SITE:	**APPROVED BY:**
CATEGORY: Archive Process (01)	**SIGNED (BLUE INK):**
PREPARED BY: Trevor Soll	**DATE SIGNED:**

ADVERSE DRUG REACTION REPORTING PROCESS

INTRODUCTION

This SOP describes how to prepare and complete an Adverse Drug Reaction (ADR) in CHARMS (Canadian Haemophilia Assessment and Resource Management System).

CHARMS is an MS Access Database that is utilized by 26 Haemophilia clinics across Canada. It collects data on product distribution, clinical outcomes, adverse events, genotyping, and has clinical, nursing and study consent modules.

Confirmed ADRs are posted in CHARMS with corresponding data placed in the Health Canada ADR Report. This information is sent out to all intended recipients via the CHARMS webserver.

Responsibilities:

Haemophilia Clinics

- Tracking of patient haemophilia records in CHARMS
  - Includes product names, lot numbers, quantity, infusion diary, etc.
- Quick response to patient concerns
- Review/update of ADR reporting in patient charts and CHARMS
- Haemophilia physician approves symptoms as ADR

AHCDC

- Notifying clinic of any discrepancies and omissions of ADR submissions
- Notifying the Principle Investigator of all discrepancies and their resolution
- Review of ADR reports

** this documentation reflects the assumption that the user has basic knowledge of the CHARMS program

AMENDMENTS FROM PREVIOUS DOCUMENT

None

DOCUMENTATION REQUIRED

This SOP Title:
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MATERIALS

Adverse Drug Reaction details

EQUIPMENT/INSTRUMENTS

PC running the CHARMS program

PRECAUTIONS

01) Ensure correct patient data is entered in CHARMS.

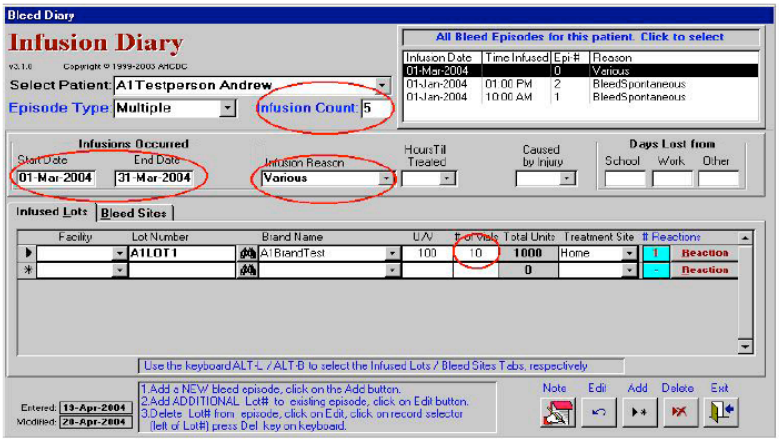
02) Ensure patient name/PHN matches the Canadian Haemophilia Registry (CHR) Number that is referenced in CHARMS

03) It is mandatory that only one designated person at each clinic have the authority to submit this report. It will be up to the Clinic Director to make this choice.

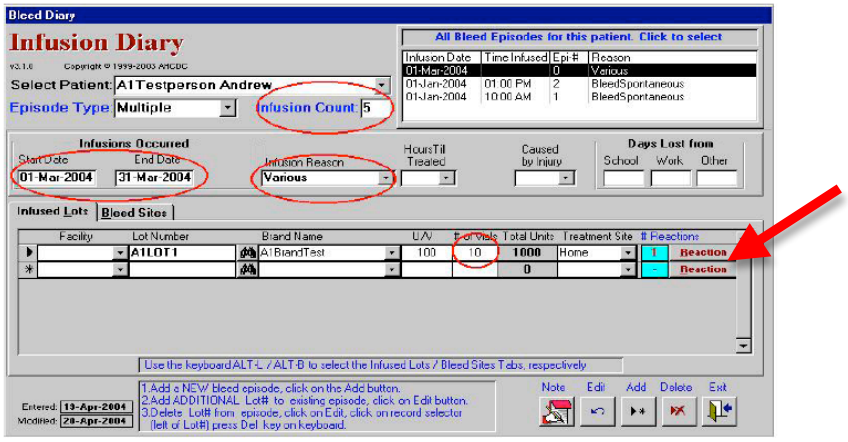
PROCESS

A. Log into CHARMS

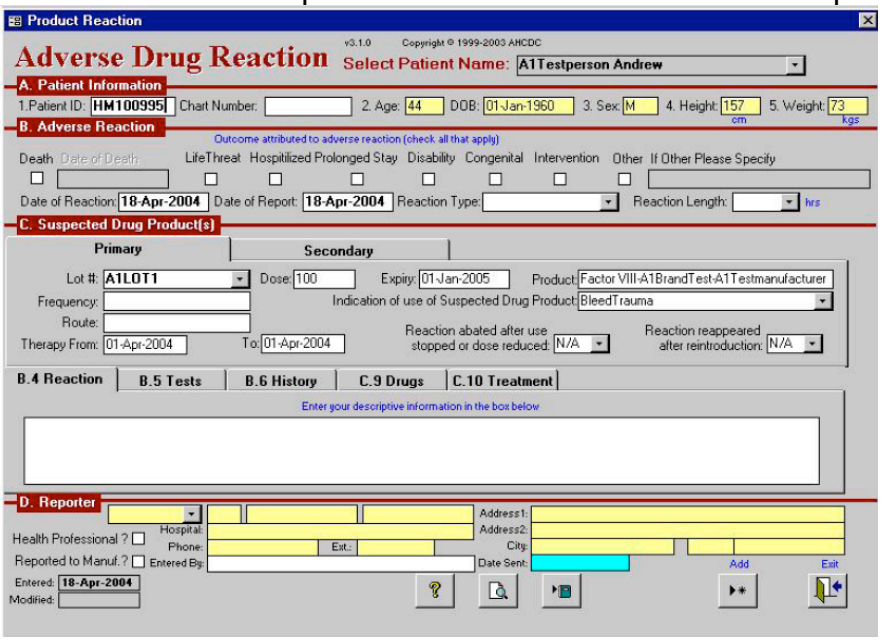
01) Upon logging into CHARMs, use the Infusion Diary and locate the infusion episode



02) Select the line item of product infused prior to the reaction reported by the patient.



03) Click on the Reaction button and proceed to fill in the Adverse Event report.

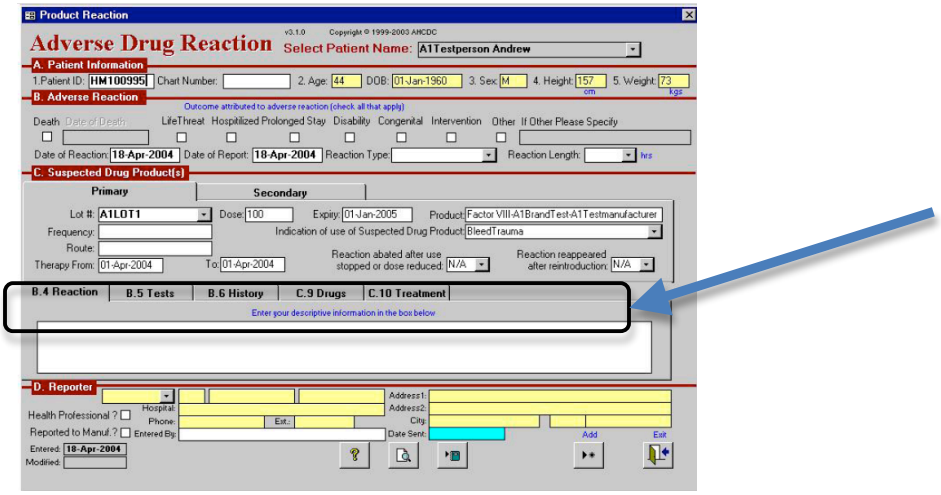


A. Some cells may be pre-populated with existing data (ie UI#, last recorded weight, age, date of birth). Please review to ensure all is correct.

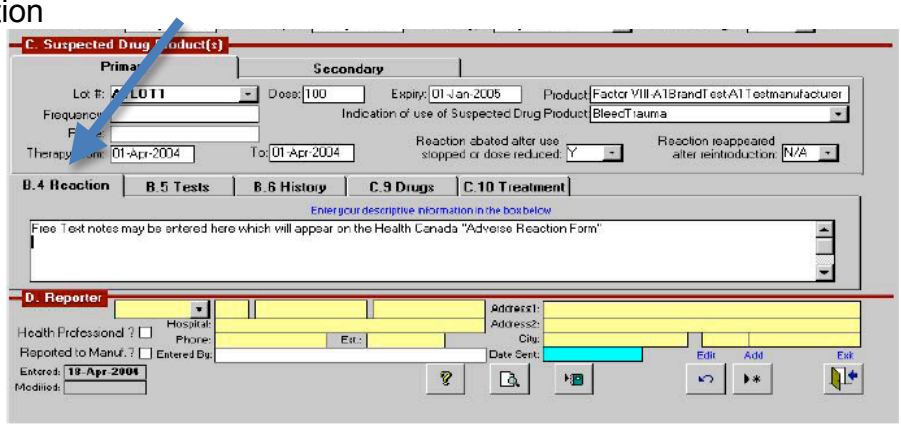
B. 'Primary' product tab. This tab records the product infused as selected from the Infusion Diary to initiate the report. If there is a need to report a secondary product infused, enter the details by selecting the 'Secondary' tab.

04) Complete 'Section C' sub-tabs (B4. Reaction, B5. Tests, B6. History, C9. Drugs, C10. Treatment).

Note: Most information is to be entered manually with the exception of B5. Tests where you can select the applicable test results as well as add text. All information inputted in each section will be added on the Health Canada 'Adverse Reaction Form'

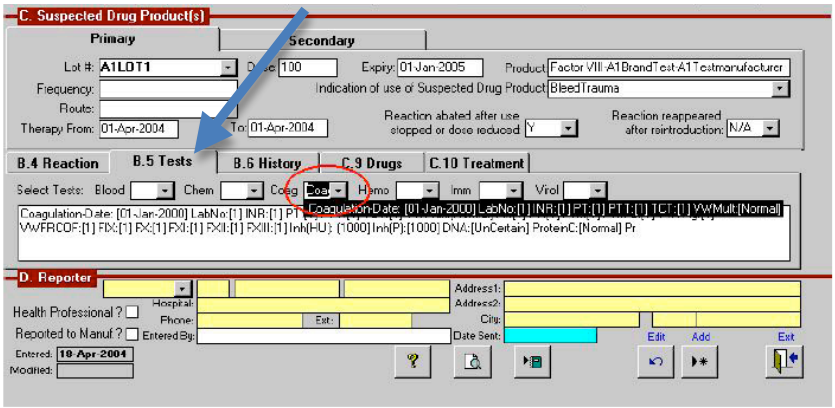


B.4. Reaction



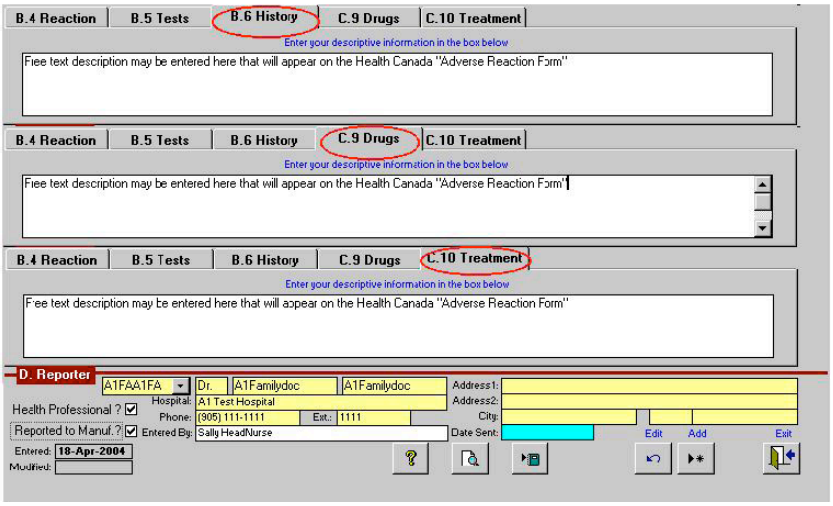
Enter patient reaction details here.

B.5. Tests



Edit and submit on the lab results that are applicable.

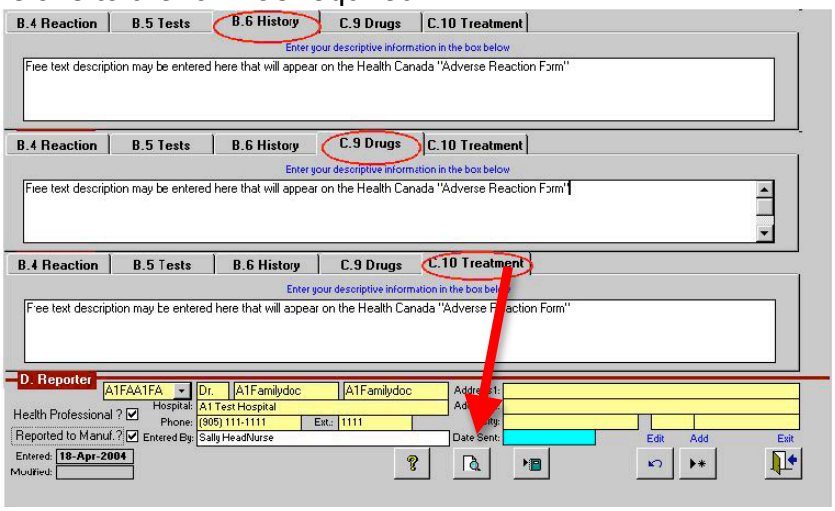
B.6-10



History, Drugs and Treatment tabs will allow all the administrator to describe each section in detail.

05) Report Preview

It is recommended that the report be reviewed by the Clinic Director or reporting Health Professional before it is submitted. To preview the report, click on the magnifying glass. Make any revisions to the form as required.



06) Submitting the Adverse Event

Click on the Save button to submit the ADR. Click 'Yes' on the popup box to finalize the submission.

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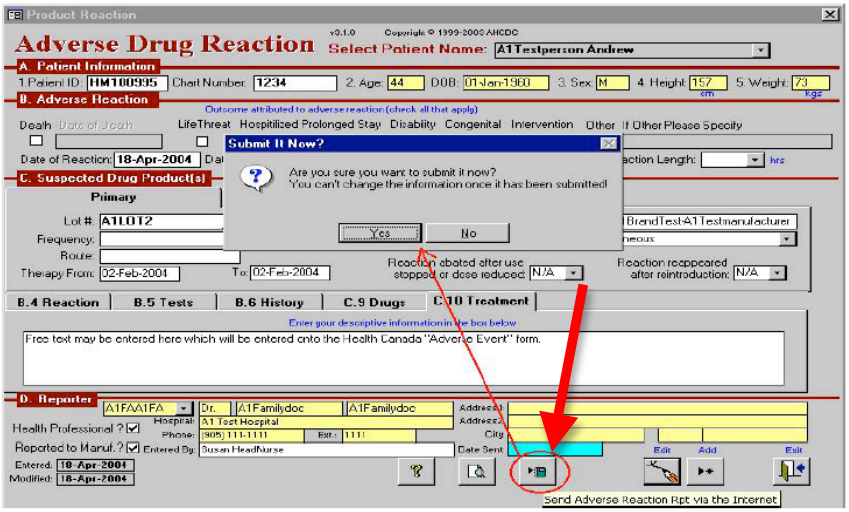
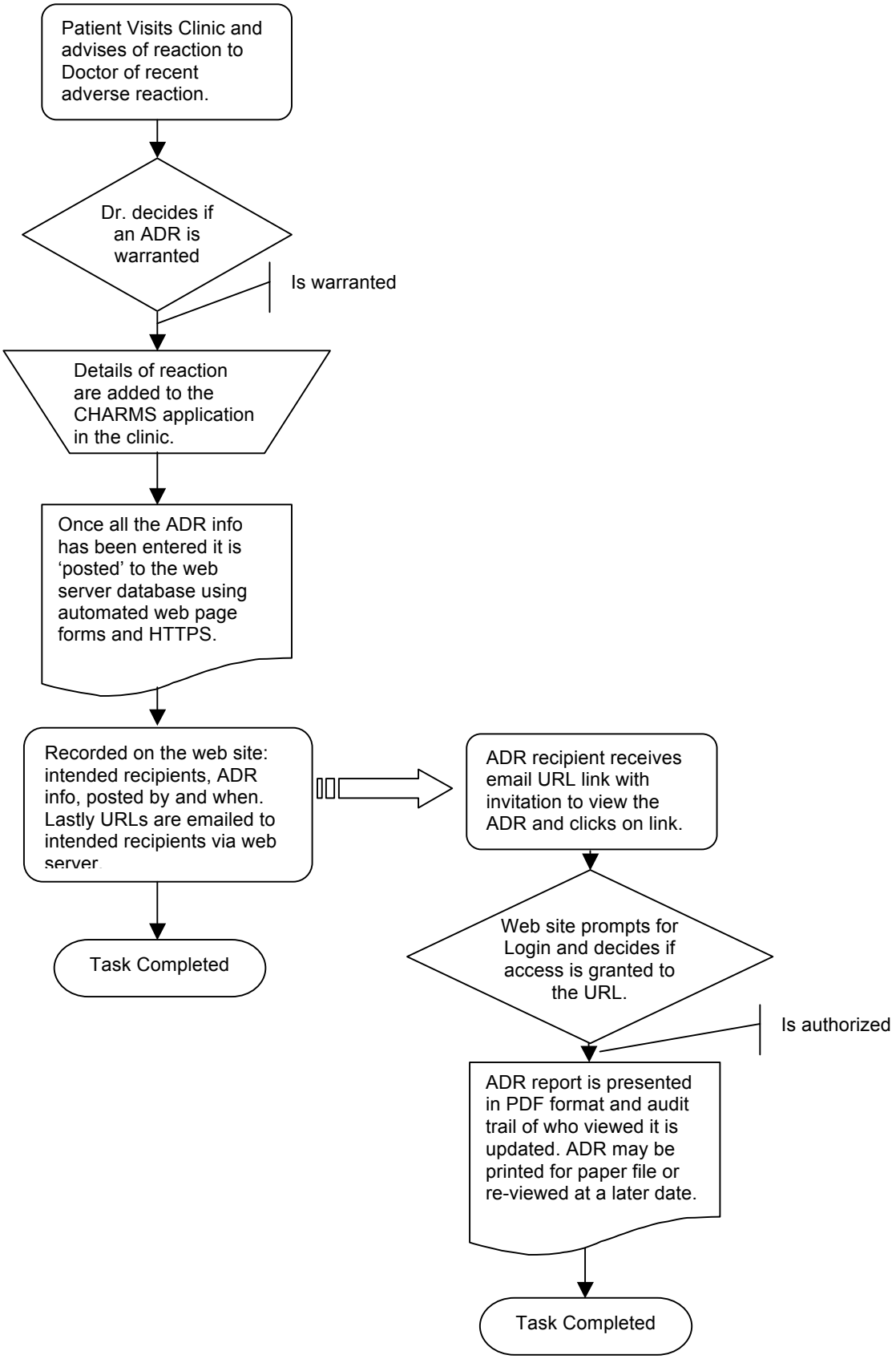


END OF SOP

CHARMS Adverse Reaction Reporting Process Data Flow Diagram



CHARMS ADVERSE EVENT REPORTING MODULE

EMAIL FLOWCHART