**Project Orbis Types**

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| **Orbis Type** | **Submission Timeline** | **Submission overlaps with FDA** | **Sharing of FDA reviews** | **Multi-country review meetings (POP TCONs)** | **POP Attendance at FDA review meetings** | **Concurrent review with FDA** | **Near concurrent action with FDA** |
| **Type A** | Application submission to POPs ≤ 1 month of FDA submission | Expected | Yes | Yes | Yes | Expected | Possible1  |
| **Type B** | Application submission to POPs > 1 month of FDA submission  | Expected | Yes | Yes | Yes | Possible | No1 |
| **Type C** | Any time after FDA submission2[[1]](#footnote-2) | Permitted2 | Yes | No | Unlikely | Unlikely | No1 |

1. Regulatory action in other jurisdictions is unlikely to occur immediately after FDA action and will follow respective health authority timelines.

2 Dependent on Project Orbis Partner (POP) guidelines. Contact specific POP(s) regarding optimal timing for submission of Type C dossier. [↑](#footnote-ref-2)