**Appendix B**: Sponsor Interview Guide for FDA CBER's OTAT Interactions with Sponsors

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Paperwork Reduction Act Statement: According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless is displays a valid OMB control number. The valid OMB control number for this information collection is 0910-0697and the expiration date is 12/31/2023. The time required to complete the information collection is estimated to average 60-120 minutes per response, including the time for reviewing and responding to the invitation email, preparing for the interview, completing the initial interview, and an optional 30-minute follow-up interview if needed.

Send comments regarding this burden estimate or any other aspects of this collection of information, including suggestion for reducing burden to PRAStaff@fda.hhs.gov.

Your participation or non-participation is completely voluntary, and your responses will not have an effect on your eligibility for receipt of any FDA services. Your input will be blinded and aggregated by a third party contractor who is conducting these interviews on behalf of FDA prior to being shared with CBER/OTAT. Any suggestions for potential future enhancements will be offered to CBER/OTAT in a non-binding fashion. In instances where respondent identity is needed (e.g., for follow-up), this information collection fully complies with all aspects of the Privacy Act and data will be kept secure to the fullest extent allowed by law.

## INTRODUCTION

This is a federally-sponsored survey conducted on behalf of the U.S. Food and Drug Administration by a third party contractor. With this interview guide, we are seeking to understand sponsors' experiences interacting with CBER/OTAT, on regulatory matters related to cell and gene therapy products. In particular, this interview guide is designed to understand sponsors' experiences across a range of interaction types, including formal submissions, formal meetings, other more informal interactions, and broader interactions involving the scientific community. The interview guide asks specifically about sponsors' reflections on the speed and responsiveness, consistency, quality / clarity, and ease of engaging with OTAT on CGT product regulatory matters. This guide is intended to be flexible enough to facilitate discussions with a range of different types of sponsors, including interviewees from large pharma companies, small biotechs, principal investigators in academia, and sponsors not explicitly mentioned in this document. Questions may be adapted based on interviewees' experiences and the flow of the conversation.

Not all participants will be asked every question below. The interviewer will use these questions as a guide and target areas relevant to the interview participant.

## QUESTIONS

**Background and context** *(~5 minutes)*

- Could you briefly tell us about [NAME OF COMPANY OR INSTITUTION] and your role there?
- Regarding which type(s) of product(s) have you / your organization had occasion to interact with OTAT, and at what stage(s) of development?
- How many IND(s) have you / your organization submitted to OTAT in the past?
- Have you / your organization ever submitted a BLA to OTAT? If so, how many?
- What goals are you commonly trying to achieve in interactions with OTAT?

**Open-ended discussion on nature of interactions with OTAT** *(~10-15 minutes)*

- Please briefly describe the types of interactions you / your organization have had recently with OTAT, including but not limited to the following types of interactions:
  - Formal submissions (e.g., INDs, BLAs, protocols, amendments, supplements, designation requests)
  - Meeting requests and formal meetings (including Type A, B, or C meetings and INTERACT meetings)
  - Less formal interactions (e.g., *ad hoc* phone calls or email exchanges)
  - Broader interactions outside the context of a specific asset (e.g., industry meetings, conferences)

**Structured discussion on dimensions of sponsor experience with OTAT** *(~10-15 minutes)*

- The purpose of this next section is to understand relative strengths and challenges in sponsor-OTAT interactions, across different types of interactions and experience dimensions. You will be asked after this to elaborate and, in some cases, provide examples for the rationale behind your responses in this section.
- Reflecting on the recent interactions you / your organization have had with OTAT (in aggregate), on a scale of 1-10, ***how well have those interactions met your / your organization's needs in each of the following areas?***
- Please give a numerical answer, on a scale of 1 to 10, with 1 being Very poorly and 10 being Very well, or answer "n/a" in areas where you / your organization do not have direct experience.

| Experience dimension | Formal submissions | Meetings / meeting requests | Informal interactions | Broader interactions |
|---|---|---|---|---|
| **Speed and responsiveness of OTAT communications** | | | | |
| • Clear expectations on timelines for communication (e.g., when and how a response or status update from CBER/OTAT can be expected) | _____ | _____ | _____ | |
| • Speed of response (e.g., timeliness of review of submissions, acknowledgement of inbound questions or requests) | _____ | _____ | _____ | |
| **Consistency of OTAT / CBER feedback and guidance** | | | | |
| • Over time | _____ | _____ | _____ | _____ |
| • Across individual reviewers / different Divisions in OTAT / Offices within CBER (e.g., OBE, OCBQ) / with other Centers | _____ | _____ | _____ | _____ |
| • Across sponsors / assets | _____ | _____ | _____ | |
| **Quality of responses** | | | | |
| • Clarity and specificity of information provided | _____ | _____ | _____ | _____ |
| • Integrative of input from all relevant disciplines | _____ | _____ | _____ | _____ |
| • Comprehensively responding to any/all questions | _____ | _____ | _____ | _____ |
| • Provision of rationale for comments | _____ | _____ | _____ | _____ |
| **Ease of engagement** | | | | |
| • Clarity on who to contact for what and how | _____ | _____ | _____ | |
| • User friendliness of technology for digitally engaging / submitting document / checking status | _____ | _____ | _____ | |
| • Clarity on what is needed from sponsor for interaction to be successful | _____ | _____ | _____ | |
| • Ease of handling administrative aspects of interactions (e.g., ease of scheduling meetings) | _____ | _____ | _____ | |
| **Other (e.g., preparedness for meetings)** | | | | |
| • *Please specify:* _____ | _____ | _____ | _____ | _____ |

- If you had to prioritize three (3) sub-bullets above (next level of detail under the four experience dimensions) for potential improvement in the future, which would those be, and why?

**Open-ended discussion on relative strengths and challenges of interactions with OTAT, and potential ideas for the future** *(~25-35 minutes)*

- Taking a step back, how would you characterize your organization's recent interactions with OTAT (positive, neutral, or negative), and why?
  - What about each of these interactions went well, from your perspective? *(Will gather examples where relevant.)*
  - Where do you see opportunity for improvement in each of these interactions? *(Will gather examples where relevant.)*
  - How has technology (e.g., web-based forms, central platforms for tracking / status updates, automated emails) facilitated or hindered your interactions with OTAT? *(Will gather examples where relevant.)*
- During your interactions with OTAT, which one of the four experience dimensions is ***most*** important to your organization's experience? *(PROMPTS FOR INTERVIEWER: speed and responsiveness, consistency, quality/clarity, and ease of engagement)*
  - Why?
  - How has your experience with OTAT been on this experience dimension specifically?
- How have interactions with OTAT affected either your ability to perform your role and/or the development of cell and gene therapy products by you / your organization? *(Will gather examples where relevant.)*
- Do you have any specific ideas that you would like CBER / OTAT to take under consideration for the future?
- Is there any other feedback would you like to share or anything else you would like for us to know?