



University College Dublin
An Coláiste Ollscoile, Baile Átha Cliath

Strengthening Regulatory Science: An Academic Sponsor's Perspective

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Enthusiastic investigator

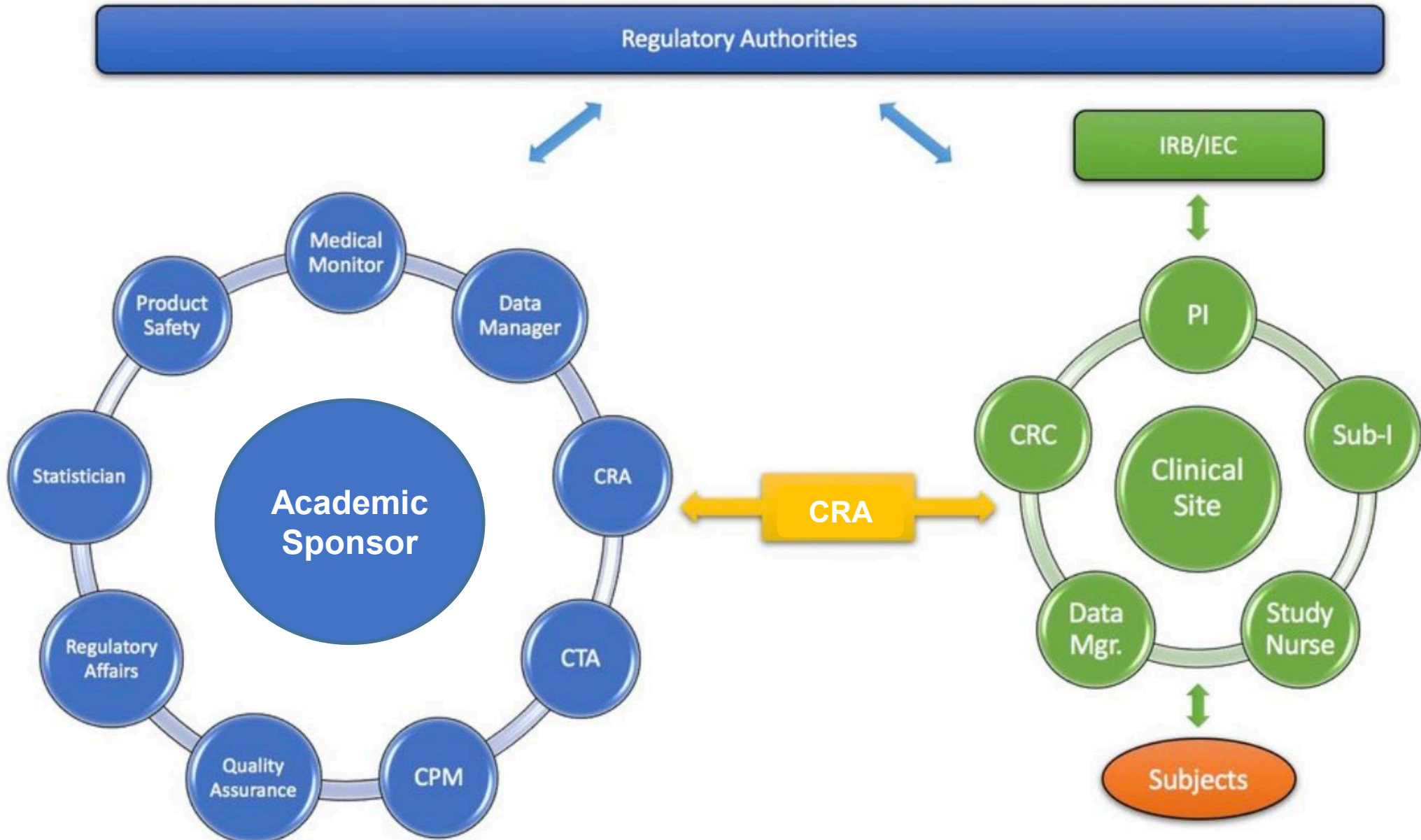
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A novel and impactful research idea
= ability to answer important medically significant questions to improve patient outcomes

In order to start an academic investigator-initiated clinical trial, need to demonstrate:

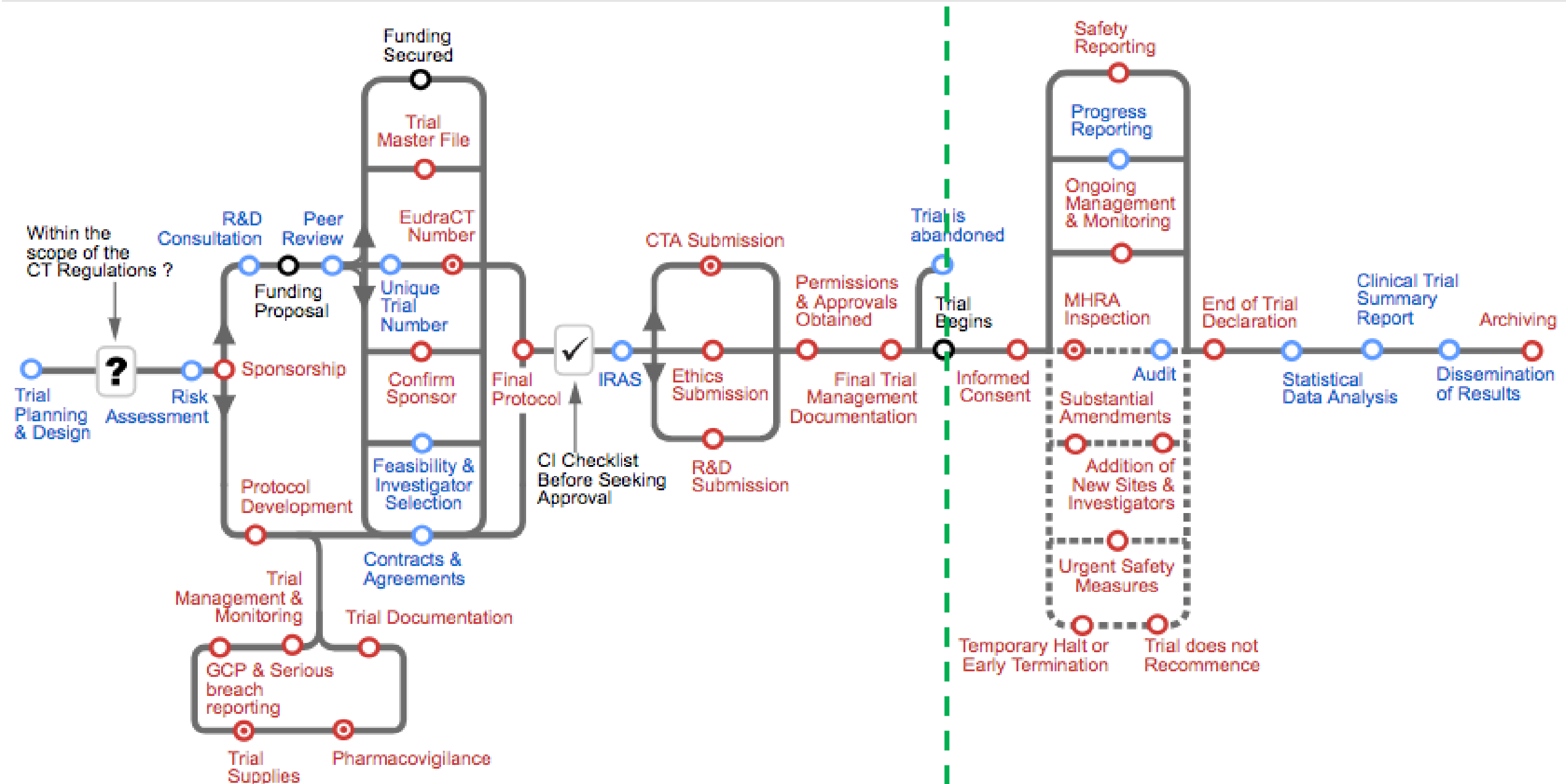
- Formal sponsorship model
- Appropriate funding
- Regulatory expertise
- Established & experienced collaborators
- Robust quality framework

Regulated Clinical Trials in Academia



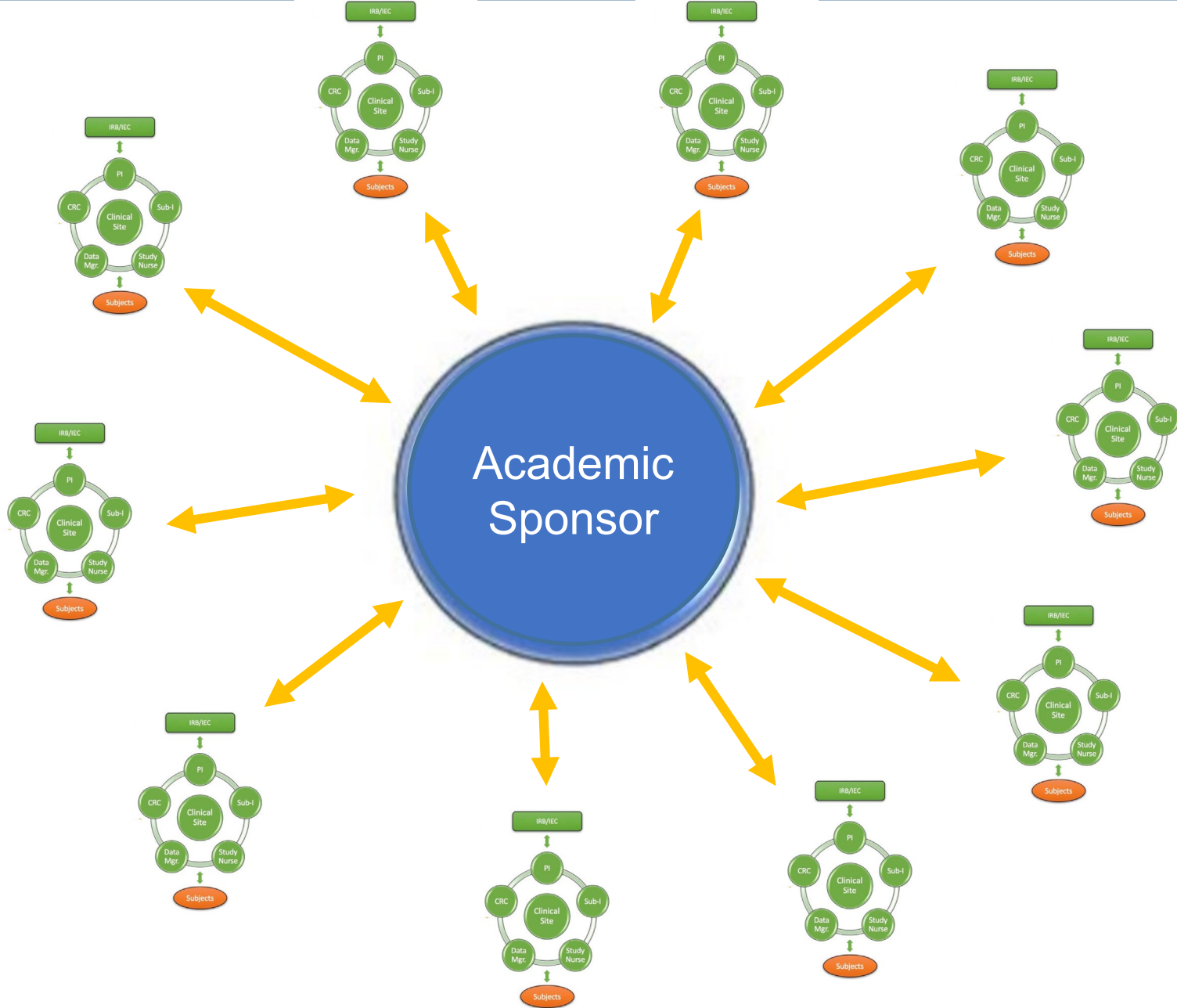


Regulatory obstacles in academic Investigator-initiated clinical trials

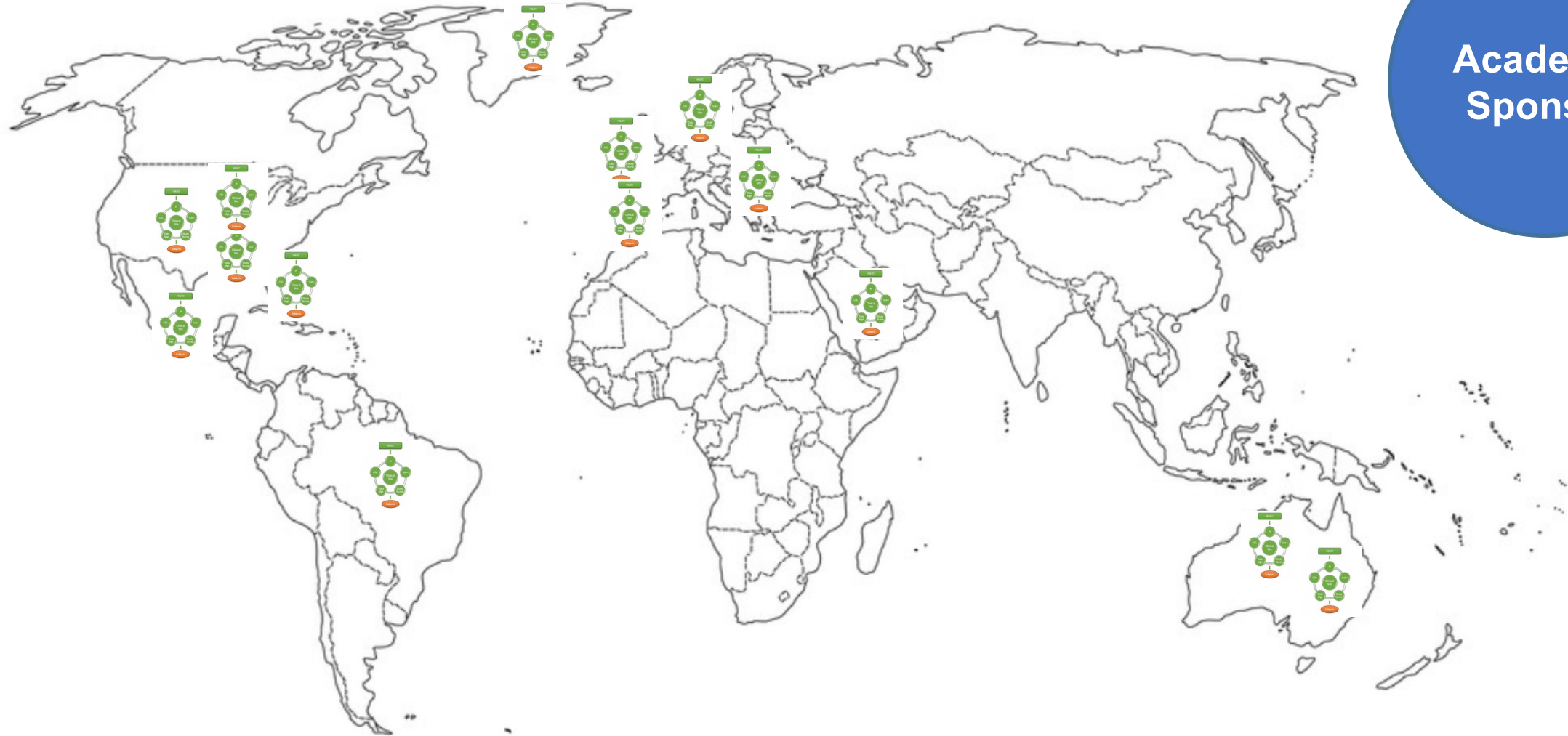


Regulated Clinical Trials in Academia

REGULATORY
AUTHORITIES



Regulated Clinical Trials in Academia – Increasing complexity.....



Academic Sponsor

Throughout the life of the trial academic sponsors are required to ensure:

- Local regulatory requirements are adhered to (including translations)
- Provision of adequate and thorough training and monitoring
- Compliance with: Protocol, ICH GCP, SOPs, Regulations (CTR & GDPR)
- IMP management – supply, management, labelling
- Robust quality management system
- Ongoing documented risk assessment

Maintain patient safety and scientific integrity of the trial

- Improve knowledge on regulatory issues in the academic world
- Improve the dialogue and communication between relevant stakeholders
- Strengthen the support for successful outcomes for regulatory scientific advice
- Nurture a positive regulatory/research environment for academia
- Encourage collaboration between academic institutes