XY Month 20XX

Food and Drug Administration

Center for Drug Evaluation and Research

Central Document Room

5901-B Ammendale Rd.

Beltsville, Md. 20705-1266

Attn: *Jane Doe*, MD

 Director, Division of Something

**Type B Meeting Request: *(Pre-IND or EOPX)* Meeting**

Dear *Dr. Doe*:

I am requesting a *(Pre-IND or EOPX)* meeting to discuss a preclinical, product and clinical issues for Phase I and the overall drug development program for the use of *(Drug XY)* in the treatment of *(WZ Syndrome).*

We have assembled large amount of information on the use of *(Drug XY)* to treat *(WZ Syndrome)*. We have, however, a number of questions that pertain to the proposed administration of *(Drug XY)* in the *(ZW affected patient population)*. The issues that we wish to discuss and obtain Agency guidance and approval relate to aspects of the clinical study design (*for example*) and the choice of endpoints (*for example*) that could be the basis of approval for *(Drug XY)* in treatment of *(ZW Syndrome)*. Enclosed is the required information relating to this *(Pre-IND or EOPX)* meeting request.

Sincerely,

*John Doe*, MD

Professor, Department of Something

Duke University

Tel: 919 684 xxxx

Fax: 919 684 xxxx

email: john.doe@duke.edu

X MEETING REQUEST

TITLE

IND Number (If known)

Name of Sponsor, Affiliations

X Professor, Department

DUKE UNIVERSTIY

Durham, NC

Date of Submission

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# APPLICATION NUMBER

*If known*

# PRODUCT NAME

# CHEMICAL NAME AND STRUCTURE

*The chemical name, established name, and/or structure.*

# PROPOSED REGULATORY PATHWAY

*(e.g., 505(b)(1), 505(b)(2))*

# PROPOSED INDICATION

*Or context of development*

# MEETING TYPE

*i.e., Type A, Type B, Type B (EOP), or Type C*

# PEDIATRIC STUDY PLANS

*If applicable*

# HUMAN FACTORS ENGINEERING PLAN

*If applicable*

# COMBINATION PRODUCT INFORMATION

*If applicable, include constituent parts, including details of the device constituent part, intended packaging, planned human factors studies.*

# SUGGESTED DATES AND TIMES

*Select dates relevant to the scheduling time frame for this type of meeting (e.g. Pre-IND meetings are scheduled within 60 days of request, EOP meetings are scheduled within 70 days of request). Indicate morning or afternoon for each date. Dates and times when the requester is not available should also be included.*

# LIST OF PROPOSED QUESTIONS

*The list of questions are critical to understanding the kind of information or input needed by the meeting requester, and should focus the discussion if the meeting is granted.*

*Questions should be grouped by discipline. Each question should be precise and include a brief explanation of the context and purpose of the question.*

*The questions submitted 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 submitted.*

## Administrative (Delete if there are no questions in this area)

*Example questions:*

1. *Are GLP animal toxicity studies performed in China acceptable to the Agency?*
2. *We plan to submit IND for the Drug XY (or biologic) and a separate IND for the related Drug XXYY (or biologic). After assessing a safety of each drug in each cohort of patients, we propose to study both drugs in combinations. Can the protocol for this combination drug study be submitted to one of the INDs and just cross-reference the second?*

## Quality (Delete if there are no questions in this area)

*Example question:*

1. *We have developed an in vitro potency assay for release and to monitor stability of the drug product, but do not feel that the assay is yet sufficiently precise and accurate to use to dose in our clinical study (see Section…). Therefore, we are planning to dose the XY drug by weight. Is this plan acceptable?*

## Nonclinical (Delete if there are no questions in this area)

*Example questions:*

1. *Section 3. outlines our proposed non-clinical studies. Is the list of studies and the proposed timing of studies acceptable?*
2. *Given the extensive toxicology data already available for the “Drug XY”, and the extensive clinical testing demonstrating safety of the “Drug XY”, is a formal animal toxicology study necessary?*
3. *We propose to perform a 5-dose infusion toxicity study in rabbits. Is this study acceptable to support the 5-dose initial Phase I clinical study?*

## Clinical (Delete if there are no questions in this area)

*Example questions:*

1. *In our initial Phase I study, we propose a multiple dosing paradigm (see section…). Is this clinical study design acceptable?*
2. *Is dosing with Drug XY at concentrations that are proposed acceptable as long as no serious adverse events are observed?*
3. *In our Phase I clinical trial design, we propose to enroll 3 healthy volunteers at each dose in this dose-escalation study design (for details, see section…). Is this study design acceptable?*
4. *Mechanistically, we feel that Drug XY will have an effect in both “this and that” patient population. We would like to pursue a clinical plan that enrolls both patient populations using different inclusion/exclusion criteria and potentially different outcomes. Is this approach acceptable to the Agency?*
5. *The protocol proposes to treat patients for a prolong period of time. Is continuous dosing of Drug XY acceptable as long as there is no serious adverse events associated with the use of the drug?*
6. *In the Section…we propose a detailed plan for managing adverse events should those occur. Does the FDA agree with this plan?*
7. *Independent data safety monitoring will be performed by Dr. John Doe, who is an expert in the field and who has no involvement with the investigation. It is proposed that the safety data assessment will be performed each time five additional subjects have been enrolled to the study. Is this frequency of review acceptable?*
8. *Is the draft informed consent acceptable?*
9. *If in the opinion of the Primary Attending Physician, the patient lacks decision making capability at the time of the initial screening visit, may consent be obtained from the surrogate?*
10. *Does a surrogate need a special consent or may we use the same consent using the wording “patient and surrogate” or “you and your love one”?*
11. *The protocol requires assessment of heart rate, oxygen saturation and blood pressure to be performed every 4 hours after loading dose. Is this acceptable?*
12. *Protocol proposes the increase of the Drug XY loading dose every 30 min. Is this rate of increase acceptable?*
13. *If a randomized control placebo study shows a statistically significant difference in the two proposed parameters, would the Agency consider this as evidence of efficacy?*

# PROPOSED MEETING FORMAT

*Face to face, teleconference/videoconference, or written response only.*

# DATE MEETING PACKAGE WILL BE SENT

*For type B meetings (except End of Phase), such as Pre-IND meetings, the meeting package should be received by the FDA no later than 30 days before the scheduled meeting.*

*For End of Phase meetings, the meeting package should be received by the FDA no later than 50 days before the scheduled meeting. If the scheduled date of a Type B (EOP) meeting is earlier than 70 days from FDA receipt of the meeting request, the requester’s meeting package will be due no sooner than 6 calendar days after FDA response time for issuing the letter granting the meeting.*

*Note that meeting packages should be included with the meeting request for all Type A meetings and those Type C meetings where the objective is to facilitate early consultation on the use of a biomarker as a new surrogate endpoint that has never been previously used as the primary basis for product approval in the proposed context of use. If the scheduled date of a Type C meeting is earlier than 75 days from FDA receipt of the meeting request, the meeting package will be due no sooner than 7 calendar days after FDA response time for issuing the letter granting the meeting.*

# PURPOSE OF MEETING

*This statement should include a brief background of the issues underlying the agenda. It also can include a brief summary of completed or planned studies and clinical trials or data that the requester intends to discuss at the meeting, the general nature of the critical questions to be asked, and where the meeting fits in overall development plans. Although the statement should not provide the details of trial designs or completed studies and clinical trials, it should provide enough information to facilitate understanding of the issues, such as a small table that summarizes major results.*

# MEETING OBJECTIVES

*Include a list of the specific objectives or outcomes the requester expects from the meeting.*

# PROPOSED AGENDA

*Below is a recommended agenda, which can also be broken down into sections for specific topic discussion.*

Introductions 5 min

Discussion of questions submitted 20 min

Discussion of issues identified by the Agency 30 min

Summary of conclusions reached at the meeting 5 min

# LIST OF ATTENDEES

## List of Sponsor Attendees

*A list of all individuals, with their titles and affiliations, who will attend the requested meeting from the requester’s organization, including consultants and interpreters.*

## List of Requested FDA Attendees

*We recommend including the FDA IND project manager as well as known FDA reviewers, and the applicable Office or Division Director.*

*Note that requests for attendance by FDA staff who are not otherwise essential to the application’s review may affect the ability to hold the meeting within the specified time frame of the meeting type being requested. Therefore, when attendance by nonessential FDA staff is requested, the meeting request should provide a justification for such attendees and state whether or not a later meeting date is acceptable to the requester to accommodate the nonessential FDA attendees.*