Project ORBIS: Does Regulatory Acceleration Translate to FASTer Global Patient Access?

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Introduction and Context[1,2]

Project Orbis was launched in May 2019 by the FDA Oncology Centre of Excellence. It consists of 8 participating countries, Australia (AUS), Brazil (BRA), Canada (CAN), Israel (ISR), Singapore (SGP), Switzerland (CH), United Kingdom (UK) and the United States (US). The purpose of the program is to accelerate access to innovative cancer treatments through a synchronized review process. Historically, innovative cancer therapies were approved first in the United States, with subsequent approvals in other countries occurring months or years later due to sequential submissions, duplicated regulatory reviews, and operational differences across agencies. Delays in global drug approvals results in inequitable access to innovative therapies, particularly in countries with limited regulatory capacity. The rising global cancer burden further underscores the importance of timely access. While evidence suggests that Project Orbis has successfully reduced international regulatory approval gaps, it remains unclear whether these efficiencies translate into earlier patient access within publicly funded healthcare systems, where downstream HTA evaluations, pricing negotiations, and funding decisions operate independently of regulatory timelines.

Figure 1: Schematic showing the process flow for Project Orbis.

Methods:

Study Design and Objectives

This study employed a review of available publications, literature and comparative policy analysis to evaluate the real-world impact of Project Orbis on global oncology drug access

Two primary methodological objectives were defined:

1. To assess the extent to which Project Orbis reduces regulatory approval timelines using empirical evidence from participating countries.
2. To evaluate whether regulatory acceleration translated into faster patient access, and to explore how Ontario's Funding Accelerated for Specific Treatments (FAST) initiative may address some of the remaining access bottlenecks.

Data Sources and Evidence Identification:

A structured review of peer-reviewed literature, regulatory agency reports, and publicly available documents was conducted. Sources included:

- Published studies evaluating Project Orbis outcomes
- Regulatory publications from agencies including the FDA, Health Canada and Swissmedic. Analyses were limited to Canada and Switzerland due to availability of published data.
- HTA and reimbursement pathway documentation

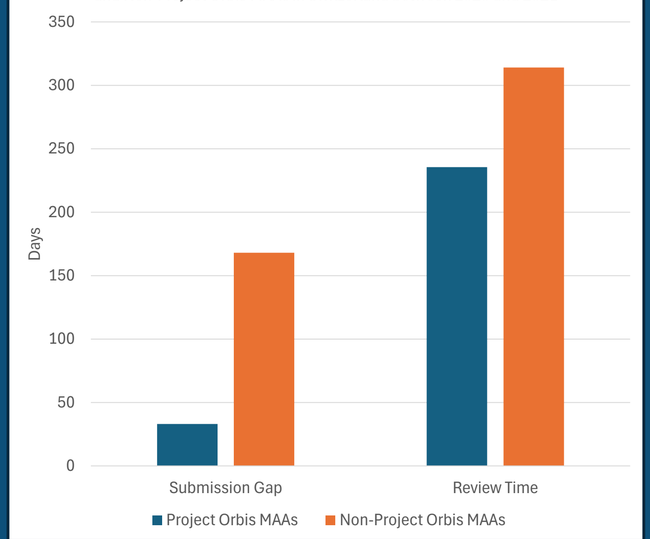
Searches focused on publications from 2019 onwards, corresponding with the launch of Project Orbis.

Figure 2: A map highlighting countries involved in Project Orbis.

Drug	Company	Indication – Tumor Type	FDA Approval	Project Orbis Participants
Acalabrutinib	AstraZeneca	Mantle Cell Lymphoma	16-JAN-25	AUS, BRA, CAN, SGP, CH
Cabozantinib	Exelixis	Pancreatic Neuroendocrine tumors	26-MAR-25	AUS, BRA
Nivolumab + ipilimumab	Bristol Myers Squibb Company	MSI-H colorectal cancer	08-APR-25	BRA, CAN, ISR, SGP
Nivolumab + ipilimumab	Bristol Myers Squibb Company	Hepatocellular carcinoma	11-APR-25	BRA, CAN, CH
Darolutamide	Bayer Healthcare Pharmaceuticals	Prostate cancer	03-JUN-25	CAN, CH, UK
Pembrolizumab	Merck	Head and neck squamous cell carcinoma	12-JUN-25	BRA, CAN, CH
Durvalumab	AstraZeneca	Gastric / Gastroesophageal adenocarcinoma	25-NOV-25	AUS, CH

Table 1[3]: An overview of the drugs with completed review through Project Orbis in 2025. 10 other drugs are currently under review through Project Orbis with the FDA

Figure 3: Time taken between Submissions and Review for Project Orbis and Non-Project Orbis MAAs in Switzerland between 2020 and 2021



Overall Results: Impact of Project Orbis[4,5]

Regulatory Timelines

Project Orbis enabled parallel regulatory review, reducing delays between US and participating countries. In Switzerland, submission gaps were reduced by 135 days ($p<0.01$) and review times were reduced by 78.5 days ($p<0.01$) between January 2020 and December 2021, for 31 Project Orbis MAAs and 41 non-Project Orbis MAAs[4]. In Canada, the median FDA-Health Canada approval delay was reduced by 175 days between 2019 and 2023 (n=77)[5].

Project Orbis consistently improves regulatory efficiency and alignment across jurisdictions

Patient Access and System Level Impact

Despite faster approvals, no consistent reduction in time to patient access was observed. Delays in patient access persisted due to: HTA review processes, price negotiations, and national/provincial funding decisions[5,6]. Several Project Orbis new indication applications were approved based on early clinical trial evidence, leading to uncertainty in real-world clinical benefit and conditional HTA recommendations[5].

Figure 3: A graph showing the time taken between submissions and review time for Project Orbis and non-Project Orbis MAAs in Switzerland between 2020 and 2021. (Project Orbis Submission Gap, n=31; Project Orbis Review Time, n=26; Non-Project Orbis Submission Gap, n=41; Non-Project Orbis Review Time, n=41) Data from Zosso-Pavic et al.

Case Study: Canada[5,7,8,9]

Current Effects of Project Orbis Regulatory Impact[5]

- Health Canada actively participates in Project Orbis to allow for a parallel review with the FDA
- Median approval delay reduced by 175 days demonstrating a clear regulatory benefit based on submissions between 2019 and 2023 (n=77).

Therapeutic Value and Evidence Limitations

- Many drugs entered via standard or conditional (NOC/c) pathways
- A limited number of products met criteria for high therapeutic value which suggests a misalignment between accelerated approval and clinical value

Reimbursement and Access Delays:

- Post-approval access is delayed due to: CADTH/pCODR HTA review, pCPA price negotiations, and provincial funding timelines
- Data suggests that whilst Project Orbis has introduced regulatory efficiencies, the potential benefit is not realized due to downstream HTA processes.

Role of Ontario FAST Programme

- FAST is a 3-year Ontario pilot program designed to fast-track 7-10 high-priority drugs to enable earlier access by up to 9 months[7,8]. It offers a complementary mechanism to address some of the access gaps that are not solved by Project Orbis. To be eligible, drugs need to have been evaluated through Project Orbis with a positive final CDA-AMC recommendation, and the manufacturer must commit to enter into a funding agreement with Ontario.
- FAST could align reimbursement timelines with accelerated Project Orbis approvals and reduce the approval-to-access gap. It may create a more efficient pipeline for earlier patient access while encouraging stronger evidence generation for conditionally approved therapies and improving coordination between federal regulatory and provincial funding access[9].

Project Orbis and FAST may function as synergistic pathways, with regulatory acceleration complemented by targeted funding mechanisms. This alignment has the potential to reduce time to patient access by accelerating the funding process; however, as FAST is newly implemented, its real-world impact remains to be demonstrated.

Key Findings and Implications

Interpretation of Key Findings: Project Orbis achieved its primary objective of reducing international regulatory delays, with consistent improvements in submission alignment and review timelines across jurisdictions. Evidence from Canada and Switzerland confirms that parallel review can enable faster regulatory decision-making without compromising regulatory independence. However, these regulatory gains do not consistently translate into earlier patient access. This reflects a persistent disconnect between regulatory approval and downstream access processes, particularly in health systems where HTA, pricing negotiations, and funding decisions operate independently of regulatory timelines, i.e., in Canada.

System-Level Implications: The findings illustrate a structural misalignment within oncology access pathways whereby regulatory processes have become more efficient while reimbursement and funding systems have been slower to adapt. This misalignment limits the real-world potential of regulatory efficiencies. In Canada, despite a substantial reduction in regulatory approval delays, access remains constrained by national HTA process and jurisdictional funding decisions, resulting in a persistent "approval-to-access" delay. In addition, the evidence suggests that many therapies approved through accelerated pathways are supported by immature clinical data. While this has shown to be suitable for innovative regulatory approvals, it contributes to uncertainty in HTA assessment which may lead to conditional or delayed reimbursement decisions. This further weakens the link between regulatory speed and patient access.

Implications for Access and Value: These findings indicate that regulatory acceleration alone is insufficient to optimize patient access to oncology therapies. While Project Orbis improves the timing of regulatory decisions, it does not alter the evidentiary, economic, and policy requirements that govern access in publicly funded healthcare systems. As a result, faster approvals do not consistently translate into earlier access, underscoring the need for complementary mechanisms across HTA, pricing, and funding processes.

Recommendations

- **Support early alignment of regulatory and HTA evidence requirements,** particularly around endpoint selection and evidence maturity, to reduce uncertainty in downstream HTA assessments.
- **Enable targeted funding mechanisms to complement accelerated regulatory approvals,** such as Ontario's FAST program, to address access bottlenecks not resolved by regulatory efficiency alone. This is particularly relevant where local funding is a separate process to national reimbursement.
- **Increase adoption of real-world evidence,** to better integrate RWD collection into R&D to support quicker HTA review and reassessment as mature data become available.

Conclusion

Project Orbis represents a significant advancement in global regulatory collaboration and has demonstrably reduced international approval delays for oncology therapies. However, its impact on real-world patient access remains limited by structural misalignment with HTA, pricing, and funding systems. Bridging the gap between regulatory approval and patient access remains the critical challenge, requiring greater coordination across regulatory, HTA, reimbursement, and funding processes, to ensure patients have timely access to treatment.

Abbreviations: FDA: Food and Drug Administration; US: United States; AUS: Australia; BRA: Brazil; CAN: Canada; SGP: Singapore; CH: Switzerland; ISR: Israel; UK: United Kingdom FAST: Funding Accelerated for Specific Treatments; MAA: Marketing Authorization Application; NOC/c: Notice of Compliance with conditions; CADTH: Canadian Agency for Drugs and Technologies in Health; pCODR: pan-Canadian Oncology Drug Review; HTA: Health Technology Assessment; CDA-AMC: Canada's Drug Agency-Agence des medicaments du Canada; RWE: Real World Evidence

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