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STRATEGIC ROLE OF FDA INTERACT MEETINGS FOR NEW DRUG TECHNOLOGIES

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ABSTRACT

Engaging the FDA early has become indispensable for developers of novel molecular entities/pharmaceutical; technologies seeking to manage/mitigate risk and accelerate progress. The INTERACT program (INitial Targeted Engagement for Regulatory Advice on CBER/CDER Products) provides sponsors with early access to regulatory input on preclinical programs, particularly in emerging modalities and critical areas such as chemistry, manufacturing and controls, toxicology program that will support further clinical program and the writing of investigational new drug application (IND). In this short communication will be reviewed the regulatory role of INTERACT meetings and highlight strategies to maximize their impact. Since new molecular entities, whether they are chemicals, biologics, or new drug delivery systems, are becoming increasingly challenging, it can be concluded that INTERACT meetings are a decisive tool for achieving strategic clarity, preventing costly delays, and reinforcing confidence among stakeholders and investors.

KEYWORDS: Interact meeting, FDA, regulatory strategy, non-clinical and preclinical development, novel new molecular entities and delivery systems, human resources.

INTRODUCTION

During the last decade, the development of advanced therapies and regenerative medicine products has been characterized by high scientific complexity and significant regulatory uncertainty. For instance:

- **Oncology Drugs.** Off-target toxicity is still uncertain, and so is long-term safety, how to determine/predict appropriate dosing in combination regimens since several patients are polymedicated. Since these kinds of drugs are directly tested on patients, clinical/ pharmacodynamic biomarkers are highly challenged by key opinion leaders to become primary endpoints to accelerate development and approvals through the overall regulatory pathway.
- A**ntibody–Drug Conjugates** with small-molecules. Complexity in pharmacokinetics, bioavailability, and safety monitoring of the conjugated small-molecule component, even though cross-references could be done because of the approval of either small molecules or antibodies.
- **CRISPR/Cas9**: questions concerning biological response regulatory uncertainty around off-target edits, durability of response, and potential germline transmission risks have required careful dialogue with FDA.
- **mRNA-Based Therapeutics**: unresolved issues include dose optimization, demonstration of intracellular mechanism when a dose is administered, nanoparticle structure before and after administration, innate immune activation, and demonstrating durable efficacy in oncology.
- **CAR-T Cell Therapies:** Challenges include patient-to-patient manufacturing variability that may impact reliability, safety and efficacy; determining potency assays for living cells, and mutagenesis down the road of chronic treatments.

Traditional IND preparation in these contexts may expose sponsors to significant delays if foundational assumptions in manufacturing, toxicology, or trial design prove misaligned with FDA expectations. To address this gap, the FDA established INTERACT meetings, which provide early, non-binding advice to support scientifically sound development strategies.[1]

Furthermore, it became a powerful tool not only for sponsors to help raising any kind of financing by mitigating the risk of complex drug developments, but also to show investors that team is well prepared and surrounded by seasoned people that may enhance the chance of avoiding pitfalls and then meeting timelines that are more than often delayed based on the above challenges.

From regulatory and timelines standpoints, FDA responds to meeting requests within 21 calendar days: meeting scheduling or Written Response Only (WRO) within 75 days. Meeting packages should be part of requests, with no more than10 questions and background material sufficient (kind of briefing book summarizing development goals and strategies).[1]

Strategic Contributions of INTERACT Meetings

INTERACT meetings are proposed and highly recommended to sponsors to answer following points:

- To identify risks as early as possible which could lead to clinical hold (2)
- To address uncertainties in:
  - In preclinical step: are *in vitro*/*in vivo* models adequate and predicative? Are bioassays discriminatory, adequately qualified or validated?
  - In toxicology (as an example, which relevant species and route of administration to be selected for intratumoral drugs).
  - In chemistry manufacturing and controls to ensure a reliability and reproducibility irrespective of the scale and clinical development.

Risk-mitigation associated with new pharmaceutical technologies/drug therapies[3,4]

Most of the time guidance and guidelines are plus or less general and are not specified to certain delivery systems. Mitigate the risk may then accelerate development time to jump in clinical development that represents a major milestone for both sponsors and investors.

Chemistry Manufacturing and Control (CMC)

For new biologic delivery systems, CMC represents the crux of the matter for INDs. Indeed, adequate characterization, reliability, reproducibility and scale-up are still difficult to obtain and remain common reasons that may cause delays and even stops in development. INTERACT may help providing a good direction on how to adopt quality by design (QbD) approach by defining critical quality attributes (CQAs) and critical process parameters (CPPs) and not to forget relevant bioassay, that is part of the CoA for drug product release. All these last points, if highlighted early and acknowledged during the FDA meeting may narrow down development time in several cases reduced later Phase I/II delays.[5]

Clinical development

By refining dose-escalation designs and endpoint selection based on FDA feedback, sponsors have reported faster IND clearance and earlier initiation of first-in-human trials.[6] And as mentioned above, time is money and will allow possibility to narrow down development time, and therefore money needed to carry out clinical study and beyond.

Enhancing Stakeholder Confidence

INTERACT outcomes are increasingly viewed as regulatory milestones that strengthen sponsor credibility with investors and partners.[7] This has been particularly important for early-stage biotech firms navigating capital-intensive areas such as gene and cell therapy where money needed only for CMC may represent more than the overall amount of money needed to develop and carry out a phase one IND package for an orally bioavailable small molecule.

Importance of Human ressources: often neglected

It is important to recognize that start-up companies are frequently founded and led by highly skilled basic-research scientists. While their expertise drives innovation, optimal progress, particularly in navigating regulatory pathways, is best achieved when these teams are complemented by professionals with demonstrated experience in regulatory affairs. Striking this balance ensures that scientific creativity is effectively aligned with regulatory strategy, reducing development risks and facilitating successful translation from bench to clinic. Basically, Biotech teams should include experienced regulatory affairs professionals to ensure INTERACT meeting briefing packages meet FDA guidance requirements. Scientific innovation alone cannot replace regulatory compliance, and the FDA will not provide exceptions solely due to novelty. Balancing robust scientific evidence with regulatory alignment is essential for an effective and productive meeting.

Lessons Learned

Our past and to date analysis of prior experiences highlights 6 chronological consistent themes:

1. Hire seasoned and proven track record people in the overall drug development process. Following points will be difficult if this point is not secured
2. Engage early but focus narrowly on high-impact risks.
3. Submit data-driven, specific questions to maximize value. It may be not possible at the Interact meeting level. As an example, toxicological studies have probably not been initiated, which at the end is a good thing since FDA may have some comments on the design. However, sponsor's strategy in that regard is highly recommended to be part of the document.
4. Engage strategically with the FDA: Do not treat FDA reviewers as consultants. Prepare your briefing book to present a clear, evidence-based strategy- "*This is our proposed approach based on X, Y, and Z strategies; do you agree?*"- rather than simply asking for their opinions. This frames the discussion around your rationale and ensures the meeting

focuses on regulatory alignment rather than advisory input.

5. Carefully review and integrate feedback from FDA meetings into preclinical, manufacturing, and clinical development strategies. Doing so ensures that regulatory guidance informs decision-making, reduces potential delays, and strengthens the likelihood of successful IND submissions and clinical advancement.
6. Use the results of FDA interactions strategically to reinforce credibility with partners, collaborators, and investors. Positive engagement demonstrates regulatory alignment and progress, providing assurance that development strategies are well-founded and reducing perceived program risk.

CONCLUSION

INTERACT meetings have emerged as a critical regulatory tool in drug and biotech development. By fostering early dialogue with FDA, they allow sponsors to de-risk programs, streamline IND review, and strengthen credibility. For developers of innovative therapies, INTERACT meetings represent not only a regulatory resource but also a strategic enabler of clinical translation and a powerful "marketing tool" to raise money and then secure development.

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