

# Specimen Data Quality Control

SCHARP Lab Data Management  
October/November 2024



# Agenda

- **Specimen Data Quality Control (SDQC)**
  - Why is SDQC important?
  - Flow of specimens & programmatic checks
  - Common specimen data QCs
- **The SDQC Web Tool (SpeQs)**
  - Viewing & resolving QCs
  - Example QC scenarios
- **Re-cap & Summary**
- **Questions & Contacts**

# Specimen Data Management

- Specimen data reconciliation for HPTN studies is overseen by SCHARP Lab Data Management (LDM)
  - **SCHARP** (Statistical Center for HIV/AIDs Research & Prevention)
    - Located in Seattle, WA, USA at Fred Hutch
- SCHARP LDM Goal
  - Ensure and preserve the integrity of laboratory data for research and clinical trials
  - SCHARP works in partnership with HPTN to perform SDQC for all studies



# Why is Lab Data Important?

Specimens collected from participants are precious and we don't want them to be wasted:

- Participant time
- Clinic time and resources
- Processing lab time and reagents
- Shipping costs
- Assay lab time and reagents

- **Study Impacts:**

- HIV Diagnostics
- Primary & secondary assays

We must ensure the accuracy of specimen data by comparing various data streams and fixing errors in a timely manner.



Clinical Research Site  
(CRS)



Specimen  
Processing Lab  
(SPL)



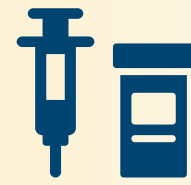
Specimen  
Storage



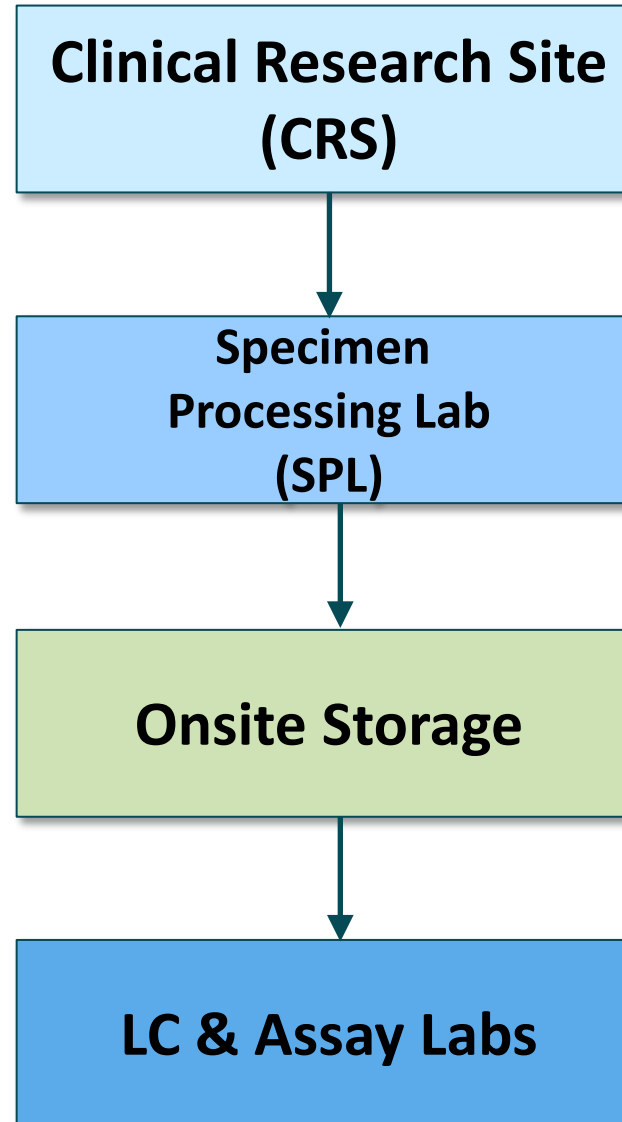
Site Testing  
Labs

Laboratory Center  
& Assay Labs

# Flow of Specimens

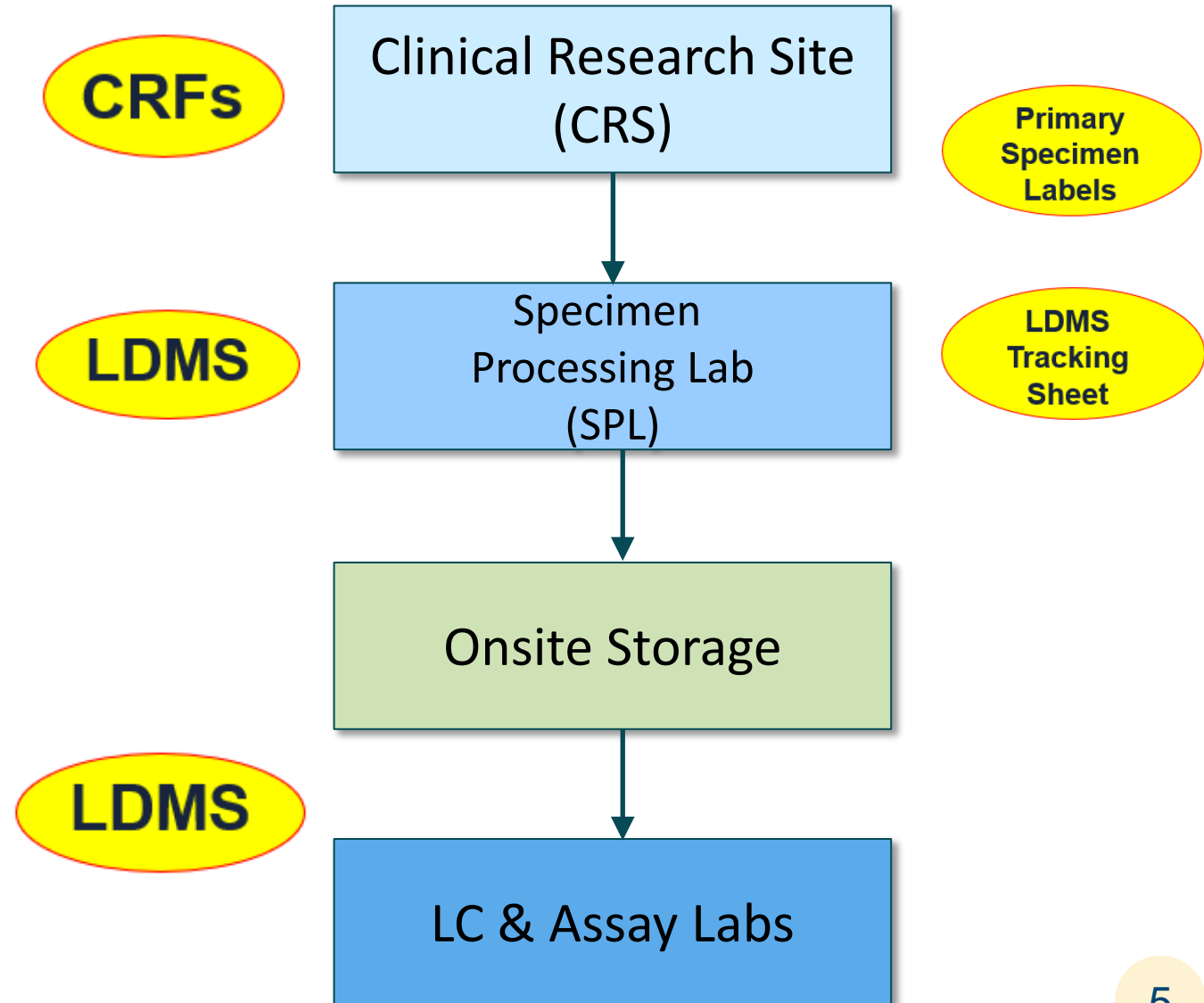


Specimens are collected at the CRS, processed at SPL, then stored or sent for testing



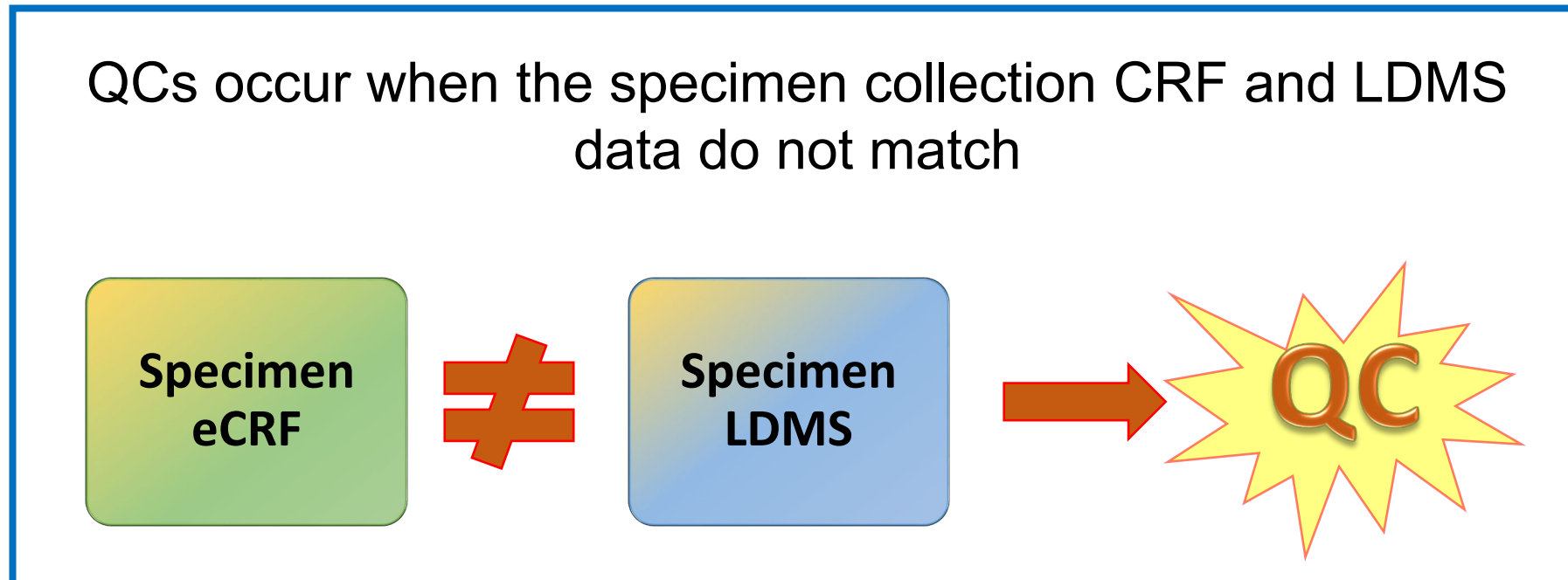
# Flow of Specimens

Specimen data is recorded in multiple places



# Specimen Data Quality Control

Some of the same data are collected on the specimen CRFs and in the lab database (LDMS)



## What do we compare between CRF and LDMS data?

- Participant ID
- Specimen Collection Date
- Specimen Type
- Visit Number/Code
- Visit Type
- Protocol number
- Primary specimen → aliquots (GUSPECs)
- Specimen Storage

We look for  
missing data,  
data mismatches,  
and data entry  
errors

# Common CRF-LDMS Discrepancies

- Missing CRF specimen information
- Missing LDMS data
- Specimens match by visit but not by collection date
- Specimens match by collection date but not visit number



# LDMS Data Checks

1

Specimen Code Combination

Specimen code combination (primary, additive, derivative, etc.) matches expectations based on Lab SSP/Manual



2

Volume & Visit Units

Aliquot volume unit matches expectations based on Lab SSP/Manual. Visit units are as expected (usually VST for HPTN).

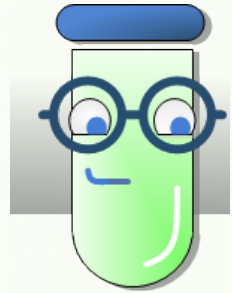
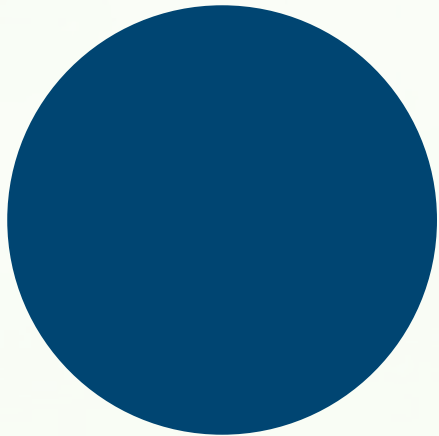


3

Storage Location

An aliquot storage location is entered into LDMS.





# SDQC Tool

SCHARP software tool for Specimen Data  
Entry Quality Control

# How will we report QCs to you?

The SDQC Tool is a reporting tool that displays the open specimen QCs for your site/lab

The screenshot shows the 'SpeQs - Specimen Data Entry QCs' web application. The header includes navigation links for 'Discrepancies' and 'Change Requests', and user options for 'Contact LDO' and 'Logout'. The main content area is titled 'CRS: Soweto - Bara' and 'Specimen Discrepancies'. A search form allows filtering by Record ID, PTID, Protocol, Specimen Type, and Status. Below the form, a table displays the results for 'Status: CRS Review / CRS Acted'. The table has columns for Record ID, Protocol, PTID, CRF Visit/LDMS Visit, Specimen Type, Error Type, Date Approved, Status, and SPL. Three records are shown, all with the error 'CRF Shows Specimen was Stored but No Match to Lab Data'.

	Record ID	Protocol	PTID	CRF Visit/LDMS Visit	Specimen Type	Error Type	Date Approved	Status	SPL
<a href="#">view</a>	400	1	999999100	8 / -	Plasma	CRF Shows Specimen was Stored but No Match to Lab Data	2016-10-21	CRS Review	Johannesburg - BARC-JHB
<a href="#">view</a>	398	1	999999100	3 / -	Plasma	CRF Shows Specimen was Stored but No Match to Lab Data	2016-10-21	CRS Review	Johannesburg - BARC-JHB
<a href="#">view</a>	399	1	999999100	5 / -	Plasma	CRF Shows Specimen was Stored but No Match to Lab Data	2016-10-21	CRS Review	Johannesburg - BARC-JHB

# SpeQs SDQC Tool



- Secure web-based application
  - Access via web browser: Internet Explorer, Firefox, Chrome
- User authentication via Atlas Portal
- User-specific views
- Search, sort, filter discrepancies
- Communication panel for comments, questions, adding attachments per QC
- User-controlled workflow
- Complete audit log
- Discrepancy status history
- Exportable data

### Specimen Discrepancies

Show Discrepancies

Record ID:

or

PTID:

or

Only protocols and specimen types with QCs can be selected.

Protocol:

Specimen Type:

Status:

Show

# SDQC Tool

**Type:** Lab Data-CRF Specimen Collection Dates Don't Match

<b>CRS:</b> Harare - Milton Park	<b>SPL:</b> 306: SekeSo UZ (306)
<b>PTID:</b> 999991498	<b>Status:</b> SPL Review
<b>Network:</b> HPTN	<b>Date Opened:</b> 5-Mar-2019
<b>Record ID:</b> 100018	<b>Date Approved:</b> 3-Sep-2024
<b>GUSPEC:</b> T7XXX7QC	<b>Date Closed:</b>
<b>Protocol:</b> 11	
<b>Specimen Type:</b> Plasma	

### Error Summary

	CRS Values	Lab Values
<b>Specimen Date:</b>	2019-02-01	2017-09-12
<b>Visit Number:</b>	2	2
<b>Specimen Time:</b>	10:07	11:43
<b>Time Pt:</b>	-	-
<b>Time Pt Unit:</b>	-	-

### All Related QC Records [View Records >](#)

	GUSPEC	LDMS Lab ID	Condition Code	Secondary Condition Code	Date Created	State	Excluded
	T7XXX7QC-01	306	SAT		2019-03-05	Open	No
	T7XXX7QC-02	306	SAT		2019-03-05	Open	No
	T7XXX7QC-03	306	SAT		2019-03-05	Open	No
	T7XXX7QC-04	306	SAT		2019-03-05	Open	No
	T7XXX7QC-05	306	SAT		2019-03-05	Open	No

### CRS Response

<b>Is CRF Data Correct:</b>	Yes
<b>Does source documentation need correction:</b>	No
<b>Comment:</b>	CRF data is correct. Lab to update records.
<i>sruss@scharp.org, 2024-09-03 4:29 PM</i>	

### SPL Response

<b>Do you have source documentation that matches the CRF data:</b>	
<b>Was the correction made in LDMS:</b>	
<b>Comment:</b>	
No response to display	

### Comments / Attachments + Add

Timestamp	User	Role	Comment
-----------	------	------	---------

# SDQC Tool

- Each record has a comments and attachments section.
  - Scroll to bottom of QC detail page to view this. This section is the only place to see comments from LDM and the LC.
- Each record has an action log so we can track all work completed on the discrepancy.

Comments / Attachments Add

Timestamp	User	Role	Comment
2021-01-12 5:39 AM	ifyoung@scharp.org	CRS	Tracking sheet is attached
2021-01-12 5:38 AM	ifyoung@scharp.org	CRS	The tracking sheet has been emailed
2021-01-07 7:09 AM	ifyoung@scharp.org	SPL	Please send updated information to lab
2021-01-07 7:07 AM	ifyoung@scharp.org	CRS	LDMS tracking sheet and labels had incorrect date

▲ Action Log

Timestamp	Action	Action By	Role	Resulting Status	Summary
2021-01-12 5:39 AM	Comment	ifyoung@scharp.org	CRS	SPL Review	Comment: Tracking sheet is attached
2021-01-12 5:38 AM	Add CRS Response	ifyoung@scharp.org	CRS	SPL Review	Is CRF Data Correct: Yes Does source documentation need correction: Yes Comment: The tracking sheet has been emailed
2021-01-07 7:09 AM	Add SPL Response	ifyoung@scharp.org	SPL	CRS Review	Was the correction made in LDMS: No Do you have source documentation that matches the CRF data: No Comment: Please send updated information to lab
2021-01-07 7:07 AM	Add CRS Response	ifyoung@scharp.org	CRS	SPL Review	Is CRF Data Correct: Yes Does source documentation need correction: No Comment: LDMS tracking sheet and labels had incorrect date
2021-01-06 3:13 PM	Approve	sruss@scharp.org	LDM	CRS Review	
2021-01-06 3:04 PM	Move to Submitted	system	System	Submitted	

# Role-Based Views



**Laboratory Center: Full Access**

**Specimen Discrepancies**

Show Discrepancies **SpeQs** · Specimen Data Entry QCs Discrepancies Change Requests

Record ID: **CRS: Medunsa**

**Specimen Discrepancies**

Show Discrepancies **SpeQs** · Specimen Data Entry QCs Discrepancies Change Requests

Record ID: **SPL: FHCRC (373)**

**Specimen Discrepancies**

Show Discrepancies **SpeQs** · Specimen Data Entry QCs Discrepancies Change Requests

Record ID: **Non-SPL: BARC Bio Banking Repository (481)**

**Specimen Discrepancies**

Show Discrepancies

Record ID:

or

PTID:

or

Only protocols and specimen types with QCs can be selected.

Protocol:

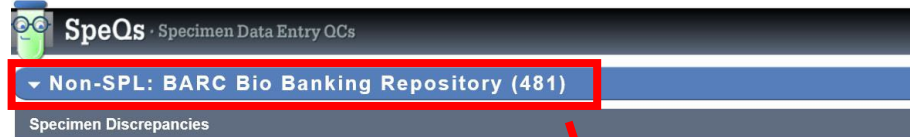
Specimen Type:

Related QC State:

Show



# Multiple Roles



SpeQs · Specimen Data Entry QCs

▼ Non-SPL: BARC Bio Banking Repository (481)

Specimen Discrepancies

Show Discrepancies

Record ID:

or

PTID:

or

Only protocols and specimen types with QCs can be selected.

Protocol:

Specimen Type:

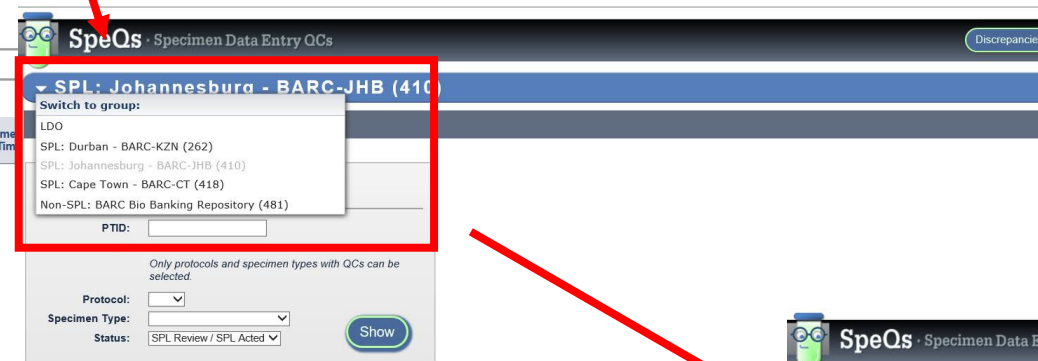
Related QC State: Open

Show

Related QC State: Open

Export

Record ID	Protocol	PTID	CRF Visit/ LDMS Visit	CRF Coll Date/ LDMS Coll Date	CRF Coll Time/ LDMS Coll Time
-----------	----------	------	--------------------------	----------------------------------	----------------------------------



SpeQs · Specimen Data Entry QCs

Discrepancies

▼ SPL: Johannesburg - BARC-JHB (410)

Switch to group:

- LDO
- SPL: Durban - BARC-KZN (262)
- SPL: Johannesburg - BARC-JHB (410)
- SPL: Cape Town - BARC-CT (418)
- Non-SPL: BARC Bio Banking Repository (481)

PTID:

Only protocols and specimen types with QCs can be selected.

Protocol:

Specimen Type:

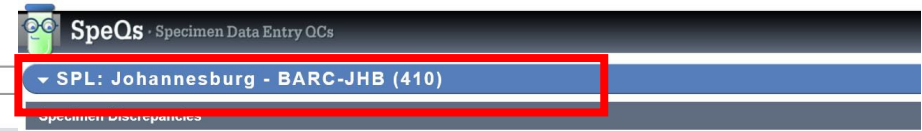
Status: SPL Review / SPL Acted

Show

Status: SPL Review / SPL Acted

Export

Record ID	Protocol	PTID	CRF Visit/ LDMS Visit	CRF Coll Date/ LDMS Coll Date	CRF Coll Time/ LDMS Coll Time	Specimen Type
-----------	----------	------	--------------------------	----------------------------------	----------------------------------	---------------



SpeQs · Specimen Data Entry QCs

▼ SPL: Johannesburg - BARC-JHB (410)

Specimen Discrepancies

Show Discrepancies

Record ID:

or

PTID:

or

Only protocols and specimen types with QCs can be selected.

Protocol:

Specimen Type:

Status: SPL Review / SPL Acted

Show

Status: SPL Review / SPL Acted

Export

Record ID	Protocol	PTID	CRF Visit/ LDMS Visit	CRF Coll Date/ LDMS Coll Date	CRF Coll Time/ LDMS Coll Time	Specimen Type	Error Type
-----------	----------	------	--------------------------	----------------------------------	----------------------------------	---------------	------------

Occasionally, a single user can have multiple user roles within the SDQC Tool.

A drop-down menu in the blue banner means that a user can switch between the role views (e.g., SPL vs. Non-SPL in this example) within the tool.

# QC Resolution Flow

## CRS Review

- First to see new discrepancies
- Reviews CRF information
- Makes corrections or comments



## SPL Review

- Reviews LDMS information and source documentation
- Makes corrections or comments
- **Informs other labs of changes**



## LC & Assay Labs (Non-SPL) Review

- Correction summary forwarded to other LDMS labs with associated specimens
- Makes corrections

- LDM, LC, and CDM are here to help.
- SCHARP LDM reviews and approves all QCs before pushing them to the sites/labs.
- SCHARP LDM monitors QC resolution in the SDQC Tool and provides assistance when needed.
- Some QCs can never be resolved (ex. Dropped tube) and we have procedures to document this.

# QC Statuses: What do they mean?

## Action Required!

- **CRS Review**
  - Needs clinic review
- **SPL Review**
  - Needs lab review
- **Non-SPL Review**
  - Needs review by LC or other assay labs\*

## Action Taken

- **CRS Acted**
  - QC will close when updated CRF data received at SCHARP
- **SPL Acted**
  - QC will close when updated LDMS received at SCHARP
- **Excluded**
  - QC will not resolve, action taken by LDM with HPTN LC approval
- **Closed**
  - Data matches! Closed by system 1 day after corrections made.

\*If your QC goes to this status, please make sure you have requested any changes needed from the non-SPL lab. The HPTN LC requires email requests.

# QC Resolution

- We aim to have all SDQCs resolved prior to data monitoring meetings and database locks.
- The goal is also to have no open SDQCs on specimens when they are shipped to other labs and/or sent for assay analysis.
- HPTN expectation: Respond to QCs within 1 week.

# Viewing & Resolving QCs

## CRS: Harare - Spilhaus

### Specimen Discrepancies

Show Discrepancies

Record ID:

or

PTID:

or

Only protocols and specimen types with QCs can be selected.

Protocol:

Specimen Type:

Status:

Show

Status: All Open

Reset Filtering and Sorting

Column visibility

Export

Showing 1 to 3 of 3 records

Previous

1

Next

Show 25 entries

	Record ID	Network	Protocol	PTID	CRF Visit/ LDMS Visit	CRF Coll Date/ LDMS Coll Date	CRF Coll Time/ LDMS Coll Time	Specimen Type	Error Type	Date Approved	Status	SPL	Days to First Action
<a href="#">view</a>	100023	HPTN	11	999990271	- / 19	- / 2015-11-04	- / 13:50	REC-PBS-SPG-N/A	Lab Data Only-No CRF Specimen Match (bad LDMS codes entered)	2024-10-25	SPL Review	306: SekeSo UZ	
<a href="#">view</a>	100013	HPTN	11	999996386	11 / 11	2019-02-06 / 2019-02-15	12:28 / 13:20	Dried Blood Spot	Lab Aliquot Generated-but CRF Notes Specimen was Not Stored	2024-10-25	CRS Review	306: SekeSo UZ	
<a href="#">view</a>	100002	HPTN	11	999998330	14 / -	2018-01-19 / -	11:00 / -	Plasma	CRF Shows Specimen was Stored but No Match to Lab Data	2024-09-03	SPL Review	306: SekeSo UZ	51

# Viewing QC List

CRS: Harare - Spilhaus

Specimen Discrepancies

Show Discrepancies

Record ID:

or

PTID:

or

Only protocols and specimen types with QCs can be selected.

Protocol:

Specimen Type:

Status:

Show

Filter by Record ID, participant ID (PTID), protocol, specimen type or status

Listing of all current QCs needing review for your site.

Status: All Open

Reset Filtering and Sorting

Column visibility

Export

Showing 1 to 3 of 3 records

Previous

1

Next

Show 25 entries

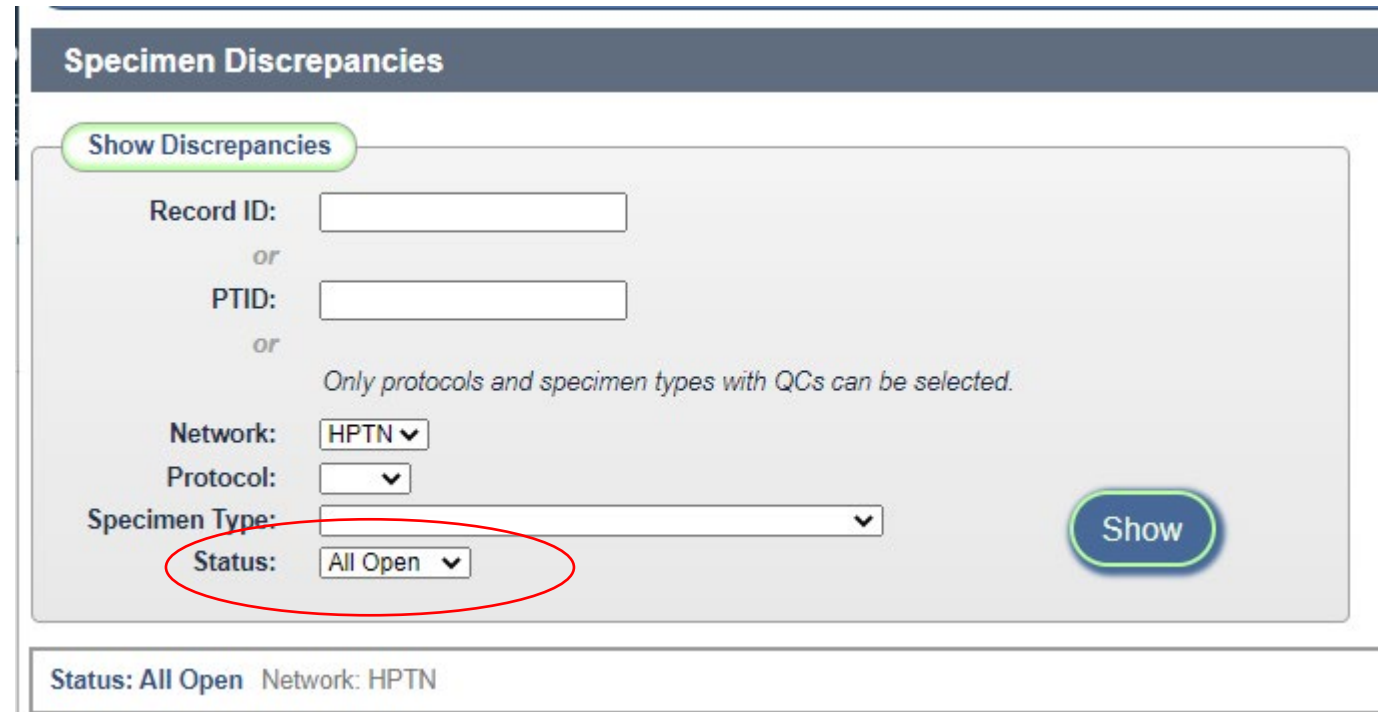
	Record ID	Network	Protocol	PTID	CRF Visit/ LDMS Visit	CRF Coll Date/ LDMS Coll Date	CRF Coll Time/ LDMS Coll Time	Specimen Type	Error Type	Date Approved	Status	SPL	Days to First Action
<a href="#">view</a>	100023	HPTN	11	999990271	- / 19	- / 2015-11-04	- / 13:50	REC-PBS-SPG-N/A	Lab Data Only-No CRF Specimen Match (bad LDMS codes entered)	2024-10-25	SPL Review	306: SekeSo UZ	
<a href="#">view</a>	100013	HPTN	11	999996386	11 / 11	2019-02-06 / 2019-02-15	12:28 / 13:20	Dried Blood Spot	Lab Aliquot Generated-but CRF Notes Specimen was Not Stored	2024-10-25	CRS Review	306: SekeSo UZ	

Click view to navigate to individual QC record page

# Status Filter: “All Open”

To see all QCs for your site, change the Status filter to “All Open”

This will show QCs in both CRS Review and SPL Review



The screenshot shows a web interface titled "Specimen Discrepancies". At the top, there is a "Show Discrepancies" button. Below it are input fields for "Record ID:" and "PTID:", with "or" text between them. A note states "Only protocols and specimen types with QCs can be selected." Below this are dropdown menus for "Network:" (set to "HPTN"), "Protocol:", "Specimen Type:", and "Status:". The "Status:" dropdown is circled in red and shows "All Open". A "Show" button is located to the right of the filters. At the bottom, a status bar displays "Status: All Open Network: HPTN".

# QC Detail Page

## QC Detail

[< Return to QC List](#)

Record ID

Type: CRF Shows Specimen was Stored but No Match to Lab Data

CRS:	Harare - Spilhaus		
PTID:	999998330	GUSPEC:	
Network:	HPTN	Protocol:	11
Record ID:	100002	Specimen Type:	Plasma
SPL:	SekeSo - UZ-UCSF (306)		
Status:	CRS Review	Date Opened:	23-Jan-2018
Date Approved:	6-Jan-2021	Date Closed:	

General information about the QC is found in this top section

### Error Summary

	CRS Values	Lab Values
Specimen Date:	19-Jan-2018	-
Visit Number:	14	-
Specimen Time:	11:00	-
Time Pt:	-	-
Time Pt Unit:	-	-

Red fields indicate discrepant specimen data

<h3>CRS Response</h3> <p>Is CRF Data Correct: <input type="button" value="v"/></p> <p>Does source documentation need correction: <input type="button" value="v"/></p> <p>Comment: <input type="text"/></p> <p><input type="button" value="Save and Update Status"/></p>	<h3>SPL Response</h3> <p>Do you have source documentation that matches the CRF data: <input type="text"/></p> <p>Was the correction made in LDMS: <input type="text"/></p> <p>Comment: <input type="text"/></p> <p>No response to display</p>
---	---

Green fields indicate that a response/action is needed

# Key to QC Info

Type: CRF Shows Specimen was Stored but No Match to Lab Data

CRS:	Harare - Spilhaus		
PTID:	999998330	GUSPEC:	
Network:	HPTN	Protocol:	11
Record ID:	100002	Specimen Type:	Plasma

SPL:	SekeSo - UZ-UCSF (306)		
Status:	CRS Review	Date Opened:	23-Jan-2018
Date Approved:	6-Jan-2021	Date Closed:	

**Type:** Description of problem or error type

**CRS:** Clinical research site

**PTID:** Participant ID

**GUSPEC:** Global Specimen ID from LDMS

**Record ID:** Unique number for this QC – use for search or to refer to QC in another discussion

**Specimen Type:** Description of specimen type, or may show LDMS specimen codes

**SPL:** Specimen processing lab & LDMS ID number

**Status:** Current status, as described in a previous slide – changes after response is made

**Date Approved:** Date approved by LDM – first date on which QC would be visible to you

**Date Opened:** First date QC was noticed by system after receiving fresh data

**Date Closed:** Date QC resolved!

# QC Response Flow

Type: CRF Shows Specimen was Stored but No Match to Lab Data

	CRS Values	Lab Values
Specimen Date:	19-Jan-2018	-
Visit Number:	14	-
Specimen Time:	11:00	-
Time Pt:	-	-
Time Pt Unit:	-	-

**CRS Response**

Is CRF Data Correct:

Does source documentation need correction:

Comment:

Save and Update Status

**CRS Response**

Is CRF Data Correct:

Does source documentation need correction:

Comment: Documentation is correct. Lab to review.

Save and Update to SPL Review

**CRS Response**

Is CRF Data Correct:

Does source documentation need correction:

Comment: Updated info has been sent to the lab.

Save and Update to SPL Review

**CRS Response**

Is CRF Data Correct:

Does source documentation need correction:

Comment: CRF was incorrect. No specimen collected. Rave has been updated.

Save and Update to CRS Acted

Depending on how questions are answered in the green boxes, the status of the QC will change to either “SPL Review” or “CRS Acted”.

- **SPL Review** – QC will move to lab for review.
- **CRS Acted** – Clinic has indicated a change will be made in Rave data. QC will close once data received.

# Adding/Viewing Comments

- If the green response box isn't showing up, you can still add a comment at the bottom of the page

Comments / Attachments Add

Timestamp	User	Role	Comment
2021-01-12 5:39 AM	ifyoung@scharp.org	CRS	Tracking sheet is attached
2021-01-12 5:38 AM	ifyoung@scharp.org	CRS	The tracking sheet has been emailed
2021-01-07 7:09 AM	ifyoung@scharp.org	SPL	Please send updated information to lab
2021-01-07 7:07 AM	ifyoung@scharp.org	CRS	LDMS tracking sheet and labels had incorrect date

▲ Action Log

Timestamp	Action	Action By	Role	Resulting Status	Summary
2021-01-12 5:39 AM	Comment	ifyoung@scharp.org	CRS	SPL Review	Comment: Tracking sheet is attached
2021-01-12 5:38 AM	Add CRS Response	ifyoung@scharp.org	CRS	SPL Review	Is CRF Data Correct: Yes Does source documentation need correction: Yes Comment: The tracking sheet has been emailed
2021-01-07 7:09 AM	Add SPL Response	ifyoung@scharp.org	SPL	CRS Review	Was the correction made in LDMS: No Do you have source documentation that matches the CRF data: No Comment: Please send updated information to lab
2021-01-07 7:07 AM	Add CRS Response	ifyoung@scharp.org	CRS	SPL Review	Is CRF Data Correct: Yes Does source documentation need correction: No Comment: LDMS tracking sheet and labels had incorrect date
2021-01-06 3:13 PM	Approve	sruss@scharp.org	LDM	CRS Review	
2021-01-06 3:04 PM	Move to Submitted	system	System	Submitted	

# Specimen at Two Labs

**QC Detail** ✕ 🛑

[< Return to QC List](#) 🔍 Record ID

Type: Lab Data - CRF Specimen Collection Dates Don't Match

CRS:	Kisumu	SPL:	475: Kisumu - KEMRI - CDC (475)
PTID:	[REDACTED]	GUSPEC:	[REDACTED]
Network:	HPTN	Protocol:	84
Record ID:	[REDACTED]	Specimen Type:	Plasma

Status:	Non-SPL Review <span style="color: green;">↔</span>	Date Opened:	25-Jan-2021
Date Approved:	10-May-2021	Date Closed:	

**Error Summary**

	CRS Values	Lab Values
Specimen Date:	12-Jan-2021	11-Jan-2021
Visit Number:	21	21
Specimen Time:	14:07	14:07
Time Pt:	-	-
Time Pt Unit:	-	-

**All Related QC Records** [View Records >](#)

GUSPEC	LDMS Lab ID	Date Created	State	Excluded
0475 [REDACTED]	300	2021-02-09	Open	No
0475 [REDACTED]	475	2021-01-25	Closed	No
0475 [REDACTED]	475	2021-01-25	Closed	No
0475 [REDACTED]	475	2021-01-25	Closed	No
0475 [REDACTED]	475	2021-01-25	Closed	No
0475 [REDACTED]	475	2021-01-25	Closed	No

QC is Closed at SPL but Open at LC lab!

➔ **Required action:** Email LC with requested changes.

# Example QC: Missing Lab Data

Type: CRF Shows Specimen was Stored but No Match to Lab Data

CRS:	Harare - Spilhaus		SPL:	SekeSo - UZ-UCSF (306)			
PTID:	999998330	GUSPEC:	Status:	CRS Review	Date Opened:	23-Jan-2018	
Network:	HPTN	Protocol:	11	Date Approved:	6-Jan-2021	Date Closed:	
Record ID:	100002	Specimen Type:	Plasma				

**Error Summary**

	CRS Values	Lab Values
Specimen Date:	19-Jan-2018	-
Visit Number:	14	-
Specimen Time:	11:00	-
Time Pt:	-	-
Time Pt Unit:	-	-

<p><b>CRS Response</b></p> <p>Is CRF Data Correct: <input type="button" value="v"/></p> <p>Does source documentation need correction: <input type="button" value="v"/></p> <p>Comment: <input type="text"/></p> <p><input type="button" value="Save and Update Status"/></p>	<p><b>SPL Response</b></p> <p>Do you have source documentation that matches the CRF data: <input type="text"/></p> <p>Was the correction made in LDMS: <input type="text"/></p> <p>Comment: <input type="text"/></p> <p>No response to display</p>
--	--

# Example QC: Missing Lab Data

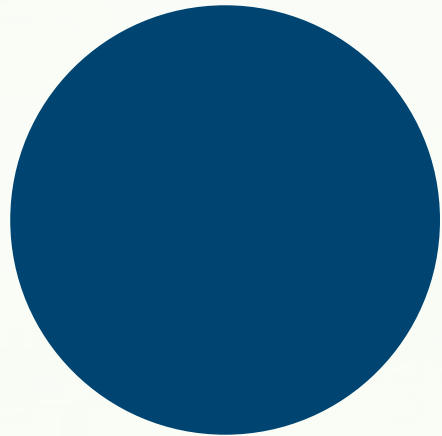
CRS Response		SPL Response	
Is CRF Data Correct:	No ▾	Do you have source documentation that matches the CRF data:	
Does source documentation need correction:	No ▾	Was the correction made in LDMS:	
Comment:	Specimen was not collected. CRF has been updated.		
<a href="#">Save and Update to CRS Acted</a>		No response to display	

## Steps to resolve this QC:

- CRS would review visit documentation for this participant.
- Confirm if a plasma specimen was collected.
- Update the specimen collection CRF.
- Respond to QC in the SDQC Tool.
- QC will close in our system once updated data is received.

# TOOL DEMO

Live QC Resolution Examples



# New Features

Highlighting new features added in 2024

# New Feature Highlights

- Choose column visibility on main page
  - Recommend adding “Comment”, “Comment Date”, and “Comment Role” or “Comment User” to see the most recent comment on the QC
- View “Days to First Action” on main page
  - This is the number of days between QC approval and when the first response/comment was made by CRS or SPL
- View LDMS sample condition code on detail page
- LDM and HPTN LC can tag users in a comment, and an email will be sent to that user
- Weekly email digest content has changed to only show open QCs

# View Customization

- Click on a check-mark column name to unselect columns you no longer want to see
- Click on column name to select the column you do not want to see

Only protocols and specimen types with QCs can be selected.

Protocol:

Specimen Type:

Status:

Show

Status: All Open

Reset Filtering and Sorting Column visibility Export

Showing 1 to 3 of 3 records Previous 1 Next Show 25 entries

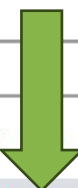
	Record ID	Network	CRF Coll Date/ LDMS Coll Date	CRF Coll Time/ LDMS Coll Time	Specimen Type	Error Type	Change	Date Approved	Status	SPL	Days to First Action
<a href="#">view</a>	100023	HPTN	- / 2015-11-04	- / 13:50	REC-PBS-SPG-N/A	Lab Data Only-No CRF Specimen Match (bad LDMS codes entered)		2024-10-25	SPL Review	306: SekeSo UZ	
<a href="#">view</a>	100013	HPTN	2019-02-06 / 2019-02-15	12:28 / 13:20	Dried Blood Spot	Lab Aliquot Generated-but CRF Notes Specimen was Not Stored		2024-10-25	CRS Review	306: SekeSo UZ	
<a href="#">view</a>	100002	HPTN	2018-01-19 / -	11:00 / -	Plasma	CRF Shows Specimen was Stored but No Match to Lab Data		2024-09-03	SPL Review	306: SekeSo UZ	51



Bonus Tip: Use ~ in the column filters to filter out a term you do not want. E.g., if you don't want to see Plasma samples, you could type "~Plasma" in the Specimen Type column

# Example Customized View

Most recent comment on the QC



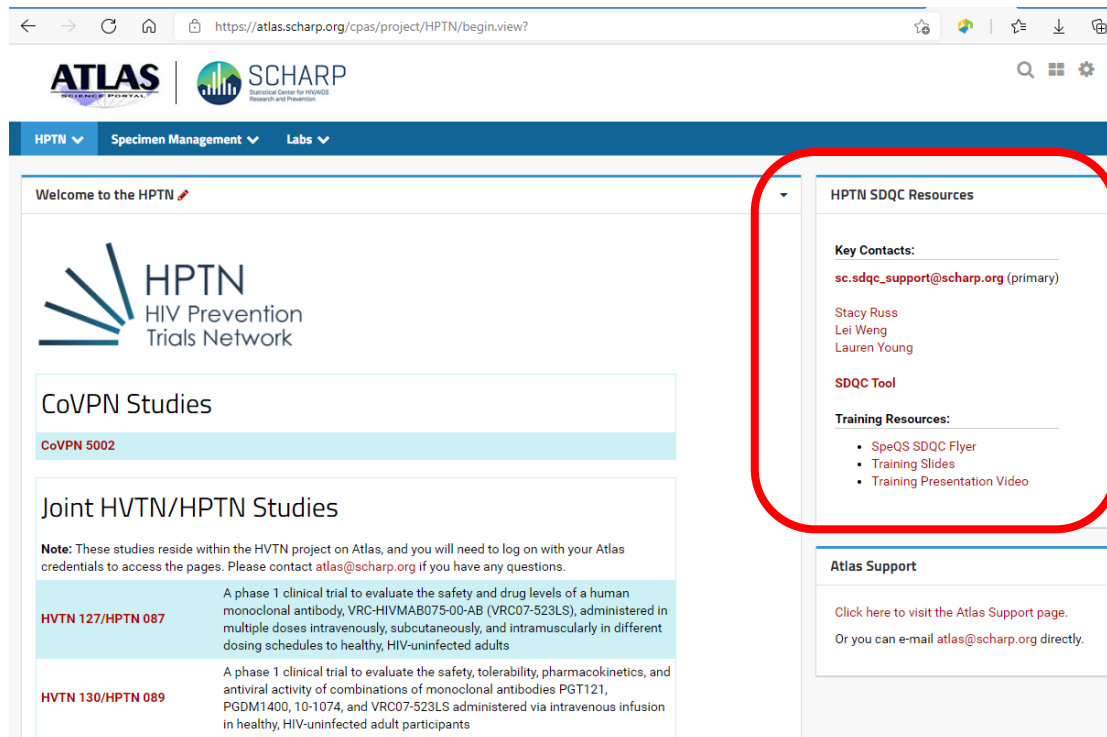
Status: All Open Network: HPTN

Showing 26 to 50 of 166 records    Previous    1    **2**    3    4    6    7    Next    Show  entries

<input type="checkbox"/>		Network	Protocol	Specimen Type	Error Type	Date Approved	Status	Comment Date	Comment Role	Comment	Days to First Action
		HPTN									
<input type="checkbox"/>	<a href="#">view</a>	HPTN	84	Dried Blood Spot (DBS)	Lab Data Only - No CRF Specimen Match	2024-10-24	CRS Review	2024-10-24	LDM	Please review source documentation and confirm if a sample was collected. Update CRF or LDMS as needed.	
<input type="checkbox"/>	<a href="#">view</a>	HPTN	84	BLD-DPE-DPE-N/A	Lab Data Only - No CRF Specimen Match (bad LDMS codes entered)	2024-10-24	SPL Review	2024-10-24	LDM	The LDMS specimen code combination (primary, additive, derivative, other specimen ID) is unexpected. Please review and adjust as needed.	
<input type="checkbox"/>	<a href="#">view</a>	HPTN	84	Plasma	Missing storage location	2024-10-24	SPL Review	2024-10-24	LDM	Please update storage information in LDMS.	
<input type="checkbox"/>	<a href="#">view</a>	HPTN	84	Plasma	Lab Data - CRF Specimen Collection Visits Don't Match	2024-10-24	SPL Review	2024-10-24	LDM	Please review source documentation to confirm the correct visit. Update either the CRF or LDMS as needed.	
<input type="checkbox"/>	<a href="#">view</a>	HPTN	84	Dried Blood Spot (DBS)	Lab Data Only - No CRF Specimen Match	2024-10-18	CRS Review	2024-10-24	SPL	LDMS logged per LRF	5
<input type="checkbox"/>	<a href="#">view</a>	HPTN	84.1	Plasma	Lab Data - CRF Specimen Collection Dates Don't Match	2024-10-04	SPL Review	2024-10-24	SPL	LDMS logged per LRF, see attached. Please provide a DCF	12
<input type="checkbox"/>	<a href="#">view</a>	HPTN	84	Plasma	Lab Data Only - No CRF Specimen Match	2024-10-18	CRS Review	2024-10-24	SPL	LDMS logged per LRF	5
<input type="checkbox"/>	<a href="#">view</a>	HPTN	84	Dried Blood Spot (DBS)	CRF Shows Specimen was Stored but No Match to Lab Data	2024-08-02	CRS Review	2024-10-24	SPL	We cannot locate the DCF, please resend the DCF	10
<input type="checkbox"/>	<a href="#">view</a>	HPTN	84	Plasma	Lab Data - CRF Specimen Collection Visits Don't Match	2024-07-30	CRS Review	2024-10-24	SPL	We cannot locate the DCF please resend	13
<input type="checkbox"/>	<a href="#">view</a>	HPTN	84.1	Dried Blood Spot (DBS)	Lab Data Only - No CRF Specimen Match	2024-10-04	CRS Review	2024-10-23	SPL	A comment was added on LDMS, please see attached.	18
<input type="checkbox"/>	<a href="#">view</a>	HPTN	84	Plasma	Lab Aliquot Generated - but CRF Notes Specimen was Not Stored	2024-10-18	CRS Review	2024-10-23	SPL	Samples logged and stored, please see the attached storage report	4

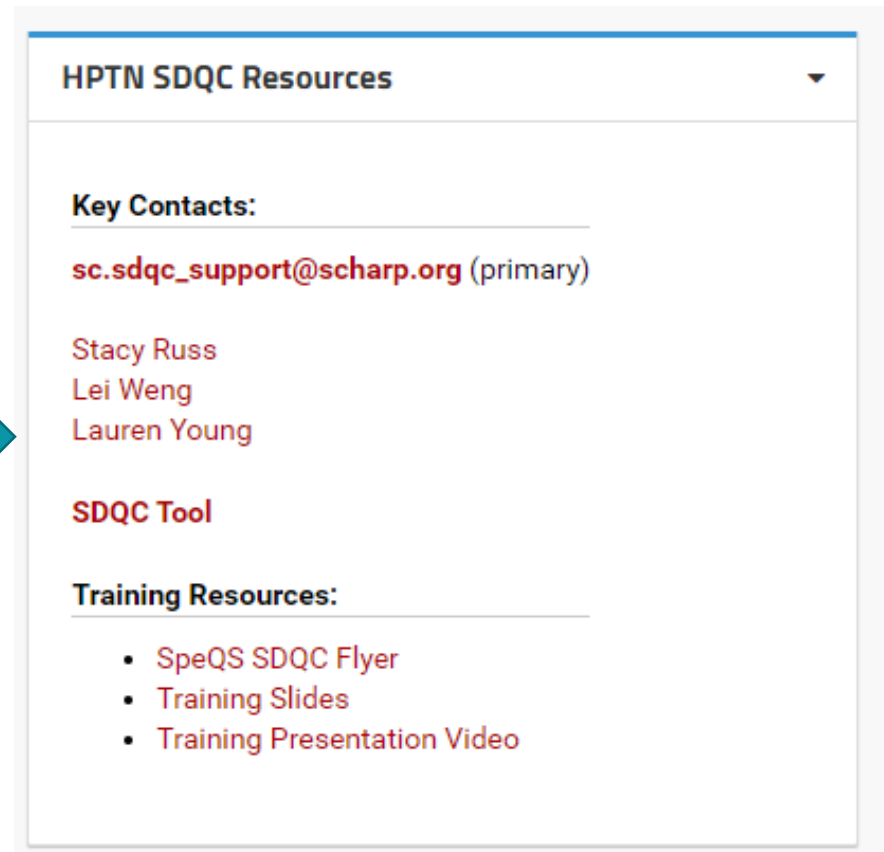
# Resource: HPTN Atlas Page

- <https://atlas.scharp.org/cpas/project/HPTN/begin.view>



The screenshot shows the HPTN Atlas website interface. The top navigation bar includes 'HPTN', 'Specimen Management', and 'Labs'. The main content area features a 'Welcome to the HPTN' message, the HPTN logo, and sections for 'CoVPN Studies' (listing CoVPN 5002) and 'Joint HVTN/HPTN Studies' (listing HVTN 127/HPTN 087 and HVTN 130/HPTN 089). A sidebar on the right, titled 'HPTN SDQC Resources', is highlighted with a red circle and contains the following information:

- HPTN SDQC Resources**
- Key Contacts:**
  - [sc.sdqc\\_support@scharp.org](mailto:sc.sdqc_support@scharp.org) (primary)
  - Stacy Russ
  - Lei Weng
  - Lauren Young
- SDQC Tool**
- Training Resources:**
  - SpeQS SDQC Flyer
  - Training Slides
  - Training Presentation Video
- Atlas Support**
  - Click here to visit the Atlas Support page.
  - Or you can e-mail [atlas@scharp.org](mailto:atlas@scharp.org) directly.



**HPTN SDQC Resources**

**Key Contacts:**

[sc.sdqc\\_support@scharp.org](mailto:sc.sdqc_support@scharp.org) (primary)

Stacy Russ  
Lei Weng  
Lauren Young

**SDQC Tool**

**Training Resources:**

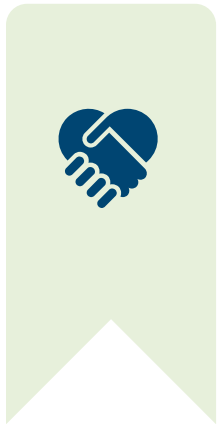
- [SpeQS SDQC Flyer](#)
- [Training Slides](#)
- [Training Presentation Video](#)

# Specimen Data Contacts

	When to Contact
<b>SCHARP Lab Data Management</b>	For clarification and guidance on QC resolution & general use of the SDQC Tool
<b>SCHARP Clinical Data Management</b>	For guidance on Rave eCRF data entry, e.g., deleting a CRF or advice on visit code usage
<b>HPTN Laboratory Center</b>	For guidance on LDMS data entry & specimen processing, e.g., LDMS code advice

- Most communication should happen within the SDQC Tool

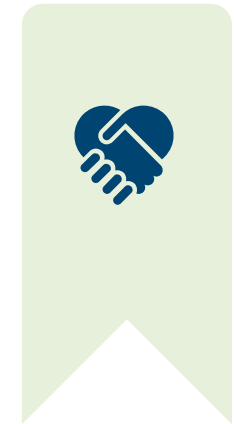
# SCHARP HPTN SDQC Contacts



**Stacy Russ**  
Lab Data Manager II  
[sruss@fredhutch.org](mailto:sruss@fredhutch.org)



**Lei Weng**  
Lab Data Manager II  
[lweng@fredhutch.org](mailto:lweng@fredhutch.org)



You may also email [SC.SDQC\\_support@scharp.org](mailto:SC.SDQC_support@scharp.org) with general SDQC questions or [atlas@scharp.org](mailto:atlas@scharp.org) for troubleshooting log-in and access issues.

# Thank you!

## Feedback:

- Do you now feel equipped to use this tool?
- Is anything still confusing to you?
- What questions do you have?



# Acknowledgments

Overall support for the HIV Prevention Trials Network (HPTN) is provided by the National Institute of Allergy and Infectious Diseases (NIAID), Office of the Director (OD), National Institutes of Health (NIH), National Institute on Drug Abuse (NIDA), the National Institute of Mental Health (NIMH), and the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) under Award Numbers UM1AI068619 (HPTN Leadership and Operations Center), UM1AI068617 (HPTN Statistical and Data Management Center), and UM1AI068613 (HPTN Laboratory Center).