HANDBOOK FOR NEW PRINCIPAL INVESTIGATORS

LIVERPOOL HEALTH PARTNERS

The Academic Health Science System for Liverpool City Region

BACKGROUND AND INTRODUCTION

This handbook has been developed to help guide you as a new Principal Investigator (PI), or an aspiring Chief Investigator when you start new as a PI in the NHS. You may be a Chief Investigator for a small, lower-risk observational study that you are developing as part of your clinical academic development.

Becoming a PI should not be a daunting issue. As a PI you take on responsibilities linked to the governance and delivery of the study, with support of the R&D department (NHS) or the Research Support Office/Clinical Research Governance Team (academia) in your organisation.

A member of any clinical discipline can become a PI, with a number of National Institute of Health and Care Research (NIHR) developmental programmes aimed at clinical staff other than physicians.

This handbook is intended to act as a guide, providing steps and processes to follow, with links to point you to the best resources in clinical research.

There are some useful tools out there from other organisations, including videos and other links that you might find of further help:

- Chief Investigator Principal Investigator (CIPI) Tool, developed by Birmingham Community Healthcare NHS Foundation Trust
- Good Clinical Practice training

There are differences between being a PI and being a Chief Investigator. The following table is a good summary of this.

Responsibilities	
Chief Investigator	**Principal Investigator**
The Chief Investigator is the overall lead researcher for a research project (outside the UK the term Coordinating Investigator or Investigator may be used). In addition to their responsibilities if they are members of a research team, chief investigators are responsible for the overall conduct of a research project. The Chief Investigator's responsibilities are set out in more detail in the UK Policy Framework for Health and Social Care Research. For CTIMPs, the HRA have produced guidance with the MHRA on who can act as the CI for CTIMPs taking place in the UK. It includes a definition of the term 'Authorised Health Professional' and examples of which professions this term applies to. MHRA and HRA position on who can act as a Chief Investigator.	An individual responsible for the conduct of the research at a research site. There should be one PI for each research site. In the case of a single-site study, the chief investigator and the PI will normally be the same person.

To discuss the PI role further, please contact your organisation's R&D Manager, Director of R&D or Clinical Research Governance Team.

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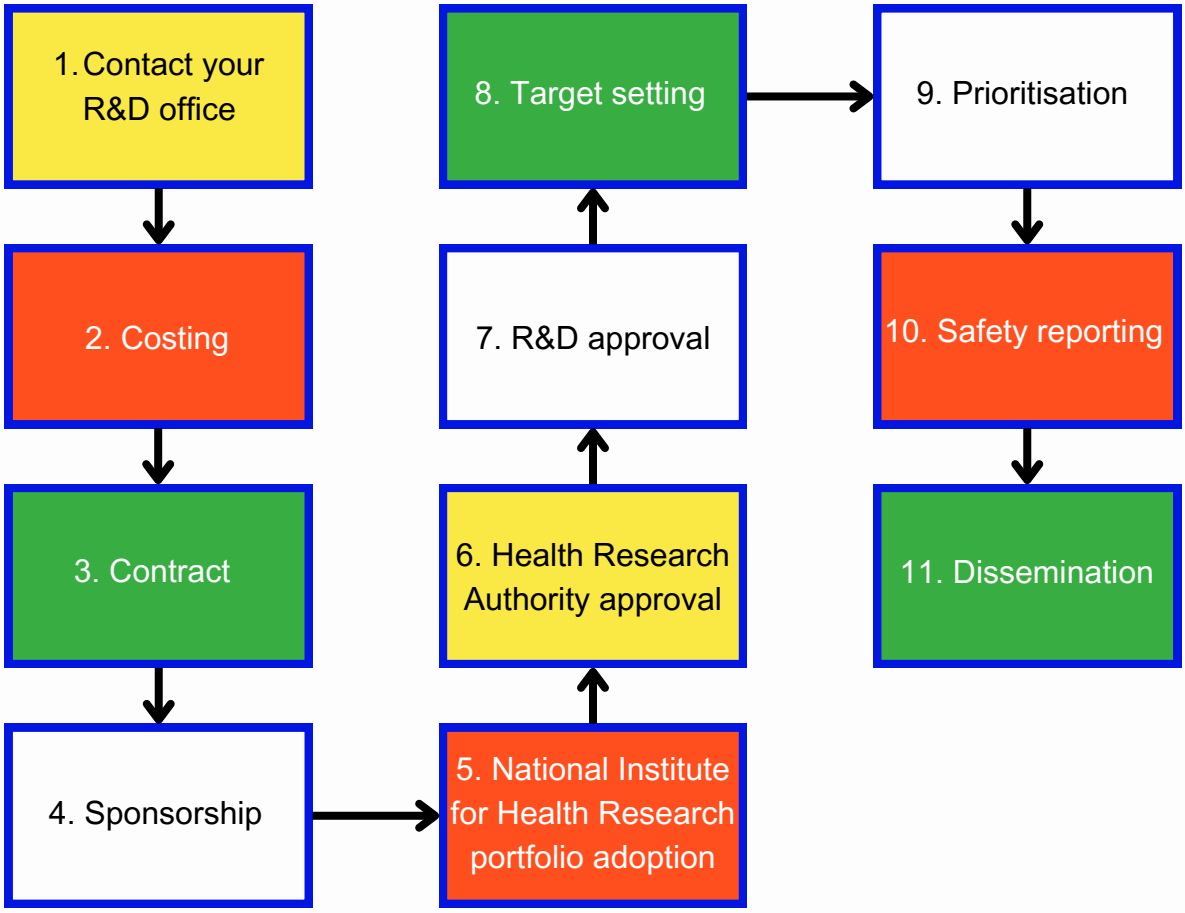
GLOSSARY OF ACRONYMS

- AcoRD – Attributing the costs of Health and Social Care Research and Development
- ADE – Adverse Device Event
- AE- Adverse Event
- AR – Adverse Reaction
- C&C – Capacity and Capability
- CDA – Confidentiality Agreement
- CI – Chief Investigator
- CPMS – Central Portfolio Management System
- CTA – Clinical Trial Agreement
- CTIMP – Clinical Trial of Investigational Medicinal Product
- fEC – full Economic Costing
- GCP – Good Clinical Practice
- HEI – Higher Education Institution
- HRA – Health Research Authority
- IMP – Investigational Medicinal Product
- IRAS – Integrated Research Application System
- JRO – Joint Research Office
- LHP – Liverpool Health Partners
- MHRA – Medicines and Healthcare products Regulatory Agency
- NIHR – National Institute for Health and care Research
- OID – Organisation Information Document
- PI – Principal Investigator
- RDN – Research Delivery Network
- REC – Research Ethics Committee
- R&D – Research & Development
- RSO – Research Support Office
- SADE – Serious Adverse Device Event
- SAE – Serious Adverse Event
- SAR – Serious Adverse Reaction
- SoECAT – Schedule of Events Cost Attribution Template
- SSUA – Study Start Up Agreement
- SUSAR – Suspected Unexpected Serious Adverse Reaction

CONTACTING YOUR LOCAL R&D OFFICE

The first step is always to contact your R&D office who will be able to guide you through the rest of the process. Some of the steps above will be determined by the type of study being done. As a PI, you are likely to take the lead on a commercial study which already has sponsorship, overall finance and generic HRA approval done. However, you will need the help of your R&D office to localise the study to your organisation. That will include identifying the costs associated with running the study at your site (which must be met by the sponsor) and ensuring that ethical approval is obtained for your site.

Flow chart of the steps for initiating clinical research as a PI.



The order is intended as a guide for new PIs; some of the steps will be determined by the type of study. Your R&D local office will guide you through the process.

COSTING RESEARCH

Properly costing research is crucial to ensure that all necessary resources are in place to successfully deliver the project.

Who is responsible?

The R&D Office supported by PI or Chief Investigator (CI) is responsible for costing their research, in collaboration with the Finance Department. In Academia, the Research Support Office will undertake this function.

Why is costing important?

Costing is essential because it determines the resources required to deliver the research, including staff, equipment, and other necessary expenses. Accurate costing ensures that your institution is adequately compensated for the work undertaken.

Costing vs. pricing your research?

- Costing: Refers to the calculation of how much it will cost your institution to conduct the research. In the UK, this is known as the Full Economic Cost (fEC) and is used by Higher Education Institutions (HEIs) during the costing process.
- Pricing: Refers to determining how much money you should request from funders based on the fEC. There is a requirement that 100% of the costs will be covered by funding.

Key cost elements in research

When costing research activities, three main elements are considered:

1.Directly incurred costs: These are costs that can be explicitly identified and recorded against a project, such as:

- Salaries for research assistants working on the project.
- Equipment purchased specifically for the project.
- Travel directly related to the project.
- Materials and supplies bought exclusively for the project.

2. Directly allocated costs: These are costs attributable to the project but estimated rather than directly recorded, including:

- A portion of your time spent on the project (e.g. 10% of your working hours)
- Shared resources or pool staff that contribute to the project.
- Use of space in your institution’s building.

3. Indirect costs: These cover the general costs of running your institution that are not directly linked to the project but need to be funded, such as:

- HR, Finance, and IT infrastructure.
- General administration costs.

Calculating costs

The methods for calculating Directly Allocated costs and Indirect costs are complex and may change over time. Your organisation R&D Office or the Grants team at the JRO will support you with this.

You must engage with your institution's Research Support Office and local finance teams to ensure the full NHS costs will be covered.

SoECAT: Schedule of Events Cost Attribution Template

What is SoECAT?

SoECAT (Schedule of Events Cost Attribution Template) is a tool used to clearly differentiate between the various costs associated with clinical research studies. It ensures proper cost attribution among research costs, NHS service support costs, and Excess Treatment Costs, providing clarity on funding responsibilities between funding bodies, NHS trusts, and research teams.

Function of SoECAT

The primary function of SoECAT is to:

Distinguish between different cost types:

- Research costs: Direct costs of conducting the research.
- Service support costs: Costs incurred by the NHS to support the research.
- Excess treatment costs: Additional costs of patient care incurred due to the research, above the standard NHS treatment.

Ensure compliance with funding frameworks: Accurate attribution in line with the NIHR AcoRD (Attributing the Costs of Health and Social Care Research and Development) guidelines is crucial for funding compliance and transparent financial management. The guidance provides a framework for the NHS and its partners to identify, recover and attribute the costs of health and social care research in a transparent and consistent way.

When is SoECAT required?

SoECAT is required for all clinical research studies involving NHS staff or facilities, whether conducted at a single site or across multiple sites. Proper completion of SoECAT is mandatory to ensure all stakeholders are aware of their financial responsibilities.

Online creation of SoECAT

Since 2023, SoECAT is created online via the Central Portfolio Management System (CPMS). To complete the SoECAT, you need to generate an Integrated Research Application System (IRAS) ID by logging into the IRAS website and creating a new project with minimal initial details, such as a short title. Guidance on obtaining an IRAS ID can be found on the IRAS website.

Timescales to consider

- Approval from investigators: Before submission, the SoECAT must be reviewed and approved by the research team.
- Grant applications: For single-stage or final-stage grant applications, the SoECAT must go through a review and authorisation process by the Research Delivery Network (RDN). It is recommended to allow up to 10 working days for this process.

Required documents for SoECAT

To complete the SoECAT, investigators need to provide:

- Study synopsis: A brief summary outlining the research study's objectives, design, and methods.
- Patient pathway: A detailed description or diagram highlighting research activities, including: Who will conduct the activities, the duration of each activity and the timeline of when activities will take place.
- Standard vs. research-specific activities: Clearly outline which parts of the research activities are standard NHS care and which are additional research-specific activities.

Getting started with SoECAT

To initiate SoECAT:

Contact resources: There are three different contact points for this. You can go via:

- The Joint Research Office.
- Your local R&D Office.
- The Research Delivery Network where you can obtain more information and access the proforma.

Visit the NIHR website for more guidance.

Accurate completion of SoECAT ensures your study meets compliance standards and secures the necessary funding to support the various aspects of your research.

SPONSORSHIP

Sponsorship is a key aspect of research governance, ensuring that research projects are conducted in compliance with ethical, regulatory, and legal standards. It is mandatory for all health and social care research, particularly those involving NHS patients, their tissue, or information.

Who is responsible?

The Chief Investigator (CI) is responsible for securing Sponsorship, supported by the R&D Office or Clinical Research Governance Team.

Why is sponsorship important?

A sponsor is the organisation or partnership that takes overall responsibility for ensuring that effective arrangements are in place to set up, run, and report a research project. All health and social care research must have a sponsor, including research involving NHS patients, their tissue, or information. The sponsor may delegate specific tasks to individuals or organisations that are willing and able to undertake them.

For clinical trials of an investigational medicinal product (CTIMP), it is a legal requirement to have a Sponsor. The Sponsor ensures that the trial complies with legislation and Good Clinical Practice (GCP) standards. More information can be found on the NIHR website.

Who can be a sponsor?

- The Sponsor is usually the substantive employing organisation of the Chief Investigator.
- Commercial funders may also serve as Sponsors.
- The Sponsor does not need to be the host of the grant.

How to apply for sponsorship?

Sponsorship must be applied for and confirmed in writing; it cannot be assumed. Generally, Sponsorship is applied for once external funding is secured. Here's how to apply:

1. Download the JRO Sponsorship Application Form from the JRO website.
2. Submit the following documents to the proposed sponsor:
    - Completed Sponsorship Application Form
    - Comprehensive study Protocol
    - Evidence of Funding
    - Independent Peer Review
    - The CI's CV and GCP Certificate

Preparation is key

Investigators should be well-prepared, as obtaining Sponsorship and regulatory approvals can take more than three months (approximately one month for Sponsorship and 60 days for ethical and MHRA approvals).

Key preparation tips:

- **Start early:** Apply well in advance to allow time for application review and potential resubmissions.
- **Submit a high-quality application:** Ensure your application addresses all ethical, regulatory, and governance issues. A well-prepared submission helps the review committees assess your project more smoothly and may prevent delays caused by the need for clarifications or resubmissions.
- **Avoid delays:** Poor-quality applications often result in requests for additional information, which can significantly delay the approval process.

R&D APPROVAL (CONFIRMATION OF CAPACITY AND CAPABILITY)

Before initiating your research, it's essential to connect with the R&D Office or the Research Support Office at your host organisation. This step ensures that your study aligns with the required governance, legal, and financial protocols essential for conducting research within the NHS and Academia.

Who is responsible?

The responsibility for obtaining R&D Approval (also known as Confirmation of Capacity and Capability [C&C]) lies primarily with the PI or CI. They are supported by the R&D Office/Research Support Office and the Finance Department, working together to manage all aspects of the study, including research compliance and financial oversight.

Why is R&D approval important?

R&D Approval is a critical component of research governance within the NHS and academia. It ensures that your study meets all legal and ethical standards, including proper indemnity and risk management. This approval safeguards participants and the institution, making it a mandatory step before commencing any research activities.

Role of R&D offices

R&D Offices are key to managing research within NHS organisations or joint entities, such as NHS Trusts and local universities. Their roles include:

- Overseeing the setup of research projects to ensure all necessary approvals are in place.
- Providing guidance to the CI on regulatory and governance requirements.
- Managing risks associated with the research.

Role of Research Support Office

In academic institutions there is usually a central Research Support Office, which supports the following areas:

- Pre-Award Team - Costing support, advice on funder schemes and terms and conditions, assistance with grant acceptance and getting a cost centre.
- Post-Award Team - Claims and financial reporting, payment of invoices for partners and/or subcontractors, applying for Grant extensions and close down of projects.
- Research Ethics and Research Integrity Team - The team help to support the culture of research ethics and research integrity within the University and operates the frameworks which aim to ensure that all research activities are undertaken in a way that safeguards the dignity, rights, health, safety, and privacy of all those involved.

R&D approval explained

R&D Approval is essential for ensuring compliance with legal requirements and obtaining appropriate indemnity for research studies. It is mandatory for:

- Clinical trials conducted on NHS premises.
- Research involving NHS patients, staff, or resources.

The R&D Office ensures that all relevant approvals, including ethical and regulatory, are secured before the study begins.

When is R&D approval required?

R&D Approval is required for any clinical trials or research projects that involve:

- NHS premises.
- NHS patients, staff, or resources.

The R&D Office must verify that all necessary approvals (e.g., HRA, REC, MHRA) are in place before the research can proceed within their organisation.

Universities do not issue R&D approval, but where they are the Sponsor, they will ensure that all necessary approvals (e.g., HRA, REC, MHRA) are in place before the research can proceed to opening at any site.

Sponsorship

R&D Offices also have responsibilities regarding sponsorship:

- **As a sponsor:** The R&D office guides the CI, oversees the trials, and manages associated risks.
- **As a host:** They facilitate the setup of externally sponsored trials and support Principal Investigators.

Research awareness

R&D Offices must be aware of all research projects involving their organisation's staff, patients, or resources to ensure proper oversight and compliance with institutional policies.

Early consultation

Early engagement with the R&D office is recommended during the study development phase. This allows researchers to:

- Access valuable support and resources.
- Identify all required approvals and proactively address any potential issues.

Cost allocation

A key aspect of R&D approval is defining cost allocation, which involves differentiating between:

- **Research costs:** Direct costs related to conducting the research.
- **NHS service support costs:** Costs incurred by the NHS to support the research.
- **Treatment costs:** Additional costs associated with the treatment provided within the study.

For guidance on cost allocation, contact the Liverpool Health Partners Joint Research Office and refer to the Department of Health's AcoRD framework.

Good practice

Research must adhere to good practice principles in clinical trial management and conduct, including, but not limited to, Good Clinical Practice (GCP), UK Policy Framework for Health and Social Care Research, and The Medicines for Human Use (Clinical Trials) Regulations 2004. This includes maintaining ethical standards, ensuring data integrity, and safeguarding participant welfare.

Study documentation

R&D Offices require specific documentation to assess the feasibility, capability, costs, and risks associated with the study. This may include:

- A study protocol.
- Patient pathways.
- Cost attribution details.

Documentation requirements may vary based on the host organisation, lead NHS Trust, and the study’s nature.

HRA APPROVAL

Health Research Authority (HRA) approval is a critical step in setting up research within the NHS and social care sector. This approval ensures that the study has undergone the appropriate ethical and regulatory review to protect participants.

Who is responsible?

The Sponsor or CI is responsible for obtaining HRA approval. As a PI, you must receive and review the HRA approval before your site is opened for the study.

Why is HRA approval important?

HRA approval provides assurance that the study is safe and ethical. It involves a national review process that evaluates the study's adherence to ethical and regulatory standards, ensuring participant protection.

What is HRA approval?

HRA approval is a review conducted by the Health Research Authority, which oversees all research conducted in the NHS and social care sector. This review confirms that the study meets all necessary ethical and regulatory requirements. The review is carried out through a REC formed by individuals from clinical and non-clinical roles, and members of the public. The committee will look at how ethical the study is, the suitability, clarity, and accuracy of the participant information documentation. Their role is to ensure participants are protected from any unintended harm derived from the study design.

Who gets involved and who do I deal with?

- **Sponsor and CI:** They apply for HRA approval for their research.
- **PI:** You must review the HRA approval specific to your site as part of the site setup process.

Where to get the proforma or contact for more information

HRA approval documents will be provided to you and your research department as part of the site setup process. You do not need to apply for these directly. The document pack typically includes:

- IRAS application form
- Study protocol and patient-facing documents
- Ethical and regulatory approval letters
- HRA approval letter

Why do we need HRA approval?

The HRA approval letter assures that the study is safe and ethical for NHS conduct, provided you adhere to the approved documents and any conditions imposed.

Key considerations when reviewing HRA approval:

1. Approved documents: The HRA approval letter includes a list of documents approved for use in the study. As the PI, you must ensure that these versions are used at your site.
2. Study conditions: The HRA letter outlines conditions under “Information to Support Study Setup.” You must comply with these conditions to conduct the study at your site.
3. IRAS form review: The IRAS form contains details on study conduct, including recruitment and consent processes. Pay particular attention to:

- Who is authorised to obtain consent.
- The minimum time participants are given to decide on participation.
- Ensuring your Trust is correctly listed as a participating site and its role. e.g., full research site or Participant Identification Centre (sites that only identify potential participants for a study which is run at a full research site. They could be primary care practices, as an example).

NIHR PORTFOLIO ADOPTION

The National Institute for Health and Care Research (NIHR) Clinical Research Network (CRN) Portfolio of studies consists of clinical research studies that are eligible for support from the NIHR CRN in England.

There are two main benefits from NIHR portfolio adoption:

- Your study has access to support from funded research staff (e.g. research nurses) at each research site located in the NHS.
- Participant recruitment to your study contributes to the NHS trust annual research recruitment goals.

A study is eligible to secure NIHR portfolio adoption if:

- It is funded by an NIHR grant.
- It is funded by an NIHR partner organisation.
- It is funded by a company (this requires a funding award letter and a minimum of two independent peer reviews).

Where to get help or ask questions

- For queries about document review, consult your Research Setup Team within your Trust.
- For questions regarding the interpretation of conditions or the HRA application, contact your study Sponsor or CI.

RESEARCH STUDY CONTRACT

Who is responsible?

The NHS Trust where the study activities are conducted is the legal entity responsible for entering into contracts related to the study. While PIs may be asked to acknowledge their responsibilities within the contract, they are not a contracting party. The Sponsor is also responsible for ensuring that all required contracts are in place before study activity begins with any organisation.

When do contracts commence?

Contract negotiations typically begin at the feasibility stage. During this stage, the NHS Trust will enter into a Confidentiality Agreement (CDA) to allow the sharing of study-specific confidential information, enabling the PI to assess whether the study is of interest.

Types of contracts

If the study proceeds and the NHS Trust is selected as a site, the appropriate type of contract will be required, depending on the nature of the study:

- **Commercial contracts:** For commercial studies, a Clinical Trial Agreement (CTA) will be needed.
- **Non-commercial contracts:** For non-commercial studies, a UK Model Agreement for non-commercial research or an Organisation Information Document (OID) (for non-CTIMPs) will be used.

The contracting process aligns with the commercial or non-commercial costing review managed by your R&D Office. There is a comprehensive list of contract types on the IRAS website.

Study Start Up Agreement (SSUA)

Some commercial Sponsors may require a Study Start Up Agreement (SSUA). This is a precursor to the Clinical Trial Agreement and outlines specific setup timelines and fees payable for tasks conducted during the setup phase. SSUAs are typically used in studies that are set up globally and clearly detail the income the Trust will receive if, through no fault of the Trust, the study is withdrawn before the formal issue of Capacity and Capability (C&C).

Importance of contracts

Ensuring that appropriate contracts are reviewed and executed by all parties is crucial for protecting both you and your NHS Trust. Contracts help manage risks and clearly outline roles, responsibilities, and financial arrangements associated with the study.

Key points to remember:

- **No disclosure without contracts:** No study documentation should be disclosed to you, and no study activity should be undertaken until all appropriate contracts are fully executed.
- **Risk management:** Contracts provide legal and financial protection, ensuring that all parties are aware of their obligations and liabilities.

Properly managed contracts are vital for safeguarding the interests of all parties involved and ensuring the smooth operation of the research study within the NHS environment.

SAFETY REPORTING (PHARMACOVIGILANCE)

Who is responsible?

The PI or CI is responsible for safety reporting (also known as pharmacovigilance), supported by the R&D Office.

Why is Pharmacovigilance important?

Pharmacovigilance is critical for research governance, compliance, and, most importantly, patient safety. It involves the science and activities related to the detection, assessment, understanding, and prevention of adverse effects or any other medicine or vaccine-related problems.

What is an Adverse Event?

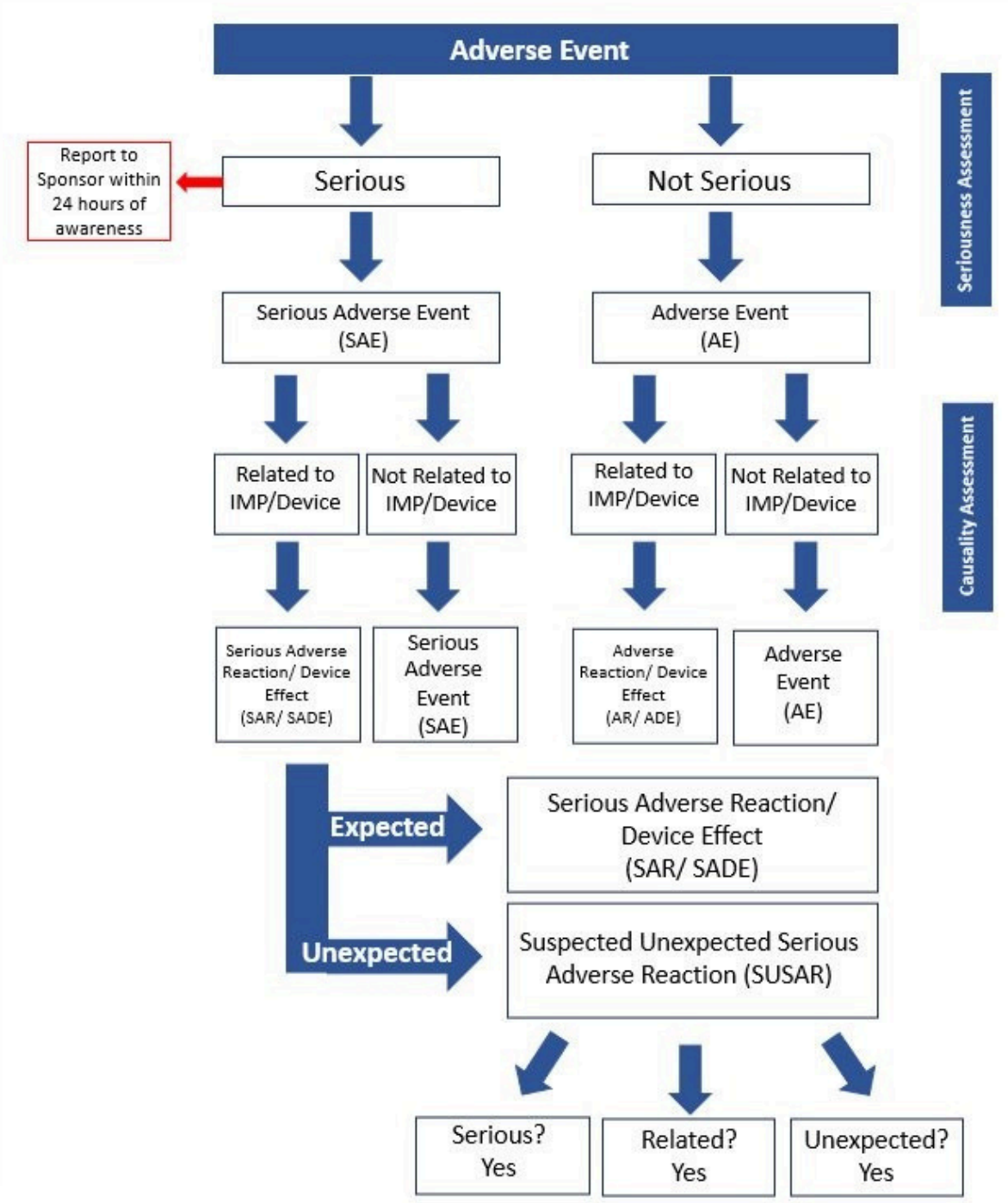
Term	Definition
AE/SAE (Adverse event/ Serious adverse event)	Any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have to have a causal relationship with this treatment. AEs are considered serious if they meet the seriousness criteria.
AR/SAR (Adverse reaction, Serious adverse reaction)	Any untoward and unintended response to an investigational medicinal product related to any dose administered. ARs are considered serious if they meet the seriousness criteria.
SUSAR (Suspected unexpected serious adverse reaction)	An adverse reaction that is both unexpected (not consistent with the applicable product information) and also meets the definition of a Serious Adverse Reaction.
ADE/SADE (Adverse device event/ Serious adverse device event)	Any adverse event related to the use of an investigational medical device or a comparator. ADEs are considered serious if they meet the seriousness criteria.

When are Adverse Events considered serious?

An adverse event is considered serious if it results in any of the following:

1. **Death**
2. **Life-Threatening:** Poses an immediate risk to life.
3. **Hospitalisation:** Requires hospital admission or extends an existing hospital stay.
4. **Disability or Incapacity:** Results in significant or persistent disability.
5. **Congenital Anomaly or Birth Defect:** Causes a congenital condition in a child.
6. **Other Medically Significant Events:** Any other event considered serious by the investigator.

Reporting timelines for Adverse Events



Clinical Trial of Investigational Medicinal Products (CTIMP) reporting timelines:

Serious Adverse Events (SAEs): Must be reported to the Sponsor within 24 hours of the investigator becoming aware of the event.

Suspected Unexpected Serious Adverse Reactions (SUSARs):

- Resulting in death or life-threatening: Must be reported to the Medicines and Healthcare products Regulatory Agency (MHRA) and the Research Ethics Committee (REC) within 7 days of the Sponsor becoming aware.
- All other seriousness criteria: Report to the MHRA and REC within 15 days of the Sponsor becoming aware.

Device reporting timelines:

SAEs, Device Deficiencies, or New Findings/Updates:

- Report to the Sponsor within 24 hours of awareness.
- Serious public health threats: Manufacturer must notify the MHRA within 2 calendar days of awareness.
- Events resulting in death or serious health deterioration: Notify MHRA within 10 calendar days of awareness.
- All other reportable events: Must be reported to MHRA within 30 calendar days of awareness.

Non-CTIMP reporting timelines:

Unexpected and related SAEs: These must be submitted to the REC within 15 days of the CI becoming aware of the event.

Urgent safety measures

Urgent safety measures should be reported immediately by telephone, followed by written documentation within 3 days. This ensures immediate action can be taken to protect participants from any immediate hazard to their health or safety.

Key takeaways for investigators

- Timeliness and accuracy: Prompt and accurate reporting is essential to maintain participant safety and comply with regulatory requirements.
- Communication with sponsor: Always inform the Sponsor within the stipulated timelines as they coordinate further reporting to the appropriate regulatory bodies.
- Documentation: Keep thorough records of all adverse events, communications, and actions taken as part of your study's pharmacovigilance activities.

These guidelines are crucial for maintaining compliance and ensuring the safety of participants in clinical trials. Always consult with your Sponsor or R&D Office if you are unsure about any reporting requirements or procedures.

TARGETS

Achieving recruitment targets is critical to the success of your study and meeting contractual obligations. Here's a guide on how to manage and meet these targets effectively:

Who is responsible?

The CI and PI are responsible for ensuring that recruitment targets are met as outlined in the study contract.

Why is this important?

Meeting recruitment targets is often tied to the release of funds from the NIHR or other funders. Failure to meet these targets can impact the funding and overall success of the study.

Key considerations for achieving targets:

1. **Define your population:** Carefully review inclusion and exclusion criteria to target the right participants.
2. **Avoid excessive screening:** Screening too many to find few eligible participants can waste resources.
3. **Understand financials:** Be aware of the funding structure; fees are usually front loaded in relation to recruitment and consent.
4. **Set realistic targets:** Be conservative with projections; overachieving modest targets is preferable.
5. **Avoid over-optimism:** Plan for realistic consent rates, typically around 1 in 10 eligible participants.
6. **Consider other studies:** Avoid competing for participants with similar studies.
7. **Strategic patient pathways:** Identify where and when to approach patients in their care pathway.
8. **Promote equity of access:** Ensure fair access for all eligible participants, including minority groups.
9. **Monitor and adjust:** Use tracking systems to monitor recruitment and address issues early.
10. **Support your team:** Keep morale high by recognizing and rewarding achievements.

Key takeaways:

- Accurate and strategic planning for participant recruitment is essential.
- Regular monitoring and adjustments based on ongoing recruitment data help in meeting the targets efficiently.
- Communication with your team and maintaining morale are just as crucial as the recruitment process itself.

PRIORITSATION

Why is this important?

Prioritisation ensures that study objectives are met, deadlines are adhered to, and research activities are balanced with clinical responsibilities.

Key considerations:

1. **Protect research time:** Clearly define, fund, and safeguard research time to prevent clinical duties from encroaching on study activities. Your organisation is responsible for providing SPA time in your contract to allow for research time as part of your job plan.
2. **Adhere to governance:** Maintaining strict adherence to study governance and protocols is crucial; lapses can have serious consequences.
3. **Prioritise research issues:** Treat research problems, including adverse events and endpoints, with the same urgency as clinical issues. Rapid reporting is essential.
4. **Work as a team:** Being part of a team enhances safety, efficiency, and provides mutual support.
5. **Hold regular team meetings:** Use meetings to monitor study performance, address challenges, and set priorities.
6. **Manage time and targets:** Focus on timely setup and early recruitment to stay on track with targets and deadlines.
7. **Plan for absences:** Arrange cover for research duties when you are off-site or on leave to maintain continuity.
8. **Communicate effectively:** If leading a multicentre trial, use newsletters or regular updates to keep all centres informed and aligned.
9. **Risk mitigation:** Predicting and preventing risk occurrence will improve performance and compliance.

DISSEMINATION

Dissemination means sharing your research findings with people who will benefit from understanding them. To maximise the benefits of the research you have done, your findings need to be communicated effectively and without delay.

There are a number of things to keep in mind when making your research results public:

- You need to be clear on who are the audience you try to reach; the way you write or present the information will be very different. Consider whether they are the general public, patients, healthcare professionals or academics.
- You need to consider the different ways you can disseminate your data: video clips, written papers in professional journals, conference poster, abstract, social media.
- What is the main message you want to share? Ensure it is written in very clear and plain English when targeting public and patients.
- You should also consider any aspects of the research that might still be confidential, and anything that could be linked to any intellectual property.

Your R&D department or Research Support Office can provide you with advice and guidance of the dissemination process.

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