

ELIC (WP2): ELN working group on international IITs

Results since ELN-Symposium 2008:

1. Setup of website substructure for initiation/organisation of IITs
 - Link to regulatory requirements (11 countries) – Crosslink to ELN
 - Collection of sample documents
 - e.g. regulatory requirements (IRB) in 8 different countries
 - European-/ country specific

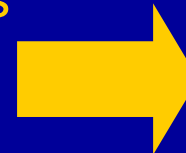
The screenshot displays the ELN LeukemiaNet website interface. The main navigation bar includes links for Home, Network Services, Leukemias, Diagnostics, Treat. Research, Physicians, Patients, and Press/Media. The current page is titled 'Information for International IITs' and is part of the 'Basic Information' section under 'International IITs'. The page content includes a description of the collection, a table of contents with links to Information, Contact, and Miscellaneous, and a section for 'European/all countries' which is currently 'under construction'. A sidebar on the left contains a menu with categories like Management, Infocenter, and Registries. A sidebar on the right features links to the European Leukemia Trial Registry (ELTR) and the European Treatment and Outcome Study (EUTOS) for CML. A footer at the bottom left mentions HON CODE certification.

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Results since ELN-Symposium 2008:

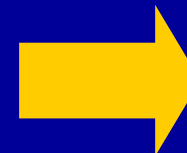
1. Setup of website substructure for initiation/organisation of IITs
 - Link-collection (authorities, expert institutes)
 - Collection of sample documents'
 - e.g. regulatory requirements (IRB) in different countries
 - European-/and country specific

2. Collaboration with further EU-projects
 - ICREL
 - EBMT/CLINT
 - ECRIN



- Combine efforts
- Distribution

3. Poll: Workshops on International IITs
 - Interest
 - Focus of the workshop



- Working groups
- Development of papers

Successfull experience with set-up of network structure for support of IITs

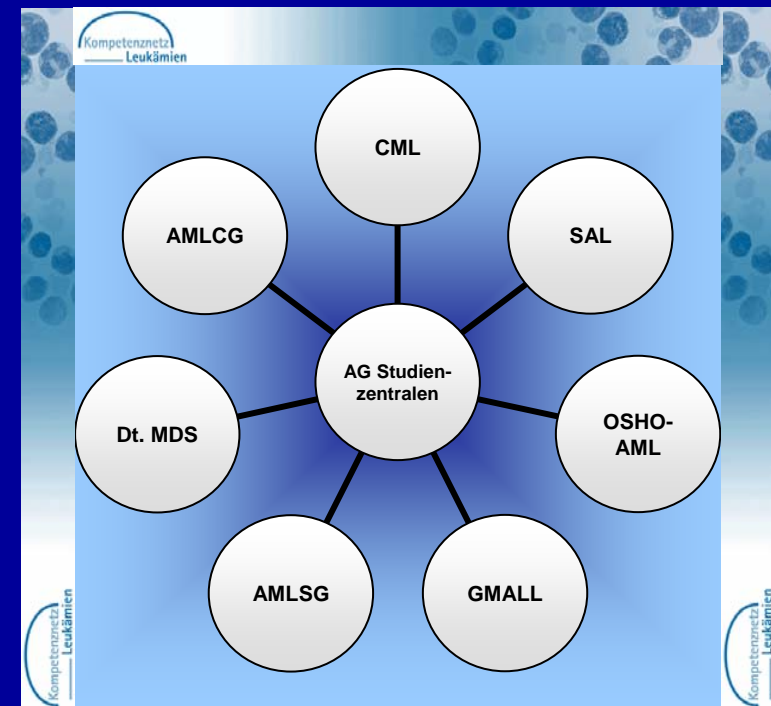
German project:

Collaboration of all large leukemia study groups

- 7 multicentric studycenters
- Clinical and study personal

Aim:

Development of practical approaches to handle IITs under new legislation.



Successfull experience with set-up of network structure for support of IITs

Results (so far):

Study management (study centers)

- Data Management
- Monitoring Basics
- Safety Management
- Education
- **Quality management for clinical trial units**
- **Link to**
 - Interdisciplinary working groups and
 - Hematological networks



Similar project for ELN?

ELN Expert Committee on International IITs (ELN-EC)

1. Overall Interest?
2. Members?
3. Budget?
4. Content?
5. Next steps?

ELN Expert Committee on International IITs (ELN-EC)

Interest?

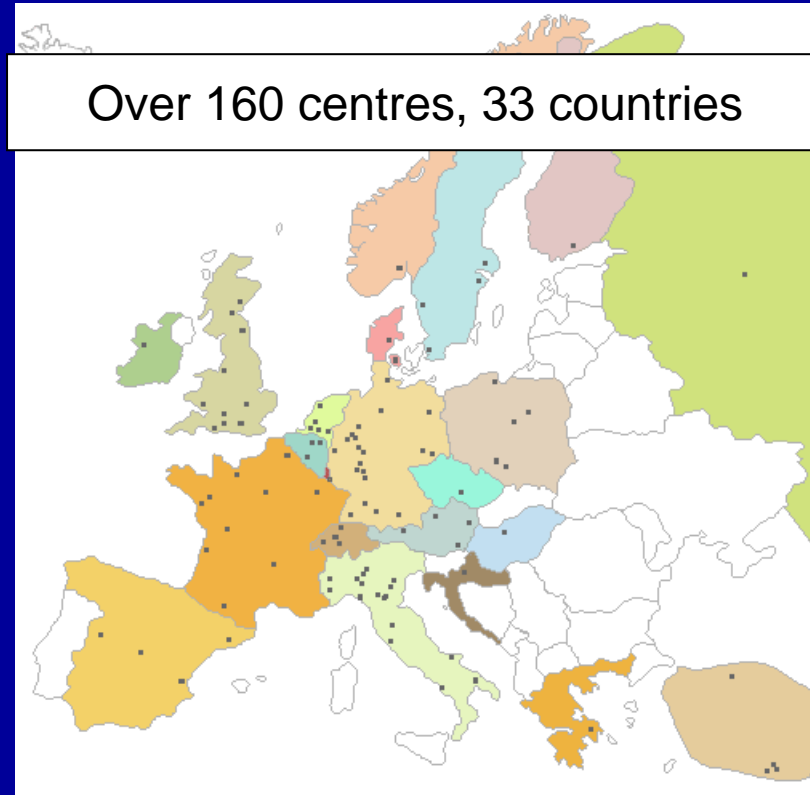
Yes

Members?

Offer:

- Central coordination: WP2
- Others are welcome

Over 160 centres, 33 countries



ELN Expert Committee on International IITs (ELN-EC)



Budget?

Possibly yes

- e.g. travel costs

Deliverables?

Month 67-78:

- Stepwise procedure for activation of a multinational clinical trial
- Allocated to different collaborating partners

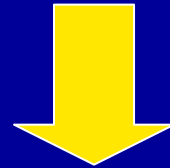
Examples:

1. Sponsor duties
 - Contract of delegation – national-specific: duties of the LCT
2. Investigator duties

ELN Expert Committee on International IITs (ELN-EC)

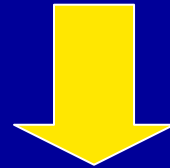
Next steps:

- ✓ Relevant topics
- ✓ Existing material
- ✓ Members



✉ E-mail from ELIC

- A: Interested members
- B: Leader of studygroups
- C: Members of EU-projects



1. No ELN-EC
2. Working group (adapting documents)
3. ELN-EC (producing documents)