

**3rd Meeting of the European Research
Initiative on CLL (ERIC)
during the 10th Meeting of the
International Working Group on CLL
(IWCLL)**

Stresa, Italy

Regina Palace Hotel

Thursday, 9 October 2003, 18.00-21.00

Sunday, 12 October 2003, 8.00-9.00

For the protocol: Michael Hallek

Agenda

1. Welcome and introduction: what is the ERIC?
2. Activity Report
 - a. Application within the European Leukemia Network (6th EU framework program)
 - b. European Research Consortium on CLL
3. Future structure of the ERIC
4. Proposed new projects
 - a. David Oscier, UK
 - b. Christian Geisler
 - c. Others?
5. Next meeting (EHA 2004, Geneva)
6. Diverse topics
7. Closing remarks

What is the ERIC?

The European Research Initiative on CLL

- *Founded in Frankfurt 2001 during the EHA meeting.*
- *The ERIC is a European organization devoted to improve the outcome of patients with CLL and related diseases.*
- *The ERIC acts within the EHA.*
- *The ERIC is OPEN to every physician or scientist working in the field of chronic lymphocytic leukemia or related disorders.*

Mission of the ERIC

● Statement:

- There are many more open questions and new drugs available in the treatment of CLL than study groups or active protocols. To achieve faster progress, open communication between study groups, physicians and scientists is a key element.

● *Clinical group*

- Cooperation on rare diseases (e.g. T-PLL) or rare clinical situations, where large patient series are difficult to recruit at a national level.
- Communication on national clinical protocols even at a planning stage to avoid overlapping or redundant studies in Europe.
- Create common standards with regard to documentation (CRFs etc.) and a common data management to make it attractive for pharmaceutical partners to launch (registration) trials in Europe.

● *European research consortium on CLL (ERCC)*

- Concerted effort of European groups could create critical mass
- Collect biological material (DNA, cells, serum...) in a standardized way and to make it available to basic researchers in Europe.

The „history“ of the ERIC

- June 2001: Foundation in Francfort
 - Decision that Michael Hallek and Guillaume Dighiero would launch this initiative and hand it over to an elected chairman or board after a successful start
- Dec 2002: 2nd ERIC meeting 2002 at ASH conference in Philadelphia
 - decision to participate at the European LeukemiaNet (R. Hehlmann) within the 6th framework
- March 2003: Application of ERIC within European LeukemiaNet (network of excellence) (support by S. Stilgenbauer, H. Döhner, G. Dighiero).
- Summer 2003: Application funded by EU!
- October 2003: Contract negotiations with the EU, definition of deliverables

Short description of the European LeukemiaNet

- Initiative to create network structures for leukemia research in Europe.
- Coordinator: Rüdiger Hehlmann, Mannheim.
- 18 work packages (WP) with
 - Network management structure
 - European Leukemia Information Center (ELIC)
 - Central Information and Communication Services (CICS)
 - Networks on CML, ALL, AML, **CLL (WP7)**, MDS, CMPD
 - Platforms on diagnostics, cytogenetics, MRD, gene profiling, SCT, supportive care, treatment research, biometry, guidelines

Which funding will the ERIC receive, and what can we do with it?

- We do not know yet.
- Funding may start in 2004.
- Estimate: 100.000-150.000 € per 18 months, or 70.000-100.000 € per year.
- The funding can be spread over several centers or used to build up central structures for the ERIC and the European CLL consortium.

What has the ERIC proposed to „deliver“? (1)

- Establishment of WP information and communication structures
- Web-based information on CLL
- WP management structure and steering committee
- Creation of CLL platform
- Regular meetings
- LP (Michael Hallek) reports to NMC structure
- Create common uniform data sets
- Set up European CLL registry
- Definitions and standardization of relevant diagnostic and therapeutic procedures
- Spreading of excellence by web-site, guidelines etc.

What has the ERIC proposed to „deliver“? (2)

- **Prepare clinical practice guidelines**
- **Define indications for stem cell transplantation in CLL**
- **Harmonization of CLL transplant protocols**
- **Exchange of study protocols amongst national study groups**
- **Common Phase I/II clinical trials on rare diseases**

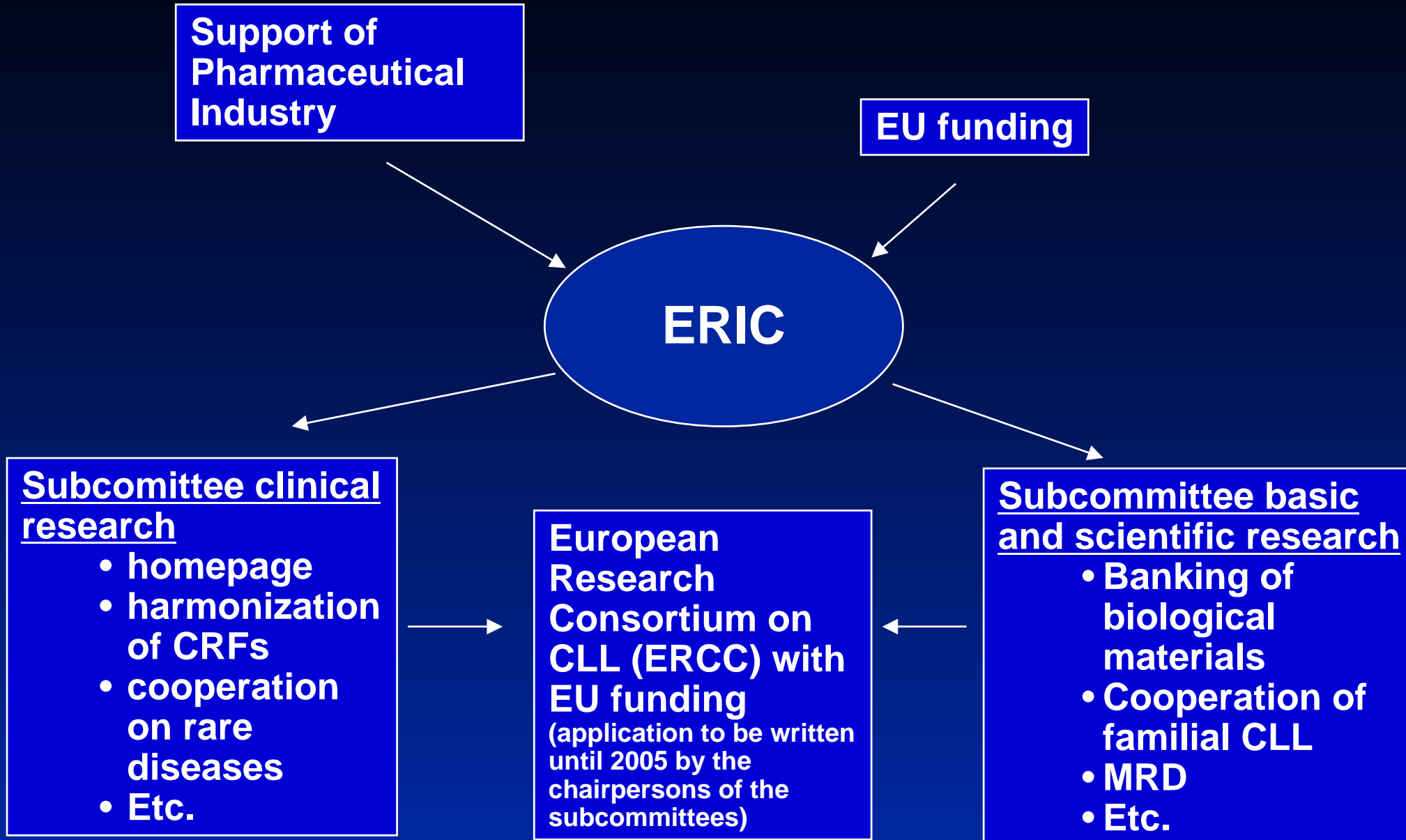
**What shall we really do with
the funding?**

You decide.

Structure of the ERIC in 2004 (1): Results of the discussion

- **Board:**
 - In the future, the board will be elected for a 2-year term by the members of the ERIC.
 - **New President:** proposed and approved by the assembly on 12 October 2003: D. Catovsky
 - **President-elect:** to be elected.
 - **Secretary and Treasurer:** to be elected.
- **1 subcommittee on clinical research (with chairperson not being on the board). In the future, the chairpersons will be proposed by the president.**
 - Chairperson proposed and approved by the assembly on 12 October 2003: M. Hallek.
- **1 subcommittee on basic and translational research (with chairperson not being on the board). In the future, the chairpersons will be proposed by the president.**
 - Chairpersons proposed and approved by the assembly on 12 October 2003: F. Stevenson and R. Küppers.
- **The bylaws of the ERIC will be written during the next months (1st Q 2003).**
- **It was decided that the ERIC funding should be used to establish the structures of the ERIC and of a European Research Consortium on CLL (ERCC, see next page).**
- **The EU grant proposal for the ERCC should be a joint effort of both subcommittees.**
- **It was emphasized that such a proposal for the ERCC would require an efficient coordinator, who needs to be determined.**
- **It was also pointed out that the selection of projects for the ERCC grant application should be based on quality alone.**
- **Finally, it was recommended that the ERIC and its subcommittees should focus on a few projects with high chances of success.**

Structure of the ERIC in 2004



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 - a. David Oscier, UK, on p53 mutated CLL (patients should be collected in a common database)
 - b. Christian Geisler, Danmark, on risk-adapted therapy in early stage CLL
5. Next meeting will be held at the EHA 2004, Geneva
6. Closing remarks