Orphan Drug Development Guidebook

Building Block U222

This document defines the content of the Building Block created for each identified tool, incentives, initiative or practice introduced by public bodies or used by developers to expedite drug development in Rare Diseases (RDs).

ITEM	DESCRIPTION
Building Block (BB) Title	INTERACT Meetings (Initial Targeted Engagement for Regulatory Advice on CBER products)
References	https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/otat-interact-meeting
Description	Development of innovative investigational products can introduce unique challenges due to unknown safety profiles, complex manufacturing technologies and issues, incorporation of innovative devices, and the use of cutting-edge testing methodologies. Through a CBER **IN**itial **T**argeted **E**ngagement for **R**egulatory **A**dvice on **C**BER produc**T**s (INTERACT) meeting, sponsors can obtain initial, nonbinding advice from FDA regarding chemistry, manufacturing and controls, 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 new delivery 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. A CBER **IN**itial **T**argeted **E**ngagement for **R**egulatory **A**dvice on **C**BER produc**T**s (INTERACT) meeting enables sponsors to obtain preliminary informal consultation with

	the Agency at an early stage of development prior to a pre-IND meeting (see BB #214), subject to Agency resource constraints. To requests for INTERACT meetings should be forwarded to INTERACT-CBER@fda.hhs.gov. In order to assess the request, please provide:1) a summary of the product and disease being treated, 2) information about the product development to date and future development plans, if appropriate and 3) questions the sponsor wishes to have addressed. Sponsors will receive a response regarding the scheduling of their requested meeting from the responsible office within 21 calendar days of receipt. Although CBER will do its best to hold INTERACT meetings within 90 calendar days of receiving requests, resource constraints may limit scheduling within this timeframe.
Category	Regulatory Building Block
Geographical scope	United States of America
Availability	Applicants developing medicines for rare and non-rare diseases.
Scope of use	An INTERACT meeting is not intended to take the place of a pre-IND meeting (see BB#214), which occurs prior to 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.[1] Conversely, an INTERACT meeting also is not a venue to provide advice to sponsors who have yet to initiate any product development activities. Products that are further along the development pathway should be discussed in the context of a pre-IND meeting. Pre-IND submissions typically include a description of product manufacturing and testing; summaries of completed and planned preclinical studies; and a Phase 1 clinical study design or protocol. Each of these elements may be further refined after the pre-IND meeting, to support an IND. The INTERACT program is also intended for such occasions when development of innovative investigational products introduces new safety concerns due to the unknown safety profiles resulting from the use of complex manufacturing technologies, innovative devices, or cutting-edge testing methodologies.
Stakeholders	Any sponsor-investigator who is preparing and/or submitting complete pre-IND applications to the Center for Biologics Evaluation and Research (CBER) at the FDA.

Enablers/ Requirements	Prior to 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.
Output	The INTERACT program generally consists of one consultation on issues that a sponsor needs to address, often this is prior to moving forward with the submission of a pre-IND meeting request. CBER advice given during INTERACT meetings is informal and non- binding. Therefore, official meeting minutes will not be issued to the sponsor. In accordance with 21CFR10.65(f), the sponsor, or other meeting participant, may prepare and submit to CBER a memorandum summarizing their understanding of issues discussed at the meeting. Since INTERACT meetings are informal and non-binding, this memorandum, if provided, will not be reviewed by CBER in any manner, no evaluation will be performed to see if the memorandum is accurate. 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.
Best time to apply and time window	The appropriate timing for an INTERACT is when you have identified the investigational product to be evaluated in a clinical study and conducted some preliminary preclinical proof-of-concept studies with the intended investigational product but has not yet designed and conducted definitive toxicology studies.

Expert tips	• INTERACT meetings are not mandatory and they may be subject to Agency resource constraints.
	
	PROs:
	
	• Purpose and process for INTERACT meetings much clearer now vs. prior pre-pre IND process
	• Useful examples provided in the SOPP for types of questions to pose
	• Free exchange of ideas – open dialogue
	• Provision of written responses in advance of meeting very helpful; should be adopted as part of SOPP
	• Valuable actionable advice provided to sponsors
	
	CONs:
	
	• Need to have the actual product candidate for the INTERACT meeting
	  ○ timing an issue especially for several small companies
	  ○ group of potential product candidates, pick one or solicit FDA feedback and perspective on the platform

	• Uncertainty about meeting request being granted
	  ○ Needed clear examples about the level of data that would support an INTERACT meeting and in what instances would the meeting be denied or a pre-IND meeting would be deemed more appropriate
	  ○ Checkbox criteria for not granting an INTERACT meeting
	• Clarity of when to have an INTERACT meeting
	  ○ It is needed to specify in the SOPP what is meant by “premature” and “too advanced” so sponsors can determine timing of an INTERACT meeting
	  ○ Provide examples
	• Ability to send briefing materials through FDA gateway