Why and When to Hold a Pre-IND Meeting with FDA

While a pre-IND Meeting with the FDA is optional, the Regulatory team at Veristat highly recommends that all drug developers planning to submit an IND to the FDA have a pre-IND meeting.

WHY DO I NEED A PRE-IND MEETING?

This is a common question from drug developers and has a straightforward answer:

The key reasons to have a pre-IND meeting are to limit the risk of regulatory surprises, establish a relationship early with the FDA review Division, and give them a heads up that your IND is coming. It is worth adding that there is no cost (fees payable to FDA) associated with pre-IND meetings, and that the sponsor has the option to request written responses in lieu of a meeting – to simplify the process when warranted.

Value of Pre-IND Meeting

Provides the opportunity to get feedback on critical development issues.

Particularly useful if:

- Developing novel compound or indication
- Uncertainty about development program scope
- Absence of guidance documents and/or precedents
- Product has potential for accelerated development
- Complex safety issues
- Development of compound in class with some historical “baggage”

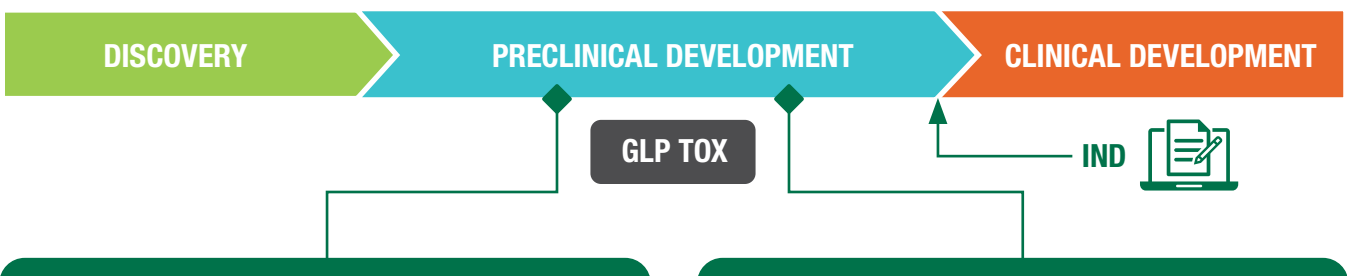
General Objective of Pre-IND Meeting

- Ensure initial manufacturing controls are acceptable
- Get alignment on preclinical safety evaluation (reduce risk of clinical hold)
- Agree on design of the initial clinical study
- Seek early input on overall development program

WHEN TO SCHEDULE A PRE-IND MEETING

A pre-IND meeting can be scheduled with the FDA any time before submitting an IND. There are two general times when you want to consider scheduling the pre-IND meeting, either before or after performing the GLP toxicology studies. You only get one pre-IND meeting, so choose the timing wisely.

Below are some reasons to schedule an early pre-IND meeting versus a later one:



“Early” Pre-IND Meetings

Typically: To discuss overall **approach** to preclinical program

- Seek agreement on GLP tox program design
- Confirm program is sufficient to address risks
- Limited material data to discuss
- Early discussion of development program scope
- More difficult to discuss features of initial clinical study (dose, safety monitoring)

“Late” Pre-IND Meetings

Typically: To discuss **data** from preclinical program to confirm acceptance

- Requires completion of key GLP tox studies
- Best opportunity to discuss translation of preclinical results to clinical program
- Able to discuss any “surprises” from GLP tox
- Note: may be on “critical path” to IND (i.e. possible delay)

ISSUES TO DISCUSS AT PRE-IND MEETING

Pre-IND meetings can be used to discuss all aspects of the development plan at a conceptual level. The FDA may or may not be willing to discuss specific longer-term details at this time.

Does FDA agree that data from these studies support the design moving forward?

Are the manufacturing controls and specifications acceptable?

Stability, analytical characterization, purity profile, etc.

IND-enabling (GLP) toxicology study design

Adequacy of quality (CMC) assessment

Proposed clinical program design

Overall registration package (especially for novel products)

Agree on key design features, such as starting dose, dose escalation scheme, patient populations SAD vs MAD, or combined SAD/MAD, etc.

Get input on overall development plan – efficacy and safety endpoints, number of pivotal studies, size of safety database, etc.

FDA will review at a conceptual level.

Meet Veristat – Getting It Right, the First Time

We understand that the stakes are high, and submitting your IND is the next critical milestone in your clinical development program. To give you an advantage, Veristat has assembled a team of scientific-minded experts adept at preparing for pre-IND meetings with FDA. Get introduced to Veristat today.

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