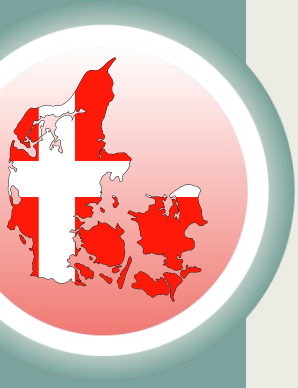


Distribution of IMP

DENMARK

Alternative ways to deliver investigational medicinal products in clinical trials

Alternative ways to deliver investigational medicinal products (IMPs) in a clinical trial can minimize the time that trial participants would spend collecting medication at the trial site. This can contribute to greater flexibility for the trial participant.

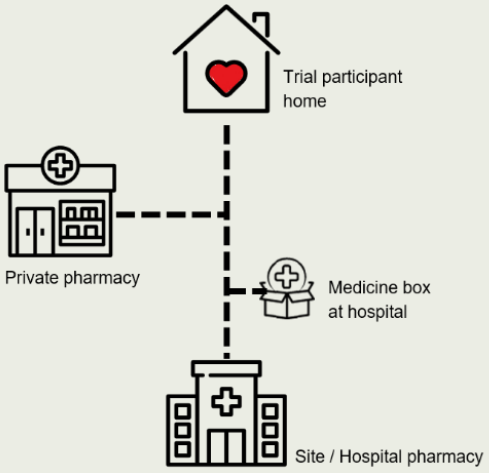
Following information sheet presents practical considerations and “how to”-support regarding delivery of IMPs in clinical trials. It builds on the Danish as well as the European recommendation paper on implementation of decentralised elements in clinical trials. Consult the two guidance papers for further insights.

Responsibility for IMP management rests with the investigator/institution. The sponsor has the overall responsibility for the process and can facilitate the drawing up of the contracts or agreements with service providers when needed, which must reflect the principal investigator’s responsibilities pursuant to ICH E6 (R3). Where activities are transferred or delegated to service providers, the responsibility resides with the investigator/institution who should maintain appropriate oversight of the activities. The arrangements for delivery of the IMP to the trial participant should be described in the clinical trial protocol.

Considerations and procedures to be followed for the delivery of an IMP depend highly on the characteristics of the investigational product e.g. the safety profile, stability, level of existing knowledge, and the complexity of the storage conditions. Applicable principles for good distribution practice (GDP) should be considered in the logistics of IMPs.

In Denmark there are different ways to deliver IMP to the trial participant in a clinical.

- From clinical site/hospital pharmacy to the trial participant's home address
- From local medicine box (managed by hospital pharmacies) to trial participant
- From local pharmacy to trial participant



From site or hospital pharmacy to the trial participant's home address.

Delivery from site/hospital pharmacy directly to the trial participant's home address is an option. Storage temperatures offered include ambient and cold. There will be validation and documentation for the conditions used.

How to get started:

- Contact the relevant site to ask for possibilities in relation to the specific trial
- Contact the relevant hospital pharmacy to ask for possibilities and capacity in relation to the specific trial
- Identify a courier, public or private, with the relevant competencies and permissions for the transport

What to consider:

- The courier will know how to handle the IMP, but not necessarily be trained in GCP/GMP-rules
- The IMP should only be handed over to the trial participant (or a representative, if applicable), or the present health care professional involved in the clinical trial, at the participant´s home address
- Trial site or hospital pharmacy must oversee the delivery of IMPs to the trial participant. The courier may deliver on precise timeslot within all temperatures and monitored

- Involving Principal Investigator (PI) in the planning process to increase collaboration and thus quality
- This is not an exhaustive list. Consult the ICH E6 (R3), the Danish and the European recommendation paper on implementation of decentralised elements in clinical trials for further insights

From local medicine box to trial participant

At the moment local medicine boxes are not generally in use for participants in clinical trials. The possibility of applying the medicine boxes in a clinical trial setting is being investigated/considered.

Medicine boxes are located at nearly all hospitals in Denmark, both regional- and University hospitals. The medicines boxes are owned and managed by hospital pharmacies. Trial participants can collect medicines 24 hours within a defined timeframe, usually up to 4 days, with double codes for identification to access the medicine box is used. Storage temperatures offered may differ between regions, as well as the state of validation and documentation of the boxes. There is an electronic registration of pick-up time, that could be supplemented with a call from the ward to the patient.

How to get started:

- Contact the relevant site to ask for possibilities in relation to the specific trial
- Contact the relevant hospital pharmacy to ask for possibilities and capabilities regarding the operational use of the medicine boxes

What to consider:

- At what temperature should the IMP be handled?
- May the IMP/device only be picked up by the participant?
- What kind of documentation is needed to follow the IMP?
- Involving PI in the planning process to increase collaboration and thus quality
- This is not an exhaustive list. Consult the ICH E6 (R3), the Danish and the European recommendation paper on implementation of decentralised elements in clinical trials for further insights

From local pharmacy to trial participant

Local private pharmacies can dispense marketed IMP in open trials (non-blinded IMP) under following conditions:

- A simple process for reimbursement of the trial participant's expenses must be established, or an agreement must exist with the pharmacy to dispense the IMP free of charge
- IMP labels must comply with the requirements in the CTR
- There must be procedures for keeping account of the IMP and checking the compliance of trial participants

Note: If considering use of an unauthorized IMP, included blinded IMP, please consult DKMA for further advice.

The private pharmacies can also distribute remedies for use in clinical trials, e.g. needles, syringes, etc.

How to get started:

- Dialog with DKMA
- Dialog with Investigator
- Contact to local pharmacies and ask for possibilities

What to consider:

- Is the IMP marketed?
- Are there other remedies to be used in the trial?
- What level of knowledge/training on GCP/clinical research should pharmacy staff have?
- Involving PI in the planning process to increase collaboration and thus quality
- This is not an exhaustive list. Consult the ICH E6 (R3), the Danish and the European recommendation paper on implementation of decentralised elements in clinical trials for further insights

From depot direct to trial participant home address

It is currently **not** possible for GDP sponsor depots to carry out the delivery of the IMP to the trial participants' home address pursuant to section 23(2) of the GDP Executive Order. The possibility of allowing sponsor depots to undertake the task of delivering the IMP directly to the trial participant is being investigated/considered

Distribution of Medical Devices

Like investigational medicinal products (IMPs), medical devices can be distributed direct to trial participants. Following distribution ways can be applied:

- From clinical site/hospital pharmacy to the trial participant's home address
- From local medicine box (managed by hospital pharmacies) to trial participant
- From local pharmacy to trial participant

Contact

For more information, please reach out to Trial Nation at contact@trialnation.dk

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