SERIOUS ADVERSE EVENT ASSESSMENT FORM

SAE Number	1
Report Type	✓ Initial ❑ Follow-up
Report Number	1

STUDY / SITE INFORMATION	
Study Protocol No.	CTN 329
Multi-centre study:	✓ Yes ❑ No
Study Site Name and No.:	McGill University Health Center, Site 102
Qualified Investigator:	Dr. Joseph Cox
Site Reporter Name and contact:	Nathalie Paisible nathalie.paisible@muhc.mcgill.ca

PARTICIPANT INFORMATION	
Participant Letter Code (if applicable):	AAF
Participant ID:	102006
Participant Age [redacted]	56 yo

SAE INFORMATION	
SAE Onset Date:	08Oct2024
Date of Notification to Sponsor/SI: ERROR 04NOV 2024	~~08Oct2024~~ 04NOV2024
Date Report Received by Study PM	04NOV 2024
SAE Name/Event: A perforated rectum due to sexual trauma	
Brief SAE Description (provide further information): Patient came to clinic for visit week 24 and informed me he had to have emergency surgery due to a perforated rectum caused by sexual trauma. Incident occurred on 08Oct2024, patient had emergency surgery on 08Oct2024. He was hospitalized for a total of 7 days. He now has a temporary stoma which should be reversed within the next 3 months. Chart to be request *Describe event, when it occurred, what happened, treatment provided. Include symptoms, abnormal test results etc.*	
List of Attached SAE documentation	✓ SAE CRF ❑ [ER report, lab results, or an additional note on SAE event from the QI]

04NOV 2024

MEDICAL MONITOR ASSESSMENT

To Medical Monitor: Submit completed assessment to Study Project Manager by 07-Nov-2024

Is the event "Serious"?[i]	☑ Yes ☐ No
Is the event "Related" to study intervention? *(Is the event at least possibly related to study intervention?)*	☐ Yes ☑ No
Is the event "Unexpected"? *(Is the event not listed in Investigator's Brochure or Product Monograph?)*	☑ Yes ☐ No
Is this an Expedited Report? (Check one) *(Is the event serious, related and unexpected?)* The timeline for reporting to Health Canada begins when the SI first learns about a serious and unexpected Adverse Drug Reaction (ADR). An ADR is subject to expedited reporting when it is **serious** and **unexpected** and **suspected** to be related to study drug: Where it is neither fatal or life-threatening, report **within 15 calendar days** after becoming aware of the information, or Where it is fatal or life-threatening, report **within 7 calendar days** after becoming aware of the information. **Within 8 calendar days** after initially informing Health Canada of the fatal or life-threatening ADR, submit as complete a report as possible.	☐ YES, 7-day report (death or life-threatening) **Reporting Deadline to Health Canada: [DD-MMM-YYYY]** ☐ YES, 8-day *follow-up* report (death or life-threatening) **Reporting Deadline to Health Canada: [DD-MMM-YYYY]** ☐ YES, 15-day report (other unexpected SADR) **Reporting Deadline to Health Canada: [DD-MMM-YYYY]** ☑ No
Medical Monitor assessment consistent with QI or sub-investigator assessment	☑ Yes ☐ No

Comments:

CASE REVIEWED AND I AGREE WITH QI REPORT

MALCOLM HEDLCOCK MD

Name and Title

Signature

6 NOV 2024

Date [DD-MMM-YYYY]

[i] An AE is to be considered serious if any of the following apply:

- **Death** during the period of protocol-defined surveillance
- **Life Threatening Event** (defined as a participant at immediate risk of death at the time of the event)
- **In-patient hospitalization or prolongation of existing hospitalization** during the period of protocol-defined surveillance
- **Results in congenital anomaly or birth defect**
- **Results in a persistent or significant disability/incapacity**
- **Any other important medical event** that may not result in one of the above outcomes, may be considered a serious adverse experience when, based upon appropriate medical judgment, the event may jeopardize the participant and may require medical or surgical intervention to prevent one of the outcomes listed above. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in in-patient hospitalization, or the development of drug dependency or drug abuse.