Winnipeg Regional Health Authority | Office régional de la santé de Winnipeg

QUALITY IMPROVEMENT & PATIENT SAFETY

ADVERSE DRUG REACTIONS (ADR) AND MEDICAL DEVICE INCIDENTS (MDI)
Site Representative & Quality Improvement and Patient Safety
Standard Operating Procedure After Submission in RL

Please reference WRHA policy:
Adverse Drug Reaction (ADR) Documentation and Reporting – #110.000.480
Medical Device Incident (MDI) Mandatory Reporting to Health Canada - #110.000.490

Step	Actions	Person Responsible	When
1	Upon RL notification of a new submission, the Site Representative will within 7 business days of the submission: • For MDIs in hospitals, consult Clinical Engineering, as required • Review and include additional information, as needed, in the mandatory fields. • De-identify information entered in the narrative fields to comply with the Personal Health Information Act (e.g. any reference to the name of the hospital, staff member or the affected person). • Select the "Health Canada Initial Report" category in the RL file	Site Representative	Within 7 business days of submission
2	If site managers with scope to access RL file also receive the RL notification for MDIs, the information in the file is not to be altered without first discussing with the Site Representative. • The RL file is NOT to be closed by anyone other than the site representative.	Site Representative (Site/Program Managers with scope to access RL files for MDIs)	Ongoing
3	On the 1st and 15th of every month, the RL system will generate an Excel spreadsheet with ADR and MDI information which will be reported to Health Canada (HC): • The information on the Excel spreadsheet will include, at minimum, the mandatory fields required by Health Canada • On the 1st of every month, the submission to Health Canada will include all ADRs and MDIs reported from the 1st to the 15th inclusive of the previous month • On the 15th of every month, the submission to Health Canada will include all ADRs and MDIs reported from the 16th to the last day inclusive of the previous month. Note: this is to allow sufficient time for the Site Representative to fully review the ADR and MDI submissions prior to their submission to Health Canada.	Quality and Patient Safety	1st and 15th of every month
4	The ADR and MDI information is to be compressed into a ZIP format and sent to Health Canada via a secure file transfer protocol (SFTP - Filezilla). Each report will include: • Report type (ADR or MDI) • Site Name/ HC Institutional ID/ WRHA/Site Representative • YYYY-MM-DD (File name must not exceed 75 characters).	Quality and Patient Safety	1st and 15th of every month

Step	Actions	Person Responsible	When
5	An email will be sent to Health Canada that includes the file names, the number of files transferred, and the date the submission was completed. • An auto-acknowledgement email will be sent by HC that only confirms the receipt of the reporter's e-mail and NOT the receipt of the submitted reports.	Quality and Patient Safety	1st and 15th of every month
6	A reference number will be assigned by Health Canada to each ADR and MDI report. An official acknowledgement letter will be sent to WRHA Quality and Patient Safety via e-mail when the reports have been entered in the HC Canada Vigilance database.	Health Canada	After receipt of ADR and MDI reports
7	Each reference number provided by Health Canada will be added to the corresponding RL file.	Quality and Patient Safety	Within two business days of receipt
8	An RL notification will be sent to inform of the reference number. Print or save for future reference.	Site Representative	Within 5 business days
9	For ADRs, the RL file can be closed. For MDIs, the role of the Site Representative may be concluded; the RL file may be closed after the Site/Program Managers with scope to access RL file have concluded with the management of the file.	Site Representative & Site/Program Managers with scope to access RL file	Upon completion of submission to Health Canada
10	For any additional information requested by Health Canada, obtain the health record and/or contact the reporter. • Enter the information in the RL file • Select the "Health Canada Follow up Report" category in the RL file (this will generate another report which will be forwarded to HC on the next submission date)	Site Representative	Upon request from Health Canada
11	Repeat Step 9 as applicable • The file can always be re-opened if additional information is requested by Health Canada.	Site Representative & Site/Program Managers with scope to access RL file	Upon completion of submission to Health Canada
12	If a change in site representative is required (e.g. retirement, change in position, etc.), inform leadership as soon as possible to avert a breakdown in the process. A replacement will be designated and the following notified: • Health Canada by e-mail: hc.canada.vigilance.sc@canada.ca • RL staff by e-mail: rl_support@wrha.mb.ca	Site Representative & Site leadership	Upon knowledge of departure