PROJECT ORBIS PARTNER

Project Orbis Partner (POP) is a programme to review and approve promising cancer drugs that helps patients gain faster access to treatments

Allows simultaneous dossier submission and review by different international Heatlh Authorities.

Speeds up patient access to innovative cancer treatments that may be more beneficial than existing therapies.

New Marketing Authorisation Applications (MAAs) or new indication applications (variations).

Coordinated by the FDA, it involves the regulatory authorities of: Australia, Canada, Singapore, Switzerland, Brazil, Israel and UK.

TYPES OF SUBMISSIONS

TYPE A

Type A: Applications to POPs should be submitted concurrently or within 30 days from FDA submission. These are termed 'Regular Orbis' and allow for maximal collaboration during the review phase and the possibility of concurrent action with FDA.

TYPE B

Type B: Applications submitted >30-day after submission to the FDA are termed "Modified Orbis" and allow possibility of concurrent review with FDA but no concurrent action.

TYPE C

Type C: If the FDA has already issued positive decision. Also called "Written Report Only Orbis", it allows the FDA to share the completed review documents with POP, but without concurrent review or action with FDA.

ADVANTAGES

AGILITY
Faster patient access to innovative cancer treatments

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SIMPLICITY
Simultaneous presentation of registration dossier

ASPHALION'S SERVICES

- Project Orbis request
- Pre-submission activities: pre-submission meetings, local regulatory requirements and Global Submission Plan (GSP)
- Dossier preparation/update
- Dossier publishing
- Support during the procedure

ASPHALION
Knowledge from experience

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