1st ELN Workshop on International Investigator Initiated Clinical Trials

Organised by WP2
European Leukemia Information Center

in collaboration with
WPs 1, 4-9 and 14

“History”

ICH-GCP Guidelines
(Initiative of regulatory authorities / pharm. industry from EU / Japan / USA , 1996)

Clinical Trials Directive 2001/20/EG
(Later: EU GCP Directive (2005/28/EC) 08.4.2005)

Transfer into national legislation

Germany
AMG Novelle 6.8.04

Other Countries
Deadline: 2004

<u>Major consequence for academic research:</u>
Therapy optimisation trials (TOPs) and Investigator Initiated Trials (IITs) have to follow the same rules as registration studies of pharmaceutical industry

European Leukemia Net 2004: Major Aim to Foster International Academic IITs in Leukemias ?

Major field

- **Rare diseases, as leukemias**
- **Treatment and research done in parallel**
  (only way for progress in rare diseases)
- **Questions without commercial interest**

Low Budget

(public funding, university budget, partly supported by industry)

High potential costs

- Multicenter, many hospitals (Health Care Standard!)
- Long-term observation
- High patient numbers

<u>IITs in Leukemias:</u>

Conduct under the new legislation severly hampered:
(1) responsibility (2) bureaucracy (3) costs

Current Situation of Leukemia IITs: Europe

Realisation of the EU Clinical Trials Directive in Different European Countries – EWALL GROUP

	Germany	UK	Spain	Italy	France
Central IRB	Yes, IRB of PI but all IRBs in parallel	Yes (hotline)	No	No	Yes
Monitoring	„Research Project“ for adapted monitoring	No (rumours..)	No	No	We try…
Safety	SUSAR 5-10d to IRBs, Authorities, all investigators	Yes	Yes	Yes	Yes
Sponsor Role	Universities partly, delegation contracts	Institutions reluctantly	Various incl. Study Groups	PI	Institutions Coop.groups Research inst.
Patient Insurance for IITs (registered drugs)	Yes	No	Yes	No (Ministery)	No

- **No harmonisation**
- **Different interpretation,realisation of laws**
- **Different attitude of authorities**
- **Excess of bureaucracy all over Europe**

Current Situation of Leukemia IITs: Germany

- **Amendments of ongoing trials**
  (to prolong studies initiated before new legislation)
- **Attempts to get prepared**
  (for studies according to new legislation)
- **Few / No new national IITS**
  (at least those without industry support)
- **No / few international IITs**

One of the major goals of the leukemia net is endangered !

The impact of the 'Clinical Trials' directive on the cost and conduct of non-commercial cancer trials in the UK ☆

J. Hearn, R. Sullivan*

EUROPEAN JOURNAL OF CANCER 43 (2007) 8–13

Method: Eight specialised UK Clinical Trials Unit (CTUs) were interviewed

Topic: Consequences of CTD on information flow, start, conduct, finalisation and cost of clinical trials

Results:

- **Doubling of the cost** of running non-commercial cancer clinical trials
- **Delay to the start of trials in the order of 6 to 10 months**
- **Reduction / stop of international trials**
- Lack of central guidance
- Lack of clarity regarding the interpretation of the guidance notes
- Increase in essential documentation and paperwork

- Staff is working beyond capacity and demoralised
- Even experienced staff anxious about correct interpretation of CTD

What can we do ?

- **Public Relations:**
  Role of TOP for general health care and clinical science in Germany and Europe
- **Political Activities**
- **Continuing education**

- **Networking of trial staff**
- **Cooperations**
  - Large multicenter study groups national – international
  - Competence networks

ELIC (WP2): Web-based Services for IITs
January 28, 2008; 16.00 – 19.30 p.m.

ELN European LeukemiaNet

Part I: General Overview

Chair: N. Gökbuget, J. Apperley

• Introduction	N. Gökbuget, ELN
• How can ECRIN support investigators for the initiation and conduct of international academic trials	C. Kubiak, ECRIN
• EORTC experience in activating international clinical trials Affairs Unit at EORTC	F. Lambert, EORTC
• Successful initiation of international pediatric trials	C. Mauz-Körholz, KPOH
• Promoting pan-European prospective clinical trials: The EBMT perspective	J. Apperley, EBMT

Part II: Experience and problems with international trials in the ELN:

Short reports from WPs

• Chair: E. Hellström-Lindberg, B. Simonsson	
• CML: European collaboration in clinical trials for CML	B. Simonsson, WP4
• AML: Expansion of the AML Intergroup Networking Study to further	
• European trial groups	T. Büchner, WP5
• ALL: Initiation of an international trial with Dasatinib for Ph+ ALL	P. Rousselot, WP 6
• CLL: International trials of the GCLLSG: Regulatory requirements	
• and corrective actions	A. Westermann, WP7
• MDS: Lenalidomide in high-risk MDS and AML with del5q or monosomi 5	E. Hellström-Lindberg, WP8
• CMPD: From ECLAP to ELN clinical trials	T. Barbui, WP 9
• SCT: Conducting academic trials under EU law, the EBMT experience	Z. Doran, EBMT
• Registries: An alternative for clinical trials?	J. Hasford, WP 17
• ELIC: Internet support for ELN trials	K. Ihrig, WP 2
• Closure	N. Gökbuget, ELN