

## Safety Reporting Timelines - Studies with Investigational 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 Investigator’s Brochure / Product Information	As applicable	As applicable			

\* Within 72 hours of receipt from Sponsor

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