The UK Registry of Chronic Myeloid Leukaemia (UKCML)

Patient Information Sheet - Adults

Version 4

27th October 2025

You are being invited to take part in a research study, collecting information about you, your diagnosis with chronic myeloid leukaemia (CML), your treatment and your response to treatment. The information we collect will be stored in the UK National Registry of Chronic Myeloid Leukaemia.
Before you decide whether or not to take part in this study it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends, relatives and your GP if you wish. Do ask if there is anything that is not clear or if you would like more information. Please take your time to decide whether or not you wish to take part.

What is the purpose of this study?

Great progress has been made in the last 15 years in the treatment of chronic myeloid leukaemia (CML) since the introduction of the group of drugs called tyrosine kinase inhibitors (TKIs). However, both patients and health professionals are still learning about the best ways to manage CML and the side effects of treatment. One way of improving our understanding is to collect information about CML patients, including responses to treatment.

Why are we asking you to participate?

We aim to collect information on all patients diagnosed with CML, who are resident in the United Kingdom.

Do you have to participate?

It is up to you to decide whether to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign the consent form at the end of this information sheet. If you decide to take part, you are still free to withdraw at anytime and without giving a reason. This will not affect the standard of care you receive. If you should decide not to participate you will receive the best current treatment available at your local hospital.

Why do we want to collect information about you for a 'registry'?

We wish to collect information about you and your illness to better help us understand the nature of CML, how common it is, how people with the illness are treated and how well they do on current forms of treatment. This will help us understand the illness better and help researchers work towards a cure.

What information do we want to collect?

We need to know some details about your CML, including the white blood count and details about related laboratory tests, together with details of your treatment and your response to it. We also need basic information about you including your initials, date of birth, a brief past medical history and some demographic data so that we

can correlate information about your CML at diagnosis with later facts and figures about your future treatment and progress. Importantly we are also requesting information on side effects. We would also like to include information on your broad ethnic grouping (white, Afro-Caribbean, etc) to investigate whether different ethnic groups respond differently to modern treatment; this is theoretically possible but has never been studied in a large number of patients, importantly we are also requesting information on side effects. We will also collect information as to whether you consented to have any blood or bone marrow stored for the purpose of research at the time of diagnosis. This is simply to let researchers know about the possibilities to collaborate and study CML cells in the laboratory.

Recently we have all become aware that some patients can respond so well to treatment that it is possible to attempt to discontinue the drugs. Approximately 50% of patients with prolonged excellent responses can remain off treatment. Until now, these attempts to discontinue therapy have only been permitted in clinical trials, but we expect that in the future, treatment will be stopped without the need to participate in a clinical trial. We would like to collect information on the results of stopping therapy to see if the results are similar to those seen in the trials, in order to try to develop advice for patients and their physicians.

We are also mindful of the fact that some patients with CML have had children after their diagnosis. Women may have stopped treatment before or during the pregnancy and we would like to know the outcome of the pregnancy for both the mother and the baby, and what happened to the CML during and after the pregnancy. We would also like to collect information on men who have had children since their diagnosis. Better information regarding the ability to have children after a diagnosis of CML will be helpful to future patients who wish to have children.

What if I change my mind?

If you wish to withdraw your permission to use your information in the registry database, your local centre would inform the UK National CML Registry team and we would not be use your data in any subsequent analysis.
If your data has already been used for an analysis and a report has been published we would not be able to retract that report, but you should be assured that there would be no way to identify you and your participation.

What if you do decide to take part?

Apart from giving your consent, nothing more is required of you. Your treatment will continue to be solely determined by the CML team at your local hospital. The study team for the National UK Registry will not interfere with the treatment decisions made by you and your local CML team.

What are the risks of participation?

None. No additional visits or tests are required, and your treatment will proceed just as if you were not in the study.

What about confidentiality?

All information which is collected about you during the course of the research will be kept strictly confidential. All data will be processed in accordance with the Data Protection Act, 2018. Personal details such as your name, date of birth, NHS number and data collected during the study will be stored, on a secure, password protected database housed in the secure CML clinical research office. The only people to have full access to your personal details will be the National Registry CML study team.
It is important that we make sure that the information we hold is accurate. If you consent to take part in this trial, any of your local hospital medical records may be inspected by the study team members as part of the monitoring process which is normal for any clinical trial or study. People may also look at them from regulatory authorities to

check that the study is being carried out correctly, though this is seen as unlikely for this type of information-gathering study.
If you so wish, we will inform your GP and/or any other medical practitioner who currently treats you about your participation in this study.

Data linkage with NHS Digital

We would like to link the registry data with data stored within specific data sets within NHS Digital in the future. These databases already exist and provide valuable information about the health of the UK population. Linking to these databases will allow us to see, for instance, if any pre-existing (before you were diagnosed with CML) medical conditions are associated with the development of CML, or if the diagnosis and treatment of CML is associated with medical conditions that occur after your diagnosis; these databases include:

- Hospital Episode Statistics (HES): this database currently records all hospital admissions for all diseases and would allow us to capture long term effects of treatment.
- Primary Care Mortality Data (PCMD) and Office for National Statistics (ONS) Mortality (Civil Registration data)): to collect mortality (cause of death) data.
- Personal Demographics Services (PDS) Registration: to gather the ethnicity data.
- Public Health England (PHE) Cancer – for cohorts: to collect data about the occurrence of second malignancies in patients with CML.

For this linkage to be possible, identifiable personal information will be exchanged with the relevant NHS Digital registries. We cannot link the databases at present but hope to do so in the future when the technology is available. We are seeking your permission now so that we do not have to come back to you at a later date.

What are we going to do with the study results?

It is likely that information from this registry will be sent to other academic institutions and pharmaceutical companies with an interest in CML. This is to compare the pattern of CML and its treatment with other treating centres.. However, before leaving the National UK Registry database, all information will be pseudonymised, so that you cannot be identified. This pseudonymisation is to preserve your privacy,, and ensures that no-one outside the team will ever be able to identify you . Pharmaceutical companies with an interest in CML may in the future request access to registry data, especially for information on side effects. If this occurs, all data will be completely pseudonymised (coded). To protect your confidentiality the pharmaceutical company will not be given the link that would enable any code to identify an individual participant. The data will not be released to pharmaceutical companies or any other commercial organisation without a genuine interest in CML.
The study results will help us to know whether current CML drugs (Imatinib, Dasatinib, etc.) are as effective as clinical trials suggest. This is important, as many patients cannot enter clinical trials. Collecting data about patients who are advised to stop treatment by their local haematologist will give us a better idea about the extent at which this relatively new strategy is applied outside the strict criteria of clinical trials. Data about pregnancy outcomes will help us to better advise future patients. Linking the data we collect on your treatment and response to that treatment with samples of blood and/or bone marrow collected at the initial diagnosis might help us understand why some patients respond better than others. We may aim to publish the results at scientific meetings and in journals to allow discussion and evaluation of these results amongst our peers.
The study has been reviewed and approved by the Research Ethics Committee.

How do we plan to collect your information?

The CML registry is hosted on an electronic server named REDCap. This server can only be accessed on Hospital site approved computers. This will ensure all information collected is secure and ensures confidentiality will be maintained. It will allow your local haematology team to enter your patient information directly into the system. Imperial College London will be hosting the database.

In this research study we will use information from you. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study. These people will include Imperial Research Team members and support staff.

Everyone involved in this study will keep the data collated as part of this study, including your personal data, safe and secure. We will also follow all privacy laws and legislation that are relevant to the specifics of the study.
At the end of the study we will save some of the data for future research.
We will make sure no-one can work out who you are from the reports we write. The following information pack tells you more about this.

How will we use Information about you?

Imperial College London is the sponsor for this study and will act as the Data Controller for this study. Being a Data Controller means that we are responsible for looking after your information and using it appropriately plus are responsible for explaining this to you. Imperial College London will keep your personal data for:

- 25 years after the study has finished in relation to data subject consent forms.
- 25 years after the study has completed in relation to primary research data.

The study is expected to finish in May 2032.

For more information / confirmation regarding the end date please contact the study team, see '**WHERE CAN YOU FIND OUT MORE ABOUT HOW YOUR INFORMATION IS USED'** for contact information.

We will need to use information (including personal data and data created as part of the study) from youfor this research project.
This information will include your initials/name/ contact details. People within the College and study team (see section 'Sharing your information with others') will use this information to do the research or to check your records (see information to be collected) to make sure that the research is being done properly and the information held (such as contact details) is accurate.
People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.
Imperial College London is the sponsor of this research and is responsible for looking after your information. We will keep this information about you safe and secure by:

- Data management plans have been created and reviewed in line with Imperial's Information Governance Policy Framework. This covers the collection, movement, processing and storage of the data.
- Data to be stored in a dedicated secure environment which underpins security measures.
- Robust pseudonymisation has been implemented to prevent identification
- Access controls have been implemented to ensure only key personnel can access the data.

Some of your information will be sent to countries outside UK (see section 'International Transfers' and 'Sharing your information with others'). They must follow our rules about keeping your information safe.
Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

LEGAL BASIS

As a university we use personally-identifiable information to conduct research to improve health, care and services. As a publicly-funded organisation, we have to ensure that it is in the public interest when we use personally-identifiable information from people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use your data in the ways needed to

conduct and analyse the research study. Our legal basis for using your information under the General Data Protection Regulation (GDPR) and the Data Protection Act 2018, is as follows:

• Imperial College London - “performance of a task carried out in the public interest”; Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the UK Policy Framework for Health and Social Care Research

Where special category personal information is involved (most commonly health data, biometric data and genetic data, racial and ethnic data etc.), Imperial College London) relies on “scientific or historical research purposes or statistical purposes”.

INTERNATIONAL TRANSFERS

We may share data about you outside the UK for research related purposes to:

- Where necessary to provide access to a data processor / service provider who will utilise your personal data as instructed by us.
- Where necessary to share with a third party organisation / collaborator (as listed) who are also involved in the study.
- Where data has been collected from outside the UK and requires additional transfer(s) as part of the study activity.

If this happens, we will only share the data that is needed. We will also make sure you can’t be identified from the data that is shared where possible. This may not be possible under certain circumstances – for instance, if you have a rare illness, it may still be possible to identify you. If your data is shared outside the UK, it will be with the following sorts of organisations:

- International partners who analyse your data, companies to pay your expenses, organisations who store your data

We will make sure your data is protected. Anyone who accesses your data outside the UK must do what we tell them so that your data has a similar level of protection as it does under UK law. We will make sure your data is safe outside the UK by doing the following

- (some of) the countries your data will be shared with have an adequacy decision in place. This means that we know their laws offer a similar level of protection to data protection laws in the UK
- We use specific contracts which stipulates that personal data must maintain the same level of protection when outside the UK as it has within the UK. For further details visit the Information Commissioner’s Office (ICO) website - www.ico.org.uk
- We do not allow those who access your data outside the UK to use it for anything other than what our written contract with them says
- We need other organisations to have appropriate security measures to protect your data which are consistent with the data security and confidentiality obligations we have. This includes having appropriate measures to protect your data against accidental loss and unauthorised access, use, changes or sharing
- We have procedures in place to deal with any suspected personal data breach. For further details about UK breach reporting rules visit the Information Commissioner's Office (ICO) website - Personal data breaches: a guide | ICO

SHARING YOUR INFORMATION WITH OTHERS

We will only share your personal data with certain third parties for the purposes referred to in this participant information sheet and by relying on the legal basis for processing your data as set out above.

- Other Imperial College London employees (including staff involved directly with the research study or as part of certain secondary activities which may include support functions, internal audits, ensuring accuracy of contact details etc.), Imperial College London agents, contractors and service providers (for example, suppliers of printing and mailing services, email communication services or web services, or suppliers who help us carry out any of the activities described above). Our third party service providers are required to enter into data processing agreements with us. We only permit them to process your personal data for specified purposes and in accordance with our policies.

POTENTIAL USE OF STUDY DATA FOR FUTURE RESEARCH

When you agree to take part in a research study, the information collected either as part of the study or in preparation for the study (such as contact details) may, if you consent, be provided to researchers running other research studies at Imperial College London and in other organisations which may be universities or organisations involved in research in this country or abroad. Your information will only be used to conduct research in accordance with legislation including the GDPR and the UK Policy Framework for Health and Social Care Research.

This information will not identify you and will not be combined with other information in a way that could identify you, used against you or used to make decisions about you.

COMMERCIALISATION

Data from the study may also be provided to organisations not named in this participant information sheet, e.g. commercial organisations or non-commercial organisations for the purposes of undertaking the current study, future research studies or commercial purposes such as development by a company of a new test, product or treatment. We will ensure your name and any identifying details will NOT be given to these third parties, instead you will be identified by a unique study number with any sample analysis having the potential to generate 'personal data'.

Aggregated (combined) or anonymised data sets (all identifying information is removed) may also be created using your data (in a way which does not identify you individually) and be used for such research or commercial purposes where the purposes align to relevant legislation (including the GDPR) and wider aims of the study. Your data will not be shared with a commercial organisation for marketing purposes.

WHAT ARE YOUR CHOICES ABOUT HOW YOUR INFORMATION IS USED?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
You have the right to ask us to remove, change or delete data we hold about you for the purposes of the study. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.
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- **OPTION if follow up data will be collected after withdrawal:** If you choose to stop taking part in the study (also known as opting out), we would like to continue collecting information about your health from [give details] If you do not want this to happen, please tell us and we will stop.
- **OPTION if data will be used for future research:** If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

WHERE CAN YOU FIND OUT MORE ABOUT HOW YOUR INFORMATION IS USED

You can find out more about how we use your information:

- by asking one of the research team
- by sending an email to imperial.uknationalcmlregister@nhs.net, or
- by ringing us on +44 20 3313 4017.

COMPLAINT

If you wish to raise a complaint about how we have handled your personal data, please contact the research team first by sending an email to imperial.uknationalcmlregister@nhs.net, or by ringing us on +44 20 3313 4017.

Following our response, if you are not satisfied please contact Imperial College London's Data Protection Officer via email at dpo@imperial.ac.uk, via telephone on 020 7594 3502 and/or via post at Imperial College London, Data Protection Officer, Faculty Building Level 4, London SW7 2AZ.

If you remain unsatisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO)- via www.ico.org.uk. Please note the ICO does recommend that you seek to resolve matters with the data controller (us) first before in

Contacting you about research progress and developments in CML

We would like to keep you informed regularly about developments in the treatment of CML. We would like your consent to contact you from time to time to let you know about new developments, and about the annual patient update meetings that we hold for CML patients and their families. These are designed to keep patients abreast of latest developments, including the projects being described in this document. The frequency with which we will contact you will vary, but is unlikely to exceed 1-2 contacts per year.

Your study contacts

Finally, if you proceed, we would like to thank you for agreeing to take part in this study. Please keep a copy of this information sheet for your records. You will also receive a copy of your signed consent form. Your local CML team will likely be able to answer most of your questions about this study.

If you would like to contact the UK National CML Registry team, please send us an email to imperial.uknationalcmlregister@nhs.net or call us on +44 20 3313 4017.

Imperial College Healthcare NHS Trust

The UK National Registry of Chronic Myeloid Leukaemia (CML)
Participant Consent Form - Adults

Version 4

27th October 2025

Collection and analysis of information about you and your illness aiming to improve the treatment of CML and keep you informed

The participant should complete the whole of this sheet him or herself.
(Please write your initials in the following boxes if you agree with the statement)

1. I confirm that I have read and understood the information sheet version 4 dated 27th October 2025for the UK Registry of CML (UKCML) collection of information for a registry and have had the opportunity to ask questions regarding the information to be collected about me.	
2. I understand that my name, date of birth, NHS number, as well as details about my illness will be entered onto an electronic server and accessed by the CML research team. I give consent for pseudonymised data from the trial to be provided to other 3rd parties (e.g. pharmaceutical companies or other academic institutions) for research, safety monitoring or licensing purposes. I understand that pseudonymised data may be transferred outside the UK, and that the destination country may not provide an equivalent or adequate level of data protection.	
3. I understand that the data held in the registry will be linked with NHS Digital. I understand that this will involve sharing self-identifiable data.	
4. I agree to take part in future research using my data saved from this study.	
5. I would like to be kept informed about the progress of research in CML and agree to researchers contacting me in writing or by email, to inform me about the progress of this study and to update me on further information on CML of relevance to patients, by post or email. Home Address: Email address:	

_____	_____	_____
Name of Patient	Date	Signature
_____	_____	_____
Name of Person taking consent	Date	Signature

1 copy for patient; 1 copy for researcher; 1 copy to be kept with hospital notes