**Investigational Medicinal Product Management (IMP) in Teletrials**

IMP in a teletrial cluster can be managed in two ways:

1. IMP is shipped directly to the satellite sites from study sponsor
2. IMP is shipped to the primary site only from study sponsor and the primary site is responsible for transferring individual patient allocated IMP to the satellite sites to be dispensed/administered to study subject

| **IMP Management** | **Required capabilities Primary Site** | **Required capabilities****Satellite Site** | **Considerations** |
| --- | --- | --- | --- |
| 1. IMP shipped directly to satellites from trial sponsor
 | Limited involvement of primary site pharmacy | Clinical Trials Pharmacist to manage trial drug accountability and IWRS system (as required)For IMP presentations requiring compounding before administration: Compounding capability for relevant IMP or acceptable SOP for transfer of IMP to a third-party compounding facility.  | Satellite sites would need to be set up individually (and separate to the primary site) in the trial IWRS.Agreement with third party compounder must include cold chain processes. CRA assessment of satellite site pharmacy capability and facilities before trial will be required given responsibilities with the satellite site under this approach. At least some on-site monitoring of IMP accountability records at satellite sites may be required, in addition to remote monitoring of the records. |
| 1. IMP shipped to primary site only from trial sponsor
 | Primary Site pharmacy resources will need to be adequate to manage transfer of allocated individual patient IMP to the satellite site(s) to be dispensed/administered to study subject. IMP Transfer SOP in place. IMP Transfer SOP must include adequate and validated methods for temperature control and monitoring. For IMP presentations requiring compounding before administration: Established processes (including validated cold chain methods) to courier IMP in vials (if satellite site has compounding facilities) or for shipping compounded IMP and oral IMP to satellite site. Established process for returns of IMP to primary site for CRA accountability. | Largely standard clinical pharmacy resources would be adequate although there will be additional trial specific activities: * trial specific patient counselling required at dispensing (if necessary, this can be done by the primary site via telehealth)
* knowledge for how to unblind if required
* temperature checking on transferred materials
* IMP drug returns to primary site and also accountability requirements for study subject returned IMP.

Separate records for each satellite site will need to be maintained at the primary siteIMP SOP Management in placeFor IMP presentations requiring compounding before administration: Compounding facilities if stability data or distance means the compounded IMP cannot be shipped from the primary site. May require shipping of returned medications back to primary site for drug accountability and destruction, or else adequate process for drug accountability information transfer back to primary site as well as adequate process for IMP destruction at satellite site. | Need to consider how written orders for trial IMP to be dispensed will be transferred from satellite site (if sub investigators located at satellite site) to primary site for IMP to be allocated and shipped to satellite site pharmacy. Need to consider communication to satellite site pharmacy if there is a need to hold dispensing of IMP at last minute (e.g. with low blood counts etc). The agreed communication plan must be documented in the supervision planThere must be sufficient time between randomisation/ treatment pack allocation and treatment for IMP delivery to satellite from primary to meet protocol requirementsNeed to consider that there may be additional wastage of IMP under this model (for instance if IMP dispensed from primary site is ultimately not dispensed to study subject and must be wasted in the IWRS system; or if temperature excursions during shipping, etc.) Mitigation plan must be in place to manage temperature excursions and shipping delays. CRA monitoring of drug accountability is more likely to be required at primary site only. IMP transfer from primary to satellite sites will increase cost. The increased cost of administration and transfer need to be factored into overall trial budget |