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1.0 Purpose

This Standard Operating Procedure (SOP) describes the preparation of Pre-IND Meeting request letters.

2.0 Scope

This SOP applies to Biopharmaceutical Development Program (BDP) and Regulatory Affairs personnel who are involved in preparation of Pre-IND (Type B) meeting request letters for clients.

To use FDA resources efficiently and before requesting a meeting, project team and regulatory staff should review the resources available on-line at the FDA website (fda.gov). A broad range of scientific and regulatory advice is available through guidance's and policies.

3.0 Authority and Responsibility

3.1 It is the responsibility of BDP Staff to notify the Regulatory Affairs (RA) Associate Director or delegate whenever they are notified that Pre-IND meeting request support has been requested.

3.2 It is the responsibility of the Regulatory Affairs Associate Director or designee to provide assistance to NCI-BRB (National Cancer Institutes-Biological Resources Branch) staff or other clients requesting assistance with preparing a Pre-IND meeting request.

3.3 Biopharmaceutical Quality Assurance (BQA) is responsible for quality oversight of this procedure.

3.4 It is the responsibility of the IND Sponsor to submit the final pre-IND Meeting Request and to ensure that the Pre-IND meeting information package is ready to be submitted no later than 30 calendar days prior to the earliest suggested meeting date in case the earliest meeting date is granted by the FDA.

4.0 Procedure

4.1 Requests for Pre-IND meetings must follow FDA Guidance Documents (See Section 5.0). The Sponsor will submit the request for a Pre-IND meeting to the appropriate FDA review division in the appropriate format using the appropriate submission mechanism (refer to FDA website for more information).

4.2 The following items should be included in the Pre-IND meeting request. A sample Pre-IND Meeting Request Cover Letter can be found as Attachment 1. A sample template to a Pre-IND Meeting Request can be found as Attachment 2. The order of items can be subject to change.

- Product name and IND application number (if previously assigned).
- Chemical name (description of molecular entity), established name, and/or structure
- The proposed regulatory pathway
- Proposed indication(s) or context of product development
- The type of meeting being requested (Type B)
- Pediatric study plans, human factors engineering plan, and combination product information (details on device, packaging etc.), if applicable.
- A brief statement of the purpose and objectives of the meeting.
  - This statement should include a brief background of the issues to be discussed. The statement can include a brief summary of completed or planned studies and clinical trials or data that the sponsor intends to discuss at the meeting. In addition, it can include an overview of the critical questions to be asked and where the meeting fits in the overall development plans. The statement should not provide detailed documentation of trial designs or completed studies and clinical trials, although a small table that summarizes major results could be included if needed to facilitate discussions. The brief summary should provide enough information to facilitate an understanding of the issues to be discussed.
- A proposed agenda, including estimated amounts of time needed for each agenda item and designated speaker(s) if applicable. It is recommended that very little time be spent introducing the proposed product/indication/clinical trial and supporting data so that the FDA can spend time responding to the critical questions. In general, after introductions, the FDA prefers to go through each question that needs discussion (questions already addressed by FDA in their written response prior to the meeting do not need to be discussed).
- A list of proposed precise questions, grouped by discipline (Chemistry, Manufacturing, Controls, Pre-Clinical, and Clinical). For each question there should be a brief explanation of the context and purpose of the question.
- A list of the individuals with their titles and affiliations who will attend the requested meeting from the sponsors or applicant's organization and consultants.

- A list of FDA staff, if known, or discipline representatives asked to participate in the requested meeting.
- The estimated date on which the Pre-IND Meeting Background/Information Package will be sent to the FDA. Generally, one states that this Background/Information Package will be provided 30 calendar days prior to the scheduled meeting date.
- A list of suggested dates and meeting times (e.g., morning or afternoon). The FDA generally schedules Type B meetings to occur within 60 calendar days of its receipt of the written request for a meeting. So, suggested dates should be about 60 days from when the meeting request letter is sent to the FDA. Remember to allow for an Information package to be sent to the FDA at least 30 calendar days prior to your earliest suggested meeting date. If there are specific dates when the requester is not available those should also be provided.
- The format of the meeting [i.e., face to face, teleconference/videoconference, or written response only (WRO)].

4.3 Reviewers of Pre-IND Meeting Request letters can include the following: The Director of BQA, the Regulatory Affairs (RA) Associate Director, the Project Scientist, and the BRB Project Director. Appropriate reviewers are determined by the RA Associate Director, with input from the BRB Project Director (as needed).

4.4 It is the responsibility of the IND sponsor to submit the pre-IND meeting request to the FDA in the appropriate format.

5.0 References and Related Documents

FDA Guidance for Industry: Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products, December 2017

FDA Guidance for Industry: IND Meetings for Human Drugs and Biologics; Chemistry, Manufacturing, and Controls Information, , May 2001

Regulations applicable to meetings on investigational products in 21 CFR 312.47

CBER Standard Operation Procedures and Policies (SOPP) 8101.1: Regulatory Meetings with Sponsors and Applicants for Drugs and Biological Products

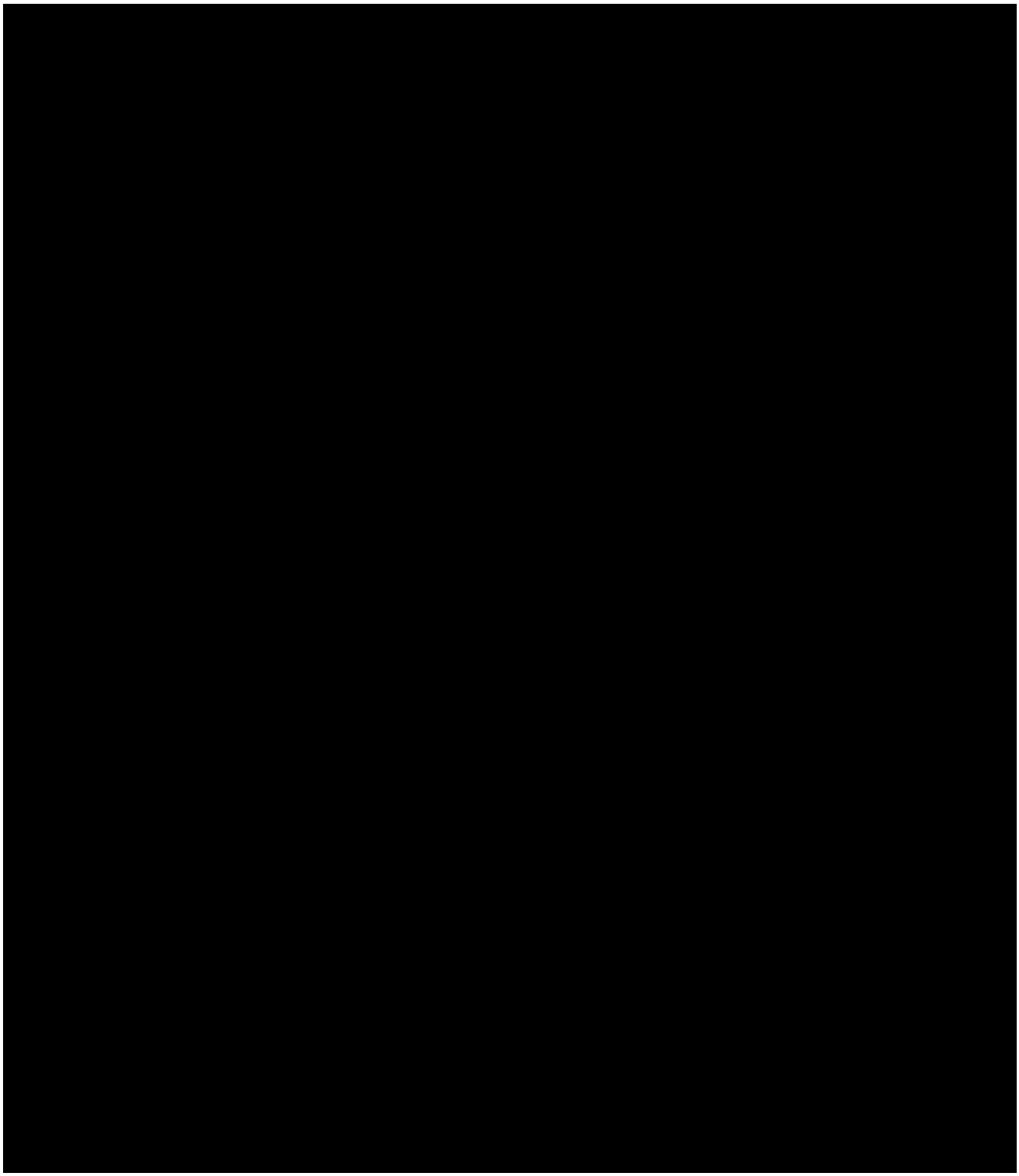
Good Review Practice, Guidance for Industry and Review Staff: Best Practices for Communication Between IND Sponsors and FDA During Drug Development, December 2017

6.0 Attachments

Attachment 1 Sample Pre-IND Meeting Request Cover Letter

Attachment 2 Sample Pre-IND Meeting Request Template

7.0 Change Summary



Attachment 1

Sample Pre-IND Meeting Request Cover Letter

Date

[Dr. John Smith- office director's name]

Office of _____

U.S. Food and Drug Administration
Center for Biologics Evaluation and Research

Document Control Center
10903 New Hampshire Avenue
WO71, G112
Silver Spring, MD 20993-0002

RE: Request for a Pre-IND Meeting (Type B) for [*Add Product Name]* as a Treatment for [*Add Treatment Type]*

Dear [*Dr. Smith]*:

We *(or file in company name*) would like to request a Pre-IND (Type B) Meeting with the FDA to discuss a proposed IND to develop [*Add product name]* as a treatment for [*add treatment type*.] [*Next you can briefly discuss current therapies for this disease and the benefits of your product.]*

The purpose of the proposed initial clinical study is to _____

[Mention safety and pharmacokinetics will be evaluated. Mention the indication and patient population to be studied. Keep this paragraph short-only a few sentences.]

[Product name] is one of a group of monoclonal antibodies derived from the [*product name]* that are specifically cytotoxic to B cells. In vitro studies of this group of monoclonal antibodies have shown that [*product name]* is the most cytotoxic to B cells. The antibody induces large pores in the membranes of B cells and cell death occurs via a biophysical phenomenon resembling necrosis. This novel form of cell death is distinct from apoptosis and complement-mediated necrosis. [*Product name]* kills a variety of human B cell lines representing various types of B cell lymphomas (lymphoblastoid, Burkitt's, DLC).

[*This third paragraph should briefly discuss the product, what it is or what it reacts with that makes it useful. Identify anything unique about the product. Include chemical name and structure.]*

Attachment 1 (Continued)

The purpose of this Pre-IND meeting is to discuss issues concerning _____ [*pre-clinical toxicology studies, proposed clinical trial design, any CMC issues. This*

statement could include a brief discussion of the types of completed or planned studies or data that the applicant intends to discuss at the meeting, the general nature of the critical questions to be asked, and where the meeting fits in the overall development plans. Lastly add a statement about what objectives/outcomes you expect to get from the meeting. This can be a general statement that the applicant hopes to gain input from the FDA concerning the pre-clinical tox studies, clinical trial protocol design, and CMC issues - you can state any specific issues you have.]

The PreIND Type B Meeting request is attached. It includes a proposed agenda including the estimated amounts of time needed for each agenda item and the designated speaker. Also, included is a list of the individuals who plan to attend the meeting, and the proposed FDA staff that we would like to participate in the meeting. In addition, a draft list of specific questions to be addressed at the meeting is included.

The attached request includes proposed dates for a _____*(indicate teleconference/videoconference, face to face, or written response only)* meeting.The meeting Information Package will be submitted at least 30 calendar days prior to the meeting date.

We appreciate your consideration of this Pre-IND meeting request. Please contact _____ at _____ to discuss meeting dates. If you need any additional information in the interim, please do not hesitate to call me.

Sincerely,

Dr. [*fill in name]*

[(title)]

[(affiliation)]

Attachment 2

Sample Pre-IND Meeting Request Template

1. **The application number:**
2. **Product Name:**
3. **Chemical name, established name, and/or structure:**
4. **The proposed regulatory pathway:**
5. **Proposed Indication:**
6. **Type of Meeting Requested:** Type B Pre-IND Meeting
7. **Pediatric Study Plans:**
8. **Human Factors Engineering Plan:**
9. **Combination Product Information:**
10. **Purpose of Meeting and Objectives:**

    Example- A Type B PreIND Meeting is requested to discuss the preclinical toxicology study design, proposed clinical trial design, and CMC issues.

11. **Proposed Agenda:**

I.	Introductions/Background	All	5 minutes
II.	Discussion of List of Questions	All	50 minutes
	• CMC Issues		
	• Preclinical Issues		
	• Clinical Trial Design		
III.	Meeting Summary	FDA RPM	5 minutes

12. **A List of Proposed Questions:**

<u>CMC Questions and/or Proposals</u>:

1.
2.
3.

<u>Preclinical Questions and/or Proposals</u>:

4.
5.
6.

Attachment 2 (Continued)

Clinical Trial Design Questions and/or Proposals:

7.

8.

13. List of Proposed Attendees: *(include name, title, and affiliation)*

A list of individuals from the sponsors or applicant's organization and consultants

A list of requested FDA staff, if known, or discipline representatives

14. Meeting Package Submission Date:

(The meeting information package will be provided to the FDA at least 30 calendar days prior to the scheduled meeting date.)

15. Suggested Dates and Times for the Meeting:

(list at least 4-5 dates and times –morning or afternoon- for the meeting; the dates should be scheduled to occur approximately 60 calendar days from the Agency's receipt of the written request for a meeting – remember for a Type B meeting, the meeting information package must be submitted at least 30 calendar days prior to the assigned meeting date by the FDA or they can cancel the meeting; usually people pick dates 6-8 weeks out so they have at least two weeks to submit the information package from the time they send in the letter. Make sure you will be ready to submit your information package at least 30 calendar days prior to the first proposed meeting date.)

16. Proposed Meeting Format*:*

(face to face, teleconference/videoconference or written response only)