

# **EUTOS for CML**

A unique collaboration

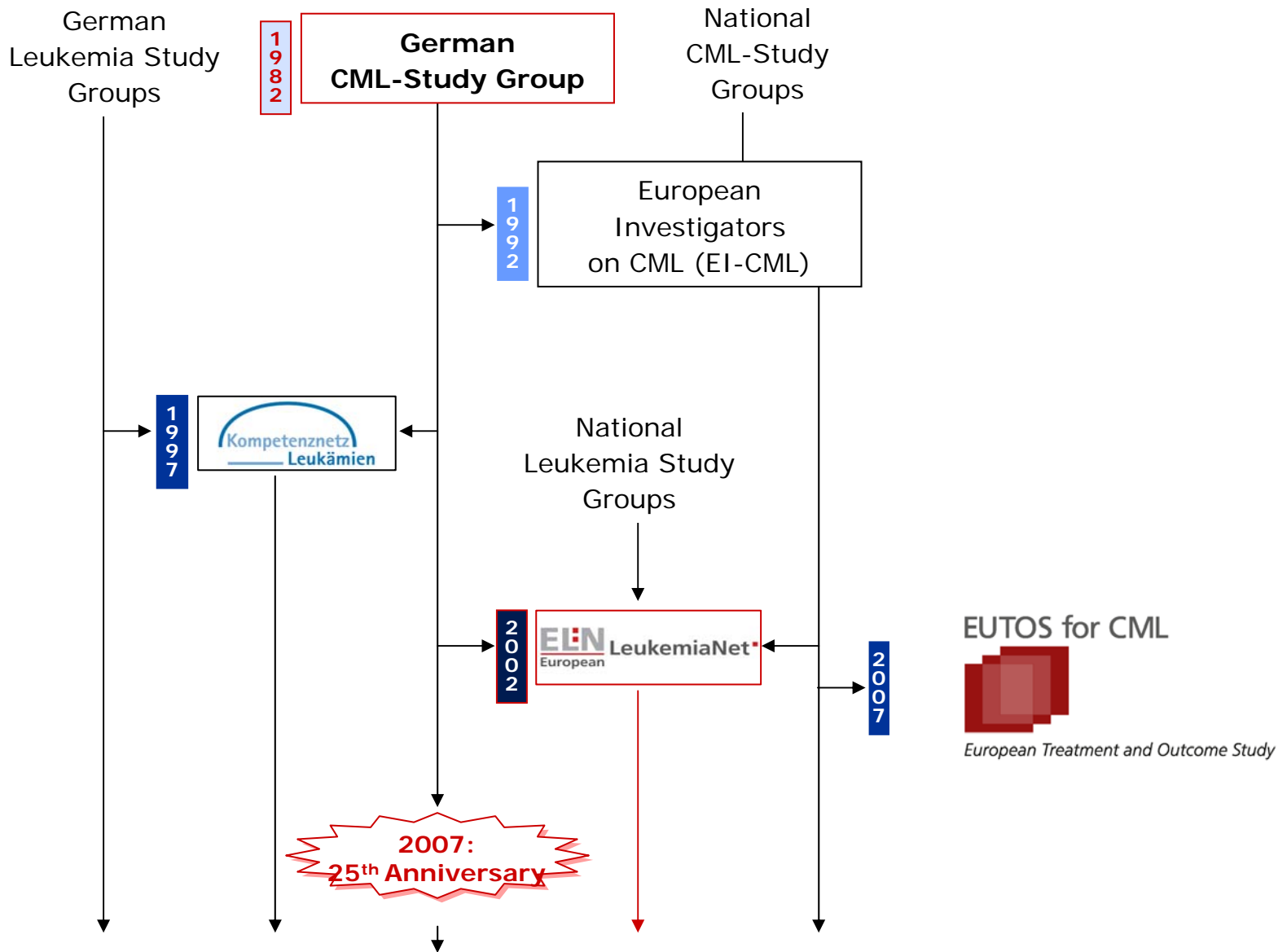
R Hehlmann



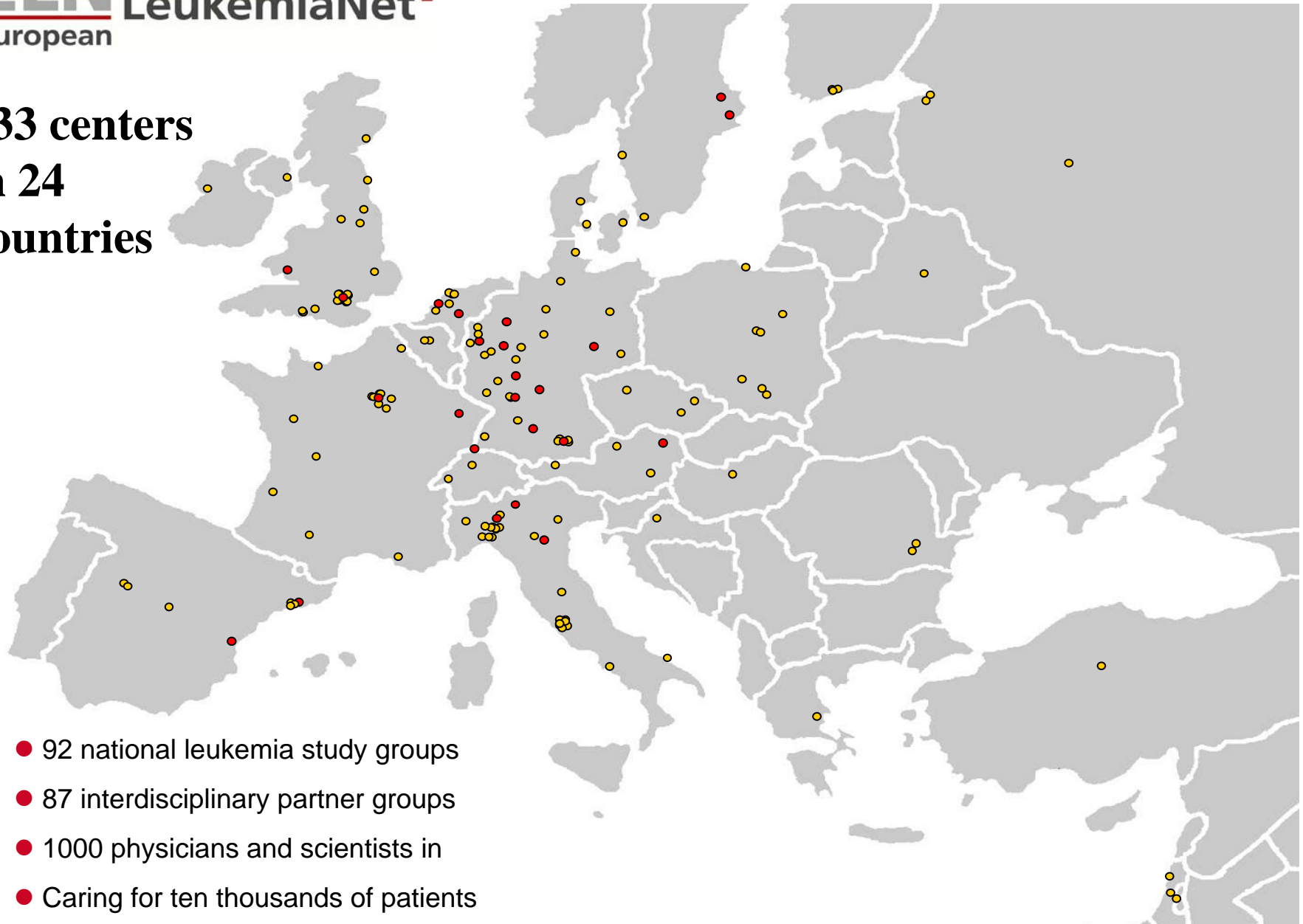
# European Treatment and Outcome Study (EUTOS)

A collaboration between ELN and Novartis

# Pedigree of the Clinical CML-Research



**133 centers  
in 24  
countries**





# EUTOS, Details

- Novartis supports the European LeukemiaNet, with nearly 14 Mill. € for 3 years
- As a cooperation of academia and industry for translational research
- Contract between University of Heidelberg (legal representative of the ELN-CML group) and Novartis
- For participation, subcontracts between Institutions and the University Heidelberg are required



# Objectives of EUTOS for CML

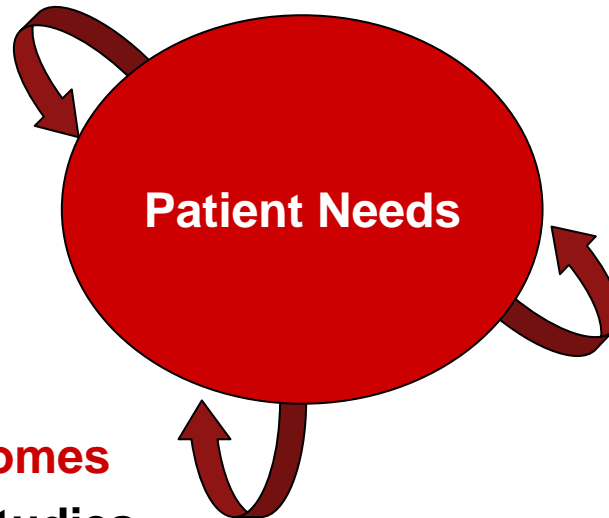
- Enhance understanding of the nature and management of CML
- Improve standardized evaluation and monitoring of treatments for CML
- Optimize treatment of CML patients across Europe



# Areas of commitment and collaboration

## Environment

- Evaluate regulatory, policy impact on access



## Clinical Outcomes

- Ongoing Studies
- Improve diagnosis and monitoring
- Compliance and persistency

## Scientific Collaboration

- Improve, support cooperation among scientists and clinicians



# Key activities of EUTOS for CML throughout Europe

- European CML registry
- Molecular monitoring
- Pharmacologic monitoring
- Spread of excellence



# CML-Registry

- Collect baseline- treatment- and outcome data across Europe to
  - determine demographics and geographic variations
  - evaluate quality controlled outcomes and implementation of ELN-recommendations
  - develop a comprehensive prognostic model to optimize treatment



# Molecular Monitoring (RQ-PCR)

- Quality controlled outcome data
- Standardized RQ-PCR for BCR-ABL quantification and mutation detection
- Prognostic significance



# Drug Monitoring

**Assessment of impact of drug levels in the event of:**

- suspicion of non-compliance
- suspicion of drug-drug interaction
- response less than expected
- unusually severe adverse effects



# Spread of Excellence

- Information and communication by:
  - Website
  - Newsletters
  - Continued medical education
  - Scientific symposia
  - Consultation

Tasks Executive Committee:

- Verify the direction of the project
- Effectively interact with public institutions, such as the European Union
- Render a final decision to any issues raised by the Steering Committee Registry or th Working Groups
- Periodically verify results vs. objectives concerning all sub-projects
- Resolve any disputes that may arise in the Steering Committee Registry or the Working Groups

Tasks Working Groups (Molecular, Therapeutic, Spread of Excellence and Registry:

- Execute operational plans agreed within the sub-projects (Annexes of the Agreement)
- Report issues and bring critical decisions to the attention of the Executive Committee (for Registry with Steering Committee Registry)
- Consult with the Executive Committee (for Registry with Steering Committee Registry) in relation to key decisions
- Interact with scientific center's representatives

Tasks Controlling:

- Responsibility for finances and controlling

# Executive Committee

Members Executive committee:  
 Michele Baccarani, Francois Guilhot, Rüdiger Hehlmann, Andreas Hochhaus, Bengt Simonsson, Guido Guidi

## Finance Committee

Members Finance Committee:  
 Rüdiger Hehlmann, Susanne Saussele, Sigurd Weinreich  
 Anna-Lena Engwall, Paolo Tombesi

Tasks CML Registry Steering Committee:

- Agree on policy and its implementation
- Raise public awareness about the registry and its rationale
- Review progress and deliverables

## CML Registry Steering Committee

### Molecular Monitoring Working group

### Pharmacol. Monitoring Working group

### Spread of Excellence Working group

### Central Data Center

Lead investigator:  
Joerg Hasford

### Scientific Registry Head Quarter

Lead investigator:  
Michele Baccarani

Members Molecular Monitoring Working Group:  
 Nick Cross  
 Andreas Hochhaus  
 Giuseppe Saglio  
 Alfredo Covelli

Members Therapeutic Monitoring Working Group:  
 Francois Guilhot  
 Francois Xavier Mahon  
 Peter Schuld

Members Spread of Excellence Working Group:  
 Francisco Cervantes  
 Rüdiger Hehlmann  
 Susanne Saussele  
 Fabrizio Pane  
 Lara Montrucchio

Members CML Registry SC:  
 Michele Baccarani  
 Joelle Guilhot  
 Joerg Hasford  
 Bengt Simonsson  
 Anna-Lena Engwall, Peter Schuld

Working Group for CML iRegistry

EUTOS for CML





# Achieved Highlights

- **Educational:**
  - Symposium: “Next steps in the evolution of targeted therapies in CML” performed
  - PocketCard, Exhibition booth completed
  - Website drafted
  - Slide kit and guidebook in schedule
- **Registry:**
  - > 2500 patients registered at Central Data Center
  - Research plan drafted
- **Molecular Monitoring:**
  - Distribution of lysates in schedule



# Summary

- Increased understanding of CML
- Access to the latest management tools and techniques for physicians across Europe
- Expanded access to state-of-the-art technology to all CML patients across Europe
- Best possible outcomes for CML patients across Europe