3 Tips for IMPD Success

The Investigational Medicinal Product Dossier (IMPD) is a critical part of the clinical trial application in the European Union (EU). This dossier provides information on the development, manufacture, and control of the investigational medicinal product and is assessed by Quality Reviewers at the National Competent Authority (NCA).

The new EU Clinical Trial Regulation gives sponsors **only 12 days** to respond to issues raised by the reviewers and creates a tight timeline for submitting responses before the application lapses. Because of the new timeline, it's imperative to make your initial IMPD submission of high-quality to avoid issues.

We suggest following these three tips to optimize your IMPD for success:

Ensure your document is thorough and concise.

The IMPD does not need to be lengthy to be comprehensive. Present information in an easy-to-read and understand format and ensure that all sections are as complete as possible in line with the phase of the study.

Seek expert guidance for authoring and review.

Work with regulatory experts with significant experience in drafting and reviewing IMPDs to ensure your dossier is in line with expectations and avoid any major unexpected objections.

Have a rapid response team ready.

With the shorter timeframe to answer questions and provide additional information, identify knowledgeable team members (and possibly outside consultants) to respond to any inquiries.

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