[HCG THOUGHT LEADERSHIP]

PROJECT ORBIS

How to stop playing ping-pong with regulators

We've helped more than 215 teams prepare for critical meetings with regulators in the United States and Europe, and one thing is crystal clear: there is no such thing as over-communicating with health authorities. Misalignment, confusing stories, or sloppy responses can undermine your credibility and delay approvals you can't afford to lose—especially in oncology.

Add the pressures of planning for concurrent submissions across multiple jurisdictions and the stakes get even higher. That's why we tuned in closely when a panel of global regulators took the stage at DIA 2025 to discuss Project Orbis.

What Project Orbis really is

Since its launch by FDA in 2019, Project Orbis has emerged as a pioneering initiative to accelerate global reviews of innovative oncology therapies. It enables concurrent submissions and coordinated reviews across regulators including, but not limited to, the FDA (United States), Health Canada, Australia's Therapeutic Goods Administration (TGA), the UK Medicines and Healthcare products Regulatory Agency (MHRA), Brazil's ANVISA, Singapore's HSA, and others. The goal is to get cutting-edge cancer treatments to patients faster—without compromising scientific rigor or safety standards.

Project Orbis creates a collaborative framework for agencies to conduct parallel reviews, sharing information and questions to reduce duplicative effort. It's not a formal work-sharing model—each agency conducts independent reviews and makes its own decisions—but it helps sponsors navigate multijurisdictional submissions with more clarity and efficiency.

The real benefits for sponsors

Done strategically, Project Orbis offers:

- Accelerated patient access: Cancer patients can't wait, and concurrent reviews can shorten timelines where it matters most.
- Resource optimization: You're not burning cycles preparing near-identical submissions for each jurisdiction, freeing time and budget.
- Streamlined communication: Agencies share questions and findings, reducing duplicate and conflicting requests so you can deliver targeted, efficient responses.

The challenges you need to respect

Project Orbis isn't a free pass:

- Each agency maintains its own timelines, clinical standards, and risk tolerance, which can lead to divergent decisions on labels or even approvals.
- It's not a joint review; you're still responsible for addressing each agency's unique requirements.
- The information-sharing environment means issues flagged in one review can surface elsewhere—we know the agencies are talking to each other daily. If you're not prepared, you'll be caught flat-footed.

How to prepare for the win

Success with Project Orbis requires early, intentional planning and proactive communication:

- Engage early with each participating agency to clarify requirements, timelines, and data expectations. Don't wait for submission day to start these conversations.
- Prepare harmonized submission packages that are clear, logical, and ready for cross-agency review, while anticipating jurisdictional nuances.
- Establish clear communication channels to respond promptly to emerging questions.
- Plan for cross-agency discussions and prepare responses to the most likely issues, so you can address potential problems before they become delays.

At HCG, we work with cross-functional teams to create simple, logical, data-backed storylines and train them to communicate complex data under pressure. The teams that win in Project Orbis are the ones that align internally before submission and develop plans to address anticipated review issues proactively. When information requests come in, these teams can respond efficiently, avoiding what one DIA panelist aptly called the "ping-pong game of Q&A" that drains both the sponsors and the agencies.

Even better, when your team speaks in a unified, clear voice and can defend the data at a moment's notice, you may reduce the likelihood of landing in an FDA Advisory Committee meeting or EMA Oral Explanation.

Now *that* is what we call a positive outcome. ■

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