

7.6 Recognition and Reporting of Adverse Events (AEs)

The Designated Satellite Investigator (DSI) or delegate must ensure prompt recognition and reporting of [Adverse Events \(AEs\)](#) to the referring specialized childhood cancer program. The specialized childhood cancer program principal investigator (PI) holds the ultimate reporting responsibility to [Children’s Oncology Group \(COG\)](#) or other cooperative group study administrators, [Ontario Cancer Research Ethics Board \(OCREB\)](#) and [Health Canada](#).

Description of AEs will be sent from the POGO Satellite Clinic program to the specialized childhood cancer program as part of the patient’s source documentation and will be reported to the study sponsor as per the protocol and to OCREB and Health Canada as per their requirements and the specialized childhood cancer program Standard Operating Procedures (SOPs).

For Severe Adverse Events (SAEs), the POGO Satellite Clinic must provide the information and all source documentation available to the specialized childhood cancer program within 24 hours of the event to ensure timely expedited reporting.

Disclaimer: Source Accuracy

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Record of Updates

Version Number	Date of Effect	Summary of Revisions
1	2/24/2022	<ul style="list-style-type: none"> Original version posted.

