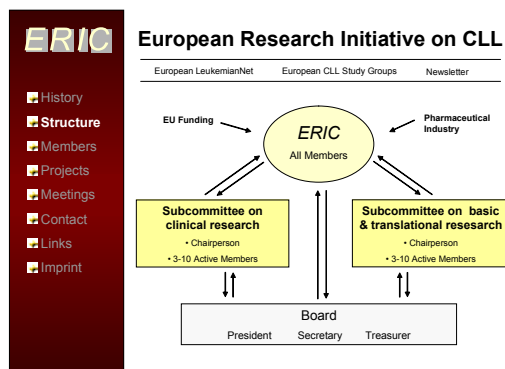


Protocol of the ERIC Business Meeting after the 3rd Scientific Symposium of ERIC at the EHA-Congress in Stockholm June 3rd 2005 6-8 pm

1. Organisational and administrative issues (Michael Hallek)

ERIC Structure: Overview



ERIC Bylaws:

Bylaws for ERIC have been proposed at Geneva 2004. The bylaws will become necessary for the representation of the ERIC as an established institution, e.g. when applying for EU funding. Please find attached to this letter the last version of the bylaws. If you have any concerns or changes please contact Michael Hallek or Carmen Schweighofer until 31 July 2005. We will then consult a lawyer to finalize and legalize the ERIC bylaws.

ERIC Homepage:

The ERIC homepage is currently in preparation by Dr Gabriele Strache (Cologne/Munich, Germany). For ideas, proposals for structure/links etc. please contact Michael Hallek or Carmen Schweighofer.

2. ERCC: European Research Committee on CLL (Ulrich Jäger, Wien, Austria)

Most important and very urgent: We need to prepare ideas for further research projects of ERIC for the next **call of funding by the European Union** (funding period 7, FP7). Common research projects on a European level are only possible if we have funding! Please – all members! – contact the person, who is responsible for your country in the European Commission, which will decide about the next funding period. If you don't know the person send your ideas/proposals to Ulrich Jäger (email: ulrich.jaeger@meduniwien.ac.at) or Carmen Schweighofer (email: carmen.schweighofer@uk-koeln.de), we will collect them and send them to the EU. The last time (2003) the EU denied putting money into CLL research. This time we have a new chance and we have to build a lobby for CLL research and to emphasize the importance of research in this field. There is a deadline in June 2005! U. Jäger will send out a prepared template where everybody can insert his ideas/proposals.

Examples proposed by U. Jäger are:

- Identification of the **cell of origin** (CLL stem cells, normal counterparts);
- Characterisation of the critical events in **transcription and cell signalling** as well as the role of the **microenvironment** for identification of potential molecular targets (sub proteomics, pharmacogenomics and pharmacoproteomics);
- Establishment of **in vitro and in vivo models** for drug testing.
- The final goal is to improve the management of the disease aiming towards a cure of CLL.

We also have to emphasize, why the proposed topic should be carried out at a European level:

While a level of standardisation and harmonisation is already established in the EU-funded European Leukemia Network, no EU funding is currently available for **basic research in CLL**. The project needs a co-operative European effort to achieve a critical mass of research potential because:

- Large number of patients from more than one country are required (subtypes, prognostic and diagnostic markers, genetic factors);
- Large scale studies on CLL require resources, expertise, infrastructure, instruments, clinicians, scientists and health authorities which can only be available through an integrated project in the European community.
- Involvement of SMEs and pharmaceutical industry in Europe with their technological capacities and experience in drug design and development.

Harmonization of MRD assessment:

This project is one of the great successes of the ERIC and the European LeukemiaNet. Consensus has been reached for the harmonization of the laboratory methods for the assessment of minimal residual disease (MRD) at the European and transatlantic level. The results were presented by Dr Andy Rawstron, UK, and will be published soon.

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Harmonization of ZAP 70 analysis (R. Letestu):

The progress in harmonization of ZAP70 assessment in CLL cells was presented by R. Letestu. An exchange of fresh/frozen samples in European and the US will probably take place in September 2005. For further information please contact Florence Cymbalista (Paris/France, email: florence.cymbalista@avc.ap-hop-paris.fr) or Remi Letestu (Paris/France, email: remi.letestu@avc.ap-hop-paris.fr).

Harmonization of clinical protocols:

The German and French CLL study groups have initiated a common protocol for early stage CLL with the comparison of watch and wait and FCR-therapy in high risk patients (CLL7). High risk will be defined by certain risk factors evaluated in this study (lymphocyte doubling time, thymidine kinase > 10 U/l, IgVH status, presence of 11p-/17p-deletion or trisomy 12). For this study, a standardization of CRFs has been achieved. These CRFs may be used as template for other CLL studies within ERIC. For further information please contact the website of the GCLLSG: www.dcllsg.de.

Studies for p53 CLL cases:

A questionnaire to collect p53 mutated/deficient CLL cases was sent out by Dr David Oscier. No response has been received. D. Oscier wants to circulate it again among ERIC members. Please give him feed back. It was also discussed that European trials should be initiated for this subgroup of CLL patients at very poor prognosis.

Familial CLL:

D. Catovsky reported that data have been collected at his center (more information about the study: www.icr.ac.uk/haemcyto/fcll/). Results will be presented at the IWCLL meeting in September 2005.

Future projects within the ERIC:

- The harmonization of FISH/cytogenetics was emphasized as one of the future, important projects of the ERIC. FISH diagnostics should be harmonized at the European and international level. First suggestions for harmonization aspects have been made by Stephan

Stilgenbauer (Ulm, Germany, email: stephan.stilgenbauer@medizin.uni-ulm.de). For information please contact Stephan Stilgenbauer or Florence Cymbalista (email: florence.cymbalista@avc.ap-hop-paris.fr).

- The presentation of Thomas Elter (Cologne/Germany) showed that further studies on the effectiveness of alemtuzumab in combination with fludarabine and other cytotoxic agents are needed in CLL. These protocols p53/17p- mutation should probably be performed at the European level, because national trials might not recruit enough patients.
- Refinement of diagnostic criteria: Some members of ERIC have asked for the re-definition of diagnostic criteria for CLL, since it is unclear at the present time, whether immunophenotyping is sufficient, whether a histopathology exam of an enlarged lymph node is requested, whether a bone marrow biopsy is still needed etc. During this year, a working group of the NCI/IWCLL will try to define new diagnostic criteria for CLL. Members of the ERIC will be kept informed. First thoughts will be discussed at the IWCLL meeting in September 2005 in Brooklyn, New York.
- European platform for phase II trials: Vincent Levy proposed to create a platform for phase I and II trials, since there are often quality deficiencies in phase I trials, which are mostly done locally at one single center and promoted by the pharmaceutical industry. Since it is often difficult to recruit patients for phase II trials, it was decided to make an inventory of phase II trials on CLL in Europe and to make this information available at the ERIC homepage. Please send your information regarding phase I or II trials which you wish to present to Carmen Schweighofer.
- For further trial evaluation within ERIC, members who wish to participate at data safety monitoring boards should indicate this to Carmen Schweighofer. This information will be distributed to ERIC members and national study groups.
- Definition of novel targets for CLL therapy/research by expression profiling/proteomics is needed.
- CLL cell banking.

Next meeting:

The next meeting will be held at the ASH Dec 11th in Atlanta/US. Further details will be announced via email.