

OMB Control No. 0910-0697
Expiration Date: 12/31/2023

Appendix A: Invitation Email for Interview regarding FDA CBER's OTAT Interactions with Sponsors

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 it displays a valid OMB control number. The valid OMB control for this information collection is 0910-0697 and the expiration date is 12/31/2023. The time required to complete this information collection is estimated to average 60-120 minutes per response, including the time for reviewing and responding to this 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 aspect of this collection of information, including suggestion for reducing burden to PRASStaff@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. 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.

DRAFT INVITATION EMAIL

Dear ...,

As you are aware, FDA's Center for Biologics Evaluation and Research's (CBER) Office of Tissues and Advanced Therapies (OTAT) leads and coordinates the Center's diverse activities pertaining to products falling within its regulatory jurisdiction, including gene therapy, tumor vaccines, xenotransplantation, stem cells, human tissue for transplantation, plasma protein therapeutics, combination products, bioengineered tissues and certain medical devices. Through the course of its regulatory work, OTAT interfaces with sponsors (companies, individuals, or other entities responsible for initiating and managing a clinical trial) of cell and gene therapies at numerous points in the development and post-marketing process, including review of formal submissions (e.g., INDs or BLAs), response to meeting requests, and other, less formal interactions.

Cell and gene therapy is a rapidly growing and evolving field with an increasingly complex array of product modalities. The increasing workload volume (e.g., >50% increase in CGT INDs between 2016-19) and complexity associated with clinical trials for these products has placed significant demands on OTAT and could continue to do so in the future, with potential implications for the effectiveness of the interaction model between CBER/OTAT and CGT sponsors. FDA is seeking to identify existing areas of strength as well as potential areas for improvement in OTAT-CGT sponsor interactions throughout the product lifecycle and across relevant types of interactions (e.g., formal meetings, submissions, etc.). This research is focused on understanding the CGT sponsor perspective, as one of many sources of input for this important effort.

To provide independent and expert perspective in the development of potential suggestions for the improvement of interactions between OTAT and sponsors, FDA is working with a third party contractor. The contractor will conduct the sponsor interviews on behalf of the FDA and then blind and aggregate the feedback before sharing it back with FDA. As part of this effort, we would like to offer the opportunity to [you / your organization] to participate in an interview with the third party contractor to provide input on the current state of interactions between OTAT and sponsors, and how they might be strengthened in the future. We are hoping to conduct all interviews in [TIME FRAME].

If [you / your organization] is interested in participating, we'd ask that you please reply with at least two (2) preferred 1-hour time windows between [DATE] and [DATE] that would work and provide us with the names of 1-2 individual(s) who will be participating in the interview by [INSERT DATE]. The interviewee(s) should have a high level of familiarity with interactions with OTAT, as well as a good perspective on the impact of those interactions on your organization and the development program for the CGT asset(s).

If you have any questions, please don't hesitate to reach out.

Thanks,
[NAME]