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Don’t Call It Project Orbis: CoGenT Global Will Pilot Collaborative Review Of Gene Therapies

by Sue Sutter

Although still in the early stages of development, the US FDA's Collaboration on Gene Therapies Global Pilot will explore the potential for concurrent submission and collaborative review of applications with international regulatory partners.

The US Food and Drug Administration and its global regulatory partners are kicking off a pilot program aimed at exploring the potential for concurrent collaborative review of gene therapy applications.

Although the FDA said the pilot is still in the early stages of development, the initiative has advanced to the point of having a name (and acronym) and a basic framework, which Center for Biologics Evaluation and Research Director Peter Marks briefly presented at the Alliance for Regenerative Medicine’s Cell & Gene State of the Industry Briefing on 8 January.

The project is called the Collaboration on Gene Therapies Global Pilot, or CoGenT Global for short, according to Marks’ slides from the presentation.

The initiative builds off of the Oncology Center of Excellence’s popular and well-regarded Project Orbis initiative, which was established in 2019 and provides a framework for concurrent submission and review of oncology products among international regulators. (Also see "*Project Orbis 2023: FDA Approves Six New Cancer Drugs, But Partner Nations Lag Behind*" - Pink Sheet, 5 Dec, 2023.)

Marks has previously said that a process where the FDA can coordinate reviews with other regulators would allow for better leveraging of global patient populations with ultra-rare diseases and attract more commercial interest in development of gene therapies for rare

diseases. (Also see "*US FDA Eyes Project Orbis-Type Approach For Cell And Gene Therapies*" - Pink Sheet, 13 Feb, 2023.)

The FDA told the *Pink Sheet* that although countries around the world have their own regulatory authorities, there are no uniform global standards for the evaluation and regulation of cell and gene therapies.

"We believe that harmonization efforts in this area can help facilitate more efficient clinical development," the agency said. "To that end, FDA supports work toward global regulatory convergence and, ultimately, global harmonization of regulations for these products. FDA is pursuing this goal with international partners, global regulators, and the World Health Organization," with CoGenT Global an example of this effort.

Framework

Although Marks' comments about CoGenT Global at the ARM event were brief, he presented a slide with several bullet points:

- Initial participation by standing regulatory members of the International Council for Harmonisation (ICH's website lists the standing regulatory members as Health Canada and Swissmedic);
- Partners may participate in internal regulatory meetings and meetings that include the sponsor;
- Specific regulatory reviews are shared and discussed with partners;
- All meetings conducted and information shared under strict confidentiality agreements; and
- Goal is to increase the efficiency of the regulatory process, reducing time and cost for agencies and sponsors.

The idea of global collaboration in gene therapy regulation is finally gaining some traction, Marks said at the ARM briefing.

"Global regulators realize that what we do is more in common than divergent. In other words, what we do at the FDA has a lot in common with what's done" at the European Medicines Agency, Marks said. "There are some subtle differences. We do certain things they don't do and vice versa. But if we can harmonize on our requirements and potentially even pool forces to review these products, we may be able to make it much more attractive for people to go into this rare disease area. So this is another lever that we have to pull."