QUICK REFERENCE TOOL FOR
SERIOUS ADVERSE EVENTS (SAEs) / UNANTICIPATED PROBLEMS (UPs)
REPORTING TIMELINES TO THE Network REB

REPORTING TIMELINES TO THE REB

Serious Adverse Event (SAE) / Unanticipated Problem (UP) Reporting Timelines

Network (Local) SAE / UP - a serious, unexpected and related or possibly related adverse event that has occurred in a research participant in a study under the REB's jurisdiction

External SAE /UP - a serious, unexpected and related or possibly related adverse event that has occurred in a research participant enrolled in a multi-centre trial at a participating site which is external to Providence St. Joseph's and St. Michael's Healthcare and the SAE /UP requires a change to the research or notification to research participants

Unanticipated Problem (UP) - Any incident, experience, outcome that meets all the following criteria: unexpected in relation to the research and/or patient population and related or possibly related to participation in the research and points to increased risk/harm to the research participant

Type of Event	Reporting Timeline* to the REB *within study team awareness of event / report
Network (Local) SAE / Unanticipated problem	**7 days**
Network (Local) SAE / Unanticipated problem that is fatal or life-threatening	**3 days**
External SAE / Unanticipated problem / requires change(s) and/or notification to participants	**7 days**
Other Unanticipated Problem	**15 days**
Updated Safety Information e.g. Periodic Safety Update Report, revised Investigator's Brochure	**15 days**
If Investigator is Study Sponsor, Health Canada approved drug trial	**Reporting Timeline* to Health Canada *within study team awareness of event / report**
Serious Unexpected–Adverse Drug Reaction (SU-ADR)	**15 days**
SU-ADR that is fatal or life threatening	**7 days with follow-up within 8 days**

Protocol Deviation Reporting Timeline

Protocol Deviation - An unanticipated or unintentional divergence from the expected conduct of an approved study that is not consistent with the current approved research protocol, consent document or study addenda

Type of Event	Reporting Timeline* to the REB *within study team awareness of event / report
Protocol Deviation	**15 days**