abdominal (tummy) pain, diarrhoea, sore mouth and ulcers, thinning of the hair or hair loss.
- ☐ Anaemia (due to low red blood cells) and bruising or bleeding (due to low platelets); this can be prolonged and you may need a transfusion.
- ☐ Cytarabine syndrome can occur 6 to 12 hours after receiving Cytarabine. Symptoms include a high temperature or chills, rash, pain in the eyes, bones, tummy and chest. Inform your doctor or nurse.
- ☐ Inflammation of the lining of the eye lids (conjunctiva) making eyes feel sore, red and itchy (this is temporary). Steroid eye drops during and for 3 days following Cytarabine treatment to prevent this will be given.

Occasional side effects:

Affecting between 1-10 in every 100 (1-10%) people

- ☐ Inflammation and ulcers of the opening end of the bowel (anus), sometimes can be severe leading to infections.
- ☐ Skin changes (redness, itching sometimes blisters), weight loss, shortness of breath, eye sight changes (reversible).
- ☐ Changes in liver and kidney function (monitored), high uric acid levels, change in colour of the eyes, nails, skin and urine.
- ☐ Heart problems with changes in the way your heart works with symptoms of fluid build-up and shortness of breath (heart failure), risk of a heart attack.
- ☐ High dose Cytarabine can cause temporary or occasionally permanent changes to the nervous system. Symptoms include seizures (fits), drowsiness, unsteadiness and mood changes. Inform your doctor or nurse.

Other risks:

- ☐ Mitoxantrone, Cytarabine may leak out of the vein while it is being given (extravasation) and can damage the tissue around the vein. Tell the nurse straight away if you have any stinging, pain, redness or swelling around the vein. It's uncommon but important to deal with quickly.
- ☐ Also, rarely high dose Cytarabine can cause changes in the lungs with shortness of breath, wheezing, cough or a fever. Please inform your doctor or nurse if you notice these symptoms.
- ☐ There may be an increased risk of tumour lysis syndrome in some patients when treatment destroys cancer cells too quickly for the kidneys to cope and leads to changes in blood tests. Rarely, dialysis may be needed. You may be prescribed medicines for prevention or treatment.
- ☐ Late effects include a very rare chance of a second cancer (years later) and problems with your heart.
- ☐ Side effects of anti-sickness medication include diarrhoea, constipation, headache.
- ☐ Before treatment you may have blood tests to check for viruses (Hepatitis B or C, HIV, or unusual infections). Treatment may weaken your natural defence (immune) system so infections like this may worsen or become active if you've had them before. You may be given medication to prevent infection.
- ☐ Growth factors (GCSF) may be prescribed to maintain number of white cells to prevent infection. You may experience bone pain, headaches, red and itchy skin around the injection site.
- ☐ Changes in your memory, concentration or ability to think clearly. There can be many causes including your treatment, diagnosis, or both.
- ☐ Cancer and its treatment can increase your risk of developing a blood clot (thrombosis), causing pain, redness and swelling in an arm or leg, breathlessness, chest pain. Tell your doctor straight away if you have any symptoms.
- ☐ Some anti-cancer medicines can damage ovaries and sperm. This may lead to infertility and/or early menopause (hot flushes, vaginal dryness).

Continue on to the next page

Patient identifier/label

Statement of health professional continued

Other risks continued:

- ☐ Some anti-cancer medicines may damage the development of a baby in the womb. It is important not to become pregnant or make someone else pregnant during treatment and for up to 6 months afterwards. Women of child bearing age will be tested for pregnancy before and during treatment. Use effective contraception throughout. Speak to your doctor or nurse.
- ☐ Complications of treatment can very occasionally be life-threatening and may result in death. The risks are different for every individual. Potentially life-threatening complications include those listed on this form, but other exceedingly rare side effects may also be life-threatening.

Statement of health professional

Patient identifier/label

Any other risks and information:

_____

_____

☐ I have discussed the intended benefit and risks of the recommended treatment, and of any available alternative treatments (including no treatment).

☐ I have discussed the side effects of the recommended treatment, which could affect the patient straight away or in the future, and that there may be some side effects not listed because they are rare or have not yet been reported. Each patient may experience side effects differently.

☐ I have discussed what the treatment is likely to involve (including inpatient/outpatient treatment, timing of the treatment, blood and any additional tests, follow-up appointments etc) and location.

☐ I have explained to the patient, that they have the right to stop this treatment at any time and should contact the responsible consultant or team if they wish to do so.

☐ I have discussed concerns of particular importance to the patient in regard to treatment

(please write details here): _____

_____

Clinical management guideline/Protocol compliant (please tick):

☐ Yes ☐ No ☐ Not available If No please document reason here:

_____

The following written information has been provided:

☐ Information leaflet for MidAC (Mitoxantrone and Cytarabine)

☐ 24 hour alert card or SACT advice service contact details

☐ SACT treatment record (cruk.org/treatment-record)

☐ Other, please state: _____

_____

Health professional details:

Signed: _____

Date: _____

Name (PRINT): _____

_____

Job title: _____

_____

Statement of interpreter **(where appropriate)**

Interpreter booking reference (if applicable):

I have interpreted the information above to the patient to the best of my ability and in a way in which I believe they can understand.

Signed: _____ Date: _____

Name (PRINT): _____ Job title: _____

Statement of patient

Patient identifier/label

Please read this form carefully. If your treatment has been planned in advance, you should already have your own copy of the form which describes the benefits and risks of the proposed treatment. If not, you will be offered a copy now. If you have any further questions, do ask – we are here to help you. You have the right to change your mind at any time, including after you have signed this form.

☐ I have had enough time to consider my options and make a decision about treatment.

☐ I agree to the course of treatment described on this form.

A witness should sign below if the patient is unable to sign but has indicated their consent. A person with parental responsibility will be asked to sign for young people under the age of 16 years.

Patient's signature: _____

Name (PRINT): _____ Date: _____

Person with parental responsibility/witness' signature: _____

Name (PRINT): _____ Date: _____

Copy accepted by patient: yes / no (please circle)

Confirmation of consent

(health professional to complete when the patient attends for treatment, if the patient has signed the form in advance)

On behalf of the team treating the patient, I have confirmed that the patient has no further questions and wishes the course of treatment/procedures to go ahead.

Signed: _____

Date: _____

Name (PRINT): _____

Job title: _____

Important notes: (tick if applicable)

☐ See also advance decision to refuse treatment

☐ Patient has withdrawn consent (ask patient to sign and date here)

Signed: _____

Date: _____

Further information for patients

Contact details (if patient wishes to discuss options later):

_____

Contact your hospital team if you have any questions about cancer and its treatment.

Cancer Research UK can also help answer your questions about cancer and treatment. If you want to talk in confidence, call our information nurses on freephone 0808 800 4040, Monday to Friday, 9am to 5pm. Alternatively visit cruk.org for more information.

These forms have been produced by Guy's and St. Thomas' NHS Foundation Trust as part of a national project to support clinicians in ensuring all patients are fully informed when consenting to SACT.

The project is supported by Cancer Research UK. This does not mean you are taking part in a clinical trial.



Guidance for health professionals

(to be read in conjunction with the hospital's consent policy)

Patient identifier/label

What a consent form is for

This form documents the patient's agreement to go ahead with the treatment you have proposed. It is not a legal waiver – if patients, for example, do not receive enough information on which to base their decision, then the consent may not be valid, even though the form has been signed. Patients are also entitled to change their mind after signing the form, if they retain capacity to do so. The form should act as an aide-memoir to health professionals and patients, by providing a checklist of the kind of information patients should be offered, and by enabling the patient to have a written record of the main points discussed. In no way should the written information provided for the patient be regarded as a substitute for face-to-face discussions with the patient.

The law on consent

See the following publications for a comprehensive summary of the law on consent. Consent: Patients and doctors making decisions together, GMC 2020 (gmc-uk.org/guidance). Reference guide to consent for examination or treatment, Department of Health, 2nd edition 2009 (doh.gov.uk).

Who can give consent

Everyone aged 16 or over is presumed to have the capacity to give consent for themselves, unless the opposite is demonstrated. For young people, it is good practice to involve those with parental responsibility in the consent discussions, unless specifically asked not to. A person with parental responsibility must sign this form for a child or young person under the age of 16. Such patients should be given the opportunity to 'assent' to treatment if they wish. If a patient has the capacity to give consent but is physically unable to sign a form, you should complete this form as usual and ask an independent witness to confirm that the patient has given consent orally or non-verbally.

When NOT to use this form

If the patient lacks the capacity to give consent, you should use an alternative form available for this purpose (dependent on patient age). A patient lacks capacity if they have an impairment or disturbance of the brain, affecting the way their mind works. For example, if they cannot do one of the following:

- understand information about the decision to be made
- retain that information in their mind
- use or weigh this information as a part of their decision making process, or
- communicate their decision (by talking, using sign language or any other means)

You should always take all reasonable steps (for example involving more specialist colleagues) to support a patient in making their own decision, before concluding that they are unable to do so. Relatives cannot be asked to sign a form on behalf of an adult who lacks capacity to consent for themselves, unless they have been given the authority to do so under a Lasting Power of Attorney or as a court deputy.

Information

Information about what the treatment will involve, its benefits and risks (including side-effects and complications) and alternatives to the particular procedure proposed, is crucial for patients when making up their minds. The courts have stated that patients should be told about 'significant risks which would affect the judgement of a reasonable patient'. 'Significant' has not been legally defined, but the GMC requires doctors to tell patients about 'significant, unavoidable or frequently occurring' risks. If patients make clear they have particular concerns about certain kinds of risk, you should ensure that they are informed about these risks, even if very small or rare. You should always answer questions honestly. Sometimes, patients may make it clear that they do not want to have any information about the options, but want you to decide on their behalf. In such circumstances, you should do your best to ensure that the patient receives at least very basic information about what is proposed. Where information is refused, you should document this on the consent form or in the patient's notes.

NHS Scotland

NHS Scotland staff should refer to Healthcare Improvement Scotland. Guidance on consent for SACT and local NHS Board guidance on consent aligned to the Scottish legal framework.

References

1. Summary of Product Characteristics for individual drugs: medicines.org.uk/emc
2. Cancer Research UK: cruk.org/about-cancer/treatment/drugs
3. Macmillan Cancer Support: macmillan.org.uk/cancer-information-and-support/treatments-and-drugs
4. Guy's and St. Thomas' NHS Foundation Trust, Chemotherapy consent form

Patient agreement to systemic anti-cancer therapy (SACT)

Midostaurin (+/- chemotherapy)

Hospital/NHS Trust/NHS Board:

_____

_____

Responsible consultant:
Name: _____

Job title:

Patient details
Patient's surname/family name:

_____

Patient's first name(s): _____

_____

Date of birth: _____

NHS number: _____
(or other identifier)

Special requirements:
(eg other language/other communication method)

_____

_____

_____

_____

Name of proposed course of treatment (include brief explanation if medical term not clear)

☐ Midostaurin chemotherapy for the treatment of FLT3 mutation positive acute myeloid leukaemia (AML).

☐ Midostaurin is given orally twice daily for 14 days starting after each cycle of chemotherapy. A separate consent form must be completed for the chemotherapy regimen.

☐ Midostaurin is given as maintenance therapy after chemotherapy treatment is complete. It is taken orally every day for twelve 28 day cycles (1 year).

Where will I have treatment?
☐ Outpatient ☐ Day unit/case ☐ Inpatient ☐ Other: _____

Statement of health professional

(to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in the hospital/Trust/NHS board's consent policy)

☑ Tick all relevant boxes

☐ I confirm the patient has capacity to give consent.

☐ I have explained the course of treatment and intended benefit to the patient.

The intended benefits (there are no guarantees about outcome)

☐ Prolong survival.

☐ Control symptoms, reduce transfusion needs and improve quality of life.

☐ Induction – therapy given in the acute state of the disease, aiming to shrink the tumour.

☐ Curative – to give you the best possible chance of being cured.

☐ Maintenance – therapy given on continuing basis, aiming to prevent disease flaring up and to control the symptoms.

☐ Disease control / Palliative – the aim is not to cure but to control the disease and reduce the symptoms. The aim is to improve both quality and quantity of life.

Statement of health professional

Patient identifier/label

You may have one or more of the side effects listed

Common side effects:

Affecting more than 10 in every 100 (>10%) people

- ☐ An increased risk of getting an infection from a drop in white blood cells – this makes it harder to fight infections and you can become very ill.
- ☐ **If you have a severe infection this can be life-threatening. Contact your doctor or hospital straight away if:**
  - **your temperature goes over 37.5°C or over 38°C, depending on the advice given by your chemotherapy team**
  - **you suddenly feel unwell (even with a normal temperature)**
- ☐ Nausea (feeling sick), vomiting (being sick), abdominal (tummy), haemorrhoids, sore mouth and ulcers.
- ☐ Skin changes (rash with flaking, peeling or redness), excessive sweating, allergic reactions, back and joint pain.
- ☐ Nose bleed, headache, difficulty sleeping (insomnia), low blood pressure.
- ☐ Low potassium, high sodium, changes in liver function – picked up and monitored in bood tests.
- ☐ Lung changes causing shortness of breath, wheezing and/or cough with fluid build-up. Please contact your doctor or nurse if you notice these symptoms.
- ☐ Midostaurin can raise your blood sugar. If you have diabetes, it may lead to higher blood sugar levels. Please ask your doctor/nurse/GP if concerned.

Occasional side effects:

Affecting between 1-10 in every 100 (1-10%) people

- ☐ Swelling around the eyelids, sensitivity to light and/or eye pain (keratitis).
- ☐ Poor concentration, shaking or trembling, sudden loss of consciousness.
- ☐ High blood pressure, build-up of fluid around the lungs, high calcium, high uric acid levels.
- ☐ Pain the bones, neck, hands and feet, dry skin
- ☐ Midostaurin can cause abnormal heart rhythms (QT prolongation). Contact your doctor or nurse if you have a change in your heartbeat, or if you feel dizzy, lightheaded, or faint.

Other risks:

- ☐ There may be an increased risk of tumour lysis syndrome in some patients when treatment destroys cancer cells too quickly for the kidneys to cope and leads to chnages in blood tests. Rarely, dialysis may be needed. You may be prescribed medicines for prevention or treatment.
- ☐ Side effects of anti-sickness medication include diarrhoea, constipation, headache.
- ☐ Before treatment you may have blood tests to check for viruses (Hepatitis B or C, HIV, or unusual infections). Treatment may weaken your natural defence (immune) system so infections like this may worsen or become active if you've had them before. You may have medicines to prevent or treat infection.
- ☐ Growth factors (GCSF) may be prescribed to maintain number of white cells to prevent infection. You may experience bone pain, headaches, red and itchy skin around the injection site.
- ☐ Changes in your memory, concentration or ability to think clearly. There can be many causes including your treatment, diagnosis, or both.
- ☐ Cancer and its treatment can increase your risk of developing a blood clot (thrombosis), causing pain, redness and swelling in an arm or leg, breathlessness, chest pain. Tell your doctor straight away if you have any symptoms.
- ☐ Some anti-cancer medicines can damage ovaries and sperm. This may lead to infertility and/or early menopause (hot flushes, vaginal dryness).
- ☐ Some anti-cancer medicines may damage the development of a baby in the womb. It is important not to become pregnant or make some else preganant during treatment and for 4 months after. Women of child bearing age must be tested for pregnancy within 7 days of starting midostaurin. Use effective contraception throughout. Speak to your doctor or nurse.
- ☐ Complications of treatment can very occasionally be life-threatening and may result in death. The risks are different for every individual. Potentially life-threatening complications include those listed on this form, but other exceedingly rare side effects may also be life-threatening.

Statement of health professional

Patient identifier/label

Any other risks and information:

_____

_____

☐ I have discussed the intended benefit and risks of the recommended treatment, and of any available alternative treatments (including no treatment).

☐ I have discussed the side effects of the recommended treatment, which could affect the patient straight away or in the future, and that there may be some side effects not listed because they are rare or have not yet been reported. Each patient may experience side effects differently.

☐ I have discussed what the treatment is likely to involve (including inpatient/outpatient treatment, timing of the treatment, blood and any additional tests, follow-up appointments etc) and location.

☐ I have explained to the patient, that they have the right to stop this treatment at any time and should contact the responsible consultant or team if they wish to do so.

☐ I have discussed concerns of particular importance to the patient in regard to treatment

(please write details here): _____

_____

Clinical management guideline/Protocol compliant (please tick):

☐ Yes ☐ No ☐ Not available If No please document reason here:

_____

The following written information has been provided:

☐ Information leaflet for Midostaurin +/- chemotherapy

☐ 24 hour alert card or SACT advice service contact details

☐ SACT treatment record (cruk.org/treatment-record)

☐ Other, please state: _____

_____

Health professional details:

Signed: _____

Date: _____

Name (PRINT): _____

_____

Job title: _____

_____

Statement of interpreter **(where appropriate)**

Interpreter booking reference (if applicable):

I have interpreted the information above to the patient to the best of my ability and in a way in which I believe they can understand.

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Patient identifier/label

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☐ I have had enough time to consider my options and make a decision about treatment.

☐ I agree to the course of treatment described on this form.

A witness should sign below if the patient is unable to sign but has indicated their consent. A person with parental responsibility will be asked to sign for young people under the age of 16 years.

Patient's signature: _____

Name (PRINT): _____ Date: _____

Person with parental responsibility/witness' signature: _____

Name (PRINT): _____ Date: _____

Copy accepted by patient: yes / no (please circle)

Confirmation of consent

(health professional to complete when the patient attends for treatment, if the patient has signed the form in advance)

On behalf of the team treating the patient, I have confirmed that the patient has no further questions and wishes the course of treatment/procedures to go ahead.

Signed: _____

Date: _____

Name (PRINT): _____

Job title: _____

Important notes: (tick if applicable)

☐ See also advance decision to refuse treatment

☐ Patient has withdrawn consent (ask patient to sign and date here)

Signed: _____

Date: _____

Further information for patients

Contact details (if patient wishes to discuss options later):

_____

Contact your hospital team if you have any questions about cancer and its treatment.

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The project is supported by Cancer Research UK. This does not mean you are taking part in a clinical trial.

Guidance for health professionals

(to be read in conjunction with the hospital's consent policy)

Patient identifier/label

What a consent form is for

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When NOT to use this form

If the patient lacks the capacity to give consent, you should use an alternative form available for this purpose (dependent on patient age). A patient lacks capacity if they have an impairment or disturbance of the brain, affecting the way their mind works. For example, if they cannot do one of the following:

- understand information about the decision to be made
- retain that information in their mind
- use or weigh this information as a part of their decision making process, or
- communicate their decision (by talking, using sign language or any other means)

You should always take all reasonable steps (for example involving more specialist colleagues) to support a patient in making their own decision, before concluding that they are unable to do so. Relatives cannot be asked to sign a form on behalf of an adult who lacks capacity to consent for themselves, unless they have been given the authority to do so under a Lasting Power of Attorney or as a court deputy.

Information

Information about what the treatment will involve, its benefits and risks (including side-effects and complications) and alternatives to the particular procedure proposed, is crucial for patients when making up their minds. The courts have stated that patients should be told about 'significant risks which would affect the judgement of a reasonable patient'. 'Significant' has not been legally defined, but the GMC requires doctors to tell patients about 'significant, unavoidable or frequently occurring' risks. If patients make clear they have particular concerns about certain kinds of risk, you should ensure that they are informed about these risks, even if very small or rare. You should always answer questions honestly. Sometimes, patients may make it clear that they do not want to have any information about the options, but want you to decide on their behalf. In such circumstances, you should do your best to ensure that the patient receives at least very basic information about what is proposed. Where information is refused, you should document this on the consent form or in the patient's notes.

NHS Scotland

NHS Scotland staff should refer to Healthcare Improvement Scotland. Guidance on consent for SACT and local NHS Board guidance on consent aligned to the Scottish legal framework.

References

1. Summary of Product Characteristics for individual drugs: medicines.org.uk/emc
2. Cancer Research UK: cruk.org/about-cancer/treatment/drugs
3. Macmillan Cancer Support: macmillan.org.uk/cancer-information-and-support/treatments-and-drugs
4. Guy's and St. Thomas' NHS Foundation Trust, Chemotherapy consent form

Patient agreement to systemic anti-cancer therapy (SACT)

Midostaurin + chemotherapy (DA and High dose Cytarabine)

Hospital/NHS Trust/NHS Board:

_____

_____

Responsible consultant:
Name: _____

Job title: _____

Patient details
Patient's surname/family name:

_____

Patient's first name(s): _____

_____

Date of birth: _____

NHS number: _____
(or other identifier)

Special requirements:
(eg other language/other communication method)

_____

_____

_____

_____

Name of proposed course of treatment (include brief explanation if medical term not clear)

☐ Midostaurin with DA (Daunorubicin & Cytarabine) and high dose Cytarabine chemotherapy for the treatment of FLT3 mutation positive acute myeloid leukaemia (AML) OR high risk myelodysplastic syndrome (MDS)*(*delete as appropriate).
☐ INDUCTION: Daunorubicin given intravenously on days 1 to 3 together with Cytarabine intravenously on days 1 to 7. Midostaurin taken orally twice a day from days 8 to 21. This is given for a maximum of 2 cycles.
☐ CONSOLIDATION: Cytarabine (high dose) intravenously twice a day on days 1, 3 & 5 (total of 6 doses). Midostaurin orally twice each day from days 8 to 21. This is given for a maximum of 2 cycles.
☐ MAINTENANCE: Midostaurin orally twice a day up to twelve 28 day cycles (1 year).

Where will I have treatment?
☐ Outpatient ☐ Day unit/case ☐ Inpatient ☐ Other:

Statement of health professional

(to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in the hospital/Trust/NHS board's consent policy)

☑ Tick all relevant boxes
☐ I confirm the patient has capacity to give consent.
☐ I have explained the course of treatment and intended benefit to the patient.

The intended benefits (there are no guarantees about outcome)

☐ Prolong survival.
☐ Control symptoms, reduce transfusion needs and improve quality of life.
☐ Induction – therapy given in the acute state of the disease, aiming to shrink the tumour.
☐ Curative – to give you the best possible chance of being cured.
☐ Maintenance – therapy given on continuing basis, aiming to prevent disease flaring up and to control the symptoms.
☐ Disease control / Palliative – the aim is not to cure but to control the disease and reduce the symptoms. The aim is to improve both quality and quantity of life.

Statement of health professional

Patient identifier/label

You may have one or more of the side effects listed

Common side effects:

Affecting more than 10 in every 100 (>10%) people

- ☐ An increased risk of getting an infection from a drop in white blood cells – this makes it harder to fight infections and you can become very ill.
- ☐ **If you have a severe infection this can be life-threatening. Contact your doctor or hospital straight away if:**
  - **your temperature goes over 37.5°C or over 38°C, depending on the advice given by your chemotherapy team**
  - **you suddenly feel unwell (even with a normal temperature)**
- ☐ Nausea (feeling sick), vomiting (being sick), abdominal (tummy) pain, diarrhoea, haemorrhoids, sore mouth and ulcers, difficulty swallowing, taste changes, loss of appetite.
- ☐ Thinning of the hair or hair loss, skin changes (rash with flaking, peeling or redness, itching, change in colour), change in nail colour, excessive sweating.
- ☐ Nose bleed, headache, difficulty sleeping (insomnia), high or low blood pressure, increase in heart rate, shortness of breath
- ☐ Allergic reactions, shortness of breath, back and joint pain, red colour urine for 1 - 2 days after treatment (due to Daunorubicin).
- ☐ Anaemia (due to low red blood cells) and bruising or bleeding (due to low platelets); this can be prolonged requiring a transfusion.
- ☐ Changes in liver and kidney function, low potassium, high sodium - monitored in blood tests.
- ☐ Midostaurin can raise your blood sugar. If you have diabetes, it may lead to higher blood sugar levels.
- ☐ Midostaurin and Cytarabine can cause lung changes with symptoms of shortness of breath, wheezing and/or cough with fluid build-up. Please inform your doctor or nurse if you notice these symptoms.
- ☐ Cytarabine syndrome can occur 6 to 12 hours after receiving Cytarabine. Symptoms include a high temperature or chills, rash, pain in the eyes, bones, tummy and chest. Inform your doctor or nurse.
- ☐ Inflammation of the lining of the eye lids (conjunctiva) making eyes feel sore, red and itchy (this is temporary). Steroid eye drops during and for 3 days following consolidation treatment to prevent this will be given.

Occasional side effects:

Affecting between 1-10 in every 100 (1-10%) people

- ☐ Severe skin changes (redness, itching sometimes blisters), inflammation and ulcers at the opening end of the bowel (anus). sometimes can be severe leading to infections.
- ☐ Poor concentration, shaking or trembling, sudden loss of consciousness.
- ☐ Swelling around the eyelids, sensitivity to light and/or eye pain (keratitis), eye sight changes (reversible).
- ☐ Build-up of fluid around the lungs.
- ☐ Daunorubicin and Midostaurin can cause heart problems with changes in the way your heart works, including abnormal heart rhythms and risk of a heart attack. Contact your doctor or nurse if you have changes in your heartbeat, or if you feel dizzy, lightheaded, or faint.
- ☐ Pain the bones, neck, hands and feet, weight loss.
- ☐ High dose Cytarabine can cause temporary or occasionally permanent changes to the nervous system. Symptoms include seizures (fits), drowsiness, unsteadiness and mood changes.

Other risks:

- ☐ All intravenous drugs may leak out of the vein while it is being given (extravasation) and can damage the tissue around the vein. Tell the nurse straight away if you have any stinging, pain, redness or swelling around the vein. It's uncommon but important to deal with quickly.
- ☐ A condition called posterior reversible encephalopathy syndrome (PRES) is a rare side effect of Daunorubicin. Symptoms include headaches, feeling confused, vision problems (including blindness), fits. Contact your doctor or nurse.
- ☐ There may be an increased risk of tumour lysis syndrome in some patients when treatment destroys cancer cells too quickly for the kidneys to cope and leads to changes in blood tests. Rarely, dialysis may be needed. You may be prescribed medicines for prevention or treatment.

Continue on to the next page

Statement of health professional continued

Patient identifier/label

Other risks continued:

- ☐ Before treatment you may have blood tests to check for viruses (Hepatitis B or C, HIV, or unusual infections). Treatment may weaken your natural defence (immune) system so infections like this may worsen or become active if you've had them before. You may have medicines to prevent or treat infection.
- ☐ Late effects include a very rare chance of a second cancer (years later) and problems with your heart.
- ☐ Growth factors (GCSF) may be prescribed to maintain number of white cells to prevent infection. You may experience bone pain, headaches, red and itchy skin around the injection site.
- ☐ Side effects of anti-sickness medication include diarrhoea, constipation, headaches.
- ☐ Changes in your memory, concentration or ability to think clearly. There can be many causes including your treatment, diagnosis, or both.
- ☐ Cancer and its treatment can increase your risk of developing a blood clot (thrombosis), causing pain, redness and swelling in an arm or leg, breathlessness, chest pain. Tell your doctor straight away if you have any symptoms.
- ☐ Some anti-cancer medicines can damage ovaries and sperm. This may lead to infertility and/or early menopause (hot flushes, vaginal dryness).
- ☐ Some anti-cancer medicines may damage the development of a baby in the womb. It is important not to become pregnant or make some else pregnant during treatment and for 6 months after. Women of child bearing age must be tested for pregnancy within 7 days of starting midostaurin. Use effective contraception throughout. Speak to your doctor or nurse.
- ☐ Complications of treatment can very occasionally be life-threatening and may result in death. The risks are different for every individual. Potentially life-threatening complications include those listed on this form, but other exceedingly rare side effects may also be life-threatening.

Statement of health professional

Patient identifier/label

Any other risks and information:

_____

_____

☐ I have discussed the intended benefit and risks of the recommended treatment, and of any available alternative treatments (including no treatment).

☐ I have discussed the side effects of the recommended treatment, which could affect the patient straight away or in the future, and that there may be some side effects not listed because they are rare or have not yet been reported. Each patient may experience side effects differently.

☐ I have discussed what the treatment is likely to involve (including inpatient/outpatient treatment, timing of the treatment, blood and any additional tests, follow-up appointments etc) and location.

☐ I have explained to the patient, that they have the right to stop this treatment at any time and should contact the responsible consultant or team if they wish to do so.

☐ I have discussed concerns of particular importance to the patient in regard to treatment

(please write details here): _____

_____

Clinical management guideline/Protocol compliant (please tick):

☐ Yes ☐ No ☐ Not available If No please document reason here:

_____

The following written information has been provided:

☐ Information leaflet for Midostaurin, Daunorubicin and Cytarabine

☐ 24 hour alert card or SACT advice service contact details

☐ SACT treatment record (cruk.org/treatment-record)

☐ Other, please state: _____

_____

Health professional details:

Signed: _____

Date: _____

Name (PRINT): _____

_____

Job title: _____

_____

Statement of interpreter **(where appropriate)**

Interpreter booking reference (if applicable):

I have interpreted the information above to the patient to the best of my ability and in a way in which I believe they can understand.

Signed: _____ Date: _____

Name (PRINT): _____ Job title: _____

Statement of patient

Patient identifier/label

Please read this form carefully. If your treatment has been planned in advance, you should already have your own copy of the form which describes the benefits and risks of the proposed treatment. If not, you will be offered a copy now. If you have any further questions, do ask – we are here to help you. You have the right to change your mind at any time, including after you have signed this form.

☐ I have had enough time to consider my options and make a decision about treatment.

☐ I agree to the course of treatment described on this form.

A witness should sign below if the patient is unable to sign but has indicated their consent. A person with parental responsibility will be asked to sign for young people under the age of 16 years.

Patient's signature: _____

Name (PRINT): _____ Date: _____

Person with parental responsibility/witness' signature: _____

Name (PRINT): _____ Date: _____

Copy accepted by patient: yes / no (please circle)

Confirmation of consent

(health professional to complete when the patient attends for treatment, if the patient has signed the form in advance)

On behalf of the team treating the patient, I have confirmed that the patient has no further questions and wishes the course of treatment/procedures to go ahead.

Signed: _____

Date: _____

Name (PRINT): _____

Job title: _____

Important notes: (tick if applicable)

☐ See also advance decision to refuse treatment

☐ Patient has withdrawn consent (ask patient to sign and date here)

Signed: _____

Date: _____

Further information for patients

Contact details (if patient wishes to discuss options later):

_____

Contact your hospital team if you have any questions about cancer and its treatment.

Cancer Research UK can also help answer your questions about cancer and treatment. If you want to talk in confidence, call our information nurses on freephone 0808 800 4040, Monday to Friday, 9am to 5pm. Alternatively visit cruk.org for more information.

These forms have been produced by Guy's and St. Thomas' NHS Foundation Trust as part of a national project to support clinicians in ensuring all patients are fully informed when consenting to SACT.

The project is supported by Cancer Research UK. This does not mean you are taking part in a clinical trial.

CANCER RESEARCH UK

Guidance for health professionals

(to be read in conjunction with the hospital's consent policy)

Patient identifier/label

What a consent form is for

This form documents the patient's agreement to go ahead with the treatment you have proposed. It is not a legal waiver – if patients, for example, do not receive enough information on which to base their decision, then the consent may not be valid, even though the form has been signed. Patients are also entitled to change their mind after signing the form, if they retain capacity to do so. The form should act as an aide-memoir to health professionals and patients, by providing a checklist of the kind of information patients should be offered, and by enabling the patient to have a written record of the main points discussed. In no way should the written information provided for the patient be regarded as a substitute for face-to-face discussions with the patient.

The law on consent

See the following publications for a comprehensive summary of the law on consent. Consent: Patients and doctors making decisions together, GMC 2020 (gmc-uk.org/guidance). Reference guide to consent for examination or treatment, Department of Health, 2nd edition 2009 (doh.gov.uk).

Who can give consent

Everyone aged 16 or over is presumed to have the capacity to give consent for themselves, unless the opposite is demonstrated. For young people, it is good practice to involve those with parental responsibility in the consent discussions, unless specifically asked not to. A person with parental responsibility must sign this form for a child or young person under the age of 16. Such patients should be given the opportunity to 'assent' to treatment if they wish. If a patient has the capacity to give consent but is physically unable to sign a form, you should complete this form as usual and ask an independent witness to confirm that the patient has given consent orally or non-verbally.

When NOT to use this form

If the patient lacks the capacity to give consent, you should use an alternative form available for this purpose (dependent on patient age). A patient lacks capacity if they have an impairment or disturbance of the brain, affecting the way their mind works. For example, if they cannot do one of the following:

- understand information about the decision to be made
- retain that information in their mind
- use or weigh this information as a part of their decision making process, or
- communicate their decision (by talking, using sign language or any other means)

You should always take all reasonable steps (for example involving more specialist colleagues) to support a patient in making their own decision, before concluding that they are unable to do so. Relatives cannot be asked to sign a form on behalf of an adult who lacks capacity to consent for themselves, unless they have been given the authority to do so under a Lasting Power of Attorney or as a court deputy.

Information

Information about what the treatment will involve, its benefits and risks (including side-effects and complications) and alternatives to the particular procedure proposed, is crucial for patients when making up their minds. The courts have stated that patients should be told about 'significant risks which would affect the judgement of a reasonable patient'. 'Significant' has not been legally defined, but the GMC requires doctors to tell patients about 'significant, unavoidable or frequently occurring' risks. If patients make clear they have particular concerns about certain kinds of risk, you should ensure that they are informed about these risks, even if very small or rare. You should always answer questions honestly. Sometimes, patients may make it clear that they do not want to have any information about the options, but want you to decide on their behalf. In such circumstances, you should do your best to ensure that the patient receives at least very basic information about what is proposed. Where information is refused, you should document this on the consent form or in the patient's notes.

NHS Scotland

NHS Scotland staff should refer to Healthcare Improvement Scotland. Guidance on consent for SACT and local NHS Board guidance on consent aligned to the Scottish legal framework.

References

1. Summary of Product Characteristics for individual drugs: medicines.org.uk/emc
2. Cancer Research UK: cruk.org/about-cancer/treatment/drugs
3. Macmillan Cancer Support: macmillan.org.uk/cancer-information-and-support/treatments-and-drugs
4. Guy's and St. Thomas' NHS Foundation Trust, Chemotherapy consent form

Patient agreement to systemic anti-cancer therapy (SACT)

Mitoxantrone

Hospital/NHS Trust/NHS Board:

_____

_____

Responsible consultant:

Name: _____

Job title: _____

Patient details

Patient's surname/family name:

_____

Patient's first name(s): _____

_____

Date of birth: _____

NHS number: _____
(or other identifier)

Special requirements:
(e.g other language/other communication method)

_____

_____

_____

_____

Name of proposed course of treatment (include brief explanation if medical term not clear)

☐ Mitoxantrone chemotherapy for the treatment of acute myeloid leukaemia (AML).

☐ Mitoxantrone is given intravenously as a single dose in relapse* OR as induction if not fit for intensive chemotherapy* (*delete as appropriate) on days 1, 2, 3, 4 and 5.

Where will I have treatment?

☐ Outpatient ☐ Day unit/case ☐ Inpatient ☐ Other: _____

Statement of health professional

(to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in the hospital/Trust/NHS board's consent policy)

☑ Tick all relevant boxes

☐ I confirm the patient has capacity to give consent.

☐ I have explained the course of treatment and intended benefit to the patient.

The intended benefits (there are no guarantees about outcome)

☐ Prolong survival.

☐ Control symptoms, reduce transfusion needs and improve quality of life.

☐ Induction – therapy given in the acute state of the disease, aiming to shrink the tumour.

☐ Curative – to give you the best possible chance of being cured.

☐ Maintenance – therapy given on continuing basis, aiming to prevent disease flaring up and to control the symptoms.

☐ Disease control / Palliative – the aim is not to cure but to control the disease and reduce the symptoms. The aim is to improve both quality and quantity of life.

Statement of health professional

Patient identifier/label

You may have one or more of the side effects listed

Common side effects:

Affecting more than 10 in every 100 (>10%) people

- ☐ An increased risk of getting an infection from a drop in white blood cells – this makes it harder to fight infections and you can become very ill.
- ☐ **If you have a severe infection this can be life-threatening. Contact your doctor or hospital straight away if:**
  - **your temperature goes over 37.5°C or over 38°C, depending on the advice given by your chemotherapy team**
  - **you suddenly feel unwell (even with a normal temperature)**
- ☐ Anaemia (low number of red blood cells) and bruising or bleeding (low number of platelets); this can be prolonged and you may need a transfusion.
- ☐ Thinning of the hair or hair loss.
- ☐ Nausea (feeling sick), vomiting (being sick).

Occasional side effects:

Affecting between 1-10 in every 100 (1-10%) people

- ☐ Sore mouth and ulcers.
- ☐ Constipation, diarrhoea, weight loss, feeling tired and weak (fatigue), shortness of breath,
- ☐ Change in colour of the eyes, nails, skin and urine.
- ☐ Heart problems with changes in the way your heart works with symptoms of fluid build-up and shortness of breath (heart failure) and risk of heart attack.

Other risks:

- ☐ Mitoxantrone may leak out of the vein while it is being given (extravasation) and can damage the tissue around the vein. Tell the nurse straight away if you have any stinging, pain, redness or swelling around the vein. It's uncommon but important to deal with quickly.
- ☐ There is a risk of tumour lysis syndrome (when treatment destroys cancer cells too quickly for the kidneys to cope and leads to changes in blood tests). Rarely, dialysis may be needed. You may be prescribed medicines for prevention or treatment.

Other risks continued

- ☐ Before treatment you may have blood tests to check for viruses (Hepatitis B or C, HIV, or unusual infections). Treatment may weaken your natural defence (immune) system so infections like this may worsen or become active if you've had them before. You may have medicines to prevent or treat infection.
- ☐ Side effects with the anti-sickness medication may include: constipation, diarrhoea, headaches.
- ☐ Late effects include a rare chance of a second cancer (years later) and problems with your heart.
- ☐ Growth factors (GCSF) may be prescribed to maintain number of white cells to prevent infection. You may experience bone pain, headaches, red and itchy skin around the injection site.
- ☐ Changes in memory, concentration, or ability to think clearly. There can be many causes of this including your treatment, diagnosis, or both.
- ☐ Cancer and its treatment can increase your risk of developing a blood clot (thrombosis), causing pain, redness and swelling in an arm or leg, breathlessness, chest pain or stroke. Tell your doctor straight away if you have any symptoms.
- ☐ Some anti-cancer medicines can damage ovaries and sperm. This may lead to infertility and/or early menopause.
- ☐ Some anti-cancer medicines may damage the development of a baby in the womb. It is important not to become pregnant or make someone else pregnant during treatment and for at least 6 months afterwards. Women of child bearing age will be tested for pregnancy before and during treatment. Use effective contraception throughout.
- ☐ Complications of treatment can very occasionally be life-threatening and may result in death. The risks are different for every individual. Potentially life-threatening complications include those listed on this form, but other exceedingly rare side effects may also be life-threatening.

Statement of health professional

Patient identifier/label

Any other risks and information:

_____

_____

☐ I have discussed the intended benefit and risks of the recommended treatment, and of any available alternative treatments (including no treatment).

☐ I have discussed the side effects of the recommended treatment, which could affect the patient straight away or in the future, and that there may be some side effects not listed because they are rare or have not yet been reported. Each patient may experience side effects differently.

☐ I have discussed what the treatment is likely to involve (including inpatient/outpatient treatment, timing of the treatment, blood and any additional tests, follow-up appointments etc) and location.

☐ I have explained to the patient, that they have the right to stop this treatment at any time and should contact the responsible consultant or team if they wish to do so.

☐ I have discussed concerns of particular importance to the patient in regard to treatment

(please write details here): _____

_____

Clinical management guideline/Protocol compliant (please tick):

☐ Yes ☐ No ☐ Not available If No please document reason here:

_____

The following written information has been provided:

☐ Information leaflet for Mitoxantrone

☐ 24 hour alert card or SACT advice service contact details

☐ SACT treatment record (cruk.org/treatment-record)

☐ Other, please state: _____

_____

Health professional details:

Signed: _____

Date: _____

Name (PRINT): _____

_____

Job title: _____

_____

Statement of interpreter **(where appropriate)**

Interpreter booking reference (if applicable):

I have interpreted the information above to the patient to the best of my ability and in a way in which I believe they can understand.

Signed: _____ Date: _____

Name (PRINT): _____ Job title: _____

Statement of patient

Patient identifier/label

Please read this form carefully. If your treatment has been planned in advance, you should already have your own copy of the form which describes the benefits and risks of the proposed treatment. If not, you will be offered a copy now. If you have any further questions, do ask – we are here to help you. You have the right to change your mind at any time, including after you have signed this form.

☐ I have had enough time to consider my options and make a decision about treatment.

☐ I agree to the course of treatment described on this form.

A witness should sign below if the patient is unable to sign but has indicated their consent. A person with parental responsibility will be asked to sign for young people under the age of 16 years.

Patient's signature: _____

Name (PRINT): _____ Date: _____

Person with parental responsibility/witness' signature: _____

Name (PRINT): _____ Date: _____

Copy accepted by patient: yes / no (please circle)

Confirmation of consent

(health professional to complete when the patient attends for treatment, if the patient has signed the form in advance)

On behalf of the team treating the patient, I have confirmed that the patient has no further questions and wishes the course of treatment/procedures to go ahead.

Signed: _____

Date: _____

Name (PRINT): _____

Job title: _____

Important notes: (tick if applicable)

☐ See also advance decision to refuse treatment

☐ Patient has withdrawn consent (ask patient to sign and date here)

Signed: _____

Date: _____

Further information for patients

Contact details (if patient wishes to discuss options later):

_____

Contact your hospital team if you have any questions about cancer and its treatment.

Cancer Research UK can also help answer your questions about cancer and treatment. If you want to talk in confidence, call our information nurses on freephone 0808 800 4040, Monday to Friday, 9am to 5pm. Alternatively visit cruk.org for more information.

These forms have been produced by Guy's and St. Thomas' NHS Foundation Trust as part of a national project to support clinicians in ensuring all patients are fully informed when consenting to SACT.

The project is supported by Cancer Research UK. This does not mean you are taking part in a clinical trial.



Guidance for health professionals

(to be read in conjunction with the hospital's consent policy)

Patient identifier/label

What a consent form is for

This form documents the patient's agreement to go ahead with the treatment you have proposed. It is not a legal waiver – if patients, for example, do not receive enough information on which to base their decision, then the consent may not be valid, even though the form has been signed. Patients are also entitled to change their mind after signing the form, if they retain capacity to do so. The form should act as an aide-memoir to health professionals and patients, by providing a checklist of the kind of information patients should be offered, and by enabling the patient to have a written record of the main points discussed. In no way should the written information provided for the patient be regarded as a substitute for face-to-face discussions with the patient.

The law on consent

See the following publications for a comprehensive summary of the law on consent. Consent: Patients and doctors making decisions together, GMC 2020 (gmc-uk.org/guidance). Reference guide to consent for examination or treatment, Department of Health, 2nd edition 2009 (doh.gov.uk).

Who can give consent

Everyone aged 16 or over is presumed to have the capacity to give consent for themselves, unless the opposite is demonstrated. For young people, it is good practice to involve those with parental responsibility in the consent discussions, unless specifically asked not to. A person with parental responsibility must sign this form for a child or young person under the age of 16. Such patients should be given the opportunity to 'assent' to treatment if they wish. If a patient has the capacity to give consent but is physically unable to sign a form, you should complete this form as usual and ask an independent witness to confirm that the patient has given consent orally or non-verbally.

When NOT to use this form

If the patient lacks the capacity to give consent, you should use an alternative form available for this purpose (dependent on patient age). A patient lacks capacity if they have an impairment or disturbance of the brain, affecting the way their mind works. For example, if they cannot do one of the following:

- understand information about the decision to be made
- retain that information in their mind
- use or weigh this information as a part of their decision making process, or
- communicate their decision (by talking, using sign language or any other means)

You should always take all reasonable steps (for example involving more specialist colleagues) to support a patient in making their own decision, before concluding that they are unable to do so. Relatives cannot be asked to sign a form on behalf of an adult who lacks capacity to consent for themselves, unless they have been given the authority to do so under a Lasting Power of Attorney or as a court deputy.

Information

Information about what the treatment will involve, its benefits and risks (including side-effects and complications) and alternatives to the particular procedure proposed, is crucial for patients when making up their minds. The courts have stated that patients should be told about 'significant risks which would affect the judgement of a reasonable patient'. 'Significant' has not been legally defined, but the GMC requires doctors to tell patients about 'significant, unavoidable or frequently occurring' risks. If patients make clear they have particular concerns about certain kinds of risk, you should ensure that they are informed about these risks, even if very small or rare. You should always answer questions honestly. Sometimes, patients may make it clear that they do not want to have any information about the options, but want you to decide on their behalf. In such circumstances, you should do your best to ensure that the patient receives at least very basic information about what is proposed. Where information is refused, you should document this on the consent form or in the patient's notes.

NHS Scotland

NHS Scotland staff should refer to Healthcare Improvement Scotland. Guidance on consent for SACT and local NHS Board guidance on consent aligned to the Scottish legal framework.

References

1. Summary of Product Characteristics for individual drugs: medicines.org.uk/emc
2. Cancer Research UK: cruk.org/about-cancer/treatment/drugs
3. Macmillan Cancer Support: macmillan.org.uk/cancer-information-and-support/treatments-and-drugs
4. Guy's and St. Thomas' NHS Foundation Trust, Chemotherapy consent form

Patient agreement to systemic anti-cancer therapy (SACT)

Sorafenib

Hospital/NHS Trust/NHS Board:

_____

_____

Responsible consultant:

Name: _____

Job title: _____

Patient details

Patient's surname/family name:

_____

Patient's first name(s): _____

_____

Date of birth: _____

NHS number: _____
(or other identifier)

Special requirements:
(eg other language/other communication method)

_____

_____

_____

_____

Name of proposed course of treatment (include brief explanation if medical term not clear)

☐ Sorafenib for the treatment of FLT3 mutation positive acute myeloid leukemia (AML) undergoing allogeneic haematopoietic stem cell transplantation (allo-HSCT).

☐ Sorafenib is taken orally twice each day. Each treatment cycle lasts for 28 days.

☐ Treatment is continued for a maximum of 2 years following stem cell transplant.

Where will I have treatment?

☐ Outpatient ☐ Day unit/case ☐ Inpatient ☐ Other: _____

Statement of health professional

(to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in the hospital/Trust/NHS board's consent policy)

☑ Tick all relevant boxes

☐ I confirm the patient has capacity to give consent.

☐ I have explained the course of treatment and intended benefit to the patient.

The intended benefits (there are no guarantees about outcome)

☐ Prolong survival.

☐ Control symptoms, reduce transfusion needs and improve quality of life.

☐ Induction – therapy given in the acute state of the disease, aiming to shrink the tumour.

☐ Curative – to give you the best possible chance of being cured.

☐ Maintenance – therapy given on continuing basis, aiming to prevent disease flaring up and to control the symptoms.

☐ Disease control / Palliative – the aim is not to cure but to control the disease and reduce the symptoms. The aim is to improve both quality and quantity of life.

Statement of health professional

Patient identifier/label

You may have one or more of the side effects listed

Common side effects:

Affecting more than 10 in every 100 (>10%) people

- ☐ Higher risk of infection from a drop in white blood cells, fever (which is sometimes severe).
- ☐ Diarrhoea, constipation, nausea (feeling sick), vomiting (being sick).
- ☐ Skin changes (rash, dryness, itching), soreness, redness, peeling on the palms of hands and soles of the feet.
- ☐ Thinning of the hair, hair loss, tiredness and feeling weak (fatigue), joint pain.
- ☐ Low phosphate levels (picked up in blood tests), weight loss, bleeding.
- ☐ High blood pressure. You will be monitored regularly and may be given tablets to control it. If your blood pressure is too high and cannot be controlled, treatment may be stopped permanently.

Occasional side effects:

Affecting between 1-10 in every 100 (1-10%) people

- ☐ Anaemia (due to low red blood cells), bruising or bleeding (due to low platelets).
- ☐ Sore mouth and ulcers, dry mouth, difficulty swallowing, taste changes, indigestion, acid reflux.
- ☐ Low thyroid, low blood sugar, low calcium, potassium, sodium – all picked up and monitored in blood tests.
- ☐ Changes in kidney and liver function (monitored), protein in the urine.
- ☐ Change in sensation in hands and feet, flushing, hoarse voice, stuffy/runny nose, ringing sound in the ears.
- ☐ Muscle pain and spasm, problems with erection.
- ☐ Increase risk of skin cancers. Protect your skin from sun exposure and check your skin for any changes in appearance, new growths or lesions (that may look like a new wart), or change in the size or colour of a mole.
- ☐ Changes in how well the heart works with symptoms of fluid build-up and shortness of breath (heart failure) and other heart problems (angina, heart attack).

Other risks:

- ☐ Allergic reactions (which may be mild or severe) are uncommon. An irregular heart rhythm is rare.
- ☐ Changes in the lungs (inflammation or scarring) causing cough, chest pain, shortness of breath are uncommon. In men, enlarged breasts are uncommon.

Other risks continiued:

Other risks continued:

- ☐ Slow wound healing. You may be asked to stop treatment before an operation or procedure, including dental work.
- ☐ A hole or abnormal opening in the intestine (fistula or perforation) is uncommon. Tell your doctor if you have intense tummy pain or blood in the vomit or stool.
- ☐ An enlargement and weakening of a blood vessel wall or tear in a blood vessel (aneurysm or artery dissection) is very rare. High blood pressure and smoking may increase the risk.
- ☐ Rarely, severe skin reactions (Stevens-Johnson Syndrome or Toxic Epidermal Necrolysis) causing sore red patches which blister and peel. Seek urgent medical advice if you have symptoms.
- ☐ Side effects with anti-sickness medication include: diarrhoea, constipation, headaches.
- ☐ Sorafenib can lower your blood sugar. If you have diabetes, please monitor your levels.
- ☐ Cancer and its treatment can increase your risk of developing a blood clot (thrombosis), causing pain, redness and swelling in an arm or leg, breathlessness, chest pain or stroke. Tell your doctor straight away if you have any symptoms.
- ☐ Changes in memory, concentration, or ability to think clearly. There can be many causes including your treatment, diagnosis, or both.
- ☐ Some anti-cancer medicines can damage ovaries and sperm. This may lead to infertility and/or early menopause (hot flushes, vaginal dryness).
- ☐ Some anti-cancer medicines may damage the development of a baby in the womb. It is important not to become pregnant or make someone else pregnant during treatment and for a few months afterwards. Women of child bearing age will be tested for pregnancy before and during treatment. Use effective contraception throughout. Speak to your doctor or nurse.
- ☐ Complications of treatment can occasionally be life-threatening and may result in death. The risks are different for every individual. Potentially life-threatening complications include those listed on this form, but other exceedingly rare side effects may also be life-threatening.

Statement of health professional

Patient identifier/label

Any other risks and information:

_____

_____

☐ I have discussed the intended benefit and risks of the recommended treatment, and of any available alternative treatments (including no treatment).

☐ I have discussed the side effects of the recommended treatment, which could affect the patient straight away or in the future, and that there may be some side effects not listed because they are rare or have not yet been reported. Each patient may experience side effects differently.

☐ I have discussed what the treatment is likely to involve (including inpatient/outpatient treatment, timing of the treatment, blood and any additional tests, follow-up appointments etc) and location.

☐ I have explained to the patient, that they have the right to stop this treatment at any time and should contact the responsible consultant or team if they wish to do so.

☐ I have discussed concerns of particular importance to the patient in regard to treatment

(please write details here): _____

_____

Clinical management guideline/Protocol compliant (please tick):

☐ Yes ☐ No ☐ Not available If No please document reason here:

_____

The following written information has been provided:

☐ Information leaflet for Sorafenib

☐ 24 hour alert card or SACT advice service contact details

☐ SACT treatment record (cruk.org/treatment-record)

☐ Other, please state: _____

_____

Health professional details:

Signed: _____

Date: _____

Name (PRINT): _____

_____

Job title: _____

_____

Statement of interpreter **(where appropriate)**

Interpreter booking reference (if applicable):

I have interpreted the information above to the patient to the best of my ability and in a way in which I believe they can understand.

Signed: _____ Date: _____

Name (PRINT): _____ Job title: _____

Statement of patient

Patient identifier/label

Please read this form carefully. If your treatment has been planned in advance, you should already have your own copy of the form which describes the benefits and risks of the proposed treatment. If not, you will be offered a copy now. If you have any further questions, do ask – we are here to help you. You have the right to change your mind at any time, including after you have signed this form.

☐ I have had enough time to consider my options and make a decision about treatment.

☐ I agree to the course of treatment described on this form.

A witness should sign below if the patient is unable to sign but has indicated their consent. A person with parental responsibility will be asked to sign for young people under the age of 16 years.

Patient's signature: _____

Name (PRINT): _____ Date: _____

Person with parental responsibility/witness' signature: _____

Name (PRINT): _____ Date: _____

Copy accepted by patient: yes / no (please circle)

Confirmation of consent

(health professional to complete when the patient attends for treatment, if the patient has signed the form in advance)

On behalf of the team treating the patient, I have confirmed that the patient has no further questions and wishes the course of treatment/procedures to go ahead.

Signed: _____

Date: _____

Name (PRINT): _____

Job title: _____

Important notes: (tick if applicable)

☐ See also advance decision to refuse treatment

☐ Patient has withdrawn consent (ask patient to sign and date here)

Signed: _____

Date: _____

Further information for patients

Contact details (if patient wishes to discuss options later):

_____

Contact your hospital team if you have any questions about cancer and its treatment.

Cancer Research UK can also help answer your questions about cancer and treatment. If you want to talk in confidence, call our information nurses on freephone 0808 800 4040, Monday to Friday, 9am to 5pm. Alternatively visit cruk.org for more information.

These forms have been produced by Guy's and St. Thomas' NHS Foundation Trust as part of a national project to support clinicians in ensuring all patients are fully informed when consenting to SACT.

The project is supported by Cancer Research UK. This does not mean you are taking part in a clinical trial.

Guidance for health professionals

(to be read in conjunction with the hospital's consent policy)

Patient identifier/label

What a consent form is for

This form documents the patient's agreement to go ahead with the treatment you have proposed. It is not a legal waiver – if patients, for example, do not receive enough information on which to base their decision, then the consent may not be valid, even though the form has been signed. Patients are also entitled to change their mind after signing the form, if they retain capacity to do so. The form should act as an aide-memoir to health professionals and patients, by providing a checklist of the kind of information patients should be offered, and by enabling the patient to have a written record of the main points discussed. In no way should the written information provided for the patient be regarded as a substitute for face-to-face discussions with the patient.

The law on consent

See the following publications for a comprehensive summary of the law on consent. Consent: Patients and doctors making decisions together, GMC 2020 (gmc-uk.org/guidance). Reference guide to consent for examination or treatment, Department of Health, 2nd edition 2009 (doh.gov.uk).

Who can give consent

Everyone aged 16 or over is presumed to have the capacity to give consent for themselves, unless the opposite is demonstrated. For young people, it is good practice to involve those with parental responsibility in the consent discussions, unless specifically asked not to. A person with parental responsibility must sign this form for a child or young person under the age of 16. Such patients should be given the opportunity to 'assent' to treatment if they wish. If a patient has the capacity to give consent but is physically unable to sign a form, you should complete this form as usual and ask an independent witness to confirm that the patient has given consent orally or non-verbally.

When NOT to use this form

If the patient lacks the capacity to give consent, you should use an alternative form available for this purpose (dependent on patient age). A patient lacks capacity if they have an impairment or disturbance of the brain, affecting the way their mind works. For example, if they cannot do one of the following:

- understand information about the decision to be made
- retain that information in their mind
- use or weigh this information as a part of their decision making process, or
- communicate their decision (by talking, using sign language or any other means)

You should always take all reasonable steps (for example involving more specialist colleagues) to support a patient in making their own decision, before concluding that they are unable to do so. Relatives cannot be asked to sign a form on behalf of an adult who lacks capacity to consent for themselves, unless they have been given the authority to do so under a Lasting Power of Attorney or as a court deputy.

Information

Information about what the treatment will involve, its benefits and risks (including side-effects and complications) and alternatives to the particular procedure proposed, is crucial for patients when making up their minds. The courts have stated that patients should be told about 'significant risks which would affect the judgement of a reasonable patient'. 'Significant' has not been legally defined, but the GMC requires doctors to tell patients about 'significant, unavoidable or frequently occurring' risks. If patients make clear they have particular concerns about certain kinds of risk, you should ensure that they are informed about these risks, even if very small or rare. You should always answer questions honestly. Sometimes, patients may make it clear that they do not want to have any information about the options, but want you to decide on their behalf. In such circumstances, you should do your best to ensure that the patient receives at least very basic information about what is proposed. Where information is refused, you should document this on the consent form or in the patient's notes.

NHS Scotland

NHS Scotland staff should refer to Healthcare Improvement Scotland. Guidance on consent for SACT and local NHS Board guidance on consent aligned to the Scottish legal framework.

References

1. Summary of Product Characteristics for individual drugs: medicines.org.uk/emc
2. Cancer Research UK: cruk.org/about-cancer/treatment/drugs
3. Macmillan Cancer Support: macmillan.org.uk/cancer-information-and-support/treatments-and-drugs
4. Guy's and St. Thomas' NHS Foundation Trust, Chemotherapy consent form

Patient identifier/label