

Pantai Hospital Kuala Lumpur Research and Ethics Committee

Safety Reporting Guidelines

Type of Events	Format	Timeline
SAEs OR SUSARs reported from Pantai Hospital Kuala Lumpur	PHKL REC Serious Adverse Event Reporting Form	<p>Fatal/ life threatening events</p> <ul style="list-style-type: none"> - As soon as possible but not later than 7 calendar days from awareness of event, follow up report within 8 additional calendar days <p>Other events (non-fatal/ non-life threatening)</p> <ul style="list-style-type: none"> - As soon as possible but not later than 15 calendar days from awareness of event
SUSARs reported from other Malaysia approved sites OR Foreign SUSARs OR Global SUSARs - Investigational Product (IP)	Individual SUSAR (CIOMS) OR Line listing - Protocol specific	3 monthly OR 6 monthly
SUSARs associated with Active Comparator OR Placebo	Individual SUSAR (CIOMS) OR Line listing - Protocol specific	Not mandatory
Temporary halt OR Early termination of the trial for safety reasons	Cover letter OR Sponsor's template	Within 15 calendar days
Annual Safety Report OR Development Safety Update Report (DSUR)	Sponsor's template	Annually