

The IMPD. General guidance

The Investigational Medicinal Product Dossier (IMPD) is part of the information that has to be supplied to the Ethics Committee in the Netherlands. The general contents for this document are described in the relevant guidelines.

In the Netherlands all documents will be reviewed by the Ethics Committee. The Competent Authority will only check the completeness of the application. This guidance is directed towards both non-commercial and commercial sponsors as well as the Ethics Committees to provide a minimum standard of documentation required. For the purpose of this guidance document the Ethics Committee and the Competent Authority are taken as one organisation (indicated as EC/CA) as the documents supplied to both bodies is identical.

Investigators brochure and IMPD. Prevent overlap.

The preclinical and clinical information can be supplied in the IB but also in the IMPD. It is left to the sponsor how to split the information between the IB and the IMPD. This also holds for the physical presentation: separate documents for the IB and the IMPD, the IB with the IMPD as an appendix, or one integrated document are all equally acceptable. It is advised to have as little overlap between the two documents as possible. This can be done by cross referencing between the two documents. The most efficient approach may be to supply the relevant chemical-pharmaceutical data in the IMPD. The relevant preclinical and clinical data and a short summary of the pharmaceutical information can then be taken up in the IB.

Recent information

All information supplied to the EC/CA must be up to date. It should be stated in the application that no extra information relevant to the submission is available. Any relevant information that becomes available during the evaluation by the EC/CA must be supplied immediately. The information is considered relevant if it conforms to the definition of a substantial amendment (see chapter on substantial amendments).

Completeness of the information

The contents of the IB and the IMPD are given in the relevant guidelines. However it needs to be stressed that the aim of this information is not the registration of the drug but rather its use in a particular clinical trial about which the EC/CA will give an opinion. It is not efficient to supply a large amount of information as this will take an inordinate amount of time of the authorities. The operational definition of the minimal information to be supplied in the Netherlands is as follows.

The information in the IB/IMPD must contain sufficient information about the treatments used in the trial for the EC/CA to give an opinion about the safety of the subjects in the proposed study. This information cannot be seen in isolation from the study protocol which will be used by the EC/CA to form its final opinion.

This indicates that the amount of information about a certain chemical or biological entity is dependent on the nature of the entity AND the nature of the intended trial. A

relatively well known entity in a simple intervention trial will require a relatively small amount of information. For a gene therapy vector the information may be extensive. The final decision about which level of detail is provided is left to the sponsor. After submission it is the EC/CA who decides if the information is sufficient and the EC/CA always has the right to request more information.

Confidentiality of information

All ethics committees and the CA are governmental agencies in the Netherlands and as such all members fall under the confidentiality requirements of Governmental bodies. In addition members have signed personal non-disclosure agreements and statements regarding absence of any conflict of interest.

If the IB is set up as a self contained document this can be supplied to investigators and study centres without the IMPD.

An example of a full IMPD

The appendix to this chapter contains an example of a full IMPD for use in the Netherlands. It contains the standard headings for an IMPD as listed in the EU guidance. It does not contain an exhaustive description of all aspects relevant to all types of drugs at all phases of development. Its purpose is only to serve as an example of the type of information that may be supplied, with help texts indicating which level of information may be appropriate for a certain situation. It is not intended as strict guidance. Also, the format of the example is not compulsory. Documents that have been prepared for general use in Europe in the sponsors' house style format are equally acceptable, provided they are in compliance with the relevant EU guidelines. The example document is also available for downloading at www.ccmo.nl.