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Project Orbis Impact: Analysis of Cancer Drug Review Times

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Executive Summary

Project Orbis is a global regulatory initiative launched by the FDA's Oncology Center of Excellence in 2019 to enable **concurrent submission and review** of high-impact oncology drug applications by multiple regulatory authorities. Since its inception, Orbis has rapidly grown: by mid-2025 it encompassed **633 regulatory submissions covering 79 distinct oncology products** across partner agencies (www.fda.gov). Analyses of Orbis-related approvals indicate that collaborative review can dramatically **shorten review timelines** at participating agencies. For example, a Swissmedic study found the *median* time from FDA submission to Swissmedic submission ("submission gap") dropped from 168 days (pre-Orbis) to **33 days** with Orbis, and Swissmedic review time fell from 314 days to **235.5 days** (www.sciencedirect.com) – a reduction of roughly 79 days (≈2.6 months). Similarly, an Australian review of the programme reported a median time to approval of **4.4 months** across Orbis partner agencies (a pooled figure, not an Australia-specific median), against **4.2 months** at the FDA (pmc.ncbi.nlm.nih.gov). Notable case studies underscore these accelerations: for instance, a lung cancer drug (osimertinib/Tagrisso) received UK approval just **4 months** after the UK joined Orbis (www.gov.uk); and a combination therapy (lenvatinib+pembrolizumab for a restricted population of advanced endometrial cancer) received **near-concurrent** expedited approvals from the FDA and Australia (17 September 2019) and Health Canada (20 September 2019) in the first Orbis review (www.canada.ca) (pmc.ncbi.nlm.nih.gov).

However, analysis of broader outcomes reveals a complex picture. A recent Lancet Oncology study found that **33%** of new FDA oncology drugs (2019–2023) went through Orbis (pubmed.ncbi.nlm.nih.gov), but noted that faster regulatory approval did **not always translate to faster patient access**. Post-approval delays in reimbursement (e.g. at NICE or CADTH) have occurred, highlighting ongoing challenges even after regulatory approval (pubmed.ncbi.nlm.nih.gov) (thelimbic.com). Nonetheless, the one controlled comparison published so

far (Swissmedic, 2020–2021) found **statistically significantly shorter submission gaps and review times** for Orbis applications, and other partners report fast Orbis decisions, although evidence from other jurisdictions is observational and mixed. This report compiles available data and case studies (“Project Orbis by the Numbers”) to quantify exactly *which* cancer drugs were approved faster under Orbis and *by how much* compared to conventional pathways, while discussing the broader context, challenges, and future implications.

Introduction and Background

Regulatory Approval Delays and the Need for Orbis

Historically, new cancer therapies have often been first filed and approved in the United States (FDA) before submission elsewhere. Other regulators (Canada, Australia, Europe, etc.) typically experience considerable *lag times* – sometimes many months or even years – before receiving the data for review, admittedly delaying patient access in those countries. For example, R&D surveys have long noted that the FDA’s first review pathway averaged shorter times than many counterparts (www.fda.gov). In recognition of this, and following decades of international coordination (e.g. “cluster calls” between FDA, EMA, Health Canada, TGA, etc.), the FDA’s Oncology Center of Excellence (OCE) launched **Project Orbis** in May 2019 to accelerate global oncology approvals (www.fda.gov) (www.fda.gov). Orbis allows manufacturers to submit a single oncology application concurrently to multiple regulatory agencies. The agencies then coordinate through joint review meetings, share information, and strive to make independent decisions approximately together, thereby reducing the usual submission delays and duplicative review efforts. Crucially, each authority retains its independent decision-making and legal timelines – Orbis facilitates parallel work, not merging decision power.

Project Orbis expansion has been rapid. It **began in May 2019** with the FDA, Australia’s TGA, and Health Canada, and quickly grew to include additional countries (www.fda.gov). Singapore and Switzerland joined in December 2019, Brazil (ANVISA) in May 2020, the UK’s MHRA in January 2021, and Israel’s Ministry of Health in July 2021 (www.fda.gov). As of the FDA’s current partner list, Project Orbis comprises the FDA plus **eight partner agencies**: Australia’s TGA, Brazil’s ANVISA, Health Canada, Israel’s Ministry of Health, Japan’s PMDA, Singapore’s HSA, Swissmedic and the UK’s MHRA (www.fda.gov) (www.canada.ca) (www.fda.gov). Because of its participant-specific framework, even non-project countries benefit indirectly: regulators use each other’s reviews, and sponsors often align global filings to Orbis schedules.

Table 1: **Orbis Participants and Milestones.** (Orbis partner agencies, join dates, and early approvals.)

Agency (Country)	Joinder to Orbis	Early Orbis Approval Examples
FDA (USA)	Launched program (May 2019)	Lenvatinib + pembrolizumab (advanced endometrial CA, not MSI-H/dMMR) – accelerated approval 9/17/2019 (www.canada.ca)
Health Canada	May 2019	<i>Lenvatinib + pembrolizumab</i> (endometrial CA) – 20 Sep 2019 (www.canada.ca) <i>Acalabrutinib</i> (CLL) – 21 Nov 2019 (www.canada.ca)
TGA (Australia)	May 2019	<i>Lenvatinib + pembrolizumab</i> – 17 Sep 2019 (concurrent; provisional approval pathway) (pmc.ncbi.nlm.nih.gov)
HSA (Singapore)	Dec 2019	(Participated from 12/2019, approvals data in panel stages)

Agency (Country)	Joinder to Orbis	Early Orbis Approval Examples
Swissmedic (Switzerland)	Dec 2019	Orbis applications 2020–21: median review time 235.5 d vs 314 d for contemporaneous non-Orbis applications (www.sciencedirect.com)
ANVISA (Brazil)	May 2020	(Collaborations beginning 2020; specific items pending publication)
MHRA (UK)	Jan 2021	<i>Osimertinib</i> (Tagrisso, adjuvant NSCLC) – May 2021 (< 4 mo after joining) (www.gov.uk)
Israel MoH	Jul 2021	(Joined mid-2021; approvals under joint review underway)

Each new partner afforded additional regional patients earlier potential access. As Dr. Richard Pazdur (FDA OCE Director) emphasized, Project Orbis addressed the problem that “important drug applications were filed first in the United States. The smaller authorities... would experience a lag... sometimes the agencies never received [them]. We asked sponsors to submit applications to other countries as closely as possible to the FDA submission” (www.fda.gov). This cooperative strategy has indeed borne out: as of mid-2025, FDA’s OCE reported **633 Orbis regulatory submissions covering 79 unique oncology products** (www.fda.gov). In the first year alone (mid-2019 to 2020) **60 applications** were handled jointly, yielding **38 approvals** (pmc.ncbi.nlm.nih.gov). In the broader frame (2019–2023), fully one-third of new FDA cancer drug approvals were Orbis-reviewed (pubmed.ncbi.nlm.nih.gov).

Thus the “numbers” behind Project Orbis are large and growing. This report will analyze those numbers in depth, focusing particularly on how much faster Orbis-reviewed therapies reached decision compared to conventional pathways.

Project Orbis Process

Project Orbis submissions come in three types based on timing:

- **Type A** (“Regular Orbis”) – Applications submitted to participating regulators *within 30 days* of the FDA submission. These undergo near-concurrent review and allow concurrent regulatory actions (if possible) (www.hsa.gov.sg).
- **Type B** (“Modified Orbis”) – Submission to partners is more than 30 days after FDA. Partners may conduct concurrent review but will delay final decisions (i.e. “no concurrent action”) (www.hsa.gov.sg).
- **Type C** – FDA review is substantially complete or FDA has already acted. The FDA shares review documents for a reliance assessment by partners; there is no concurrent review or action (www.hsa.gov.sg).

The key feature is **information sharing**. Orbis partners hold joint product discussions, share queries and data responses, and often attend each other’s review meetings (www.hsa.gov.sg) (www.fda.gov). However, *each agency remains legally independent* and follows its own internal review procedures. For example, an Orbis submission still goes through the FDA’s Priority Review process (target 6 months) and, say, Australia’s Priority or Provisional pathway simultaneously (pmc.ncbi.nlm.nih.gov).

By design, Orbis focuses on “high-impact” cancer products – typically new molecular entities or major new indications that carry significant clinical benefit ([pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov)). The intention is to prioritize “practice-changing” therapies, not every incremental oncology drug. Nevertheless, to date dozens of distinct molecules (and combinations) have been submitted under Orbis. Some notable therapeutic classes include: targeted kinase inhibitors (e.g. **acalabrutinib**, **riporetinib**, **tucatinib**), immunotherapies and combinations (e.g. **ipilimumab + nivolumab** for liver cancer, **pembrolizumab + lenvatinib** for endometrial cancer), and other solid tumor agents (e.g. **osimertinib** for lung cancer) (www.canada.ca) ([pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov)) (www.gov.uk).

Quantitative Impact: How Much Faster?

Study of ORBIS vs Conventional Review Times

One way to gauge Orbis's effect is to compare **actual review timelines** for identical or similar applications with and without Orbis. A comparative analysis by Zosso-Pavic et al. (Lancet Oncology, 2024) looked at oncology marketing authorisation applications submitted to Swissmedic in 2020–2021, with decisions up to June 2022. Among 72 oncology applications during that period, 31 were Orbis-project applications and 41 were non-Orbis (www.sciencedirect.com). The results were striking (Table 2):

- **Submission Gap:** For Orbis cases, the *median* gap between the FDA filing date and the Swissmedic filing date was **33.0 days** (95% CI 19–57). By contrast, non-Orbis applications saw a median gap of **168.0 days** (95% CI 56–351). That is a **135-day (4.5 month) reduction** in initial submission delay (www.sciencedirect.com).
- **Review Time:** Swissmedic's median review time (submission to decision) was shorter for Orbis applications: **235.5 days** (≈7.8 months) versus **314.0 days** (≈10.3 months) for non-Orbis. This **≈78.5-day (2.6 month) difference** was statistically significant ($p=0.0002$) (www.sciencedirect.com).
- **Overall Access:** Although approval rates (proportion approved) were similar between Orbis and non-Orbis at Swissmedic, the shorter timelines meant Swissmedic decisions on Orbis applications came **months earlier** relative to FDA submission; the study did not measure actual patient access, which also depends on reimbursement (www.sciencedirect.com) (www.sciencedirect.com).

The Swiss study thus provides hard numbers for that jurisdiction: Orbis applications were associated with markedly shorter submission gaps and review times. As the authors noted, “submission gap and review time for oncology applications at Swissmedic were significantly reduced by participation in Project Orbis,” implying “faster patient access” (www.sciencedirect.com) (www.sciencedirect.com).

Similar findings emerge elsewhere. An Australian review of regulatory reforms (Yoffe et al., Therapeutic Innovation & Regulatory Science, 2022) listed Project Orbis cases handled by the Therapeutic Goods Administration (TGA). By end of 2020, multiple applications had been processed: e.g. **lenvatinib + pembrolizumab** (advanced endometrial CA) in 54 working days (provisional approval pathway), **acalabrutinib** in 35 working days, **nivolumab+ipilimumab** in 68 days, **riporetinib** in 123 days, and **tucatinib** in 113 days ([pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov)). For context, TGA's priority review pathway targets 150 working days, while 255 working days is the legislated limit for standard evaluations; these Orbis cases were completed well inside those clocks. The paper summarized: “evaluations via Project Orbis have been completed within very

impressive timeframes, median time to approval by FDA was 4.2 months and by Orbis partners 4.4 months” ([pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov)) The 4.4-month figure is pooled across partner agencies, and comparing it with a review-time goal shows performance against a target, not a measured saving relative to non-Orbis reviews.

Synthesizing these data yields the following pattern: **Orbis submission windows allow near-concurrent filings**, so partner agencies start later than FDA by only weeks rather than many months. In the one controlled comparison (Switzerland), review itself was also about 2.6 months shorter; elsewhere, comparable non-Orbis cohorts have not been published, so savings cannot be generalised. Table 3 illustrates key median timeline differences:

Agency (Process)	Orbis Review (median)	Conventional/Target	Time Saved	Source
Swissmedic (Oncology)	Submission gap: 33 days Review time: 235.5 days	168 days 314 days	–135 days –78 days (www.sciencedirect.com)	Swissmedic analysis (Zosso-Pavic et al., 2024)
FDA (Priority Review)	4.2 months (≈126 days)	~6 months (≈180 days) priority goal	≈54 days inside the goal, not a measured saving (pmc.ncbi.nlm.nih.gov)	Yoffe et al., 2022 (Australia)
Orbis partners (pooled) *	4.4 months (≈132 days)	No pooled non-Orbis comparator reported	Not estimable (pmc.ncbi.nlm.nih.gov)	Yoffe et al., 2022 (Australia)

**Yoffe et al. report 4.4 months as a median across Orbis partner agencies, not a TGA-specific figure. The FDA comparison is against its 6-month priority review goal.*

Thus **by how much faster?** The only controlled estimate comes from Switzerland: Orbis submissions were filed **4.5 months earlier** than otherwise, and review durations were **2.5 months shorter** (www.sciencedirect.com). For Orbis partners overall, Yoffe et al. report a pooled median of 4.4 months to approval ([pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov)). At the FDA, the corresponding median was about 4.2 months, inside its 6-month priority review goal.

It bears emphasizing that **“time saved” depends on context**. For Type A (fully concurrent submissions) the saving is greatest. The Swiss analysis reports a median submission gap of 33 days for Orbis applications, but this does not establish how many were Type A. For Type B or C (staggered submissions), time gains accrue more modestly (as Type B still allows concurrent review, albeit without synchronized decisions). Nevertheless, even in Type B cases the sharing of FDA review materials usually accelerates partner assessments relative to standalone review.

Lastly, some broad stats from FDA's OCE itself underscore the program's scale: as of summer 2025, “633 applications for 79 products” had been reviewed under Orbis (www.fda.gov). Given those figures, Statistics on overall Orbis throughput are:

- **Applications (2019–mid-2025):** 633 total

- **Unique products:** 79 (FDA, mid-2025). Separately, Jenei et al. found that 81 of 244 (33%) FDA cancer drug approvals between May 2019 and November 2023 were reviewed through Orbis; the two figures use different units and periods (pubmed.ncbi.nlm.nih.gov)
- **Partners:** 8 partner agencies besides the FDA on the FDA's current list (www.fda.gov) (www.fda.gov)

These applications include major therapies in breast, lung, blood, and other cancers. Together, they represent a substantial fraction of cutting-edge oncology approvals. The Orbis process has thus engaged hundreds of applications and dozens of life-saving therapies, delivering measurable shortening of review schedules as shown above.

Selected Case Studies

Beyond medians, specific drug examples illustrate the Orbis acceleration ("which drugs got through faster"). We highlight several illustrative cases:

- **Pembrolizumab + Lenvatinib (Keytruda + Lenvima)** – *Indication:* Advanced endometrial carcinoma after progression (post-platinum). *Impact of Orbis:* This combination was the very first Orbis case. FDA and TGA approved it on September 17, 2019 and Health Canada on September 20, 2019 after a joint review, each under an expedited, confirmatory-evidence pathway (FDA accelerated approval, TGA provisional approval, Health Canada conditional authorization) for patients whose tumours are not MSI-H/dMMR and who progressed after prior systemic therapy (www.canada.ca). Health Canada's press release notes the therapy was authorized on September 20, 2019, "the first review conducted under Project Orbis," enabling Canadian patients to access it at the same time as the US and Australia (www.canada.ca). (Without Orbis, Health Canada's own review would likely have started months later.)
- **Osimertinib (Tagrisso)** – *Indication:* Adjuvant treatment for EGFR-mutant non-small-cell lung cancer post-surgery. *Orbis Role:* After the FDA approved adjuvant osimertinib in Dec 2020, the UK's MHRA (new Orbis partner as of Jan 2021) issued its first Orbis authorization four months later, in May 2021 (www.gov.uk). MHRA itself notes this was "only four months after the agency joined the scheme" (www.gov.uk). Thus, UK patients gained access with minimal delay attributable to global coordination.
- **Acalabrutinib (Calquence)** – *Indication:* Chronic lymphocytic leukemia (CLL). *Orbis Impact:* As above, Health Canada, FDA, and TGA reviewed this simultaneously. Canada authorized acalabrutinib on Nov 21, 2019 after an Orbis review (www.canada.ca). In Australia, the acalabrutinib CLL application was approved in 35 TGA working days under Orbis ([pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov)), far shorter than typical timelines. (By contrast, in 2019 the EU/EMA had still not finalized its assessment of this indication.)
- **Ipilimumab + Nivolumab (Yervoy + Opdivo)** – *Indication:* Hepatocellular carcinoma (HCC) previously treated with sorafenib (FDA accelerated approval, March 2020); first-line HCC approval came only on April 11, 2025, itself reviewed under Orbis (www.fda.gov). *Orbis Impact:* Yoffe et al. list a nivolumab/ipilimumab Orbis approval in Australia in 68 working days, without specifying the indication ([pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov)).

- **Ripretinib (QINLOCK)** – *Indication:* Fourth-line gastrointestinal stromal tumor (GIST). *Orbis Impact:* FDA approval came May 15, 2020. The TGA granted approval under Priority Review in 123 working days ([pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov)). Switzerland, by contrast, first authorised Qinlock on 7 October 2021 under Article 13 of its Therapeutic Products Act, relying on a foreign reference authority's assessment rather than a concurrent Orbis approval (www.swissmedic.ch).
- **Tucatinib (TUKYSA)** – *Indication:* HER2-positive metastatic breast cancer (with trastuzumab + capecitabine). *Orbis Impact:* After FDA approval in April 2020, Switzerland first authorised Tukysa on 7 May 2020 (www.swissmedic.ch), and Australia finalized approval in 113 working days under Orbis ([pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov)).

Table 4 lists these and other representative drugs, along with their approximate Orbis-driven review timelines:

Drug (Brand)	Indication	Regulators	Orbis Timeline	Notes
Osimertinib (Tagrisso)	Adjuvant EGFR+ NSCLC lung cancer	FDA + MHRA (UK)	UK approval ~May 2021 (~4 months after MHRA joined Orbis (www.gov.uk))	First MHRA Orbis approval; early-stage lung cancer.
Pembrolizumab + Lenvatinib	Advanced endometrial carcinoma (not MSI-H/dMMR, after prior therapy)	FDA + HC (Canada) + TGA	Near-concurrent expedited approvals 17 Sep (FDA, TGA) and 20 Sep 2019 (HC) (www.canada.ca) (pmc.ncbi.nlm.nih.gov)	First Orbis case; joint FDA-HC-TGA review.
Acalabrutinib (Calquence)	CLL	FDA + HC + TGA	HC authorization 21 Nov 2019 (www.canada.ca); TGA approval in 35 working days (pmc.ncbi.nlm.nih.gov)	Second Orbis review; CLL indication
Ipilimumab + Nivolumab (Y/O)	HCC after sorafenib (FDA, 2020)	FDA + TGA	FDA Mar 2020; TGA 68 working days, indication not specified by source (pmc.ncbi.nlm.nih.gov)	First-line HCC approved by FDA only in April 2025.
Ripretinib (Qinlock)	Fourth-line GIST	FDA + TGA	FDA May 2020; TGA 123 working days (pmc.ncbi.nlm.nih.gov)	Swissmedic authorised it in October 2021 under Article 13, not via a concurrent Orbis approval.
Tucatinib (Tukysa)	HER2+ metastatic breast cancer	FDA + TGA + Swissmedic	FDA Apr 2020; TGA 113 working days (pmc.ncbi.nlm.nih.gov)	Swissmedic first authorised it on 7 May 2020.

Each entry above reflects an internationally coordinated review. Partner timing varied widely, from within weeks of the FDA decision to well over a year (riporetinib in Switzerland). By contrast, traditional staggered filings might have delayed partner approvals by many more months. For example, contemporaneous non-Orbis oncology applications reached Swissmedic a median **168 days after FDA** submission (www.fda.gov); under Orbis that gap shrank to just over a month (www.sciencedirect.com).

Statistical Summary of Orbis Timelines

Combining all available data, we can make the following observations about Orbis-driven timings (“**by how much faster**”):

- **Submission gap reduction:** The typical FDA-to-partner submission delay shrinks from several months to just weeks in Orbis. Swissmedic saw the median gap fall from 168 days to 33 days (www.sciencedirect.com). For Health Canada, Orbis applications are filed close to the FDA submission rather than after the multi-month lags FDA describes for the pre-Orbis era (www.fda.gov) (www.canada.ca).
- **Review time reduction:** Swissmedic’s median review time was 78.5 days (~25%) shorter for Orbis applications (www.sciencedirect.com); for partners overall only a pooled 4.4-month median to approval is reported, with no non-Orbis comparator (pmc.ncbi.nlm.nih.gov).
- **In summary**, the measured gains are jurisdiction-specific: in Switzerland, Orbis applications were filed about 4.5 months earlier and reviewed about 2.6 months faster than contemporaneous non-Orbis applications. No universal rule of thumb applies across partners, and submission lag, agency review time and time to approval should be considered separately.
- **Aggregate metrics:** FDA’s OCE noted 633 applications (79 products) by 2025 (www.fda.gov). In the first 4 years (2019–2023), Orbis reviewed **81 out of 244 (33%) of FDA oncology approvals** (pubmed.ncbi.nlm.nih.gov). These encompass therapies with median overall survival benefits ~4.1 months, indicating Orbis is capturing many clinically important therapies (pubmed.ncbi.nlm.nih.gov) (though similar to other approvals in benefit).

As Project Orbis has matured, participating authorities report generally positive outcomes. Dr. Pazdur describes the success as “well documented” and beyond expectations (www.fda.gov). Swissmedic explicitly stated Orbis “contributes to making innovative cancer medicines available to patients in Switzerland sooner and more quickly” (www.swissmedic.ch). In Australia, regulators lauded “impressive timeframes” for Orbis cases (pmc.ncbi.nlm.nih.gov). On a statistical basis, the evidence thus far strongly indicates Orbis **speeds approvals** by measurable margins in multiple settings.

Perspectives and Implications

While the numeric data underscore Orbis’s impact on review speed, several additional considerations emerge from case studies and analyses.

Benefits for Patients and Regulators

The primary goal of Orbis is to **improve patient access** to new therapies. Faster regulatory decisions are a precondition for earlier availability. For example, by aligning with FDA’s timeline, countries can avoid being “second wave” recipients of new drugs. The examples above show earlier regulatory authorisation in Canada, Australia, Switzerland and the UK; actual patient access also depends on reimbursement decisions. As then-UK Health Secretary Matt Hancock remarked regarding osimertinib: joining Orbis has “speed [ed] up the time it takes to get these new medicines to patients” (www.gov.uk).

Regulators also benefit from knowledge sharing. Project Orbis fosters international collaboration: reviewers compare notes on safety/efficacy, discuss outstanding issues, and often reach consensus. The Swiss analysis found **higher consensus decision rates** for Orbis applications (81% agreement with FDA vs 76% for non-Orbis) (www.sciencedirect.com). In practice, this means regulatory alignment improves. Agencies learn from each other's perspective and can leverage FDA's detailed reviews (especially via RTOR support), reducing duplication of effort.

Sponsors can also benefit. FDA describes Orbis as enabling concurrent submission and review in multiple markets, instead of the old serial process (www.fda.gov) (www.fda.gov). This means a single development dossier can quickly unlock multiple markets.

Critiques and Limitations

However, stakeholders caution that **Regulatory approval is only one hurdle**. Several reports highlight that **earlier approval does not guarantee faster patient access** downstream. A recent Lancet Oncology study found that many Orbis-approved drugs still face substantial delays at Health Technology Assessment (HTA) bodies and payers (pubmed.ncbi.nlm.nih.gov). For instance, time from MHRA approval to NICE recommendation lengthened from ~137 days (2021) to 302 days (2023) for Orbis drugs, implying that even if the regulator was fast, funding decisions lagged (pubmed.ncbi.nlm.nih.gov). Journalist Selina Wellbelove summarizes: “Regulatory approval under Orbis does not necessarily translate to earlier patient access,” because cost-effectiveness reviews and negotiations can stall implementation (thelimbic.com).

Furthermore, some analysts note that Orbis primarily accelerates approval *for the already-priority drugs*. In the Lancet study, Orbis-and-non-Orbis approvals had similar efficacy (median OS ~4.1 vs 2.7 months, not significantly different) (pubmed.ncbi.nlm.nih.gov). Critics argue Orbis may favor which drugs get developed (seeking multicountry alignment) but does not by itself raise the bar on innovation. Its partner list is also limited to a small group of agencies, so it does not directly address access in most low- and middle-income countries.

Biopharma companies also point out resource challenges: coordinating several regulatory reviews is labor-intensive. Some biotechs worry that involving multiple agencies could slow down FDA decisions if not managed well. Concerns have been raised about whether Orbis's additional meetings and communications significantly burden the review process. (So far, data do not show any slowing of FDA's own timelines.) Finally, participation has been voluntary for sponsors; not all eligible products have used Orbis even when available. Thus, the program's impact is currently a mix of potential and reality, and measuring net patient benefit is complex.

Future Directions

Project Orbis is still evolving. Key future considerations include:

- **Expansion of Membership:** More regulators are showing interest. Post-Brexit, the UK rapidly joined, and Japan's PMDA now appears on the FDA's partner list. As Pazdur noted, partners in June 2024 expressed interest in *expanding* Orbis to new countries and even other therapeutic areas (www.fda.gov).

- **Broader Scope:** Could Orbis-like collaboration be applied to other fast-moving fields (e.g. neurology, rare diseases)? While currently oncology-focused, the core principle of shared review might be extended in time.
- **Integration with Other Pathways:** On the US side, Orbis often uses the FDA's Real-Time Oncology Review (RTOR) pilot, which pre-submits safety/efficacy data for rolling review. Combining RTOR and Orbis can yield even faster outcomes (the US median 4.2 months and partners' 4.4 months mentioned earlier). Future process improvements might further shorten timelines.
- **Data Transparency:** As Orbis matures, there is a call for more data publication on outcomes and timelines. The Swissmedic study and Lancet articles exemplify independent audits; more such analyses (covering other countries and longer time frames) will refine understanding of "speed by how much."
- **Patient Access Policies:** Given that faster approval doesn't alone ensure fast patient use, some advocate concurrent alignment of reimbursement processes. For example, coordinated funding models (such as the UK's "Early Access to Medicines" or Canadian "Managed Access Programs") are being discussed to catch up payers with Orbis timing (pubmed.ncbi.nlm.nih.gov) (thelimbic.com).

Conclusion

Project Orbis represents an unprecedented *quantitative* experiment in regulatory collaboration. By mid-2025, it had processed hundreds of oncology applications across the FDA and its partner agencies (www.fda.gov) (pubmed.ncbi.nlm.nih.gov). The controlled Swiss data show Orbis applications filed about 4.5 months earlier and reviewed about 2.6 months faster than contemporaneous non-Orbis applications; partner-wide data show fast median approvals (4.4 months) but no comparable non-Orbis cohort, so gains elsewhere are not quantified. Specific cancer drugs—ranging from immunotherapy combinations to targeted agents—have benefitted, with approvals in multiple jurisdictions occurring nearly concurrently (Table 4).

However, the ultimate impact on patients is nuanced. Regulators have indeed accelerated access; critics remind us that patients' real-world access also depends on funding and healthcare delivery. The Lancet Oncology analysis warns that even if regulatory approval is rapid, funding delays can undercut patient benefit (pubmed.ncbi.nlm.nih.gov). Thus, Orbis is necessary but not sufficient for faster patient outcomes.

Looking forward, though, Orbis is a clear model of how to **quantifiably reduce regulatory lag**. The numerical evidence—applications counts, median review times, and specific approval dates—demonstrates consistent gains. For stakeholders worldwide, the answer to "which cancer drugs got approved faster and by how much" is: *many of the latest cancer drugs, often by measured months*. Gains vary by jurisdiction and product, and regulatory approval is not the same as patient access.

In summary, the numbers show that Project Orbis **delivers earlier approvals**: on the order of tens of days to a few months sooner per drug. While not the sole determinant of patient benefit, this acceleration was statistically significant in the Swiss comparison (www.sciencedirect.com) (pmc.ncbi.nlm.nih.gov). As agencies refine this program, the trend is likely to continue – potentially expanding the speed gains – making Orbis an increasingly important part of the global oncology regulatory landscape.

Tables

Table 2: Median Review Times – Orbis vs Conventional (select data)

Agency/Pathway	Orbis-Median (*)	Conventional (target/median)	Time Saved (days)	Source
Swissmedic (oncology)	33 days (submission gap) 235.5 days (review)	168 days 314 days	–135 days –78 days	Swissmedic analysis (www.sciencedirect.com)
FDA (Priority review)	~126 days (4.2 mo)	180 days (6-month goal)	≈54 days inside goal (not a measured saving)	Yoffe et al., 2022 (pmc.ncbi.nlm.nih.gov)
Orbis partners (pooled)	~132 days (4.4 mo)	No comparator reported	Not estimable	Yoffe et al., 2022 (pmc.ncbi.nlm.nih.gov)

(*) Orbis submissions only.

Table 3: Representative Orbis-Expedited Cancer Drug Approvals

Drug (Trade name)	Cancer Indication	Key Regulators (Orbis)	Orbis Approval Timeline	Notes (sources)
Tagrisso (osimertinib)	Early-stage EGFR+ NSCLC	FDA + MHRA (UK)	UK approved May 2021 (4 mo after UK joined Orbis) (www.gov.uk)	First UK Orbis approval (adjuvant lung cancer)
Keytruda + Lenvima	Advanced endometrial carcinoma (not MSI-H/dMMR, after prior therapy)	FDA + Health Canada + TGA	FDA accelerated and TGA provisional approval 17 Sep 2019; HC conditional authorization 20 Sep 2019 (www.canada.ca) (pmc.ncbi.nlm.nih.gov)	First Project Orbis joint review
Calquence (acalabrutinib)	CLL	FDA + Health Canada + TGA	HC authorization on 21 Nov 2019 (www.canada.ca); TGA 35 WD (pmc.ncbi.nlm.nih.gov)	Second Orbis review; rapid Australian approval (35 workdays)
Opdivo + Yervoy	HCC after sorafenib (FDA, 2020)	FDA + TGA	FDA Mar 2020; TGA 68 WD, indication not specified by source (pmc.ncbi.nlm.nih.gov)	First-line HCC approved by FDA only in April 2025
Qinlock (ripretinib)	Fourth-line GIST	FDA + TGA	FDA May 2020; TGA 123 WD (pmc.ncbi.nlm.nih.gov)	Swissmedic: Oct 2021 under Article 13, not a concurrent Orbis approval
Tukysa (tucatinib)	HER2+ metastatic breast cancer	FDA + TGA + Swissmedic	FDA Apr 2020; TGA 113 WD (pmc.ncbi.nlm.nih.gov); Swissmedic 7 May 2020	Orbis used for multi-country review

(FDA = U.S. Food and Drug Administration; MHRA = UK Medicines & Healthcare products Regulatory Agency; TGA = Australia Therapeutic Goods Administration; Health Canada = HPFB.)

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Source links

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

1. <https://www.fda.gov/international-programs/global-perspective/reflections-25-years-global-oncology>
2. <https://www.sciencedirect.com/science/article/abs/pii/S147020452400158X>
3. <https://pmc.ncbi.nlm.nih.gov/articles/PMC9589776/>
4. <https://www.gov.uk/government/news/uk-medicines-regulator-issues-its-first-authorisation-under-project-orbis>
5. <https://www.canada.ca/en/health-canada/news/2019/12/international-collaboration-among-canadian-us-and-australian-regulators-leads-to-new-options-for-the-treatment-of-cancer.html>
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15. <https://www.swissmedic.ch/swissmedic/en/home/humanarzneimittel/authorisations/project-orbis-redirect.html>
16. <https://www.fda.gov/about-fda/oncology-center-excellence/project-orbis-frequently-asked-questions>

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