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Preparing an IND: Common Errors and Solutions

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ABSTRACT

Proper preparation of an Investigational New Drug (IND) application is a carefully orchestrated process that requires many disciplines to collaborate in delivering a consistent message regarding the safety of an investigative compound. Proactively identifying and avoiding common IND submission pitfalls can help ensure that your application is clear, concise, and error-free.

MEDICAL WRITING

Preparation of an Investigational New Drug (IND) application is a critical early step in clinical trial development as it enables sponsors to obtain an exemption to the federal law that prohibits the transport of drugs across state lines prior to marketing approval. The process of preparing an IND requires careful coordination of many players with different specialties who must work together to demonstrate the safety of the investigative compound.

The IND application must contain three areas of information:[1]

1. Animal pharmacology and toxicology studies
2. Manufacturing information
3. Clinical protocols and investigator information

While there are different types of IND submission, there are errors that are commonplace amongst all application types. In this paper, we look at common submission pitfalls and strategies for avoiding them.

Common errors

1. Underestimating the resources and time needed to pull together and publish the IND

Given the diverse areas of information required, many disciplines will need to contribute to the components of the IND. Coordinating all the pieces, and ensuring that they deliver a consistent and effective message, can be extremely time-consuming.

The process of preparing an IND requires careful coordination of many players with different specialties who must work together to demonstrate the safety of the investigative compound.

Common errors

1. Underestimating the resources and time needed to pull together and publish the IND
2. Disorganized information
3. Forgetting to edit
4. Failure to follow the FDA guidance

2. Disorganized information

Sponsors should keep in mind that the FDA reviewer will need to evaluate all information provided. Providing unnecessary information, disorganized data, or dense text may not only increase the length of time required to review your submission, but also open the door to possible errors, increasing the likelihood of rejection. In some cases, providing excess information could reveal a much bigger problem within a company – a lack of strategy.

Another common pitfall is forgetting to provide explanations and supporting data for results, or failing to match results to the protocol [e.g., dose, dose duration, and Chemistry, Manufacturing, and Controls (CMC)].

3. Forgetting to edit

Too often, the focus of an IND submission is solely on the science, and editing for grammar and/or formatting is forgotten. This can easily happen when departments are overworked and under-resourced. Editing may seem like a trivial detail compared to the data, but it matters. Submissions that are difficult to read or review are more likely to be rejected or put on hold.

4. Failure to follow the FDA guidance

The FDA provides a detailed description of what they look for in an IND submission, but sponsors often fail – or forget – to follow the guidance.[1,3]

Strategies for a successful IND submission

These common errors may seem small or insignificant, but every detail affects how an IND submission is received. Following these simple rules can help you with submitting a clear, concise, and error-free application:

1. Organize your submission in a way that is easy to review and understand

Do not create your submission on the fly! Using a Target Product Profile (TPP) helps you have a clear goal and organizational structure for your application by specifying the proposed draft product label. While it may sound premature, doing this allows you to align your strategy and goals first and then work backwards, providing you with a clearer path from the beginning.[2] This way, each component of your submission becomes a rung on your IND ladder: every single section will be built upon the last with overlapping support.

2. Document rationales for conclusions in a concise, well-thought-out way, and include supporting data

Provide explanations and supporting data for results, and ensure that your results match your protocol. Leave out any irrelevant information as it can dilute your text. In addition, check that your key messages support the importance of your submission.[3]

3. Remember: brevity is the soul of wit

Length does not equal understanding, so stay focused. Use simple terms – rather than jargon – with correctly defined abbreviations, and find ways to use tables and figures rather than paragraphs of text.

Don't forget to format and proofread! If multiple vendors contribute to a submission, you will likely find different writing styles throughout your application. Editing the IND into a consistent writing style and making sure there is enough white space will make it easier to read.

Remember, the IND is a living application that may continue to evolve until the New Drug Application (NDA) is approved, and paying attention to the details can make the approval process much smoother.

4. Use the FDA guidance

Using the FDA guidelines as a checklist helps ensure that your IND includes everything the FDA requires.

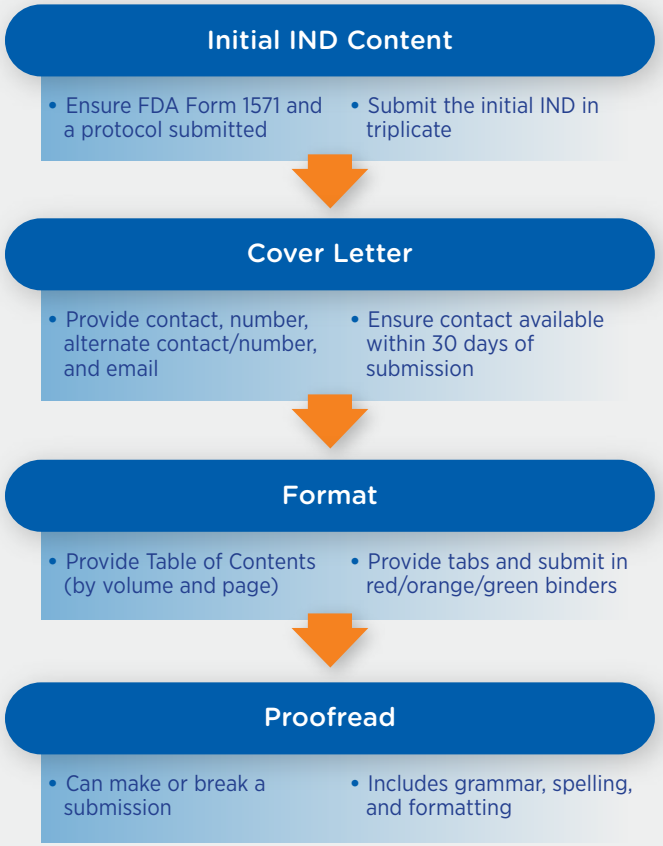
If you are confused or have questions, request a pre-IND meeting. These meetings are incredibly useful as the FDA can inform you of any items you may still need in your submission. They also provide an opportunity to ask the FDA questions before the submission clock starts ticking. Taking advantage of this meeting can only improve your submission, increasing the likelihood of a fast turnaround and approval. However, these meetings should not be taken lightly. Make sure you are prepared to make a good first impression with the FDA.

It is also important to remember that as of May 5, 2018, all commercial IND submissions must be submitted in eCTD format. Paper submissions will no longer be accepted.

5. Seek support from an experienced CRO

Working with a contract research organization (CRO) that has experience with IND submissions can help alleviate the stress of preparing an IND and facilitate the teamwork and resource sharing to help you not only perform better, but also produce higher quality work. With a deep understanding of FDA guidances and how to effectively navigate meetings with FDA personnel, a CRO can help with every step of the clinical development process, from creating a TPP and conducting a pre-IND meeting to submitting an IND application, conducting a trial and, ultimately, seeking market approval.

Figure: Tips from the FDA for submitting an IND[3,4]



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