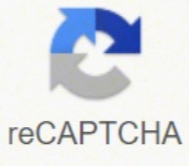


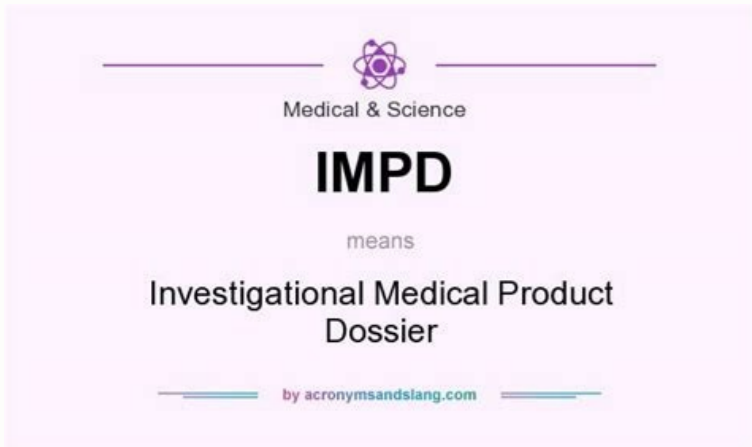


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Investigational medicinal product dossier template



The Investigational Medicinal Product Dossier (IMPD) is one of several pieces of Investigational Medicinal Product (IMP) related data required whenever the performance of a clinical trial is intended in one or more European Union Member States. It includes various summaries of information related to the quality, manufacture and control of an IMP (including reference product and/or placebo), data from non-clinical studies and from its clinical use, and the product's developmental phase. The IMPD is divided into four sections which summarize the relevant information on quality, pre-clinical, clinical studies, including critical analyses of the non-clinical and clinical data related to the possible risks and benefits of the proposed study, as well as any available previously generated human data and an assessment of the overall risk/benefit. There are also situations where the SmPC of a Marketed Product will suffice as the IMPD. A SmPC may be submitted if the IMP has a Marketing Authorisation in any EU Member State and is being used in the same form, for the same indication and with a dosing regimen covered by the SmPC. The SmPC will also be sufficient for studies of dosing regimens where the Sponsor can demonstrate that information in the SmPC justifies the safety of the new dosing regimen. The data is logically structured, and it normally follows the headings of the Common Technical Document (CTD) with the amount of information contained, therefore being dependent on various factors such as product type, indication and development phase. There exists guidance on the section headings to be used in a full IMPD, although the format is not obligatory. The IMPD can also follow the structure of a Common Technical Document (Module 3). The IMPD need not be a large document as the amount of information to be contained in the dossier is dependent on various factors such as product type, indication, development phase etc. If limited or no data is provided within the technical headings, then this must be properly justified. Certain products such as vaccines, antibodies and gene therapy, are also covered by other EU guidelines and have additional data requirements. IMPD not only forms the basis for CTA approval but also forms the basis for the CTD to support future marketing authorisation application (MAA). The informative value of the IMPD contributes to the success of drug development programmes and licensing procedures. Investigational New Drug (IND) applications are the equivalent in the United States. The guidance is based on Regulation (EU) No 536/2014 on Clinical Trials on Medicinal Products for Human Use (Repealing Directive 2001/20/EC) on the approximation of laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use (also commonly referred to as the 'Clinical Trials Directive'). The Investigational Medicinal Product Dossier (IMPD) is a document containing information about an investigational medicinal product (IMP) to be marketed in the EU. The Regulation comes into force in 2016, harmonising the laws, regulations and administrative provisions of the Member States relating to the implementation of Good Clinical Practice (GCP) in the conduct of clinical trials on medicinal products for human use. European Member States have transformed the requirements outlined in the Directive into the respective national laws. The IMPD includes summaries of information related to the quality, manufacture and control of any IMP (including reference product and placebo), and data from non-clinical and clinical studies. Freyr has a proven record of preparing IMPDs resulting in swift acceptance of CTAs by competent authorities. What is the format of an IMPD? If you would like to streamline the process for quick approval of your CTA and to know more on missing or misleading information in your IMPD, reach us at sales@freyrsolutions.com. However, vital biopharmaceutical products such as vaccines, antibodies and advanced therapy medicinal products (ATMPs) have additional data requirements. Investigator's Brochure (IB) stands as one of the important documents for clinical trial applications (CTAs) which includes part of the data to be presented in the IMPD. Referring to the IB for the preclinical and clinical sections, the IMPD can be prepared. IMPDs are submitted as part of the Clinical Trial Application Dossier, as the basis for approval of clinical trials by competent regulatory authorities within the European Union. What is a Substantial Amendment? Utilizing a Trilogy dedicated team to prepare not only the initial trial applications, but also subsequent trial documentation (e.g. protocols, Informed Consent Forms, Investigator's Brochures, study reports, subject narratives, Risk Management Plans, Periodic Safety Update Reports, etc.) ensures consistency and continuity - making the overall writing process more efficient - and the conclusions much clearer. When applying for a clinical trial authorisation, a full IMPD is required when little or no information about an IMP has been previously submitted to competent authorities, when it is not possible to cross-refer to data submitted by another sponsor and/or when there is no MA in the Community. Full and simplified IMPDs The guidance allows for the IMPD's content to be adapted to the existing level of knowledge and the product's phase of development. What is an IMPD? On the section headings to be used in a full IMPD, applicants can take clues from the industry guidance, although the format is not obligatory. The IMPD can also follow the structure of a CTD. It is not necessary that IMPD be a large document as the amount of information to be contained in the dossier is dependent on various factors such as product type, indication, development phase etc. If limited or no data is provided within the technical headings, then it must be properly justified. Few vital products such as vaccines, antibodies and gene therapy, are also covered by other EU guidelines and have additional data requirements. Guidance and legal basis Guidance concerning IMPD Dossiers can be found in the communication from the European Commission titled "Detailed guidance on the request to the competent authorities for authorisation of a clinical trial on a medicinal product for human use, the notification of substantial amendments and the declaration of the end of the trial". However, there are situations where a simplified IMPD will be sufficient. A simplified IMPD may be submitted if information has been assessed previously as part of a Marketing Authorisation in any MS or a clinical trial to that competent authority. The assessment of an IMPD is focussed on patient safety and any risks associated with the IMP. Whenever any potential new risks are identified the IMPD has to be amended to reflect the changes. Certain amendments are considered substantial in which case the competent authority has to be informed of the substantial amendment. This may be the case for changes in IMP impurities, microbial contamination, viral safety, TSE and in some particular cases to stability when toxic degradation products may be generated. Further information about substantial amendments can be found here.

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