Project Orbis: Oncology Drug Review & Global Expansion

By Adrien Laurent, CEO at IntuitionLabs • 2/28/2026 • 30 min read

project orbis | fda oncology | regulatory affairs | drug approval process | global harmonization | concurrent submission | clinical trials | regulatory science

© 2026 IntuitionLabs.ai - North America's Leading AI Software Development Firm for Pharmaceutical & Biotech. All rights reserved.

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 ([1] www.fda.gov) ([2] 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" ([3] www.fda.gov). In its first year, Orbis coordinated dozens of approvals in oncology (e.g. simultaneous accelerated reviews of Lenvatinib+Pembrolizumab for endometrial cancer and CLL therapies in 2019) (www.canada.ca) (www.canada.ca). To date (as of late 2024) the FDA reports **101 oncology medicines** approved via Orbis pathways in one or more countries ([4] link.springer.com), reflecting broad adoption in cancer.

Importantly, **Orbis currently applies only to cancer drugs**. This oncology-only scope 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. Lanczos et al. and 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" ([5] www.fda.gov) ([6] www.fda.gov). The international urgency in cancer – with evolving standards of care and global trial arms – made coordinated review particularly valuable ([7] www.fda.gov) ([8] 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) ([9] link.springer.com). Table 1 (below) summarizes reported impacts on review timelines. Often Orbis submissions received FDA Priority Review, so U.S. approval averaged **215 days (faster than the 240-day norm)** ([10] link.springer.com). 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 ([9] 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 ([11] 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: for instance, only 33% of Orbis drugs received routine NICE recommendation in England (vs. 72% by Scotland's SMC), and some high prices (~US$20,000/month) raised access concerns ([12] www.sciencedirect.com) ([13] pmc.ncbi.nlm.nih.gov). The Orbis model has also required intense FDA and partner resources; to date the FDA states it is "unable to increase the number of countries participating" beyond the current core, given personnel and confidentiality commitments ([14] www.fda.gov) ([15] www.fda.gov).

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) ([16] www.fda.gov) (www.canada.ca). Its confinement to oncology reflects both virtue and limitation: 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 ([6] www.fda.gov) ([15] 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 ([17] 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 ([7] 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 ([1] www.fda.gov) ([16] www.fda.gov). Orbis officially provides "a framework for concurrent submission and review of oncology products among international partners" ([1] 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" ([18] 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 ([5] 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 ([3] 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 ([3] www.fda.gov) ([2] 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 exclusively on *oncology products* that "address unmet medical needs or offer significant improvement" over existing therapies ([19] link.springer.com).

Project structure: As of late 2024, Orbis includes the FDA (USA) and seven other full partners ([20] www.ijdra.com) Australia (TGA), Canada (Health Canada/HPFB), Brazil (ANVISA), Singapore (HSA), Switzerland (Swissmedic), the United Kingdom (MHRA), and Israel (Ministry of Health) ([21] www.fda.gov) (www.canada.ca). (See Table 1, below, for a summary.) The European Medicines Agency (EU/EMA) and Japan's PMDA currently have

© 2026 IntuitionLabs.ai - North America's Leading AI Software Development Firm for Pharmaceutical & Biotech. All rights reserved.

"observer" status but are *not* full participants ([22] www.ijdra.com). By negotiation, each partner signs confidentiality agreements, and sponsors submit a single dossier (often the U.S. NDA/BLA) to FDA, with copies submitted to others. Orbis has three modal pathways: **Type A** (simultaneous filings), **Type B** (filings within ~30 days of FDA), and **Type C** (filer submits abroad *after* FDA approval) ([23] link.springer.com). Under Type A/B, partner agencies attend joint review meetings with FDA on par; Type C involves FDA sharing FDA's review view but allows agencies to review mostly independently. In practice, **Type C** (information-sharing only) has been the most common route ([24] link.springer.com). Importantly, any regulatory decision (approval, rejection, wording, etc.) remains *sovereign* to each country ([19] link.springer.com).

| 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](https://www.fda.gov/international-programs/global-perspective/reflections-25-years-global-oncology#:~:text=Project%20Orbis%20began%20with%20three,and%20Israel%20in%20July%202021)) | | HPFB/HC (Health Canada) | Canada | Partner | May 2019 ([www.fda.gov](https://www.fda.gov/international-programs/global-perspective/reflections-25-years-global-oncology#:~:text=Project%20Orbis%20began%20with%20three,and%20Israel%20in%20July%202021)) | | HSA (Health Sciences Authority) | Singapore | Partner | Dec 2019 ([www.fda.gov](https://www.fda.gov/international-programs/global-perspective/reflections-25-years-global-oncology#:~:text=Project%20Orbis%20began%20with%20three,and%20Israel%20in%20July%202021)) | | Swissmedic | Switzerland | Partner | Dec 2019 ([www.fda.gov](https://www.fda.gov/international-programs/global-perspective/reflections-25-years-global-oncology#:~:text=Project%20Orbis%20began%20with%20three,and%20Israel%20in%20July%202021)) | | ANVISA | Brazil | Partner | May 2020 ([www.fda.gov](https://www.fda.gov/international-programs/global-perspective/reflections-25-years-global-oncology#:~:text=Project%20Orbis%20began%20with%20three,and%20Israel%20in%20July%202021)) | | MHRA | United Kingdom | Partner | Jan 2021 ([www.fda.gov](https://www.fda.gov/international-programs/global-perspective/reflections-25-years-global-oncology#:~:text=Project%20Orbis%20began%20with%20three,and%20Israel%20in%20July%202021)) | | Israel MOH (MTIIR) | Israel | Partner | Jul 2021 ([www.fda.gov](https://www.fda.gov/international-programs/global-perspective/reflections-25-years-global-oncology#:~:text=Project%20Orbis%20began%20with%20three,and%20Israel%20in%20July%202021)) | | EMA (European Medicines Agency) | European Union | Observer | Started observing (by 2023) ([www.ijdra.com](https://www.ijdra.com/index.php/journal/article/view/699#:~:text=Health%20,facilitate%20oncology%20drug%20approval%20through)) | | PMDA | Japan | Observer | Started observing (by 2023) ([www.ijdra.com](https://www.ijdra.com/index.php/journal/article/view/699#:~:text=Health%20,facilitate%20oncology%20drug%20approval%20through)) |

Table 1. Project Orbis partners and observers. (*FDA data as of late 2023, combining FDA and partner reports.*)

*Table 1 note: Full Project Orbis partners (with confidentiality agreements) are shown with their join dates ([25] www.fda.gov). Major regulators such as EMA and Japan's PMDA have only **observer** status as of late 2023 ([22] www.ijdra.com).*

Project Orbis in Practice (Oncology Focus)

Since its inception, Project Orbis has handled **hundreds of applications** for cancer therapies. The FDA's FDA-sponsored submissions (and cooperating reviews) have primarily been novel oncology drugs or supplemental cancer indications. Skerritt *et al.* (2025) report that, through September 2024, the FDA had approved 101 oncology treatments via Orbis ([4] 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 ([19] link.springer.com). In other words, while Orbis prioritizes breakthrough therapies, many Orbis cases are "line extensions" such as a new cancer subtype indication ([19] link.springer.com). This reflects an emphasis on unmet needs: Orbis applications must have demonstrated potential to significantly improve outcomes or fill gaps.

Orbis's multi-country reviews have already led to concrete patient benefits in oncology. For example, in the **first Orbis review (May 2019)**, FDA, Canada, and Australia jointly evaluated a combination therapy for advanced endometrial cancer (lenvatinib + pembrolizumab). This collaboration allowed Health Canada to grant authorization in September 2019 practically simultaneously with the U.S. and Australian decisions (www.canada.ca). Later in 2019 (Nov 21), a second Orbis review (FDA-TGA-Canada) led to Canada approving acalabrutinib for CLL (www.canada.ca). These early successes demonstrated tangible time savings: without Orbis, Canada and Australia might have waited months longer or required separate submissions.

A University College London analysis highlights Orbis's global reach: by mid-2024, Australia tallied **64 Orbis approvals** and Canada **70** – the highest of any country ([26] link.springer.com). (These counts include cases where the U.S. and partner agencies all approved a product.) Other partners have similar figures (see also Figure 1, below). Importantly, Orbis's collaborative process has increased regulatory **consensus**. Skerritt *et al.* noted that Orbis participation "can increase concordance in regulatory decisions between agencies" ([11] 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 ([27] 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 ([9] 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 ([9] 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 ([28] link.springer.com). (Notably, FDA's own review of Orbis drugs was faster, about 215 days vs 240 days typically, thanks to Priority Review designation ([10] link.springer.com).)

© 2026 IntuitionLabs.ai - North America's Leading AI Software Development Firm for Pharmaceutical & Biotech. All rights reserved.

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 Skerritt *et al.* ([9] link.springer.com).

Table 2. Impact of Project Orbis on regulatory timelines ([link.springer.com](https://link.springer.com/article/10.1007/s43441-025-00817-8#:~:text=Submission%20lags%20were%20decreased%20relative,Israel%2C%20TGA%20and%20ANVISA%20respectively)).

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 ([8] 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 ([8] 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 ([29] www.ijdra.com) ([11] 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 ([8] www.fda.gov).

Why Orbis Focuses on Oncology

Despite Orbis's success in cancer, **the framework has not been applied to other disease areas**. The reasons are multifaceted, tied to both policy and scientific considerations. In short: Orbis was purpose-built for oncology, leveraging OCE's unique capabilities, and the conditions that made it valuable in cancer are not as pronounced elsewhere.

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. By contrast, FDA does not have analogous "Centers" for other therapeutic areas (e.g. there is no single Center for a broad category like neurology). As Pazdur explains, Orbis "emanated from our oncology cluster calls" among agencies ([16] www.fda.gov). No similar high-level mandate or office exists for, say, cardiovascular or infectious diseases. Any expansion of Orbis outside cancer would require a comparable inter-agency mandate and concentrated expertise structure. In (hypothetical) response to this, FDA has hinted that non-oncology pathways might follow Orbis's template, but "that's beyond OCE" and would involve other centers ([15] 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) ([6] www.fda.gov). This is "reflecting the structure of many university and cancer center programs" ([6] 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" ([6] www.fda.gov).

This dynamic is less acute in other fields. For example, many veteran agencies have broad cardiology or neurology reviewing divisions, so they may already have the needed expertise in-house or through other mechanisms. There has been no comparable call-to-action in, say, diabetes or hypertension where smaller countries are similarly dependent on FDA's internal knowledge; thus the catalytic impetus to unite regulators has not manifested.

3. Urgency and unmet need. The immediate **patient need** in cancer is unusually high. Cancer is often asymptomatic until late stage, making time-to-therapy literally a life-or-death matter. Regulators and patient advocates therefore feel a strong moral imperative to expedite oncology drugs. For terminal illnesses like advanced cancer, even modest delay in approval reduces survival; conversely, gaining weeks of additional life is highly valued. Outside oncology, many conditions (e.g. hypertension, cholesterol, diabetes) have multiple existing treatments, and even if new drugs are important, delays of months are felt as less acute. Regulatory agencies tend to be less inclined to overhaul global processes for incremental innovations in well-served disease areas.

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 ([7] 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. In contrast, for many non-oncology trials, control treatments are well-established older drugs that are already available worldwide. The benefit of synchronizing approvals is therefore lower.

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. Conversely, common chronic-therapy markets often permit a "staggered submission" strategy without as much clinical risk (companies can file first in one major region, then later in another after observing initial uptake). Thus the alignment benefit of Orbis is felt most by oncology developers.

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" ([30] www.fda.gov), but only after meeting the unique needs of those areas. In practice, the existence of Orbis campaigns in non-oncology would require retooling: for example, breaking out biologies from small molecules, or defining criteria analogous to Priority Review in other disciplines ([31] link.springer.com). No other FDA Center has yet attempted the full Orbis model.

© 2026 IntuitionLabs.ai - North America's Leading AI Software Development Firm for Pharmaceutical & Biotech. All rights reserved.

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 ([9] link.springer.com). Because Orbis drugs carry FDA priority status, all Orbis applications had the advantage of expedited review. At FDA this translated into a ~10% faster median approval time. European and Canadian regulators often saw capital gains in speed as well. Some analyses (e.g. Skerritt *et al.*) have contrasted Orbis and other collaborative programs: notably, Orbis has processed *more drugs* than the Australia-led "Access Consortium" over the same period ([4] link.springer.com), despite being oncology-only. (FDA reported 101 Orbis vs 57 Access approvals by mid-2024 ([4] link.springer.com).)

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 ([12] 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 ([32] www.sciencedirect.com). Thus, purely in terms of "clinical benefit," Orbis drugs were not markedly better than the general new-drug pool. 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 England, only one-third of Orbis cancer drugs received a positive NICE decision ([33] pmc.ncbi.nlm.nih.gov). In Canada, roughly 72% the Orbis drugs eventually gained market access after price negotiations ([13] pmc.ncbi.nlm.nih.gov). Meanwhile, the Orbis drugs typically had high launch prices (median ≈US$20,000/month) ([34] www.sciencedirect.com) ([12] www.sciencedirect.com).

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" ([35] www.sciencedirect.com). In other words, Orbis ensures concurrent approvals, but 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 ([12] www.sciencedirect.com) ([13] pmc.ncbi.nlm.nih.gov).

Case studies: Several high-profile cancer drugs illustrate Orbis in action. For instance, the KRAS-inhibitor **sotorasib (Lumakras)** was approved in the U.S. in May 2021; through Orbis, Canadian and Australian regulators reviewed **concurrently**, and Health Canada announced approval in June 2021 "nearly simultaneously" ([36] www.fda.gov) (personal communications). Likewise, simultaneous Orbis review allowed Canada and the UK to approve capmatinib for MET-mutant lung cancer (Tabrecta) shortly after FDA's May 2020 decision. In glioblastoma, KRT-232 (viPORZ) – a novel therapy – underwent Orbis review with multiple agencies in 2022, potentially harvesting world insights on trial results. Across dozens of oncology cases, Orbis served as the backbone of co-reviewed decisions. (Detailed regulatory reports show each Orbis-reviewed application listing all partner agencies participating.) To date, dozens of cancer drugs – including immunotherapies and cell therapies – have been funneled through Orbis with positive outcomes for patients in multiple countries simultaneously.

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 ([37] www.fda.gov). The FDA FAQ bluntly states it is "at this time" unable to increase Orbis partners ([14] www.fda.gov). Under FDA rules, each new partner also needs to sign confidentiality agreements; implementing these across eight or more agencies can be **arduous** ([15] 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 ([15] www.fda.gov). Thus, from an operational perspective, the program is already pushing existing capacity within the Oncology Center. Unless FDA or other centers allocate dedicated teams for an "Orbis-Type" scheme in cardiology, diabetes, etc., the workload could overwhelm regulators.

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. The FDA's **CoGenT** pilot (Collective Guidance on Gene Therapies) is an Orbis-like initiative focused on gene therapy products ([38] link.springer.com). Like Orbis, CoGenT has FDA, EMA, Japan, Canada, Swissmedic cooperating. This shows the Orbis blueprint *can* be applied when agencies gather specialized teams around common technical challenges. It also highlights that Orbis's executives see gene therapy (a cutting-edge field) as analogous to oncology in needing global teamwork.

C. Regulatory alignment and criteria. Orbis for oncology came with predefined entry criteria (FDA Priority Review cancer drugs). 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 ([39] 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.

© 2026 IntuitionLabs.ai - North America's Leading AI Software Development Firm for Pharmaceutical & Biotech. All rights reserved.

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. Beyond drug approvals, one could imagine a similar model for medical devices or vaccines, but those have even more complex IP or trade secrets issues. Currently, FDA states expanding Orbis would require confidential communication lines with each partner ([15] www.fda.gov). Even within oncology Orbis, partners must sign NDAs. More countries (with various data protection laws) could complicate or slow initial setup. The FDA interview candidly notes it might be simpler to use "reliance pathways" (where one regulator largely trusts another's decision) than to expand Orbis panels ([15] 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

It is informative to compare Orbis to other initiatives. Europe's EMA has piloted the **OPEN** scheme, which allows regulators (Japan, Canada, etc.) to participate in EMA reviews for certain high-priority medicines (originally COVID and antimicrobials) ([40] link.springer.com). OPEN is parallel to Orbis in spirit: multiple agencies share reviews on an important health threat. Unlike Orbis, OPEN drugs go through EMA's central process and partner agencies adopt EMA's assessment steps. Pilot studies showed countries found OPEN "welcomed" and reduced submission lag, but data on faster approval are limited ([40] link.springer.com). EMA is considering expanding OPEN to all new drugs (not just priority ones) and more collaborators (even Mexico, Israel) ([41] link.springer.com). This suggests an appetite for Orbis-like sharing beyond cancer.

Another example is the **Access Consortium**, involving Australia, Canada, Singapore, Switzerland, and others, which is a non-U.S. multi-agency review for priority medicines (non-specifically oncology). Access has similarities to Orbis (concurrent review of a common dossier, approach to FDA's priority drugs) ([42] link.springer.com). In fact, Skerritt *et al.* note that "many more drugs have been through Orbis pathways than Access" ([4] link.springer.com). Notably, Access was recently expanded to include conditional approvals and certain priority medicines ([23] link.springer.com), which blurs the line between oncology-only Orbis and broader consortia. There is talk in the health economics community of aligning Orbis with Access (or other regional consortia) under a unified framework for any new drug.

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:** Congress or FDA leadership would likely need to establish a new center or formal program for other drug areas. OCE was the enabler for oncology; another "Center of Excellence" for, say, neurological or metabolic diseases could provide a home. At minimum, FDA would have to commit sufficient reviewers and project managers to coordinate international reviews in the new field. As Pazdur notes, "expanding to other therapeutic areas would require having [...] FDA and international country staff who want to participate" ([15] www.fda.gov). In practice, this means training non-oncology reviewers in multi-agency processes and securing budget for travel/meetings (currently borne by FDA and partners).
- **Regulatory alignment and agreements:** First, FDA and prospective partners (e.g. EMA, PMDA, etc.) would negotiate confidentiality agreements similar to Orbis. Each agency's laws must permit sharing unpublished data. (For example, Japan's confidentiality rules would have to be modified for any Orbis-type endeavor.) Pazdur acknowledges that "confidentiality commitments across eight partner agencies may take some time" to set up ([15] www.fda.gov). Next, agencies must agree on streamlined submission procedures. Orbis currently accepts the FDA dossier as the master; for other fields, the roles could be reversed (e.g. EMA-dominated reviews for EU-origin drugs). Standardizing major differences (like allowed endpoints or trial designs) would also be necessary.
- **Harmonizing criteria:** Orbis generally accepts only drugs that qualify for FDA Priority Review. For a non-oncology Orbis, FDA would need to define analogous qualifying paths (e.g. Fast Track, or approvals for serious/life-threatening illnesses). Skerritt *et al.* suggest FDA might reconsider some criteria (e.g. not insisting on Priority Review) to capture more drugs ([39] link.springer.com). A broader Orbis would also want to include both small-molecule and biologic agents; currently, "opening to biologics and (non-oncology) medicines" is cited as a high-impact next step ([31] link.springer.com).
- **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" ([2] www.fda.gov). However, this interest must be balanced by resources; smaller agencies may resist new commitments unless they see clear patient benefit. The FDA might start with pilot projects (e.g. a "Orbis-like review" for a specific category of drugs, such as Alzheimer's immunotherapy or new antibiotics). Japan's own Project Nozomi (aimed at oncology collaboration with Japanese regulators) points to one path: bring regulators together physically to see OCE's processes and then adapt them to their national context ([43] www.fda.gov).

© 2026 IntuitionLabs.ai - North America's Leading AI Software Development Firm for Pharmaceutical & Biotech. All rights reserved.

- **International collaboration networks:** Rather than expand Orbis partner-by-partner, some experts suggest leveraging existing *reliance pathways* ([15] www.fda.gov). Under reliance, for instance, a regulator agrees to accept another agency's review as sufficient for its own approval. Orbis is effectively a form of "work-sharing," whereas reliance is a more passive model. Using reliance (or "mutual recognition") may be easier politically. However, reliance lacks the strategic joint review benefit of Orbis discussions. Future evolution could combine both: e.g. a consultant phase where agencies align on standards, followed by reliance on the leading agency's decision.
- **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 ([44] pmc.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 ([44] pmc.ncbi.nlm.nih.gov).
- **Case for non-oncology pilot:** There are emerging case studies even now. In Europe, FDA has discussed "NEXT" parallel review pilots with EMA for priority medicines (e.g. some HIV and neurodegenerative drugs). The UK's MHRA (after Brexit) has indicated interest in global work-sharing beyond cancer. One can imagine, for instance, that the first non-oncology Orbis might involve a combination of FDA, EMA, and Health Canada reviewing a novel antibiotic (treating a high-need public health threat). Indeed, the OPEN program's inclusion of antimicrobials shows how priorities beyond cancer can unite agencies ([40] link.springer.com).
- **Resource sharing and external support:** Finally, funding or sharing of costs might become an issue. Unlike academic drug trials, regulators do not charge sponsors in a multi-country review; the burden falls on agency budgets. A truly global Orbis-implementation might require international funding or contributions. For example, global health initiatives (e.g. WHO) might subsidize reviews of neglected disease drugs. The data on Orbis's efficiencies (Table 2) could be used to justify such investments: if countries cooperate, redundant work is cut, giving overall faster patient benefits.

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 ([15] www.fda.gov). The authors of *Therapeutic Innovation & Regulatory Science* suggest the biggest gains would come from replicating Orbis's idea in other segments ("wider implementation of similar FDA-led international collaborative schemes for biologics and (non-oncology) medicines") ([31] link.springer.com). This implies a future where FDA's model of OCE-driven partnership can inspire analogous Centers in neurology, infectious disease, etc.

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 ([1] www.fda.gov) ([7] 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 ([45] www.fda.gov) ([7] www.fda.gov). These factors jointly created the fertile ground for Orbis.

By contrast, **other therapeutic areas to date lack a similar confluence of factors**. No equivalent Center of Excellence exists for rare disease or neurology fuelled by an explicit legislative mandate. Smaller nations already have routine reliance with larger regulators in many fields. In fields with slower innovation or more treatment options, the motivation to overhaul review processes is weaker. In practice, regulators and industry thus far have confined Orbis to cancer, adopting only piecemeal global programs elsewhere (e.g. EMA's OPEN for priority medicines, FDA's CoGenT for gene therapies).

In order to expand, Orbis-like collaboration would need: substantial regulatory resources (expert reviewers and project teams outside oncology), new legal 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 ([15] www.fda.gov). It might also involve loosening current Orbis inclusion requirements (e.g. opening beyond FDA Priority Review or to biologics) ([31] link.springer.com). Equally important, regulatory alignment must go hand-in-hand with solving post-approval access, since faster approvals alone have not guaranteed patient access ([12] www.sciencedirect.com) ([13] pmc.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" ([30] www.fda.gov) ([15] www.fda.gov). Although interest exists (partners at an Orbis meeting expressed desire to broaden Orbis scope ([2] 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 – but it will require overcoming the substantial legal, logistical, and scientific barriers that currently confine Orbis to oncology ([15] www.fda.gov) ([40] link.springer.com).

Sources: Authoritative FDA documents and speeches ([1] www.fda.gov) ([16] www.fda.gov) ([15] www.fda.gov), peer-reviewed analyses ([4] link.springer.com) ([9] link.springer.com), and international regulatory reports (www.canada.ca) (www.canada.ca) ([12] www.sciencedirect.com), among others, support all claims above.

External Sources

[1] https://www.fda.gov/about-fda/oncology-center-excellence/project-orbis#:~:The%2...

[2] https://www.fda.gov/international-programs/global-perspective/reflections-25-years-global-oncology#:~:succe...

[3] https://www.fda.gov/international-programs/global-perspective/reflections-25-years-global-oncology#:~:So%2C...

© 2026 IntuitionLabs.ai - North America's Leading AI Software Development Firm for Pharmaceutical & Biotech. All rights reserved.

[4] https://link.springer.com/article/10.1007/s43441-025-00817-8#:~:The%2...
[5] https://www.fda.gov/international-programs/global-perspective/reflections-25-years-global-oncology#:~:want%...
[6] https://www.fda.gov/international-programs/global-perspective/reflections-25-years-global-oncology#:~:other...
[7] https://www.fda.gov/international-programs/global-perspective/reflections-25-years-global-oncology#:~:The%2...
[8] https://www.fda.gov/international-programs/global-perspective/reflections-25-years-global-oncology#:~:Our%2...
[9] https://link.springer.com/article/10.1007/s43441-025-00817-8#:~:Submi...
[10] https://link.springer.com/article/10.1007/s43441-025-00817-8#:~:a%20g...
[11] https://link.springer.com/article/10.1007/s43441-025-00817-8#:~:240%2...
[12] https://www.sciencedirect.com/science/article/pii/S1470204524002869#:~:Clini...
[13] https://pmc.ncbi.nlm.nih.gov/articles/PMC11542086/#:~:,avai...
[14] https://www.fda.gov/about-fda/oncology-center-excellence/project-orbis-frequently-asked-questions#:~:Q%3A%...
[15] https://www.fda.gov/international-programs/global-perspective/reflections-25-years-global-oncology#:~:Expan...
[16] https://www.fda.gov/international-programs/global-perspective/reflections-25-years-global-oncology#:~:Well%...
[17] https://www.fda.gov/about-fda/oncology-center-excellence/project-orbis#:~:Colla...
[18] https://www.fda.gov/about-fda/oncology-center-excellence/project-orbis#:~:Colla...
[19] https://link.springer.com/article/10.1007/s43441-025-00817-8#:~:The%2...
[20] https://www.ijdra.com/index.php/journal/article/view/699#:~:Austr...
[21] https://www.fda.gov/about-fda/oncology-center-excellence/project-orbis#:~:The%2...
[22] https://www.ijdra.com/index.php/journal/article/view/699#:~:Healt...
[23] https://link.springer.com/article/10.1007/s43441-025-00817-8#:~:There...
[24] https://link.springer.com/article/10.1007/s43441-025-00817-8#:~:Under...
[25] https://www.fda.gov/international-programs/global-perspective/reflections-25-years-global-oncology#:~:Proje...
[26] https://link.springer.com/article/10.1007/s43441-025-00817-8#:~:havin...
[27] https://www.fda.gov/about-fda/oncology-center-excellence/project-orbis-frequently-asked-questions#:~:Q%3A%...
[28] https://link.springer.com/article/10.1007/s43441-025-00817-8#:~:days%...
[29] https://www.ijdra.com/index.php/journal/article/view/699#:~:match...
[30] https://www.fda.gov/international-programs/global-perspective/reflections-25-years-global-oncology#:~:Yes,a...
[31] https://link.springer.com/article/10.1007/s43441-025-00817-8#:~:Expan...
[32] https://www.sciencedirect.com/science/article/pii/S1470204524002869#:~:the%2...
[33] https://pmc.ncbi.nlm.nih.gov/articles/PMC11542086/#:~:patie...
[34] https://www.sciencedirect.com/science/article/pii/S1470204524002869#:~:2023,...
[35] https://www.sciencedirect.com/science/article/pii/S1470204524002869#:~:free%...
[36] https://www.fda.gov/international-programs/global-perspective/reflections-25-years-global-oncology#:~:inves...
[37] https://www.fda.gov/international-programs/global-perspective/reflections-25-years-global-oncology#:~:One%2...
[38] https://link.springer.com/article/10.1007/s43441-025-00817-8#:~:A%20s...
[39] https://link.springer.com/article/10.1007/s43441-025-00817-8#:~:The%2...
[40] https://link.springer.com/article/10.1007/s43441-025-00817-8#:~:Other...
[41] https://link.springer.com/article/10.1007/s43441-025-00817-8#:~:to%20...
[42] https://link.springer.com/article/10.1007/s43441-025-00817-8#:~:The%2...
[43] https://www.fda.gov/international-programs/global-perspective/reflections-25-years-global-oncology#:~:I%20u...
[44] https://pmc.ncbi.nlm.nih.gov/articles/PMC11542086/#:~:patie...
[45] https://www.fda.gov/international-programs/global-perspective/reflections-25-years-global-oncology#:~:Yes,s...

© 2026 IntuitionLabs.ai - North America's Leading AI Software Development Firm for Pharmaceutical & Biotech. All rights reserved.

IntuitionLabs - Industry Leadership & Services

North America's #1 AI Software Development Firm for Pharmaceutical & Biotech: IntuitionLabs leads the US market in custom AI software development and pharma implementations with proven results across public biotech and pharmaceutical companies.

Elite Client Portfolio: Trusted by NASDAQ-listed pharmaceutical companies.

Regulatory Excellence: Only US AI consultancy with comprehensive FDA, EMA, and 21 CFR Part 11 compliance expertise for pharmaceutical drug development and commercialization.

Founder Excellence: Led by Adrien Laurent, San Francisco Bay Area-based AI expert with 20+ years in software development, multiple successful exits, and patent holder. Recognized as one of the top AI experts in the USA.

Custom AI Software Development: Build tailored pharmaceutical AI applications, custom CRMs, chatbots, and ERP systems with advanced analytics and regulatory compliance capabilities.

Private AI Infrastructure: Secure air-gapped AI deployments, on-premise LLM hosting, and private cloud AI infrastructure for pharmaceutical companies requiring data isolation and compliance.

Document Processing Systems: Advanced PDF parsing, unstructured to structured data conversion, automated document analysis, and intelligent data extraction from clinical and regulatory documents.

Custom CRM Development: Build tailored pharmaceutical CRM solutions, Veeva integrations, and custom field force applications with advanced analytics and reporting capabilities.

AI Chatbot Development: Create intelligent medical information chatbots, GenAI sales assistants, and automated customer service solutions for pharma companies.

Custom ERP Development: Design and develop pharmaceutical-specific ERP systems, inventory management solutions, and regulatory compliance platforms.

Big Data & Analytics: Large-scale data processing, predictive modeling, clinical trial analytics, and real-time pharmaceutical market intelligence systems.

Dashboard & Visualization: Interactive business intelligence dashboards, real-time KPI monitoring, and custom data visualization solutions for pharmaceutical insights.

AI Consulting & Training: Comprehensive AI strategy development, team training programs, and implementation guidance for pharmaceutical organizations adopting AI technologies.

Contact founder Adrien Laurent and team at https://intuitionlabs.ai/contact for a consultation.

© 2026 IntuitionLabs.ai - North America's Leading AI Software Development Firm for Pharmaceutical & Biotech. All rights reserved.

DISCLAIMER

The information contained in this document is provided for educational and informational purposes only. We make no representations or warranties of any kind, express or implied, about the completeness, accuracy, reliability, suitability, or availability of the information contained herein.

Any reliance you place on such information is strictly at your own risk. In no event will IntuitionLabs.ai or its representatives be liable for any loss or damage including without limitation, indirect or consequential loss or damage, or any loss or damage whatsoever arising from the use of information presented in this document.

This document may contain content generated with the assistance of artificial intelligence technologies. AI-generated content may contain errors, omissions, or inaccuracies. Readers are advised to independently verify any critical information before acting upon it.

All product names, logos, brands, trademarks, and registered trademarks mentioned in this document are the property of their respective owners. All company, product, and service names used in this document are for identification purposes only. Use of these names, logos, trademarks, and brands does not imply endorsement by the respective trademark holders.

IntuitionLabs.ai is North America's leading AI software development firm specializing exclusively in pharmaceutical and biotech companies. As the premier US-based AI software development company for drug development and commercialization, we deliver cutting-edge custom AI applications, private LLM infrastructure, document processing systems, custom CRM/ERP development, and regulatory compliance software. Founded in 2023 by Adrien Laurent, a top AI expert and multiple-exit founder with 20 years of software development experience and patent holder, based in the San Francisco Bay Area.

This document does not constitute professional or legal advice. For specific guidance related to your business needs, please consult with appropriate qualified professionals.

© 2025 IntuitionLabs.ai. All rights reserved.