INFO SHEET

FORTREA REGULATORY STRATEGY

End-of-Phase II meetings: Where pivotal development decisions are made

Overview

A well-prepared End-of-Phase II (EOP2) meeting helps Sponsors align with regulators on pivotal trial design, evidence expectations and next-step strategy; mitigating risk downstream and before major Phase III investment is committed.

Why your EOP2 meeting matters:

A critical inflection point for your asset

The EOP2 meeting defines whether your Phase III program is likely to support NDA/BLA submission—and how efficiently you get there.

Misalignment at this stage is a leading driver of failed Phase III trials, regulatory delays and missed commercial opportunity.

A successful EOP2 meeting is critical to de-risk the Phase III program. Effective planning requires multidisciplinary review of the available data, along with considerations of the market positioning, to verify the clinical evidence supports label claims and payer expectations.

In a development environment where expectations on pivotal design and evidence credibility continue to evolve, getting this right the first time is essential.

What needs to be clear before you move to Phase III

A successful EOP2 meeting provides alignment on:

- ☐ **Pivotal trial design:** Endpoints, patient population, statistical approach and sample size must align with regulatory expectations
- ☐ **Evidence package:** What data is sufficient for approval and where additional studies may be required
- ☐ **Safety database:** Adequacy of exposure, tolerability and identification of potential risk signals
- ☐ **Regulatory strategy:** Alignment on approach, including eligibility for expedited or facilitated programs

Whilst the European Medicines Agency (EMA) does not formally define EOP meetings in the same way as the FDA, similar engagement can be achieved via targeted Scientific Advice requests at key development transition points.

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Fortrea's integrated approach to EOP2 preparation

We recommend starting to plan for your EOP2 strategy six to eight months before the end of their Phase II study so we can set up contracts, access and review data, discuss strategy and develop the briefing package. Balancing timing carefully is crucial: engage too early, and the data may be insufficient; engage too late, and you risk avoidable re-work, delays between phases and lost momentum.

Fortrea develops a tailored EOP2 package combining data-driven insights, pivotal trial strategy and focused regulatory questions to guide productive agency discussions. Our integrated teams align clinical, regulatory and evidence strategy to position your asset for confident progression into Phase III.

- **Start earlier, avoid re-work:** We bring regulatory thinking into development earlier—so Phase III is designed correctly from the outset, rather than adjusted later
- **Connect strategy to execution:** Our combined consulting and clinical teams align regulatory, clinical and evidence strategy into a single, coherent plan—reducing fragmentation and handoffs
- **Eliminate "white space" between phases:** By engaging ahead of EOP2, we reduce delays between study completion and regulatory interaction—supporting a more continuous development pathway
- **Support the full decision, not just the meeting:** We help shape the questions, stress-test the data and translate regulatory feedback into an actionable, clear plan forward

EOP2 in action

Challenge: An Asia based biotech was expanding into the U.S. market having conducted all nonclinical and clinical work thus far in China. They needed to understand the FDA acceptability of their data package in supporting a Phase III study in the U.S. and how it would affect the planned Phase III trial design and need for additional studies.

Solution: Fortrea's regulatory strategy group conducted scientific review of the data package and worked with the client to define questions and the briefing package for a Pre-IND meeting.

The team provided a rapid response to a high volume of FDA preliminary feedback, including scenario mapping and contingency planning to enable productive discussion during the FDA meeting.

Value delivered:

Clarity	Acceleration	Risk mitigation
The client achieved a clear FDA-aligned pathway to the U.S. Phase III development that resulted in a successfully opened IND	A clear and well designed EOP2 engagement strategy enabled accelerated transition from China-only development to global development strategy	Reduced regulatory risk by pro-actively addressing FDA concerns early and avoided delays that could have arisen from relying on written only feedback

Fortrea regulatory consulting

Fortrea integrates regulatory strategy, intelligence and execution across the full asset lifecycle—helping you to make confident decisions earlier and design development programs that stand up to regulatory and commercial scrutiny. Through continuous regulatory intelligence, regional fluency and thoughtful use of advanced technology, we reduce risk, prevent re-work and keep development on track from early planning through post approval commitments

At Fortrea Consulting, we believe together, exceptional is possible.

EOP2 is where scientific promise is translated into a defensible development plan

Speak to Fortrea's regulatory team to align your development strategy ahead of your meeting request.

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