



OpenClinica Monitor's Manual

TABLE OF CONTENTS

1. INTRODUCTION.....	3
2. LOGIN INTO OPENCLINICA.....	3
2.1 Login.....	3
2.2 Reset password.....	3
2.3 Homepage.....	4
2.4 Change Study or Site.....	4
3. MODULES AND TASKS AVAILABLE TO A MONITOR.....	5
3.1 Monitor and Manage Data.....	5
3.1.1 Subject Matrix.....	5
3.1.2 Source Data Verification (SDV).....	8
3.1.2.1 View Source Data Verification status.....	10
3.1.2.2 Reset Source Data Verification status.....	10
3.1.3 Notes and Discrepancies.....	10
3.1.3.1 Discrepancy Notes types and status.....	11
3.1.3.2 Discrepancy Note creation.....	11
3.1.3.3 View, update and manage a Discrepancy Note.....	12

1. INTRODUCTION

This manual provides an introduction to OpenClinica particularly designed for the Monitor user, including key terminology and concepts, as well as basic skills such as navigation. The software is web based and users can access it with a standard web browser and internet connection.

2. LOGIN INTO OPENCLINICA

2.1 Login

To access OpenClinica login page use the URL provided by Syntax for Science for the current Study.



Figure 1

Provide your authorized *User Name* and *Password*, and then click *Login*. Remember both your User Name and Password are case sensitive.

Note: You should take into account to use recommended web browsers: Firefox or Internet Explorer. If you use other web browsers the OpenClinica login page will advise you with the following message: “*OpenClinica recommends using Firefox 25 and Internet Explorer 11. While OpenClinica is designed to work on all standards-compliant browsers, we have not verified that the application functions correctly on other browsers or browser versions. If you do not have one of the above browsers installed you may need to contact your IT support group for assistance.*”

2.2 Reset password

For security purposes, OpenClinica system might be configured so that under certain conditions (e.g. first login) you must reset your password when you try to log in. When the Reset password page displays, complete the fields in the page:

1. Specify the original password provided by Syntax for Science
2. Enter the desired new password (your new password must be at least eight characters long)

3. Re-enter the desired new password
4. Choose a password challenge question
5. Specify the answer to the password challenge question
6. Click Change Password

You can also change your password anytime you need from Change User Profile page by clicking your User Name (on the top right).

If you forget the password, click on *Forgot Password?* link next to the Login button (Figure 1) and the Request Password page opens. For further help, please contact with Syntax for Science.

2.3 Homepage

After login into OpenClinica, the homepage will be displayed providing tools and links to different features. The body of the homepage shows to the Monitor the *Source Data Verification (SDV)* page of the current Study/Site (Figure 2).

We will see SDV page in more detail in section [Source Data Verification \(SDV\)](#).

01 - OpenClinica Demo Study (DEMO001) | Change Study/Site

monitor (monitor) en | Log Out

Home | Subject Matrix | SDV | Notes & Discrepancies | Tasks

Report Issue | Support | Study Subject ID | Go

Alerts & Messages
Your current active study has been changed successfully.

Instructions
If needed you may change the study/site or request access to a new study with a different role.

Other Info
Study: 01 - OpenClinica Demo Study
Start Date: 09-Jan-2015
End Date: N/A
PI: none
Protocol Verification/IRB Approval Date:

Welcome to 01 - OpenClinica Demo Study

Notes & Discrepancies Assigned to Me: 1

View By Event CRF | View By Study Subject ID

15 | Show More | The table is sorted by Event Date

Select: All Shown, None

SDV Status	Study Subject ID	Site ID	Event Name	Event Date	CRF Name / Version	SDV Requirement	CRF Status	Actions
✓	test002	DEMOsite001	Randomization(1)	13-Jan-2015	DEMO-Visit Date/ V1.0	Not Required	✓	
✓	test002	DEMOsite001	Randomization(1)	13-Jan-2015	DEMO-Vital Signs/ V1.0	Not Required	✓	
✓	test002	DEMOsite001	Randomization(1)	13-Jan-2015	DEMO-Incl-excl criteria/ V1.0	Not Required	✓	
✓	test002	DEMOsite001	Randomization(1)	13-Jan-2015	DEMO CAT/ V1.0	Not Required	✓	
☐	test003	DEMOsite001	Screening(1)	13-Jan-2015	DEMO-Pregnancy/ V1.0	Not Required	☐	SDV
☐	test003	DEMOsite001	End of study(1)	14-Jan-2015	DEMO CAT/ V1.0	Not Required	✓	SDV
✓	test002	DEMOsite001	Screening(1)	14-Jan-2015	DEMO-Pregnancy/ V1.0	Not Required	✓	
✓	APSL	DEMOsite001	Screening(1)	14-Jan-2015	DEMO-Visit Date/ V1.0	Not Required	✓	
☐	APSL	DEMOsite001	Screening(1)	14-Jan-2015	DEMO-Informed Consent/ V1.0	Not Required	✓	SDV
☐	APSL	DEMOsite001	Screening(1)	14-Jan-2015	DEMO-Incl-excl criteria/ V1.0	Not Required	✓	SDV
☐	APSL	DEMOsite001	Screening(1)	14-Jan-2015	DEMO-Demographics/ V1.0	Not Required	✓	SDV
☐	APSL	DEMOsite001	Screening(1)	14-Jan-2015	DEMO-Vital Signs/ V1.0	Not Required	✓	SDV
☐	APSL	DEMOsite001	Screening(1)	14-Jan-2015	DEMO-Smoking Habits/ V1.0	Not Required	✓	SDV
☐	APSL	DEMOsite001	Screening(1)	14-Jan-2015	DEMO-Pregnancy/ V1.1	Not Required	✓	SDV
☐	APSL	DEMOsite001	Screening(1)	14-Jan-2015	DEMO CAT/ V1.0	Not Required	✓	SDV

Resultados 1 - 15 de 103.

Submit Cancel

Figure 2

2.4 Change Study or Site

When working in OpenClinica, you are always working in reference to a specific Study/Site. You will only be able to view those which you have been given access to.

Most Monitors will only have access to one Study/Site, therefore they **will not need to use the ‘Change Study/Site’ link**.

If you have access to more than one Study/Site, as shown in [Figure 3](#), you must select the right Study/Site before proceeding:

1. Click the *Change Study/Site* link
2. Select the Study/Site you want to change (studies are indicated in bold and sites in regular font)
3. Click *Change Study* button to confirm

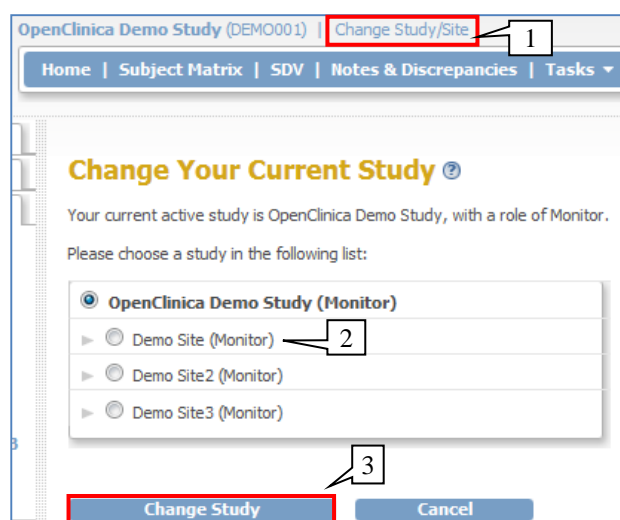


Figure 3

3. MODULES AND TASKS AVAILABLE TO A MONITOR

Modules (groups of Tasks, [Figure 4](#)) available for the Monitor are:

- Monitor and Manage Data
- Extract Data
- Other

Some Tasks a Monitor can perform are:

- View Subjects (Subject Matrix)
- View Events
- Source Data Verification
- View and Manage Notes and Discrepancies
- Study Audit Log
- View Datasets
- Create Datasets

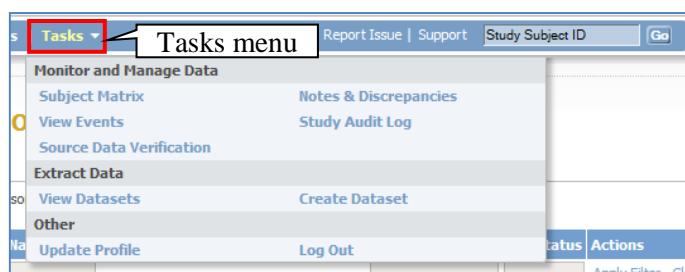


Figure 4

3.1 Monitor and Manage Data

OpenClinica's *Monitor and Manage Data* module allows OpenClinica users to oversee and validate data for a study, increasing productivity in clinical trials management.

To access features in the *Monitor and Manage Data* module, click *Tasks* button from the navigation bar ([Figure 4](#)) and select the feature you want.

In the following sections the most important features are explained. If you need any further information, please contact with Syntax for Science.

3.1.1 Subject Matrix

The Subject Matrix can be accessed from the Navigation bar.

The Subject Matrix is a table with information of all subjects included in a Study/Site. There is one Subject per row and one column for each Event Definition in the Study ([Figure 5](#)).

Each cell in the matrix contains an icon that identifies the Event status (check the Icon Key in the sidebar (Figure 6)).

Subject’s information and events can be managed in two different ways:

- Clicking any Event icons, or
- Clicking *View Subject Record* icon

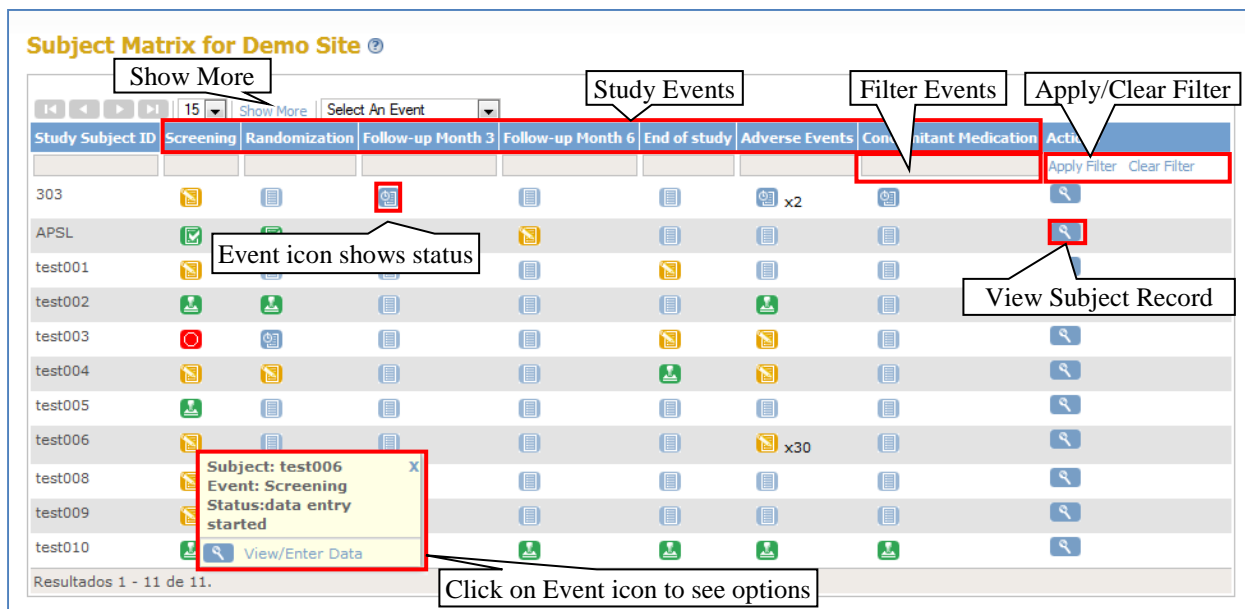


Figure 5

To see data of a Subject in a specific Event, put click over the icon and select the action: View/Enter Data

Clicking the *Show More* link widens the matrix giving you more information about the subjects:

- Subject Status
- Site ID
- Sex
- Secondary ID
- Group Information

Stop showing this additional information by clicking the *Hide* link.

To view details for an event select it from *Select Event* drop-down list (Figure 7). In the *Subject Matrix* the columns show the different Case Report Forms (CRFs) for the related Study Event.

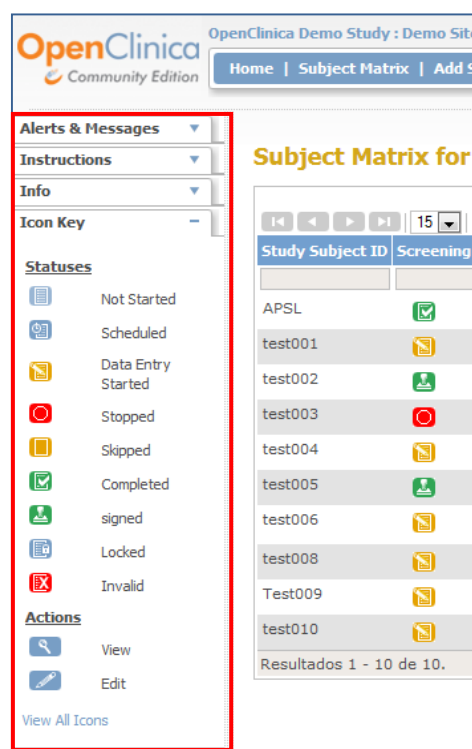


Figure 6

Icons in the columns show the CRFs status for each subject. Put the cursor over an icon to see more information in a pop-up window. To perform actions in a specific subject’s CRF, click the icon, and select the action you want to perform.

Subject Matrix for Demo Site

15 Show More Events: Randomization Add New Subject

Select Event Study Event CRFs View

Study Subject ID	Event Status	Event Date	DEMO-Visit Date	DEMO-Vital Signs	DEMO-Incl-excl criteria	DEMO-Randomization2	DEMO CAT	Action
test002		13-Jan-2015						
Test009								
test005								
test008								
APSL		14-Jan-2015						
test004		14-Jan-2015						
test010								
test003		14-Jan-2015						
test006								
test001								

Resultados 1 - 10 de 10.

Exit

Figure 7

To see all study information for a subject click the *View* icon in the *Actions* column (Figure 5, Figure 6).

The *View Subject* page will be opened showing the different sections. Click the plus or minus sign next to each section to show or hide the information. By default the Events section will be shown (Figure 8).

View Subject: Test009

Study Subject Record Events

Page 1 of 1

Search events Find Schedule New Event View CRF data

Event (Occurrence Number)	Start Date	Location	Status	Actions	CRFs (Name, Version, Status, Updated, Actions)
Screening	13-Mar-2015		data entry started		DEMO-Informed Consent V1.0 DEMO-Incl-excl criteria V1.0 DEMO-Demographics V1.0 DEMO-Vital Signs V1.0 DEMO-Smoking Habits V1.0 DEMO-Pregnancy V1.1 DEMO CAT V1.0 DEMO-Lab test V1.0 DEMO Eligibility v0.1 DEMO Medical history v0.1 DEMO-Visit Date V1.0 13-Mar-2015 (democr)

Group Global Subject Record Return to subject list

Go Back to Subject List

Figure 8

3.1.2 Source Data Verification (SDV)

When reviewing the conformity of data in CRFs, you can use the OpenClinica *Source Data Verification (SDV)* feature to track your evaluations helping to ensure the study is complete, accurate, and verifiable.

The SDV feature is presented as a table where you can check which CRFs have been verified or not. After confirming data, you can mark CRFs as verified, either individually or as a group.

You can view the table either by event CRF (Figure 9) or by study subject ID (Figure 10).

Source Data Verification for OpenClinica Demo Study

View By Event CRF | View By Study Subject ID

15 | Show All | The table is sorted by Event Date

Select: All Show All

SDV Status	Study Subject ID	Site ID	Event Name	Event Date	CRF Name / Version	SDV Requirement	CRF Status	Actions
<input type="checkbox"/>	test001	DEMOsite001	Screening(1)	08-Jan-2015	DEMO-Visit Date/ V1.0	100% Required	<input checked="" type="checkbox"/>	<input type="button" value="SDV"/>
<input type="checkbox"/>	test001	DEMOsite001	Screening(1)	08-Jan-2015	DEMO-Informed Consent/ V1.0	100% Required	<input checked="" type="checkbox"/>	<input type="button" value="SDV"/>
<input checked="" type="checkbox"/>	test001	DEMOsite001	Screening(1)	08-Jan-2015	DEMO-Demographics/ V1.0	100% Required	<input checked="" type="checkbox"/>	
<input checked="" type="checkbox"/>	test001	DEMOsite001	Screening(1)	08-Jan-2015	DEMO-Vital Signs/ V1.0	100% Required	<input checked="" type="checkbox"/>	
<input checked="" type="checkbox"/>	test001	DEMOsite001	Screening(1)	08-Jan-2015	DEMO-Smoking Habits/ V1.0	100% Required	<input checked="" type="checkbox"/>	
<input type="checkbox"/>	test001	DEMOsite001	Screening(1)	08-Jan-2015	DEMO-Pregnancy/ V1.0	100% Required	<input checked="" type="checkbox"/>	<input type="button" value="SDV"/>
<input type="checkbox"/>	test001	DEMOsite001	Screening(1)	08-Jan-2015	DEMO CAT/ V1.0	100% Required	<input checked="" type="checkbox"/>	<input type="button" value="SDV"/>
<input type="checkbox"/>	test001	DEMOsite001	Screening(1)	08-Jan-2015	DEMO-Lab test/ V1.0	100% Required	<input checked="" type="checkbox"/>	<input type="button" value="SDV"/>
<input type="checkbox"/>	test001	DEMOsite001	Randomization(1)	08-Jan-2015	DEMO-Randomization2/ V1.0	100% Required	<input checked="" type="checkbox"/>	<input type="button" value="SDV"/>
<input type="checkbox"/>	test001	DEMOsite001	Randomization(1)	08-Jan-2015	DEMO-Incl-excl criteria/ V1.0	100% Required	<input checked="" type="checkbox"/>	<input type="button" value="SDV"/>
<input type="checkbox"/>	test001	DEMOsite001	Adverse Events(1)	08-Jan-2015	DEMO-Adverse Events Autocomplete/ V1.1	100% Required	<input checked="" type="checkbox"/>	<input type="button" value="SDV"/>
<input type="checkbox"/>	test001	DEMOsite001	Follow-up Month 3(1)	08-Jan-2015	DEMO-Visit Date/ V1.0	100% Required	<input checked="" type="checkbox"/>	<input type="button" value="SDV"/>
<input type="checkbox"/>	test001	DEMOsite001	Follow-up Month 3(1)	08-Jan-2015	DEMO-Vital Signs/ V1.0	100% Required	<input checked="" type="checkbox"/>	<input type="button" value="SDV"/>
<input type="checkbox"/>	test001	DEMOsite001	Follow-up Month 3(1)	08-Jan-2015	DEMO CAT/ V1.0	100% Required	<input checked="" type="checkbox"/>	<input type="button" value="SDV"/>
<input type="checkbox"/>	test001	DEMOsite001	Randomization(1)	08-Jan-2015	DEMO CAT/ V1.0	100% Required	<input checked="" type="checkbox"/>	<input type="button" value="SDV"/>

Resultados 1 - 15 de 93.

Figure 9

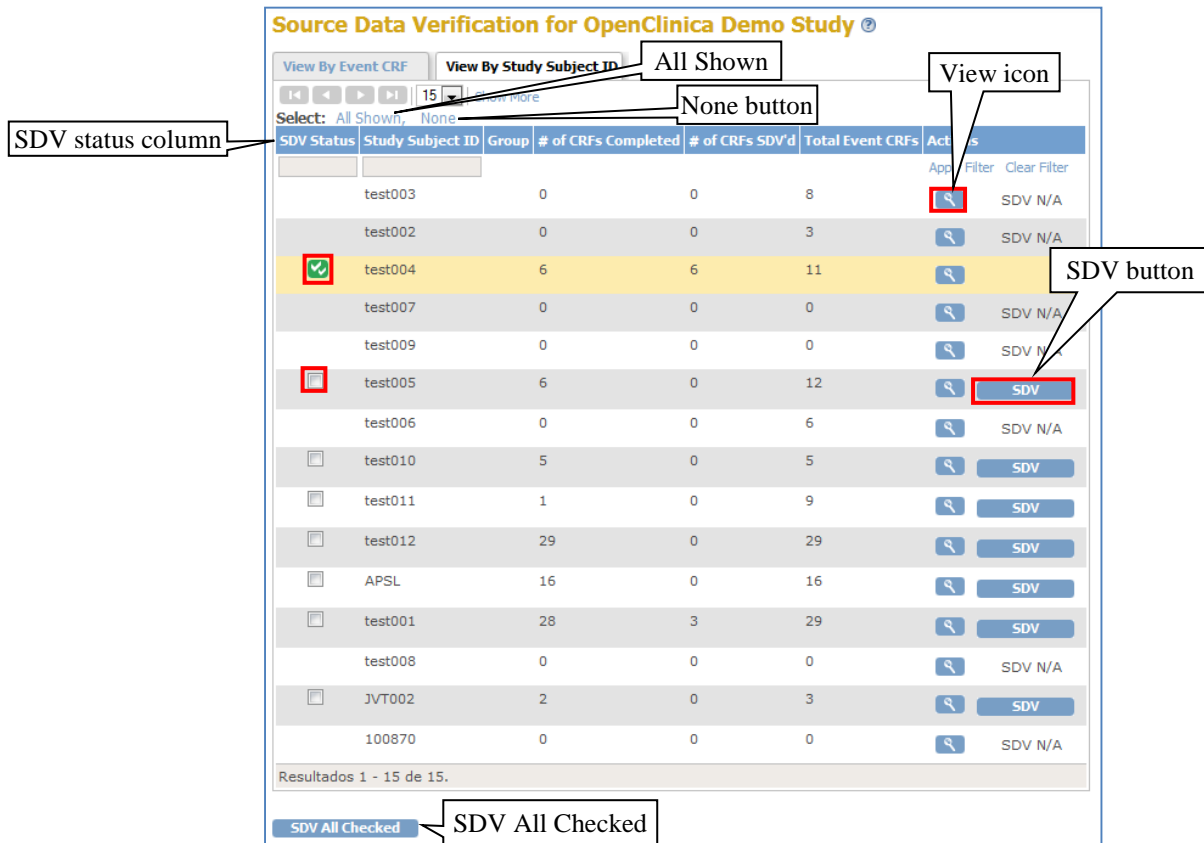


Figure 10

To perform SDV follow the next steps:

1. Select SDV (Navigation bar)
2. Customize the view of the SDV by clicking the pertinent tab. By default the view will be by *Event CRF* which lists only CRFs that are marked complete and therefore ready for SDV (the view by *Study Subject ID* lists all subjects in the current study or site).
3. Identify CRFs whose data you want to verify. Access to the CRF will depend on the SDV view you have selected:
 - View by **Event CRF**: click the icon in the CRF Status column (Figure 9).
 - View by **Study Subject ID**: click the *View* icon in the *Actions* column, the page will show all subject event CRFs ready for verification (Figure 9). Then click the CRF status icon of the CRF you want to view.
4. Once the completed CRF has been opened in a new window, review the data in the related subject CRF. In this stage, you can add a *Query type Discrepancy Note* to record a question about any item (see [Notes and Discrepancies](#)). When the data review has been finished, click the *Close* button in the CRF window to conclude (notice that if you click *Exit* instead of *Close*, the window will remain open showing the subject details).
5. Mark the data as verified by clicking the *SDV* button of the CRF. In the *SDV Status* column, the checkbox will be replaced by a SDV complete icon .

Remember you can mark multiple CRFs as verified in any of these ways:

- **All Eligible CRFs for a Subject:** In the *Study Subject ID* view, click the *SDV* button of the subject you want to mark as verified.
- **Selected CRFs or Subjects:** In either the *Event CRF* or *Study Subject ID* view, select the checkbox in the *SDV Status* column for all CRFs or subjects you want to mark as verified. You can deselect a row by clicking its checkbox, or clear all selected rows by clicking the *None* link. Finally, click the *SDV All Checked* (Figure 10).
- **All CRFs or Subjects Shown:** In either the *Event CRF* or *Study Subject ID* view, select all CRFs or subjects on the page, click the *All Shown* link which selects all checkboxes in the *SDV Status* column on that page. You can deselect a row by clicking its checkbox, or clear all selected rows by clicking the *None* link. Finally, click the *SDV All Checked* button.

3.1.2.1 View Source Data Verification status

In the view by *Event CRF* the icons in the *SDV Status* column indicates which CRFs have SDV completed (☑) and which have it not (☐). Use the filter for the *SDV Status* column to show only those CRFs with SDV complete, or only those CRFs that have not had SDV completed.

In the view by *Study Subject ID*, icons in the *SDV Status* column indicates if the subjects have the SDV completed (☑) or not (☐). In addition, you can view for each subject how many CRFs have the SDV completed (shown in the # of *CRFs SDV'd* column), as well as the number of CRFs eligible for verification (shown in the # of *CRFs Completed* column), which provides a summary of the *SDV status* by subject.

3.1.2.2 Reset Source Data Verification status

Source Data Verification (SDV) status can be reset as verified or unverified manually at any time by clicking over the SDV complete icon.

OpenClinica can make the reset automatically only under certain conditions: whether the CRF data changes, or if an *Annotation Discrepancy Note* is added to the CRF.

3.1.3 Notes and Discrepancies

The feature *Notes and Discrepancies* allows users to document, communicate, and manage issues about data in clinical trials to facilitate the accuracy and completeness of the data.

As a Monitor, you might use *Discrepancies Notes* to request further information about data provided for an item. You should also review and/or reply all *Discrepancies Notes* to help to resolve the issue. Once it is resolved, Monitor should close the Note.

The original note is referred to as the ‘parent note’. Responses to the original note are referred to as ‘child notes’. The thread of a single parent note with child notes under it is referred to as one *Discrepancy Note*.

Once a Discrepancy Note has been created, it cannot be deleted. If it has been created by mistake, a common practice is to add a new child note with *Closed* status, explaining that it was a mistake.

Discrepancy Notes allow you many possibilities. In following sections you will find a review and explanation about their basics features.

3.1.3.1 Discrepancy Notes types and status

Depending on the purpose, OpenClinica has different Discrepancy Note types as follows:

- **Failed Validation Check:** is used for data that does not comply with expected values. When validation checks have been created, OpenClinica will automatically generate it. Nevertheless, *Failed Validation Checks* can be also created by the Investigator.
- **Query:** is used to request further information about data provided for an item. Only the Monitor can create and assign the *Query* to a specific user, and also send a notification email. Investigator cannot create a *Query* but should review and reply it.
- **Reason for Change:** is used to explain the reason for changing a data item after a CRF has been marked complete. It can only be created by an Investigator.
- **Annotation:** is used to make comments or provide further information about the data to the Monitor. It can only be created by an Investigator.

The status of a Discrepancy Note indicates what has been done and what should be done next. The different status are:

- **New** 🚩: A new discrepancy note has been created and requires a response.
- **Updated** 📄: Information has been added to the note thread, but it requires further follow up or additional information.
- **Resolution Proposed** 🟢: Investigator answers a Discrepancy Note (fixing a data or explaining why the existing data is correct) in a child note and the response is awaiting to be reviewed by a Monitor.
- **Closed** 🟡: The final action. A Monitor has reviewed the proposed resolution to the discrepancy note, and has found that the response is satisfactory.

Only a Monitor can mark a Discrepancy Note as Closed. When a note has a status of Closed, it cannot be changed in any way.

- **Not Applicable** 🚫: No action or resolution is required.

The Discrepancy Note type determines what status are allowed:

	Use	Status
Failed Validation Check	Used for data that does not comply with expected values.	New, Updated, Resolution Proposed, Closed
Query	Used to request further information about data provided for an item.	New, Updated, Resolution Proposed, Closed
Reason for Change	Used to explain the reason for changing a data item after a CRF has been marked complete.	Not Applicable
Annotation	Used to make comments or provide information about the data to the monitor.	Not Applicable


Table 1

Notice: When there is more than one Discrepancy Note associated with a CRF item, only the most urgent status is shown.

3.1.3.2 Discrepancy Note creation

Discrepancy Notes can be created manually by a Monitor or automatically by OpenClinica:

- **Manually-Created Discrepancy Notes** (when reviewing a CRF)

When reviewing a CRF Item, click the *Add Discrepancy Note* icon  next to the item. The *Add Discrepancy Note* window opens for that item and you can proceed to complete the fields.

Some available options are based on the circumstances under which the Discrepancy Note has been created. The most common Manually-Created Discrepancy Notes for a Monitor are Queries, which are used to make comments or request further information to the Investigator.

Once a manually Discrepancy Note has been added, follow the next steps:

1. Complete the Description and Detailed Note fields.
2. Select the Type from the drop-down list. The list includes only the appropriate options.
3. Select the Status for the Discrepancy Note from the drop-down list. The list includes only the appropriate options.
4. Assign to user from the drop-down list and click on the checkbox if you want to send an email to the assigned user.

Finally, click *Submit & Close*. A message will replace the contents of the window, indicating the note was created. In the CRF page, the flag icon for the item will change to a color reflecting the status of the Discrepancy Note.

Notice: When there are multiple Notes associated with an item and you want to create new one for that item, click the flag icon of the existing Note and then click *Begin New Thread*. Complete the process as a *Manually-Created Discrepancy Note*.

3.1.3.3 *View, update and manage a Discrepancy Note*

There are different ways to view a Discrepancy Note:

1. Click *Notes & Discrepancies* in the navigation bar to view the table of all Notes and Discrepancies.
2. In the Homepage click the blue link “*Notes & Discrepancies Assigned to Me*” to see only the Notes and Discrepancies assigned to you.
3. Go to the CRF page that contains the Discrepancy Note and click over the related flag icon.

We recommend using the first option where a table summarizes all Notes and Discrepancies for the current study or site ([Figure 11](#)) containing among others:

- Entity Name: refers to the CRF item that is associated with the Note
- Entity Value: is the value recorded in the CRF for the item
- Description: is the definition provided in the Discrepancy Note
- Assigned User: to whom the Discrepancy Note is assigned (if anyone)

From the Notes and Discrepancies table you can:

- **View Details for a Note:** To view all details of a single Discrepancy Note, click the *View* icon in the *Actions column* ([Figure 11](#)).
- **View CRF and Note Details:** In the *Actions column*, click the *View within Record* icon. OpenClinica opens the Discrepancy Note window ([Figure 12](#)) as well as the CRF page.

Notes and Discrepancies ⓘ

Hide summary statistics

	Query	Failed Validation Check	Reason for Change	Annotation	Total
New	1	--	--	--	1
Updated	--	--	--	--	--
Resolution Proposed	1	1	--	--	2
Closed	1	--	--	--	1
Not Applicable	--	--	--	--	--
Total	3	1	--	--	4

Summary

View within Record

View icon

Study Subject ID	Type	Resolution Status	Site ID	Days Open	Days Since Updated	Event Name	CRF	Entity Name	Entity Value	Description	Assigned to	Action
test001	Failed Validation Check	Resolution Proposed	DEMOsite001	91	91	Screening	DEMO-Smoking Habits	SHCURRENT	3	RULE6 Patient never smokes but smoking information has been added. Please check.	()	Apply Filter Clear Filter
test001	Query	Closed	DEMOsite001	0		End of study	DEMO-End of study	EOSYN	1	Is it correct?	monitor monitor (monitor)	View icon
test001	Query	Resolution Proposed	DEMOsite001	91	91	Screening	DEMO-Incl-excl criteria	IEEXCL02	0	Pregnancy test result is positive ¿?	Marina Llopis (mllopis)	View icon
test001	Query	New	DEMOsite001	41	41	Screening	DEMO-Visit Date	VISDAT	2015-01-12	prova	Marta Rodriguez (mrodriguez)	View icon

Resultados 1 - 4 de 4.

Figure 11

VSHEIGHT: Notes and Discrepancies Exit Window

"VSHEIGHT" Properties:

Subject: **test004** Event: **Screening**
 Event Date: **14-Jan-2015** CRF: **DEMO-Vital Signs**
 Current Value: **119** More: [Data Dictionary](#)
[Audit History](#)

Note Details

RULE8 Height should be between 120 and 250 cm. Please check
 Last updated: **14-Jan-2015** by **mllopis**
 Assigned to: **()**

ID	Type	Current Status	# of Notes
1	Failed Validation Check	New	1

Note	Status	Updated by
RULE8 Height should be between 120 and 250 cm. Please check	New	14-Jan-2015 by mllopis

Update Note **Close Note**

Begin New Thread

Audit History

Audit Event	Date/Time of Server	User	Value Type	Old	New
Item data status changed	14-Jan-2015 12:22:30	mllopis	VSHEIGHT	auto-removed	available
Item data status changed	14-Jan-2015 12:22:22	mllopis	VSHEIGHT	unavailable	auto-removed
Item data value updated	14-Jan-2015 09:07:45	mllopis	VSHEIGHT		119

(This item was initially entered on 14-Jan-2015.)

Figure 12

To update any Discrepancy Note:

- Click *Update Note* (Figure 12): to add information that needs to be reviewed.
- Click *Close Note*: to close the Note giving a reason.

In both cases, the Discrepancy Note will include the information you have added as a new child Note in the thread (Figure 13). In the CRF and in the Notes and Discrepancies table, the color of the flag icon will change to reflect the new status (Figure 14).

Note: A Monitor should know how an Investigator manages *Discrepancies Note*. Please, remember to read Investigator’s Manual.

EOSYN: Notes and Discrepancies

"EOSYN" Properties:

Subject: **test001** Event: **End of study**
 Event Date: **13-Jan-2015** CRF: **DEMO-End of study**
 Current Value: **1** More: [Data Dictionary](#)
[Audit History](#)

Note Details

Is it correct? Last updated: **14-Jan-2015 by monitor**
 Assigned to: **monitor monitor (monitor)**

ID: 20	Type: Query	Current Status: Closed	# of Notes: 3
Is it correct?	Status: New	14-Jan-2015 by monitor Assigned to: Marina Llopis (mllopis)	
I thing this subject did not complete the study	Status: Updated	14-Jan-2015 by monitor Assigned to: monitor monitor (monitor)	
Sorry it is right, I was wrong	Status: Closed	14-Jan-2015 by mllopis Assigned to: monitor monitor (monitor)	

Begin New Thread

Audit History

Audit Event	Date/Time of Server	User	Value Type	Old	New
Item data status changed	15-Jan-2015 09:30:27	investigator	EOSYN	auto-removed	available
Item data status changed	15-Jan-2015 09:30:18	investigator	EOSYN	available	auto-removed
Item data status changed	13-Jan-2015 17:14:55	demouser	EOSYN	auto-removed	available
Item data status changed	13-Jan-2015 17:14:48	demouser	EOSYN	unavailable	auto-removed
Item data value updated	12-Jan-2015 13:30:20	mllopis	EOSYN		1

(This item was initially entered on 12-Jan-2015.)

Figure 13

DEMO-End of study V1.0 **test001**

▼ **CRF Header Info**

Click the flag icon next to an input to enter/view discrepancy notes. Please note that you can only save the notes if CRF data entry has already started.

EOF (0/4)

Title: End of Study

Did the subject complete the study? Yes * Last Visit Date: 12-Jan-2015

Withdrawal Reason:

Detail Reason:

New Status: Closed

Figure 14