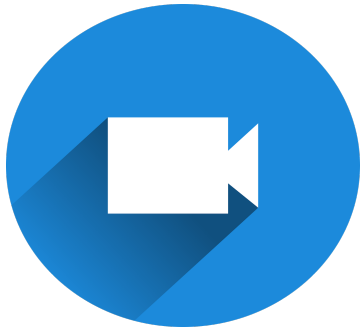
The Essentials of Research Sponsorship

NHS
Research and
Development Forum

Housekeeping



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Welcome

Please share a little bit about yourselves or let me know in Slido what you are hoping to get from this session.

Outline

1 hour training workshop: A general overview (NHS Essentials of Research)

By the end of the session you should understand:

1. The evolving role of the Sponsor in a health care setting
2. Main Sponsor responsibilities
3. Key areas of practice & challenge

We also hope that you will take away some great ideas of where to go next in your Sponsorship journey.

What is a Sponsor?

"The individual organisation or partnership that takes on overall **responsibility** for **proportionate, effective arrangements** being in place to **set up**, **run** and **report** a **research** project"

(UK Policy Framework for Health and Social Care Research)

Who can act as Sponsor?

- Employing Organisation
- Funder
- Charity
- University Partner
- Other

Sponsors Role Defined in Regulation, UK Policy & Guidance

Table 1. (Reproduced with kind permission from the MHRA Guide ISBN 978 0 11 708107 9)

Sponsor's Function and Responsibilities	UK SI 2004/1031 Reference
A. Authorisation for clinical trials and research ethics committee opinion	
Obtain required authorisations to commence the trial (clinical trial authorisation and favourable ethics committee opinion)	**Part 3:** Regs. 12, 13, 17, 18, 19 and 20 Schedules 3,4 and 5
Keep records of all amendments to the authorisations and obtain approval where approvals are required	**Part 3:** Regs. 22, 24, 25 and 26
Produce undertaking to allow inspection of premises in third countries if required	**Part 3:** Reg. 21
Notify all relevant bodies of the conclusion or termination of the trial within the specified timeframes	**Part 3:** Reg. 27
B. GCP and the conduct of clinical trials	
Ensure that the conditions and principles of Good Clinical Practice are satisfied and adhered to	**Part 4**, Reg. 28 Schedule 1
Implement and maintain quality assurance and quality control systems including appropriate SOPs for the conduct and management of clinical trials	
Ensure that the trial is conducted in accordance with the protocol and subsequent amendments	**Part 4**: Reg. 29
Utilise appropriately qualified individuals to supervise the overall conduct of the trial and prior to initiating the trial ensure all trial-related duties and functions are defined and allocated appropriately.	
Notify any serious breaches of Good Clinical Practice or the protocol, or any urgent safety measures taken to the appropriate authorities	**Part 4**: Regs. 29A and 30
Keep a trial master file to hold all documents relating to that trial	**Part 4**: Reg. 31A
Ensure trial essential documents are archived appropriately	**Part 4**: Reg. 31A

MHRA "Grey Guide"

C. Pharmacovigilance	
Ensure an investigator's brochure/product information exists for the trial and that it is validated and where required, updated annually	**Part 1**: Reg. 3A
Keep records of all adverse events relating to that trial which are reported by investigators	**Part 5**: Reg. 32
Record and report suspected unexpected serious adverse reactions to appropriate authorities within specified timelines	**Part 5**: Reg. 33
Ensure all suspected unexpected serious adverse reactions including those in third countries are entered into the European database	**Part 5**, Reg. 34
Provide an annual safety report to the appropriate bodies	**Part 5**: Reg. 35
C. Manufacture and labelling of investigational medicinal product	
Meet requirements for the authorisation to manufacture and import investigational medicinal product	**Part 6**: Regs. 36 and 37 Schedules 6, 7 and 8
Ensure appropriate manufacturing, packaging, labelling and coding of IP	
Ensure investigational medicinal product is labelled	**Part 7**: Reg. 46

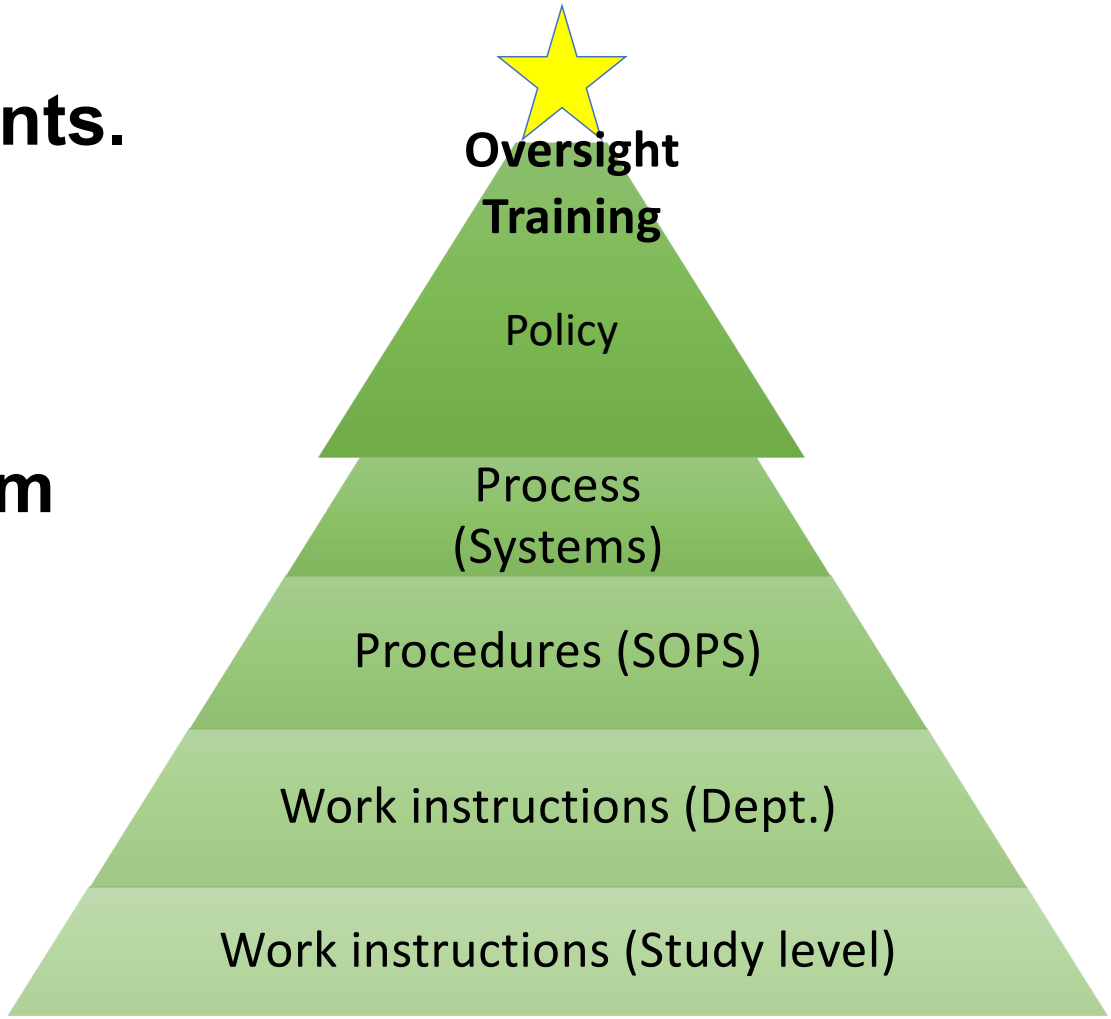
Responsible for arrangements.

What arrangements?

Quality Management System

Ensures standards in research

Assures quality in research



Along the entire research pathway:

Roles & Responsibilities

Planning | Set up | Initiation

Should we Sponsor this?
Can we have oversight of this?
Can we be ethical, safe & compliant with regulations & good science principles?
Are we ready to go?
Are we considering people?

What can we enable?
Involvement
Team Science
Early Conversations
Complete applications
Value in Research
System wide improvements e.g. IG

- 'Selecting' Qualified Investigators
- Risk Assessment
- Appropriate Peer Review: Quality of Design Public Involvement, Diversity & Inclusion
- Delegation of Responsibilities
- Research Registration
- Funding & Contracts
- Securing Regulatory Authorisations & REC
- Indemnity
- Ensuring Everything Is In Place to Start: Essential Documents & Training (Also at Sites)
- Secure Legal Rep (CTIMPS)

Roles & Responsibilities

Running

Analysis

Are we delivering as we should?
Are we compliant with regulation?
Is our data of high quality?
Are our participants safe?
Are we being transparent?
Are we able to analyse the data?

Are we considering people & our participants?

- Provide Information & Resources to Conduct & Close Down the Study
- Communication (Sites, Vendors, Research Team, Participants, Funders, Regulators)
- Ensuring Protocol, & Regulatory compliance
- Ensure Reporting (Annual & Safety)
- Monitoring (Data, Safety, Deviations, Breaches, Compliance)
- Amendments to Essential Documents
- Securing Regulatory Authorisations & REC
- Managing Feedback, Complaints & Improvements
- Audit & Inspection

Roles & Responsibilities

Reporting

Archiving

Impact

Have we reported on time?
Is our report high quality & of integrity? Are we regulatory compliant?
Are we being transparent?
Are we communicating back to those involved?
Is our data secure, complete, consistent & enduring ?
Are our findings useful?

Are we considering people & our participants?

- Ensuring End of Study Reports Submitted to Regulators & Funders on Time
- Ensuring Study Findings Communicated to All Involved Including Sites & Participants
- Ensuring Lay Summaries in the Public Domain
- Archiving of Essential Documents
- Audit & Inspection
- Data Sharing
- Appropriate Destruction of Information

Proportionate & Effective

- Understand the type of research, the legislation & standards that apply.
- Apply the relevant ones to the right research
- **Don’t treat everything as a CTIMP**
- Spend time getting to grips with the principles & work out how to apply them.
- Every project is different so you can’t just apply a tick box, one size fits all approach
- One size doesn’t fit all – but every project doesn’t come from Mars.
- Establish policies and processes that provide you with foundations for different research scenarios so you don’t have to work out everything from scratch every time.

Proportionate & Effective

- Get to know and work with your institutional ‘experts’: they may not all understand the differences between what they normally do and research (especially for data protection!)
- Help them to understand and point them to other experts who do understand research.
- Ask regulators/ REC for advice: getting approvals is not an exam with trick questions
- Take a project management approach: create plans and risk and issue logs
- Delegation of sponsor responsibilities to CIs does not mean handing it all over.
- Give them policies to work to, tools and templates to help them, staff and resources with the right expertise, and check what they are doing.

Organisational Sponsor Capability & Systems

What do we need in a Sponsor team?

- Facilitation
- Expertise
- Authorisation
- Oversight
- Funding
- Indemnity
- Support
- …?

Who might help?

- Oversight group
- Peer review database
- Community organisations
- Partner organisations
- Leadership team
- CTUs
- Funders

- Networks: Local & National
- Regulators
- NHS R&D Forum Colleagues
- NHS R&D Forum: REX
- www.rdforum.nhs.uk

What do you need now?