Slide 1

FDA Center for Biologics Evaluation
and Research (CBER) INitial Targeted Engagement for Regulatory Advice on CBER producTs (INTERACT) Meetings

Speaker’s Notes:

The following presentation provides an overview of the FDA Center for Biologics Evaluation and Research (**or CBER**) INitial Targeted Engagement for Regulatory Advice on CBER producTs (**or INTERACT**) Program.

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# What is an INTERACT meeting?

* Replaces CBER pre-pre-Investigational New Drug (IND) meeting process
* Assists sponsor-investigators with clarifying CBER’s product development expectations
* Streamlines product development

**NOTE:** An INTERACT meeting is not an FDA requirement.

Speaker’s Notes:

What is an INTERACT Meeting?

The INTERACT meeting replaces the CBER pre-pre-Investigational New Drug (**or IND**) meeting process for all biologic products.

An INTERACT meeting can assist sponsor-investigators with clarifying CBER’s expectations regarding product development programs, as well as, streamline product development by helping sponsor-investigators avoid unnecessary preclinical or other preparatory studies.

Please note that although highly recommended by FDA, an INTERACT meeting is not an FDA requirement.

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# What is an INTERACT meeting? (cont’d)

An INTERACT meeting enables sponsor-investigators to:

* Obtain preliminary informal consultation with the Agency/CBER at an early stage of development prior to a pre-IND meeting
* Foster timely engagement with CBER on issues critical to early product development
* Obtain initial, nonbinding advice from FDA regarding chemistry, manufacturing and controls (CMC), pharmacology/toxicology, and/or clinical aspects of the development program
* Avoid unnecessary preclinical or other preparatory studies
* Plan initial clinical development strategies

Speaker’s Notes:

The INTERACT meeting can be used to help facilitate more efficient product development by enabling sponsor-investigators to obtain preliminary, informal consultation with CBER prior to requesting a pre-IND meeting. Sponsor-investigators can obtain non-binding advice regarding:

* Planning initial clinical development strategies
* Chemistry, manufacturing and controls (or CMC)
* Pharmacology/Toxicology

And

* Clinical aspects of the product development program

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# Why request an INTERACT meeting?

* You are conducting early product characterization and pre-clinical proof-of-concept studies
* To initiate discussion for new delivery devices
* To obtain information on overall early-phase clinical design elements
* To identify critical issues or deficiencies to address in the development of innovative products

**NOTE:** An INTERACT meeting is not intended to take the place of a pre-IND meeting nor is it a prerequisite to requesting a pre-IND meeting.

Speaker’s Notes:

Why request an INTERACT meeting?

If you are a sponsor-investigator conducting early product characterization and preclinical proof-of-concept studies and/or you want to initiate discussion for a new delivery device, you should request an INTERACT meeting.

If you are seeking to obtain information on overall early-phase clinical design elements or you want to identify critical issues to address in the development of new and innovative products *early* in product development, you should request an INTERACT meeting.

Please note that an INTERACT meeting is not intended to take the place of a pre-IND meeting nor is it a prerequisite to requesting a pre-IND meeting.

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# At what point in pre-clinical development should an INTERACT meeting be requested?

* After selection of a specific investigational product or a product-derivation strategy for clinical study.
* When development of innovative investigational product(s) introduces new safety concerns because of unknown safety profiles from use of:
* complex manufacturing technologies,
* innovative devices; or
* cutting-edge testing methodologies.

Speaker’s Notes:

At what point in pre-clinical development can an INTERACT meeting be requested?

 An INTERACT meeting can be requested AFTER the sponsor-investigator has selected a specific investigational product or a product-derivation strategy to evaluate *in a clinical study* and/or when innovative investigational product development introduces new safety concerns due to unknown safety profiles.

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# What does the INTERACT program involve/consist of?

* One consultation with CBER to address the issues the sponsor-investigator submitted for discussion

 For example:

* Choice of appropriate preclinical models
* Necessary toxicology studies
* INTERACT meetings are held via teleconference only
* Calls are generally 1 hour

Speaker’s Notes:

What does the INTERACT program involve/consist of?

* The INTERACT program consists of *one* consultation on issues that the sponsor-investigator needs to address (such as the choice of appropriate preclinical models or necessary toxicology studies).
* Meetings are held as a teleconference only, generally for one hour.

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# How do I request an INTERACT meeting?

Send requests to INTERACT-CBER@fda.hhs.gov

* Specify request for INTERACT meeting via both cover letter and email subject line
* Identify CBER Office where request is directed (<https://www.fda.gov/about-fda/about-center-biologics-evaluation-and-research/contacts-center-biologics-evaluation-research-cber>).
* Define specific areas of input requested from CBER in meeting request

Speaker’s Notes:

How do I request an INTERACT meeting?

INTERACT meeting requests should be sent to **INTERACT-CBER@fda.hhs.gov** .

Be sure to specify that the request is for an INTERACT meeting on the cover letter AND in the email subject line and use the link included in the 3rd bullet of this slide to assist with identifying the CBER Office to which to direct your request.

Sponsor-investigators should also define in the meeting request the specific areas of input requested from CBER.

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# How do I request an INTERACT meeting? (cont’d)

* Establish secure email with FDA **BEFORE** submitting INTERACT meeting request to CBER
* [SOPP 8119: Use of Email for Regulatory Communications (Appendix 1)](https://www.fda.gov/media/108992/download)

* Establish secure email with FDA by sending requests to SecureEmail@fda.hhs.gov

**Note:** Allow adequate time for FDA’s secure email set-up before anticipating email responses from FDA.

Speaker’s Notes:

How do I request an INTERACT meeting? (Cont’d)

In order for FDA to provide regulatory information in response to a sponsor-investigator’s email, the email must first route through a secure email partner to allow FDA to digitally sign and encrypt the message.

It is preferred that sponsor-investigators establish secure email with FDA **BEFORE** submitting an INTERACT meeting request to CBER. For details on setting up secure email with FDA, sponsor-investigators should review SOPP 8119: Use of Email for Regulatory Communications (Appendix 1).

Requests to establish secure email with FDA should be sent to **SecureEmail@fda.hhs.gov**.

Be sure to allow adequate time for FDA’s secure email set-up before anticipating email responses from FDA.

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# What should I expect after an INTERACT meeting is requested?

* Sponsor-investigators will receive a response from CBER within 21 calendar days of receipt
* Meeting will be held within 90 calendar days of request (based on the availability of CBER resources)
* INTERACT meeting request submissions must be accompanied by a meeting package

**Note:** For a productive meeting, FDA recommends that sponsor-investigators review: SOPP 8214, *INTERACT Meetings with Sponsors for Drugs and Biological Products.* <https://www.fda.gov/media/124044/download>

Speaker’s Notes:

What should I expect after an INTERACT meeting is requested?

After an INTERACT meeting is requested, you should expect to receive a response regarding the scheduling of your requested meeting from the responsible CBER office within 21 calendar days of receipt.

The meeting will be held within 90 calendar days of receipt of the request, based on the availability of CBER resources.

For a productive meeting, FDA recommends that sponsor-investigators review:  [SOPP 8214, entitled “INTERACT Meetings with Sponsors for Drugs and Biological Products](https://www.fda.gov/media/124044/download)”.

This SOP describes the INTERACT meeting request submission process and outlines the requirements for the INTERACT meeting package (which must accompany an INTERACT meeting request submission).

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# What should the INTERACT meeting package contain?

* Description of product and disease or condition being treated or prevented
* Information about current and future product development plans (if appropriate)
* Brief statement summarizing purpose of meeting
* List of questions for discussion, grouped by topic, with summary for each question to explain need or context for question.

 Questions regarding *combination products* should be grouped together.

**Note:** Meeting packages should be no more than 50 pages.

Speaker’s Notes:

What should the INTERACT meeting package contain?

An INTERACT meeting package should contain:

* A description of the product and disease or condition being treated or prevented.
* Information about the product development to date and future development plans, if appropriate.
* A brief statement summarizing the purpose of the meeting.
* A list of questions for discussion, grouped by topic, with a summary for each explaining the need or context for the question **(grouping together questions regarding combination products)**

The meeting package should not to exceed 50 pages.

And the questions submitted to CBER within a single meeting request should be limited to those that can be reasonably answered within one hour, taking into consideration the complexity of the questions.

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# What should the INTERACT meeting package contain? (cont’d)

* Summary of data to support discussion organized by topic and question
* List of all meeting participants from the sponsor-investigator’s organization (including consultants and interpreters), with their titles and affiliations
* Suggested dates and times (e.g., morning or afternoon) for the meeting
* Non-availability dates and times

Speaker’s Notes:

The meeting package should also include:

* A summary of data to support discussion organized by topic and question.

**As well as**

* A list of all meeting participants from the sponsor-investigator’s organization, with their titles and affiliations. This list should also include any consultants or interpreters.

The sponsor-investigator should also include suggested dates and times for the meeting (specifying morning or afternoon) as well as non-availability dates and times. The suggested timeframes will only be considered within the context of CBER resource availability.

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# Can an INTERACT meeting request be denied?

An INTERACT meeting request can be denied when:

* Requested feedback is not appropriate or is outside the scope for an INTERACT meeting
* Stage of product development is either premature or too advanced for an INTERACT meeting
* A previous meeting for same purpose already held and no substantially new information available
* Requested feedback is not appropriate for a meeting with CBER

**Note:** If meeting request is denied, CBER will provide sponsor-investigator reason(s) for denial.

Speaker’s Notes:

Can an INTERACT meeting request be denied?

Yes. CBER may deny a sponsor-investigator’s request for an INTERACT meeting if:

* The requested feedback is not appropriate or is outside of the scope for an INTERACT meeting.

**OR**

* If the stage of development is either premature or too advanced for an INTERACT meeting**. Of note, CBER will generally inform the sponsor-investigator if a different meeting type is more appropriate.**
* A meeting request can also be denied if a previous meeting for the same purpose has already been held and no substantially new information has become available.

**OR**

* If the requested feedback is not appropriate for a meeting with CBER.

If a meeting request is denied, CBER *will* provide the sponsor-investigator with a reason for the denial.

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# Can an INTERACT meeting be rescheduled?

Yes, in instances when:

* Sponsor-investigator asks to reschedule
* When additional CBER reviewers or management input is needed but cannot be obtained prior to original meeting date
* Required CBER attendees become unexpectedly unavailable and appropriate substitutes cannot be identified

Speaker’s Notes:

Can an INTERACT meeting be rescheduled?

Yes. An INTERACT meeting may be rescheduled by CBER and a new date immediately identified. An INTERACT meeting can also be rescheduled if the sponsor-investigator asked to reschedule the meeting and a new date is immediately identified, or, when additional CBER consult reviewers or management input is needed but cannot be obtained prior to the original meeting date. The meeting can also be rescheduled in instances when required CBER attendees become unexpectedly unavailable and appropriate substitutes cannot be identified.

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# CBER INTERACT COMMENTS

* Sponsor-investigator may receive responses to questions before meeting to facilitate discussion.
* Once comments are provided by CBER, additional questions from sponsor-investigator will not be accepted.
* Meeting discussion will be limited to initial questions submitted in meeting package.

Speaker’s Notes:

CBER INTERACT Comments

* Before the scheduled meeting date, CBER may send responses (or comments) to the sponsor-investigator’s questions contained in the meeting package to facilitate the discussion.
* If the sponsor-investigator receives responses from CBER, additional questions from the sponsor-investigator will not be accepted and meeting discussion will be limited to the initial questions submitted in the meeting package.

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# CBER INTERACT COMMENTS (cont’d)

* Sponsor-investigator may cancel meeting (if satisfied with CBER INTERACT comments), by sending formal written notification to CBER, referencing assigned pre-submission tracking number (PTS #), before scheduled meeting date.

 **NOTE:** Requests to cancel **AFTER** the meeting has been scheduled require a “formal” request submission to CBER, sent via email, referencing the Regulatory Project Manager and pre-submission tracking number (or PTS #) assigned to the meeting. Requests to cancel the meeting **PRIOR** to receiving a meeting date and PTS # can also be sent via email.

* Sponsor-investigator can cancel meeting in writing for any other reason; CBER will confirm cancelation.

Speaker’s Notes:

CBER INTERACT Comments (cont’d)

* If satisfied with the CBER INTERACT comments, the sponsor-investigator may cancel the meeting by sending written notification to CBER as soon as possible before the scheduled meeting date. The sponsor-investigator can also ask to cancel the meeting (in writing) for any other reason.
* **PLEASE NOTE:** If you request to cancel the meeting **AFTER** it has been scheduled, for documentation purposes, you will need to submit a formal request to CBER, via email, referencing the pre-submission tracking number (or PTS number) assigned to the meeting. If you request to cancel the meeting **PRIOR** to receiving a meeting date and PTS number, the request for cancellation can also be sent via email.
* Upon receipt of written notification, CBER will confirm cancelation. CBER will not encourage the cancelation of INTERACT meetings.

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# Meeting Minutes

* CBER advice given during INTERACT meetings is informal and non-binding.
* CBER will not issue official meeting minutes to sponsor-investigator.
* Any sponsor-investigator meeting minutes submitted to CBER will not be reviewed by CBER in any manner.
* CBER will not review minutes for completeness nor accuracy.
* Sponsor-investigator meeting minutes do not alter any pre-meeting comments provided by CBER (written or verbal) and are not the official minutes of the meeting.

Speaker’s Notes:­

Meeting Minutes

* The advice given by CBER during an INTERACT meeting is informal and non-binding. Therefore, CBER will not issue official meeting minutes to the sponsor-investigator.
* Any meeting minutes the sponsor-investigator provides to CBER will not be reviewed by CBER in any manner. CBER will not review the minutes for completeness nor accuracy. Sponsor-investigator meeting minutes do not alter any pre-meeting comments provided by CBER (in either written or verbal format) and are not the official minutes of the meeting.

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# INTERACT vs. Pre-IND Meeting (1)

| **Meeting Type** | **When to Request** | **Benefit to Sponsor-Investigators** | **Scope of Meeting Topics** |
| --- | --- | --- | --- |
| **INTERACT** | * Occurs prior to a pre-IND Meeting
* Request meeting **after** the specific investigational product or product-derivation strategy to evaluate in a clinical study has been selected and product development activities have been initiated

 **NOTE:** An INTERACT meeting is not a pre-requisite for requesting a pre-IND meeting. | * Opportunity to clarify CBER’s expectations regarding your product development program
* Help with facilitating more efficient product development

  | Obtain informal, non-binding advice from FDA regarding :* CMC
* Pharm/Tox
* Clinical aspects of the development program in the early phases of clinical trial design
 |
| **Pre-IND** | * Occurs prior to an IND submission
* Request meeting for investigational products further along the developmental pathway

(e.g. Post proof of concept studies) | * Reduce time to market by helping to minimize potential clinical hold issues from arising
* Assists with developing a strategy for drug development
 | * Discuss the scope and design of planned initial studies
* Discuss design of animal studies needed to support human clinical testing
* Discuss IND formatting

 |

Speaker’s Notes:

INTERACT vs. Pre-IND Meeting Table

Slides 17 – 19 include a table that illustrates some of the differences between an INTERACT meeting and a Pre-IND meeting.

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# INTERACT vs. Pre-IND Meeting (2)

| **Meeting Type** | **Meeting Package Content** | **Meeting Package “Dos & Don’ts”** |
| --- | --- | --- |
| **INTERACT** | * Description of product and disease or condition being treated/prevented
* Information re: product development to date and future development plans
* Brief statement summarizing meeting purpose
* List of questions for FDA (grouped by topic) with a summary for each question explaining the context for the question
 | **Do** identify the specific investigational product to be evaluated in a clinical study and initiate strategic product development activities **prior** to requesting an INTERACT meeting.**NOTE:** Sponsor-investigators should not include questions re: investigational product selection/identification in the INTERACT meeting package.**Don’t** request an INTERACT meeting if the sponsor-investigator has already requested and obtained formal regulatory advice about a similar product/indication. **Don’t** include questions regarding the adequacy and design of definitive toxicology studies in the INTERACT meeting package. **NOTE:** Any questions regarding definitive preclinical toxicology study design should be submitted as part of a pre-IND (vs. INTERACT) meeting package.**Don’t** include requests for pre-review of completed proof-of-concept or toxicology studies. **NOTE:** IND submissions (vs. INTERACT meetings) involve FDA review of final study reports for completed studies.**Don’t** include questions re: preclinical testing plan(s) without providing preliminary data from pilot studies. **NOTE:** Request for review of clinical study designs or protocols should be included in a pre-IND submission vs. an INTERACT meeting package. |

Speaker’s Notes:

The table includes such information as at what point in product development to request each meeting type, the scope of meeting topics covered in an INTERACT vs. Pre-IND meeting **and** meeting package “dos and don’ts” for each meeting type.

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# INTERACT vs. Pre-IND Meeting (3)

| **Meeting Type** | **Meeting Package Content** | **Meeting Package “Dos & Don’ts”** |
| --- | --- | --- |
| **Pre-IND** | * Description of product manufacturing and testing
* Completed and planned preclinical study summaries
* Phase 1 clinical study design or protocol

 **NOTE:** Questions for pre-IND meetings are included with the meeting request submission and it is also recommended that pre-IND questions be included in the meeting package. | **Do** make sure that a pre-IND meeting is needed (i.e. ensure that the answers to your questions are not available in FDA guidance documents).**Do** include adequate CMC information.**NOTE:** Include a description of the manufacturing scheme for the active pharmaceutical ingredient (API) and formulation for clinical study.**Do** include sufficient pre-clinical support.**Don’t** submit an unacceptable clinical trial design. **Do** comply with Good Clinical Practices (GCPs). **Do** include adequate dosage selection information. **Don’t** present data during the meeting that is not included in the meeting packet. **Do** submit a copy of the meeting request with the meeting package including updates to reflect the most current information. |

Speaker’s Notes:

I won’t review the table in detail, as it is included as a resource to assist sponsor-investigators in navigating the INTERACT meeting request and submission process.

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# GTRP Clinical Coordinating Center (CCC) Services

The NHLBI Gene Therapy Resource Program (GTRP) Clinical Coordinating Center (CCC) can provide regulatory consultation and assistance to sponsor-investigators to:

* Prepare INTERACT meeting package (working with the sponsor-investigator)
* Schedule INTERACT meeting
* Participate as listeners on INTERACT teleconference meeting
* Prepare INTERACT meeting minutes
* Provide meeting minutes to sponsor-investigator and, if instructed, to CBER.

**NOTE:** Any meeting minutes drafted by the CCC are unofficial and, if submitted, will not be reviewed by CBER in any manner.

For information regarding the GTRP service request process, contact the GTRP CCC at GTRPCCC@s-3.com.

Speaker’s Notes:

GTRP Clinical Coordinating Center (CCC) Services

As a provided service of the Gene Therapy Resource Program (**or GTRP**), the Clinical Coordinating Center (**or CCC**) can provide regulatory consultation and assistance, working with the sponsor-investigator in the preparation of an INTERACT Meeting Package and in the scheduling of an INTERACT meeting.

The CCC can also participate as listeners on the INTERACT teleconference meeting, prepare INTERACT meeting minutes, provide the meeting minutes to the sponsor-investigator and, if instructed by the sponsor-investigator, to CBER. Please note that any meeting minutes drafted by the CCC are unofficial and, if submitted, will not be reviewed by CBER in any manner.

For information regarding the GTRP service request process, contact the GTRP CCC at [GTRPCCC@s-3.com](file:///C%3A%5CUsers%5CJBevett%5CAppData%5CLocal%5CMicrosoft%5CWindows%5CTemporary%20Internet%20Files%5CContent.Outlook%5CS1YHJFWT%5CGTRPCCC%40s-3.com).

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# Resources

* [SOPP 8214: INTERACT Meetings with Sponsors for Drugs and Biological Products (V1.0, dated October 1, 2018)](https://www.fda.gov/media/124044/download)

* [FDA in Brief: FDA announces program to enhance early communications with biological product developers](https://www.fda.gov/news-events/fda-brief/fda-brief-fda-announces-program-enhance-early-communications-biological-product-developers) (dated June 22, 2018)
* [INTERACT Meetings (Initial Targeted Engagement for Regulatory Advice on CBER products)](https://www.fda.gov/vaccines-blood-biologics/industry-biologics/interact-meetings-initial-targeted-engagement-regulatory-advice-cber-products)
* [Small Business and Industry Assistance: Frequently Asked Questions on the Pre-Investigational New Drug (IND) Meeting](https://www.fda.gov/drugs/cder-small-business-industry-assistance-sbia/small-business-and-industry-assistance-frequently-asked-questions-pre-investigational-new-drug-ind) (dated September 1, 2015)

Speaker’s Notes:

Please note the resources included on this slide. It is highly recommend that sponsor-investigators review these documents to assist with determining the appropriate meeting type for your stage of early product development **AND** meeting INTERACT request and submission requirements. Please contact the GTRP CCC at [GTRPCCC@s-3.com](file:///C%3A%5CUsers%5CJBevett%5CAppData%5CLocal%5CMicrosoft%5CWindows%5CTemporary%20Internet%20Files%5CContent.Outlook%5CS1YHJFWT%5CGTRPCCC%40s-3.com) for more information regarding our services.

Thank you for your attention.