# Procedure

# Scope

This Standard Operating Procedure (SOP) supports clinical trials conducted under the Teletrial Model and applies to Investigational Medicinal Product (IMP) that is supplied to a Teletrial primary site for supply to all patients within the Teletrial Cluster. This SOP does not apply when IMP is shipped directly to all sites within the Teletrial Cluster by the sponsor and normal clinical trial pharmacy procedures are followed. This SOP does not apply when IMP is shipped directly to a third-party compounder who distributes IMP to all sites in the Teletrial Cluster.

# Definitions

* 1. The definition of a Teletrial ‘primary site’ includes:
* The primary site contains the Principal Investigator for the clinical study and is responsible for the conduct, coordination and supervision of the clinical trial across the primary site and all related satellite sites.
  1. The definition of a ‘satellite site’ includes:
* A geographically separate study site participating in a clinical trial under the supervision of the primary site Principal Investigator using the teletrial model.
  1. The definition of a ‘teletrial cluster’ includes:
* A primary site and related satellite sites participating in a clinical trial using the tele-trial model

# Teletrials Primary Site Responsibility for IMP

If all IMP for the Teletrial Cluster is supplied to the Teletrial primary site pharmacy, then that pharmacy will be responsible for all IMP storage, accountability, compounding, shipping, dispensing, returns and destruction across the teletrial’s cluster. Any delegation of responsibilities to teletrial satellite sites must be documented in writing in the Supervision Plan and agreed with the clinical trial sponsor.

# Transfer of Investigational Medicinal Product within a Teletrial Cluster

# Transfer Criteria

As required to comply with the clinical trial protocol the Primary Site Pharmacy will transfer Investigational Medicinal Product (IMP) for dispensing/administration to satellite sites in the teletrial cluster.

IMP will only be transferred and transported to satellite sites when the following has been met:

# Approval from the sponsor for the IMP supply logistics (especially transport methodology or if third party compounding to be utilised) and for any proposed delegation of responsibilities with IMP to the satellite site, including confirmation of satellite site facilities and staffing (as part of the teletrial cluster site selection process)

# Receiving teletrial satellite co-investigator, study staff and site pharmacy have been appropriately trained in relation to their obligations under the clinical trial protocol with respect to prescribing, handling, dispensing and accounting for IMP at the satellite site (as a part of the Site Initiation Visit process)

* Protocol that uses the IMP(s) has been authorized to conduct HREC approved clinical research at the satellite.

# Request for Transfer

Once all the above criteria have been met and this has been confirmed in writing by the sponsor, study investigator and/or study co-ordinator, the Primary Site Pharmacy will transfer IMP for administration or storage to satellite sites in the teletrial cluster.

The request for transfer must include the following information:

* Protocol number and study name
* Subject(s) number and patient initials
* Investigational product name
* Location of satellite where drug is to be dispensed
* Date and time of patient appointment where IMP is to be dispensed for patient use
* The order for the IMP and any necessary IVRS/IWRS information

The primary site is responsible for ensuring a courier service with cold chain processes (if required) is contracted to use during the teletrial.

# Transfer procedure of Dispensed IMP to Satellite Sites:

* + 1. IMP is dispensed and/or prepared according to protocol, IVRS system is updated (as applicable) and accountability logs are completed.
    2. IMP is then sealed in a non-transparent bag clearly labelled with full study protocol number, study subject number and full patient name.
    3. An Acknowledgement of Receipt form and a copy of the prescription are attached to the outside of the bag of IMP.
    4. The bag of IMP is placed into a suitable container (e.g. box or padded envelope) and labelled and packaged for transport
    5. A cold pack is to be included for IMP requiring refrigerated storage. The agreed validated transport methodology is followed.
    6. Primary site pharmacy to include a temperature-monitoring device (unless otherwise instructed by the sponsor) with instructions to be followed by receiving satellite site pharmacy.
    7. The pharmacist/study coordinator at the satellite site is contacted by telephone or email to notify them of the delivery.
    8. The courier service is contacted.
    9. Upon receipt by the satellite site, the primary site pharmacy will ensure that a faxed or emailed signed copy of the Acknowledgement of Receipt and confirmation of temperature status is received from the satellite site and is filed with the original prescription in the Pharmacy folder at the primary site.
    10. In the event that the Acknowledgement of Receipt (and confirmation of temperature status) is not received by the primary site pharmacy within 48 hours, the primary site pharmacy will contact the receiving satellite site to check that the parcel has been received.
    11. In the event that IMP shipments are not received within the required timeframe, are damaged or have had temperature excursions, the primary site pharmacy will be responsible for documenting and follow-up activities (e.g. wasting supplies in the IWRS system, checking with sponsor regarding temperature excursions as appropriate, arranging additional IMP to be shipped, etc)

1. **Return of IMP from Satellite Sites**

When the study protocol/agreed procedures require return of dispensed (whether used or unused) IMP from satellite sites to the primary site pharmacy, suitable arrangements will be put in place to document the transfer process.

This will include:

* 1. Ensuring the satellite site notifies the primary site when IMP is being returned to the primary site and that the primary site documents receipt of the returned IMP to the satellite site pharmacy.
  2. Ensuring all returned IMP is clearly labelled as “IMP Returns” and that it is stored separately to unused IMP in the primary site
  3. Ensuring that an inventory of the IMP returns (suitably detailed for example at an IMP number/study subject number level) is made in the satellite site before return to the primary site and signed by the responsible pharmacist satellite site.
  4. The satellite site retaining a copy of the returned IMP inventory with a copy of the acknowledgement of receipt from the primary site for the returns.
  5. The primary site will maintain a separate log of the Returned IMP inventory documents and will ensured all IMP dispensing records are reconciled against the IMP returns from the satellite sites (as per the agreed study procedures).

1. **Destruction of IMP dispensed to Satellite Sites**

When the study protocol/agreed procedures allows destruction of IMP at the primary site, the primary site pharmacy will be responsible for destruction of all IMP for the study, unless specific arrangements including agreed processes and documentation have been made to allow destruction of IMP at satellite sites.

If specific arrangements have been made to allow destruction of IMP at satellite sites, the following must occur:

* 1. The primary site will ensure all IMP dispensing records are reconciled against the IMP returns (if any) from the satellite sites before destruction of IMP by satellite sites.
  2. A clearly documented process for the authorisation of destruction of IMP by the primary site pharmacy at satellite sites is in place
  3. Satellite sites must ensure that the original returned IMP inventories (suitably detailed for example at a medication number/study subject number level) with the original Returned IMP destruction records are maintained in the satellite site pharmacy and copies are supplied to the primary site pharmacy.
  4. Primary site pharmacy must ensure it obtains and appropriately files copies of returned IMP inventories (suitably detailed for example at a medication number/study subject number level) with the original Returned IMP destruction records in an ongoing and timely fashion.