Routemap

Sponsorship

Trial Planning Phase

The Sponsorship station follows the Risk Assessment station and precedes a parallel process in which the Protocol is developed and R&D Consultation takes place. Sponsorship is a legal requirement which is relevant to all trials. This station is part of the 'trial planning phase' group of stations.

Sponsorship is required for studies under the UK Policy Framework for Health and Social Care Research including trials that that fall within the scope of the Clinical Trial Regulations. It may take some time to secure a sponsor(s)*, so identification of the sponsor must be considered early in the planning process.

**Note: More than one entity can sponsor a clinical trial. This is referred to as joint or co-sponsorship.*

For Clinical Trials of Investigational Medicinal Products (CTIMPs), the term sponsor is defined in the Clinical Trial Regulations as: the person who takes responsibility for the initiation, management, and financing (or arranging the financing) of that trial. The person(s) responsible for the sponsor's functions must also be named on the Clinical Trial Authorisation (CTA).

The sponsor has specific legal responsibilities under the Clinical Trials Regulations. Before initiating a trial, the sponsor should define, establish and allocate all trial-related duties and functions. The NHS R&D Forum Sponsorship Principles document provides a comprehensive summary of requirements, including various models of sponsorship and guidance on the allocation of

responsibilities, duties or functions.

Brexit

From 1st January 2021, UK sponsors conducting CTIMPs with sites in the European Economic Area (EEA), must establish a legal representative in a country on the approved country list (currently all countries in the EU/EEA). Further guidance on the requirements for a legal representative can be found in the Sponsorship Principles document. In addition, the MHRA has produced guidance on the requirements for substantial amendments relating to changing the sponsor or legal representative of a clinical trial.

Further reading:

- Insurance and compensation in the event of injury in Phase I clinical trials: (.PDF) Guidance developed by the Association for the British Pharmaceutical Industry, the Bio Industry Association and the Clinical Contract Research Association, in consultation with the Department of Health and the National Research Ethics Service.
- NHS R&D Forum webpages: Resources, training and a community of practice for non-commercial sponsor organisations.

Brexit:

- Guidance on substantial amendments to a clinical trial.