

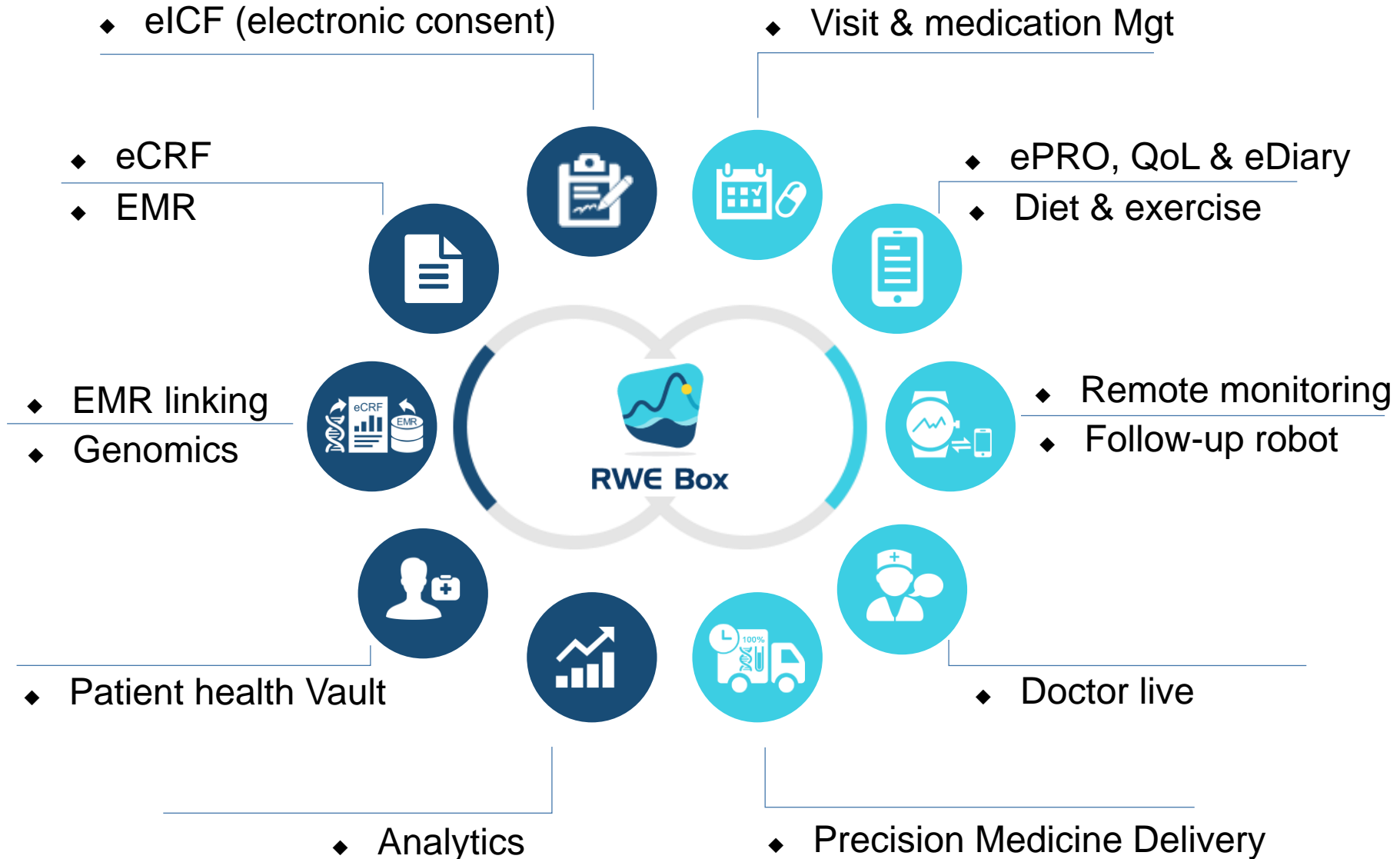


Introduction to RWE Box

Shanghai GenomSeqCare Biotechnology Co. Ltd

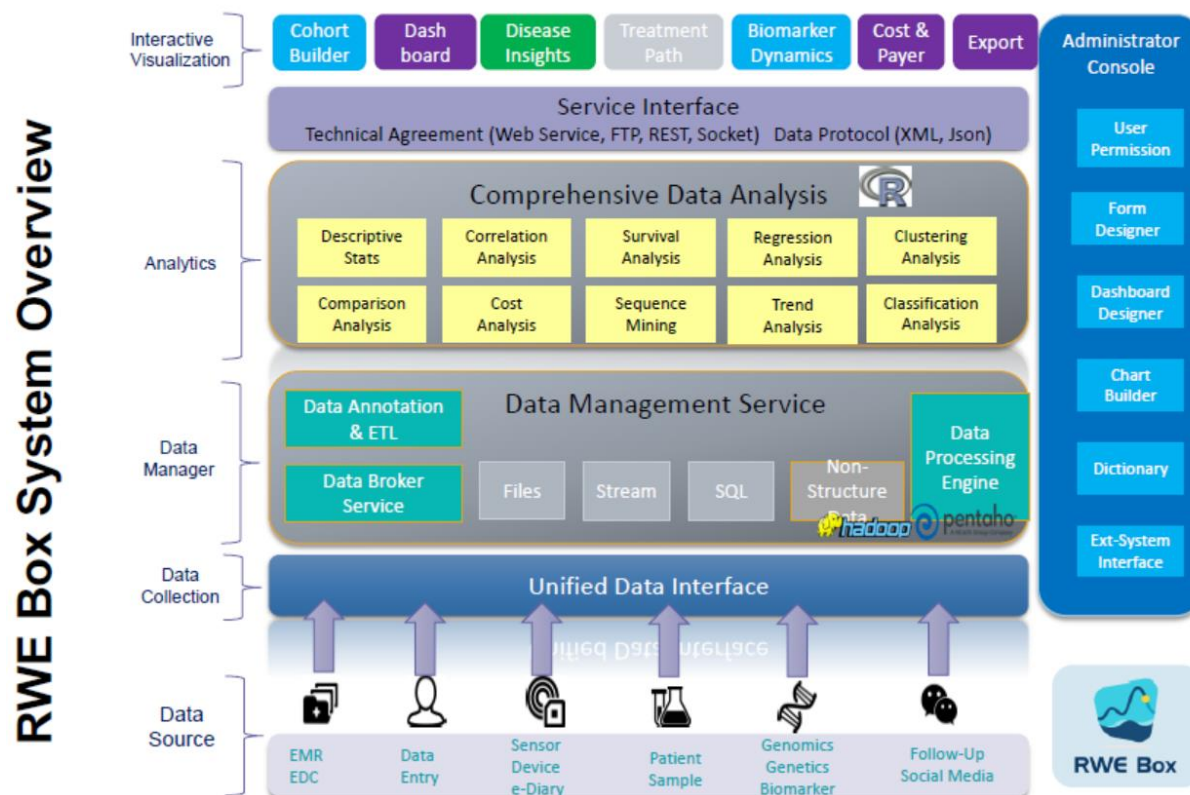


RWE Box: Enabling Real World Evidence Research



What is RWE Box?

A comprehensive electronic data capture, management and analytics platform to enable clinical, medical and real world evidence research. It is hosted in Cloud with a web based user interface.



RWE Box EDC Features



- Study sites can enter data straight from source document into RWE Box
- Existing EMR or registry data can be integrated into RWE Box through custom import modules or RWE Box API.
- Study sites can check and resolve errors, inconsistencies, missing data, etc., in real time at data entry
- Communication, query guidance applied by DM to sites directly within RWE Box (rather than via email)
- Audit trail captures all changes made to an eCRF within RWE Box
- Study dashboard can be customized to report study highlights, and site/country/region recruitment status.
- Simple and advance searches allow users to build cohorts to answer specific scientific questions.
- Real time analytics enable users to quickly derive insights from clinical data.

RWE Box EDC User Roles





User Role	Privileges
Country Coordinator	Study dashboard presents summary of current Study with the specified country.
HCP/Investigator	<p>Study dashboard presents summary of current Study with the specified site.</p> <p>Submit Data:</p> <ul style="list-style-type: none">○ Add and Manage Subjects○ View, Update, Remove, and Enter Data into CRFs○ Response to Queries○ Add and Manage Hard copy○ Activate ePRO and Manage ePRO <p>Investigator signature to sign off subject data</p>
Study Coordinator	Same privileges as HCP except Investigator signature.
Monitor/DM	<p>Study dashboard presents summary of current Study with specified sites.</p> <p>Monitor and Manage Data:</p> <ul style="list-style-type: none">○ View Subjects○ View CRFs○ Study Audit Log and Source Data Verification○ View Hard Copy○ Raise Queries○ Manage Queries: export and update status


RWE Box Navigation - Login



- After trainings, a user can access RWE Box by login into RWE Box web portal


RWE Box

 admin



☐ Remember Me [Forgot password?](#)

[EULA & Privacy Policy](#)

Login

沪ICP备13035915号-2

- RWE Box provides access to all types of studies implemented at a site for which a user has access

RWE Box Navigation – Select Study

- Once in the RWE Box web site, select a study to access

The screenshot displays the RWE Box web application interface. On the left, a dark blue sidebar contains a search bar and a navigation menu with icons for CVRM, Respiratory, and Oncology. The main content area is titled "DISCOVER CaReMe Global Registry" and shows a status of "Open" with an enrollment start date of "11/07/2017". A date range selector is set to "05/08/2021 - 06/06/2021". A world map highlights enrollment locations, and a bar chart shows a range from "Low 0" to "High 6212". A central box displays "262/288 HCPs". Below, the "REGISTRY ENROLLMENT" section features a line graph titled "Registry Enrollment" showing the number of enrolled subjects (as of 2021-06-06) and a table listing HCPs and their counts.

REGISTRY ENROLLMENT

Registry Enrollment
Number of enrolled subjects (as of 2021-06-06)

HCP	#
AGO-000001	0
AGO-000002	0

RWE Box Navigation – Navigation Bar (specific to User Roles)

The image displays three screenshots of the RWE Box navigation bar, each representing a different user role. The navigation bar is a dark blue sidebar on the left of the application interface. The top of the sidebar features the RWE Box logo and a search bar. Below the search bar, the word 'NAVIGATION' is displayed in white capital letters. The navigation items are listed below, each with an icon and a right-pointing arrow. Red arrows point from the text labels to the corresponding navigation items in each screenshot.

Study dashboard

- Dashboard
- Patient
- Patient visit matrix
- Tasks for a user
- Analytics dashboard
- Training & study documents

Patient dashboard

- Dashboard
- Patient
- Tasks
- Search and cohort builder
- Search
- Advanced Search
- Cohort List
- Data QC
- Document

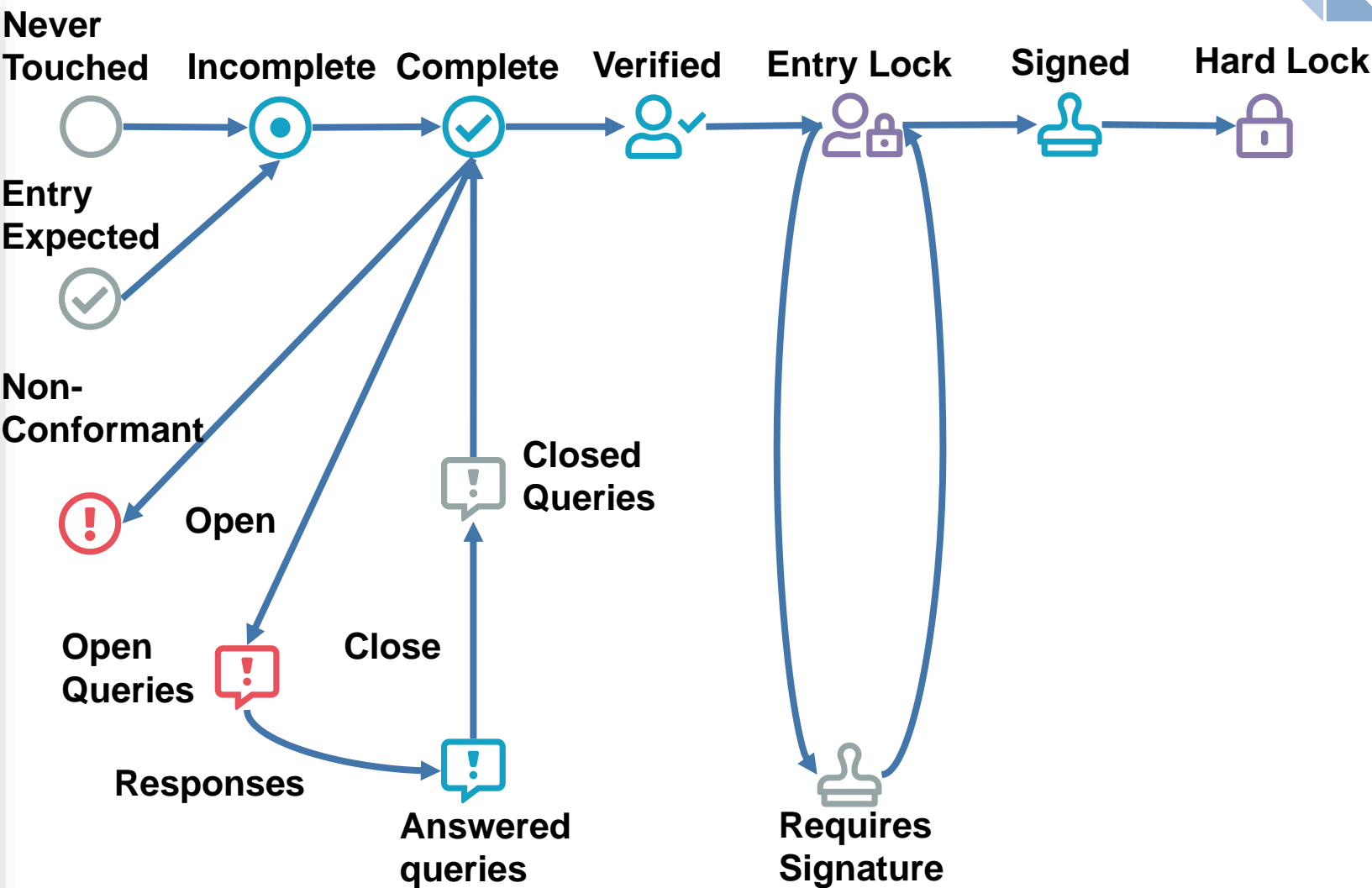
Search and cohort builder

- Dashboard
- Patient
- Tasks
- Search
- Data QC
- Query mgmt and QC report
- Query
- Data Cleaning Progress Report
- Study Form Status Report
- Query Report
- Patient Hardcopy Report
- Critical/mandatory Data Points Report
- Document

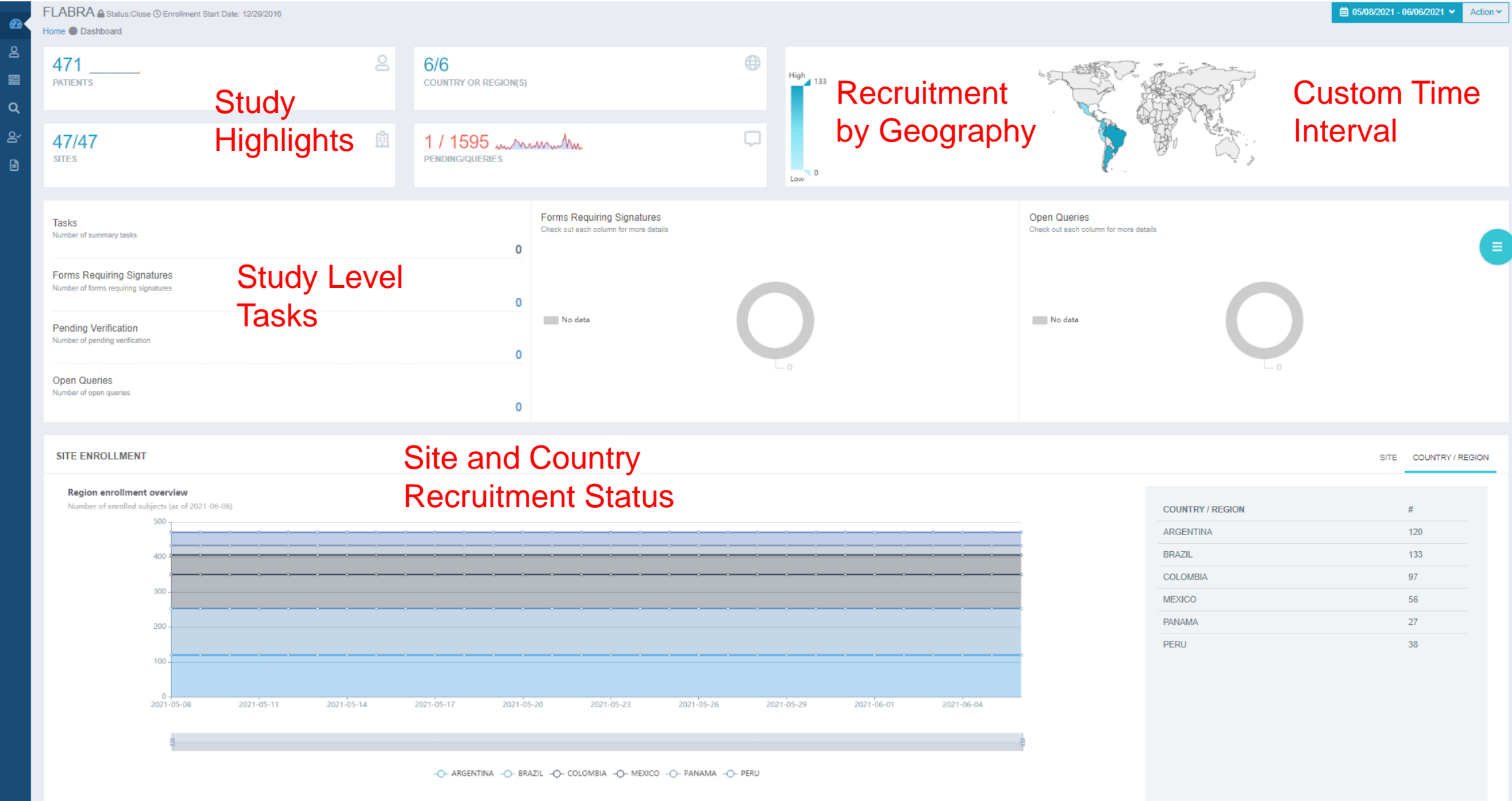
RWE Box Navigation – CRF Icons



	Never Touched: this icon indicates that the CRF is empty.
	Entry Expected: This icon indicates that the CRF is empty and you are expected to fill in the data.
	Complete: Data entry for the CRF is complete.
	Entry Lock: The CRF is locked (sites cannot change data).
	Non-Conformant: The CRF has any active discrepancies or other discrepancies.
	Verified: The CRF has been verified.
	Signature Requested: The CRF is waiting for signature.
	Signed: The CRF has been signed off.
	Hard Lock: The CRF is hard locked (Reversible by Monitor).



RWE Box Navigation - Study Dashboard



RWE Box Navigation – Patient List and Card View with Search & Filtering

PATIENTS (41)

Search...

Date Created: Newest to Oldest

Identifier ID	Gender	Name Initials	Location	Date of Birth	APP	Date of Enrollment
86-01-12	Female	■■■■	13-01	06/29/1991	📱	06/29/2019
78-01-34	Male	■■■■	78-01	02/02/1970		06/29/2019
01-01-31	Male	■■■■	78-01	02/01/2000	📱	06/29/2019
01-01-28	Male	■■■■	78-01	02/08/2000	📱	06/29/2019
78-01-36	Female	■■■■	78-01	06/23/1994		06/29/2019
78-01-33	Female	■■■■	78-01	06/29/1930		06/29/2019
01-01-30	Male	■■■■	78-01	02/01/2000		06/29/2019
01-01-27	Male	■■■■	78-01	02/03/2000	📱	06/29/2019
13-01-13	Male	■■■■	13-01	06/23/1965	📱	06/29/2019
78-01-35	Male	■■■■	78-01	06/29/1990	📱	06/29/2019
01-01-32	Male	■■■■	78-01	02/08/2000	📱	06/29/2019
01-01-29	Male	■■■■	78-01	02/08/2000	📱	06/29/2019
01-01-26	Male	■■■■	78-01	12/29/1999	📱	06/28/2019

78-01-36

Female ■■■■

06/29/2019
78-01

78-01-33

Female ■■■■

06/29/2019
78-01

01-01-30

Male ■■■■

06/29/2019
78-01

01-01-27 📱

Male ■■■■

06/29/2019
78-01

13-01-13 📱

Male ■■■■

06/29/2019
13-01

78-01-35 📱

Male ■■■■

06/29/2019
78-01

01-01-32 📱

Male ■■■■

06/29/2019
78-01

01-01-29 📱

Male ■■■■

06/29/2019
78-01

86-01-12 📱

Female ■■■■

06/29/2019
13-01

78-01-34

Male ■■■■

06/29/2019
78-01

01-01-31 📱

Male ■■■■

06/29/2019
78-01

01-01-28 📱

Male ■■■■

06/29/2019
78-01

RWE Box Navigation - Create Patient



Patient

Home ● Patient

8
TOTAL PATIENTS
VIEW MORE

4
STAGE 2
VIEW MORE

0
STAGE 3A
VIEW MORE

2
STAGE 3B
VIEW MORE

1
STAGE 4
VIEW MORE

1
STAGE 5
VIEW MORE

Create Patient

PATIENTS (8)

Search...

Date Created: Newest to Oldest

780101

780101

07/24/2019

7801

780108

780108

07/24/2019

7801

780104

780104

07/24/2019

7801

780107

780107

07/24/2019

7801

Create Patient

Basic Info

	Identifier ID *	Identifier Type	Location
<input checked="" type="radio"/>	Automatic patient identifier	CKD identifier	7801

Age *

Gender

☐ Male ☐ Female

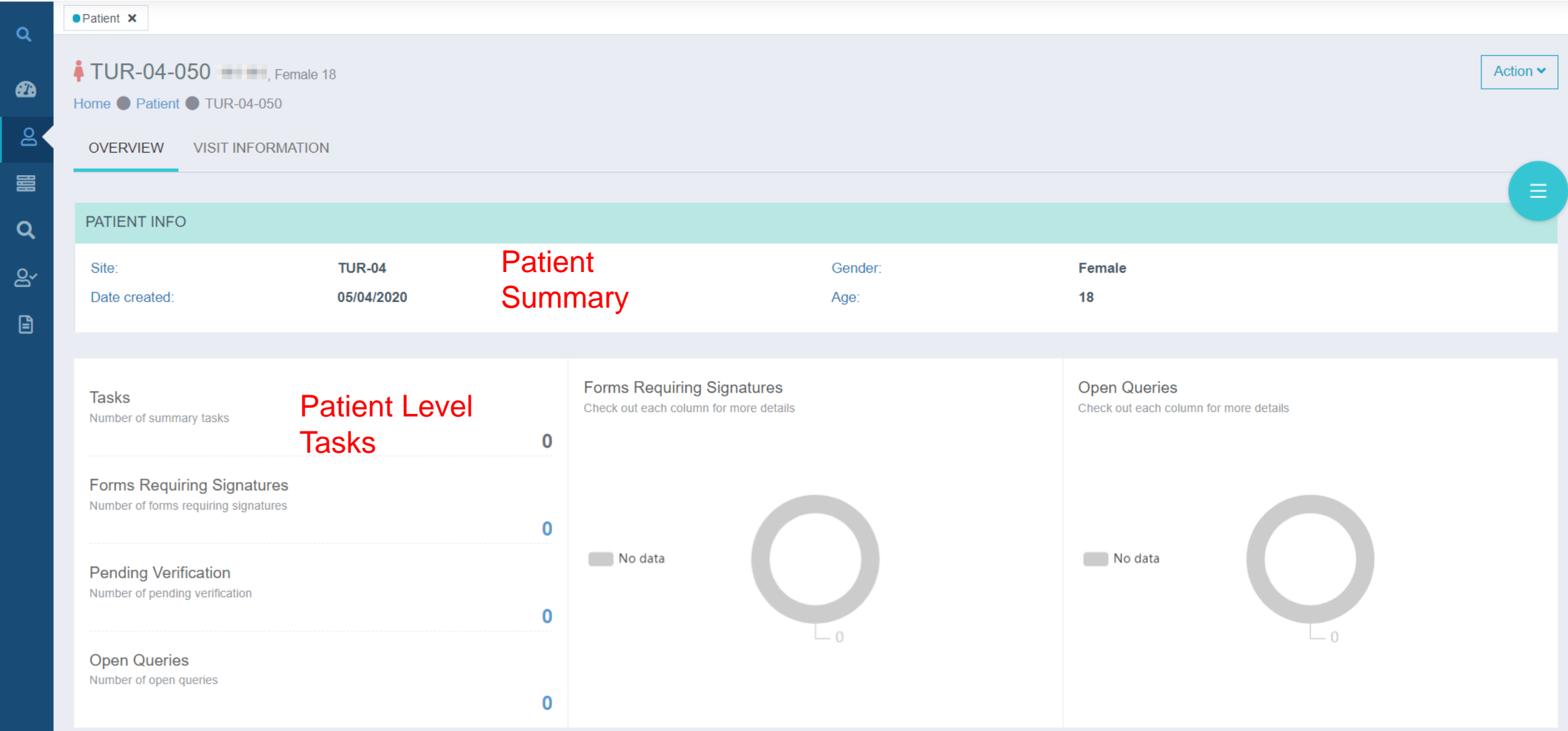
Date of Enrollment *

07/24/2019

Cancel

Save

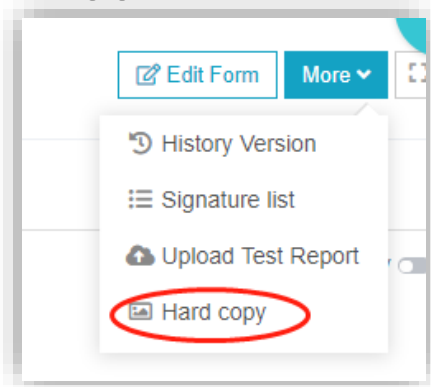
RWE Box Navigation – Patient Dashboard



- [illegible]

RWE Box Navigation – Manage Hard Copies

- Hard copy allows a user to upload additional patient data (paper ePRO, images) in photos, scanned images and PDFs.
- Hard copy can be accessed from Actions menu on each form. Each uploaded hard copy can be tagged.



This screenshot shows the 'HARD COPY' form in the RWE Box interface. The form includes fields for 'Title', 'From', and 'To'. It also has buttons for 'Cancel', 'Edit', and 'Batch upload'. The 'Batch upload' button is highlighted with a red circle. Below the form, there are checkboxes for 'All Tags', 'RAPA', 'WPAI', 'SF-36 QUESTIONNAIRE', and 'PATIENT SYMPTOM INFORMATION'. The status 'No Records' is displayed.

This screenshot shows the 'HARD COPY' form in the RWE Box interface. The form includes a 'Hard copy' field with a '+ Select file' button. Below this is a 'Title' field. At the bottom, there is a '+ Add hard copy' button and a 'Tag' button. The 'Tag' button is highlighted with a red circle. The form also includes checkboxes for 'RAPA', 'WPAI', 'SF-36 QUESTIONNAIRE', and 'PATIENT SYMPTOM INFORMATION'. An 'Upload' button is at the bottom.

RWE Box Navigation – Export Patient Casebook



Transverse

A4

Export

ID: #IND-011-083

OT

PATIENT INFO

PATIENT INFO

Site:

TST-01

Age:

32

Gender:

Male

Date of patient creation:

04/29/2021

VISIT INFORMATION

VISIT

BASELINE

29/04/2021 - 29/04/2021

6

INCLUSION AND EXCLUSION CRITERIA

+

DEMOGRAPHICS

+

COMORBIDITY BURDENS

+

FAMILY CANCER HISTORY

1

INITIAL PRESENTATION AND DIAGNOSIS OF PROSTATE CANCER

1

TREATMENTS AT INITIAL DIAGNOSIS OF PROSTATE CANCER

6

Query Management in RWE Box



- Data, medical and coding queries are raised, reviewed, answered and resolved within RWE Box
- There are two main types of queries:
 - ❖ **System queries:** Automatically generated and placed in real time by RWE Box when a form is saved with data that is missing (left blank) or when a data point does not conform to a pre-specified edit check.
 - ❖ **Manual queries:** Raised by a Study Data Manager, Medical Reviewer or Study Monitor upon manual review of the data for clarification on or correction to a specific item.
- Query management status report summarizes data QC KPI.

Query Management in RWE Box - Raising Manual Queries



The screenshot shows a web application interface. In the background, there is a form with a list of items. The fourth item is "4. Availability of medical records at the participating site reflect follow-up from the index date (unless the patient died or was...". To the left of this item is a blue icon of a speech bubble with a checkmark inside. This icon is circled in red. Overlaid on the bottom half of the screen is a "NEW" popup window. The popup has a title bar with a red "NEW" label, a date "04/06/2021", and a user "admin". It contains a "Query Type" dropdown menu with "Choose" selected, a "Query Text" text area, and "Cancel" and "Submit" buttons at the bottom.

Study Monitors or Data Managers can select a subject. Locate and choose a form. Click on the blue icon next to the field to create a new query in the popup.

Query Management in RWE Box – Handle Queries

- After login, check for open queries at the bottom of the study dashboard and on the patient dashboard marked “Tasks.” Click “Open Queries”. A user will be directed to Task Center to handle each query.

The screenshot displays the RWE Box interface, specifically the Task Center. The top section shows a summary of tasks and queries:

- Tasks:** Number of summary tasks: 1040
- Forms Requiring Signatures:** Number of forms requiring signatures: 0
- Pending Verification:** Number of pending verification: 12
- Open Queries:** Number of open queries: 1028

The middle section shows two donut charts:

- Forms Requiring Signatures:** A donut chart showing 0 unsigned (orange) and 22 signed (blue) forms.
- Open Queries:** A donut chart showing 1027 new (red), 2613 closed (gray), and 1 updated (yellow) queries.

The bottom section shows the Task Center interface, which includes a sidebar with navigation links and a main area displaying a table of unanswered queries.

Task Center Sidebar:

- Forms Requiring Signatures: 0
- Pending Verification: 12
- Unanswered Queries: 1026
- Answered Queries: 1
- Canceled Queries: 51

Unanswered Queries Table:

	Identifier	Query Type	Query Text	Study Event	Form Name	Visit Start Date	Assign to	Creator	Date Created	Action
4	IND-011-082	Data entry error	Data entry error	Baseline	FAMILY CANCER HISTORY	25/04/2021	lixin-hcp	admin	04/06/2021	View
2	IND-011-083	Mandatory field-missing	'Data collection date' is missing.	Baseline	INCLUSION AND EXCLUSION CRITERIA	29/04/2021	admin	System	04/06/2021	View

The "View" button for the first query (IND-011-082) is highlighted with a red box.



Resolving System Queries



QUERY

Pending

Closed

S

System

04/06/2021 10:46

Mandatory field-missing (Data collection date)

'Data collection date' is missing.

NEW Click on query type to scroll to the corresponding data point

Delete

Edit

S

System

04/06/2021 10:46

Edit Check (Date of informed consent)

'Date of informed consent' is blank, however, 'Not Applicable' is also missing, please verify.

NEW

Delete

Edit

<

1

>

INCLUSION AND EXCLUSION CRITERIA

DATA COLLECTION INFORMATION

Date of informed consent

[] Not Applicable

ICF file:

Data collection date

INCLUSION

Once the data field is corrected and the form is saved, a system query will be resolved automatically and go away.

Resolving Manual Queries



Click B if data correction is needed. The query status will be updated.

QUERY

Pending

Closed

A

admin

Incorrect choice (Self-report ethnicity)

The selection is not correct, please choose again.

NEW

06/03/2019 12:39 PM

A

Edit

<

1

>

Click A if no data change is needed. The query will be updated.

NEW

RAISED DATE: 06/03/2019 12:39 PM

RAISED BY: ADMIN

Description

Incorrect choice

Detailed query:

The selection is not correct, please choose again.

Status *

Answered

☒ Enter a response

☐ If necessary, change data & give reason for change

COMMENTS

Type a message here

Cancel

Submit

NEW

RAISED DATE: 06/03/2019 12:39 PM

RAISED BY: ADMIN

Description

Incorrect choice

Detailed query:

The selection is not correct, please choose again.

Status *

Answered

☐ Enter a response

☒ necessary, change data & give reason for change

Question Concept *

Self-report ethnicity

Answer Concept *

Mixed (e.g., brown, mulatto, others)

Comment

Edit Reason *

☐ Delete this Observation

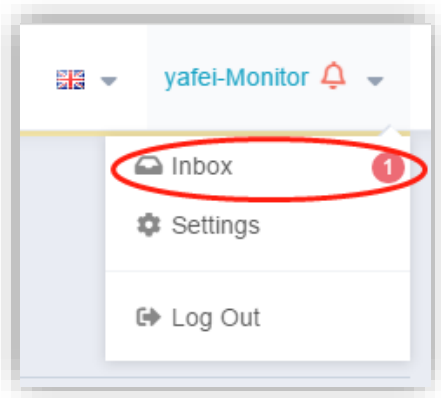
Created By yafet hcp - 06/03/2019 12:31 PM UTC+06:00

Raised By Super User - 06/03/2019 12:39 PM UTC+06:00

Cancel

Submit

Query Management in RWE Box – Query Reminder



From a user’s Inbox, all queries needing user’s actions are listed.

Inbox

☐

Action ▾

1 - 10 of 24

<

>

☰

<input type="checkbox"/>	★ admin	CRF has been signed (SF-36 QUESTIONNAIRE of CHN-01-33 enrolled by CKD-01)	06/04/2019 11:03 AM
<input type="checkbox"/>	★ yafei-Monitor	Signature request alert (WPAI of CHN-01-26 enrolled by CKD-01)	06/04/2019 11:02 AM
<input type="checkbox"/>	★ yafei-Monitor	Signature request alert (SF-36 QUESTIONNAIRE of CHN-01-33 enrolled by CKD-01)	06/04/2019 11:01 AM
<input type="checkbox"/>	★ admin	Query changes to Updated by admin alert (CRF SF-36 QUESTIONNAIRE of CHN-01-33 enrolled by CKD-01)	06/04/2019 11:00 AM
<input type="checkbox"/>	★ admin	New query alert (CRF SF-36 QUESTIONNAIRE of CHN-01-33 enrolled by CKD-01)	06/04/2019 11:00 AM
<input type="checkbox"/>	★ admin	New query alert (CRF WPAI of CHN-01-26 enrolled by CKD-01)	06/04/2019 10:59 AM
<input type="checkbox"/>	★ admin	New query alert (CRF DEMOGRAPHICS of CHN-000001-00020 enrolled by CKD-000001)	06/03/2019 11:26 AM

Query Management in RWE Box – Export Queries

A user can navigate to all queries page under Data QC menu to export queries.

QUERY

Export

Page 1 of 365 | View 10 records | Found total 3,641 records

ID	Title	Description	Form Name	Concept Name	Visit Start Date	Status	Patient Identifier	Assign to	Creator	Date Created	Actions
					<div>From</div> <div>To</div>					<div>Fr</div> <div>To</div>	<div>Search</div> <div>Reset</div>
10964	Data entry error	Data entry error	FAMILY CANCER HISTORY	Any Family Cancer History?	25/04/2021	New	IND-011-082	lixin-hcp	admin	04/06/2021	<div>View</div>
10962	Mandatory field-missing	'Data collection date' is missing.	INCLUSION AND EXCLUSION CRITERIA	Data collection date	29/04/2021	New	IND-011-083	admin	System	04/06/2021	<div>View</div>
10963	Edit Check	'Date of informed consent' is blank, however, 'Not Applicable' is also missing, please verify.	INCLUSION AND EXCLUSION CRITERIA	Date of informed consent	29/04/2021						

	A	B	C	D	E	F	G	H	I	J	K	L
1	ID	Patient Id	Title	Description	Form Name	Concept Name	Visit Start Date	Author	Date Created	Assign to	Last modified	Status
2	10964	IND-011-082	Data entry error	Data entry error	FAMILY CANCER HISTORY	Any Family Cancer History?	25/04/2021	admin	04/06/2021	lixin-hcp		Open
3	10962	IND-011-083	Mandatory field-missing	'Data collection date' is missing.	INCLUSION AND EXCLUSION CRITERIA	Data collection date	29/04/2021	System	04/06/2021	admin		Open
4	10963	IND-011-083	Edit Check	'Date of informed consent' is blank, however, 'Not Applicable' is also missing, please verify.	INCLUSION AND EXCLUSION CRITERIA	Date of informed consent	29/04/2021	System	04/06/2021	admin		Open
5	10508	IND-011-082	Field Check	'Any Family Cancer History' is missing.	FAMILY CANCER HISTORY	Any Family Cancer History?	25/04/2021	System	11/05/2021	dongweipin		Open
6	10429	IND-011-082	Field Check	'Any Family Cancer History' is missing.	FAMILY CANCER HISTORY	Any Family Cancer History?	29/04/2021	System	11/05/2021	admin		Open
7	10387	IND-011-082	Edit Check	'Date' is late	TREATMENT	radical retractor	25/04/2021	System	29/04/2021	dongweipin		Open
8	10388	IND-011-082	Edit Check	'Date' is late	TREATMENT	radical per	25/04/2021	System	29/04/2021	dongweipin		Open
9	10389	IND-011-082	Edit Check	'Date' is late	TREATMENT	cryosurgery	25/04/2021	System	29/04/2021	dongweipin		Open
10	10390	IND-011-082	Edit Check	'Date' is late	TREATMENT	orchiectomy	25/04/2021	System	29/04/2021	dongweipin		Open
11	10386	IND-011-082	Edit Check	'Date' is late	TREATMENT	Transureth	25/04/2021	System	29/04/2021	dongweipin		Open

Source Data Verifications



- Based on the Data Review Plan and Study Monitoring Plan, study team determines on which CRFs and fields to place Verify icon within RWE Box
- During site monitoring visits, study monitors check for Pending Verification tasks at the bottom of the study dashboard and on the patient dashboard marked “Tasks.” Click “Pending Verification”. A user will be directed to Task Center to handle SDV.
- Study monitors use Verify icon to document their reviews
- Study monitors can place manual queries for the site to review and address

The screenshot illustrates the Source Data Verification (SDV) process within a study dashboard. On the left, the 'VISIT' sidebar shows a 'BASELINE' visit for the period 20/04/2021 - 20/04/2021, with a 'Verify' icon (a person with a checkmark) highlighted by a red box. The main 'FORMS' section displays the 'INCLUSION AND EXCLUSION CRITERIA' form, also with a 'Verify' icon highlighted by a red box. Below the form, a 'DATA COLLECTION INFORMATION' table is visible. In the foreground, two modal windows are shown: a confirmation dialog asking 'Are you sure? Are you sure you want to mark the data as verified?' with 'Cancel' and 'OK' buttons, and a 'Success' message stating 'The data has been reported as verified successful!' with an 'OK' button.

Audit Trails – Form Level

- All changes that have made to a specific item on an eCRF can be viewed via the audit trail
- To access an item's audit trail, navigate to the completed form and click the Audit Trail icon.
- Audit trail will show each user who and when enters data, changes data, responds to queries, etc.

The screenshot displays a patient form for 'TEST1003', a 41-year-old female. The interface includes a top navigation bar with 'Home', 'Patient', and 'TEST1003' tabs. Below this is a section for 'PATIENT INFO' with fields for Site (BPESN-Test01), Date of patient creation (06/08/2020), Gender (Female), and Age (41). A right-hand 'Action' menu is open, showing options like 'Edit Patient', 'Delete Patient', 'Audit Trail', 'Verify', 'Signature Request', 'Sign', 'Entry Lock', 'Hard Lock', and 'Export'. The 'Audit Trail' option is highlighted. Below the patient info, there are three summary boxes: 'Tasks' (4), 'Forms Requiring Signatures', and 'Open Queries'. At the bottom, a modal window titled 'AUDIT TRAIL' is open, showing a log entry: 'Version 1 | admin' and 'admin saved (Update patient)' on 19/04/2021 at 16:47 UTC+08:00.

PATIENT INFO			
Site:	BPESN-Test01	Gender:	Female
Date of patient creation:	06/08/2020	Age:	41

Tasks	Forms Requiring Signatures	Open Queries
Number of summary tasks	Check out each column for more details	Check out each column for more details
4		

AUDIT TRAIL

Version 1 | admin

admin saved (Update patient)	19/04/2021 16:47 UTC+08:00
------------------------------	----------------------------

Audit Trails – Study Level

- Navigate to Study Audit Trail page from Data QC menu.

Study Audit Trail

[Home](#) ● [Study Audit Trail](#)

STUDY AUDIT TRAIL

Export

Page < 1 > of 614 | View 10 records | Found total 6,134 records

<input type="checkbox"/>	Version	Event Type	Event Date	Old	Event Object	Patient Identifier	Creator	Location	Actions
<input type="checkbox"/>			<div>From <div></div>To <div></div></div>						<div>Search</div> <div>Reset</div>
<input type="checkbox"/>	178775	CREATE	04/06/2021 11:51	10964	Patient	IND-011-082	admin	TST-01	<div>Detail</div>
<input type="checkbox"/>	178763	CREATE	04/06/2021 10:46	1416517	Visit	IND-011-083	admin	TST-01	<div>Detail</div>
<input type="checkbox"/>	178753	CREATE	04/06/2021 09:28	231821	Encounter	IND-011-076	admin	TST-01	<div>Detail</div>
<input type="checkbox"/>	164162	UPDATE	11/05/2021 14:46		EncounterVerificationItem				
<input type="checkbox"/>	163912	CREATE	11/05/2021 10:02						<div>Search</div> <div>Reset</div>
<input type="checkbox"/>	163090	UPDATE	29/04/2021 13:08						
<input type="checkbox"/>	163071	UPDATE	29/04/2021 13:08						
<input type="checkbox"/>	163048	UPDATE	29/04/2021 11:32						<div>Detail</div>
<input type="checkbox"/>	163044	UPDATE	29/04/2021 11:31						<div>Detail</div>
<input type="checkbox"/>	163031	UPDATE	29/04/2021 11:21						<div>Detail</div>
<input type="checkbox"/>	162959	CREATE	29/04/2021 10:33	119342	Patient	IND-011-083	admin	TST-01	<div>Detail</div>
<input type="checkbox"/>	160460	CREATE	25/04/2021 18:07	119339	Patient	IND-011-082	lixin-hcp	TST-01	<div>Detail</div>
<input type="checkbox"/>	159562	UPDATE	25/04/2021 13:29	119337	Patient	IND-011-081	dongweiping-HCP	TST-01	<div>Detail</div>
<input type="checkbox"/>	159561	UPDATE	25/04/2021 13:26	119337	Patient	IND-011-081	dongweiping-HCP	TST-01	<div>Detail</div>

AUDIT TRAIL DETAIL

Version	160460	Event Type	CREATE
Event Date	2021-04-25 18:07:19	Event Object	Patient
OID	119339	Creator	lixin-hcp
Patient Identifier	IND-011-082		

Data point	Old Data	New Data
Age		31
Gender		Male
Identifier Type		REMPRO Registry identifier
Patient Identifier		IND-011-082
Site		TST-01

Entry Lock



- HCP who entered the data can create Entry Lock.
- After the HCP creates an "Entry lock", the form enters the entry lock state, in which the form can't be edited, but a query can still be raised.
- If the HCP wants to edit the form again, he/she needs to click "Undo Entry Lock."

The screenshot shows a web interface titled "FORMS". At the top, there are buttons for "Edit Form", "Delete Form", "More", "Legend", and a settings icon. Below this, there are two tabs: "INCLUSION AND EXCLUSION CRITERIA" (active) and "DEMOGRAPHICS". Under the active tab, there is a row of buttons: "Entry Lock" (highlighted with a red circle), "Verify", "Sign", and "Hard Lock". To the right of these buttons is a "Show History" toggle switch. Below the buttons, the text "INCLUSION AND EXCLUSION CRITERIA" is visible.

The screenshot shows the same web interface as the previous one, but now the "Entry Lock" button has been replaced by an "Undo Entry Lock" button, which is highlighted with a red circle. The other elements, including the "FORMS" title, top buttons, tabs, and "Show History" toggle, remain the same.

Hard Lock

- When the HCP enters the "Entry lock" state on the form, only the monitor has the privilege "to execute the "Hard lock" on the form. After a hard lock, a query may not be added to the form nor can the HCP unlock the entry lock unless the monitor unlocks it.

The screenshot displays a web application interface for managing forms. At the top, a 'FORMS' header is followed by action buttons: 'Edit Form', 'Delete Form', 'More', 'Legend', and a settings icon. Below this, a tabbed interface shows 'INCLUSION AND EXCLUSION CRITERIA' as the active tab, with 'DEMOGRAPHICS' and 'LIFESTYLE' as alternatives. A status bar contains icons for 'Entry Locked', 'Verify', 'Signed', and 'Hard Lock', with the 'Hard Lock' button highlighted by a red circle. A 'Show History' toggle is also present. The main content area is titled 'INCLUSION AND EXCLUSION CRITERIA' and contains a section for 'DATA COLLECTION INFORMATION'. This section includes a table with the following data:

Date of informed consent	08/06/2020
	[] Not Applicable

Electronic Signature



- The RWE Box provides electronic signature capabilities that meet regulatory requirements.
- Any changes to the subject's electronic data within the system will result in the signature being destroyed in which case the investigator must sign again.
- A user who receives the signature requests through email can navigate to the Investigator Signature page in the task summary section of the study dashboard following the link in the email.

The screenshot displays the RWE Box interface with three main sections: Tasks, Requiring Signatures, and Open Queries. The 'Requiring Signatures' section shows a large orange circle and a legend for 'Unsigned' (orange square) and 'Signed' (blue square). Two modal windows are overlaid on the interface.

REQUIRING SIGNATURES

Page < 1 > of 1 | View 10 records
| Found total 2 records

Form Name	Author	Date Created	Action
LIFESTYLE	yafei-HCP	27/05/2019 18:37	Link
SF-36 QUESTIONNAIRE	yafei-HCP	27/05/2019 18:03	Link

Page < 1 > of 1 | View 10 records
| Found total 2 records

[Back](#)

SIGNATURE

I certify that all entries on the CRFs for this subject accurately and completely reflect the results of the examinations, tests, and evaluations performed on the dates specified.

Please review data and sign
Opened by yfontela by admin (07/12/2018 01:57 UTC+08:00)

Enter your user name and password when you have entered all data for this patient. You should also resolve all queries before this page. If you change any data for this patient your 'Signature' will be revoked and you will need to return to this page to re-sign.

User Name *

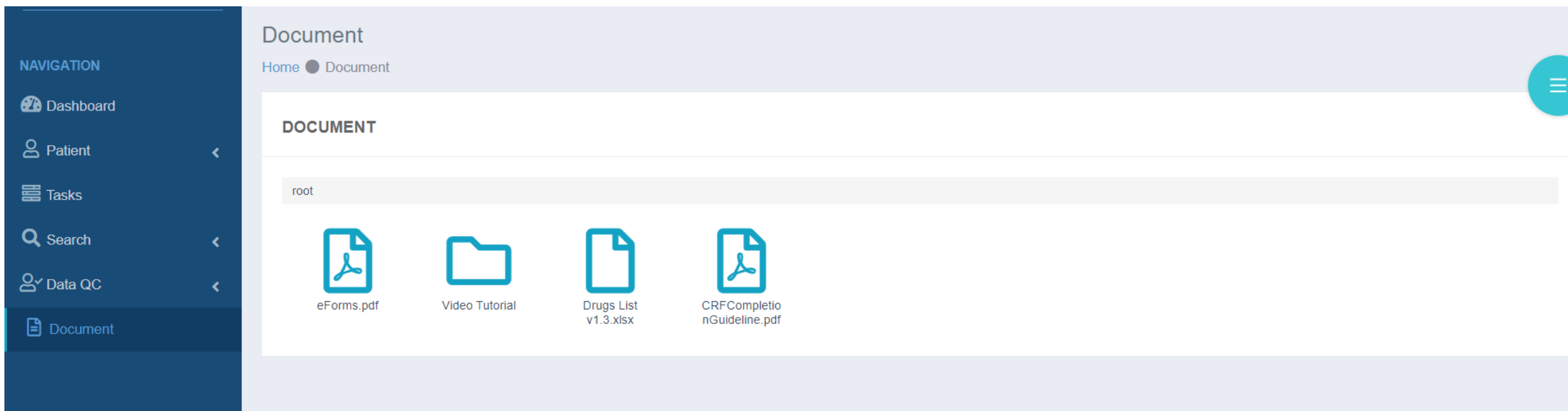
Password *

[Cancel](#) [Submit](#)

Resources within RWE Box



- Documents menu on Navigation bar provides access to these materials:
 - Video Tutorial: tutorial videos of RWE Box module by module in different languages (based on study needs)
 - Annotated CRF
 - CRF Completion Guideline
 - Standard terms used for CRF (medications, diagnosis, procedures etc)



Resources within RWE Box

- Once within a study, you can click on the icon highlighted in red below on any page to access Help information relevant to that page or Contact RWE Box support 24/7 through study specific email.



Search...

NAVIGATION

- Dashboard
- Patient
- Matrix
- Tasks
- Search
- Data QC
- Document

Dashboard x Document x Patient x

Patient

Home Patient

14740 TOTAL PATIENTS

0 PATIENTS MAJOR QUALITY UNMET

6914 PATIENTS HAVE EXAM(S) DUE

8653 PATIENTS NEED FOLLOW UP

PATIENTS (14740)

Search...

Age: 0 - 120

Date Created: Newest to Oldest

MEX-000007-00278

JL HM
06/05/2021
MEX-000007

MEX-000011-00376

SA MJ
06/05/2021
MEX-000011

MEX-000011-00379

A ZG
06/05/2021
MEX-000011

MEX-000011-00378

R GL
06/05/2021
MEX-000011

MEX-000012-00289

G SM
06/05/2021
MEX-000012

MEX-000012-00288

S BA
06/05/2021
MEX-000012

IND-000005-03575

PHL-000028-00007

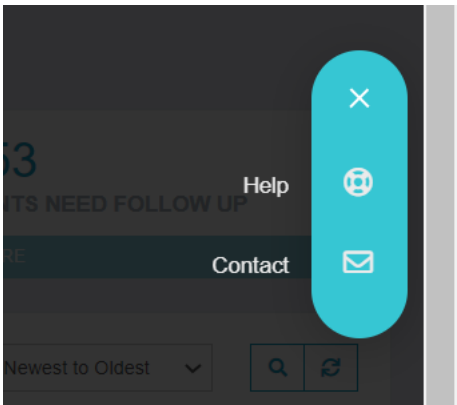
14740 PATIENTS

17/24 COUNTRY OR REGION(S)

262/288 HCPS

Dashboard is the landing page of a study. It gives you an overview of the study on study, country, site or HCP level. What you can see depends on your access permissions.

Skip Prev Next



To... discover_cvrm_registry_support@genomseqcare.com

Cc...

Send Subject Feedback

Please follow these instructions to let us know the problems you were encountered:

- 1.Press ALT+PRNSCRN to send a screenshot of the active window to your clipboard
- 2.Press CTRL+V to paste the image in this email
- 3.Describe the problems you were having with the system

Please DONOT modify the following information,

User Name: xxx

User Id: 22

Email Address: xxxx

Advanced Topics - Search (Simple and Advanced)



Search

Home ● Search

SEARCH ADVANCED SEARCH

Sidebar Search

Demographics

GENDER

Any

AGE

to

BIRTHDATE RANGE

to

SEARCH

Displaying 1 to 50 of 76

All Patients

No.	Gender	Age	Id
1	♀	34	IN
2	♀	28	IN
3	♀	11	IN
4	♂	41	IN
5	♂	87	IN
6	♂	47	IN
7	♂	26	IN
8	♂	56	IN

SEARCH

Displaying 1 to 50 of 76

Concept Id

Create Cohort

NOT AND OR

+ Add group

query patients with ANY LOT (Line of Therapy) = First line

Edit Delete

Search

Create Cohort

SEARCH

Displaying 1 to 50 of 76

Concept Id

Create Cohort

NOT AND OR

+ Add group

query patients with ANY LOT (Line of Therapy) = First line

Edit Delete

query patients with ANY Method of Assessment = Biochemical

Edit Delete

Search

Create Cohort

Advanced Topics - Cohort Builder



SEARCH Displaying 1 to 50 of 76

NOT AND OR

query patients with ANY LOT (Line of Therapy) = First line

query patients with ANY Method of Assessment = Biochemical

Search

Create Cohort

Concept Id

CREATE COHORT

Cohort name *

Cancel

Save Cohort

Cohort List

[Home](#) ● Cohort List

Cohort List

COHORT LIST

Refresh

Page 1 of 2 | View 10 records | Found total 13 records

Cohort Name	Generated datetime	Patient Number	Encounter number	Status	Time cost	Action
ALL Patients				Waiting		<div>Run Remove</div>
IND-011-062	31/03/2021 19:30	1	1	Completed	00:08	<div>Download Edit</div> <div>Run Remove</div>

Advanced Topics – Create Report and Export (restricted to Lead DM)

Cohort List

Home ● Cohort List

☰ Cohort List

COHORT LIST Refresh

Page < 1 > of 2 | View 10 records | Found total 13 records

Cohort Name	Generated datetime	Patient Number	Encounter number	Status	Time cost	Action
ALL Patients				Waiting		Run Remove
IND-011-062	31/03/2021 19:30	1	1	Completed	00:08	Download Edit Run Remove

Download Excel, CSV, TSV or PDF

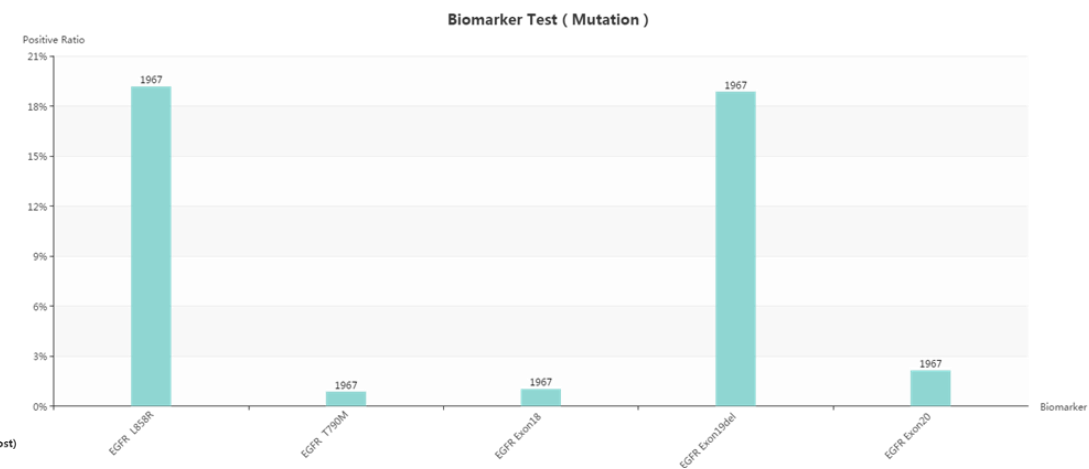
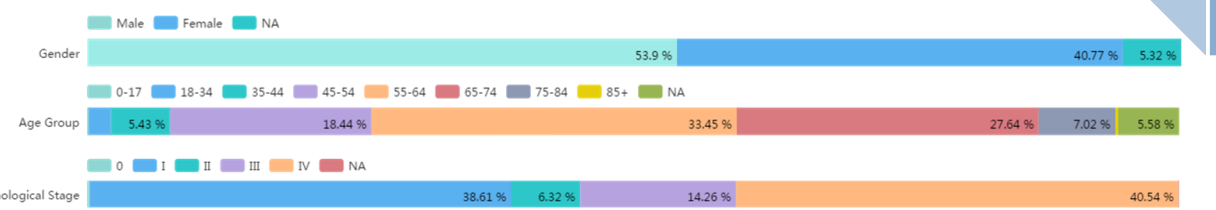
RUN REPORT

- Type of data * ☒ Matched Encounter Dataset ☐ All Dataset
- Output format * ☒ Microsoft Excel - Office Open XML
☐ CSV - Comma-separated values
☐ TSV - Tab-separated values ☐ PDF - Pdf Archive
- Type of excel * ☒ Multiple excels ☐ Excel with multiple worksheets
- Form * ☒ Check all
☒ SYSTEMIC TREATMENT at mCRPC
☒ DIAGNOSIS at mCRPC at INDEX DATE
☒ INCLUSION AND EXCLUSION CRITERIA
☒ RADIOTHERAPY at mCRPC

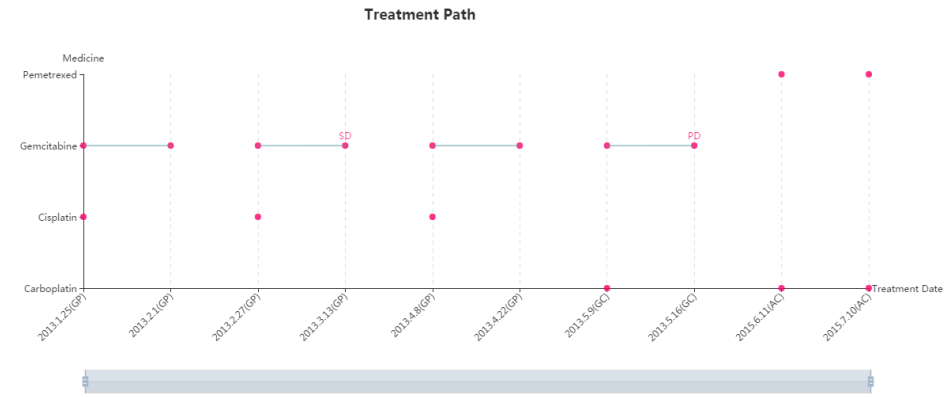
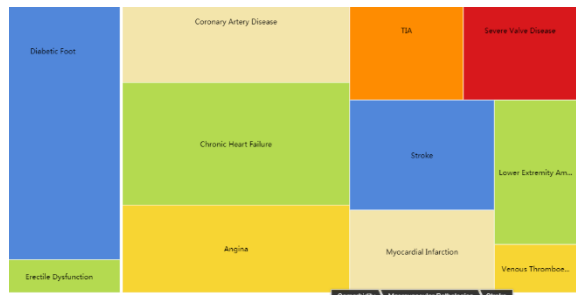
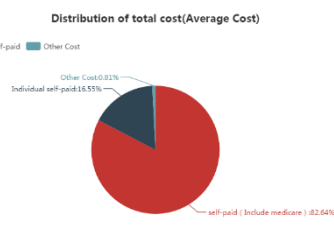
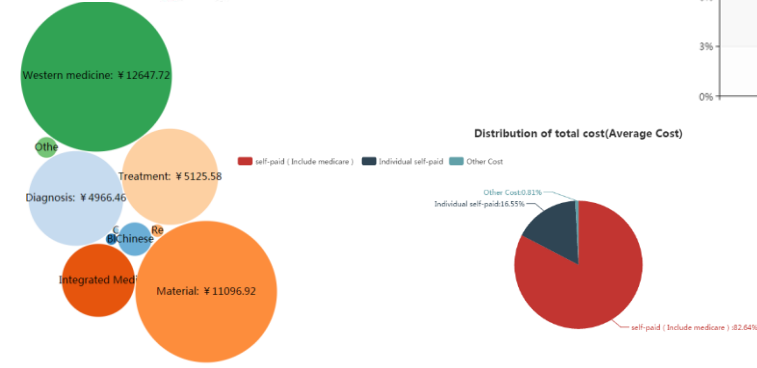
Advanced Topics – Study Specific Analytics Dashboard



- Demographics
- Geographic dist. of quality of care metrics
- Biomarkers and lab test results
- Comorbidities
- Treatments
- Side effects
- Costs



1st Line	2nd Line	3rd Line	Multiple Line
Carboplatin/Pemetrexed	Docetaxel	Docetaxel	Radiotherapy
Carboplatin/Gemcitabine	Docetaxel	Docetaxel	Pemetrexed
Radiotherapy	Pemetrexed	Pemetrexed	Docetaxel
Gemcitabine	Carboplatin/Pemetrexed	Carboplatin/Pemetrexed	Gemcitabine/Vinorelbine
Pemetrexed	Gemcitabine/Vinorelbine	Gemcitabine/Vinorelbine	Gemcitabine
Docetaxel/Nedaplatin	Docetaxel/Nedaplatin	Docetaxel/Nedaplatin	Gemcitabine
Carboplatin/Etoposide	Gemcitabine	Docetaxel/Nedaplatin	Etoposide
Cisplatin/Gemcitabine	Docetaxel	Nedaplatin/Pemetrexed	Bevacizumab/Gemcitabine
Docetaxel	Carboplatin/Gemcitabine	Vinorelbine	Docetaxel/Nedaplatin
Carboplatin/Paclitaxel	Carboplatin/Paclitaxel	Carboplatin/Paclitaxel	Abiraterone
Cisplatin/Pemetrexed	Nedaplatin/Pemetrexed	Gemcitabine	CPT-11
Carboplatin/Vinorelbine	Gemcitabine	Tarceva	Carboplatin/Pemetrexed
Cisplatin/Etoposide	Cisplatin/Etoposide	Docetaxel	Irinotecan
Cisplatin/Docetaxel	Gemcitabine	Gemcitabine/Vinorelbine	Docetaxel
Iressa	Iressa	Gemcitabine/Vinorelbine	Bevacizumab
Irinotecan	Cisplatin/Gemcitabine	Gemcitabine/Nedaplatin	Irinotecan
Vinorelbine	Gemcitabine/Nedaplatin	Irinotecan	Iressa
Tarceva	Docetaxel/Pemetrexed	Docetaxel/Pemetrexed	Nedaplatin/Pemetrexed
Cisplatin/Vinorelbine	Nedaplatin/Paclitaxel	Nedaplatin/Paclitaxel	Docetaxel/Pemetrexed
Carboplatin/Docetaxel	Docetaxel	Etoposide	Sunitinib





Thanks!

