Place in Site Master File #10

Drug Transfer Procedure

Upon request by CRIC representative, site investigators can be asked to facilitate transfer of trial medication (IMP) between trial sites.

Redistribution of IMP between trial sites will be performed when necessary to ensure that active trial sites have sufficient IMP for trial patients.

Please read and adhere to the following instructions:

Before IMP transfer (from site "A" to "B"):

- CRIC representative will inactivate specific boxes/vials of IMP at trial site "A".
- Upon contact from CRIC representative local investigator from site "A" will prepare these boxes for transfer according to instructions given by CRIC representative, and fill out the "Before IMP transfer"-section in the "Drug Transfer Form (v.2.0_20170602 – provided by CRIC representative).

During IMP transfer (arranged by CRIC representative):

- If possible, official inter-hospital pharmacy transport services will be used as per regional standards, otherwise transport by a private courier service will be arranged by CRIC representative.
- IMP will be transported in original secondary package (boxes)
- Temperature monitoring will be used – unless specific valid reason for leaving this out is documented.

After IMP transfer:

- Transferred IMP received by local investigator at site “B”, according to instructions by CRIC representative.
- “Drug Transfer Form” completed by site “B” and returned to CRIC representative Birgit Agerholm Larsen (bal@cric.nu).
- Upon receival of completed “Drug Transfer Form” transferred IMP will be re-activated at site “B”, by CRIC representative.
- Local site investigator at site “B” will be informed, when transferred IMP is “activated” in the SUP-ICU medication module and ready for use at site “B”.

If any questions, please contact:

CRIC Project manager Birgit Agerholm Larsen
(bal@cric.nu)
Or

Coordinating investigator Søren Marker Jensen
(soeren.marker.jensen.01@regionh.dk)