

► Presenter and Co-authors' Bio

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Acquiring a Compound with Multiple Clinical Trials? Let's get ready for a Type C Meeting! Key Considerations for Preparing Its Regulatory Submission

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Disclaimer

This presentation represents the authors' viewpoints and suggestions derived from their experience from Type C preparation efforts at GSK. Neither GSK nor the authors are responsible for any unexpected results.

Overview of this Presentation

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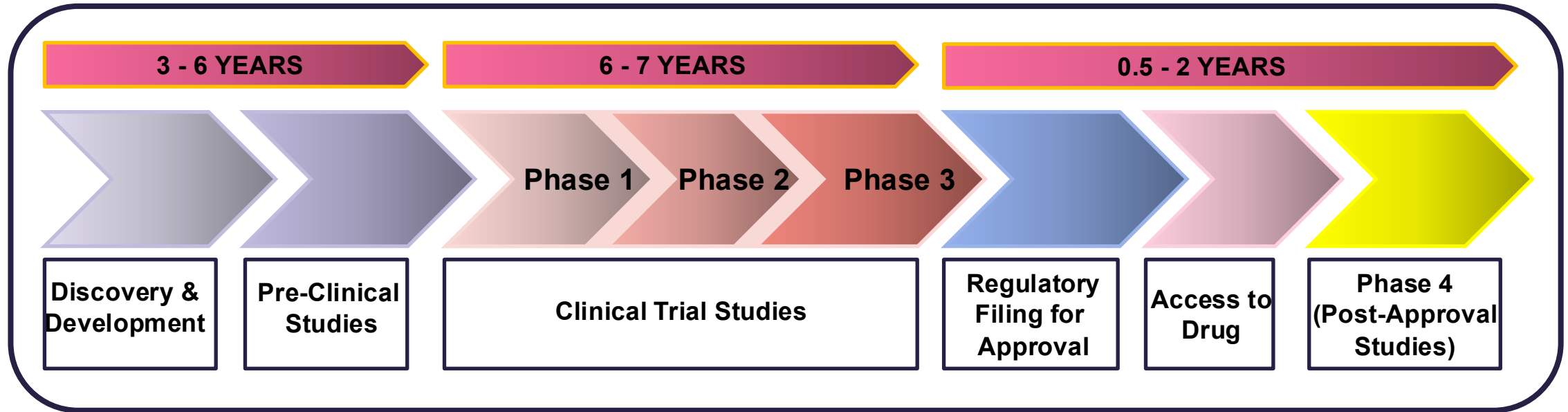
Key Factors for a Successful Outcome

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Drug Development Process

The drug development process is a 5-stage journey from lab to market, to ensure new medicines are safe and effective for public use, a process often taking over a decade and costing billions.



Key Reasons for Sponsor's Interactions with FDA pertinent to Its Drug Development Programs

Guidance & Alignment: Get expert advice on complex products (like cell/gene therapies) and align development strategies with agency expectations to streamline the path to approval.

Risk Mitigation: Identify and address potential deficiencies early, preventing clinical holds, submission delays, or marketing refusals.

Regulatory Compliance: Understand and meet stringent requirements for study design, data quality, patient safety, and monitoring.

Product-Specific Feedback: Receive tailored advice on Chemistry, Manufacturing, and Controls (CMC), nonclinical data, and clinical trial design.

Strategic Planning: Discuss overall development pathways, milestone achievements, and future study designs (Phase 1, 2, 3) to build a robust program.

FDA-Sponsor Meeting Types



Type A Meeting

Stalled product development program to proceed or to address an important safety issue



Type B Meeting

Milestone Meeting or an Entitled Meeting to discuss product development and next steps.



Type B (end of phase (EOP)) B Meeting

This typically occurs after the completion (or near completion) of a clinical stage (Phase 1 or Phase 2) to discuss the results of that stage



Type C Meeting

This refers “any meeting other than a Type A, Type B, Type B (EOP), Type D, or INTERACT meeting



Type D Meeting

For rapid, focused feedback on narrow regulatory issues that do not require a full Type A or B meeting.



INTERACT Type B Meeting

Initial Targeted Engagement for Regulatory Advice on CDER and CBER Products

Type C Meeting – Key Features

Broader Coverage: The Type C meeting is an opportunity for a formal discussion to address any scientific or regulatory aspects that may arise during the drug development process, particularly those **NOT** covered by the **Type A** (stalled development) or **Type B** (milestone) meetings.

Right Forum: It provides a forum to raise questions and concerns about stage of drug development to avoid delays and align with FDA expectations.

Optimal Duration: These meetings are typically 60 minutes and cover the following key features:

Flexibility: Addresses diverse issues that do not fit other categories, from early-stage research to Phase 4.

"Catch-All" Scope: Covers topics such as nonclinical studies, protocol changes, biomarker use, labeling, manufacturing, or pediatric study plans.

Timing: Can occur at any point in the product lifecycle, offering proactive regulatory guidance.

Specific Use Case: A notable example is discussion of new new surrogate endpoints not previously used for approval.

Stake Holders and Cross Functional Teams Involved in Type C Meeting Preparation



Regulatory Team



Medical Writing



**Safety & Efficacy
Leads**



Statistician



**Statistical
Programming**



**Technology &
Platform
Development
Team**



**Institutional
Clinical Data
Standards Team**



**Institutional
eSubmission
Standards Team**

Prior Considerations on Essential Tasks that support various components of the Type C Meeting Preparation

In our experience, the following representative tasks helped our team focus efforts and significantly contributed to successful Type C meeting preparation:

- **Comprehensive Study Contact List:** Study level contacts (lead programmer, statisticians, data management contact, vendor contacts) for reaching out for any questions.
- **Study Inventory Summary:** List of studies with their protocol titles, brief scope, phase, vendors for SDTM and ADaM components, study start date, study end date.
- **Technical Standards Overview:** List of studies/trials with their technical details – CDISC versions used in SDTM and ADaM, WHO Drug Dictionary details, MedDRA versions and CDISC Controlled Terminology (NCI CT versions).
- **Non-clinical Studies' Summary:** Protocol titles, brief scope, CDISC SEND Standards, and associated Controlled Terminology versions.
- **Investigator Brochure:** A highly resourceful document providing a comprehensive overview of the therapeutic compound/biologic and the related clinical and non-clinical studies.
- **Acquisition Due Diligence Checklist:** A thorough checklist covering components from study packages completed prior to their acquisition.

Recommended Components for Type C Meeting Request

There is no specific predefined list of documents to be included. It depends on the scope of the trial-specific requests submitted by the sponsor to the FDA.

The following is an example list:

- Protocols
- Statistical Analysis Plan (SAP)
- SAP for any Integration Summary Development (If any)
- Study Data Standardization Plan (SDSP)
- BIMO Package Planning
- Any questions related to the software tools to be used in Statistical programming
- Any issues or challenges related to Studies that were completed prior to the Acquisition
- List of Critical Questions to be included

When to Request an FDA Type C Meeting



A Type C meeting is a versatile option for sponsors seeking FDA input on topics that do not fall within the scope of Type A or Type B meetings.



Sponsors should consider requesting a Type C meeting when they need feedback on these non-critical yet important aspects of their drug development program.



To ensure timely scheduling, it is advisable to submit the meeting request approximately 75 days before the desired meeting date.



This proactive approach allows for thorough preparation and a more productive discussion with the FDA.

Scheduling and Timelines for a Meeting Request



Type C meetings follow FDA-established timelines.



FDA will respond to a meeting request within 75 days of receipt.



Meetings can be conducted as face-to-face discussions, teleconferences, or written responses only (WRO).



The background package may be submitted with the meeting request or 47 days before the scheduled meeting date (or expected written response date of WRO)



Well-crafted questions, a well-structured meeting request, and a data-supported briefing document are the keys to a productive discussion.

Key Factors for a Successful Outcome

Prior to the Meeting

-
- Precise planning for Type C Meetings**
- Define Clear Objectives**
- Prepare a Strong Briefing Package**
- Understand Meeting Scope**
- Prepare Your Team**
- Summarize & Confirm**

Execution of the Meeting

- Skip Presentations**
- Stay Focused & Manage Time**
- Be Clear & Concise**
- Listen Actively**
- Summarize & Confirm**

Post-meeting Events

- Document & Distribute Minutes**
- Feedback Implementation**

Maximizing the Outcome of a Type C FDA Meeting

To get the most value from a Type C meeting, sponsors should:

- **Clearly Define Objectives:** Specify key questions and regulatory challenges requiring FDA input.
- **Focus on Priorities:** Limit the agenda to essential topics for precise, actionable feedback from the FDA.
- **Submit a strong briefing package:** Provide clear, well-organized data to support the discussion.
- **Engage regulatory experts:** Collaborate with experienced professionals to craft compelling questions to ensure you get the answers you need to move your program forward.
- **Follow Up effectively:** Address FDA feedback and integrate it into the development plan.

What to anticipate from the FDA after Type C meeting

After a Type C meeting with the FDA, sponsors can anticipate the following:

- **Official Minutes (Within 30 Days):** The FDA provides a written summary of the discussion, agreements, and action items.
- **Actionable Advice:** The agency will give feedback on topics like non-clinical studies, protocol amendments, manufacturing, and other areas to incorporate into the development plan.
- **Clarification Period:** If necessary, sponsors have 20 days to request clarification; FDA responds within 20 days.
- **Documentation Alignment:** Ensure all project team members review the minutes to stay aligned on agreed regulatory path.
- **Next Regulatory Steps:** The advice may require updating protocol designs, initiating new studies, or revising CMC (Chemistry, Manufacturing, and Controls) strategies.

Conclusion

The sponsors can enhance outcomes and build a productive relationship with the FDA by focusing on these key steps:

- **Identify Gaps & Define Questions:** Clarify scopes, expectations, and critical questions for FDA input.
- **Plan and Gather Information:** Coordinate across cross-functional teams to collect necessary data
- **Develop a Clear Strategy:** Establish internal communications and execution plans, align interactions with the agency.
- **Prepare Focused Materials:** Use crystal-clear objectives, a concise briefing package with well-organized data, and a streamlined meeting agenda with designated speakers.
- **Execute Follow-Up Actions:** Implement FDA feedback and translate discussions into actionable outcomes integrated into development plans.



Sincere Thanks to the GSK Leadership For Supporting This Presentation

Any Questions ?

