

SOPP 8214: INTERACT Meetings with Sponsors for Drugs and Biological Products

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I. Purpose

This Standard Operating Policy and Procedure (SOPP) serves as a guide for the Center for Biologics Evaluation and Research (CBER) staff for scheduling and conducting CBER **I**nitial **T**argeted **E**ngagement for **R**egulatory **A**dvice on **C**BER **P**roduc**T**s (INTERACT) meetings between CBER representatives and regulated industry and/or individual sponsor-investigators to provide preliminary informal non-binding consultation for innovative investigational products at an early stage of development on issues that are not yet at the pre-IND meeting phase.

II. Scope

- A. This SOPP applies to all CBER regulated products that meet the criteria for an INTERACT meeting. See [Appendix A: INTERACT Meeting Criteria and Examples](#).
- B. This SOPP does **not** cover formal regulatory meetings for products under Investigational New Drug (IND), Abbreviated/New Drug Application (A/NDA), Biologics License Application (BLA), amendments, and supplements. See *SOPP 8101.1: Regulatory Meetings with Sponsors and Applicants for Drugs and Biological Products*.

- C. This SOPP does **not** cover formal device meetings that fall under the Q-Submission Program for medical devices. See the Guidance for Industry and Food and Drug Administration Staff: *Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program*.

III. Background

- A. Development of innovative investigational products can introduce unique challenges related to unknown safety profiles, complex manufacturing processes, technologies and issues, incorporation of innovative devices, and the use of cutting-edge testing methodologies.
- B. Through an INTERACT meeting, sponsors can obtain initial, non-binding advice from FDA regarding chemistry, manufacturing and controls (CMC), pharmacology/toxicology, and/or clinical aspects of the development program. This informal meeting can: 1) assist sponsors conducting early product characterization and preclinical proof-of-concept studies, 2) initiate discussion for novel devices, 3) inform sponsors about overall early-phase clinical trial design elements, and 4) identify critical issues or deficiencies for sponsors to address in the development of innovative products.
- C. An INTERACT meeting is not intended to take the place of a pre-IND meeting, which occurs before the submission of an IND to discuss the scope and design of planned initial studies, design of animal studies needed to support human clinical testing, and the format for the IND. Conversely, an INTERACT meeting also is not a venue to provide advice to sponsors who have yet to initiate any product development activities. Before requesting an INTERACT meeting, a sponsor needs to have selected a specific investigational product or a biological product-derivation strategy to evaluate in a clinical study.

IV. Definitions

- A. **Sponsor** - For the purposes of this SOPP, is an individual, pharmaceutical company, governmental agency, academic institution, private organization, or other organization who requests an INTERACT meeting to address questions they have when in the process of developing a biological product, drug or device regulated by CBER.
- B. **INitial Targeted Engagement for Regulatory Advice on CBER productS (INTERACT) meetings** - An informal non-binding consultation with the Center for Biologics Evaluation and Research (CBER) at an early stage of product development to address issues in advance of a future pre-IND meeting.

V. Policy

A. General

1. INTERACT meetings are intended for novel products that introduce unique challenges due to unknown safety profiles resulting from complex manufacturing technologies and issues, development of innovative devices, and the use of cutting-edge testing methodologies. INTERACT meetings are only for issues not yet at the pre-IND stage. A sponsor needs to have selected a specific investigational product or a biological product-derivation strategy to evaluate in a clinical study before requesting an INTERACT meeting. INTERACT meetings are **not** a prerequisite to requesting a pre-IND meeting.
2. The sponsor of an INTERACT meeting is expected to have reviewed this SOPP in preparation for submission of the meeting request and meeting package. CBER will refer all inquiries regarding formal meetings to *SOPP 8101.1: Regulatory Meetings with Sponsors and Applicants for Drugs and Biological Products* or to the *Guidance for Industry and Food and Drug Administration Staff: Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program* as appropriate.
3. In accordance with 21 CFR 10.65(e) and FDA policy, meetings with sponsors and applicants may **not** be electronically recorded.
4. INTERACT meetings are informal communications that are scheduled based upon the availability of CBER resources. Although no formal performance goals are set, CBER will endeavor to schedule INTERACT meetings **within 21 calendar days** and hold the meeting **within 90 calendar days of receipt of the request**. INTERACT meetings will be held via teleconference only, and generally last for one hour.
5. For the FDA to send regulatory information via email, the email must be sent to a secure email partner to allow the FDA to digitally sign and encrypt the message. Requests to establish secure email with the FDA should be sent to SecureEmail@fda.hhs.gov. Adequate time should be allotted for a secure email set-up before expecting email responses from the FDA. For more information, refer to *SOPP 8119: Use of Email for Regulatory Communications*.

B. Meeting Request and Meeting Package

1. Meeting requests and packages are submitted to CBER by email to INTERACT-CBER@fda.hhs.gov.
2. The cover letter and email subject line should be clearly marked as a request for an INTERACT meeting and identify the CBER Office where the request is directed. In the meeting request, sponsors are encouraged to define the specific areas of input requested from CBER. The questions submitted to CBER, within a single meeting request, should be limited to

those that can be reasonably answered within the allotted meeting time taking into consideration the complexity of the questions considered.

3. Meeting packages for INTERACT meetings are to be submitted with the meeting request. Meeting packages are expected to be succinct and should **not** exceed 50 pages. The INTERACT meeting package must include the following:
 - a. A description of the product and the disease or condition being treated or prevented.
 - b. A summary of information about the product development to date and future development plans, if appropriate.
 - c. A brief statement summarizing the purpose of the meeting.
 - d. A list of questions for discussion, grouped by topic (such as Chemistry, Manufacturing, and Controls (CMC), Pharmacology / Toxicology or Clinical, with a summary for each question to explain the need or context for the question. **Note:** Questions regarding combination products should be grouped together.
 - e. A summary of the data to support a discussion organized by topic and question.
 - f. A list of all participants, with their titles and affiliations, who will attend the meeting from the sponsor's organization, including consultants and interpreters.
 - g. The sponsor may also include suggested dates and times (e.g., morning or afternoon) for the meeting. Non-availability dates and times should also be included. The suggested timeframes will only be considered within the context of CBER resource availability.

C. Scheduling the Meeting

1. INTERACT meetings will generally be scheduled **within 21 calendar days of receipt of the meeting request** and be held **within 90 calendar days of request receipt** subject to the availability of CBER resources. INTERACT meetings will be held via teleconference only, and generally last for one hour. Regulatory Template *T 820.03: Meeting Confirmation* will be used to confirm the logistics of the meeting once scheduled.

D. Reasons a Meeting may not be Held

1. The request for a meeting may be **denied**. Denials will be based on a substantive reason, not merely on the absence of a minor element of the meeting request or a minor element of the meeting package. If a meeting

request is denied, the sponsor will be given a reason for the denial. Regulatory Template *T 820.07: Meeting Denied* will be used to convey the reasons for the denial to the sponsor. Examples of reasons for denial include:

- a. A meeting package does not accompany the INTERACT meeting request.
 - b. The meeting package is substantially deficient, significantly limiting the ability to provide constructive feedback.
 - c. The requested feedback is not appropriate for an INTERACT meeting. See [Appendix A](#) for examples of topics or questions that are outside the scope for CBER INTERACT meetings.
 - d. The stage of development is either premature or too advanced for an INTERACT meeting. CBER will generally inform the sponsor if a different meeting type is more appropriate.
 - e. A previous meeting for the same purpose has already been held and no substantially new information has become available.
 - f. The requested feedback is not appropriate for a meeting with CBER.
2. The meeting may be **rescheduled** by CBER and a new date will immediately be identified. Regulatory Template *T 820.08: Meeting Rescheduled/Change in Meeting Format* will be used to confirm the logistics of the meeting once rescheduled. Examples of reasons for rescheduling a meeting include:
- a. The sponsor asked to reschedule the meeting and a new date is immediately identified.
 - b. Additional consult reviewers or management input is needed but cannot be obtained before the original meeting date.
 - c. Required CBER attendees become unexpectedly unavailable, and appropriate substitutes cannot be identified.
3. The meeting may be **cancelled** by the sponsor by sending a written notification to CBER. Upon receipt of written notification, CBER will confirm cancellation using Regulatory Template *T 820.09: Meeting Cancellation*. Examples of reasons a sponsor may cancel the meeting include:
- a. The sponsor is satisfied with the CBER INTERACT comments and cancels the meeting.

- b. The sponsor asks to cancel the meeting for any other reason.

E. CBER INTERACT Comments

1. CBER will send written responses to the sponsor's questions contained in the meeting package before the meeting to facilitate the discussion. No additional questions from the sponsor will be accepted, and the meeting discussion will be limited to the initial questions submitted in the meeting package.

F. Meeting with Sponsor

1. Discussions during INTERACT meetings with the sponsor will focus on the questions submitted in the original meeting package. The sponsor may cancel the meeting if the CBER comments are sent before the meeting and the sponsor does not desire further discussion.

G. Meeting Minutes

1. CBER advice given during INTERACT meetings is informal and non-binding. Therefore, official meeting minutes will not be issued to the sponsor.
2. Sponsor's meeting minutes
 - a. In accordance with 21 CFR 10.65(f), the sponsor, or other meeting participant, may prepare and submit a memorandum summarizing their understanding of issues discussed at the meeting to CBER. Since INTERACT meetings are informal and non-binding, this memorandum, if provided, will **not** be reviewed by CBER in any manner. An evaluation to see if the memorandum is accurate will not be performed. Sponsor meeting minutes do **not** alter CBER's pre-meeting comments provided in writing or by verbal communication and they are not the official minutes of the meeting.

VI. Responsibilities

A. Document Control Center (DCC) –Processes all incoming meeting requests and meeting packages, including loading electronic submissions into CBER's Electronic Respository (CER).

B. INTERACT Triage Group – Monitors, retrieves, and initially processes meeting requests submitted to the INTERACT-CBER@fda.hhs.gov email inbox. Responsibilities include assessing requests for appropriate office assignment, forwarding requests to Office Management for evaluation and scheduling, and forwarding requests to DCC for initial data entry into CBER's systems.

- C. Office Management** – Supervisory chain, including Division Directors or designees, within a Division that evaluates the meeting request and makes the decision on whether to hold the meeting, participates in the evaluation of the meeting package, participates in the meeting, and works with the Review Team as necessary.
- D. Regulatory Information Specialist (RIS)** – Coordinates with the RPM to schedule and organize INTERACT meetings with sponsors.
- E. Regulatory Project Manager (RPM)** – Overall management of the meeting request. These responsibilities include reviewing assigned sections, ensuring the requested meetings are scheduled, ensuring regulatory and administrative actions are completed on time, including all notifications to sponsor are sent, performs quality control checks, ensures all communications are entered in the appropriate regulatory system through CBER Connect, and ensures the file is administratively complete.
- F. Review Team Member** - Reviews meeting requests and packages, provides comments, and participates in CBER INTERACT meetings.

VII. Procedures

A. Processing an INTERACT Meeting Request

1. INTERACT meeting requests shall be received via submission to the INTERACT-CBER@fda.hhs.gov email address:
 - a. Forward the meeting request to DCC for submission logging. **[INTERACT Triage Group]**
 - b. Process electronic submissions and notify the appropriate Office per *DCC Procedure Guide 22: Procedure for Processing, Routing, and Storing Electronic Submissions*. **[DCC]**
 - c. Upon receipt of notification from DCC, ensure that the necessary information is entered into the Biologics Information Tracking System: Pre-Application Tracking Module (BITS-PTS). **[RIS]**
2. Evaluate the initial request for completeness and appropriateness for an INTERACT meeting based upon the INTERACT meeting criteria listed in [Appendix A](#) of this SOPP. **[Office Management]**
3. Make the decision on whether the meeting will be held. **[INTERACT Triage Group/Office Management]**
4. Notify the sponsor of CBER's decision within the timeline set in meeting management procedural goals table (see Table 1 in [Appendix A](#)). **[INTERACT Triage Group, RPM, RIS]**

- a. If the meeting is denied, notify the sponsor that the meeting request is denied using Regulatory Template *T 820.07: Meeting Denied*.
[INTERACT Triage Group, RPM]
- b. If the meeting is granted, notify the sponsor using Regulatory Template *T 820.03: Meeting Confirmation*. **[RPM]**

B. Evaluation of Meeting Package and Preparation of CBER INTERACT Comments

1. Evaluate whether all appropriate disciplines and participants have been included and request additional disciplines as necessary. **[RPM]**
2. Review the meeting package and prepare CBER INTERACT comments. Comments, will be sent to the sponsor no later than one calendar day before the meeting. **[Review Team Members, Office Management as appropriate]**
3. If a request to cancel the meeting is received from the sponsor, acknowledge the request using Regulatory Template *T 820.09: Meeting Cancellation* and notify all appropriate Agency personnel. **[RPM]**

C. Meeting with the Sponsor

1. Conduct the meeting. **[RPM/Review Team/Office Management]**
2. Notify the sponsor that meeting minutes will not be sent because INTERACT meetings are informal in nature. **[RPM/Review Team/Office Management]**
3. Notify sponsor that any meeting minutes they prepare and send to CBER will not be reviewed and an evaluation will not be performed to see if they are accurate. Remind the sponsor that their meeting minutes do not alter CBER's pre-meeting comments provided in writing or by verbal communication and they are not the official minutes of the meeting.
[RPM/Review Team/Office Management]

VIII. Appendix

A. [INTERACT Meeting Information](#)

IX. References

A. References below are CBER Internal:

1. JA 820.06: Procedures for Scheduling and Conducting INTERACT Meetings with Sponsors

2. T 820.03: Meeting Confirmation
 3. T 820.07: Meeting Denied
 4. T 820.08: Meeting Rescheduled/Change in Meeting Format
 5. T 820.09: Meeting Cancellation
 6. T 820.11: INTERACT Meeting Comments
 7. DCC Procedure Guide 22: Procedure for Processing, Routing and Storing Electronic Submissions
- B.** References below may be found on the Internet:
1. [SOPP 8101.1: Regulatory Meetings with Sponsors and Applicants for Drugs and Biological Products](#)
 2. [SOPP 8119: Use of Email for Regulatory Communications](#)
 3. [Guidance for Industry and Food and Drug Administration Staff: Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program](#)
 4. [INTERACT Meeting Information on FDA.gov](#)

X. History

Written/Revision	Approved	Approval Date	Version Number	Comment
M. Monser	N/A	December 11, 2020	3	Technical Update for retirement of EDR
X. Tang	Darlene Martin, PMP, MS	June 12, 2020	2	Update to improve the INTERACT Program
RMCC	Christopher Joneckis	September 28, 2018	1	Original Document

SOPP 8214 Appendix A: INTERACT Meeting Information

I. INTERACT Meeting Scope and Examples

CBER advice for INTERACT meetings is informal and non-binding. INTERACT meetings are intended for novel products that introduce unique challenges due to unknown safety profiles resulting from complex manufacturing technologies and issues, development of innovative devices, and the use of cutting-edge testing methodologies. INTERACT meetings are only for issues not yet at the pre-IND stage. A sponsor needs to have selected a specific investigational product or a biological product-derivation strategy to evaluate in a clinical study before requesting an INTERACT meeting.

A. Examples of questions and topics **within the scope** of an INTERACT meeting:

1. Chemistry, Manufacturing and Controls (CMC)
 - a. Innovative technologies for the qualification of new cell substrates.
 - b. Product-manufacturing (e.g., cell sources, donor eligibility determination for allogenic cellular products, and qualification of international donors).
 - c. Product dependent and manufacturing process dependent reagents, starting materials, and critical product components.
 - d. Qualification of a novel delivery device related to a specific investigational product.
 - e. Discussion of complex software issues and strategies to support device use in clinical studies.
2. Pharmacology/Toxicology
 - a. Overall advice related to the design of proof-of-concept or other pilot safety/biodistribution studies necessary to support administration of an investigational product in a first-in-human clinical trial.
 - b. Specific questions on the adequacy of the selected animal models; study design (e.g., endpoints, dose levels, route of administration, dosing regimen); and acceptability of innovative preclinical testing strategies, products, and/or delivery modalities.
 - c. Advice on modification of a preclinical program or study design, as applicable, to ensure the judicious use of animals.

3. Clinical

- a.** General recommendations regarding a future first-in-human trial in a target clinical population. These recommendations may vary based on scientific knowledge about the disease and regulatory experience with the disease.

4. Cross-cutting/Other

- a.** Provide recommendations regarding the approach for further development of an early stage product for which limited CMC, pharmacology/toxicology and/or clinical data were collected outside of a U.S. IND.

5. BLA Device

- a.** Provide recommendations regarding complex software issues or analytical performance requirements to developers of innovative blood screening devices regulated as BLAs by CBER.

B. Examples of questions and topics **outside the scope of INTERACT meetings:****1. Topics suitable for discussion with [CBER Advanced Technologies Team \(CATT\)](#).**

- a.** Questions about candidate innovative product selection for further development (including circumstances where the sponsor has not decided between multiple product options or the investigational product has not been identified).
- b.** Questions about novel technologies that can impact product development, manufacturing process and control strategies
- c.** Questions that are not necessarily product-specific, such as novel technologies that can significantly impact on a product class.

2. Other examples of topics / situations outside of the scope of INTERACT meetings**a. Chemistry, Manufacturing and Controls**

- i.** Questions about candidate product selection for further development (including circumstances where the sponsor has not decided between multiple product options or the investigational product has not been identified).

- ii. Situations in which the sponsor has previously received formal regulatory advice about a similar product and indication.
- b. Pharmacology/Toxicology**
- i. Questions regarding the adequacy and design of definitive toxicology studies. Agency input on the design of definitive preclinical toxicology studies occurs in the context of pre-IND meetings.
 - ii. Pre-review of completed proof-of-concept or toxicology studies. Reviews of the final study reports for the completed studies occurs in the setting of IND submissions.
 - iii. Questions regarding a preclinical testing plan where no preliminary data from pilot studies are provided.
- c. Clinical**
- i. Routine questions regarding specific aspects of clinical study protocol design, such as inclusion and exclusion criteria. (Review of clinical study designs or protocols occurs in the context of pre-IND submissions.)

II. Meeting Management Procedural Goals

Table 1: Summary of Meeting Management Procedural Goals

Meeting Type	FDA's Response to Request	FDA's Receipt of Meeting Package	FDA's Comments to Sponsor	Sponsor's Response to FDA's INTERACT Comments	FDA's Scheduled Meeting Date (days from receipt of request)	FDA's Meeting Minutes to Sponsor
INTERACT	21 calendar days	With meeting request; WRO not applicable for these meetings	No later than 1 calendar day before meeting	No changes to the original questions will be accepted; may cancel prior to the meeting at sponsor's request	Within 90 calendar days (subject to availability of CBER resources)	N/A

Additional notes:

- Email subject line and cover letter should clearly identify the meeting request is for an INTERACT meeting and identify the CBER Office where the request is directed.