IRDiRC
INTERNATIONAL RARE DISEASES RESEARCH CONSORTIUM

Orphan Drug Development Guidebook

Building Block U213

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	FDA Type C, A meetings
References	https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM590547.pdf
Description	Per Reference above: **Type A Meeting:** "Type A meetings are those that are necessary for an otherwise stalled product development program to proceed or to address an important safety issue. Examples of a Type A meeting include: -Dispute resolution meetings as described in 21 CFR 10.75, 312.48 and 314.103 and in the guidance for industry and review staff Formal Dispute Resolution: Sponsor Appeals Above the Division Level. -Meetings to discuss clinical holds: (1) in which the requester seeks input on how to address the hold issues; or (2) in which a response to hold issues have been submitted, and reviewed by the FDA, but the FDA and the requester agree that the development is stalled and a new path forward should be discussed. -Meetings that are requested after receipt of an FDA Nonagreement Special Protocol Assessment letter in response to protocols submitted under the special protocol assessment procedures as discussed in the guidance for industry Special

	Protocol *Assessment*. -Post-action meetings requested within 3 months after an FDA regulatory action other than an approval (i.e., issuance of a complete response letter). -Meetings requested within 30 days of FDA issuance of a refuse-to-file letter. To file an application over protest, applicants must avail themselves of this meeting (21 CFR 314.101(a)(3)).” **Type C Meeting:** “A Type C meeting is any meeting other than a Type A, Type B, or Type B (EOP) meeting regarding the development and review of a product, including meetings to facilitate early consultations 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”. Under the Prescription Drug User Fee Act (PDUFA), meeting management goals have been established to assist requesters who seek advice relating to the development and review of investigational new drugs and biologics, and drug or biological product marketing applications.
Category	Regulatory Building Block
Geographical scope	United States of America
Availability	Applicants, who can be based in a public, non-profit, university, or private company developing medicines for rare and non-rare diseases.
Scope of use	Utilize a type A or type C meeting to discuss the topics raised as outlined in description above. It helps address specific regulatory concerns between a sponsor and the FDA.
Stakeholders	• FDA • Drug developers.
Enablers / Requirements	To submit a meeting request, per the reference above you must include “The proposed meeting format, […] The date the meeting background package will be sent by the requester. […] A brief statement of the purpose of the meeting. […] A list of the specific objectives or outcomes the requester expects from the meeting. […] A proposed agenda, including estimated times needed for discussion of each agenda item. […] A list of

	planned attendees from the requester's organization, including their names and titles. […] A list of requested FDA attendees and/or discipline representative(s)." Per the above reference, you should include "The application number (if previously assigned). […] The product name […] The chemical name, established name, and/or structure. […] The proposed regulatory pathway (e.g.; 505(b)(1), 505(b)(2). […] The proposed indication(s) or context of product development. […] The meeting type being requested […] Pediatric study plans, if applicable. […] Combination product information […] Suggested dates and times (e.g., morning or afternoon) for the meeting that are consistent with the appropriate scheduling time frame for the meeting type being requested […] A list of proposed questions, grouped by FDA discipline.
Output	Meeting minutes will be issued to the requester within 30 calendar days after the meeting.
Best time to apply and time window	Per reference "Before submitting a Type A meeting request, requesters should contact the review division or office to discuss the appropriateness of the request."
Expert tips	Contact FDA and seek input early. PROs: – Obtain clear input from the FDA on navigating the regulatory issues at various stages of therapeutic development.