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Project Orbis: Oncology Drug Review & Global Expansion

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Executive Summary

Project Orbis is a U.S. FDA-led global initiative (launched May 2019 by the Oncology Center of Excellence) to **synchronize regulatory reviews of cancer drugs** across countries (www.fda.gov) (www.fda.gov). By allowing manufacturers to submit the same oncology application nearly concurrently to multiple agencies (e.g. FDA, Health Canada, Australia's TGA, UK's MHRA, etc.), Orbis has prioritized “significant drugs that had a major impact on patients with cancer – not ‘me-too’ drugs” (www.fda.gov). Skerritt et al. (2025) report **101 FDA Orbis approvals** by early September 2024 (link.springer.com), reflecting broad adoption in cancer.

Orbis is an OCE-led initiative focused on oncology. FDA's 2022 report includes alpelisib (Vijoice) for PIK3CA-related overgrowth spectrum (PROS) in both its Orbis table and its rare-disease approvals discussion ([FDA 2022 report](#)). This focus stems from multiple factors: rapid innovation and unmet need in cancer; multicountry clinical trials; FDA's unique oncology expertise; and the legal/political mandate of the Oncology Center itself. FDA leaders note that oncology has “10–15 new molecular entities approved annually, representing ~30–40% of companies' yearly activities,” and that **smaller regulators lacked the subspecialized expertise found in FDA's cancer teams**, making Orbis “enable these agencies to confer with FDA regulators who have disease-specific knowledge” (www.fda.gov) (www.fda.gov). The international urgency in cancer – with evolving standards of care and global trial arms – made coordinated review particularly valuable (www.fda.gov) (www.fda.gov).

Through Orbis, multiple studies have documented **shorter submission lags and generally faster approvals** for oncology drugs. For example, one analysis found that Orbis reduced the time from FDA filing to partner filing by hundreds of days (e.g. ~395 days less for Australia's TGA and ~165 days for Health Canada) (link.springer.com). Table 2 (below) summarizes reported impacts on review timelines. However, review-time benefits varied: Swissmedic and Singapore each shaved over 90 days off review time, whereas Australia (TGA), Brazil (ANVISA), and Israel saw slight *increases* in median review duration for Orbis drugs (link.springer.com) (likely reflecting backlog or coordination delays). In all cases, though, the collaboration improved confidence – “smaller agencies [...] increased confidence and support earlier decision making,” and regulators could resolve scientific uncertainties jointly (link.springer.com).

Nevertheless, **Orbis's impact is limited by context**. Crucially, global patient access depends on more than synchronized approvals – pricing and health-technology assessment (HTA) decisions play a huge role. Recent analysis found that many Orbis-approved cancer drugs still face delayed or denied reimbursement: in Jenei et al.'s May 2019–November 2023 cohort, routine availability covered 6/18 MHRA approvals in England and 13/18 in Scotland. Among assessed applications, NICE recommended 6/15 for routine use and 5/15 through the Cancer Drugs Fund; SMC recommended 14/14. These are different outcomes and denominators ([original study](#)). The Orbis model also requires FDA and partner resources. Japan formally joined on September 10, 2026 ([MHLW notice](#)); the FAQ's older statement about being unable to add countries should not be treated as a permanent membership limit.

In sum, Project Orbis has **demonstrated the value of a coordinated multi-country review process in oncology** (with concrete examples of expedited cancer treatment access) (www.fda.gov) (www.canada.ca). Its oncology focus reflects both strengths and limitations: leveraging FDA's oncology teams and global cancer trial networks makes Orbis feasible, but extending this model to other diseases would require replicating that specialized infrastructure and overcoming new barriers (www.fda.gov) (www.fda.gov). This report reviews Orbis's history and achievements in cancer, analyzes why the model is tailored to oncology, and examines what would be needed (regulatory, resource, and policy changes) to adapt Orbis-like collaboration to non-oncology areas.

Introduction and Background

Drug regulatory approval is traditionally measured by national submissions and reviews. In practice, however, **global drug development** often involves multinational trials. Particularly in oncology, pivotal trials are commonly run across continents (www.fda.gov). Disparities in when a drug is submitted to various agencies can create *lag* in global access: a novel cancer treatment may reach U.S. patients months or years before it reaches Canada or Australia. This is especially problematic in cancer, where “we want control arms to be the contemporary standard of care in the U.S.” but those treatments may not yet be available elsewhere (www.fda.gov).

Recognizing these issues, the U.S. Congress in the 21st Century Cures Act (2016) mandated the creation of an Oncology Center of Excellence (OCE) within FDA. OCE's mission was to expedite development of oncology drugs via cross-center collaboration. In May 2019, Dr. Richard Pazdur (Director of OCE) announced Project Orbis under OCE (www.fda.gov) (www.fda.gov). Orbis officially provides “a framework for concurrent submission and review of oncology products among international partners” (www.fda.gov). Unlike prior cluster discussions between agencies, Orbis establishes **formal confidentiality agreements** among multiple regulators so that they can review the *same* application simultaneously and exchange information. The hope is that by aligning regulatory review, patients in all partner countries can “receive earlier access to products” (www.fda.gov). In effect, Orbis leverages FDA's expertise and established benchmarks in cancer to bring smaller regulators on the same timeline.

Key motivations: In interviews, FDA leaders emphasize several oncology-specific drivers. Dr. Pazdur notes oncology is evolving rapidly – about *10–15 new molecular entities per year*, roughly one-third of industry's R&D focus (www.fda.gov). Many of these first seek U.S. approval, leaving smaller countries waiting. Orbis directly addresses this by asking sponsors to file abroad “as closely as possible” to the U.S. filing

(www.fda.gov). The most critical cancer therapies (high unmet need) were targeted first, with FDA insisting that partner agencies agree to participate before sponsors are invited, ensuring real-time multi-country review (www.fda.gov) (www.fda.gov). As one regulator put it, “This was the first review conducted as part of the Project Orbis partnership,” linking FDA, Canada and Australia on an accelerated timeline (www.canada.ca). By design, Orbis focuses on *oncology products* that “address unmet medical needs or offer significant improvement” over existing therapies (link.springer.com).

Project structure: As of October 13, 2026, FDA's partner list includes Australia (TGA), Brazil (ANVISA), Canada (Health Canada), Israel (Ministry of Health), Japan (PMDA), Singapore (HSA), Switzerland (Swissmedic), and the United Kingdom (MHRA) ([FDA partner list](#)). Japan formally joined on September 10, 2026 ([MHLW notice](#)). EMA was described as an observer in FDA's July 17, 2025 interview ([FDA interview](#)).

Submission pathways: MHRA defines **Type A** as concurrent or near-concurrent submissions within 30 days of FDA submission. **Type B** covers submissions delayed by more than 30 days, or regulatory action more than three months after FDA action. Type A permits possible concurrent action; Type B permits possible concurrent review, without concurrent action. For **Type C**, MHRA describes sharing completed reviews after FDA action, while its timing table permits submission after FDA submission subject to the specific partner's guidelines ([MHRA guidance](#)). Health Canada describes Type C as following a positive FDA decision, without concurrent review or action ([Health Canada guidance](#)). Sponsors should consult the participating regulator's timing rules. Each agency retains its own decision, labeling negotiations and timelines ([FDA FAQ](#)).

Table 1. Project Orbis partners and historical observer information. (*Partner list checked October 13, 2026; earlier join dates from FDA's July 2025 interview.*)

Agency (Acronym)	Jurisdiction	Status	Joined (Start Date)
FDA (US Food & Drug Administration)	United States	Partner	May 2019 (launch)
TGA (Therapeutic Goods Administration)	Australia	Partner	May 2019 (www.fda.gov)
HPFB/HC (Health Canada)	Canada	Partner	May 2019 (www.fda.gov)
HSA (Health Sciences Authority)	Singapore	Partner	Dec 2019 (www.fda.gov)
Swissmedic	Switzerland	Partner	Dec 2019 (www.fda.gov)
ANVISA	Brazil	Partner	May 2020 (www.fda.gov)
MHRA	United Kingdom	Partner	Jan 2021 (www.fda.gov)
Israel MOH (MTIIR)	Israel	Partner	Jul 2021 (www.fda.gov)
EMA (European Medicines Agency)	European Union	Observer (historical description)	Described as an observer in July 2025 (FDA interview)
PMDA	Japan	Partner	September 10, 2026 (MHLW notice)

Table 1 note: Japan's former observer status is historical. The current FDA partner list includes PMDA ([FDA](#)).

Project Orbis in Practice (Oncology Focus)

Since its inception, Project Orbis has handled **hundreds of applications** for cancer therapies. Sponsor submissions reviewed by FDA and cooperating regulators have primarily been novel oncology drugs or supplemental cancer indications. Skeritt *et al.* (2025) report that, through September 2024, the FDA had approved 101 oncology treatments via Orbis ([link.springer.com](#)). Notably, only about one-third of those (≈33%) were entirely **new active substances**; the rest were often new indications or extensions of existing cancer drugs ([link.springer.com](#)). In other words, while Orbis prioritizes breakthrough therapies, many Orbis cases are “line extensions” such as a new cancer subtype indication ([link.springer.com](#)). This reflects an emphasis on unmet needs: Orbis applications must have demonstrated potential to significantly improve outcomes or fill gaps.

The review by Skeritt, Mayer and Francer highlights Orbis’s global reach: in its September 2024 snapshot, Australia tallied **64 Orbis approvals** and Canada **70** – the highest of any country ([link.springer.com](#)). (These counts include cases where the U.S. and partner agencies all approved a product.) Other partners also recorded approvals. Importantly, Orbis’s collaborative process has increased regulatory **consensus**. Skeritt *et al.* noted that Orbis participation “can increase concordance in regulatory decisions between agencies” ([link.springer.com](#)), meaning when FDA approves a cancer drug, its project partners *usually* do as well. Of course, sovereign reviews mean occasional divergences do occur (e.g. slight differences in labels between countries ([www.fda.gov](#))), but overall alignment is high.

Impact on Timelines

Studies have quantified Orbis’s timing benefits. Table 2 (below) summarizes one comparative analysis ([link.springer.com](#)). Across agencies, Orbis typically **reduced the submission lag** (time between FDA submission and partner submission) by several months (even over a year in Australia’s case, 395 days saved). Most participating regulators saw faster median review times for Orbis drugs than for other oncology submissions. For example, Health Canada’s median review was 77 days shorter with Orbis, and Swissmedic’s 120 days shorter ([link.springer.com](#)). In contrast, in a few cases (Israel, TGA, ANVISA) median review times were slightly longer than usual, likely because Orbis cases tended to be complex and might have added coordination overhead ([link.springer.com](#)).

Table 2. Impact of Project Orbis on regulatory timelines ([link.springer.com](#)).

Agency	Reduction in Submission Lag* (vs. non-Orbis)	Change in Review Time (median)
Australia (TGA)	–395 days (lag shortened)	+23 days (slightly longer)
Canada (HC)	–165 days	–77 days (faster review)
Switzerland (Swissmedic)	–233 days	–120 days (faster review)
Singapore (HSA)	–39 days	–94 days (faster review)
Brazil (ANVISA)	–90 days	+50 days (longer review)
Israel (MOH)	–75 days	+2 days (slightly longer)

Table note: Negative values indicate a reduction in time. For example, in Australia the waiting period between U.S. filing and Australian filing was 395 days shorter for Orbis drugs. Review time changes are median differences between Orbis and other oncology approvals. Data from Skerrett *et al.* (link.springer.com).

Beyond timelines, Orbis emphasizes communication. Unlike most regulatory reviews (which are “behind closed doors”), Orbis involves joint review meetings where experts from all agencies discuss data together (www.fda.gov). FDA reviewers have found value in “discuss[ing] the independent viewpoints of these other regulators” rather than relying on a single perspective (www.fda.gov). This interaction builds regulatory “camaraderie” and may help harmonize science. For example, a Swiss analysis reported that Swissmedic’s decisions became more aligned with FDA’s after joining Orbis (www.ijdra.com) (link.springer.com). The ongoing willingness of partners to use Orbis and even to send medical officers to ASCO meetings together suggests the program has strengthened international trust in oncology regulation (www.fda.gov).

Why Orbis Focuses on Oncology

Orbis was purpose-built around OCE’s oncology expertise. FDA’s 2022 Orbis table also includes Viojoy for PROS, discussed in the report among rare-disease approvals ([FDA 2022 report](#)). Its oncology focus should therefore not be described as an absolute exclusion of every related non-malignant indication. Broader collaboration raises questions about expertise, staffing and agreements.

1. Legislative and organizational origin.

Project Orbis owes its existence to the creation of FDA’s Oncology Center. The 21st Century Cures Act specifically authorized OCE to “facilitate the development” of cancer drugs and use cross-product expertise for expedited review. As Pazdur explains, Orbis “emanated from our oncology cluster calls” among agencies (www.fda.gov).

2. Subspecialized expertise.

Cancer is a field of extreme complexity and fragmentation. Even within FDA, review teams are sub-specialized by cancer type (e.g. lung, breast, myeloma, pediatric cancers) (www.fda.gov). This is “reflecting the structure of many university and cancer center programs” (www.fda.gov). Oncology evolves so rapidly that having such focused teams is essential. Smaller regulatory authorities (Canada, Singapore, etc.) generally **lack** equivalent depth in cancer expertise. By joining Orbis, these agencies gain direct access to FDA’s disease-specific experts. As Pazdur notes, “outside of the U.S., smaller agencies do not have [this internal] expertise. Project Orbis enables these agencies to confer with FDA regulators who have disease-specific knowledge” (www.fda.gov).

3. Urgency and unmet need

Approval timelines, access to treatment and clinical benefit are distinct outcomes. Jenei *et al.* found no statistically significant difference in survival gains between the Orbis and comparison cohorts ([original study](#)). This finding does not establish that each approval delay reduces survival or that delays outside oncology are less urgent.

4. Global trial standard-of-care alignment.

Dr. Pazdur emphasized a practical problem: if a cancer drug trial's control arm uses the latest U.S. standard of care, but that care is not approved abroad, running a global trial is difficult (www.fda.gov). Getting all countries on the “same page” quickly is thus crucial for trial feasibility. This specific issue is most pronounced when standards of care shift rapidly – as they do in oncology with new targeted/immuno therapies.

5. Epidemiology and market incentives.

Oncology drug development and commercial strategies tend to be global from the outset. Many modern cancer drugs target rare mutations or subtypes, necessitating international trial enrollment and broad markets. Pharmaceutical companies have strong incentives to pursue simultaneous filings. Overall, **it is not that the Orbis process “can’t work” technically for other drugs – it’s that its rationale and structure are deeply intertwined with how we develop and regulate cancer therapies.** FDA officials themselves acknowledge that “what we have done in oncology could serve as a framework for other therapeutic areas” (www.fda.gov), but only after meeting the unique needs of those areas. Broader collaboration would require participating staff and suitable expertise ([FDA interview](#)). This concerns therapeutic scope; biologics already fall within the application types accepted by Orbis ([FDA FAQ](#)).

Data Analysis and Case Examples

Regulatory metrics

As summarized in Table 2, studies show Orbis has measurably shortened timelines in oncology. Submission lags were dramatically reduced in every partner region, by an average of several months (link.springer.com). FDA describes candidates as generally qualifying for priority review; Orbis participation does not itself establish a separate designation for every application ([FDA FAQ](#)).

Clinical and economic outcomes

One recent Lancet Oncology study (Jenei *et al.*, 2024) compared outcomes of Orbis-reviewed cancer drugs to other new cancer drugs. They found **no statistically significant difference in survival gains** between Orbis and non-Orbis drugs (www.sciencedirect.com). Median overall survival improvement was 4.1 months for Orbis drugs and 2.7 months for others – a numerical difference but not statistically significant in their analysis (www.sciencedirect.com). The study did not find statistically significant differences in overall-survival or progression-free-survival gains. What Orbis did achieve, the authors note, is **faster multi-country decision times**: conventional sequence of approvals (U.S. then months later in UK/Canada) was compressed substantially, although the study found mixed effects on actual *patient access*. They report that, after FDA approval, federal HTA/reimbursement bodies often delayed or limited coverage of Orbis drugs. In the May 2019–November 2023 cohort, routine availability covered 6/18 MHRA approvals in England and 13/18 in Scotland. Among assessed applications, NICE recommended 6/15 for routine use and 5/15 through the Cancer Drugs Fund, while SMC recommended 14/14 ([original study](#)). The study's median US monthly treatment-price estimate was about US\$20,000, based on RedBook average wholesale prices and FDA-label dosage assumptions; eight drugs lacked price data. This is a US treatment-price estimate, not a launch-price or negotiated-price series across partner countries ([study methods and Table 1](#)).

These findings highlight a complex point: Orbis effectively harmonizes **regulatory timing** for oncology drugs, but that is only one component of patient access. If reimbursement lags or refuses expensive therapies, the regulatory gain may not reach patients. The Lancet Oncol authors and others therefore argue that *even with Orbis*, “drugs must demonstrate value [with] large clinical benefits and sustainable prices”

(www.sciencedirect.com). Orbis facilitates coordinated review; simultaneous approvals are not guaranteed because each agency retains its own decision and timelines ([FDA FAQ](#)). Stakeholders (HTA agencies, insurers, etc.) still need convincing evidence. In summary: from a data perspective, Orbis has accelerated international regulatory alignment (Table 2 evidence), yet real-world access remained constrained by cost/value hurdles (www.sciencedirect.com) (pmc.ncbi.nlm.nih.gov).

Challenges and Barriers to Expansion

While oncology’s unique aspects made Orbis feasible, **applying the Orbis model to other therapeutic areas faces significant hurdles**. These challenges fall into several categories:

A. Resource and organizational constraints

Orbis requires considerable coordination: FDA officials reported one limiting factor is personnel. Acknowledging this, Dr. Pazdur gave “very small team” credit for achieving Orbis, but noted that to roll out Orbis in other fields would require *more* staff with expertise and project management skill (www.fda.gov). The FAQ’s earlier statement about being unable to add countries should be read in historical context: Japan formally joined in September 2026 ([MHLW notice](#)). Under FDA rules, each new partner also needs to sign confidentiality agreements; implementing these across eight or more agencies can be **arduous** (www.fda.gov). In short, expanding Orbis means front-loading a lot of bureaucratic work. As one summary notes, expanding new Orbis collaboration to non-oncology would depend heavily on FDA resources and legal agreements (www.fda.gov). Broadening collaboration would require sufficient participating staff ([FDA interview](#)).

B. Therapeutic expertise gap

Even if resources were allocated, Orbis would still need domain knowledge. In oncology, the FDA’s existing sub-specialty teams (breast, lung, GI, etc.) provide the clinical insight. In other fields, FDA expertise is organized differently (for example, by divisions like Diabetes/Endocrine, Neurology, etc.), and Japanese or European regulators likely already have home-grown expertise. For some areas — notably rare diseases or gene therapies — each country’s reviewers may be thin. Interestingly, collaborative pilots have begun in these niches. FDA’s report names the **Collaboration on Gene Therapies (CoGenT) Global Pilot** ([FDA report](#)). This is a separate collaboration initiative, rather than an expansion needed to make biologics eligible for Orbis.

C. Regulatory alignment and criteria

FDA says candidates should generally qualify for priority review ([FDA FAQ](#)). To apply Orbis to, say, neurology, one would need similar shared criteria: e.g. global diseases with high unmet need, parallel triage for important novel vaccines or Alzheimer’s drugs. Some experts suggest that Orbis’s requirement for FDA priority review could be loosened even within oncology to catch more drugs (link.springer.com); similarly, to expand to other fields one might waive or redefine priority status. Without a clear funnel of “must-include” drugs, agencies might struggle to find common ground. There is also the question of which agencies would lead or participate.

The current Orbis partners volunteered for cancer, but for a new “cardiology Orbis,” would, say, the European Medicines Agency or regulatory networks in Asia join? This depends on international will: EMA has existing projects (see below) but no published plan for an FDA-partnered or cardio Orbis.

D. Incentives and value proposition

From a pharmaceutical industry perspective, Orbis helps justify paying for multiple submissions (a big cost for small markets). For blockbuster or orphan drugs, firms can be convinced it’s worth it. Outside cancer, it may be harder to quantify the benefit. For example, consider antibiotics (a classic unmet need): the FDA has its own programs (GAIN Act) but there is already an EU pathway, and uptake can be done country-by-country. There might be less “market access anxiety” in pharmaceuticals when first launching outside oncology, making Orbis less compelling to sponsors. In oncology, sponsors see clear ROI in saving even a year of launch delay; in other fields, the financial calculus differs.

E. Complexity of sharing confidential data

Orbis relies on exchanging detailed review information, including unpublished safety/efficacy data. Broadening Orbis means more such exchanges. Currently, FDA states expanding Orbis would require confidential communication lines with each partner (www.fda.gov). Orbis partners need confidentiality agreements for sharing information. More countries (with various data protection laws) could complicate or slow initial setup. The FDA interview suggests reliance pathways may be more achievable than adding more Orbis partners (www.fda.gov). In global drug law, reliance is already used (e.g. WHO collaborative registration procedure), suggesting an alternative model.

Comparative and Alternative Collaboration Programs

EMA’s **OPEN** framework enables regulators to evaluate certain medicines in parallel with EMA while remaining scientifically and procedurally independent. It began as a COVID-19 pilot; EMA extended its scope in July 2023. Current eligibility covers antimicrobial resistance and novel antimicrobials, PRIME-designated medicines, high unmet medical need, and public health threats or emergencies, including vaccines ([EMA OPEN framework](#)).

Another example is the **Access Consortium**, involving Australia, Canada, Singapore, Switzerland, and others, which supports work-sharing for new active substances across therapeutic areas. Its New Active Substance Work Sharing Initiative considers new chemical or biological entity applications submitted to more than one member regulator and supports standard and priority review pathways ([TGA NASWSI Q&A](#)) ([review](#)). In fact, Skerritt *et al.* note that “many more drugs have been through Orbis pathways than Access” (link.springer.com). The **Promise pathway** streamlines priority-review requests within NASWSI. Under the consortium’s published Q&A, applications for provisional or conditional approval remain outside the scope of Access submissions, including Promise; future inclusion may be considered ([Access Promise Q&A](#)). Skerritt *et al.* recommended including drugs designated for conditional or provisional approval; they did not report that this expansion had occurred ([review](#)).

Finally, international clusters (e.g. FDA–EMA–Japan monthly calls) form an informal network akin to Orbis. These pre-date Orbis and continue to operate monthly, discussing major submissions. In some ways, Orbis institutionalized what cluster calls started: multi-lateral dialogue with confidentiality. Outside oncology, regulators already have expert clusters (e.g. on rare diseases) but no formal “Orbis project.” The COVID-19 pandemic also saw a flurry of collaboration (ICMRA discussions, WHO reliance on FDA/EMA), but mainly on information sharing, not a joint review.

Summary of comparators: Agency-led schemes like OPEN, Access, and clusters indicate that global regulators see value in harmonization beyond cancer. However, each initiative has its own scope. The general lesson is that while Orbis is oncology-centric, the template can be (and is being) used in other niches: OPEN (COVID/AMR), CoGenT (gene therapy). No single system yet covers “all innovation” internationally, but various disease-specific pilots exist.

Implications and Future Directions

Given the above, what would it **take to expand Orbis (or an Orbis-like model) beyond oncology?** We synthesize insights from FDA officials, the literature, and analogous programs:

- **Dedicated institutional support:** A new center or formal program could be considered as a policy proposal; it is not an established legal prerequisite. FDA identifies willing staff in participating agencies as a requirement for broader therapeutic collaboration ([FDA interview](#)).
- **Regulatory alignment and agreements:** FDA states that a potential participant must be able to enter confidentiality agreements needed for information sharing ([FDA interview](#)). This requirement concerns agreements and capacity to share data; it does not establish that any named jurisdiction must amend its legislation.
- **Harmonizing criteria:** FDA says candidates should generally qualify for priority review. Orbis already accepts NDAs, BLAs and supplemental oncology applications ([FDA FAQ](#)). Expanding therapeutic areas is therefore distinct from adding biologics as a new product modality.
- **Partner engagement:** All current Orbis partners participated because of shared interest in cancer. Expanding beyond oncology will require gauging interest from agencies less motivated by cancer. Interestingly, Pazdur reports that at an Orbis partners meeting, “participants uniformly expressed interest in expanding Orbis to other [...] therapeutic areas” (www.fda.gov). However, this interest must be balanced by resources; smaller agencies may resist new commitments unless they see clear patient benefit.
- **International collaboration networks:** WHO defines reliance as giving significant weight to another authority’s assessment while reaching an independent decision. Recognition is a formal process, grounded in legal provisions, that accepts a reference authority’s decision without additional regulatory assessment ([WHO guidance](#)).
- **Addressing HTA and access:** Critically, expansion must consider health technology assessment (HTA). Orbis has highlighted that regulatory approval alone doesn’t guarantee access. If any Orbis-like program is created for drugs or devices, parallel engagement with payers is wise. The relationship

between regulatory agencies and HTA bodies will become more important, as noted by health economists ([pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov/)). For example, as Orbis grows, a “comprehensive collaboration between regulatory agencies and HTA bodies” is recommended so that faster approvals actually lead to timely reimbursement ([pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov/)).

- **Collaboration beyond oncology:** EMA's OPEN framework provides a documented example of collaboration beyond cancer, including medicines addressing antimicrobial resistance and public health threats ([EMA framework](#)).
- **Resource sharing and external support:** Orbis does not remove national application fees: MHRA requires the relevant national authorisation fee for applications made through Orbis ([MHRA fees guidance](#)). Sponsor fees should be distinguished from agency coordination costs. Additional international funding is a policy proposal, rather than an established feature of the program.

In summary, **expanding Orbis beyond oncology is conceptually feasible, but would demand adaptations at every level.** It would require: committing sufficient scientific expertise in the new field; forging confidentiality and legal pacts among new partner agencies; securing funding and staff for a collaborative process; and aligning on which products merit this treatment. FDA's current stance reflects caution: “other avenues like reliance pathways... may be more achievable” than formally adding more Orbis partners (www.fda.gov). These considerations concern broader therapeutic collaboration, rather than making biologics newly eligible ([FDA FAQ](#)).

Conclusion

Project Orbis has proven that **a collaborative international review model can work effectively in oncology**, delivering earlier multi-country approvals for cancer drugs and building cross-regulator understanding (Table 2 results and case examples (www.fda.gov) (www.fda.gov)). Its success rests on features unique to oncology: an established FDA oncology bureaucracy, fast-evolving standards of care, and pressing patient need with global clinical trial networks (www.fda.gov) (www.fda.gov). These factors jointly created the fertile ground for Orbis.

Orbis's oncology focus does not justify a categorical cancer-only description: FDA's 2022 report includes Viojoy for PROS in its Orbis table and rare-disease discussion ([FDA report](#)). OPEN and CoGenT illustrate distinct international collaboration initiatives.

In order to expand, Orbis-like collaboration would need: substantial regulatory resources (expert reviewers and project teams outside oncology), appropriate confidentiality agreements, and a compelling patient-benefit case in those fields. As one regulatory review notes, expanding to other diseases would require aligning staff willingness and building the necessary confidentiality infrastructure across agencies (www.fda.gov). Equally important, regulatory alignment must go hand-in-hand with solving post-approval access, since faster approvals alone have not guaranteed patient access (www.sciencedirect.com) ([pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov/)).

In conclusion, **Project Orbis works for oncology because it was tailor-made for oncology**—from its expert teams to its international problem set. Expanding the model “would take a similar framework, expertise and commitment in other disease areas” (www.fda.gov) (www.fda.gov). Although interest exists (partners at an

Orbis meeting expressed desire to broaden Orbis scope (www.fda.gov)), the path forward will involve careful planning. Any extension of Orbis's principles will likely roll out gradually—perhaps via pilot programs in high-need areas, building on related initiatives like OPEN and CoGenT. If realized, such an expansion could bring the same cross-border efficiencies to other medicines that Orbis achieved for cancer.

Sources: Authoritative FDA documents and speeches (www.fda.gov) (www.fda.gov) (www.fda.gov), peer-reviewed analyses (link.springer.com) (link.springer.com), and international regulatory reports (www.canada.ca) (www.canada.ca) (www.sciencedirect.com), among others, support all claims above.

Source links

Links cited in this article, in order of first appearance. Full addresses are provided for readers using extracted text.

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About IntuitionLabs

IntuitionLabs is an AI consulting, custom software development and data engineering firm serving pharmaceutical, biotechnology, medical-device and other life-science organizations. We work with clinical, regulatory, medical-affairs, commercial, quality and IT teams to connect technology decisions with the work people need to accomplish.

AI consulting and adoption

Our AI enablement services cover readiness assessments, use-case selection, governance and policies, team workshops, adoption measurement and ongoing advisory support. We help organizations structure the information layer behind AI: source material, context, permissions and maintained knowledge that make generated answers useful and reviewable. Private LLM inference and hosted AI options support teams evaluating how to operate AI with appropriate control over their data and infrastructure.

Software, data and life-science workflows

IntuitionLabs develops custom software for pharma and biotech, integrates enterprise systems, and builds data engineering and business intelligence solutions. Areas of focus include AI agents, regulatory research, medical writing, medical affairs, CMC information, competitive intelligence and clinical-document workflows. Our eTMF intelligence work includes cross-system reconciliation and inspection-readiness support.

Enterprise platforms and regulated delivery

We provide Veeva services, application support, managed services, integrations and custom applications, alongside enterprise content work involving platforms such as Egnyte. For regulated workflows, our services include GxP enablement, computer-system validation and software development addressing 21 CFR Part 11 requirements. The applicable controls, validation responsibilities and acceptance criteria are defined for each engagement.

Work with IntuitionLabs

Explore [AI enablement](#), [pharma and biotech software development](#), [data engineering and BI](#), and [Veeva services](#). [Contact IntuitionLabs](#) to discuss your workflow, information sources and implementation needs.

IntuitionLabs publishes educational research to help life-science teams make informed technology decisions. Coverage of a product or organization does not imply a client relationship, endorsement or partnership.

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