White Paper

Drug Registration 2022

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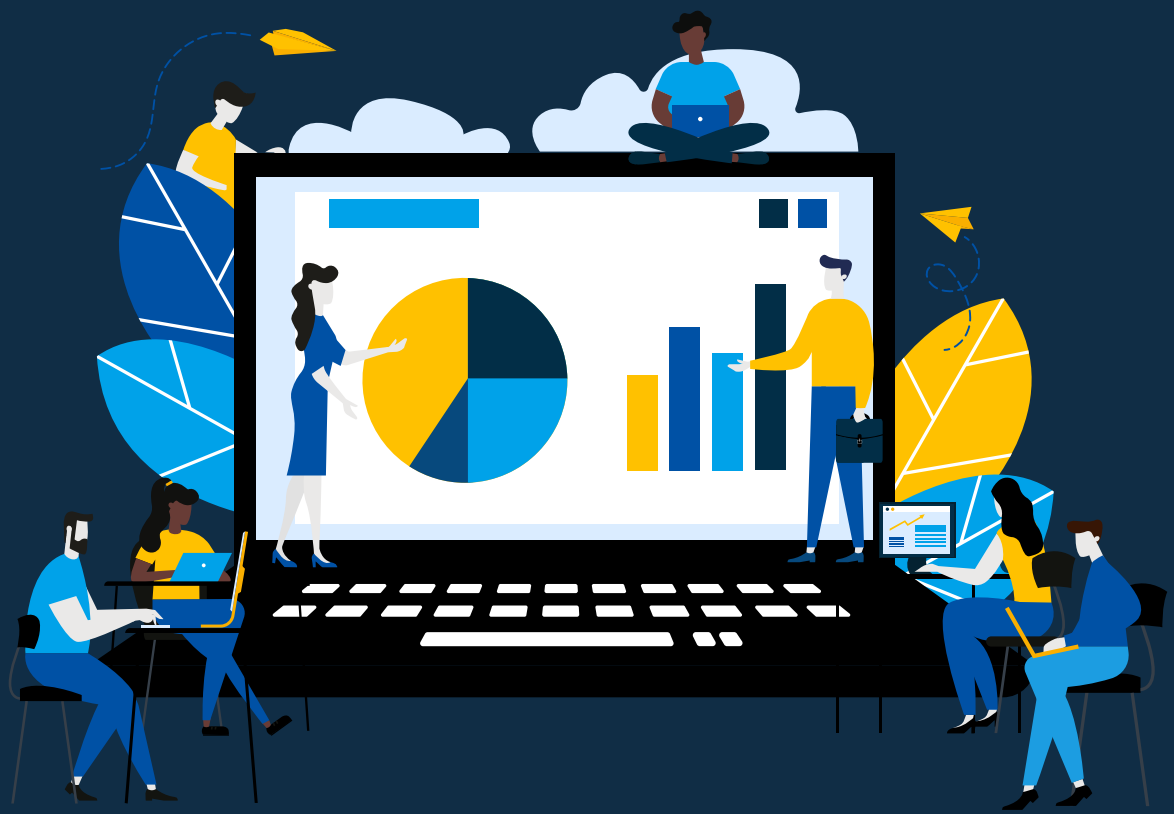
Project Orbis



Introduction

Project Orbis is an international collaborative e-framework initiated by the United States (US) Food & Drug administration (FDA) Oncology Center of Excellence (OCE) in May 2019. It was created to achieve one main objective, which is to facilitate the submission, review, and approval of oncology medicinal products. This framework allows concurrent submission and review amongst the Project Orbis Partners (POP's) [1].

This white paper will summarise how sponsors can get their oncology product approved via Project Orbis and how sponsors can utilise services provided by BlueReg Consultancy.

Current Members

1. U.S Food & Drug Administration (FDA)
2. Australian Therapeutics Goods Administration (TGA)
3. Brazil's National Health Surveillance Agency (Agência Nacional de Vigilância Sanitária (ANVISA)
4. Health Canada (HC)
5. Israel Ministry of Health (IMOH) Pharmaceutical Administration
6. Singapore Health Sciences Authority (HSA)
7. Switzerland Swissmedic
8. United Kingdom Medicines and Healthcare Products Regulatory Agency (MHRA)

Eligibility Criteria

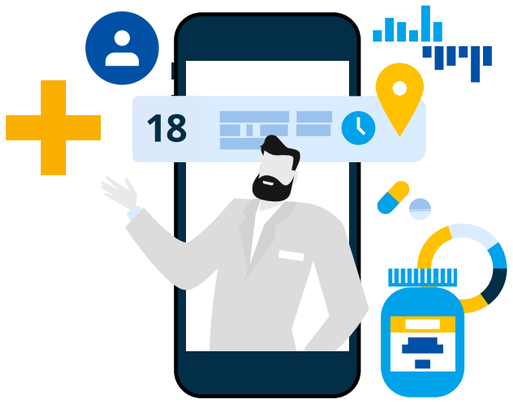
The product must be an oncology product and the procedure must be:

- A new marketing authorisation application (MAA) or
- A new indication application (variation)

All Project Orbis submissions must also meet the local POP's criteria.

The FDA is the primary coordinator and POP's may propose potential candidate products for consideration to the FDA. Similarly, sponsors can propose an application for Project Orbis, however it is important to understand that Project Orbis route cannot be chosen, selection remains at the US FDA's discretion.

Once results from registrational clinical trials are available an application for Project Orbis can be submitted to the FDA. When selected, the FDA will approach the sponsor to confirm, the product/indication which will be shared with all POP's to confirm interest in participation.



Application Requirements

A minimum of 2 POP's is required and must include the FDA to create a Project Orbis Working Group (POWG)

- Dossier must be in eCTD format and in English *(Exemptions might be made for country specific Module 1 documents)*
- Each application should conform to local requirements
- National fees will be applicable

For submission Type A and B (detailed further below), applicants must also provide an Assessment Aid (AAid) [2]. This is a document that helps increase review efficiency and reduce the need to seek clarification from the applicant throughout the review process. The AAid will be shared between POP's and it will serves as the core document for discussions between the agencies.

Sponsor Authorisation Letters (SAL) are also a requirement for all participating POP's. However, SAL's are not a requirement for non-participating countries. When a SAL is provided to non-participating members it allows the FDA to provide minimal redacted reviews to the non-participating Orbis countries.

Sponsor Authorization TEMPLATE Orbis.docx (live.com)

Submission Types

Type A :
These are applications submitted to Project Orbis Partners concurrently with the FDA submission or within 30 days.

Type B :
Applications which are submitted to POPs more than 30 days after US FDA submission.

Type C :
In the case where the US FDA has already taken regulatory action or will shortly approve an application the FDA will share complete review documents with participating POP's. (Applicant to submit all Response to Questions (RtQ) in Module 1).

Table 1. Types of Project Orbis submission plans [2]

	Project Obis Type	Sharing of FDA reviews	Multicountry meetings	Concurrent review with FDA	Plan for concurrent action with FDA
Type A	Regular	Yes	Yes	Yes	Possible
Type B	Modified	Yes	Yes	Possible	No
Type C	Written Report Only	Yes	No	No	No

Pre-submission Process

Application gets nominated.

The FDA sends a proposal POP to confirm their interest and availability to participate.

Sponsor gets acceptance notification and invited to meet and discuss timelines.

Sponsor send SAL to participating POP's.

Sponsor determines if Pre-submission meeting with each agency is required.

Once the Project Orbis partners are identified, FDA confirms the Global Submission Plan (GSP) through the sponsor.

Project Orbis-Global Submission Plan February 2022.docx (live.com)

Sponsors can be selective in POP's they would like to be involved in the review of their application. Therefore, an applicant can use this strategy to target only the counties they have commercial interest in.

Submission, Review and Approval

POP's will have regular conference call to collaborate and discuss the evaluation of the application.

Requests for information (RFI)- will sent directly to the regional sponsor.

POPs will share RFI prior to sending to the sponsor to limit duplication.

Sponsor to send response RFI to all POPs involved in the application.

Project Orbis Partners maintain independence on the regulatory outcome after a joint review - in contrast to the European Medecines Agency (EMA), where member states must comply with final authorization decisions.

As each Partner is independent in their regulatory decision making, to adhere to country specific regulation. This may result in differences approval or rejection of marketing authorization, the wording of the indications, and approval of other labelling content across the POP's.

Applicants will follow the post-market surveillance requirements of each member state.

Conclusion

Project Orbis can deliver fast access to innovative oncology therapies to patients. With a wide range of expertise and experience BlueReg can help you navigate through this regulatory maze and ensure high quality submissions to aid fast approvals via Project Orbis.

Abbreviations

A

AAid:
Assessment Aid

E

EMA:
European Medicines Agency

G

GSP:
Global Submission Plan

O

OCE:
Oncology Center of Excellence

P

POPs:
Project Orbis Partners

POWG:
The Project Orbis Working Group

R

RFI:
Request for Information

RTQ:
Response to Questions

S

SAL:
Sponsor Authorization Letter

U

US FDA:
United States (US) Food & Drug Administration

Bibliography

- **[1]** M. Shah, "FDA Approval Summary: Tucatinib for the Treatment of,» CLINICAL CANCER RESEARCH, 2021".
- **[2]** R. A. d. Claro, "Project Orbis: Global Collaborative Review Program,» CLINICAL CANCER RESEARCH, 2020".

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Any questions? Contact-us!

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