Safety Reporting Timelines – Studies with Investigations Medicinal Products (IMPs)

Safety Event/Report	Sponsor			Local Principal Investigator	
	Investigators	HREC	TGA	RGO	Sponsor
SSIs (excluding USMs)	≤ 15 days	≤ 15 days	≤ 15 days	≤ 72 hours	
USMs	≤ 72 hours	≤ 72 hours	≤ 72 hours (strongly recommend ≤ 24 hrs)	≤ 72 hours	≤ 24 hours
SUSARs (Australian participants only)			Fatal/life-threatening – immediately but ≤ 7 days All other ≤ 15 days	≤ 72 hours (Local SUSARs only)	≤ 24 hours
SAEs (except those that do not require expedited reporting					≤ 24 hours
AEs/Lab Evaluations (critical to safety)					Per protocol
Annual Safety Report		Same time as Annual Progress Report			
Updated IB/PI	As applicable	As applicable			

Safety Reporting Timelines – Studies with Investigations Medical Devices (IMDs)

Safety Event/Report	Sponsor			Local Principal Investigator	
	Investigators	HREC	TGA	RGO	Sponsor
SSIs excluding USMs	≤ 15 days	≤ 15 days	≤ 15 days	≤ 72 hrs	
USMs	≤ 72 hrs	≤ 72 hrs but strongly recommend ≤ 24 hrs	≤ 72 hrs but strongly recommend ≤ 24 hrs	≤ 72 hrs	≤ 24 hours
USADEs (Australian participants only)			Fatal/life-threatening - immediately but ≤ 7 days All other USDAEs - ≤ 15 days	Local USDAEs only ≤ 72 hrs	≤ 24 hours
SAEs and device deficiencies that could have led to a SADE					Without unjustified delay
AEs and Device Deficiencies					per protocol
Pregnancies					per protocol
Annual Safety Report (or *DSUR)		(Same time as Annual Progress Report)			
Updated IFU/IB	(as applicable)	(as applicable)			