INTERACT MEETING PACKAGE

Name of Product

Name of Sponsor Investigator, MD

Professor, Department of

Duke University

Date of Submission

*\* Note: The sponsor of an INTERACT meeting is expected to have reviewed* ***SOPP 8214: INTERACT Meetings with Sponsors for Drugs and Biological Products*** *in preparation for submission of the meeting request and meeting package. This is available at:* [*https://www.fda.gov/media/124044/download*](https://www.fda.gov/media/124044/download)*.*

*\*\*Meeting Packages are expected to be succinct and should not exceed 50 pages.*

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# Introduction

## Background

*Background on the product and the disease or condition being treated or prevented.*

## Product Name

*“Biologic XY”-name of the biologic such as vaccine construct for example*

## Description of Product

*Biologic XY is a 1 and 2 region deleted adenoviral vector expressing “this and that” human cDNA…”*

## Proposed Indication

*A description of the disease or condition being treated or prevented*

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# Product Development Summary

*A summary of information about the product development to date and future development plans, if appropriate.*

## Product Manufacturing

## Pre-Clinical Studies

## Proposed Clinical Trial

# Purpose of Meeting

*A brief statement summarizing the purpose of the meeting.*

*Example: “The requested meeting is an INTERACT meeting to discuss the overall “Biologic XY” development program including chemistry, manufacturing and controls, pharmacology/toxicology, and/or clinical aspects of the development program”*

# List of Specific Questions

*A list of questions for discussion, grouped by topic, with a summary for each question to explain the need or context for the question. Sponsors are encouraged to define in the meeting request 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. For each question, you may wish to include a statement on the Sponsor’s position.*

## Chemistry, Manufacturing and Controls (CMC)

*The types of questions or topics related to CMC covered will depend on your product. For example, you may seek Agency input on:*

* *Innovative technologies for the qualification of new cell substrates*
* *Product-manufacturing (e.g., cell sources, donor eligibility determination for allogenic cellular products and qualification of international donors)*
* *Product dependent and manufacturing process dependent reagents, starting materials and critical product components*
* *Qualification of a novel delivery device related to a specific investigational product*
* *Discussion of complex software issues and strategies to support device use in clinical studies*

*Questions about candidate product selection for further development are not appropriate for the INTERACT meeting (including circumstances where the sponsor has not decided between multiple product options or the investigational product has not been identified). Before requesting an INTERACT meeting, a sponsor needs to have selected a specific investigational product or a product derivation strategy to evaluate in a clinical study.*

## Pharmacology/Toxicology

*In the INTERACT meeting, it is appropriate it ask questions 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.*
* *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.*
* *Modification of a preclinical program or study design, as applicable, to ensure judicious use of animals.*

*Note that Agency input regarding the adequacy and design of definitive toxicology studies is typically outside the scope of the INTERACT meeting and occurs in the context of pre-IND meetings. Review of the final study reports for the completed studies occurs in the setting of IND submissions.*

## Clinical

*It is appropriate to seek Agency advice regarding general recommendations for 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. Review of clinical study designs or protocols occurs in the context of pre-IND submissions.*

# Summary of Supporting Data

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

## Chemistry, Manufacturing and Controls (CMC)

## Pharmacology/Toxicology

## Clinical

# Proposed Agenda

**Agenda Item Time**

Introductions 5 min

Discussion of questions submitted 20 min

Discussions of issues identified by the Agency 30 min

Summary of conclusions reached at the meeting 5 min

# List of Sponsor Attendees

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

| **Attendee** | **Title** | **Affiliation** |
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# Suggested Dates and Times

*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.*

*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 as teleconference only generally for one hour.*

# References