

<b>SITE:</b>	<b>APPROVED BY:</b>
<b>CATEGORY: Archive Process (01)</b>	<b>SIGNED (BLUE INK):</b>
<b>PREPARED BY: Trevor Soll</b>	<b>DATE SIGNED:</b>

## **ADVERSE DRUG REACTION REPORT REVIEW PROCESS**

### **INTRODUCTION**

This SOP describes how to review an Adverse Drug Reaction (ADR) that has been sent out by 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

- Ensure an up-to-date list of ADR recipients is made available to the AHCDC
- Quick response/review of the ADR
- Haemophilia physician approves symptoms as ADR

AHCDC

- Review of ADR and verify ADR access by intended
- Follow-up with non-reviewers to determine if they received the ADR email

\*\* this documentation reflects the assumption that the user has basic computer skills \*\*

### **AMENDMENTS FROM PREVIOUS DOCUMENT**

None

### **DOCUMENTATION REQUIRED**

This SOP Title:  
File name:

### **MATERIALS**

None

Version Date: Mardch 15, 2012	Document control #:	<b>CHARMS-ADR2</b>
Print Date: 2012-09-18	Document Type:	SOP
Page: 1 of 6	Controlled copy #:	1. Master

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# ADVERSE DRUG REACTION REPORTING

AHCDC

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PREPARED BY: Trevor Soll

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## EQUIPMENT/INSTRUMENTS

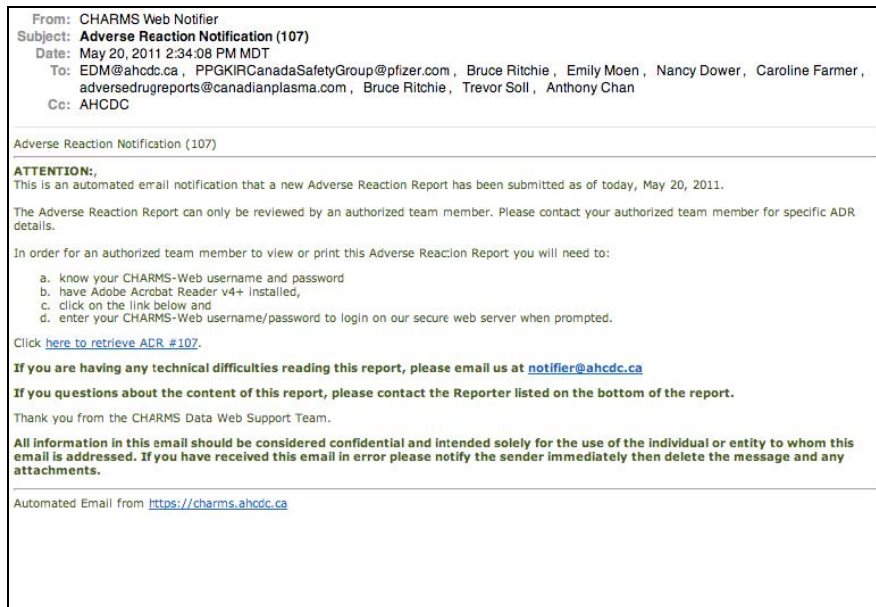
PC running Adobe Acrobat Reader v4+

## PRECAUTIONS

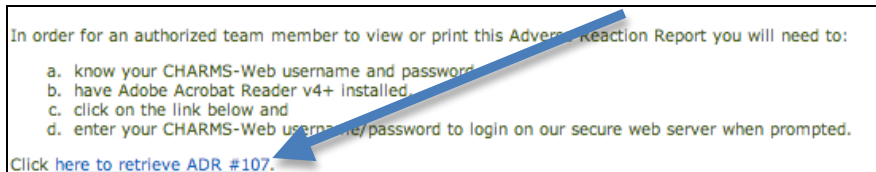
01) Ensure each approved ADR recipient has their CHARMS-Web username and password.

## PROCESS 1 – How to review a posted ADR

01) Upon final logging of an ADR by the clinic, the following email (sample) will be sent out to the intended recipients notifying them that an ADR has been submitted.



02) Click on 'here to retrieve ADR #xxxx'



03) This will launch your web-browser (ie. Internet Explorer, Firefox, Safari) taking you to the CHARMS Data-web login (<https://charms.ahcdc.ca/login.asp>)

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Document control #:

**CHARMS-ADR2**

Print Date: 2012-09-18

Document Type:

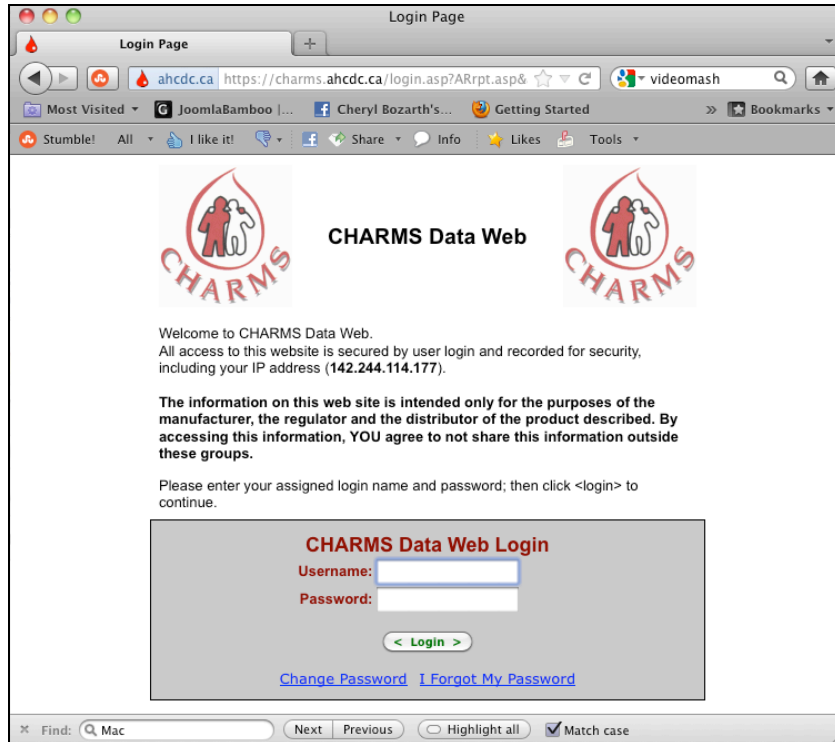
SOP

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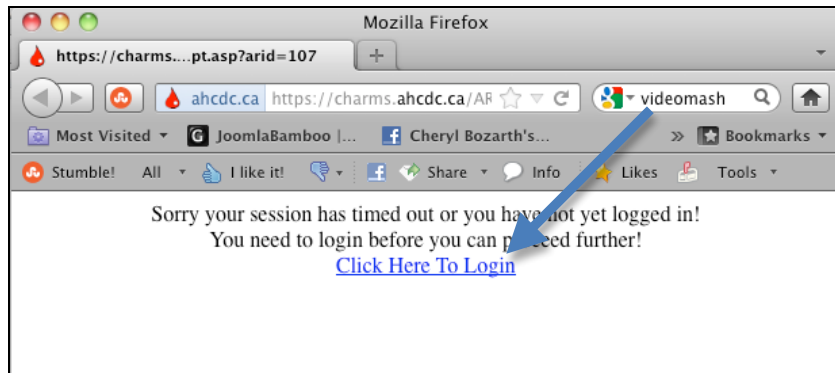
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If you have previously entered into this system, you may be directed to re-login. Follow the 'Click here to Login' which takes you back to the main log-in screen.



04) Enter your Username and Password and click 'Login'

05) The ADR data will be downloaded to your computer and your Adobe Reader program will open showing the completed Health Canada Adverse Reaction Reporting Form

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<b>Canada Vigilance Adverse Reaction Reporting Form</b> Report of suspected adverse reactions to marketed health products in Canada																																																																							
See instructions and information on adverse reaction reporting and confidentiality on Page 2. Complete all mandatory items, marked by *, and provide as much information as possible for the remaining items. PROTECTED WHEN COMPLETED - B**																																																																							
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th colspan="2" style="background-color: #4a4a8a; color: white;">A. Patient Information</th> </tr> <tr> <td style="width: 50%;">1. Identifier <small>EDM TEST (#107)</small></td> <td style="width: 50%;"></td> </tr> <tr> <td>2. Age</td> <td>3. Sex* <input type="checkbox"/> Male <input type="checkbox"/> Female</td> </tr> <tr> <td><input type="checkbox"/> Years <input type="checkbox"/> Months</td> <td>4. Height <small>cm / feet</small></td> </tr> <tr> <td></td> <td>5. Weight <small>kg / lbs</small></td> </tr> </table> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th colspan="2" style="background-color: #4a4a8a; color: white;">B. Adverse Reaction</th> </tr> <tr> <td colspan="2">1. 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** As per the Treasury Board of Canada Secretariat Government Security Policy A program of MedEffect™ Canada HC Pub: 100251 (April 2010)																																																																							
																																																																							

**END OF PROCESS 1**

**PROCESS 2 – How to view ALL previous ADR’s submitted by your Clinic**

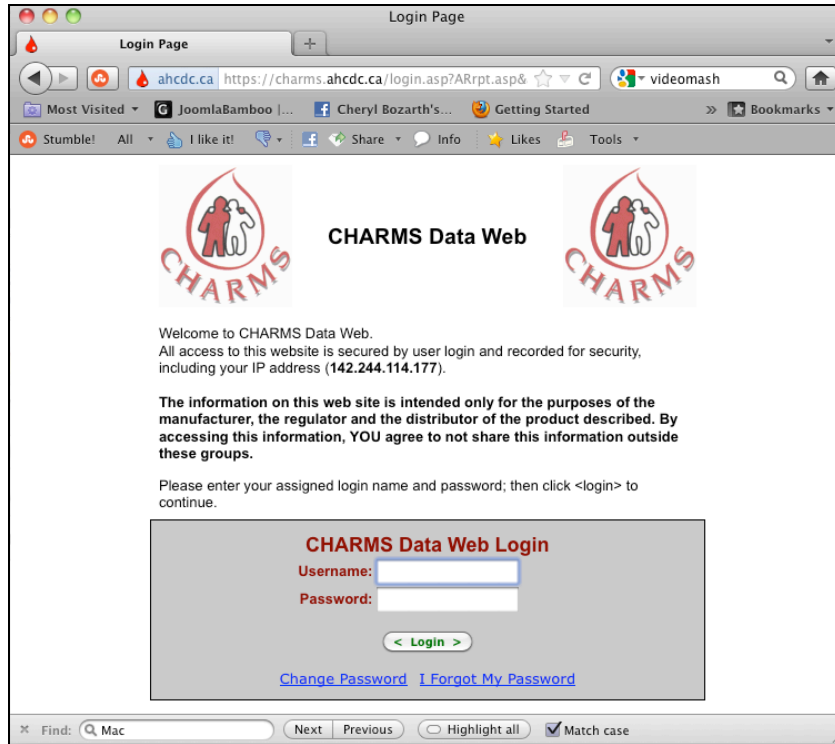
This section informs the users that they can login using their individual access codes to view ALL previously reported ADR’s submitted by your clinic.

01) Launch your web-browser (ie. Internet Explorer, Firefox, Safari) taking you to the CHARMS Data-web login (<https://charms.ahcdc.ca/login.asp>)

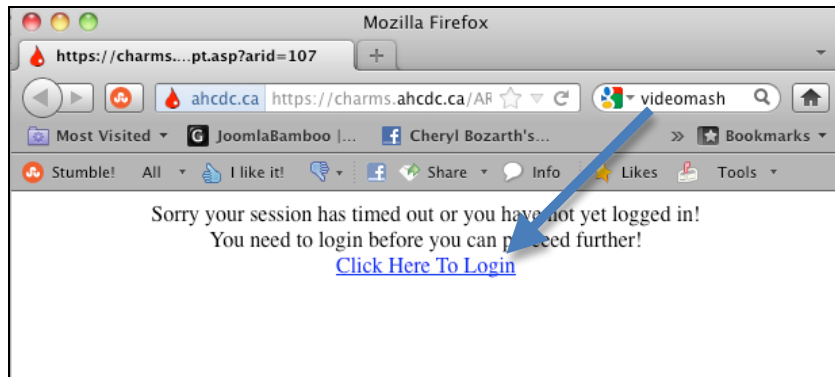
02) Enter your username password when prompted

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<b>PREPARED BY: Trevor Soll</b>	<b>DATE SIGNED:</b>



If you have previously entered into this system, you may be directed to re-login. Follow the 'Click here to Login' which takes you back to the main log-in screen.



03) Enter your Username and Password and click 'Login'

04) From the main menu click on 'Adverse Reaction Reporting'

# ADVERSE DRUG REACTION REPORTING

AHCDC

<b>SITE:</b>	<b>APPROVED BY:</b>
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05) A list of all ADR's from your clinic will be displayed, you can view the details of each ADR by clicking in the blue hilited "AR RPT" column.

The prefilled Health Canada form will be displayed.

AR Rpt	Rpt Date	Product Description	Manufacturer	Last Accessed	From IP	Accessed By
122	Feb 7, 2012	Factor VIII-AHCDCBrand-AHCDC	AHCDC			Theresa Almonte (HAM)
121	Feb 6, 2012	Factor VIII-Citrix Test Brand-AHCDC	AHCDC			Theresa Almonte (HAM)
120	Feb 3, 2012	Factor VIII-AHCDCBrand-AHCDC	AHCDC			Theresa Almonte (HAM)
119	Feb 3, 2012	Factor VIII-AHCDCBrand-AHCDC	AHCDC			Theresa Almonte (HAM)
118	Feb 3, 2012	Factor VIII-AHCDCBrand-AHCDC	AHCDC			Theresa Almonte (HAM)
117	Jan 10, 2012	Factor VIII-Citrix Test Brand-AHCDC	AHCDC			Theresa Almonte (HAM)
115	Nov 24, 2011	Factor VIII-AHCDCBrand-AHCDC	AHCDC	Nov 24, 2011 3:37 pm	142.21.40.214	Theresa Almonte (HAM)
114	Nov 16, 2011	Factor VIII-AHCDCBrand-AHCDC	AHCDC			Theresa Almonte (HAM)
113	Sep 25, 2011	Factor VIII-Citrix Test Brand-AHCDC	AHCDC			Theresa Almonte (HAM)
112	Sep 25, 2011	Factor VIII-Citrix Test Brand-AHCDC	AHCDC			Theresa Almonte (HAM)
98	May 19, 2011	Factor VIII-AHCDCBrand-AHCDC	AHCDC	Oct 19, 2011 3:27 pm	142.21.40.214	Theresa Almonte (HAM)
71	Nov 19, 2010	Factor VIII-AHCDCBrand4-Baxter Corporation	Baxter Corporation			Theresa Almonte (HAM)
70	Nov 19, 2010	Factor VIII-AHCDCBrand4-Baxter Corporation	Baxter Corporation	Nov 19, 2010 3:20 pm	142.21.40.235	Theresa Almonte (HAM)
67	Nov 16, 2010	Factor VIII-AHCDCBrand-AHCDC	AHCDC	Nov 16, 2010 12:19 am	142.21.30.211	Theresa Almonte (HAM)
66	Nov 8, 2010	Factor VIII-AHCDCBrand-AHCDC	AHCDC	Nov 15, 2010 3:34 pm	142.21.40.239	Theresa Almonte (HAM)
64	Nov 3, 2010	Factor VIII-AHCDCBrand-AHCDC	AHCDC	Nov 3, 2010 3:13 pm	142.21.30.213	Theresa Almonte (HAM)
60	Sep 21, 2010	Factor VIII-AHCDCBrand-AHCDC	AHCDC			Theresa Almonte (HAM)
59	Jun 9, 2009	Factor VIII-TestingOnly-TestingOnly				Theresa Almonte (HAM)
58	Mar 16, 2009	Factor VIII-Advate-Baxter				Theresa Almonte (HAM)
57	Mar 17, 2009	Factor XI-Factor XI-B P L				Theresa Almonte (HAM)
54	Oct 29, 2008	Factor VIII-TESTPRODUCT-Baxter				Theresa Almonte (HAM)
46	Sep 30, 2008	Factor VIII-TESTPRODUCT-Baxter				Theresa Almonte (HAM)
24	Jun 24, 2008	Factor VIII-TESTPRODUCT-Baxter				Theresa Almonte (HAM)

END OF PROCESS 2

END OF SOP

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