JAMES COOK UNIVERSITY

REQUIRED SAFETY MONITORING AND REPORTING IN CLINICAL TRIALS

SPONSOR RESPONSIBILITIES **NOTE: Whet(#84 (2DC 0122E)5.7 (:)32 (W)-5.3(h)-0e)-6 es.

Involving Investigational Medicinal Products (IMPs)

SPONSOR RESPONSIBILITIES

TYPE	Action	Time Frame

Advise the TGA, Investigators and their institutions of any decision to withdraw approval.	

INSTITUTION RESPONSIBILITIES

An Institution should:	
Assess whether any safety reports received, impact on medico-legal risk, the responsible conduct of research, adherence to contractual obligations or the trial's continued site authorization and, where applicable, facilitate the implementation of corrective and preventative action.	Develop clear guidance for investigators details the requirements of safety reporting and monitoring in clinical trials. This document should cover the requirements for externclf3.44 l (s)-4.3( )]TJ3p cll2w.9(s24 48 Tm.re)-349(s24 -3(n)2d0 Tm .3(al)(l)-

	One or more occurrences of an event that is not commonly associated with drug exposure, but is otherwise uncommon in the population exposed to the drug (e.g., tendon rupture). An aggregate analysis of specific events observed in a clinical trial (such as known consequences of the underlying disease or condition under investigation or other events that commonly occur in the study population independent of drug therapy) that indicates those events occur more frequently in the drug treatment group than in a concurrent or historical control group.
Investigator's Brochure (IB)	The document containing a summary of the clinical and non-clinical data relating to an investigational medicinal product that are relevant to the study of the product in humans.
Product Information (PI)	The approved Australian summary of the scientific information relevant to the safe and effective use of a prescription medicine. Note: In a trial in which the IMP is an approved product, the Product Information may replace the investigator's brochure. If the conditions of use differ from those authorised, the PI should be supplemented with a summary of relevant clinical and non-clinical data that supports the use of the IMP in the trial. The Australian Product Information should be used where available for each trial IMP adopted across Australian sites.
Reference Safety Information (RSI)	The information contained in either an investigator's brochure or an approved Australian Product Information (or another country's equivalent) that contains the information used to determine what adverse reactions are to be considered expected adverse reactions and on the frequency and nature of those adverse reactions.
Safety Critical Adverse Events	Adverse events and/or laboratory abnormalities identified in the protocol as critical to safety evaluations that should be reported to the sponsor according to the reporting requirements specified in the protocol.
Serious Adverse Event (SAE)/Serious Adverse Reaction (SAR)	Any adverse event/adverse reaction that results in death, is life-threatening, requires hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or is a congenital anomaly or birth defect. Note: Life-threatening in the definition of a serious adverse event or serious adverse reaction refers to an event in which the participant was at risk of death at the time of the event. It does not refer to an event that hypothetically might have caused death if it were more severe. Note: Medical and scientific judgement should be exercised in deciding whether an adverse event/ reaction should be classified as serious in other situations. Important medical events that are not immediately life-threatening or do not result in death or hospitalisation, but may jeopardise the participant or may require intervention to prevent one of the other outcomes listed in the definition above should also be considered serious.

Significant Safety Issue (SSI)