

Safety Reporting Timelines - Studies with Investigational 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 hours	
USMs	≤ 72 hours	≤ 72 hours but strongly recommend ≤24 hrs	≤ 72 hours but strongly recommend ≤ 24 hrs	≤ 72 hours	≤ 24 hours
USADEs (Australian participants only)			Fatal/life-threatening – immediately but ≤ 7 days All other ≤ 15 days	** ≤ 72 hours (Local USADEs only)	≤ 24 hours
SAEs and device deficiencies that could have led to a SADE					Without unjustified delay
AEs and Device deficiencies					Per protocol
Pregnancies		Same time as Annual Progress Report			Per protocol
Annual Safety Report (or *DSUR)		As applicable			
Updated IFU / IB	As applicable	As applicable			

* Within 72 hours of receipt from Sponsor

** Within 72 hours of Sponsor confirmation that the reported event is a SUSAR