

FREQUENTLY ASKED QUESTIONS

EUTOS FOR CML

The purpose of this document is to provide answers to some of the key questions that physicians are likely to ask ELN members regarding the EUTOS for CML program

What is EUTOS for CML?

The European Treatment and Outcome Study for CML (EUTOS for CML) is a unique scientific collaboration between the European LeukemiaNet (ELN) and Novartis. It aims to use the strengths of the two organizations – the clinical expertise and experience of the ELN, allied to Novartis' outreach potential and funding provision – to help physicians optimize the treatment of CML.

Why do we need EUTOS for CML?

Strategies for the management of CML have evolved rapidly over the past few years, with Europe playing a leading role in this process. The EUTOS for CML program has been designed to keep our region at the forefront of this advancement in the coming years, and to foster continuing improvements in outcomes for patients with CML.

How will EUTOS for CML accomplish this?

There are four key projects:

1. *CML registry* – expanding the existing ELN registry to facilitate the collection of baseline, treatment, and outcome data from representative samples of European patients with CML
2. *Molecular monitoring* – promoting quality-controlled, standardized monitoring of therapeutic outcomes at the molecular level
3. *Pharmacological monitoring* – increasing the availability of imatinib blood-level testing
4. *Spread of excellence* – promoting continuing medical education and awareness of CML

Why should I get involved?

The four EUTOS for CML projects have been designed by the ELN and Novartis to improve outcomes in CML. By taking part, you will help the European medical community to understand the epidemiology of CML, and how different interventions affect treatment success. The molecular and pharmacological monitoring projects also have the potential to directly improve the outcomes of patients in your care.

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European Treatment and Outcome Study

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Do I have to join the ELN?

Yes, ELN participation is a prerequisite for actively taking part in the EUTOS for CML program. More information on joining the ELN can be obtained from local Novartis representatives or through ELN network participation centers.

What are the differences between the (European) EUTOS for CML and the (global) CML Alliance programs?

The two programs share a similar main objective: to help physicians optimize the treatment of CML. However, there are some important differences. First, the CML Alliance is a Novartis program, whereas the EUTOS for CML program is a scientific collaboration between the ELN and Novartis. Second, EUTOS for CML is specifically targeted at physicians and patients in Europe, whereas the CML Alliance focuses on the rest of the world. Third, some of the projects within the two programs are different. For example, the EUTOS for CML registry is an extension of the current ELN CML registry, and has no direct equivalent in the CML Alliance program.

CML Registry

What is the purpose of the CML registry?

Population-based data on the epidemiology, treatment, and outcomes of CML are currently lacking. The existing ELN CML registry will be expanded to create a pan-European registry containing:

- Baseline and follow-up data on treatment and outcome from *de novo* patients, both inside and outside clinical trials
- Epidemiological data on patients treated outside clinical trials

Can patient data submitted to the EUTOS for CML registry also be published locally?

Physicians are free to use the data as they wish, and their data may be published at both local and regional level.

Is there any lower or upper limit on the number of patients that can be enrolled per center?

The ELN and Novartis are interested in all countries and centers, whether large or small, and a dedicated steering committee is in place to map and manage all requests.

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Molecular monitoring

Why monitor molecular response?

Because the introduction of imatinib has revolutionized the treatment of CML, allowing many more patients to achieve complete hematologic and cytogenetic responses, more sensitive methods of assessing residual disease have been developed. The monitoring of *BCR-ABL* levels provides the highest sensitivity, allowing treatment decisions to be made based on sound molecular evidence, as well as hematologic and cytogenetic data.

What is the purpose of the EUTOS for CML molecular monitoring project?

This project aims to make internationally standardized real-time quantitative PCR (RQ-PCR) analysis for *BCR-ABL* quantification available across Europe. A network of national reference centers will allow physicians across the continent to submit samples to monitoring laboratories, in their own or nearby countries.

How much will it cost?

Molecular monitoring will be provided free of charge for participating centers. EUTOS for CML will put in place local laboratories and standardization.

Where and how can I submit samples?

Local Novartis representatives can provide further information on how and where to submit samples.

Pharmacological monitoring

Why monitor blood levels of imatinib?

Trough plasma levels of imatinib greater than 1000 ng/mL have been associated with greater likelihood of cytogenetic and molecular responses.

However, trough imatinib plasma levels may vary greatly between patients, for a given dose. There are several potential causes, including pharmacokinetic factors such as drug–drug interactions, and patient-related factors such as adherence.

If a patient is not responding to imatinib as expected, blood-level testing is an essential tool for checking the adequacy of plasma imatinib levels. It should not be assumed that inadequate response is primarily caused by resistance to imatinib.

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What is the purpose of the EUTOS for CML pharmacological monitoring project?

This project aims to standardize blood-level testing and increase its availability across Europe. Quality-controlled monitoring laboratories will be set up across the continent, although while these laboratories are awaiting certification, monitoring will be performed at a central facility in Bordeaux.

How much will it cost?

Pharmacological monitoring will be provided free of charge for participating centers.

Where and how can I submit samples?

Local Novartis representatives can provide further information on how and where to submit samples.

Spread of excellence

What is the purpose of the spread of excellence project?

This project will increase knowledge and information on CML in Europe, and raise awareness of the EUTOS for CML program and the ELN. It will also support activities that promote the realization of a European CML registry, and that broaden access to molecular and pharmacological monitoring.

What materials are being prepared?

A comprehensive toolkit of materials and activities to support the EUTOS for CML program, including:

- A dedicated EUTOS for CML website
- Educational slide sets
- A summary card of the ELN management guidelines for CML
- Scientific and educational meetings