CHARMS

Canadian Hemophilia Assessment and Resource Management Information System

Version 3.1.0 - April 2004

UPDATE GUIDE

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CHARMS V3.1.0 – OVERVIEW OF ENHANCEMENTS

There are four major enhancements in CHARMS V3.1.0 . In addition, numerous changes and added functionality has been implemented. The following pages will show most if not all of these.

1. **Splitting the demographic and clinical components** into separate database files.
   The purpose was to ensure greater security of patient data and to enable the technical support team to trouble shoot without having access to confidential patient demographics.

   In addition to the usual CHARMS login username/password, an additional security access password has been added. This new password is encrypted and is required after the initial login to CHARMS. Access without this security password will only allow the user to view the clinical information and no demographics. The clinical information will only be identified by a numerical combination of a system key identifier and the CHR#.

2. **Patient "Unique Identifier" assignment**.
   Every registered active patient that has a CHR# will now be assigned a new Unique Identifier. This UI# will identify each patient uniquely but anonymously throughout the CHARMS system of databases in Canada. It is this UI# that will be used to register patients in the Pharmaceutical databases that track bleed events and product infusions.
   UI#'s will automatically be assigned with the initial upgrade of CHARMS. For those patients that have missing information, which will prevent CHARMS from auto assigning a UI, a report will be available to print. The UI# that are assigned, will remain the same if the patient moves from one clinic to another, providing that the qualifying information remains the same.

3. **Adverse Event Reporting**: A new, more detailed form has been added to capture any reactions that a patient reports to the HTC. It is specifically linked to product infused and is recorded via the Infusion Diary. The process in brief is as follows; the reaction record is first captured in CHARMS. The HTC administrator is given the capability to view the information, as it would look on an actual Health Canada Adverse Event form prior to submitting the report.
   Once the HTC administrator has approved the local previewed report, they may then request CHARMS to submit the report to the web server. CHARMS web services are hosted by Hamilton Health Sciences Hospital. No submission of an Adverse Event is allowed without the appropriate HTC assigned password. The HTC password is authenticated and will only be provided to one person at any HTC and only to the administrator of that HTC. After a successful submission, an automatic notification will be sent to the pre designated parties via email. The Adverse Event Report will be available to only the parties that received the notification and have security access to view it.

4. **Research Studies and Patient Consents**: A master Study form has been added to enable the HTC's the capability to record any study that will require patient consents to be recorded. The Master Study module captures the details for each specific study along with any specific consent agreements. The Patient Consent module will record the patient as a participant in a specific study.

CHARMS UPGRADE MANUAL – What to Expect

1. How to get the New CHARMS V3.1.0

The UPDATE CHARMS Icon on your desktop will get the new version of CHARMS for you. You will be notified either by email or telephone that CHARMS V3.1.0 is ready to download. For those HTCs that have their data portion of CHARMS on their hospital servers, you need not worry, as CHARMS will prompt you for the location of your data files. For those HTC's that have their data still stored on their local PC's, the update will automatically upgrade CHARMS without the prompt to locate the data. One important note; All HTC's should have their data tables on their hospital servers. For security reasons as well as proper nightly backups. If you are unsure whether your data tables are on your hospital server, please contact CHARMS Support to investigate and make arrangements to have this done.

2. CHARMS-Upgrade Process: Patience is a Virtue.

Once you have initiated the process, the upgrade should proceed without any problems. You must be connected to the internet in order to activate the upgrade process. CHARMS upgrade will be processing many functions and we hope that you will be patient during this process. You may see some system messages in the bottom left hand corner during the upgrade that will indicate the progress. At the completion of the upgrade you will be displayed a message indicating whether the Upgrade was successfully completed or otherwise. Should you get the "otherwise" message, please contact CHARMS Support to trouble shoot.the process for you.

3. Security Access Screen : Initial default password is "password" .

You will have to change this password as the security of your patient data depends on it. Once you change the password, IMPORTANT….write it down and store it in a safe place. It is this password that will give you access to the patient's demographic information. If you forget it, call your CHARMS Support but please be aware it will take more time to return the password to you then in the past. This password is encrypted and will not be easily retrieved.

4. UI# assignments: New unique identifiers (UI#) will be automatically assigned.

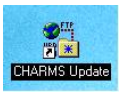
The automatic assignment of the new UI's will be initiated with each access to CHARMS if the user is connected to the internet. CHARMS will attempt to assign the UI# for all registered patients that have pre-qualifying information in the database as not missing.
The pre qualifiers are: Date of Birth (DOB), Extra Identifier (EXID), Gender, CHR#.
The information screen, which will be displayed to you, will provide more detail of this process. Any patients that CHARMS is unable to assign a UI#, will be listed and available to print. You may then edit these records to fill in the missing information and manually individually assign a UI# .

5. CHARMS Main Menu – when all upgrade processes have completed, the CHARMS Main Menu will be displayed. At this point you are ready to access your patient data and proceed with your normal work activities.
It is suggested that you take a few minutes to view the different menu options and screen changes that we show in this upgrade manual.

Additional remarks for What to Expect: We have tried to ensure that most of your requested changes were included in this release and that all previous problems have been fixed. If you have any problems or get any unusual error messages, please record them and forward to the CHARMS Support Team.

CHARMS UPGRADE MANUAL

CHARMS Upgrade V3.1.0 – How to get it.



Use your desktop Icon as above to get the latest version of CHARMS V3.1.0.
You will be prompted to enter in the username and password for this utility application.

Username : DBA Password : (as you know it)
This password will be the same one that you use to access your CHARMS application.

Using the CHARMS Utility program to download CHARMS V3.1.0.

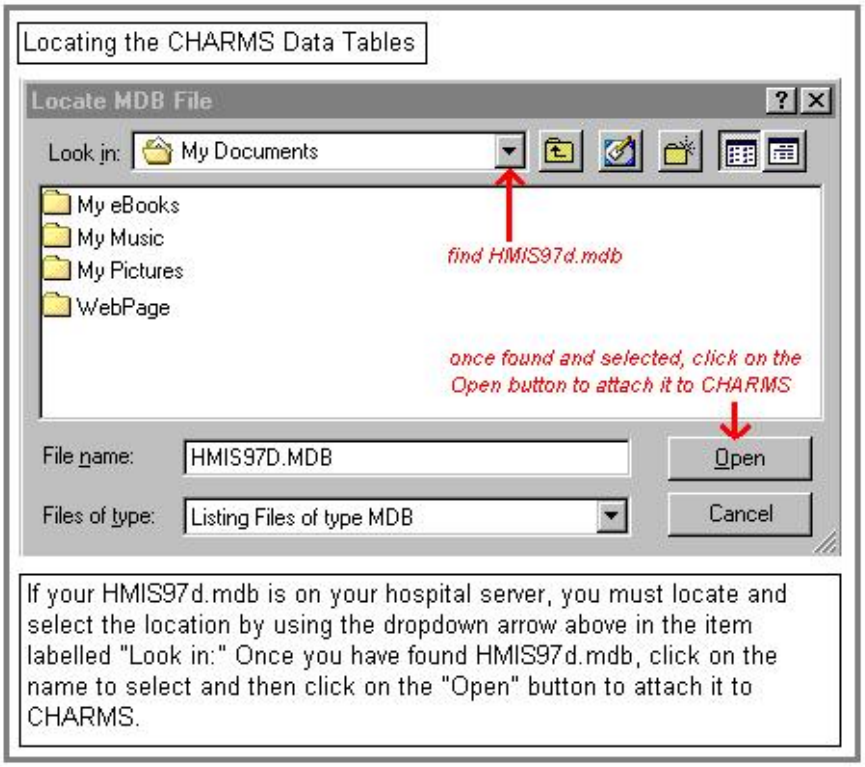
The above Server and Username will be pre filled for you. Just click your mouse pointer on the Update button and the download process should start.

A series of system information messages will be displayed. If you encounter any error messages during this process, please contact your CHARMS Support Team.

LOCATING THE CHARMS DATA TABLES

Once you have initiated the upgrade process, CHARMS will check your local computer for the CHARMS data tables. If your data tables are on the hospital server, you will be prompted for the location on the server where the data tables reside.

Use the dropdown arrow to find the drive letter that has been mapped CHARMS on your hospital server.



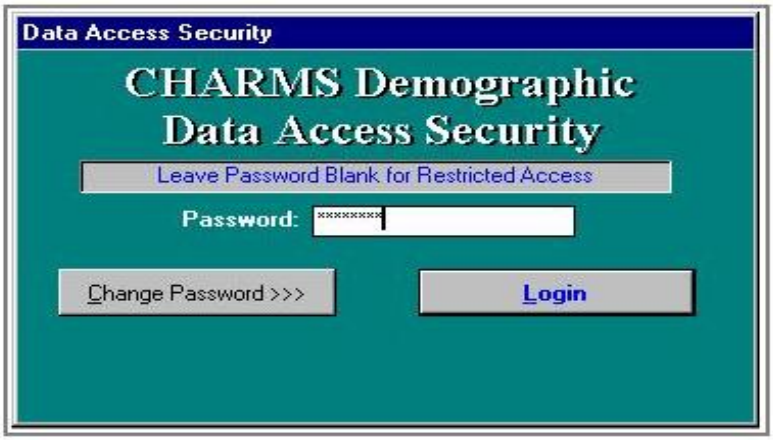
If you have problems locating your data tables, please call your CHARMS Support Team or contact your local IT department for help. In most cases, you will find the location mapped near the bottom of the list of directories in your dropdown list. Once you locate the location of the HMIS97d.mdb tables, click on it to select and then click on OPEN as above.

CHARMS UPGRADE PROCESS

You will see a series of system messages; just allow the process to continue. If you do not get the message indicating a successful upgrade as below, please contact your CHARMS Support Team.

You will be prompted to enter the new security access password, which will grant you the ability to see the patient demographic information. You will still be able to access CHARMS without this password but you will not be able to see any patient names, address and any other demographic information.

CHARMS Data Access Security Login Screen



During this initial upgrade, your login password is : "password" , donot include the quotes and type in as lowercase. Now you can click on the Login button.

You may change your password BUT...remember to WRITE IT DOWN and store it in a safe place.

Password replacement if you forget will cause you delays as you will need to contact CHARMS support. When you record your password on paper, also remember if its Lower or Upper case characters that you used.

CHANGING YOUR DATA ACCESS SECURITY PASSWORD

Initial default password = password

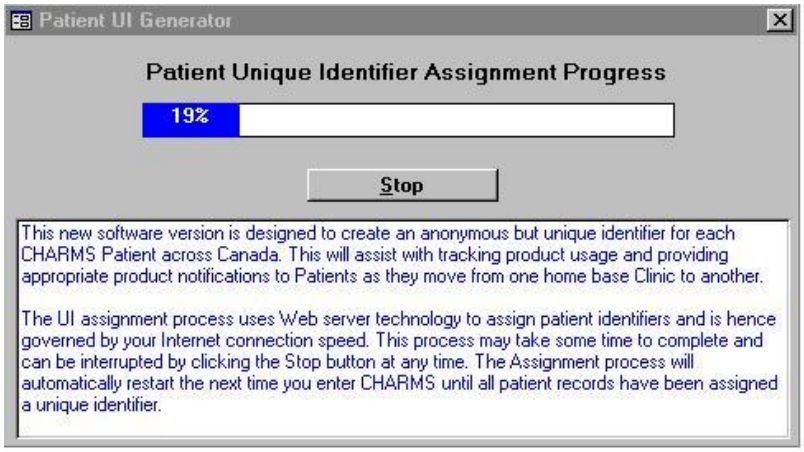
Change the default password to something that you will easily remember but consists of upper and lower case characters and/or numbers. Ensure that you WRITE this password down and store in a secure location.

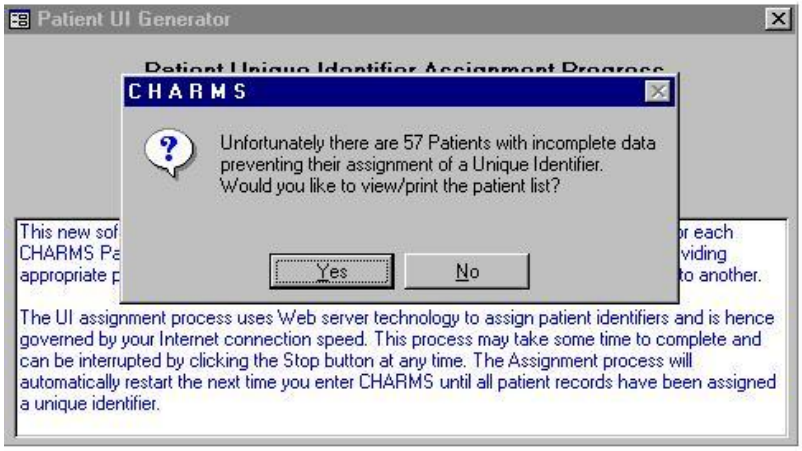
Without this additional security password, you will not be granted permission to see any demographic information in CHARMS.

After you have successfully logged in, CHARMS will start the automatic assignment of UI#'s for all patients that are registered in CHARMS. Qualifiers for a UI# assignment is as follows;

Must have : Date of Birth(DOB), Gender, Extra Identifier(EXID) and a CHR#.

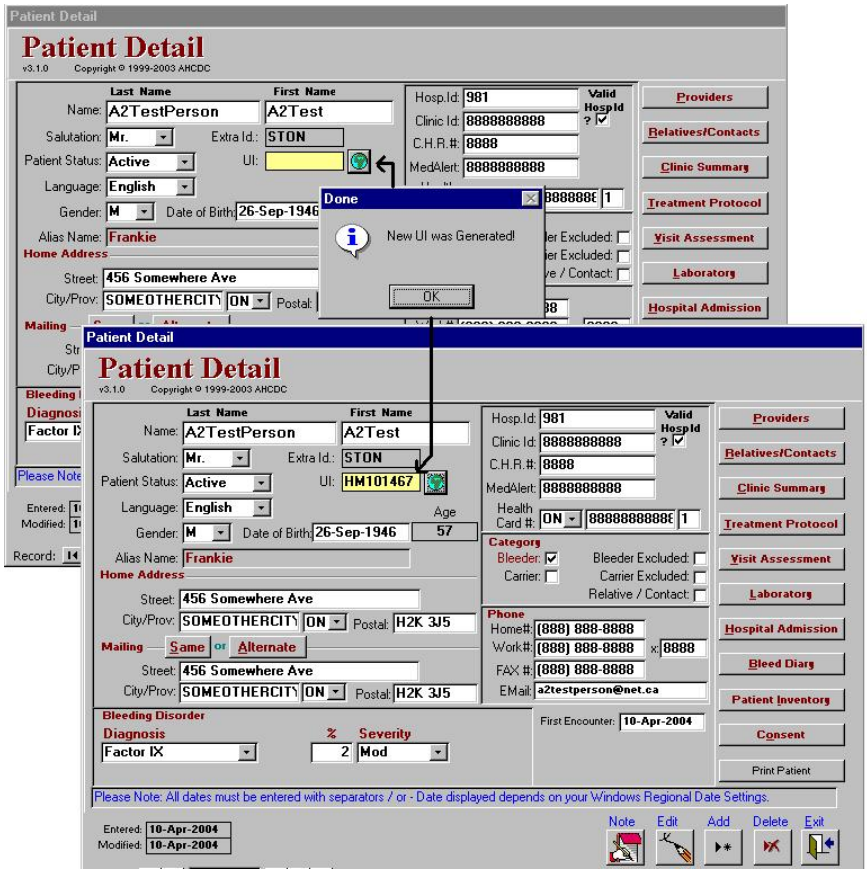
The assignment process will be initiated with each login till all qualified people have been assigned a UI#. The following screen dialogue will be displayed, you have the option to stop it if need be. For those records that did not get an assignment, a report will be available at the end of the process to be printed.





UI #'s may be individually assigned from the Patient Demographic Screen. The same qualifiers apply. The following is the UI# assignment sample.

Note: the UI field is empty on the 1st form. The Globe button when clicked will initiate the request process for the UI# assignment. Once a UI# has been assigned to a patient, it may not be changed or deleted.

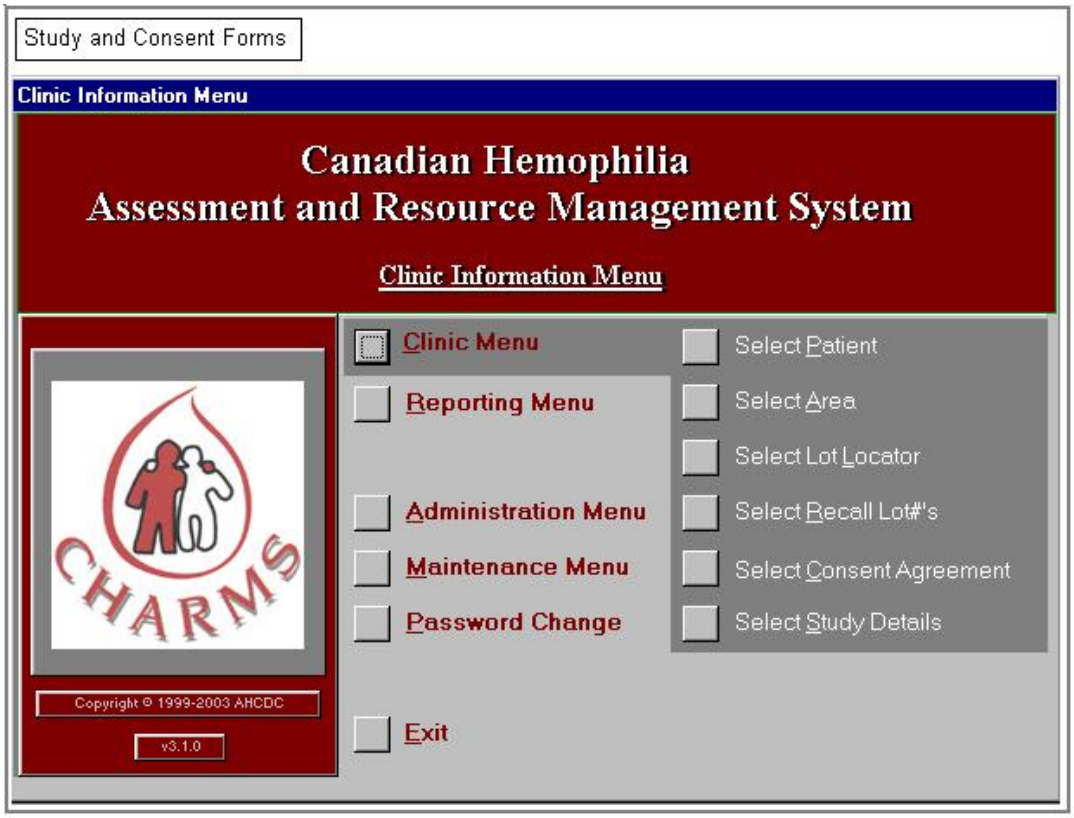


CHARMS MAIN MENU - STUDY AND PATIENT CONSENT SCREENS

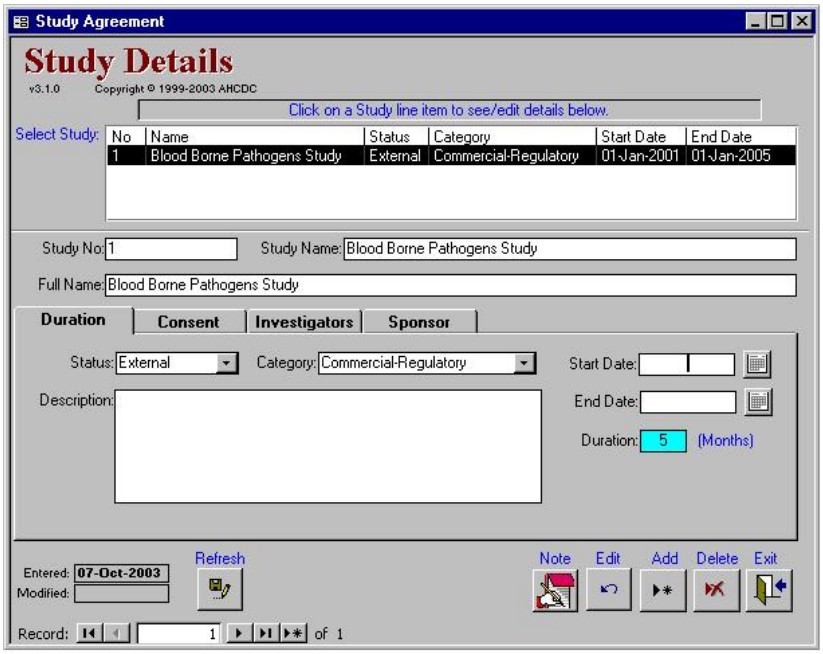
1. Select Study Details – records any internal or external Studies. For local studies, you may enter the Study details as provided by your Clinic Director.

   For External studies that your clinic may participate in, you will be provided with the Study Details, which you may then enter.

2. Select Consent Agreement - records patients that are participating in a Study previously recorded in the Study Details.



STUDY DETAILS

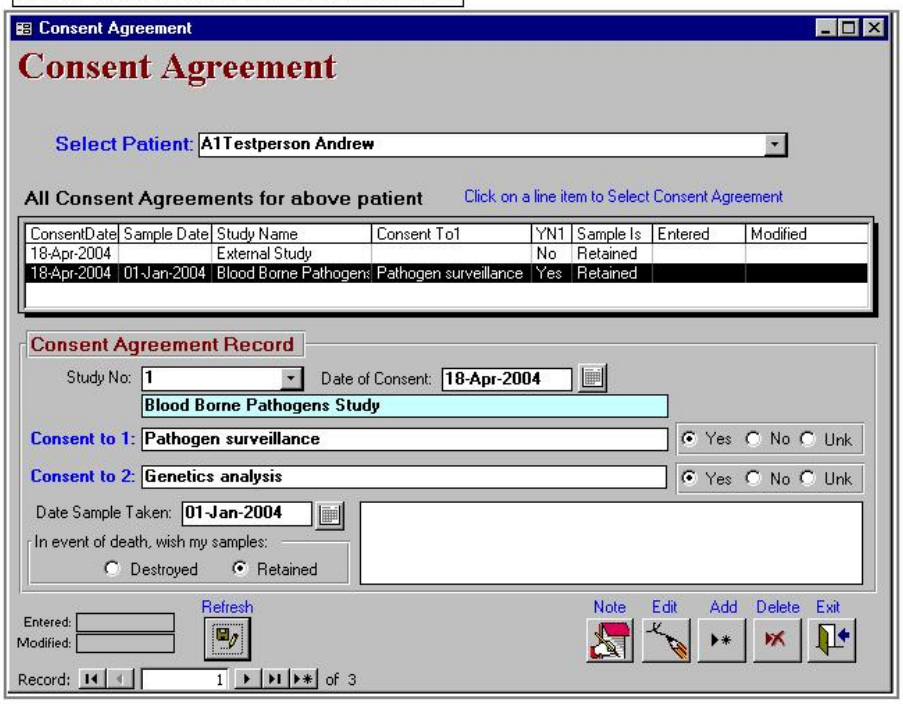


To enter a new study record, you must enter a unique Study number to identify the Study. Selecting the tabbed headers may enter the details for; (Duration, Consent Agreements, Investigators and Sponsor) some of this detail is optional.

PATIENT CONSENT SCREEN

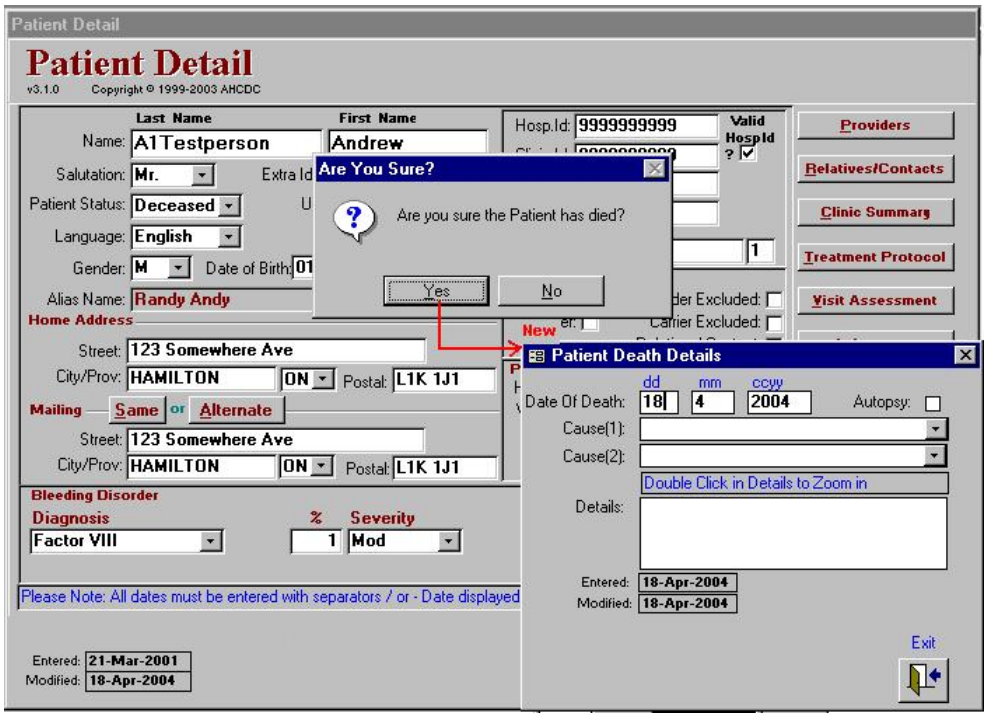
From the dropdown selection, you may select any registered patient that is to participate in an existing Study. A patient may be registered as participating in more than 1 study.
Study details are pre filled from the master Study Details that you select by using the dropdown arrow in the Study No item field.
Calendar buttons have been provided and may be used to select the date(s) for the date fields.

Patient's Consent Form to Participate in Clinic Studies



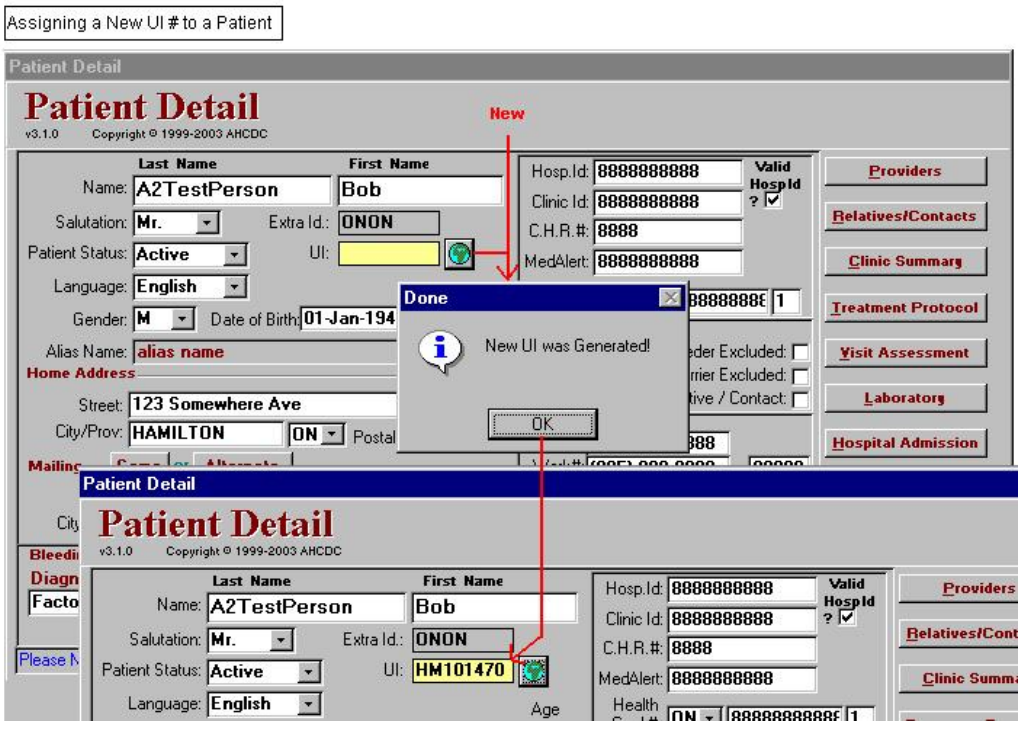
Patient Detail – What's New

Patient Status: If the patient status is changed to Deceased, you will be prompted to enter in the Date of Death and any other related information.



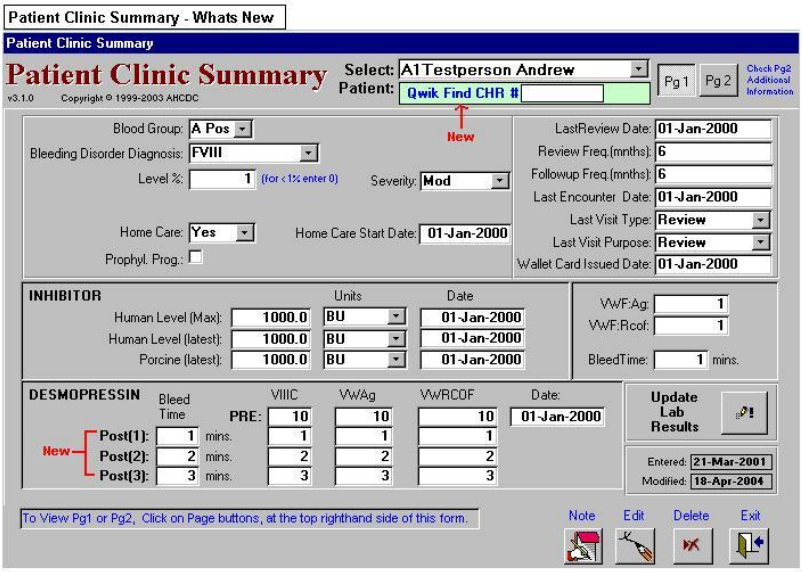
Patient Detail – What's New. – Assigning a UI# to a new patient.

As described previously, to assign a new UI#, simply click on the Globe button. You must have access to the Internet in order for the assignment to process.



CHARMS UPGRADE MANUAL-V3.1.0

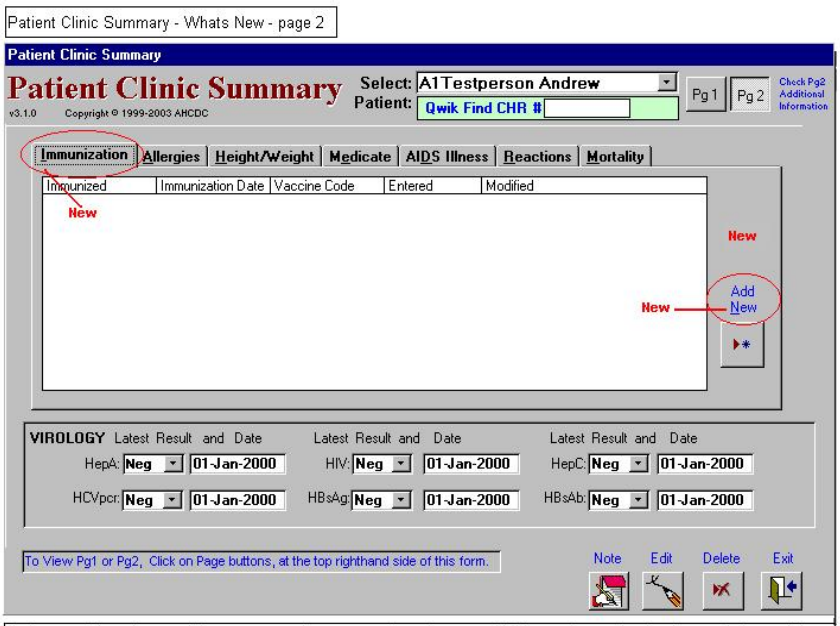
PATIENT CLINIC SUMMARY – WHAT'S NEW.



Qwik Find CHR : You will see this Qwik find on some of the selected screens in CHARMS. This allows you to search for your patient by CHR# and will also work with your HandHeld Scanner if a CHR Barcoded # is scanned. Note, your cursor has to be in the Qwik Find CHR field first if you are using the scanner.

Desmopressin Post Bleed Times and Results: 2 additional sets of Post values has been added, as well as in the Lab Coagulation screen.

PATIENT CLINIC SUMMARY – WHAT'S NEW.



Each one of the tabs noted above can now be accessed by using your ALT key and pressing the Letter of the word that is underlined instead of using your mouse pointer to access each of these sections.

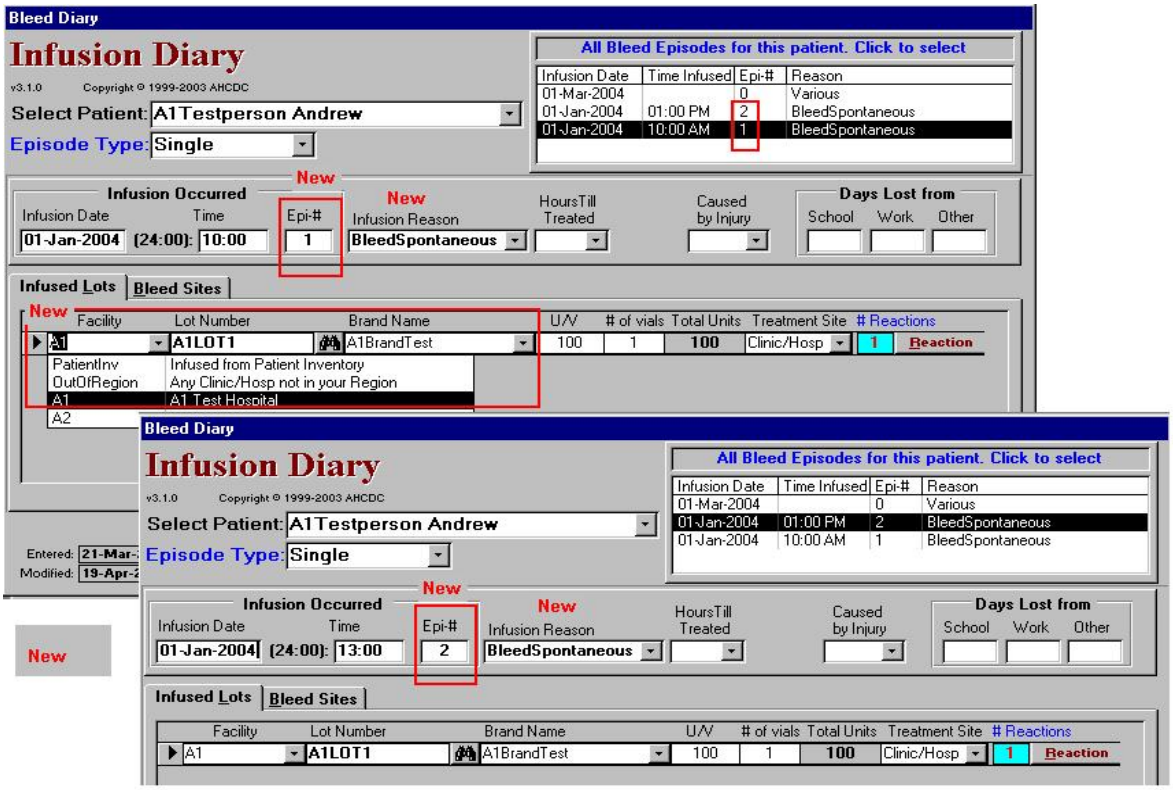
To add a New record, Press the ALT and N keys, to access Allergies, Press the ALT and A keys on your keyboard.

INFUSION DIARY – WHAT'S NEW

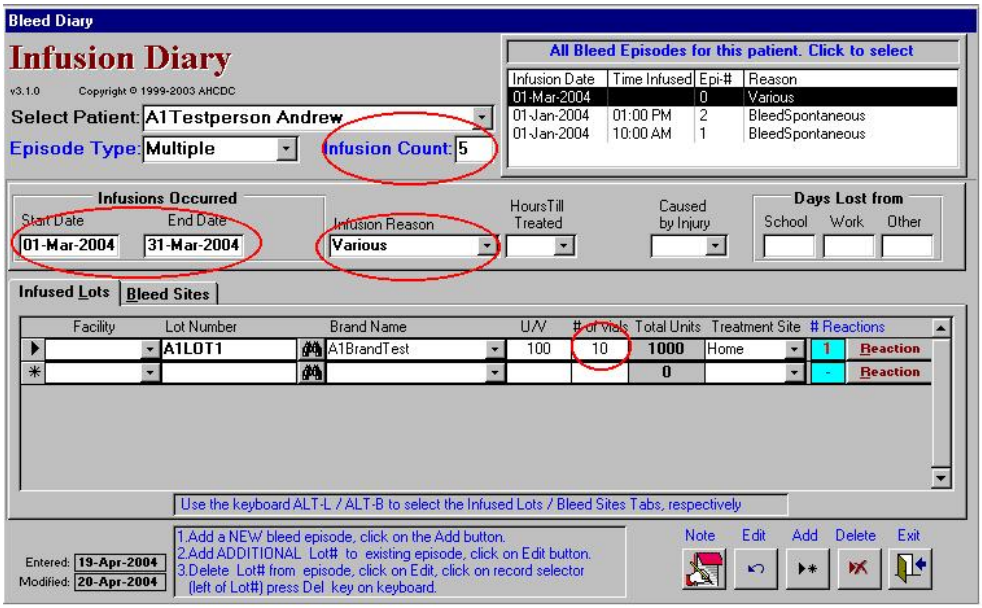
The Infusion Diary has been enhanced with the following features;

1. Epi-#; you will be able to indicate by using the Epi# the number sequence of infusions that a patient may have had in the same day. If the patient has 2 separate bleed episodes on the same day as the example shows, the first one occurred at 10:00 am and is assigned Epi#1 and the second at 1:00 pm and is assigned Epi#2.

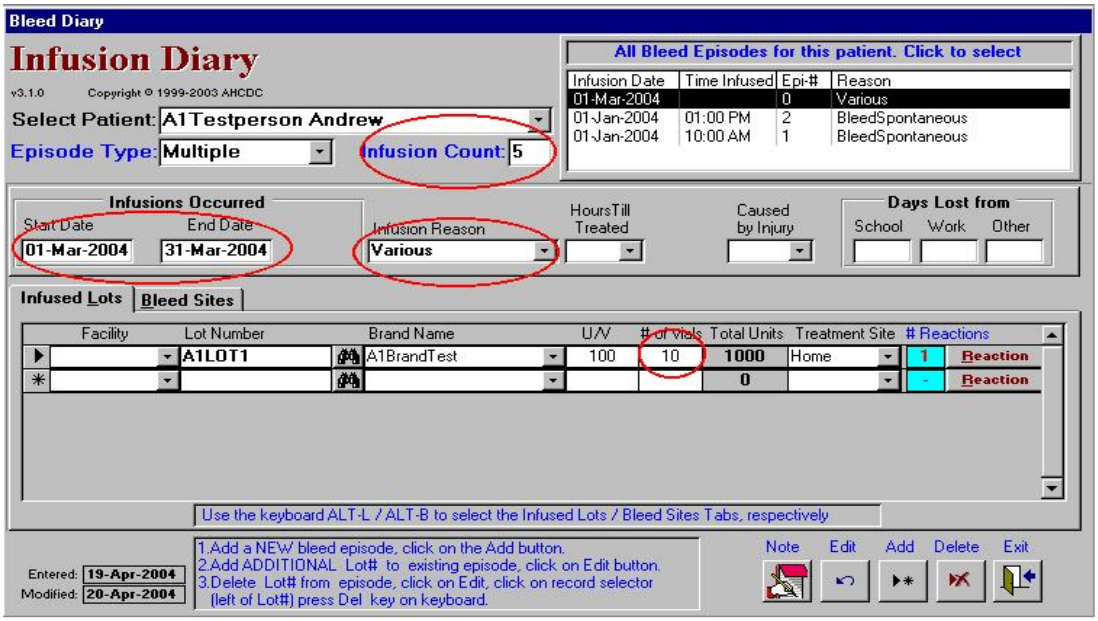
2. Facility dropdown selector is now prompted before the entry of the Lot#. This will allow you to indicate whether the infused product came from the Regional Inventory for this infusion or whether the patient used their home inventory for the infusion. When you enter the lot#, the selection process is now quicker as we do not have to check both the inventories to be displayed. You can still however use the binoculars to select the product infused.



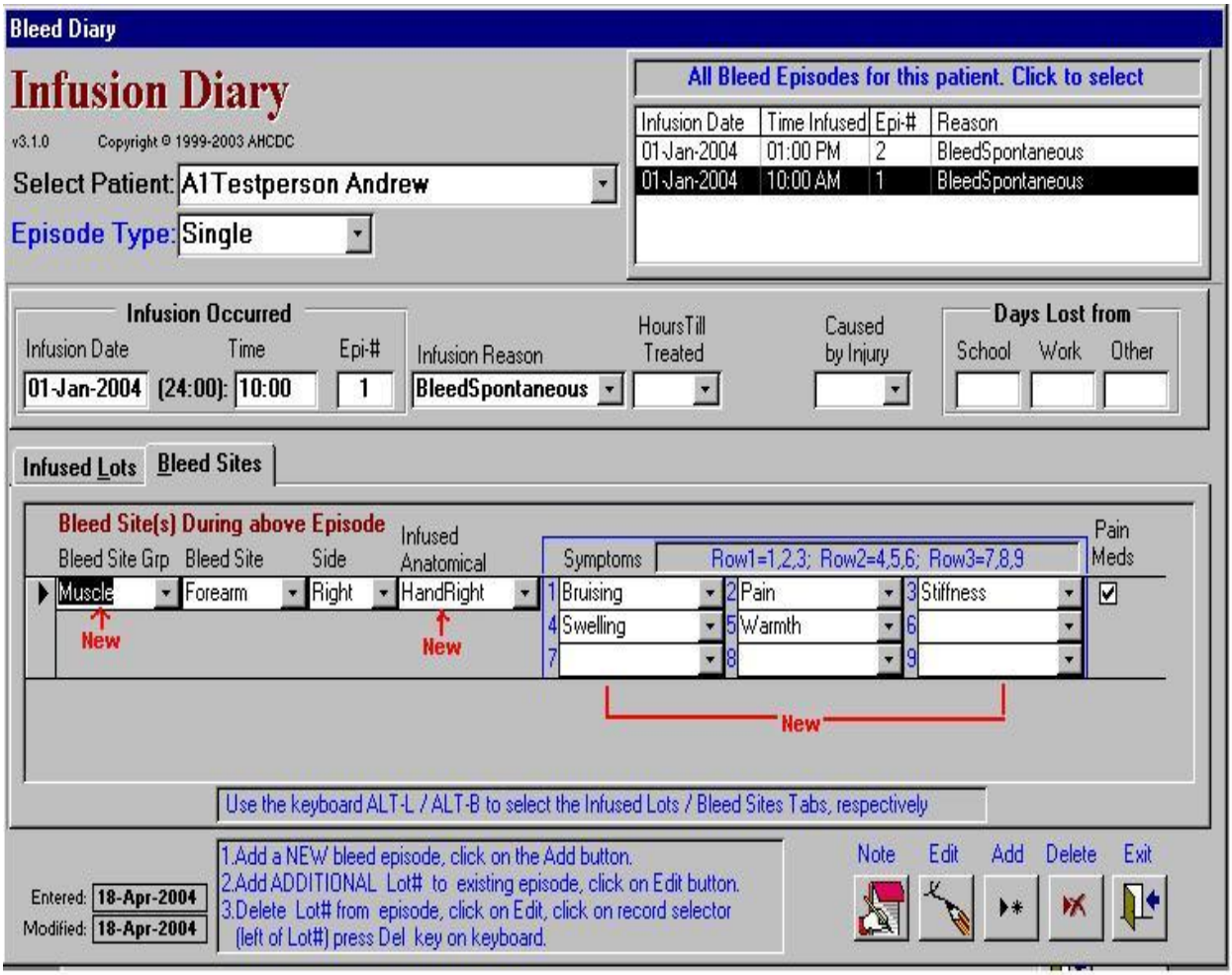
INFUSION DIARY – WHAT'S NEW



For Multiple infusion episodes, you can now enter the approximate number of infusions that this bulk entry Is covering for the date range that you have specified.



In the above example, the patient had approximately 5 infusion episodes for the period covering March 1 to March 31. Infusion reason indicates for Various reasons (previously Bulk Entry) and that there was 10 vials over this period that were infused.



Bleed Site Details have now include the Bleed Site Group. You may now specify the group that the bleed site belongs to as indicated above under "Bleed Site Grp".

Infused Anatomical; you may indicate where the patient infused the product.
Symptoms now allow up to 9 possible different entries for each infusion episode to be recorded.

ADVERSE REACTION REPORTING – WHAT'S NEW

When a patient reports to the HTC that he/she has had a reaction, such as fever or palpitations, etc. The HTC administrator will record this reaction in CHARMS. In addition, the HTC administrator can now submit this report electronically on Health Canada's Adverse Event report form.

The pre-defined recipients for notification of an Adverse Event will be notified by email that an Adverse Event report has been submitted and that they may view this report on the CHARMS web server.

Only the intended recipients will be allowed to view the specific reports that were intended for them.

The recipients are: Health Canada, Canadian Blood Services, Quebec Blood Secretariat and the Manufacturer of the specific product that was linked to the reaction reported by the patient.

Access to these reports is by specific usernames and passwords, which are assigned to all recipients and are authenticated at time of request to view the report. Each request is logged and the requestors IP address is recorded.

The Adverse Reaction form in CHARMS has a lot of detail that must be filled out. Some of the information is pre-filled from information already captured, such as latest weight, age and infusion details. Some of the information required to be reported may be selected from dropdown options such as Lab results. The user may may select any available lab results which will populate the form and can be edited to only include the the applicable test results.

There are additional options on the CHARMS Reaction form, such as ; Links to the web site with reference to reporting of Adverse Events and other useful information. Preview of what the Adverse Event form will look like before submission and finally the capability to submit the Adverse Event Report for distribution to the designated recipients.

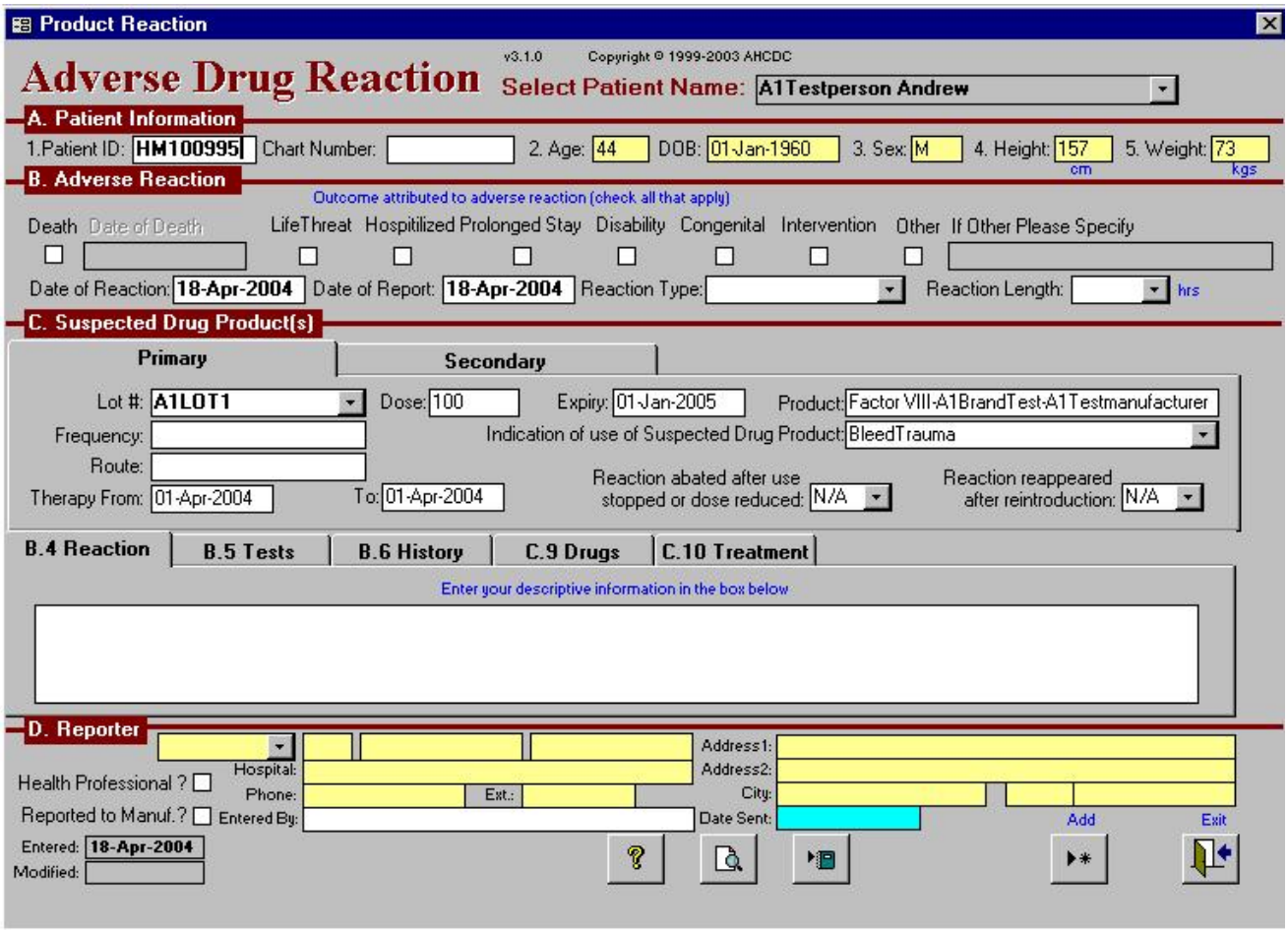
Who Should Submit the Adverse Event Report ?

Each HTC administrator will be provided with their clinic's username and password. 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. The HTC administrator will be notified and assigned a username and password, which will be required to submit the report via CHARMS.

Once a report has been submitted, it may not be submitted a second time. It is important that the designated person who will be authorized to submit, reviews the report and preferably prints it to get final authorization from the Clinic Director or the reporting Health Professional before submitting.

ADVERSE REACTION REPORTING – WHAT'S NEW

To record an Adverse Event, use the Infusion Diary and locate the infusion episode, then select the line item of product infused prior to the reaction reported by the patient. Click on the Reaction button and proceed to fill in the Adverse Event report.



Note: In the above example, some of the items have been pre-filled where data in CHARMS was available. Such as the UI#, last recorded weight, age , date of birth. The Infusion date and the product infused prior to the reaction.

The Primary product tab records the product infused as selected from the Infusion Diary to initiate this report. If there is a need to report a secondary product infused, then you may enter this information by selecting the Tab Secondary.

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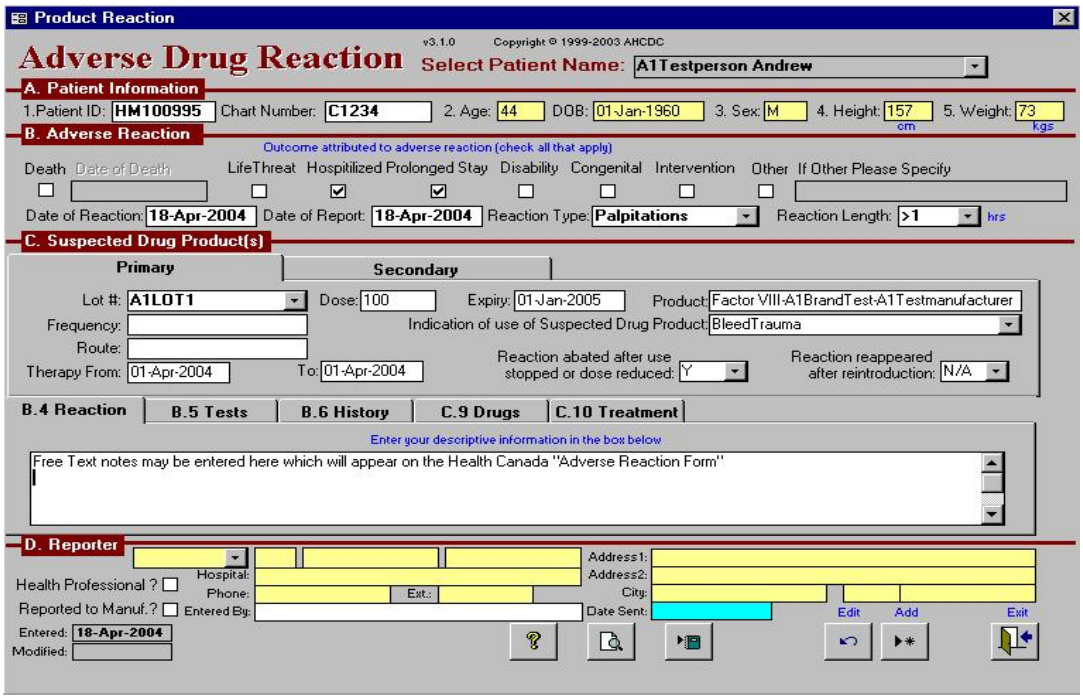
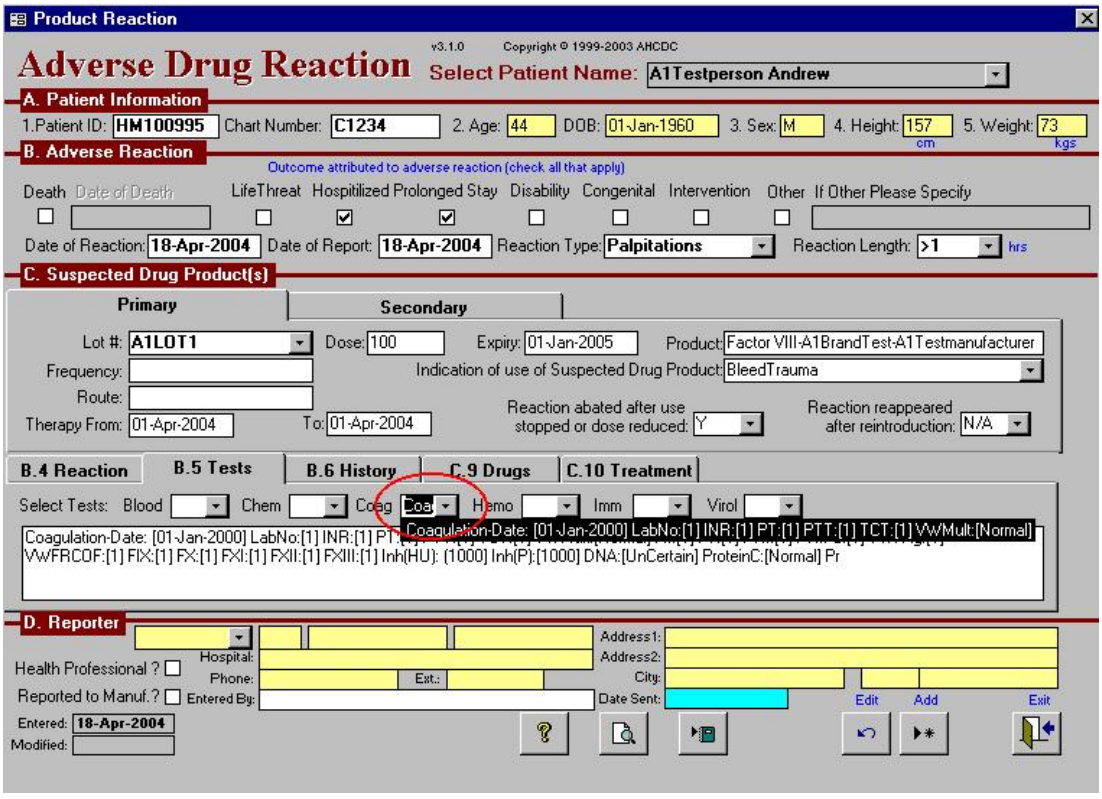
ADVERSE REACTION REPORTING – WHAT'S NEW



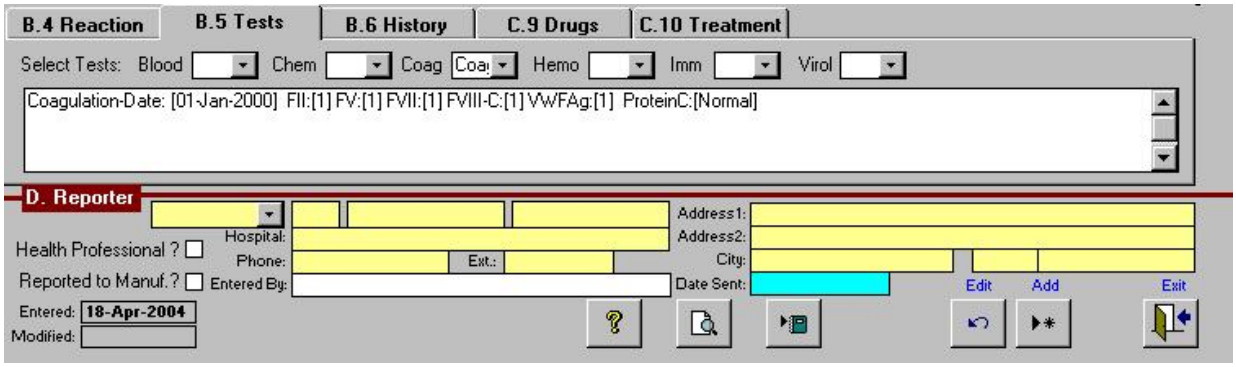
Note: Section C – Tabbed items, B.4 Reactions, B.5 Tests, B.6 History, C.9 Drugs and C.10 Treatment These items of information may be accessed and entered by clicking on the appropriate TAB.

Most is entered in free text, with the exception of B.5 Tests; On this form, you will be allowed to select the applicable lab tests as well as free text for submission.

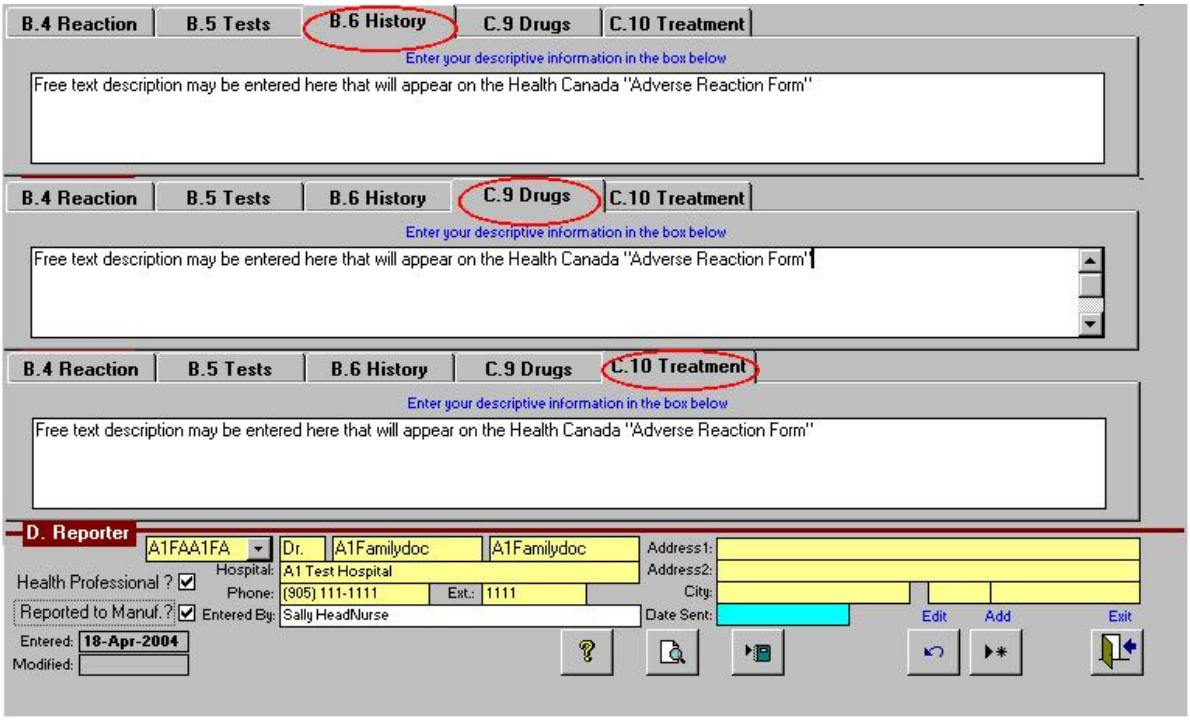
ADVERSE REACTION REPORTING – Select and auto fill from CHARMS Laboratory Results



ADVERSE REACTION REPORTING – Edit and submit only the lab results that are applicable.



ADVERSE REACTION REPORTING – Enter in free text format any other applicable data.

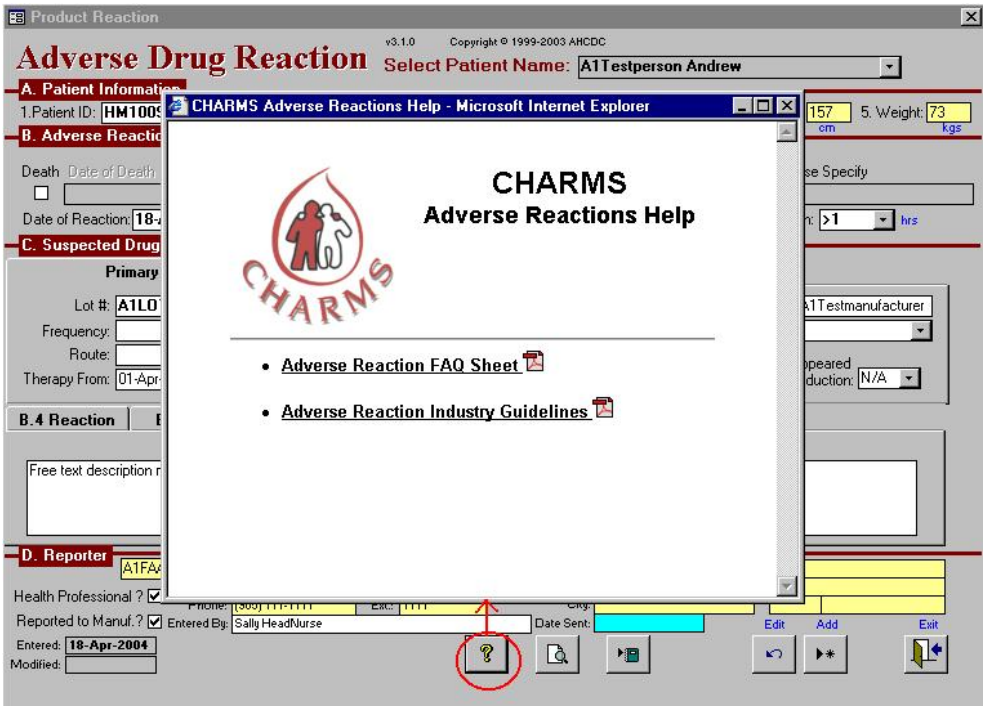


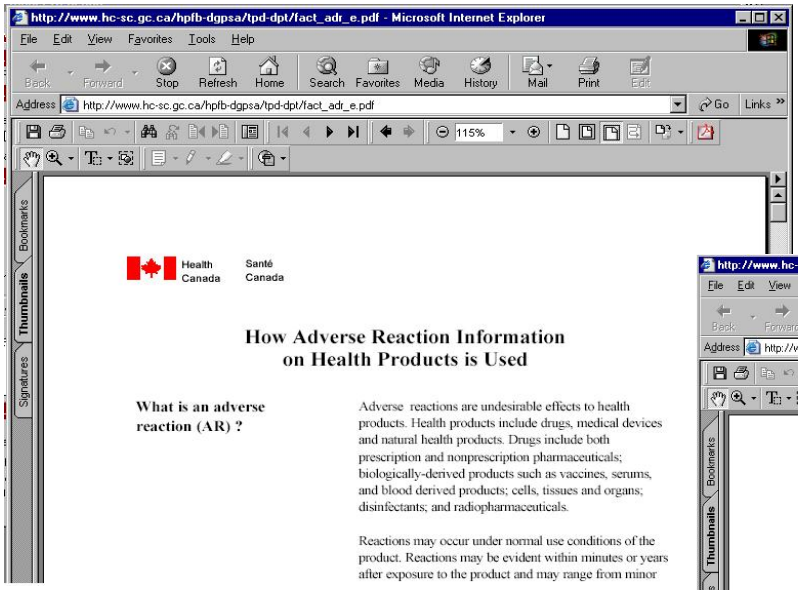
History, Drugs and Treatment Tabs, will allow the Clinic administrator to enter in free text to describe each section in detail. This information will then be displayed on the Health Canada "Adverse Reaction" Report Form.

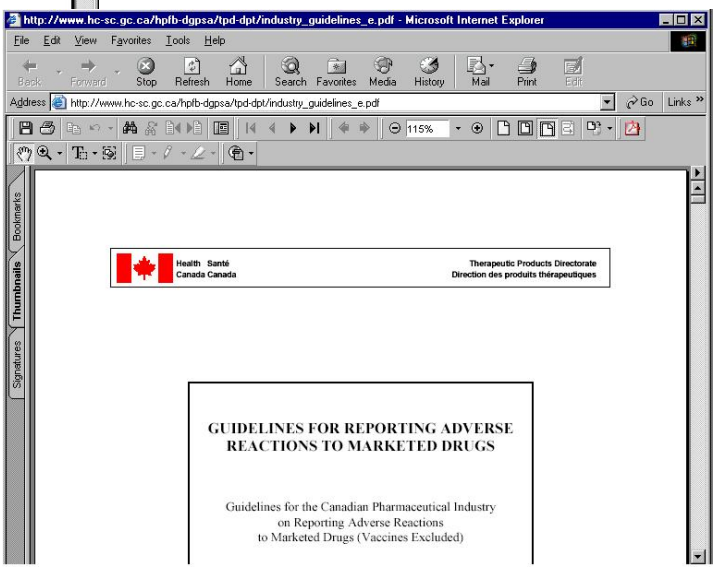
D. Reporter: This information is partially filled in from the master Providers form. i.e. Address, City..etc.
Entered By: This item would hold the name of the person filling out the form on behalf of the Doctor submitting the Adverse Reaction form.

ADVERSE REACTION REPORTING – Web site links to FAQ's

Web links to Health Canada's FAQ's on Adverse Reaction. Link to these sites can be accessed from within CHARMS by clicking on "Question" symbol button in the Adverse Reaction form.

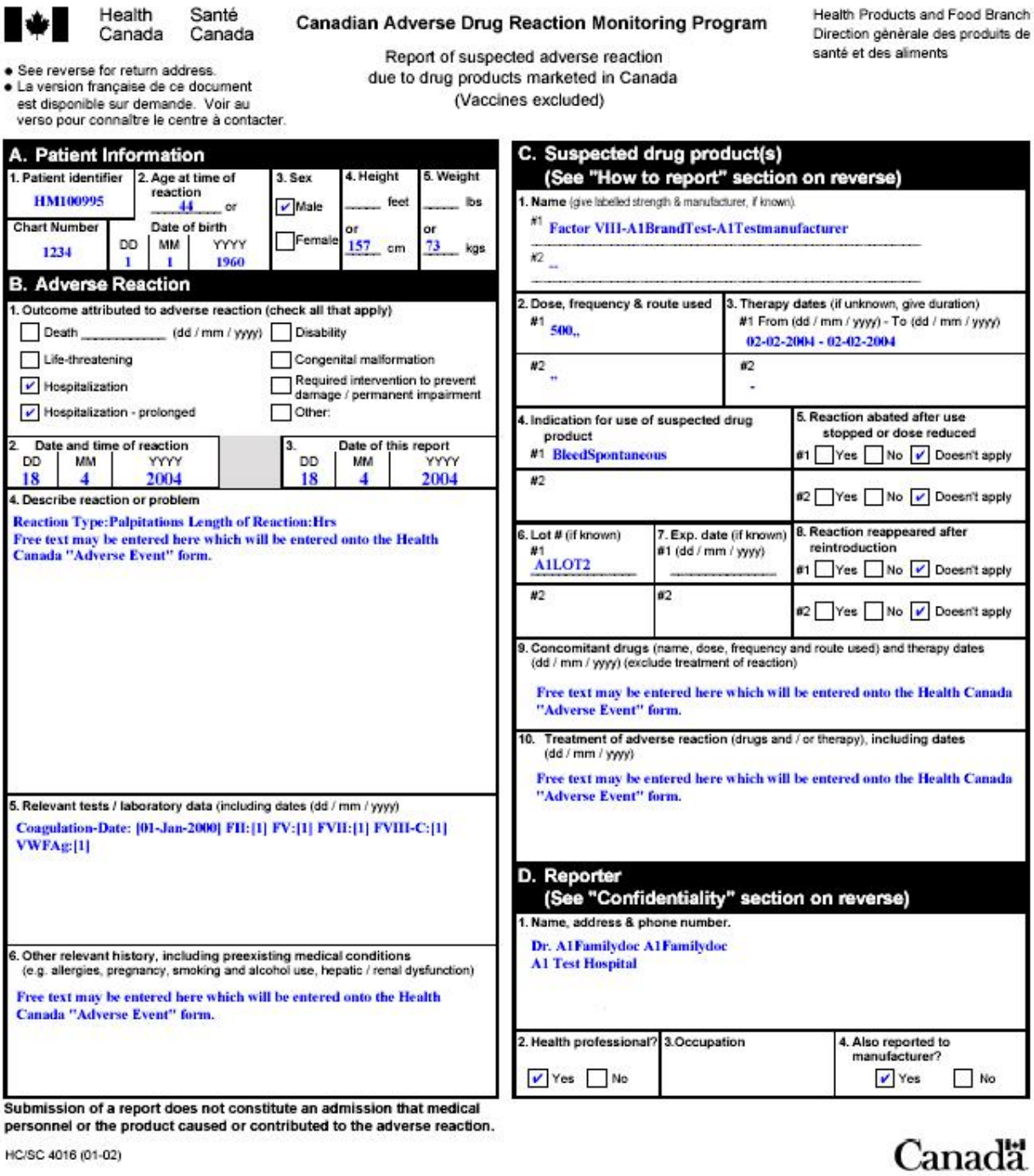






ADVERSE REACTION REPORTING – PRE VIEW OF THE REPORT.

You may preview the report as it will look to the recipients after submission. It is recommended that this Report be reviewed by the Clinic Director or the reporting Health Professional before it is submitted. To view this report, use the button on the form that looks like this:



Health Canada Santé Canada

Canadian Adverse Drug Reaction Monitoring Program

Report of suspected adverse reaction due to drug products marketed in Canada (Vaccines excluded)

Health Products and Food Branch
Direction générale des produits de santé et des aliments

- See reverse for return address.
- La version française de ce document est disponible sur demande. Voir au verso pour connaître le centre à contacter.

A. Patient Information

1. Patient identifier	2. Age at time of reaction	3. Sex	4. Height	5. Weight
HM100995	44 or	☑ Male ☐ Female	feet or 157 cm	lbs or 73 kgs
Chart Number: 1234	Date of birth: DD 1 MM 1 YYYY 1960			

B. Adverse Reaction

1. Outcome attributed to adverse reaction (check all that apply)

☐ Death _____ (dd / mm / yyyy) ☐ Disability
☐ Life-threatening ☐ Congenital malformation
☑ Hospitalization ☐ Required intervention to prevent damage / permanent impairment
☑ Hospitalization - prolonged ☐ Other:

2. Date and time of reaction DD	MM	YYYY	3. Date of this report DD	MM	YYYY
18	4	2004	18	4	2004

4. Describe reaction or problem

Reaction Type:Palpitations Length of Reaction:Hrs
Free text may be entered here which will be entered onto the Health Canada "Adverse Event" form.

5. Relevant tests / laboratory data (including dates (dd / mm / yyyy)

Coagulation-Date: [01-Jan-2000] FII:[1] FV:[1] FVII:[1] FVIII-C:[1] VWFAg:[1]

6. Other relevant history, including preexisting medical conditions (e.g. allergies, pregnancy, smoking and alcohol use, hepatic / renal dysfunction)

Free text may be entered here which will be entered onto the Health Canada "Adverse Event" form.

C. Suspected drug product(s) (See "How to report" section on reverse)

1. Name (give labelled strength & manufacturer, if known).
#1 Factor VIII-A1BrandTest-A1Testmanufacturer
#2 --

2. Dose, frequency & route used	3. Therapy dates (if unknown, give duration)
#1 500,,	#1 From (dd / mm / yyyy) - To (dd / mm / yyyy) 02-02-2004 - 02-02-2004
#2 "	#2 -

4. Indication for use of suspected drug product	5. Reaction abated after use stopped or dose reduced
#1 BleedSpontaneous	#1 ☐ Yes ☐ No ☑ Doesn't apply
#2	#2 ☐ Yes ☐ No ☑ Doesn't apply

6. Lot # (if known)	7. Exp. date (if known)	8. Reaction reappeared after reintroduction
#1 A1LOT2	#1 (dd / mm / yyyy)	#1 ☐ Yes ☐ No ☑ Doesn't apply
#2	#2	#2 ☐ Yes ☐ No ☑ Doesn't apply

9. Concomitant drugs (name, dose, frequency and route used) and therapy dates (dd / mm / yyyy) (exclude treatment of reaction)

Free text may be entered here which will be entered onto the Health Canada "Adverse Event" form.

10. Treatment of adverse reaction (drugs and / or therapy), including dates (dd / mm / yyyy)

Free text may be entered here which will be entered onto the Health Canada "Adverse Event" form.

D. Reporter (See "Confidentiality" section on reverse)

1. Name, address & phone number.

Dr. A1Familydoc A1Familydoc
A1 Test Hospital

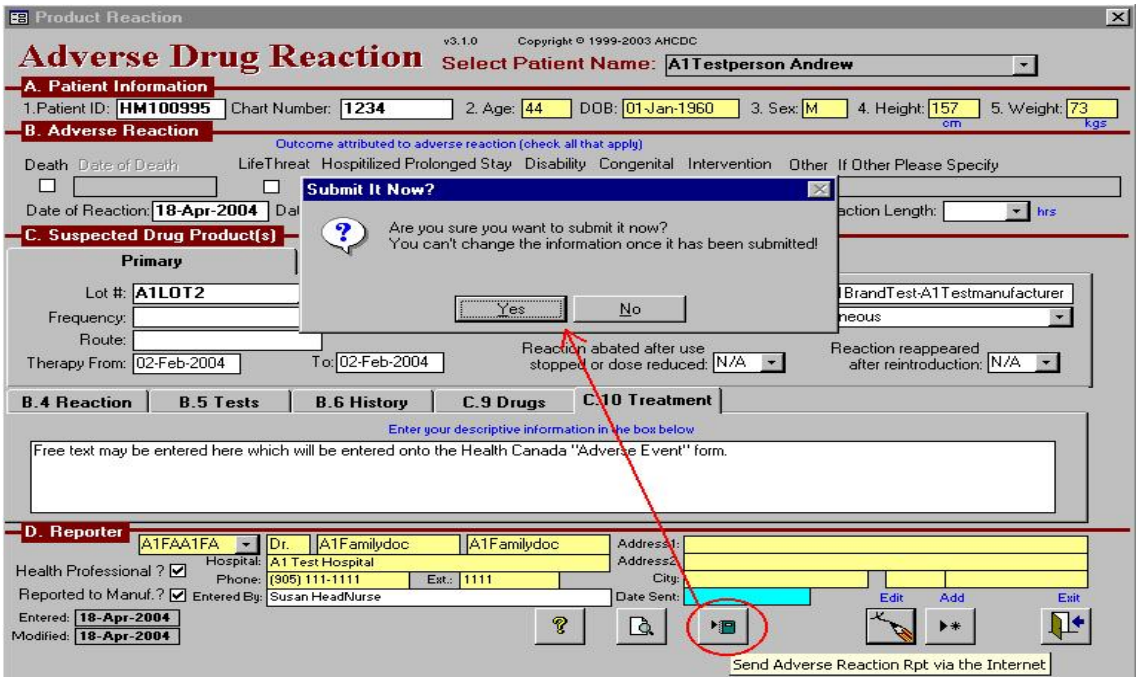
2. Health professional?	3.Occupation	4. Also reported to manufacturer?
☑ Yes ☐ No		☑ Yes ☐ No

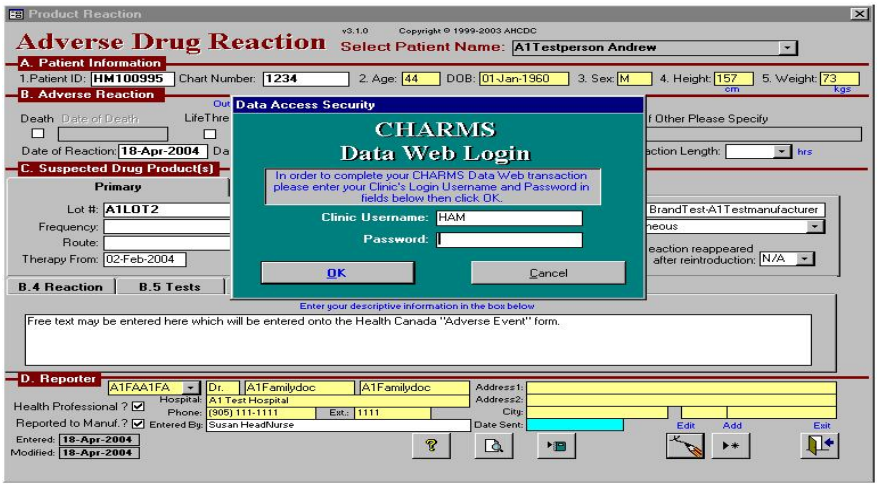
Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the adverse reaction.

HC/SC 4016 (01-02)

Canada

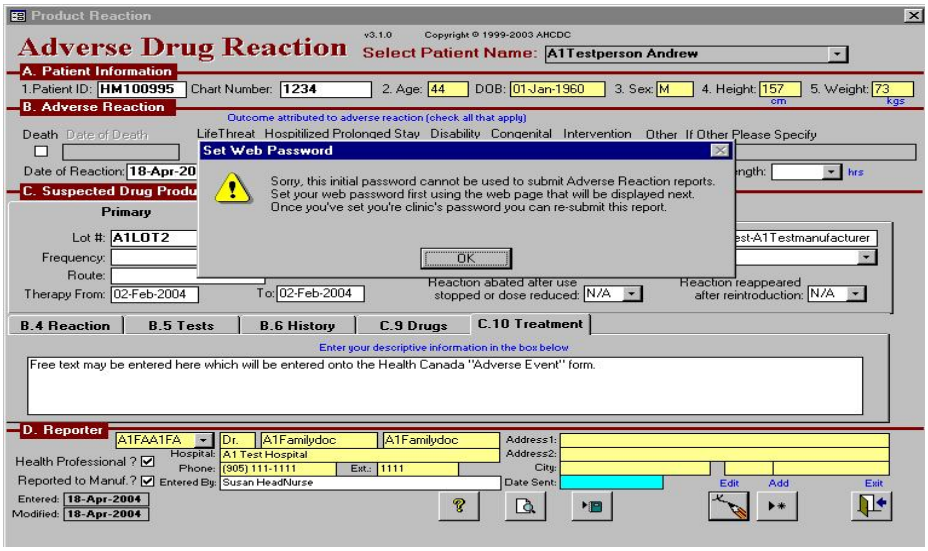
ADVERSE REACTION REPORTING – SUBMITTING THE ADVERSE EVENT



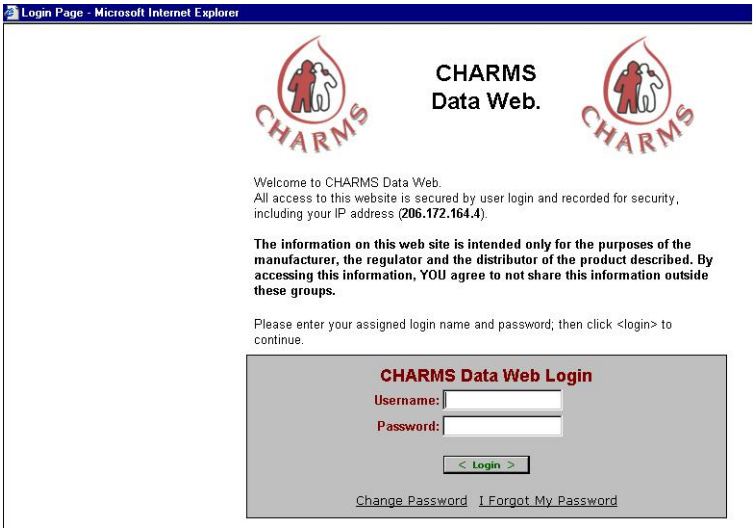


CHARMS UPGRADE MANUAL-V3.1.0

ADVERSE REACTION REPORTING – CHARMS DATA WEB



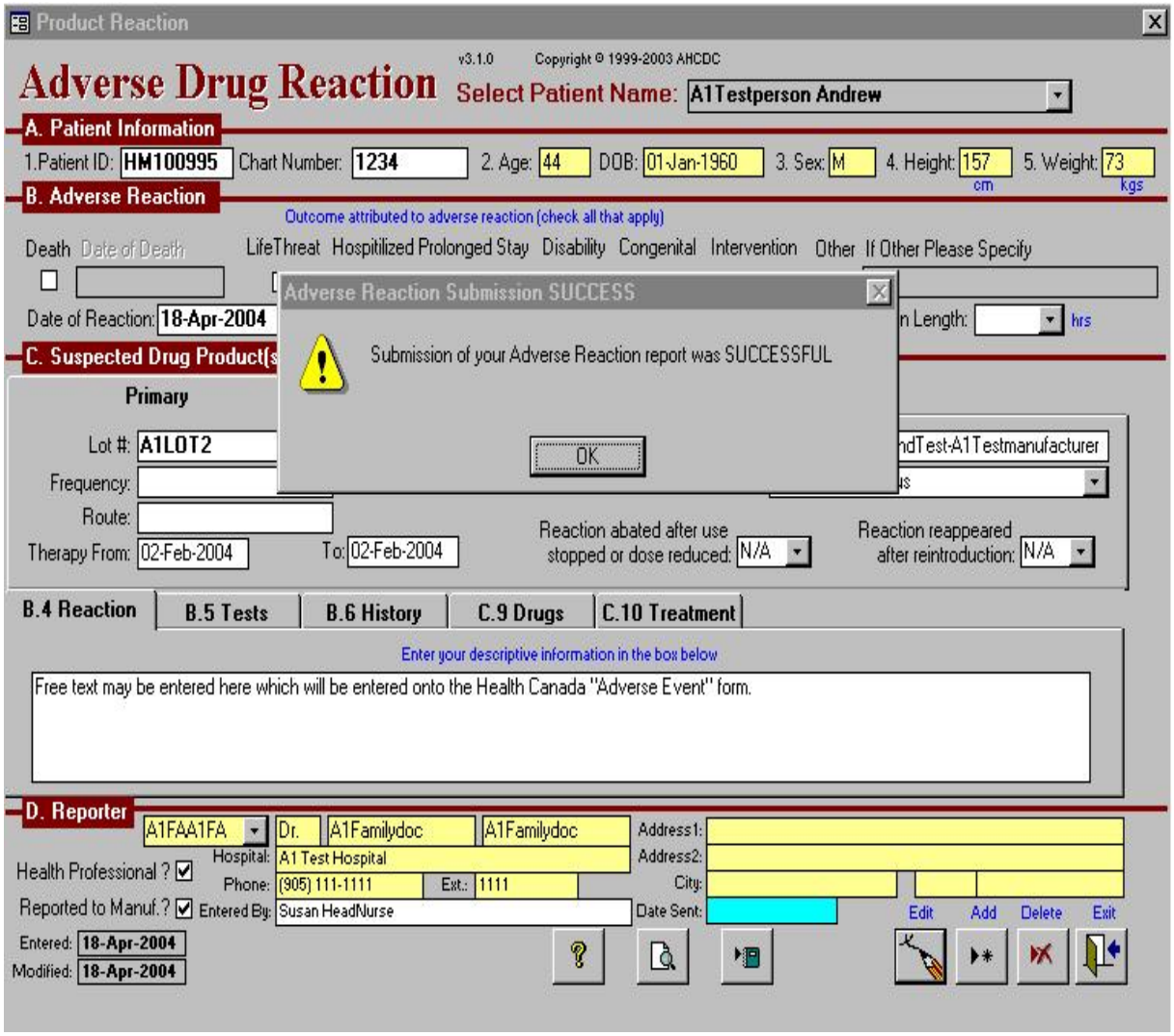
CHARMS DATA WEB – The first time you access, you will be required to change your password from the default assignment.




CHARMS Data Web Login
Username:
Password:
Enter your old password above then enter a new password below. Enter the new password a second time to confirm the change then click login as usual to change your password as well as login.
When choosing a new password please keep security as paramount importance and select a password of sufficient complexity so it cannot be guessed. As guidelines: use a minimum length of 8 characters and a combination of upper and lower case letters, numbers and symbols e.g. "MyAcct$1". Do not use birthdates or any combination of family member names.
New Password:
Re-enter New Password:
< Login >
Cancel Change Password
I Forgot My Password

ADVERSE REACTION REPORTING – CHARMS DATA WEB – Initial web access established, now You can submit the Adverse Event Report.

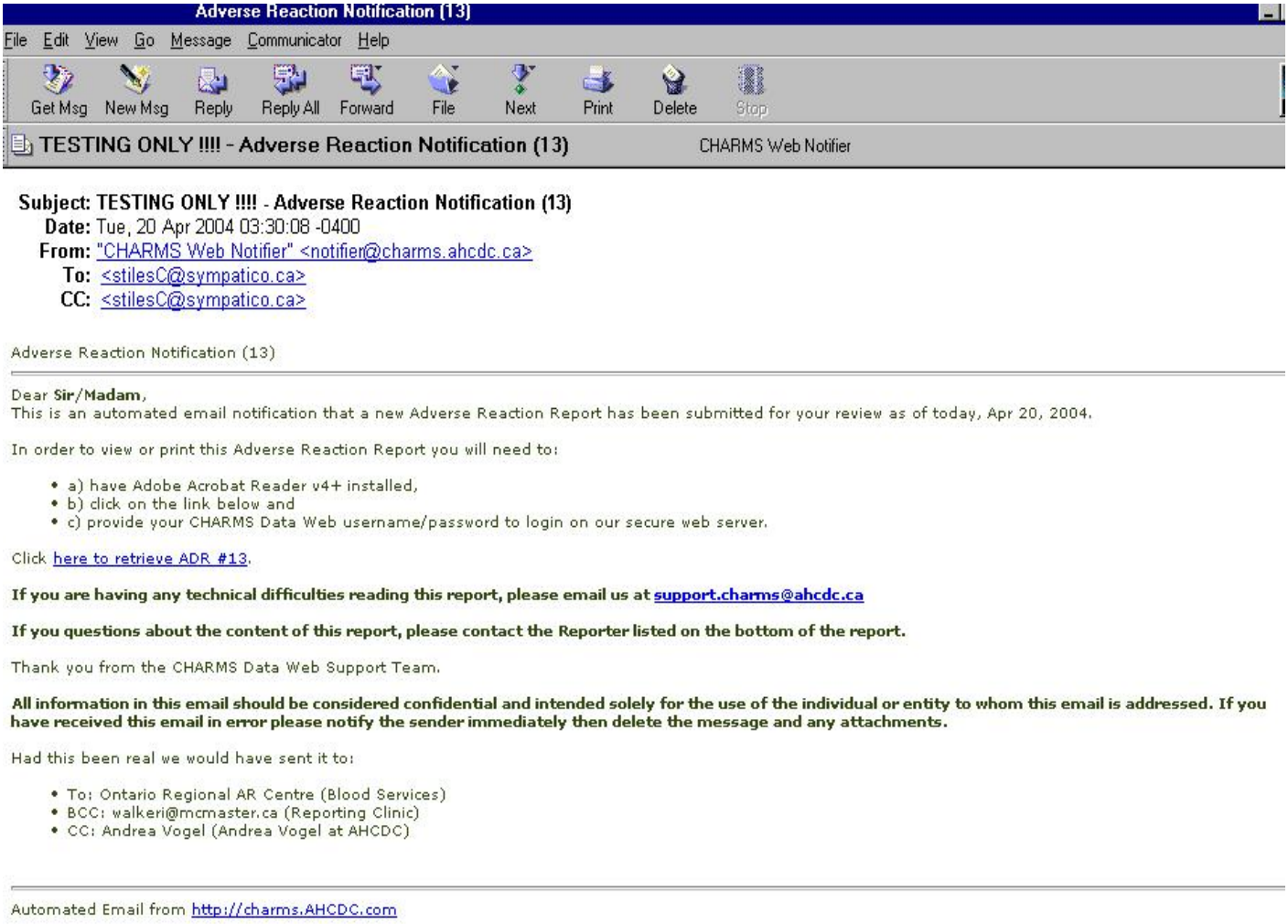
Unless you get the SUCCESSFUL submission message, your report has not been submitted. You may Try to submit until you get the SUCCESSFUL message. If you encounter any problems, please contact Your CHARMS Support.



ADVERSE REACTION REPORTING – EMAIL NOTIFICATION SENT TO RECIPIENTS

The following is a sample of the email notification that will be sent out to the intended recipients notifying Them that an Adverse Event has been submitted.

Each request to view is logged along with the requestor's IP address. Only the people notified will be able to view the report that was intended for them only.



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