Routemap

Trial Supplies

Trial Planning Phase

The Trial Supplies station follows the Trial Documentation station and precedes the Pharmacovigilance station. Trial Supplies is a legal requirement and is specific for trials within the Clinical Trial Regulations scope. This station is part of the 'trial planning phase' group of stations.

To ensure all regulatory and governance requirements are met, it is essential that investigators obtain advice and support from those with specialist knowledge relating to Investigational Medicinal product (IMP) supplies (for example from a Clinical Trial Pharmacist, Clinical Trials Unit (CTU) or Contract Research Organisation (CRO)).

Advice should be sought early in the trial planning process as requirements may impact on trial design and any funding application.

The status of the IMP used in a clinical trial influences the reference document that may be required. The MHRA Risk-adapted Approaches to the Management of Clinical Trials of Investigational Medicinal Products (PDF) (.PDF) gives the following guidance:

"*If the IMP is authorised in any EU Member State and is used according to the terms of the marketing authorisation, the Summary of Product Characteristics (SmPC) will replace the Investigator's Brochure. If the IMP is authorised in an ICH country (USA or Japan) a copy of the prescriber's information (equivalent to the SmPC) will replace the Investigator's Brochure.*

If this document is originally in a language other than English, an English translation should be provided.

When the conditions of use in the clinical trial differ from those authorised, the SmPC or equivalent should be complemented with a summary of relevant data that support the use of the IMP in the clinical trial. This can be provided as an Investigator's Brochure or, in some cases, may be incorporated into the protocol.'"

Where an Investigator's Brochure (IB) is required for a non-commercial trial, it may be supplied by the Marketing Authorisation Holder of the IMP under trial. If it cannot be obtained from the Marketing Authorisation Holder or the IMP is being developed 'in house', the sponsor **must ensure** that an IB is produced.

Pharmacy Assurance

Pharmacy Assurance process a single technical review for eligible studies across the UK. Further information can be found on the IRAS webpages. The process involves the completion of a single pharmacy technical review per study, which can be used to streamline the pharmacy capacity and capability assessment carried out by each participating site.

Brexit Transition

The MHRA has published Guidance on how medicines will be regulated after 31st December 2020. This guidance includes information on Importing IMP from countries on a list to Great Britain (England, Wales and Scotland) and a confirmation of the List of Approved Countries for clinical trials and IMP from the 1st January 2021. In addition, the MHRA has produced guidance on the requirements for substantial amendments relating to Investigational medicinal product (IMP) certification and importation following Brexit.

Further reading:

Brexit:

- Importing investigational medicinal products into Great Britain from approved countries.
- Supplying investigational medicinal products to Northern Ireland.

- Guidance on substantial amendments to a clinical trial relating to IMP certification and importation.