

Glossary of Terms

Adverse Event (AE) – any untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in a trial participant that is not related to intervention.

Adverse Reaction (AR) – adverse event that is related (i.e., reasonable possibility of a causal relationship to intervention) to the IMP/behavioural intervention (i.e., related to any dose/behavioural intervention administered).

Adverse Device Effect (ADE) – adverse event related to the IMD (i.e., related to the use of an investigational medical device).

Non-Serious Breach Report (Deviation) - is any breach, divergence or departure from the requirements of Good Clinical Practice or the clinical trial protocol and does not have a significant impact on the continued safety or rights of participants or the reliability and robustness of the data generated in the clinical trial. Deviations that are considered to be a serious breach should be reported using the Serious Breach Report Form (Sponsor).

Serious Adverse Event (SAE) – adverse event that is serious and not related to the intervention and that led to: (a) death; (b) serious deterioration in the health of the participant, that either resulted in: a life-threatening illness or injury, or a permanent impairment of a body structure or a body function, or in-patient or prolonged hospitalisation, or medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure of a body function; or (c) led to fetal distress, fetal death or a congenital abnormality or birth defect.

Serious Adverse Reaction (SAR) – adverse event that is serious and related to the IMP (or behavioural intervention) and results in any of the consequences characteristic of a serious adverse event.

Suspected Unexpected Serious Adverse Reaction (SUSAR) – serious adverse reaction that was unexpected.

Serious Adverse Device Effect (SADE) – adverse event that is serious and related to the IMD and results in any of the consequences characteristic of a serious adverse event.

Serious Breach Report – serious breach is a breach of Good Clinical Practice or the Clinical Trial protocol that is likely to affect to a significant degree the safety or rights of a research participant or the reliability and robustness.

Suspected Breach Report - suspected breach is a report that is judged by the investigator as a possible serious breach but has yet to be formally confirmed as a serious breach of Good Clinical Practice or clinical trial protocol by the sponsor.

Unanticipated Serious Adverse Device Effect (USADE) – serious adverse device effect that was unanticipated (i.e., effect which by its nature, incidence, severity or outcome has not been identified in the current version of the risk analysis report).

Significant Safety Issue (SSI) – safety issue that could adversely affect the safety of participants or materially impact on the continued ethical acceptability or conduct of the trial.