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A Strategic Analysis of Work-Sharing: Access Consortium, Project Orbis, and Project Optimus

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Abstract

A more cooperative paradigm is replacing the days of strictly sequential, nation-by-nation drug approvals. Navigating the terrain of international cooperation is now a core competency for the modern regulatory professional rather than a specialized skill. This article goes into detail about three collaborative models that could change the way regulatory affairs professionals work: the Access Consortium, Project Orbis, and Project Optimus. It breaks down the different ways that Access and Orbis share work, which are changing the timelines for submissions, and compares them to Project Optimus, a scientific project that is fundamentally changing the DNA of oncology development. This paper goes beyond merely describing the programs to examine how they operate, what strategic trade-offs they entail, and where they might be able to exert greater influence. The goal is to provide organizations with the information they need to navigate this new, collaborative world and transform regulatory complexity into a competitive edge.

Keywords: collaborative review; Project Orbis; Project Optimus; Access Consortium; global regulatory strategy; oncology

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1. Introduction

Historically, the global submission process for new drugs was predictable. A sponsor will typically secure approval from the United States Food and Drug Administration (FDA) or European Medicines Agency (EMA) and then begin the methodical country by country process for the rest of the world. This linear and duplicative model is rapidly becoming absolute due to several important factors. (1)

The emergence of radical science, including cell and gene therapies, complex biologics, and precision medicines, presents novel scientific and regulatory challenges that are difficult for any single agency to manage alone. Furthermore, the patient access imperative makes it increasingly difficult to justify lengthy delays between a life-saving drug's approval in a primary market and its availability elsewhere. Clinical trials are globalized operations that generate vast datasets intended for submission in multiple jurisdictions, making it logical for the regulatory review process to reflect this international reality. Simultaneously, National Regulatory Authorities (NRAs) face challenges with increased workload necessitating the adoption of more efficient review methods.

These different factors have led to a new era of regulatory cooperation, which goes beyond simply sharing information and into the realm of structured work-sharing. These are real working frameworks where agencies share the assessment of drug approval applications. (1)

Regulatory cooperation exists on a spectrum that begins with harmonization, such as the International Council for Harmonisation (ICH) guidelines, and moves through reliance, where one agency leverages the work of another. At the far end of this spectrum is work-sharing, which is most dramatically altering professional practice of each region. In a work-sharing model, multiple NRAs concurrently assess the same application. NRAs divide the assessment, peer-review each other's work, and coordinate the questions to the sponsor. A critical feature of this model is that each agency retains its sovereign authority to make the final, independent decision on marketing authorization. It is this combination of shared effort and independent authority that defines the power and complexity of these models. This article will analyze three of the most impactful models: the Access Consortium, Project Orbis, and Project Optimus. (1)

2. The Access Consortium

2.1 Origins and purpose

The Access Consortium offers a strong strategic path for organizations that want efficiency and predictability outside of the major FDA and EMA blocs. It is a practical partnership between five "like-minded" and well-

respected regulatory agencies: Australia's Therapeutic Goods Administration (TGA), Health Canada (HC), Singapore's Health Sciences Authority (HSA), Swiss medic and The UK's Medicines and Healthcare products Regulatory Agency (MHRA). These agencies have similar review standards and face similar challenges. Hence, by strategizing through work-sharing procedures, the process of assessing and providing approvals for medicines gets smoother. The scope is notably broad, including new chemicals, generics, and biosimilars. (2)

2.2 Operational framework and review process

Access Consortium has few working groups, subgroups and networks, of which New Active Substance Work-Sharing Initiative (NASWSI) and the Generic Medicine Work-sharing Initiative (GMWSI) comprise the engine room of Access due to the well-established process by these working groups for new active substance and generic medicines. A comprehensive understanding of this process is required to navigate it successfully. (3)

The process is initiated when a sponsor signals their interest by submitting an Expression of Interest form to a minimum of two-member agencies, ideally well in advance of the intended submission date. If the application is deemed a suitable candidate, a pre-submission meeting is arranged between the sponsor and the participating NRAs. This meeting provides a valuable opportunity to align on timelines and dossier expectations, thereby reducing submission risks. The subsequent step is the simultaneous submission of the identical eCTD, specifically Modules 2 through 5, to all participating agencies. Module 1 remains customized to meet the distinct administrative requirements of each country, necessitating seamless internal coordination by the sponsor. Following the submission, the agencies convene to allocate work, assigning a "lead" assessor for each major review area, such as non-clinical or quality. It is important to note that the sponsor does not participate in this step. During the review, the designated lead for each module prepares the primary evaluation report, which is then shared with the other agencies for peer review and comment. This model's effectiveness stems not only from the division of work but also from the built-in peer review that helps forge consensus on key scientific questions. A significant efficiency for the sponsor comes at the next stage, where a single, consolidated Request for Information (RFI) is issued, replacing multiple, staggered query cycles from each agency. After the sponsor's response to the RFI is assessed, each agency proceeds with its national-specific steps, such as label negotiations, before making its own final, independent marketing authorization decision. (4)

2.3 Strengths and Limitations

The Access pathway offers sponsors distinct strategic benefits. The use of a single set of questions and a coordinated review timeline introduces greater predictability across multiple countries. The need to respond to one consolidated RFI substantially lessens the regulatory burden compared to managing multiple, often overlapping, query cycles from different agencies. This parallel process also significantly increases the probability of achieving marketing authorization in several mature markets within a condensed timeframe, enabling the potential for a synchronized launch. (2-4)

However, there are important challenges and considerations. The pathway demands intensive upfront planning to ensure a high-quality common dossier is ready for simultaneous submission, as any deficiencies will be scrutinized by all participating agencies concurrently. A degree of strategic uncertainty is introduced by the fact that the sponsor has no control over which agency is designated the "lead" for reviewing a specific module, and different agencies may have different areas of focus. Finally, while the scientific review is collaborative, labeling negotiations remain a national responsibility. Sponsors must therefore still manage separate and sometimes divergent discussions to finalize product information in each jurisdiction. (2-4)

3. Project Orbis: Accelerating Access to cancer therapies

3.1 The mission

Project Orbis is a targeted initiative focused on oncology, led and coordinated by The U.S. FDA's Oncology Center of Excellence (OCE). The mission of OCE is to create a system for reviewing and submitting high-impact oncology products at the same time, so that patients all over the world can access them faster. FDA is the main coordinator for this model. The partners are a group of trusted global regulators, and many of them are Access members. The following agencies are Project Orbit partners. FDA (lead), Australia's TGA, Brazil's National Health Surveillance Agency (NHSA), Canada's (HC), Israel's Ministry of Health Pharmaceutical Administration (MHPA), Singapore's HAS, Swissmedic, and the UK's MHRA. (6)

3.2 The Orbis framework: Review Type and Submission Models

Project Orbis is not a rigid process to follow for sponsors. One of its best features is that it can be used in different ways depending on the sponsor's global filing strategy. The three types tell you what kind of collaboration it is:
Type A (Regular Orbis): This is the highest level of concurrency. Within 30 days of sending in the FDA application, the sponsor sends the application to the partner agencies. This allows for the most collaborative review possible, with Project Orbis partners attending FDA review meetings and sharing their assessments in real time, with the goal of deciding as close to the same time as possible. (5-6)
Type B (Modified Orbis): In this model, application is sent to Project Orbis partners more than 30 days after the FDA filing, but while the US-FDA's review is still active. This allows for a lot of concurrent review, but the collaboration is not as strong as in Type A. Project Orbis partners still get a head start by being able to read FDA review reports. (5-6)

Type C (Written Report Only Orbis): In this type, there is no concurrent review. The application is only sent to Project Orbis partners after FDA has taken action to regulate it. There is no review at the same time. Instead, this is an accelerated reliance pathway in which the FDA sends its completed review package to partners to expedite their national reviews. (5,6)

3.3 Impact on Oncology Product Approvals

A sponsor cannot unilaterally determine the utilization of the Orbis pathway; the product must be classified as an appropriate fit. The procedure usually commences with a proposal to FDA demonstrating the clinical benefit of the candidate that accelerates the approval across the globe.

FDA leads the review and designates Project Orbis partners to evaluate specific sections as lead or secondary reviewers in a collaborative effort via regular teleconference. The sponsor's team should be prepared to handle inquiries from multiple authorities within a limited timeframe. Notwithstanding this extensive collaboration, the ultimate approval decision is an autonomous determination for each nation. As a result, it is common for the final approved criteria or post-marketing obligations to vary across jurisdictions. (5-6)

3.4 Challenges and Sustainability Considerations

The primary strategic advantage for sponsors is the potential for unparalleled speed-to-market, as Project Orbis provides the quickest pathway to simultaneous or almost simultaneous multi-market approval for new oncology medicine. A seamless FDA assessment can positively impact and enhance the momentum of applications with partner agencies. The FDA's coordination role, albeit demanding, can introduce a level of organization to the otherwise chaotic management of multiple, separate, rapid reviews. Nonetheless, the obstacles are considerable. Entry requirements are stringent, as eligibility is often confined to high-impact cancer applications that meet the criteria for Priority Review, and the FDA rigorously selects the drugs that are approved. A Type A Orbis submission represents one of the most rigorous regulatory processes, necessitating a well-structured, resource-rich team adept at functioning under significant strain. The procedure is fundamentally FDA-centric, indicating that any delays in the FDA's review timeframe will produce immediate and substantial repercussions across all partner applications. (6-7)

4. Project Optimus: A paradigm shifts in dose selection

Project Optimus operates by modifying regulatory expectations, which are executed via new FDA guidelines and changing review practices. It is essential for regulatory professionals to assimilate these new standards, as they are rapidly shaping global development norms. Sponsors are primarily expected to perform randomized, parallel-group, dose-ranging studies early in the development process, prior to the commencement of a pivotal Phase 3 study. A mandate for dosage comparison currently exists, requiring sponsors to advance multiple doses from early development for thorough review. This entails generating comparative data regarding the efficacy and safety of a minimum of two doses, including the maximum tolerated dosage (MTD) and one or lesser doses.

The rationale for the chosen dosage must now be substantiated by a comprehensive evidence package. This package must encompass tumor response data, pharmacokinetics (PK), pharmacodynamics (PD), exposure-response modeling, and, importantly, patient-reported outcomes (PROs) to comprehensively define tolerability. The US-FDA has explicitly indicated that sponsors must participate in a focused dialogue regarding their dosage optimization plan prior to concluding the design of a crucial registration trial. (8)

Initiated by the US- FDA, Project Optimus is generating a worldwide impact. As the majority of prominent oncology projects are intended for global submission, these elevated the US-FDA standards are essentially becoming the standard requirements worldwide. Regulators at other prominent agencies have a philosophical alignment with this approach and are posing equally stringent inquiries regarding dose justification. This alignment fosters a type of "intellectual collaboration"; by meeting the requirements of Project Optimus, a sponsor concurrently cultivates a dossier that is significantly designed to succeed in other prominent jurisdictions. This program profoundly transforms early-stage development, necessitating a novel degree of synergy among regulatory, clinical, and commercial strategies. Input from regulatory affairs is essential from the initial clinical trial phases preparation to guarantee that the dose optimization method will endure future examination by health authorities. (8,9)

5. Comparing the collaborative models

To effectively utilize these programs, a clear understanding of each of them is essential. The accompanying **Table 1** provides comparative analysis between the three models.

Table 1. Comparative Analysis of ACCESS, Orbis, and Optimus

Feature	Access Consortium	Project Orbis	Project Optimus
Purpose	Procedural work-sharing	Procedural work-sharing	Scientific harmonization:
Approach	A formal division of assessment modules with peer review	A concurrent, collaborative review centrally coordinated by the FDA	Alignment of regulatory expectations for clinical development evidence
Functional category	Submission pathway	Submission pathway	Development standard
Sponsor's role	To proactively initiate the process and manage a coordinated, multiagency submission	To propose a candidate drug and manage an accelerated, FDA-led review	To redesign early clinical plans to generate robust dose-justification data
Desired outcome	Near-simultaneous approvals in 2-5 mature markets with greater predictability	The fastest possible route to multicountry approval for a breakthrough oncology drug	A robust dossier with a well-justified dose, able to withstand global regulatory scrutiny

These models can be combined to form a powerful, integrated global strategy. A potentially successful commercialization strategy for a new oncology product may encompass all three elements. The groundwork would

be established combining all three projects. Project Optimus has a clinical program meticulously structured to ascertain an appropriate dosage via randomized trials, underpinned by an extensive dataset. After a successful pivotal study, the sponsor could utilize this robust data package and significant unmet medical need to advocate for the drug's approval via Project Orbis Type A. The implementation will entail submitting the application to the US-FDA and designated Project Orbis partners. Access affiliates, including the TGA, HC, Swissmedic, and the MHRA. These agencies would thereafter cooperate under the Orbis framework to execute an effective, concurrent global assessment. The projects are not chosen independently but are arranged and integrated synergistically. Project Optimus offers the solid scientific basis necessary for an Orbis application, whilst Orbis supplies the procedural structure for a consortium of principal worldwide regulators to perform a concurrent evaluation.

6. Conclusion

Due to significant transition towards collaboration, the regulatory profession is evolving as well. The global regulatory framework has a significant impact of Access Consortium, Project Orbit and Project Optimus as these are transforming conventional approval process towards more dynamic, concurrent and strategically complex tasks. In this changing landscape, regulatory professionals must augment their skills to become global strategists, scientific interpreters, and internal advocates. To traverse these complex, interrelated pathways, one must plan and strictly follow established protocols. The function of the regulatory expert has transitioned from only comprehending regulations to devising a comprehensive global strategy. With the inclusion of such framework, regulatory leaders may expedite development, enhance patient access to treatment, and confer a competitive edge to their companies in an increasingly interconnected environment.

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Conflict of Interest

The authors declare that they have no competing interests related to this work.

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Abbreviations

EMA - European Medicines Agency
FDA - Food and Drug Administration
GMWSI - Generic Medicine Work-Sharing Initiative
HC - Health Canada
ICH- International Council for Harmonisation
MHPA - Ministry of Health Pharmaceutical Administration
MHRA - Medicines and Healthcare products Regulatory Agency
MTD - Maximum Tolerated Dose
NASWSI - New Active Substance Work-Sharing Initiative
NHSA - National Health Surveillance Agency
NRA - National Regulatory Authorities
OCE - Oncology Center of Excellence
PD - Pharmacodynamics
PK - Pharmacokinetics
PROs - Patient Reported Outcomes
TGA - Therapeutics Goods Administration

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