Oncology Center of Excellence Project Orbis (PO)
Request for Participation and Global Submission Plan

For FDA Use ONLY
PO#_____

Application Numbers	NDA/BLA # (pre-assigned if applicable)	Supplement #	IND number
Sponsor / Applicant			
Product Name			
Review Division			
Request Date			
Topline efficacy and safety results	Attach summary of topline results (maximum two pages)		
Combination Treatment ☐ Yes / ☐ No	If **YES** provide details of other application and if different applicant, indicate lead company. Ensure the 2nd company submits GSP and SALs. • Sponsor: • Product: • Application #s: • Lead Company for Project Orbis communications:		

Country	Application Type (*NME/NAS/BLA or supplement)	Proposed Indication	Proposed complete dossier submission (mm/dd/yyyy)	Sponsor or Sponsor-affiliate responsible for submission (contact info: name, phone, email)
USA				
Australia				
Brazil				
Canada				
Israel				
Japan				
Singapore				
Switzerland				
United Kingdom				

*NME/NAS: New Molecular Entity/New Active Substance

Country	a) provide rationale if not submitting to a POP(s) b) If not submitting to a POP(s), would you reconsider if POP is interested in participating?	Proposed Approval Pathway(s) and Requested Timeline (e.g., Standard/Priority)	Clinical Trial(s) Supporting Proposed Indication	Other relevant regulatory information (e.g., PIP or Orphan designation, NAS used with medical device, break through therapy designation, fast track designation, rolling review or real-time oncology review etc.)
USA	a) b)			
Australia	a) b)			
Brazil	a) b)			
Canada	a) b)			
Israel	a) b)			
Japan	a) b)			
Singapore	a) b)			
Switzerland	a) b)			
United Kingdom	a) b)			