FDA INTERACT meetings: What you need to know

We asked Parexel regulatory expert and former FDA regulator Steve Winitsky to share his insights for getting the most out of an FDA INTERACT meeting

1 What is an INTERACT meeting?

INTERACT stands for INitial Targeted Engagement for Regulatory Advice on CBER producTs. It is one of two early engagement meetings that you can have with the FDA Center for Biologics Evaluation and Research (CBER) prior to submitting your IND (the other is a pre-IND meeting).

www.fda.gov/vaccines-blood-biologics/industry-biologics/interact-meetings

2 What are the differences between the INTERACT and pre-IND meetings?

The INTERACT meeting allows sponsors to obtain preliminary informal feedback on CMC, Non-clinical, and Clinical issues for innovative investigational products earlier in development than the pre-IND stage.

Unlike pre-IND meetings, there is no Prescription Drug User Fee Act (PDUFA) mandated date for FDA to schedule the INTERACT meeting, and you need to submit your briefing document in conjunction with the INTERACT meeting request letter.

3 What is the best timing for submitting an INTERACT meeting request?

The FDA denies around two-thirds of all INTERACT meeting requests, with the most common reason being that the meeting request is submitted too early or too late in development. It's important to remember that the optimal timing for submitting an INTERACT meeting request is after you obtain proof-of-concept data, which demonstrate preliminary evidence of safety and efficacy from in vitro and in vivo non-clinical studies, but prior to having conducted your pivotal non-clinical studies.

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4 What are some pointers for getting the most out of the INTERACT meeting?

It's important to keep in mind that although the content of an INTERACT briefing document is fairly limited (with the average length being about 20-30 pages), you must include sufficiently detailed information for FDA to be able to provide substantive feedback on your questions.

It's really important to include detailed questions with the briefing document, which will help FDA focus on addressing your specific CMC and non-clinical issues.

Consider providing a thumbnail sketch of the proposed clinical trial so that FDA can view the CMC and non-clinical data you provide in the context of the clinical trial. This way, they can judge whether the CMC and non-clinical data adequately support the proposed clinical trial.

Choosing the right partner

Keeping pace with the rapidly growing biotech environment requires agility and the vision to anticipate and adapt to development challenges before they happen. Our experts can partner with you to provide the experience and guidance you need to help you reach your development goals every step of the way. So you can get your innovation to the patients who need it most. **#NeverStopBioteching**

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Connect with Steve

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Steve brings over 11 years of former FDA experience as a Medical Officer, Team Leader, and Acting Branch Chief in the Office of Tissues and Advanced Therapies (OTAT, formerly known as OCTGT) in the Center for Biologics Evaluation and Research (CBER). Dr. Winitsky gained extensive experience with review and supervision of cell and gene therapy files — INTERACTs (previously known in OTAT/OCTGT as pre-preINDs), INDs, and BLAs; plasma protein files — INDs and BLAs; device files — 510(k)s, IDEs, PMAs; and combination biologic and device files.

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