Planning for an IND Submission

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Getting Started

- Establish secure email with the FDA
  - Contact SecureEmail@fda.hhs.gov
- Review relevant FDA Guidance Documents
- Seek guidance early in product development process
- Commercial INDs require submission in the electronic Common Technical Document (eCTD) format.

Build Your Team

- Preclinical
- Manufacturing
- Quality Control (QC)
- Quality Assurance (QA)
- Biostatistician
- Protocol Writer
- Clinical PI/Clinical study team
- Regulatory
- Technology Transfer

INTERACT Program

The Initial Targeted Engagement for Regulatory Advice (INTERACT) Program enables sponsors to obtain preliminary, **informal, nonbinding** advice from the FDA at an early stage of development prior to a pre-IND meeting.

"The program is intended for discussion of innovative investigational products that introduce unique challenges related to unknown safety profiles, complex manufacturing/technology issues, incorporation of innovative devices, or use of cutting edge testing methodologies."

https://www.fda.gov/vaccines-blood-biologics/industry-biologics/interact-meetings-initial-targeted-engagement-regulatory-advice-cber-products

INTERACT Program (cont'd)

An INTERACT meeting request should be submitted only after a Sponsor has identified a specific investigational agent to evaluate in a clinical study and early proof of concept and feasibility data is available.

Meeting request and package should include:

Description of the product and disease/condition to be treated or prevented	Summary of information about product development to date and future development plans	Statement summarizing purpose of the meeting	List of questions to be discussed	Summary of available data to support discussion

INTERACT Program (cont'd)

- Requests should be sent to INTERACT-CBER@fda.hhs.gov
- FDA will respond within **21 days** of receipt of request whether meeting request is granted or denied
- Meeting will be scheduled within **90 days** of receipt (subject to availability of CBER staff)
- Meeting is held by teleconference only, generally for one hour

Type B Pre-IND Meeting Request

21 CFR 312.82

Planning	Prepare Pre-IND Meeting Package	Submit Pre-IND Meeting Request	FDA Response to Meeting Request	Submit Pre-IND Meeting Request	Pre-IND Meeting
• Seek guidance early in product development	• Identify key questions to be addressed by the FDA • Recommend that meeting package is near final prior to submitting a meeting request	• Pre-IND Meeting Request must be submitted to the FDA **at least 60 days prior to the desired meeting date**	• FDA will respond **within 21 calendars from date of receipt of the meeting request**	• FDA requests the Pre-IND Meeting Package be submitted **at least four weeks prior to the scheduled meeting**	• Prior to the scheduled meeting date/time, FDA will provide preliminary responses and comments

Pre-IND Meetings

What concerns do you have with respect to preclinical data, manufacturing or clinical plan?

If you are asking "Should we bring this up?"

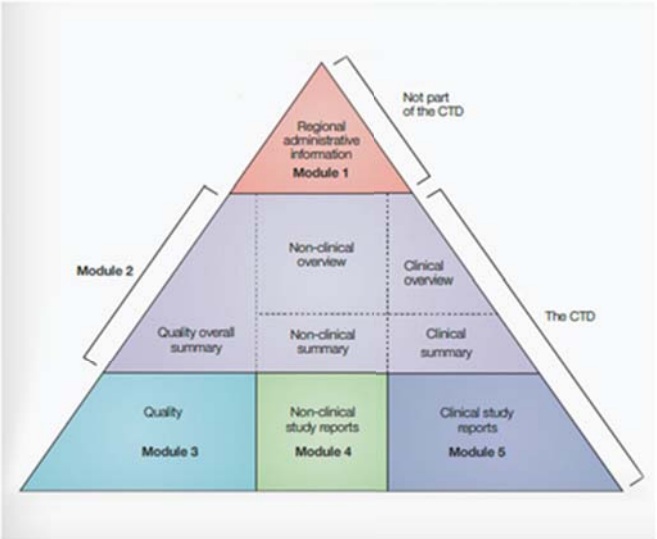
This is the time to bring issues forward and discuss with the FDA

Time to Submit

- **Key Components:**
  - Pharmacology/Toxicology
  - Clinical Protocol
  - Manufacturing Information

- **Format:**

  Common Technical Document (CTD)
  - Module 1 - Administrative Information
  - Module 2 - Summaries
  - Module 3 – Quality
  - Module 4 – Non-Clinical Study Reports
  - Module 5 – Clinical Study Reports



Tips for Successful IND Filing

- Seek FDA Guidance early in product development process
- Meet regularly with your team
- Plan accordingly to ensure timely accurate filing (QC, publishing)
- Clear and organized data is critical
- Present information clearly and concisely
- Review all sections for consistency
- Documentation is key through the product and IND life cycle