

Expanded CML Registry

EUTOS for CML



European Treatment and Outcome Study

Objectives

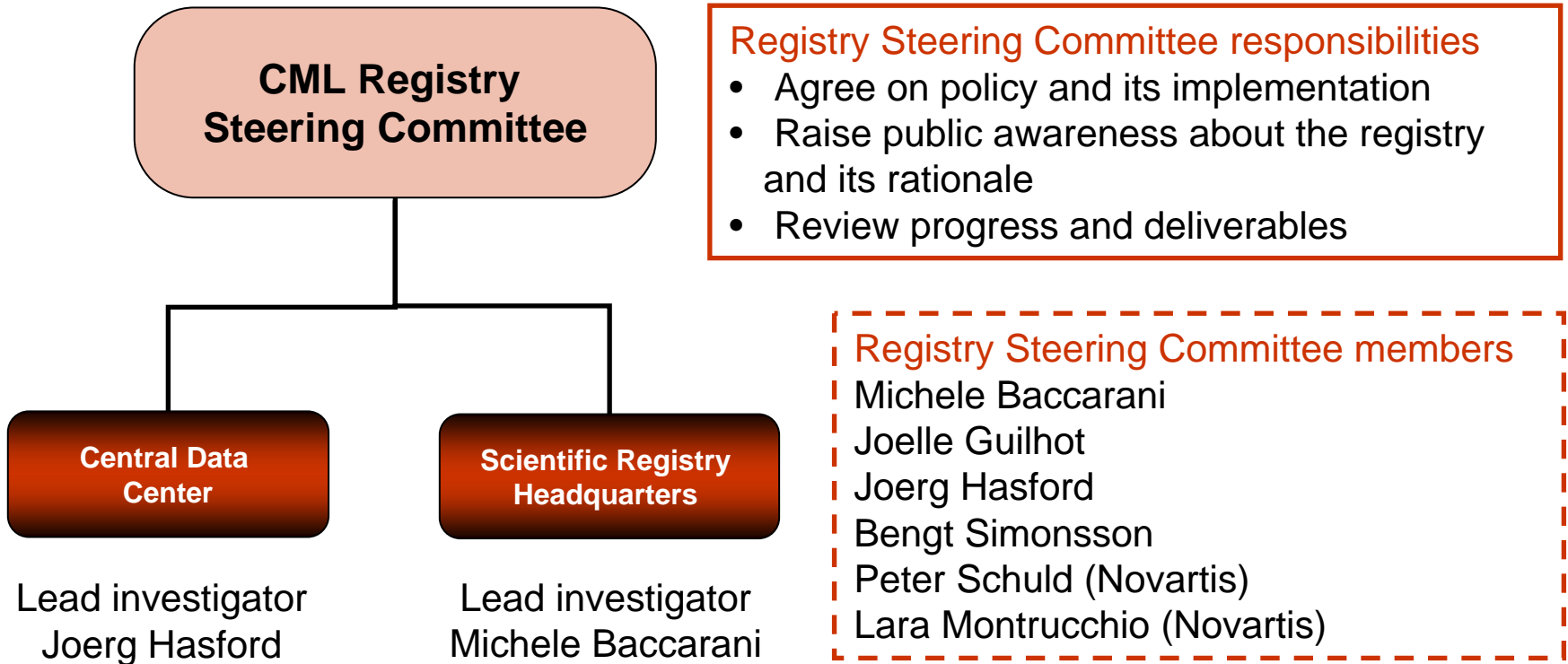
- The CML Registry will collect baseline, treatment and outcome data on patients with CML in Europe, in order to
 - Determine variations considering demographics and geographic region
 - Evaluate quality-controlled outcomes and implementation of ELN recommendations
 - Develop a comprehensive prognostic model to optimize treatment

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Organization



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Composition

- To achieve its objectives, the EUTOS for CML Registry is divided into three patient groups
 - **In-study:** patients from national study groups enrolled in prospective studies, taking imatinib frontline
 - **Out-study:** patients already registered in existing databases, irrespective of frontline treatment
 - **Prospective:** newly diagnosed patients not previously in registries or clinical studies

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In-study patients

- This group will include ~2500 patients enrolled in on-going studies of imatinib-based regimens frontline
- All patients were diagnosed between 2002 and 2006
- High quality and quantity of data are expected, due to the rigorous study protocols enforced by the respective Study Groups
- Patients in this group will have substantial follow-up data (4–8 years in 2010)

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Out-study patients

- Will include ~1900 patients currently registered in already existing or planned databases of national/regional study groups or reference centers
- All patients were diagnosed between 2002 and 2006
- Out-study patients will serve as a control group for the in-study patients (the selection bias is different)
- Creation of the out-study group also allows countries with no in-study patients to contribute to the Registry
- Patients in this group will have substantial follow-up data (4–8 years in 2010)

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Prospective patients

- The prospective patient group will include ~1700 patients who are newly diagnosed from 2009 onwards
- The prospective patient group should be representative of Europe, including as many countries as possible
- Study groups should include all newly diagnosed CML patients of a whole country or a region of a country (details to be negotiated with study groups or with reference centers)

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Scientific committees

Committee

- Prognostic studies
- Population-based registries
- Imatinib failures
- Other/additional chromosomal abnormalities
- Point mutations
- Complete molecular response
- Imatinib discontinuation in complete responders
- Pharmacosurveillance, adverse events

Coordinator

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Current status (Jan 2009)

- A study plan for the **in-study** and **out-study** patient groups has been finalized, including:
 - Patient numbers (per study group) and reimbursement
 - Patient eligibility criteria
 - Minimal core dataset for patient registration
- Data from ~2500 eligible in-study and out-study patients have already been registered at the Central Data Center
- A study plan for the **prospective** patient group will be finalized by the Steering Committee in the coming months

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Summary

- CML Registry will collect baseline, treatment and outcome data on patients with CML in Europe
- Registry is divided into in-study, out-study and prospective groups
- Significant progress has already been made with the in- and out-study registries; data collection for the prospective registry will begin in 2009
- Groups interested in participating in the CML Registry should contact Michele Baccharani (michele.baccharani@unibo.it)

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