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Project Orbis: Concurrent Oncology Drug Review Process

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Executive Summary

Project Orbis is an innovative international regulatory collaboration launched by the U.S. Food and Drug Administration (FDA) Oncology Center of Excellence (OCE) in May 2019. It establishes a framework for the concurrent submission and review of cancer drug applications across multiple countries, aiming to accelerate the availability of novel oncology therapies to patients worldwide (ascopost.com) (www.hsa.gov.sg). Originally involving the FDA together with the Australian Therapeutic Goods Administration (TGA) and Health Canada (HC), the framework expanded to additional authorities. Verified on 13 October 2026, the FDA lists eight partner authorities: Australia, Brazil, Canada, Israel, Japan, Singapore, Switzerland, and the United Kingdom, alongside the coordinating FDA ([FDA](https://www.fda.gov)). Japan formally joined on 10 September 2026 ([MHLW](https://www.mhlw.go.jp)). Shared review can support multinational approval, with independent national decisions.

The success of Project Orbis lies in its ability to **reduce approval delays**. For instance, Swissmedic's analysis found that Orbis-reviewed applications had a median submission gap of only 33 days from FDA versus 168 days for non-Orbis cases, and a shorter review time (median 236 vs 314 days) (archive-ouverte.unige.ch). Across 2019–2023, roughly one-third of all new FDA cancer drug approvals (81 of 244) involved Orbis collaboratives (www.sciencedirect.com). Regulatory authorisation and actual patient access are separate outcomes; each participating authority retains its own decision and timeline ([FDA FAQ](https://www.fda.gov)).

However, Project Orbis does **not** merge regulatory decisions. Each country conducts its own independent risk-benefit analysis and labeling, even as they meet together on common review issues (www.gov.uk) (ascopost.com). Thus far, Orbis has yielded **mostly positive outcomes** (with over 80% approval congruence between FDA and Orbis partners for Swiss cases (archive-ouverte.unige.ch)), but not every application succeeds in every jurisdiction. Moreover, even after approval, patient access depends on each country's reimbursement pathway. Thus, the broader impact on patient access must consider not only speed of approval but also cost, reimbursement decisions, and healthcare system readiness. Although Project Orbis is chiefly an oncology initiative, its model exemplifies **global collaboration** in drug regulation. By pooling expertise and review resources, partners share the workload and build trust—setting a template for future international initiatives to expedite critical therapies for patients worldwide.

Introduction and Background

IARC estimated approximately **9.7 million cancer deaths worldwide in 2022** ([IARC](https://gco.iarc.fr)). Medical innovation has raised hopes of reducing this toll, but a key bottleneck remains: regulatory approval. Oncology drugs require rigorous review of complex clinical trial data before they can reach patients. Historically, this review has been performed **sequentially** in each country. As Dr. Richard Pazdur (former Director of FDA's Oncology Center) has explained, pivotal cancer drug applications often arrive **first** at the FDA, with smaller regulators receiving them months or even years later (www.fda.gov). This lag delays global trial enrollment and keeps potentially life-saving medicines out of reach for many patients. An analysis noted that smaller agencies like Australia's TGA and Canada's HC typically experienced a “filing delay” of months to years compared to the U.S., meaning control-arm standards of care in global trials could differ, jeopardizing trial viability (www.fda.gov).

Recognizing this problem, the FDA had long **convened “cluster” teleconferences** to discuss oncology applications with other regulators for over a decade ([ascopost.com](#)) ([www.fda.gov](#)). These early multilateral discussions built trust but did not align timelines. Project Orbis was conceived as a next step. Launched by the FDA's Oncology Center of Excellence in May 2019 ([ascopost.com](#)) ([cure4cancerglobal.org](#)), Orbis creates a formal framework for **concurrent review** of cancer drug submissions. The initiative's goal is succinct: to enable **simultaneous submission, review, and if appropriate, approvals of clinically important oncology products across multiple countries** ([cure4cancerglobal.org](#)) ([pmc.ncbi.nlm.nih.gov](#)). In other words, instead of a company filing in the U.S. then months later in allies, Orbis invites sponsors to file in several regulatory agencies nearly together. Regulators then hold joint meetings and share review questions, although each agency ultimately decides independently. The FDA describes Orbis as a framework for concurrent submission and review; national decisions remain independent ([FDA](#)).

The launch of Orbis reflected broader global health initiatives. It was touted as part of the revised U.S. “Cancer Moonshot” agenda, emphasizing international cooperation to halve cancer mortality by 2047 ([cure4cancerglobal.org](#)). The program emanated directly from OCE's global cluster calls: Dr. Pazdur explained that the idea originated when agency representatives noticed that “the most important drug applications were filed first in the United States” ([www.fda.gov](#)). To fix this, the FDA approached companies to submit the same high-impact oncology applications to other countries “as closely as possible” to the FDA submission ([www.fda.gov](#)). The ambition was “significant drugs that had a major impact on patients with cancer – not 'me-too' drugs” ([www.fda.gov](#)). In practice, Orbis started in mid-2019 with oncology treatments in areas of urgent medical need.

Project Orbis Framework

Participating Partners and Scope

Project Orbis is **coordinated by the FDA** Oncology Center of Excellence. As verified on 13 October 2026, the FDA lists eight partner authorities, making nine participating authorities including the FDA ([FDA](#)):

- **Australia** – Therapeutic Goods Administration (TGA)
- **Brazil** – Agência Nacional de Vigilância Sanitária (ANVISA)
- **Canada** – Health Canada (HC)
- **Israel** – Ministry of Health
- **Japan** – Pharmaceuticals and Medical Devices Agency (PMDA)
- **Singapore** – Health Sciences Authority (HSA)
- **Switzerland** – Swissmedic
- **United Kingdom** – Medicines and Healthcare products Regulatory Agency (MHRA)

Japan formally joined on 10 September 2026 ([MHLW](#)). Participation in an individual review depends on the agencies and the application.

Orbis accepts oncology NDAs, BLAs, and supplemental applications, including new indications. Applications should generally be high-impact and clinically significant and qualify for FDA priority review because of improvement in safety or efficacy ([FDA FAQ](#)). MHRA accepts new marketing authorisation applications and

new indication variations; its submissions must meet FDA clinical criteria for priority review ([MHRA](#)). Orphan designation is not an exclusion: TGA reports that approximately 15 Orbis submissions had orphan designation as of 30 September 2023 ([TGA](#)). This does not mean every type of line extension or generic filing is eligible.

A key point is that **each agency remains sovereign**. All Orbis partners independently apply their national laws and standards in making their approval decision ([www.gov.uk](#)). Participating regulators meet regularly (via multi-agency teleconferences) to discuss review findings, questions, and identified issues, but there is **no binding joint decision**. The collaboration is explicitly for information-sharing and harmonization of review questions. As a UK summary puts it: Orbis “provides a framework for concurrent submission and review of oncology products among international partners,” but each country retains “complete autonomy” over final approval ([www.gov.uk](#)) ([www.gov.uk](#)). In practice, regulatory actions—the label text, conditions, and timeline—are determined at each agency. Approval dates can differ between partners ([FDA](#)).

Orbis collaboration is **tiered by submission timing**, with partner-specific implementation ([HSA](#); [TGA](#); [MHRA](#)):

Orbis Type	Submission timing relative to FDA	Concurrent review	Near-concurrent independent action
Type A	Within one month of FDA submission	Expected	Possible
Type B	More than one month after FDA submission	Possible	Not expected
Type C	Any time after FDA submission, subject to partner guidance	Unlikely; HSA describes no concurrent review	Not expected

Type C supports regulatory reliance on FDA's completed review documents. Sponsors should confirm optimal dossier timing with the relevant partner; it is not an advisory-only pathway. MHRA's narrative describes Type C when FDA has already taken regulatory action, while its table makes submission timing dependent on partner guidance. All partners retain independent decisions, labelling negotiations, and timelines.

Benefits and Mechanisms

By fostering parallel review, Orbis aims to yield several concrete benefits:

- **Potential Earlier Authorisation:** Regulators can discuss an application in parallel while retaining independent national decisions and timelines ([FDA FAQ](#)). Authorisation is distinct from reimbursement, supply, launch timing, and measured patient outcomes.
- **Regulatory Efficiency through Collaboration:** Orbis brings review teams together across borders. Participating agencies **jointly discuss substantive issues** in teleconferences or joint meetings. This means that if, for example, the FDA has a major safety or efficacy question, it can be discussed in the same forum with the TGA, HC, HSA, etc. Any “regulatory divergence” between countries can be identified earlier in the review process ([ascopost.com](#)). If one agency is considering a different approach (say, on a labeling statement or a clinical data gap), the others can weigh in with their perspectives. The ASCO summary of Orbis notes that this collaborative review allows any differences to be ironed out collaboratively, rather than surprising a partner at the end ([ascopost.com](#)) ([www.hsa.gov.sg](#)). Multiple regulators benefit by learning from each other’s review expertise. As one is quoted: “Experts from all

agencies independently perform their evaluation but jointly discuss the critical, identified issues. This forms the perfect basis for a well-informed sovereign decision for each jurisdiction” (ascopost.com). Indeed, banking the insight of participating oncology regulatory agencies tends to **strengthen confidence** in the shared data and can even uncover issues one agency might miss. It also encourages companies to submit earlier to multiple countries; as Australia’s TGA said, the Orbis collaboration “encourages earlier drug submission in Canada” and provides “both an additional pathway for earlier access... and an opportunity to further enhance the TGA’s knowledge base” (ascopost.com).

- **Leveraging Expedited Review Pathways:** Most Orbis filings also use each agency’s fastest review channels. For example, if a company seeks breakthrough or priority review at the FDA, it can often also do so at partner agencies. The TGA reports that **over half of its Orbis-led approvals** have been through priority or provisional pathways (www.tga.gov.au). Swissmedic, HC, and others typically prioritize Orbis applications to align with the schedule. The FDA itself often integrates Orbis apps with its other programs (e.g. Real-Time Oncology Review, Assessment Aid) so that the FDA’s own decision comes out very quickly, allowing partners to take advantage (pmc.ncbi.nlm.nih.gov). Ultimately, Orbis projects disproportionately target **high-need therapies**. As Pazdur notes, Orbis focused on drugs that have “a major impact on patients with cancer” (www.fda.gov). The clinical benefit of each therapy requires assessment on its own evidence; new molecular entity status alone does not establish high clinical benefit.
- **Alignment with Global Goals:** Project Orbis exemplifies an emerging trend of regulatory harmonization in health. In the wake of Brexit and other geopolitical shifts, countries have been seeking **new bilateral and multilateral frameworks** for access to medicines. The UK, for instance, announced in late 2020 that it would join Orbis (and a separate Access Consortium) precisely to “speed up the approval of innovative medicines” in the post-transition era (www.gov.uk) (www.gov.uk). High-level statements emphasize that Orbis could “uphold and strengthen international cooperation” and show U.S. leadership in global health (cure4cancer.global.org) (cure4cancer.global.org). In practice, this has meant the UK’s MHRA observing Orbis reviews and beginning to participate as a partner in oncology submissions (www.gov.uk) (www.gov.uk). Ultimately, Orbis advances the concept that lifesaving drugs for cancer shouldn’t be handicapped by borders. It aligns with initiatives like the Cancer Moonshot that emphasize global research and shared standards (cure4cancer.global.org).

While the advantages are clear, Orbis also acknowledges important caveats. Because agencies act independently, **outcomes can still differ**. In a Swiss study, 77% of Orbis-reviewed submissions were ultimately approved in Switzerland, essentially identical to the non-Orbis approval rate of 76% (archive-ouverte.unige.ch). Moreover, Orbis does not guarantee access – pricing and reimbursement depend on each country’s health system. FDA states that Orbis partners retain independent regulatory decisions and timelines ([FDA FAQ](https://www.fda.gov/fda-faq)). Regulatory collaboration therefore should not be presented as proof of funded or delivered patient access.

Project Orbis in Action: Case Studies

These historical cases illustrate concurrent regulatory review and the importance of country-specific decisions. The dates below describe the cited historical authorisations.

Tucatinib (Tukysa): HER2-Positive Breast Cancer, 2020

FDA approved tucatinib on **17 April 2020**, in combination with trastuzumab and capecitabine, for adults with advanced unresectable or metastatic HER2-positive breast cancer, including patients with brain metastases, who had received one or more prior anti-HER2-based regimens in the metastatic setting ([FDA approval package](#)). Swissmedic reports its separate Swiss authorisation on **7 May 2020** and concurrent assessment with FDA, TGA, Health Canada, and HSA ([Swissmedic](#)). The Swiss authority is Swissmedic, in Switzerland. Concurrent assessment did not produce identical decision dates.

Osimertinib (Tagrisso): Adjuvant Lung Cancer Therapy, 2020–2021

The FDA supplemental approval letter, signed **18 December 2020**, authorised osimertinib as adjuvant therapy after tumour resection in adults with NSCLC whose tumours have EGFR exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test ([FDA approval letter](#)). MHRA's Orbis record gives **6 May 2021** for its separate adjuvant authorisation after complete tumour resection in adults with these specified mutations ([MHRA](#)). These decisions were months apart.

Amivantamab (Rybrevant): Historical Accelerated Approval, 2021

On **21 May 2021**, FDA granted accelerated approval to amivantamab-vmjw for adults with locally advanced or metastatic NSCLC with EGFR exon 20 insertion mutations detected by an FDA-approved test, whose disease had progressed on or after platinum-based chemotherapy. This historical approval was based on overall response rate and response duration; continued approval could be contingent on verification and description of clinical benefit in confirmatory trials ([FDA](#)). FDA collaborated with ANVISA and MHRA under Orbis and reported that their application reviews were still ongoing when it announced its decision. FDA reported approval two months ahead of its goal date; this does not establish how much time Orbis alone saved.

Data Analysis: Outcomes of Project Orbis

Project Orbis has operated long enough to generate measurable outcomes. Multiple independent analyses and agency reports provide data on applications handled and their impact on timelines and access.

- **Volume of Orbis Reviews and Approvals:** The FDA's annual counts and independent studies agree that Orbis has reviewed a substantial fraction of new oncology therapies. Between June 2019 and June 2020, only the first year, **60 marketing applications** were submitted under Orbis, representing 16 unique drug programs which yielded 38 approvals ([ascopost.com](#)). In the longer term (May 2019–Nov 2023), a peer-reviewed analysis identified **244 total cancer drug approvals by FDA, of which 81 (33%) were reviewed through Orbis** ([www.sciencedirect.com](#)). These 81 Orbis cases included 47 new molecular entities (58%) and 34 supplemental applications (42%) ([www.sciencedirect.com](#)). The annual distribution of the 81 Orbis approvals was 3 (4%) in 2019, 22 (27%) in 2020, 27 (33%) in 2021, 17 (21%) in 2022, and 12 (15%) in 2023 through the study cutoff of 1 November. These percentages use the pooled 81 approvals as the denominator ([Jenei and colleagues](#)).

The Office of Global Policy and Strategy newsletter (March 2024) reports that **19 unique oncology drugs were approved under Orbis in calendar 2023** (content.govdelivery.com), indicating steady continued use. TGA reports that, as of 30 September 2023, it had approved approximately 25 new medicines and 35 new indications through Orbis ([TGA](#)). (One should note partial overlap: as many partners approve the same products, counting “unique drugs” can be complex.) Nevertheless, these figures illustrate Orbis as a major pathway: dozens of global oncology drug approvals have been batched through this international review.

- **Time Reduction:** The core premise is that Orbis can shorten regulatory delay. Evidence supports that sponsors submit earlier to countries participating in Orbis, and the review clock is indeed accelerated. For example, the Lancet Oncology’s Swiss analysis quantified this: the **median submission gap** between FDA filing and Swissmedic’s submission was only **33 days for Orbis applications** (95% CI 19–57) versus 168 days (CI 56–351) for comparable non-Orbis oncology filings ($p < 0.0001$) (archive-ouverte.unige.ch). In other words, Swiss agencies received the dossier essentially immediately after FDA, rather than many months later. Furthermore, Switzerland’s **review time** was significantly shorter for Orbis cases (median 235 days) compared to non-Orbis (314 days, $p = 0.0002$) (archive-ouverte.unige.ch). Swissmedic concluded that Orbis allowed the regulator to join “critical identified issues” discussions quickly, yielding faster evaluation.

Similar patterns emerge in other Orbis partners. A recent retrospective analysis across USA, UK (MHRA), Canada (HC), and their health-technology bodies found median delays from FDA approval to other regulators were on the order of a few months (shorter than historical lags). For instance, **median time from FDA approval to UK MHRA approval was ~172 days (IQR 135–223)** (www.sciencedirect.com) and to Health Canada approval ~148 days (IQR 56–272) (www.sciencedirect.com). By comparison, historical mean delays were often over a year. The median time from FDA to Health Canada approval increased from 49 days in 2020 to 235 days in 2023 ([Jenei and colleagues](#)).

A **comparison table** lists the key approval and HTA intervals:

Milestone	Median Time from FDA Approval (days)	Source
FDA to UK MHRA approval	172 (IQR 135–223)	UK MHRA data (www.sciencedirect.com)
FDA to Health Canada approval	148 (IQR 56–272)	Jenei and colleagues (Jenei and colleagues)
FDA to NICE recommendation (England)	447 (IQR 330–513)	NICE data (www.sciencedirect.com)
FDA to SMC recommendation (Scotland)	434 (IQR 327–696)	SMC data (www.sciencedirect.com)
FDA to CADTH recommendation (Canada)	377 (IQR 320–591)	Canadian data (www.sciencedirect.com)

Table: Median delays from FDA approval to key regulatory/HTA milestones in Orbis context (www.sciencedirect.com).

All table intervals start at FDA approval, including the HTA rows. Separately, the median intervals from national approval to HTA recommendation were 208 days for MHRA to NICE, 299 days for MHRA to SMC, and 216 days for Health Canada to CADTH ([Jenei and colleagues](#)).

- **Consensus and Outcomes:** Importantly, Orbis reviews have not produced major misalignment in clinical outcomes. The Swiss scrutiny found that the **approval rate** (77% or 76% depending on definition) was essentially identical for Orbis vs non-Orbis oncology applications ([archive-ouverte.unige.ch](#)). Consensus decisions (instances where Swissmedic and the FDA ultimately agreed) were also very similar (81% vs 76%). In practice, agencies often concur on whether the benefit-risk profile is acceptable. A Lancet Oncology editorial confirms that Orbis partners generally reach unanimous or consistent decisions on most applications ([pmc.ncbi.nlm.nih.gov](#)). As one Orbis participant remarked, different agencies may have divergent standards, but Orbis provides a forum to **"identify any regulatory divergence"** early ([ascopost.com](#)).
- **Clinical Benefit of Orbis Drugs:** Another important question is whether Orbis-prioritized drugs deliver significant clinical benefit. The Lancet comparative study found that FDA-approved cancer drugs reviewed by Orbis had broadly **similar efficacy endpoints** (overall survival, progression-free survival) as those reviewed outside Orbis. Of the 81 Orbis approvals, 47 (58%) were new drugs and 34 (42%) were supplemental indications ([Jenei and colleagues](#)). However, the study also cautioned that "concerns have been raised about regulators approving cancer drugs with modest overall survival gains" across the board ([www.sciencedirect.com](#)). For evaluable comparisons, the median overall survival (OS) gain was 4.1 months for Orbis approvals versus 2.7 months for other FDA cancer drug approvals during the same period ($p=0.11$; [Jenei and colleagues](#)). The study's under-three-month figure describes separate historical background on FDA and EMA cancer drug approvals over the preceding decade ([study introduction](#)). OS data were available at approval for 20 of 81 Orbis approvals (25%); single-arm studies with survival data were excluded from gain calculations. The median gain therefore does not describe all 81 approvals ([Jenei and colleagues](#)).
- **Reimbursement and Cost Considerations:** Rapid approval is only part of the story. Orbis-approved drugs must still navigate each country's healthcare system to reach patients. Data show **gaps remain**. Among completed appraisals, NICE issued positive recommendations for 6 of 15 drugs (40%), with another 5 of 15 (33%) under the Cancer Drug Fund; SMC recommended all 14 reviewed drugs (100%). Separately, eventual availability was 6 of 18 MHRA approvals (33%) routinely in England and 13 of 18 (72%) in Scotland ([Jenei and colleagues](#)). CADTH reviewed 49 of 58 Health Canada Orbis approvals (84%), conditionally recommended 44 of the 49 assessed drugs (90%), and issued negative recommendations for 5 (10%). Eventual availability was 42 of 58 approvals (72%) in Canada ([Jenei and colleagues](#)).

The **costs** of these therapies are also a concern. The same analysis reports a median monthly price of ~\$20,000 USD for Orbis drugs ([www.sciencedirect.com](#)), raising sustainability issues for payers (especially public systems). High prices can further slow reimbursement decisions or lead to restrictive access. As one commentary notes, "drugs must demonstrate value: large clinical benefits and sustainable costs"

(www.sciencedirect.com), yet many new cancer drugs do not meet high HTA thresholds. Thus, even expedited approval via Orbis does not guarantee patients will afford or even have public coverage of these treatments. This is an important caveat: Orbis is a regulatory accelerator, not a pricing or coverage solution.

Implications and Critical Perspectives

Project Orbis represents a significant shift in how we perceive drug approval. Its implications span from patient health to industry strategy and international policy. We discuss key themes and future directions:

- **Patient Access and Health Impact:** Patients stand to benefit from earlier drug availability when effective treatments exist. Moreover, Orbis encourages sponsors to invest in having global dossiers ready together, which may also increase inclusion of diverse populations in trials. In Dr. Pazdur's words, Orbis (and related initiatives) arose from a desire to align global standards of care and trial designs, benefiting "countries where there could be regulatory delays" ([pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov)). Enhanced equity is cited often: advocates note that joining programs like Orbis expands "global health equity by expanding access to clinical trials and precision oncology worldwide" (cure4cancerglobal.org).
- **Industry Strategy:** For pharmaceutical developers, Orbis offers both challenge and opportunity. Coordinating multiple submissions is logistically demanding and potentially costly, but it also accelerates time to revenue in multiple markets. Firms targeting global patient populations may see higher value in engaging Orbis to avoid staggered launches. Additionally, Orbis sponsors can use the shared platform to address global regulatory questions early and avoid duplication. As noted in industry analyses, any improvement in the review calendar (if additional large markets join) can substantially up the "return on investment" of global trials (cure4cancerglobal.org).

However, companies must also navigate networking with multiple authorities and possibly harmonize labeling differences. Each country's final label and indication might vary slightly, so sponsors need to reconcile those after a shared review. The data on pricing suggests that Orbis drugs are often very high-priced (median ~\$20k/month (www.sciencedirect.com)), which can create payor pushback; biotech companies must balance accelerated access with reimbursement negotiations later. Still, overall sentiment from regulators has been positive. For example, Australia's TGA publicly stated that Orbis offered "an additional pathway for earlier access" and helped improve its own assessment knowledge base (ascopost.com).

- **Regulatory Science and Convergence:** Orbis is not formally a harmonization treaty (like ICH standards), but it is a de facto cooperative evaluation. It **demonstrates** how some convergence is possible: agencies form trust that shared meeting discussions won't undermine sovereignty. As Richard Pazdur notes, Orbis grew out of earlier multi-agency cluster calls that had the ethos "the purpose was not to achieve consensus, but to understand our differences" (www.fda.gov). Orbis extends that into a structured program where regulators actively align question sets. Many see this as a blueprint for future cross-border regulatory science. The Lancet Oncol editorial even suggests expanding Orbis (or similar pilots) to other therapeutic areas and including more countries to offset delays (e.g. as a buffer during crises like COVID-19) ([pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov)).

- **Limitations and Criticisms:** Project Orbis is not without constraints. A primary technical limitation is that **regulatory authorities retain independent standards**. They may disagree on evidentiary sufficiency, meaning a drug could get FDA approval under Orbis but still be rejected (or restricted) elsewhere. Indeed, one policy review noted that while Orbis was a promising framework, its *“framework...has not yet guaranteed that reviews in all jurisdictions result in simultaneous approvals”* ([ascopost.com](#)). For example, even with Orbis, scheduling and resource limits mean some partners defer decision until after FDA's, so they approve later. In practice, FDA often leads the timing, then others catch up a few months after.

Orbis covers regulatory review rather than reimbursement, pricing, supply, or measured patient outcomes. Those outcomes need separate evidence. FDA states that each partner retains independent decisions and timelines ([FDA FAQ](#)). The clinical-benefit estimates and their evaluable subset are discussed in the data-analysis section above.

Membership statements also need a verification date. Japan formally joined on 10 September 2026 ([MHLW](#)); the FDA's partner list was checked on 13 October 2026 ([FDA](#)).

- **Future Directions:** EMA's CHMP minutes of 8 September 2025 record information on EMA participation in FDA Project Orbis as an observer ([EMA minutes](#)). This observer role should be distinguished from a full partner role.

Possible improvements proposed here include clearer outcome reporting and better infrastructure for shared review. These are author proposals, rather than announced commitments by Belgium, Spain, MHRA, or ICMRA. Any expansion into other therapeutic areas would require a separately documented initiative.

Conclusion

Project Orbis provides a framework for concurrent submission and review of oncology products among international regulators ([FDA](#)). Its observed submission and review-time findings support continued evaluation of the collaborative process.

Each participating authority retains its own decision, labelling negotiations, and timeline ([FDA FAQ](#)). Earlier authorisation should therefore be distinguished from reimbursement, supply, actual launch, and measured patient outcomes. The case studies above show why concurrent review does not imply identical national approval dates.

Project Orbis illustrates the value of **international collaboration in regulatory science**. Pooling expertise and discussing applications can support national review without replacing national authority. Future assessments should measure both regulatory outcomes and the subsequent availability and use of therapies. Membership was verified against the FDA list on 13 October 2026; historical authorisation dates are identified separately in the case studies. References are supplied inline.

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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