This information should not be considered to represent advice or guidance on behalf of the U.S. Department of Health and Human Services or any agency or office thereof.

INTERACT Meetings with FDA

Refer to the **NIH SEED Regulatory Knowledge Guides** for more specific guidance on the regulation of:

- Small Molecules
- Biological Products
- Cell and Gene Therapies

Context

Developers of new small molecule and biological therapies often have regulatory questions as they navigate the development process. The U.S. Food and Drug Administration (FDA) has two centers that supervise this process: the Center for Biological Evaluation and Research (CBER) and the Center for Drug Evaluation and Research (CDER). Among the earliest resources available to innovators is the opportunity to engage in formal discussions with CBER or CDER through **IN**itial **T**argeted **E**ngagement for **R**egulatory **A**dvice on **C**BER/**C**DER Produc**T**s (INTERACT) meetings. These meetings allow innovators to gain input on novel products and development programs that present unique challenges during the early stages of product development, addressing issues prior to a pre-IND (Investigational New Drug) meeting.

Key Takeaways

- An INTERACT meeting may be your first interaction with FDA if you have a novel product/development program. It can be highly beneficial, helping you identify the data required for to support a pre-IND meeting request and potentially conserving time and funds.
- Thoroughly research the regulatory process and read relevant online resources before scheduling an INTERACT meeting. The meeting request and briefing package must meet specific criteria set by FDA.
- The appropriate time to schedule an INTERACT meeting is after your investigational product has been identified and initial preclinical proof-of-concept studies have been conducted but before starting definitive toxicology studies.
- The timing is critical—FDA will decline a meeting request if the development program is at an inappropriate stage—either too preliminary or too far advanced.

How to Prepare

For advice on whether your development program is at the right stage for an INTERACT meeting, consult the OTP INTERACT meeting website for CBER OTP regulated products.
For other products, consult the draft guidance for formal meetings including INTERACT at FDA draft guidance for formal meetings. This resource offers comprehensive guidelines for evaluating whether your program meets requirements for an INTERACT meeting or is premature or too advanced for an INTERACT meeting. If, based on the developmental stage of your program and the available information, it seems appropriate to proceed with an INTERACT meeting, follow the steps outlined in the draft guidance to contact the FDA. For general resource information, please also refer to FDA draft guidance for formal meetings.

To maximize the effectiveness of your FDA interaction, it is essential to understand the agency's expectations and requirements. If your development program is novel and meets requirements for INTERACT, proper preparation can significantly enhance the likelihood of your meeting request being accepted and positively impact the future development trajectory of your novel investigational product.

For an INTERACT meeting, an innovator should be ready to supply the following information.

Chemistry, Manufacturing, and Controls (CMC) – Provide a succinct yet comprehensive description of the product, detailing the manufacturing process, the proposed tests for product characterization and batch release, and a rationale for the questions posed. Include references to any published data relevant to the product and attach copies of these publications.

Pharmacology/Toxicology – Offer a detailed summary of all preclinical studies (both in vitro and in vivo) that have been performed using the product intended for clinical use, along with the outcomes of these studies. Incorporate findings from pertinent publications into this summary and supply copies of these documents. Also, present a thorough discussion, including outlines of proposed protocols, for any additional preclinical studies you believe are necessary to support the product's use in the intended patient group. Your stance and the reasoning behind any questions you pose should be clear. Note that questions about definitive preclinical safety studies, typically addressed during the pre-IND meeting, should not be part of the INTERACT submission.

Clinical – In the context of an INTERACT meeting, clinical discussions are generally broad, encompassing guidance on the entire clinical development program rather than the intricacies of a specific clinical protocol. The briefing package should outline the targeted condition, the intended patient population, available data on the condition's natural progression, current treatment options, and a preliminary sketch of the proposed initial human study.

Recommendations

Remember, preparation is critical. To prepare for an INTERACT meeting with FDA, it's essential to

articulate your questions and demonstrate a thorough understanding of the regulatory requirements and expectations. Based on the thoroughness and relevance of the submitted information, FDA will determine if the sponsor is sufficiently prepared for an INTERACT meeting.

Effective communication with FDA ensures patient safety and complies with regulatory standards. It is essential to present detailed data and clear justifications for your methodologies to foster a constructive exchange and receive valuable feedback from the agency. FDA's feedback will reflect the latest scientific insights and established regulatory precedents. The feedback may also be influenced by the details of your product and the evidence you submit. So, anticipate various feedback scenarios and be equipped with supplementary data or alternative strategies for discussion.

Regulatory Resources

Innovators should use the extensive sources of product development information that are publicly available before seeking a meeting. In addition, FDA develops and maintains web pages, portals, and databases and participates in interactive media to advise on matters outside of established guidance, policy, or practices.

- FDA Resources
  - Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products Guidance for Industry provides recommendations for innovators of CBER and CDER regulated products
  - CBER OTP INTERACT meeting guidance offers innovators the opportunity to have an early, informal meeting with CBER to discuss early-stage product development for a range of products including cell and gene therapy.
  - CBER OTP Learn: Video Instructional Webinars for Sponsors

- NIH network
  - Work with program officers to obtain feedback within NIH
  - NIH awardees can request a meeting with the NIH Small Business Education and Entrepreneurial Development (SEED) Innovator Support Team to ask questions about this process and request a review of a draft cover letter. The SEED office does not review or comment upon the scientific validity or data elements of the submission.

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