



International IISs Challenges and Strategies

Zoë Doran
Director, Clinical Trials Operations
EBMT

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The European Group for Blood and Marrow Transplantation

Sponsorship

Potential Sponsors

- Cooperative Group
- National Body
- University
- Lead Institution

Needs

- Resources to fulfil obligations of Sponsor
- Insurance

Sponsorship

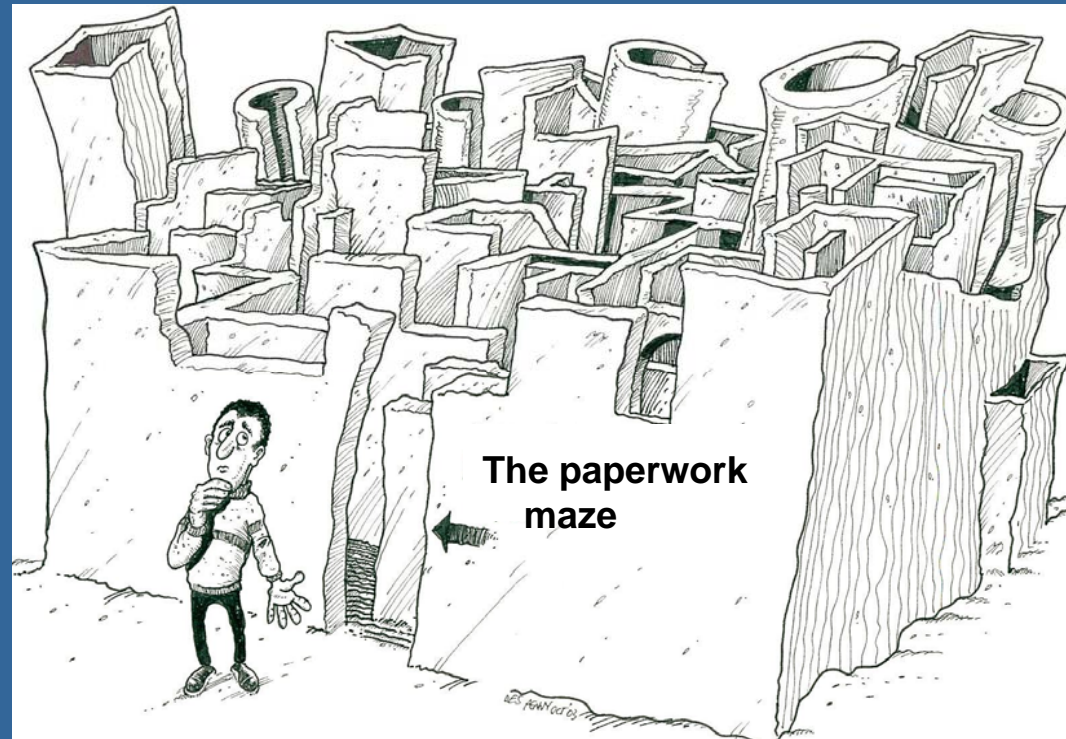
- ❑ Delegation by contract
 - ❑ Delegates sponsorship duties to institution/CRO/PI
 - ❑ Sponsor/Institutional sign-off
 - ❑ Ensure written documentation of authority
 - ❑ Responsibilities
 - ❑ Principle Investigator
 - ❑ Inter/intra institutional or departmental

Version Control

- ❑ Potential Nightmare!!
- ❑ Strategies:
 - ❑ One person in charge
 - ❑ Version number and date
 - ❑ Protocol = PIL/Consent
 - ❑ Patient Information leaflet/Informed Consent
 - ❑ Sample in Protocol
 - ❑ Institution specific version
 - ❑ Avoid amendments
 - ❑ Test submit
 - ❑ Keep listings of changes required by CAs/ECs etc.
 - ❑ Scientific/Administrative
 - ❑ Submit when unavoidable
 - ❑ New PIL/IC – even if NO changes required

Multi-national Submissions

- ❑ The Challenge?
 - ❑ What?
 - ❑ When?
 - ❑ To Whom?
 - ❑ How Many?
 - ❑ Translate?



What Helps?

- ❑ Identify per country requirements
 - ❑ Don't re-invent the wheel – ask!
 - ❑ Compile files – update
 - ❑ CA – if in doubt submit
 - ❑ IMP definition grey
- ❑ “Test” submit
 - ❑ Target demanding CA/EC
 - ❑ Identifies potential issues

What Helps?

- Know your PIs/Ethics Committees
 - Chose for success
- Submission packs
 - Keep common documents
- Check for local requirements
- Take the paperwork away from the PIs
 - Centralise or CRO where possible
 - Support
 - Identify local resource
 - Junior clinicians, nurses etc

Non-national Requirements



National Approval - 3mths

The image features a large iceberg floating in a dark blue sea under a light blue sky. The visible tip of the iceberg is small and white, while the submerged part is much larger and has a deep blue, translucent appearance. Two blue text boxes are overlaid on the image: one on the tip of the iceberg and one on the submerged part.

Approval at an Institutional Level - 10mths

The European Group for Blood and Marrow Transplantation

Non-National Requirements

- ❑ Identify early/parallel process
 - ❑ Regional/Institutional

- ❑ Approvals
 - ❑ Local ethics, research committee, pharmacy.....

- ❑ Contracts and agreements
 - ❑ Institutional Governance – no costs
 - ❑ Legal liability – protocol focussed
 - ❑ Documentation of academic/charitable status

Monitoring Your Study

- ❑ Requirements
 - ❑ Before, during, after
- ❑ Potential Resources
 - ❑ Inter or Intra institutional
 - ❑ Small cost effective CROs
 - ❑ Use resources from a funded study to support an unfunded study in the same institution
 - ❑ Remote monitoring
 - ❑ provide checklist for “self monitoring” by site
 - ❑ anonymised reports

Monitoring Your Study

- ❑ What helps?
 - ❑ Focus on essential data
 - ❑ Peer review end points
 - ❑ Sample monitor – quality check
 - ❑ Statistical analysis for trends and anomalies in submitted data

Pharmacovigilance

- What helps?
 - Clear forms/tick boxes
 - Training
 - IBs/SMPCs/Disease
 - Store in format compatible with reporting
 - Hospitalisation log
 - Survival log
 - SAE exclusion criteria
 - Anomalies or mistakes?
 - document, document, document

CRFs

- ❑ KISS principle
 - ❑ Demographics
 - ❑ Epidemiology
 - ❑ End points
 - ❑ Safety

If you don't crunch it – you don't need it!

Study Site Assessment

- Collegial approach to all comers not viable
- Local resources vital
 - timely submission and recruitment
- Exposure of Sponsor an issue
 - Essential documents
 - Pharmacovigilance

Profile for Success?

- ❑ Plan ahead
 - ❑ science and resources
- ❑ Group wide scientific strategy
 - ❑ timely submission and recruitment
- ❑ Limit number of countries/sites
- ❑ Centralise the paperwork

Conclusion

- ❑ Academic research no longer a “weekend activity”
- ❑ Requires greater commitment
- ❑ Be creative
 - ❑ Explore options/resources
- ❑ Adapt
 - ❑ The more you do the better you get