



VOICE PSRT Query Message Board

Last updated: 4-Dec-09

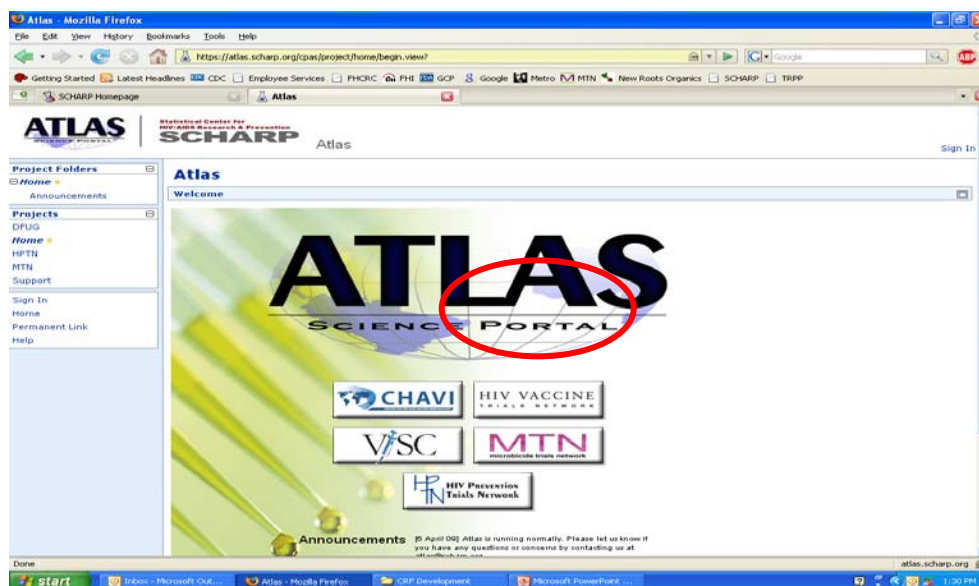
Updated by: Karen Patterson

Introduction

When sites need to submit Protocol Safety Review Team (PSRT) queries, they complete the MS Word query document and e-mail it to the Protocol Safety Physicians. The Protocol Safety Physicians will review the query document, add their recommendations to the document, and post the updated document to the message board. As a user of the message board, you can view the content of the attached queries and post responses - to the queries themselves and to the recommendations of the Protocol Safety Physicians - directly on the message board. You can also configure your preferences for receiving e-mail notifications from the message board when a new query or response is posted.

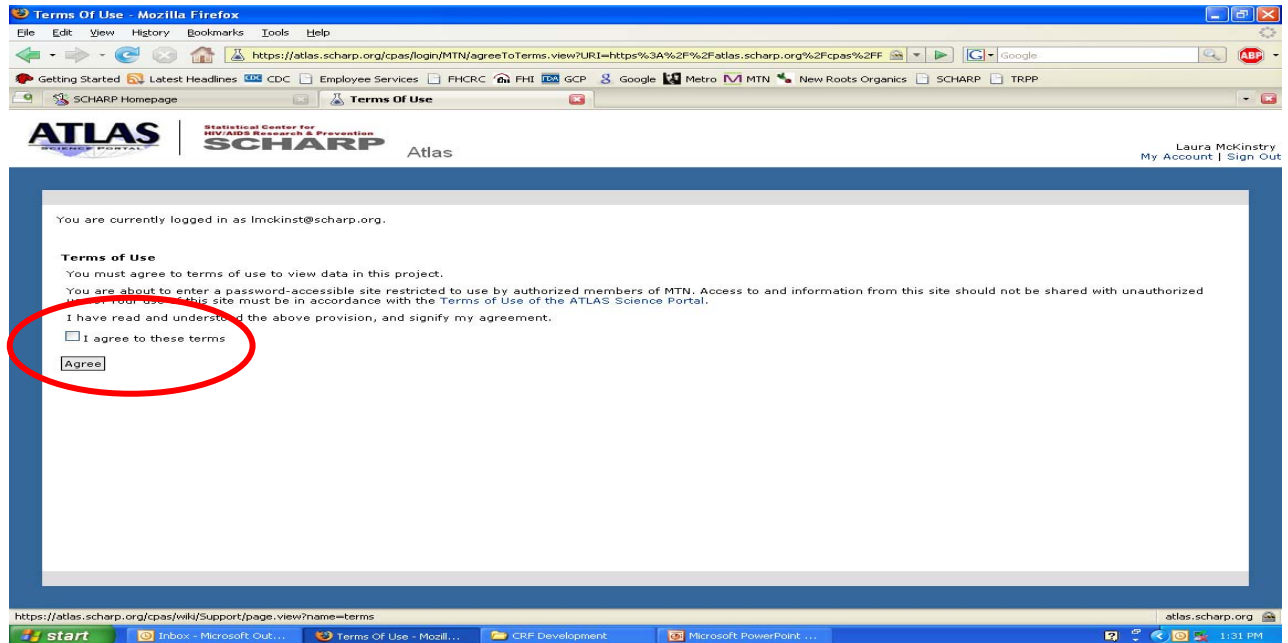
Please note that site staff should NOT post queries directly to Atlas; rather, they should e-mail the queries to the Protocol Safety Physicians per the query document instructions.

The VOICE PSRT Query Message Board is password-protected. Access to the message board is limited to members of the SCHARP Atlas group and to users who are subscribed to the PSRT alias list (mtn003psrt@mtnstopshiv.org). (Visit the MTN web site to see a complete list of members subscribed to the alias list: <http://www.mtnstopshiv.org/people/emailgroups/100/cards>). The message board is located on the Atlas Science Portal: <https://atlas.scharp.org>. The home page appears below.

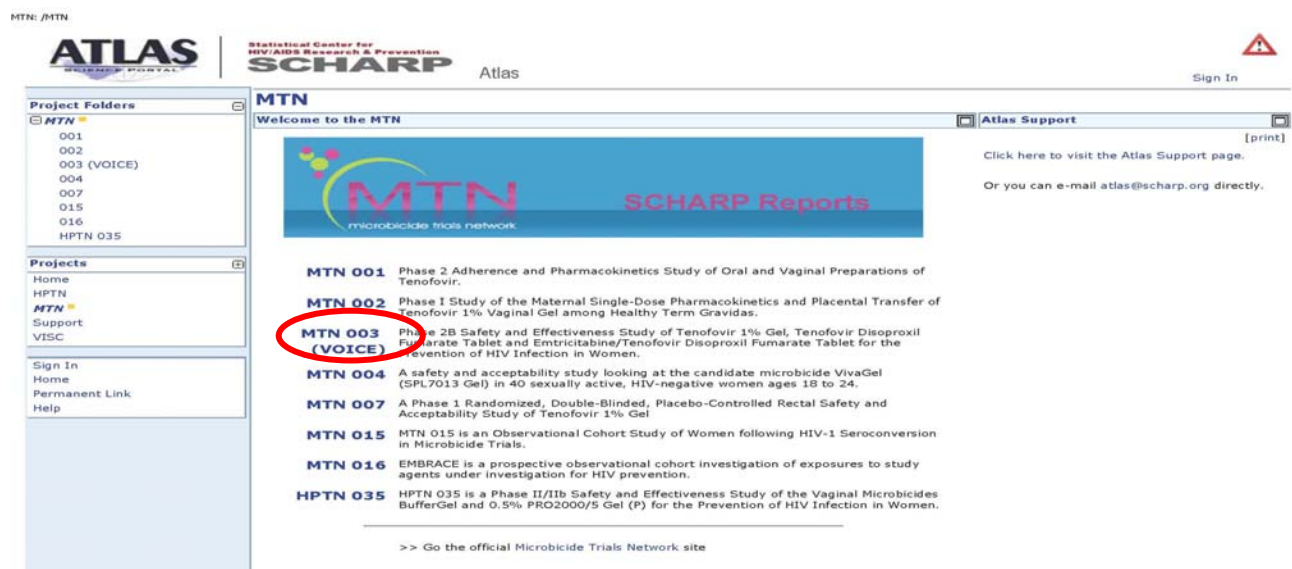




Click on the “MTN” button on the main page (or the “MTN” link on the left-hand side menu). This will bring you to the “Terms of Use” page which appears below. Click on the box next to “I agree to these terms”, then click on the “Agree” button.



Next, you will see the page below listing each of the MTN studies on Atlas. Click on “MTN 003 (VOICE)” to navigate to the MTN-003 (VOICE) Atlas page.





Below is the MTN-003 (VOICE) Atlas page. To view the PSRT page, click on the link “Click here to view the Secure PSRT Reports and Queries.”

3 (VOICE): /MTN/003 (VOICE)

ATLAS | Statistical Center for HIV/AIDS Research & Prevention **SCHARP** Atlas

003 (VOICE)

Welcome to MTN 003 (VOICE)

The VOICE Study – Vaginal and Oral Interventions to Control the Epidemic – is the first study to compare the safety and efficacy of oral versus topical pre-exposure prophylaxis (PrEP) for prevention of sexual transmission of HIV. VOICE is designed as a five-arm, double-blinded study in which women are first randomized to receive either gel or oral PrEP, and then within each group, randomly assigned to either tenofovir topical gel or placebo gel; or to oral tenofovir, oral Truvada or oral placebo. The study will enroll 4,950 women at 16 sites in South Africa, Malawi, Uganda, Zambia and Zimbabwe.

MTN 003 Open Reports

Document:	Reporting Period:
Enrollment and Retention	Current

Memos

Document:
Enrollment and Retention Reports - Key to Interpretation

MTN 003 Secure Sections

- >> [Click here to view the SAFETY Message Board](#)
- >> [Click here to view the PRODUCT ADHERENCE Message Board](#)
- >> [Click here to view the Secure PSRT Reports and Queries](#)
- >> [Click here to view the Secure DSMB Reports](#)

You will be prompted to sign on to Atlas with your user name and password. If you have any questions, please visit our Support page.

MTN 003 (VOICE) Dashboard

Protocol Statisticians: Ben Masse
Barbra Richardson

Project Managers: Karen Patterson
Laura McKinstry

Statistical Research Associates: Cliff Kelly
Sharavi Gandham
Joleen Borgerding

Clinical Affairs Safety Associate: Molly Swenson

Data Coordinator: Jennifer Schille

Protocol Programmers: Hongli Li
Jami Moksness
Martha Doyle

Reporting Programmer: James Sundberg

ACASI Programmer: Lynda McVarish

Laboratory Programmer: Mark Bollenbeck

Document Specialist: Stacie Kentop

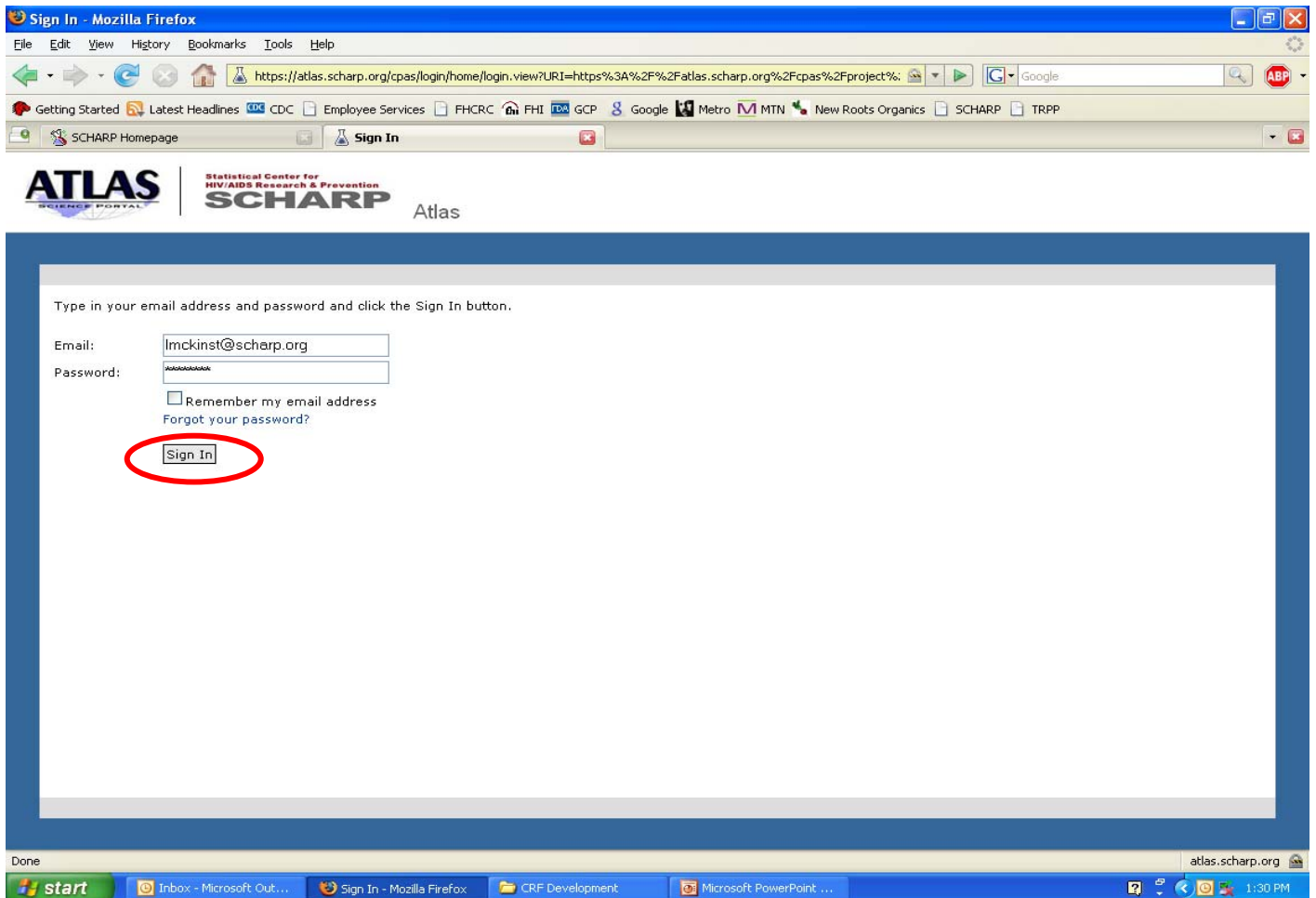
Atlas Support

Click here to visit the Atlas Support page.

Or you can e-mail atlas@scharp.org directly.



You will be prompted to log in to Atlas to view the message board. Below is how the log-in page will appear. Enter the e-mail address associated with your Atlas account. If you have an existing Atlas account, log in with the same e-mail address and password that you have used in the past to access other secure reports on Atlas. If you are a new Atlas user, enter your e-mail address as it appears in the “Welcome to Atlas” message you received from Shane Coultas at SCHARP. Enter your password, then click the “Sign In” button. If you do not remember your password, click on the “Forgot your password?” link. You may also e-mail atlas@scharp.org directly for assistance logging in to Atlas.





Once you have logged in, you will see the VOICE Atlas PSRT page below. Click on the link “PSRT Queries” to go the PSRT Query Message Board.

Statistical Center for HIV/AIDS Research & Prevention
SCHARP Atlas

karenp@scharp.org
My Account | Sign Out

PSRT

MTN 003 (VOICE) Protocol Safety Review Team Reports

Document:	Reporting Period:
Protocol Safety Review Reports	Current Archive
Product Hold Report	Current

Description of MTN 003 (VOICE) PSRT Report Tables

PSRT Queries
Click here to view the PSRT Queries.

MTN 003 (VOICE) Dashboard

Protocol Statisticians: Ben Masse
Barbra Richardson

Project Managers: Karen Patterson
Laura McKinstry

Statistical Research Associates: Cliff Kelly
Sharavi Gandham
Joleen Borgerding

Clinical Affairs Safety Associate: Molly Swenson

Data Coordinator: Jennifer Schille

Protocol Programmers: Hongli Li
Jami Moksness
Martha Doyle

Reporting Programmer: James Sundberg

ACASI Programmer: Lynda McVarish

Laboratory Programmer: Mark Bollenbeck

Document Specialist: Stacie Kentop

Confidentiality Statement

Study safety data reports are intended for use and distribution to PSRT members only. The data in these reports and any review, comments, conclusions, or decisions arising from them are regarded as confidential and may not be distributed, shared, or discussed with individuals outside of the PSRT unless specific authorization from the PSRT Chair has been obtained.

Atlas Support [print]

Click here to visit the Atlas Support page.

Or you can e-mail atlas@scharp.org directly.






Viewing PSRT Queries and Discussions

Below is how the PSRT Query Atlas page will appear. You will see a table listing by title (the “Query Topic” column) all active/pending PSRT queries submitted to date in VOICE. Each query will appear as its own separate row, and the queries will appear in chronological order with the most recent query at the top of the table. You may change which queries appear by choosing an option under “Filtered views”, which is circled in green in screenshot below. To see previous PSRT queries that have been resolved, click on the link “Resolved Queries”. To see PSRT queries that did not require a response or were submitted in error, click on the link “Other Queries”. To see a complete list of all PSRT queries submitted to date (resolved and active), click on the link “Whole List”.

To view a query, click on the document icon of the query you would like to see. An example is circled below in red. To view all discussion related to a given query, click on the box in the far left column of the query you would like to see. For example, to see discussion related to “CM: Bleeding” in the example below, click on the box circled in purple.

PSRT Queries [edit] [manage] [history] [print]

Text here about using the message boards, or an introduction.

Query Date:	Query Topic:	Site:	Query Form:
<input type="checkbox"/> 17 Nov 2009	CM: Bleeding	MU-JHU	
<input type="checkbox"/> 23 Nov 2009	CM: Creatinine/Creatinine ...	MU-JHU	
<input type="checkbox"/> 18 Nov 2009	CM: Creatinine/Creatinine ...	MU-JHU	
<input type="checkbox"/> 25 Dec 2009	Eligibility Question	RK Khan	
<input type="checkbox"/> 17 Nov 2009	Product Hold: Hypophosph...	RK Khan	

Page 1 of 1 Displaying 1 - 5 of 5

Views [edit] [manage] [history] [print]

Enter a new query - only editors can see this link

Edit an existing query - only editors can see this link

- Filtered views**
- >> Resolved Queries
 - >> Other Queries
 - >> Whole List

MTN 003 (VOICE) Dashboard [print]

- Protocol Statisticians:** Ben Masse
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Laura McKinstry
- Statistical Research Associates:** Cliff Kelly
Sharavi Gandham
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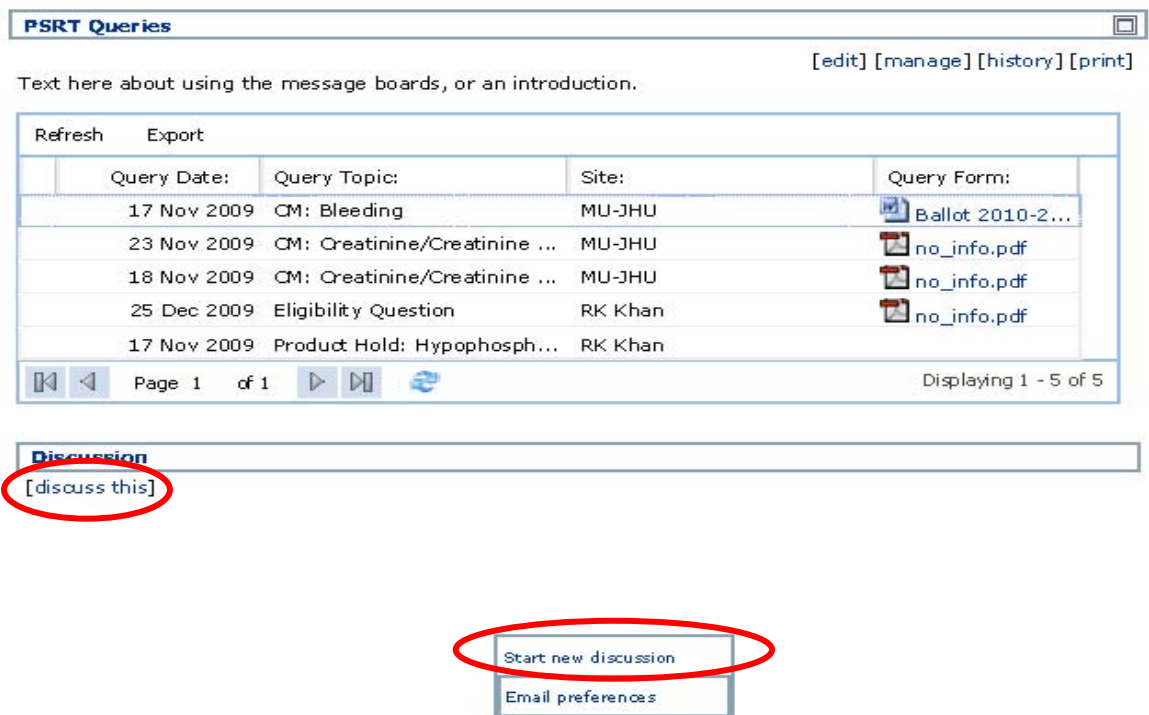
Posting Responses to PSRT Queries

When you click on the box in the far left column of a given query, all posted discussion related to the query will appear at the bottom of the Atlas page.

Starting a New Discussion

Below is a screenshot of what the page will look like if no responses have been posted yet to a given query. To post the first response to a given query, and thus start a new discussion about the query, click on the link “[discuss this]”. A pop-up menu will appear; click on “Start new discussion”. Any member of the PSRT may start a new discussion.

The pop-up menu also has an “Email preferences” link that you can use to set your preferences for receiving notifications about postings to the PSRT Query message board. This will be discussed in more detail at the end of this document.



PSRT Queries [edit] [manage] [history] [print]

Text here about using the message boards, or an introduction.

Query Date:	Query Topic:	Site:	Query Form:
17 Nov 2009	CM: Bleeding	MU-JHU	Ballot 2010-2...
23 Nov 2009	CM: Creatinine/Creatinine ...	MU-JHU	no_info.pdf
18 Nov 2009	CM: Creatinine/Creatinine ...	MU-JHU	no_info.pdf
25 Dec 2009	Eligibility Question	RK Khan	no_info.pdf
17 Nov 2009	Product Hold: Hypophosph...	RK Khan	

Page 1 of 1 Displaying 1 - 5 of 5

Discussion

[discuss this]

Start new discussion

Email preferences

Adding to an Existing Discussion

Below is a screenshot of what the page will look like if responses have already been posted to a given query. To post a new response to the discussion, click on the “Post Response” button. Any member of the PSRT may post a response.

PSRT Queries [edit] [manage] [history] [print]

Text here about using the message boards, or an introduction.

Query Date:	Query Topic:	Site:	Query Form:
17 Nov 2009	CM: Bleeding	MU-JHU	Ballot 2010-2...
23 Nov 2009	CM: Creatinine/Creatinine ...	MU-JHU	no_info.pdf
18 Nov 2009	CM: Creatinine/Creatinine ...	MU-JHU	no_info.pdf
25 Dec 2009	Eligibility Question	RK Khan	no_info.pdf
17 Nov 2009	Product Hold: Hypophosph...	RK Khan	

Page 1 of 1 Displaying 1 - 5 of 5

Discussion [see discussions (1)]

Discussion X

A discussion about Query Topic: CM: Creatinine/Creatinine Clearance Shane Coultas [edit] 2009-11-17 11:31

A discussion about Query Topic: CM: Creatinine/Creatinine Clearance

Shane Coultas responded: [edit] [delete] 2009-11-17 11:32

A discussion about Query Topic: CM: Creatinine/Creatinine Clearance

A discussion about Query Topic: CM: Creatinine/Creatinine Clearance





A discussion about Query Topic: CM: Creatinine/Creatinine Clearance

Post Response
Delete Message

A response section will appear at the bottom of the page, as in the example below. Please note that the response section may take a minute to load and appear on the page. Enter your response in the field labeled “Body”. If you would like to attach a document related to your response, you may do so by clicking on the link “Attach a file”. When you have completed your response, click on the “Submit” button to post your response to the query. This will allow you and other users to view your response.

PSRT Queries [edit] [manage] [history] [print]

Text here about using the message boards, or an introduction.

Query Date:	Query Topic:	Site:	Query Form:
17 Nov 2009	CM: Bleeding	MU-JHU	
23 Nov 2009	CM: Creatinine/Creatinine ...	MU-JHU	
18 Nov 2009	CM: Creatinine/Creatinine ...	MU-JHU	
25 Dec 2009	Eligibility Question	RK Khan	
17 Nov 2009	Product Hold: Hypophosph...	RK Khan	

Page 1 of 1 Displaying 1 - 5 of 5

Discussion [discuss this]


Start a new discussion

Title: **A discussion about Query Topic: CM: Bleeding**

Body

Render AS: **Plain Text**

Attachments

 Attach a file

NOTE: Replying to an e-mail notification from Atlas **DOES NOT** add the response into the discussion on Atlas. To post a response, you must log into Atlas, navigate to the appropriate query discussion page, and post your response there (per the above instructions).

Viewing, Sorting, and Filtering Query Discussions

You may reorder the list of queries to sort by the date the query was posted (“Query Date”), by the title of the query (“Query Topic”), or by study site (“Site”). Simply move the cursor over a column header, and click on the small black arrow that appears to the right of the header text. A small menu will appear, as seen in the screenshot below. You may choose to sort in ascending or descending order within a given column. For example, to view the list of queries by site and in alphabetical order, click on “Sort Ascending”.

PSRT Queries [edit] [manage] [history] [print]

Text here about using the message boards, or an introduction.

Refresh	Export	Query Date:	Query Topic:	Site:	Query Form:
		17 Nov 2009	CM: Bleeding	MU-JHU	Ballot 2010-2...
		23 Nov 2009	CM: Creatinine/Creatinine ...	MU-JHU	no_info.pdf
		18 Nov 2009	CM: Creatinine/Creatinine ...	MU-JHU	no_info.pdf
		25 Dec 2009	Eligibility Question	RK Khan	no_info.pdf
		17 Nov 2009	Product Hold: Hypophosph...	RK Khan	

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- Sort Ascending
- Sort Descending
- Columns

Displaying 1 - 5 of 5



Editing Responses

Users may only edit or delete responses that they have posted.

Configuring E-mail Preferences

By default, each user has his/her e-mail preferences set to “All” notifications and “Individual” notification type, as specified below. This means that each user will receive an immediate e-mail notification each time a new query or response is posted to the message board, and each time a query or response is edited or deleted. You may choose to change your e-mail settings depending on your preference. To do so, simply click on the “[discuss this]” link or the “[see discussions]” link and then click on “Email preferences” which appears on the pop-up menu. Here you can choose from the following options:

Send email notifications for these messages

- **None** - Don't send me any e-mail for this message board
- **Mine** - Send me e-mail for posts to my messages (I've posted to the message) (*Default setting*)
- **All** - Send me e-mail for all posts

Notification type

- **Individual** - send a separate e-mail after each post
- **Daily Digest** - send one e-mail each day that summarizes all posts (*Default setting*)

After you've selected which e-mail option you would like, click the “[Update]” button under the options list. This saves your preferences for this message board only. If you are a member of other message boards, you will have to set your preferences for each individual message board.