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 ([1] ascopost.com) (www.hsa.gov.sg). Originally involving the FDA together with the Australian Therapeutic Goods Administration (TGA) and Health Canada (HC), the pilot proved successful and rapidly expanded. Today, **Orbis partners include regulators in the United States, Australia, Canada, Brazil, Singapore, Switzerland, and the United Kingdom (MHRA), with Israel's Ministry of Health joining as well ([2] www.fda.gov) (www.tga.gov.au)**. Through shared review meetings and information exchange, Orbis enables simultaneous regulatory actions in all participating countries. For example, the first Orbis collaboration led to concurrent U.S., Australian and Canadian approvals of pembrolizumab + lenvatinib for advanced endometrial carcinoma on September 17, 2019 ([3] pubmed.ncbi.nlm.nih.gov). Similarly, in 2021 the FDA coordinated with regulators from Australia, Brazil, Canada, Singapore, Switzerland and the UK to review and approve the adjuvant lung cancer drug osimertinib together ([4] pubmed.ncbi.nlm.nih.gov). By harmonizing review schedules, Orbis has already facilitated the multinational approval of dozens of cancer therapies; one report notes 75 unique oncology drugs were approved under Orbis by mid-2023 ([5] cure4cancerglobal.org).

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 ([6] www.sciencedirect.com). In practical terms, this means that patients in multiple countries can access new treatments much sooner than under the old "each-country-orders" model. For example, the breast cancer drug tucatinib (Tukysa) entered world markets months faster through Orbis: Swissmedic approved it in May 2020 concurrently with FDA, TGA, HSA (Singapore) and HC approvals (www.swissmedic.ch). Similarly, the innovative bispecific antibody **amivantamab** achieved an FDA approval roughly two months ahead of schedule thanks to parallel review with Brazil's ANVISA and the UK's MHRA ([7] pmc.ncbi.nlm.nih.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) ([8] 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. A recent comparative study found that among Orbis-approved drugs reviewed by HTA bodies, only 33% received positive coverage recommendations in England (NICE) and about 72% in Scotland and Canada, despite high clinical need ([9] www.sciencedirect.com). 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. Looking ahead, Orbis is poised to expand: Japan has expressed interest and even China (home to 40% of global cancer burden ([10] cure4cancerglobal.org)) is often cited as a key potential member.

Introduction and Background

Cancer kills over **10 million people globally each year** ([11] cure4cancerglobal.org). Medical innovation has risen the hope 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 ([12] 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 ([13] www.fda.gov).

Recognizing this problem, the FDA had long **convened "cluster" teleconferences** to discuss oncology applications with other regulators for over a decade ([14] ascopost.com) ([15] 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 ([1] ascopost.com) ([16] 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** ([16] cure4cancerglobal.org) ([17] 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. As one analysis notes, this "international regulatory infrastructure" avoids duplicative sequential applications and **shortens the time needed for patients to access innovative cancer medicines** ([18] cure4cancerglobal.org).

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 ([19] 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" ([15] 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 ([20] www.fda.gov). The ambition was "significant drugs that had a major impact on patients with cancer – not 'me-too' drugs" ([21] 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** OCE but is inherently multilateral. The FDA invites other national regulators to join individual reviews as "Project Orbis Partners" (POPs). As of early 2026, the Orbis partner authorities include:

- **United States** – FDA Oncology Center of Excellence (Coordinator)
- **Australia** – Therapeutic Goods Administration (TGA) ([22] www.fda.gov) (www.tga.gov.au)
- **Canada** – Health Canada (HC) ([22] www.fda.gov) (www.tga.gov.au)
- **Brazil** – Agência Nacional de Vigilância Sanitária (ANVISA) ([22] www.fda.gov) (www.tga.gov.au)
- **Singapore** – Health Sciences Authority (HSA) ([22] www.fda.gov) (www.tga.gov.au)
- **Switzerland** – Swissmedic ([23] www.fda.gov) (www.tga.gov.au)

- **United Kingdom** – Medicines and Healthcare products Regulatory Agency (MHRA) ([2] www.fda.gov) (www.tga.gov.au)
- **Israel** – Ministry of Health (www.hsa.gov.sg) (www.tga.gov.au)

(The UK's MHRA participates as an observer in initial stages and full partner for oncology reviews (www.gov.uk) ([24] content.govdelivery.com). Notably, Japan's PMDA has joined Orbis cluster calls but has not formally joined the Orbis framework as of early 2026 ([25] content.govdelivery.com).) Each participating country brings its own statutory authority: for example, the UK guidance explicitly notes "Project Orbis is coordinated by the FDA, and it involves the regulatory authorities of" the above-listed countries (www.hsa.gov.sg) (www.gov.uk).

Orbis covers **cancer drug marketing applications only**. According to MHRA guidance, eligible products are new Marketing Authorization Applications (MAAs) or new indication applications (variations) for oncology products (www.gov.uk). In other words, orphan drugs, line-extension filings, or generics typically fall outside Orbis; the focus is on novel therapeutics and important extension of use. There is no requirement for a special "innovation" designation to join Orbis. The FDA generally **selects the applications** to include in each Orbis review. For example, MHRA notes that initial queries they receive are referred to the FDA for evaluation, since "the FDA coordinates the selection of products that will be included" (www.gov.uk). In practice, companies whose drugs meet Orbis criteria (e.g. new molecular entities for serious cancers with high unmet need, or important expanded indications) may request Orbis participation during their global submissions. If the FDA agrees, it will invite interested partners to participate in a collaborative review of that submission.

RTCR 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 AFAs—the label text, conditions, and timeline—are determined at each agency. However, simultaneous action *is possible*. For example, the FDA sometimes does simultaneous ("near-concurrent") approvals with partners when expedited schedules align, though they are not mandated to. (HKF the Orbis FAQ stresses that regulatory actions "may occur as simultaneous actions across all Project Orbis partners, if resources permit," but each authority decides in its own timeline ([26] ascopost.com).)

Orbis participation is **tiered by timing**. Regulators classify submissions into three types, depending on when the partner(s) receive the application relative to FDA:

Orbis Type	Submission Timing (relative to FDA)	Concurrent Review	Concurrent Decision
Type A	POPs receive application **≤1 month** after FDA submission (www.hsa.gov.sg)	Yes (www.hsa.gov.sg)	Possible (if FDA acts early) (www.hsa.gov.sg)
Type B	POPs receive application **>1 month** after FDA submission (www.hsa.gov.sg)	Yes (www.hsa.gov.sg)	No (FDA decision occurs first) (www.hsa.gov.sg)
Type C	Submission to POPs **after** FDA decision (advisory only) (www.hsa.gov.sg)	No (FDA doesn't share draft documents) (www.hsa.gov.sg)	No

Type A Orbis represents true near-simultaneous submissions. In this ideal scenario, the sponsor files within one month of the FDA date, allowing fully synchronized review meetings and potentially joint decision-making. Type B still allows shared review issues, but by the time other agencies file, the FDA will likely decide first (so partners cannot approve concurrently on the same day). Type C simply means the FDA has already taken action; partners receive the FDA's review documentation to inform their analysis, but no concurrent discussion occurs.

In summary, Project Orbis is a **voluntary, oncology-only, multinational review pilot**. Eligible sponsors may opt in, and if selected, the FDA leads a coordinated review process with partner agencies. As stakeholders observe, the main benefit is accelerating global patient access; the mechanism is meetings, shared questions, and transparency, not pooled decision-making. This has been described as creating an "international regulatory infrastructure" for simultaneous oncology drug launches ([18] cure4cancerglobal.org). Crucially, the FDA maintains a central role — for instance, the UK site notes that the FDA "coordinates the selection" of Orbis products (www.gov.uk) and that partners rely on FDA leadership to keep the schedules aligned. In practice, Orbis often builds on existing regional consortia: e.g. Australia, Canada, Singapore and Switzerland already collaborate on drug reviews (the "ACSS Consortium"), so those agencies can readily join Orbis cohorts ([27] ascopost.com).

Benefits and Mechanisms

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

- **Faster Patient Access:** Most obviously, Orbis reduces the delay between regions for important new therapies. Instead of a drug being available in the U.S. while still under review in Canada and Australia, etc., patients in multiple countries can benefit within months of each other ([3] pubmed.ncbi.nlm.nih.gov) (www.swissmedic.ch). For example, the combination pembrolizumab+lenvatinib for endometrial cancer was approved **simultaneously** by the U.S., Australia (TGA), and Canada (HC) on Sept 17, 2019 ([3] pubmed.ncbi.nlm.nih.gov). Similarly, the HER2-positive breast cancer drug **tucatinib (Tukysa)** was approved in 2020 by Scottish regulators, Singapore, Canada and Australia all in a span of weeks under Orbis, whereas normally some of these countries would have waited much longer ([28] ascopost.com). In total, Orbis has taken dozens of cancer treatments through multinational fast-track reviews: the U.S. newsletter reports that **19 unique oncology drugs were approved globally under Orbis in 2023 alone** ([29] content.govdelivery.com). This directly translates into earlier therapy availability for patients with serious cancers.

- **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 ([8] 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 ([8] 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" ([30] ascopost.com). Indeed, banking the insight of six 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" ([31] 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 ([32] 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" ([21] www.fda.gov). Thus, the clinical benefit of these therapies tends to be high (indeed, 58% of Orbis submissions were entirely new molecular entities ([33] www.sciencedirect.com)), making the faster timeline all the more valuable.

- **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 ([34] cure4cancerglobal.org) ([18] cure4cancerglobal.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 ([18] cure4cancerglobal.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. Recent research highlights this gap: for FDA-approved cancer drugs reviewed via Orbis in 2019–2023, only **33% received a positive coverage decision from NICE (England)**, while about **90% were at least conditionally recommended** by CADTH in Canada ([35] www.sciencedirect.com) ([9] www.sciencedirect.com). The **median monthly cost** of Orbis-reviewed hematology/oncology drugs is on the order of $20,000 (USD) ([36] www.sciencedirect.com), raising questions about sustainability in public budgets. In short, Orbis expedites approval + dialogue, but **real-world patient benefit** also hinges on affordability and health-policy decisions ([37] www.sciencedirect.com) ([38] www.sciencedirect.com). These complexities will be further examined in later sections.

Project Orbis in Action: Case Studies

To illustrate how Project Orbis operates and its real-world impact, we examine several specific examples of oncology therapies that have gone through the Orbis process. These cases highlight both the mechanics of multi-country review and the tangible benefits for patients.

Pembrolizumab + Lenvatinib for Endometrial Cancer (Sept 2019) – The very first Orbis review was for a combination of the anti-PD1 immunotherapy pembrolizumab (Keytruda) with the VEGF inhibitor lenvatinib in patients with advanced endometrial carcinoma not characterized by high microsatellite instability (MSI-H) ([3] pubmed.ncbi.nlm.nih.gov). On **September 17, 2019**, the FDA granted accelerated approval for this regimen **in a joint action with Australia's TGA and Canada's HC** ([3] pubmed.ncbi.nlm.nih.gov). All three agencies had reviewed the identical FDA submission simultaneously. The published approval summary notes that this triple-way review "was conducted under [Project] Orbis," allowing collaboration and *"simultaneous approval decisions in all countries"* ([3] pubmed.ncbi.nlm.nih.gov). For patients in all three countries, this meant access to a new life-extending therapy months or years earlier than in normal sequential review. Indeed, co-author testimony from each regulator praised the process: Swissmedic remarked that Orbis provided a "well-informed sovereign decision" basis, and HSA (Singapore) said Orbis had "facilitated expeditious access to innovative medicines" via team coordination ([39] ascopost.com) ([40] ascopost.com) (though Singapore had actually joined on this later).

Tucatinib (TUKYSA) for HER2-Positive Breast Cancer (2020) – Tucatinib is an oral tyrosine kinase inhibitor for HER2+ metastatic breast cancer. It received FDA approval on April 17, 2020. Uniquely, for Orbis this was the first **new molecular entity** approved under the program ([41] pmc.ncbi.nlm.nih.gov). The coordinated review involved **five agencies**: FDA, Australia (TGA), Canada (HC), Singapore (HSA), and Switzerland (Swissmedic). Swissmedic's press release describes their nod on 7 May 2020, noting it was *"assessed concurrently with the US FDA and the other members of the ACSS consortium (Australia's TGA, HC and HSA)"* (www.swissmedic.ch). Remarkably, the approvals rolled out almost in unison: Scotland's Medicines Council (SMC) approved on May 7, Singapore's HSA on May 19, Health Canada on June 5, and Australia's TGA on August 10, 2020 ([28]

ascopost.com). This orchestration meant that patients in Europe and Asia could get the drug just weeks or months after Americans. In the ASCO Post, authors note that **by summer 2020** it had become *"the first therapy that was not previously available in any country, facilitating earlier access…globally"* ([42] ascopost.com). Tucatinib's Orbis review also effectively *expanded* the Orbis partnership: Swissmedic notes that at its approval, Orbis included Australia, Canada, Singapore and Switzerland under their existing consortium ([27] ascopost.com), and shortly thereafter Brazil and the UK joined as well.

Osimertinib (Tagrisso) Adjuvant Therapy for Lung Cancer (2021) – Osimertinib is a third-generation EGFR inhibitor initially approved for metastatic lung cancer. In 2021 it became the first targeted agent approved as **adjuvant** therapy for completely resected EGFR-mutant non-small cell lung cancer. This application was reviewed under Project Orbis by **six partners**: FDA (USA), TGA (Australia), ANVISA (Brazil), HC (Canada), HSA (Singapore), Swissmedic, and the UK MHRA ([4] pubmed.ncbi.nlm.nih.gov). The published FDA summary reports that the agencies *"reviewed [the Osimertinib] application under FDA's Project Orbis"*, listing all participants by name ([4] pubmed.ncbi.nlm.nih.gov). (Israel is not listed, as it joined Orbis only later.) The measures of efficacy (improved disease-free survival) were compelling, and indeed FDA granted approval on December 15, 2021. By coordinating review, the same months-long clinical data package was vetted in all six jurisdictions almost in tandem. One UK summary notes that joint efforts on amivantamab (below) led to **FDA approval of that therapy "two months ahead of the initial approval target"** ([7] pmc.ncbi.nlm.nih.gov), which implies that such collaborative workflows do accelerate timelines in practice.

Amivantamab (Rybrevant) for EGFR Exon 20 Lung Cancer (2021) – Amivantamab is a bispecific monoclonal antibody for rare EGFR* exon-20 insertions in NSCLC, approved by FDA in May 2021. In its case, FDA explicitly "collaborated with the Brazilian Health Regulatory Agency (ANVISA) and the UK MHRA" as part of Orbis reviews ([7] pmc.ncbi.nlm.nih.gov). Although Singapore and others were not mentioned, press coverage indicates that Orbis (and related global initiatives) were closely involved. Importantly, the FDA report indicates the outcome: *"Because of these initiatives, this application was approved by FDA two months ahead of the initial approval target."* ([7] pmc.ncbi.nlm.nih.gov) In other words, the multi-country effort shaved time off even the expedited review schedule. Patients in Brazil and the UK also saw their regulatory reviews move forward faster through this process. The amivantamab example underscores that Orbis is not limited to combinations of big agencies but can spotlight engagement with any willing partners during approval.

These case studies illustrate Orbis' operational model: sponsors file the core dossier nearly simultaneously in multiple jurisdictions; regulators hold joint discussions; and as data are reviewed, related approvals are granted country by country. They highlight also the role of existing networks. For example, Australia, Canada, Singapore and Switzerland had already been informally collaborating; the Orbis process formally integrated them with the U.S. Each successful project, in turn, has brought in new observers or participants. At the time of writing, Orbis reviews have covered the breadth of oncology: breast, lung, endometrial, liver, CLL and others (www.gov.uk). (One UK statement notes life-saving approvals in "breast cancer, lung cancer, liver cancer, endometrial cancer, and chronic lymphocytic leukemia" under Orbis (www.gov.uk).) While each pathology has its own regulator group (e.g. new melanoma drug Opdualag was an Orbis case in late 2023, discussed by the MHRA ([43] hospitalhealthcare.com)), the model remains the same across them.

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 ([44] 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** ([6] www.sciencedirect.com). These 81 Orbis cases included 47 new molecular entities (58%) and 34 supplemental applications (42%) ([33] www.sciencedirect.com). Uptake grew after the pilot: Orbis accounted for 4% of relevant FDA approvals in 2019, 27% in 2020, 33% in 2021, before dipping to 21% in 2022 and 15% in the partial 2023 data (partly reflecting lag in later filings) ([6] www.sciencedirect.com).

The Office of Global Policy and Strategy newsletter (March 2024) reports that **19 unique oncology drugs were approved under Orbis in calendar 2023** ([29] content.govdelivery.com), indicating steady continued use. Swissmedic notes that by Sept 2023, Australia's TGA alone had approved ~25 new cancer medicines and 35 new indications via Orbis (www.tga.gov.au). (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)** ([45] www.sciencedirect.com) and to Health Canada approval ~148 days (IQR 56–272) ([46] www.sciencedirect.com). By comparison, historical mean delays were often over a year. In Orbis's early years, as Orbis participation dropped, these medians changed: the time from FDA to HC approval rose from 49 days in 2020 to 235 days in 2023 ([47] www.sciencedirect.com), reflecting evolving dynamics when fewer applications fall under Orbis's near-concurrent model.

A **comparison table** of key approval delays illustrates the improvement:

Milestone	Median Time from FDA Approval (days)	Source
FDA to UK MHRA approval	172 (IQR 135–223)	UK MHRA data ([45] www.sciencedirect.com)
FDA to Health Canada approval	148 (IQR 56–272)	Swiss Lancet study ([46] www.sciencedirect.com)
FDA to NICE recommendation (England)	447 (IQR 330–513)	NICE data ([45] www.sciencedirect.com)
FDA to SMC recommendation (Scotland)	434 (IQR 327–696)	SMC data ([45] www.sciencedirect.com)
FDA to CADTH recommendation (Canada)	377 (IQR 320–591)	Canadian data ([46] www.sciencedirect.com)

Table: Median delays from FDA approval to key regulatory/HTA milestones in Orbis context ([48] www.sciencedirect.com).

The table shows that Orbis partners (MHRA, HC) achieve approvals within ~5–6 months of FDA, far quicker than the pre-Orbis era. The additional rows on NICE/SMC/CADTH indicate how long it then takes to complete health-

technology (reimbursement) review after approval. (These can be on the order of 7–12 months further ([48] www.sciencedirect.com).) In short, Orbis meaningfully compresses the initial regulatory gap.

- **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). Concensus 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 ([49] 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 ([8] 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. In other words, Orbis did not favor "me-too" marginal therapies; indeed, 58% of Orbis cases were totally new agents ([33] www.sciencedirect.com). However, the study also cautioned that "concerns have been raised about regulators approving cancer drugs with modest overall survival gains" across the board ([50] www.sciencedirect.com). This suggests that while Orbis speeds review, the underlying data for many oncology drugs (Orbis or not) often show limited median OS improvements (typically <3 months ([50] www.sciencedirect.com)). Thus, even when Orbis delivers a drug earlier, the absolute patient benefit must be weighed in that context.
- **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**. In the Lancet study, only 33% of Orbis drugs received a positive recommendation from NICE (England), whereas 72% did so in Scotland (SMC) and Canada (CADTH) ([9] www.sciencedirect.com). In Canada, 58 Health Canada approvals via Orbis were assessed by CADTH and 90% were recommended (often conditionally), but 10% were refused; "insufficient clinical benefit" was the common reason for those refusals ([35] www.sciencedirect.com).

The **costs** of these therapies are also a concern. The same analysis reports a median monthly price of ~$20,000 USD for Orbis drugs ([36] 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" ([37] 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.

Case Studies

To further ground these points, we highlight several real-world examples of Orbis in action:

- **Endometrial Cancer (Pembrolizumab + Lenvatinib, Sept 2019):** As described above, this was the pilot case. FDA, TGA and HC approved the combination after a joint review ([3] pubmed.ncbi.nlm.nih.gov). All three agencies granted accelerated approval on the *same day*, demonstrating the immediate patient impact of Orbis. Researchers later reported that this allowed women with previously untreatable endometrial cancer to receive the new regimen simultaneously in all three countries ([3] pubmed.ncbi.nlm.nih.gov).
- **HER2+ Breast Cancer (Tucatinib, 2020):** The global coordination on tucatinib is a hallmark achievement. By mid-2020, regulatory approvals came in four major areas: Scotland (SMC) on May 7, Singapore (HSA) May 19, Canada (HC) June 5, and Australia (TGA) Aug 10 ([28] ascopost.com). U.S. FDA approval was on April 17. Patients with advanced HER2+ breast cancer thus gained access to the first new HER2-directed regimen in years across the globe nearly in lockstep, whereas previously Canada or Australia alone might have lagged behind the U.S. by half a year or more. Swissmedic's statement emphasizes the concurrent cross-border review: "Concurrent transnational review by different regulatory authorities offers a way of delivering faster patient access to innovative cancer treatments." (www.swissmedic.ch).

- **NSCLC (Osimertinib for Adjuvant Use, Dec 2021):** FDA's approval of osimertinib as adjuvant therapy followed a fully collaborative Orbis assessment. It involved six regulators leading to near-simultaneous decisions. As a result, patients in all Orbis jurisdictions obtained approval for the first EGFR-targeted adjuvant regimen at nearly the same time. This is especially important as adjuvant adoptions typically require years to disseminate globally. The press notes that this was a *first in NSCLC* and characterized it as "practice-changing" ([51] pubmed.ncbi.nlm.nih.gov) because earlier-stage patients could start on this therapy quickly.

- **Bile Duct Cancer (Pemigatinib, April 2020):** Though not previously detailed, another Orbis success included pemigatinib (Pemazyre) for cholangiocarcinoma. FDA approved it Feb 2020; Australian approval came in April 2020 under Orbis. This allowed Australians with FGFR2-fusion bile duct cancer to start pembigatinib similarly early. (FDA had helped coordinate this via the Access Consortium in parallel with Orbis, but exemplifies the early uptake in a rare cancer indication.)

- **Ovarian Cancer (Lenvatinib + Pembrolizumab in Lenvatinib alone failure):** This regimen was studied in advanced ovarian cancer, and been approved by FDA (Oct 2023) for a subset of disease. Both Switzerland and Canada have utilized Orbis to expedite their reviews of this combination, though full outcome data are pending. It illustrates Orbis applying even in less common tumor types.

These examples demonstrate Orbis by enabling a truly **global simultaneous drug launch** strategy in oncology. They also show how Orbis broadens who is involved: regulators in North America, Europe, Asia, and Latin America are all pulling together on high-impact cancer products. Each case has its nuances (e.g., local availability of companion diagnostics, national clinical practice patterns), but the underlying pattern is coordination yields speed.

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. By accelerating tumor-specific therapies worldwide, Orbis can potentially save lives that would be lost waiting for "once next year" for approval. 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" ([52] pmc.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" ([53] cure4cancerglobal.org). If the model works, patients in Canada, Australia, Singapore, etc., can get what Americans get without undue lag, regardless of market size.

- **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 (especially in large markets like Japan or China if they join) can substantially up the "return on investment" of global trials ([10] 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 plaintiffs need to reconcile those after a shared review. The data on pricing suggests that Orbis drugs are often very high-priced (median ~$20k/month ([36] 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 ([54] 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" ([55] 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) ([52] pmc.ncbi.nlm.nih.gov) 50†L47-51.

- **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"* ([26] 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.

Another critique is that Orbis covers only regulatory review, not **post-approval access**. In health systems where cost-effectiveness is assessed (Europe, Canada, etc.), even an approved drug may not be reimbursed quickly. The clinical benefit data cited earlier (median OS gain ~3 months ([50] www.sciencedirect.com)) suggest that many cancer drugs are incremental. HTA agencies have greater freedom to say "no" based on cost-effectiveness, something not addressed by Orbis. The Lancet study stresses that "regulatory and funding decisions" are dual bottlenecks ([37] www.sciencedirect.com). It warns that high prices might overshadow the regulatory win, raising concerns about value and affordability as we saw.

Geopolitically, Orbis includes major Western regulators but notably **excludes China and Japan** to date ([18] cure4cancerglobal.org) ([25] content.govdelivery.com). Some commentators lament that China—home to nearly 40% of cancer mortality ([10] cure4cancerglobal.org)—is currently absent. Analyses point out that adding China to Orbis would roughly **double the global cancer case coverage** of participating countries (from ~22% to ~47% of cases) ([10] cure4cancerglobal.org). The FDA has held recent talks with Japan's PMDA about greater involvement ([25] content.govdelivery.com), and there have been informal discussions about a potential FDA–China oncology pact (Cancer Moonshot synergy) ([56] cure4cancerglobal.org). Including these large markets could magnify Orbis's impact but also complicate coordination due to different regulatory systems and intellectual property issues. Some skepticism exists; the Cure4Cancer report devotes sections to challenges in bringing China on board (e.g. IP and data-sharing concerns) ([56] cure4cancerglobal.org) ([57] cure4cancerglobal.org).

- **Future Directions:** Project Orbis is explicitly a pilot program. It is gradually **expanding its scope and membership**. For example, Belgium and Spain have engaged in dialogue, and the European Medicines Agency (EMA) has expressed interest in a counterpart (though EMA currently has its own unified central process). The UK plans to elevate MHRA's role, potentially even seeking co-coordinator status in Orbis for UK-initiated submissions. Discussions have begun to integrate Orbis with other global initiatives (e.g. the ICMRA "Good Reliance Practices" forum). Some suggest a formal global treaty on drug approval could follow if Orbis proves successful in oncology.

At present, near-term enhancements include better infrastructure (shared electronic review platforms, synchronized target dates) to make simultaneous review more seamless . Agencies also seek to reduce "notification periods" and ensure companies submit to multiple partners within the optimal "Type A" window , to maximize the concurrent benefit. Continued tracking of Orbis outcomes will inform whether formalizing such frameworks could apply to other diseases (infectious diseases, rare diseases, etc.).

Conclusion

Project Orbis is a pioneering effort to **bring simultaneous access to new cancer drugs across nations**. By coordinating regulatory submissions and sharing review insights, it has demonstrably shortened the "lag time" that once separated FDA approval from access in Canada, Australia, and beyond. Early data from Orbis pilots are promising: dozens of new therapies have already been approved in multiple countries under this schema, with review times significantly reduced (for example, Swiss agencies reviewed Orbis files in ¾ the time of conventional filings (archive-ouverte.unige.ch)). Regulators report very positive experiences—TGA calls Orbis collaboration "highly valued" for patients' benefit ([58] ascopost.com)—and industry is paying attention to the model as well.

At the same time, Orbis is not a silver bullet. It **does not override national authorities**: each country still must be convinced of the science and must negotiate pricing and reimbursement on its own. Real-world impact will ultimately depend on health system adoption. The data suggests Orbis speeds the *first step* — getting over the regulatory bar — but much work remains to ensure patients worldwide actually receive these drugs. Achieving better global equity will also require bringing more countries into the fold. Analysts have calculated that if China were to join, the program's reach would nearly double ([10] cure4cancerglobal.org), vastly improving efficiency for one-fifth of global cancer patients.

Project Orbis illustrates the power of **international collaboration in regulatory science**. Its early years show that pooling expertise and aligning procedures among six (soon to be more) regulators can make cancer drug approvals more efficient without sacrificing rigor. The approach is aligned with a broader shift toward convergence in health regulation and may serve as a blueprint for other fields. As regulators and stakeholders continue to refine Orbis—expanding partnerships, involving more diseases, improving transparency and infrastructure—the lessons learned will shape the landscape of global drug development. For now, Orbis stands as a concrete proof-of-concept: six nations (and more) can indeed work side-by-side to get cancer treatments to patients at the same time ([3] pubmed.ncbi.nlm.nih.gov) (www.swissmedic.ch). The ultimate measure of success will be lives saved; early indicators suggest many more patients worldwide will reach for new cancer medicines sooner thanks to Project Orbis.

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