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 ([1] 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** ([2] www.sciencedirect.com) – a reduction of roughly 79 days (≈2.6 months). Similarly, in Australia the median approval time for Orbis applications was **4.4 months**, only slightly longer than the FDA's median **4.2-month** review, both well under the typical 6-month priority review goal ([3] 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 endometrial cancer) was **simultaneously approved** by FDA, Health Canada, and Australia on September 17, 2019 under Orbis (www.canada.ca) ([4] 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 ([5] 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 ([6] pubmed.ncbi.nlm.nih.gov) ([7] thelimbic.com). Nonetheless, overall evidence indicates Orbis has **statistically significantly increased the speed of review** in participating countries, yielding earlier approvals for many cancer therapies. 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 ([8] 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 ([9] www.fda.gov) ([10] 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 ([11] 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 ([11] www.fda.gov). Today, Project Orbis spans at least **10 regulatory authorities** (USA, Canada, Australia, Singapore, Switzerland, Brazil, UK, Israel, Health Canada, Singapore's HSA) with others observing (e.g. EMA has observer status) (www.canada.ca) ([11] 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 (endometrial CA) – approved 9/17/2019 (www.canada.ca)
Health Canada	May 2019	*Lenvatinib + pembrolizumab* (endometrial CA) – 20 Sep 2019 (www.canada.ca) *Acalabrutinib* (CLL) – 21 Nov 2019 (www.canada.ca)
TGA (Australia)	May 2019	*Lenvatinib + pembrolizumab* – 17 Sep 2019 (concurrent) ([4] pmc.ncbi.nlm.nih.gov)
HSA (Singapore)	Dec 2019	(Participated from 12/2019, approvals data in panel stages)
Swissmedic (Switzerland)	Dec 2019	Participated in 2020–21 evaluations, median approval 236d (Orbis), much faster than prior 314d ([2] www.sciencedirect.com)
ANVISA (Brazil)	May 2020	(Collaborations beginning 2020; specific items pending publication)
MHRA (UK)	Jan 2021	*Osimertinib* (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" ([12] 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** ([1] www.fda.gov). In the first year alone (mid-2019 to 2020) **60 applications** were handled jointly, yielding **38 approvals** ([13] pmc.ncbi.nlm.nih.gov). In the broader frame (2019–2023), fully one-third of new FDA cancer drug approvals were Orbis-reviewed ([5] 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) ([14] 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 ([15] 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 ([16] pmc.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**, **ripretinib**, **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) ([15] pmc.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 landmark analysis by Läubli et al. (2024) looked at Swissmedic submissions from 2020–2021. Swissmedic had the choice of participating through Orbis or handling applications independently. Among 72 oncology submissions during that period, 31 were Orbis-project applications and 41 were non-Orbis ([2] 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** (IQR 18–58). By contrast, non-Orbis applications saw a median gap of **168.0 days** (IQR 56–351). That is a **135-day (4.5 month) reduction** in initial submission delay ([2] www.sciencedirect.com).
- **Review Time**: Swissmedic's median review time (submission to decision) was drastically shorter for Orbis applications: **235.5 days** (≈7.8 months) versus **314.0 days** (≈10.3 months) for non-Orbis. This **≈79-day (2.6 month) improvement** was statistically significant (p=0.0002) ([2] www.sciencedirect.com).
- **Overall Access**: Although approval *rates* (proportion approved) were similar between Orbis and non-Orbis at Swissmedic, the streamlined timelines meant patients in Switzerland received approved therapies **months earlier** on average ([2] www.sciencedirect.com) ([17] www.sciencedirect.com).

The Swiss study thus provides hard numbers: in that jurisdiction, Orbis cut several months out of the process. It attributed this largely to earlier submission and joint review meetings. 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" ([2] www.sciencedirect.com) ([18] www.sciencedirect.com).

Similar findings emerge elsewhere. An Australian analysis (Yoffe et al., 2022) examined 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 (Priority Approval), **acalabrutinib** in 35 days (Provisional Approval), **nivolumab+ipilimumab** in 68 days, **ripretinib** in 123 days, and **tucatinib** in 113 days ([15] pmc.ncbi.nlm.nih.gov). For context, TGA's standard Priority pathway allows up to 255

working days. Thus these Orbis cases were often **completed in a fraction of the usual time**. 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"* ([3] pmc.ncbi.nlm.nih.gov) (vs the 6-month goal in each country). This roughly equates to 126 and 132 days, about 1–2 months faster than conventional targets.

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. Once in review, the shared process (and often simultaneous filings) yields decisions roughly **1–3 months sooner** on average. 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 ([2] www.sciencedirect.com)	Swissmedic analysis (Läubli et al., 2024)
FDA (Priority Review)	4.2 months (≈126 days)	~6 months (≈180 days)	–54 days ([3] pmc.ncbi.nlm.nih.gov)	Yoffe et al., 2022 (Australia)
TGA (Priority) *	4.4 months (≈132 days)	~6 months (≈180 days)	–48 days ([3] pmc.ncbi.nlm.nih.gov)	Yoffe et al., 2022 (Australia)

**FDA and TGA "target" refer to the standard Priority Review goal (~180 days).*

Thus **by how much faster**? Roughly speaking, Orbis cut median review timelines by **1½–3 months** in these examples. Another way: in Switzerland, Orbis submissions were filed **4.5 months earlier** than otherwise, and review durations were **2.5 months shorter** ([2] www.sciencedirect.com). In Australia, Orbis reviews often finished in ~130 days, against 180-day targets ([3] pmc.ncbi.nlm.nih.gov). Even at the FDA, Orbis/RTOR cases closed in ~126 days on median instead of up to 180.

It bears emphasizing that **"time saved" depends on context**. For Type A (fully concurrent submissions) the saving is greatest. In the Swiss analysis, the Orbis applications were nearly all Type A (filed within 1 month of FDA submission), so Swissmedic could act very soon after FDA. 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 ([1] www.fda.gov). Given those figures, Statistics on overall Orbis throughput are:

- **Applications (2019–mid-2025)**: 633 total
- **Unique products**: 79 (33% of all FDA-approved cancer drugs in period) ([5] pubmed.ncbi.nlm.nih.gov)
- **Countries**: 8 active partners (plus observers) ([11] 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, Health Canada, and TGA all **simultaneously approved** it on September 17–20, 2019 as part of a joint review (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) after prior therapy. *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, acalabrutinib was approved in just 35 TGA working days under Orbis (Provisional Approval) ([15] pmc.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*: First-line therapy for advanced hepatocellular carcinoma (HCC). *Orbis Impact*: The FDA approved on March 16, 2020. Australia's TGA followed via Orbis: the combination was approved in 68 working days ([15] pmc.ncbi.nlm.nih.gov). (Swissmedic also took part in this review session, approving the combo in May 2020.) This rapid co-approval under Orbis meant concurrent availability in those regions.

- **Ripretinib (QINLOCK)** – *Indication*: Fourth-line gastrointestinal stromal tumor (GIST). *Orbis Impact*: FDA approval came May 15, 2020; Switzerland and Australia used Orbis to expedite review. Notably, the TGA granted approval under Priority Review in 123 working days ([15] pmc.ncbi.nlm.nih.gov). (Without Orbis, Australia's usual workforce approach might have taken longer.)

- **Tucatinib (TUKYSA)** – *Indication*: HER2-positive metastatic breast cancer (with trastuzumab + capecitabine). *Orbis Impact*: After FDA approval in April 2020, Australia finalized approval in 113 working days under Orbis ([15] pmc.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	FDA + HC (Canada) + TGA	Simultaneous approval on 17–20 Sep 2019 (www.canada.ca) ([4] pmc.ncbi.nlm.nih.gov)	First Orbis case; joint FDA-HC-TGA review.
Acalabrutinib (Calquence)	CLL post-therapy	FDA + HC + TGA	HC authorization 21 Nov 2019 (www.canada.ca); TGA risk-based approval (35 days) ([15] pmc.ncbi.nlm.nih.gov)	Second Orbis review; CLL indication
Ipilimumab + Nivolumab (Y/O)	Unresectable HCC	FDA + TGA + Swissmedic	FDA Mar 2020; TGA 68 working days (Apr 2020) ([15] pmc.ncbi.nlm.nih.gov); Swiss May 2020	Concurrent global review; also EU under review.

Drug (Brand)	Indication	Regulators	Orbis Timeline	Notes
Ripretinib (Qinlock)	Fourth-line GIST	FDA + TGA + Swissmedic	FDA May 2020; TGA 123 working days (Aug 2020) ([15] pmc.ncbi.nlm.nih.gov)	Swiss also approved in July 2020 via Orbis.
Tucatinib (Tukysa)	HER2+ metastatic breast cancer	FDA + TGA + Swissmedic	FDA Apr 2020; TGA 113 working days (Jul 2020) ([15] pmc.ncbi.nlm.nih.gov)	Swissmedic approved June 2020 via Orbis.

Each entry above reflects an internationally coordinated review. In most cases, the *Orbis timeframe* denotes final approval roughly in the range of 1–4 months after FDA's decision. By contrast, traditional staggered filings might have delayed partner approvals by many more months. For example, prior to Orbis, Swissmedic routinely received oncology filings **~6 months after FDA** on average ([10] www.fda.gov); under Orbis that gap shrank to just over a month ([2] 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 ([2] www.sciencedirect.com). Health Canada now often submits days to weeks after FDA, rather than the 6–12+ months typical pre-Orbis ([8] www.fda.gov) (www.canada.ca).
- **Review time reduction:** Median review times at partner agencies are shortened by roughly 20–30%. Swissmedic's median fell by 78 days (~25%) ([2] www.sciencedirect.com); Australian partners completed reviews in ~130 days vs 180-day targets ([3] pmc.ncbi.nlm.nih.gov).
- **In summary**, a **rough rule of thumb** from these cases is that an Orbis-reviewed drug reaches decisions **2–3 months earlier** on median in partner countries than it would via the old sequential approach. (Exact gains vary by product and country.) This is illustrated in Table 3 above and corroborated by multiple reports.
- **Aggregate metrics:** FDA's OCE noted 633 applications (79 products) by 2025 ([1] www.fda.gov). In the first 4 years (2019–2023), Orbis reviewed **81 out of 244 (33%) of FDA oncology approvals** ([5] pubmed.ncbi.nlm.nih.gov). These encompass therapies with median overall survival benefits ~4.1 months, indicating Orbis is capturing many clinically important therapies ([5] 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 ([12] 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 ([3] 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 can literally translate into more lives saved. For example, by aligning with FDA's timeline, countries can avoid being "second wave" recipients of new drugs. The real-world examples above show patients in Canada, Australia, Switzerland, and the UK gaining access months earlier thanks to Orbis. 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) ([2] 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.

Industry sponsors clearly find value too. CEOs and executives have stated that Orbis encourages them to file globally. As one analysis notes, companies report Orbis as a "major advance" because it enables "concurrent submission, review and regulatory action" in multiple markets, instead of the old serial process ([12] www.fda.gov) ([1] 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 ([6] 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 ([6] 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 ([7] 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) ([5] 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. The Fitch *BMI* report (July 2024) suggested that Orbis has had **limited success improving timely access** in low- and middle-income countries, partly because not all authorities have joined or have the capacity to parallel-review.

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. The EMA currently observes Orbis and is exploring how to align with such models. Other countries (e.g. Korea, Russia, China) might embark on agreements or similar schemes in oncology. As Pazdur noted, partners in June 2024 expressed interest in *expanding* Orbis to new countries and even other therapeutic areas ([19] 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 ([6] pubmed.ncbi.nlm.nih.gov) ([7] thelimbic.com).

Conclusion

Project Orbis represents an unprecedented *quantitative* experiment in regulatory collaboration. By mid-2025, it has processed hundreds of oncology applications across nearly ten agencies ([1] www.fda.gov) ([5] pubmed.ncbi.nlm.nih.gov). The data are clear that Orbis reviews are **substantially faster** than traditional sequential reviews: in Switzerland by roughly 2–3 months, in Australia by ~1–2 months, and generally cutting the usual multi-month waiting periods by half. 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 ([6] 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*. For example, therapies that might have taken up to a year or more to reach patients in partner countries have instead arrived within four to six months thanks to Orbis coordination.

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 is statistically significant and clinically meaningful for cutting-edge cancer treatments ([2] www.sciencedirect.com) ([3] pmc.ncbi.nlm.nih.gov). As agencies refine this program, the trend is likely to continue – potentially expanding the speed gains (§Implications§) – 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 ([2] www.sciencedirect.com)
FDA (Priority review)	~126 days (4.2 mo)	180 days (6 mo)	–54 days	Yoffe et al., 2022 ([3] pmc.ncbi.nlm.nih.gov)
TGA (Priority review)	~132 days (4.4 mo)	180 days (6 mo)	–48 days	Yoffe et al., 2022 ([3] 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	FDA + Health Canada + TGA	All approved 17–20 Sep 2019 (www.canada.ca) ([4] pmc.ncbi.nlm.nih.gov)	First Project Orbis joint review
Calquence (acalabrutinib)	CLL (post-chemo)	FDA + Health Canada + TGA	FDA/HC simultaneously: HC on 21 Nov 2019 (www.canada.ca); TGA 35 WD ([15] pmc.ncbi.nlm.nih.gov)	Second Orbis review; rapid Australian approval (35 workdays)
Opdivo + Yervoy	Unresectable HCC (liver)	FDA + TGA + Swissmedic	FDA Mar 2020; TGA 68 WD (Apr 2020) ([15] pmc.ncbi.nlm.nih.gov); Swiss May 2020	Simultaneous multi-country review
Qinlock (ripretinib)	Fourth-line GIST	FDA + TGA + Swissmedic	FDA May 2020; TGA 123 WD (Aug 2020) ([15] pmc.ncbi.nlm.nih.gov); Swiss Jul 2020	Concurrent global review
Tukysa (tucatinib)	HER2+ metastatic breast cancer	FDA + TGA + Swissmedic	FDA Apr 2020; TGA 113 WD (Jul 2020) ([15] pmc.ncbi.nlm.nih.gov); Swiss Jun 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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