

Conducting Academic Trials Under EU Law The EBMT Experience

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EBMT



ELN, Heidelberg, January 2008

Major Challenges

- Sponsorship
- The Approval Process
- Monitoring/Quality Assurance
- Support Infrastructure



Sponsorship

- The Problem?
 - *Requirement for Overall Sponsor*

Sponsorship Potential Solutions

1. Funded Studies

- *Sponsor – academic group*
- *Sponsor – national body*
- *Sponsor – university*
- *Sponsor – lead institution*



Non funded studies: a creative approach



Lyon, March 2007
ELN, Heidelberg, January 2008



Sponsorship Potential Solution

1. Non - Funded Studies

“A sponsor may delegate any or all of his trial-related functions to an individual, a company, an institution or an organisation. However, in such cases, the sponsor shall remain responsible for ensuring compliance”



Delegation by Contract

- *Delegates ALL sponsorship obligations to each centre*
- *Sign-off EBMT – highest level*
- *MUST be signed by institutional Representative (written documentation of authority) as well as PI*
 - *responsibilities institutional and intra-departmental*



The Contract

- Insurance
- Translations
- Submissions
- Data Management
- Pharmacovigilance
- Monitoring



But remember!

EBMT

- figurehead
 -but legally responsible
-
- Participating Institutions
 - in reality self sponsored
 -but legally not responsible



The Approval Process

- The Problem?

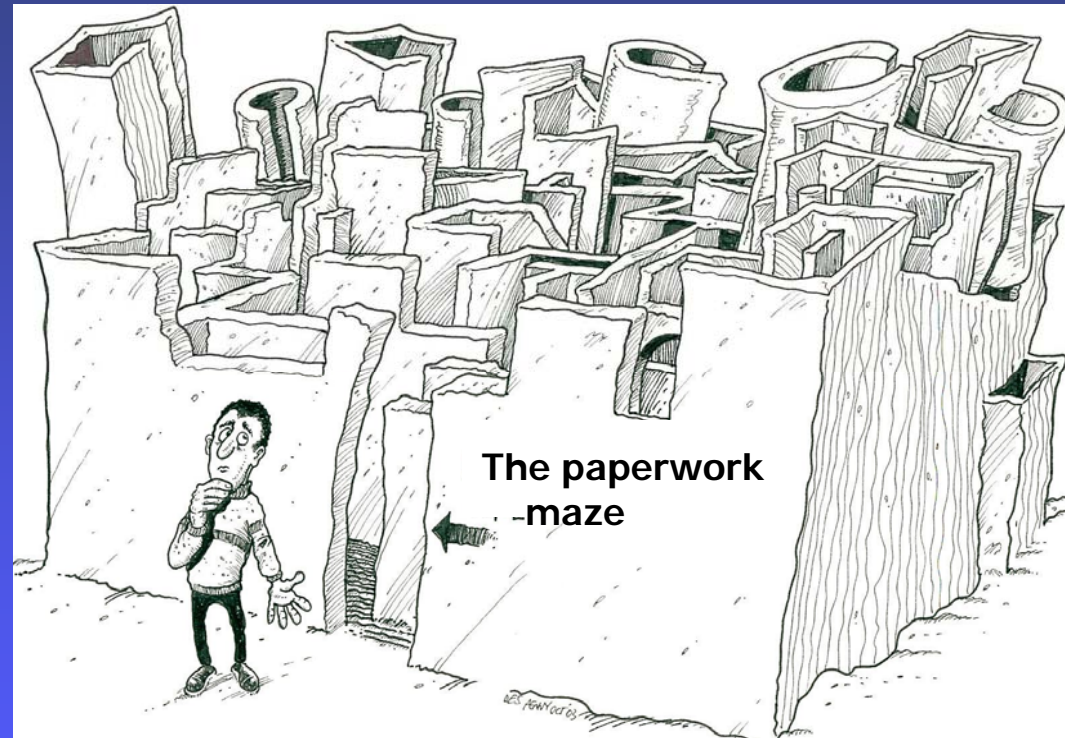
What?

When?

To whom?

How many?

Translate?



An iceberg floating in the ocean. The tip of the iceberg is above the water surface, and the much larger base is submerged below. The sky is blue with light clouds, and the water is a deep blue. The iceberg is white and blue, with some internal textures visible.

National Approval

Approval at an Institutional Level

The Paperwork Maze

- Local requirements
 - Local government
 - Institution
 - local ethics, R&D, pharmacy, agreements...
 - Language barriers
 - information/required submission documents

Potential Strategies

- Process in parallel
- Personal communication
 - Ethics / CA
 - Institutional Governance
 - No extra costs to institution
 - Pharmacy
 - Legal
 - additional liability protocol focussed

Potential Strategies

- Provide documentation for the most conservative
- If in doubt submit – let the authorities make the decision (e.g. IMP or not)
- “Grey Area” – get it in writing
- Ensure that academic status clear
- Compile central files of requirements based on available info, updated by experience



Potential Strategies

- Bank information
 - CA/EC addresses
 - CVs
 - Lab norms
 - Centre information



Monitoring/Quality Assurance

- Monitoring Obligations
 - Initiation, During, Close
- What and by whom not specified
- Tailor to
 - resources
 - checking of data quality (QA)
 - safety



Potential Strategies

- Use of teleconferences supported by slides to initiate
- Monitoring
 - CROs, Inter/intra departmental, "remote"
 - Focus on safety and protocol compliance
- Keep it simple and standardise
 - CRFs
 - Patient files

Potential Strategies

- Quality Assurance/End Point Review
 - Investigator review endpoints
 - Institution
 - Overall
 - Central review
 - Lab data
 - Digital scans



Current Support Infrastructure

London

Director, CTO

PCT Op Mgr

Coordinators 2FTE

Supervisor 1 FTE

Database manager 0.5 FTE

Leiden

Coordinators 1.5FTE

Data manager 1FTE

IT support 8hrs/week

Leipzig

Monitor 1FTE



Current Infrastructure

- Relatively small team
 - Language issues
- Reliance on
 - Country leads
 - Institutional resources
- End Result
 - Deceased control/takes longer



The Future

- The “Ideal”
 - Central support administration to submit and support centres
- Vital in the EU era
- Needs Investment



Consider

- Stop Gap for Today
 - Chose country leads with care
 - Ethical committee
 - Local resources
- Give maximum support centrally
 - EudraCT/CTA applications
 - Templates
- Minimal number of countries/institutions

Conclusions

- Academic Research is no longer a “weekend activity”
- Requires greater commitment from participating centres
- Be creative, explore your options/resources
- Adapt
- The more you do the better you get

Not easy but nor is it impossible!

