Introduction to RWE Box

Shanghai GenomSeqCare Biotechnology Co. Ltd
RWE Box: Enabling Real World Evidence Research

- eICF (electronic consent)
- eCRF
- EMR
- EMR linking
- Genomics
- Patient health Vault
- Analytics
- Visit & medication Mgt
- ePRO, QoL & eDiary
- Diet & exercise
- Remote monitoring
- Follow-up robot
- Doctor live
- Precision Medicine Delivery
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

<table>
<thead>
<tr>
<th>User Role</th>
<th>Privileges</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Country Coordinator</strong></td>
<td>Study dashboard presents summary of current Study with the specified country.</td>
</tr>
</tbody>
</table>
| **HCP/Investigator** | Submit Data:  
  - 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  
  Investigator signature to sign off subject data |
| **Study Coordinator** | Same privileges as HCP except Investigator signature. |
| **Monitor/DM** | Study dashboard presents summary of current Study with specified sites.  
  Monitor and Manage Data:  
  - 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 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
RWE Box Navigation – Navigation Bar (specific to User Roles)

- Study dashboard
- Patient dashboard
- Patient visit matrix
- Tasks for a user
- Analytics dashboard
- Search and cohort builder
- Query mgmt and QC report

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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).

**Diagram Description**:
- **Never Touched** → **Incomplete** → **Complete** → **Verified** → **Entry Lock** → **Signed** → **Hard Lock**
- **Incomplete** → **Closed Queries** → **Open Queries**
- **Open Queries** → **Close** → **Answered queries**
- **Non-Conformant** → **Open** → **Responses** → **Requires Signature**

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

<table>
<thead>
<tr>
<th>Patient ID</th>
<th>Gender</th>
<th>Name Initials</th>
<th>Location</th>
<th>Date of Birth</th>
<th>APP</th>
<th>Date of Enrollment</th>
</tr>
</thead>
<tbody>
<tr>
<td>01-01-27</td>
<td></td>
<td></td>
<td>75-01</td>
<td>06/29/1983</td>
<td></td>
<td></td>
</tr>
<tr>
<td>01-01-28</td>
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<td>75-01</td>
<td>06/29/1983</td>
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<td></td>
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<tr>
<td>01-01-23</td>
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<td>75-01</td>
<td>06/29/1983</td>
<td></td>
<td></td>
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<tr>
<td>78-01-36</td>
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<td>06/29/1983</td>
<td></td>
<td></td>
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<tr>
<td>78-01-33</td>
<td></td>
<td></td>
<td>75-01</td>
<td>06/29/1983</td>
<td></td>
<td></td>
</tr>
<tr>
<td>13-01-13</td>
<td></td>
<td></td>
<td>75-01</td>
<td>06/29/1983</td>
<td></td>
<td></td>
</tr>
<tr>
<td>88-01-12</td>
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<td>06/29/1983</td>
<td></td>
<td></td>
</tr>
<tr>
<td>01-01-30</td>
<td></td>
<td></td>
<td>78-01</td>
<td>06/29/1983</td>
<td></td>
<td></td>
</tr>
<tr>
<td>01-01-27</td>
<td></td>
<td></td>
<td>78-01</td>
<td>06/29/1983</td>
<td></td>
<td></td>
</tr>
<tr>
<td>78-01-35</td>
<td></td>
<td></td>
<td>78-01</td>
<td>06/29/1983</td>
<td></td>
<td></td>
</tr>
<tr>
<td>01-01-32</td>
<td></td>
<td></td>
<td>78-01</td>
<td>06/29/1983</td>
<td></td>
<td></td>
</tr>
<tr>
<td>01-01-28</td>
<td></td>
<td></td>
<td>78-01</td>
<td>06/29/1983</td>
<td></td>
<td></td>
</tr>
<tr>
<td>01-01-31</td>
<td></td>
<td></td>
<td>78-01</td>
<td>06/29/1983</td>
<td></td>
<td></td>
</tr>
<tr>
<td>01-01-29</td>
<td></td>
<td></td>
<td>78-01</td>
<td>06/29/1983</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Notes:**
- The table above shows a sample of patient information.
- The card view displays patient details such as ID, gender, name initials, location, date of birth, and date of enrollment.
- The search and filtering feature allows users to easily locate and manage patient data.
RWE Box Navigation - Create Patient
RWE Box Navigation – Patient Dashboard

Patient Summary

Patient Level Tasks

Site: TUR-04
Date created: 05/04/2020
Gender: Female
Age: 18

Tasks
Number of summary tasks: 0

Forms Requiring Signatures
Number of forms requiring signatures: 0

Pending Verification
Number of pending verification: 0

Open Queries
Number of open queries: 0

Forms Requiring Signatures
Check out each column for more details

Open Queries
Check out each column for more details

No data
RWE Box Navigation – Access Forms

INCLUSION AND EXCLUSION CRITERIA

DATA COLLECTION INFORMATION

Date of informed consent

Not Applicable

Data collection date

INCLUSION

Patients fulfilling all the following inclusion criteria will be eligible for participation:

1. Male patients ≥ 18 years of age or legal age of being an adult in the country as per local regulations.*
   - Yes
   - No

2. Patient or next of kin/representative (for deceased patients at study entry, unless a waiver is granted) willing and able to provide written informed consent according to the local regulations.*
   - Yes
   - No

3. Patients with a diagnosis of metastatic (stage IV) mCRPC, confirmed by either biopsy of a metastatic tumour site, or by history of biopsy-proven localized disease and evidence of metastatic disease on imaging studies (which is clearly noted in hospital/clinical records) and progression on ADT alone between 01 January 2016 and 31 December 2018.*
   - Yes
   - No

4. Availability of medical records at the participating site reflecting at least one LOT received in the mCRPC setting and 12 months of follow-up from the index date (unless the patient died or was lost to follow-up within the first 12 months after diagnosis).*
   - Yes
   - No
RWE Box Navigation – Edit Forms

Inclusion and Exclusion Criteria

Data Collection Information

- Date of informed consent
  - Not Applicable
- Data collection date

Inclusion

Patients fulfilling all the following inclusion criteria will be eligible for participation:

1. Male patients ≥ 18 years of age OR legal age of being an adult in the country as per local regulations
   - Yes
   - No
2. Patient or next of kin/legal representative (for deceased patients at study entry, unless a waiver is granted) willing and able to provide written informed consent according to the local regulations
   - Yes
   - No
3. Patients with a diagnosis of metastatic (stage IV) mCRPC, confirmed by either biopsy of a metastatic tumour site, or by history of biopsy-proven localized disease and evidence of metastatic disease on imaging studies (which is clearly noted in hospital/clinical records) and progression on ADT alone between 01 January 2016 and 31 December 2018
   - Yes
   - No
4. Availability of medical records at the participating site reflecting at least one LOT received in the mCRPC setting and 12 months of follow-up from the index date (unless the patient died or was lost to follow-up within the first 12 months after diagnosis)
   - Yes
   - No

Exclusion

Patients fulfilling any of the following exclusion criteria will not be eligible for participation:
RWE Box Navigation – Patient Matrix

• The Patient matrix page is the only page in RWE Box that provides a study event-oriented view of the expected and entered CRFs for the displayed patients in a matrix format.

• When working with the matrix at the Patient matrix page, a user can use study events checkbox dropdown list to select visits for the currently displayed set of patients.
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.
ID: #IND-011-083 CT

PATIENT INFO

<table>
<thead>
<tr>
<th>Site</th>
<th>TST-01</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td>Male</td>
</tr>
<tr>
<td>Age</td>
<td>32</td>
</tr>
<tr>
<td>Date of patient creation</td>
<td>04/29/2021</td>
</tr>
</tbody>
</table>

VISIT INFORMATION

VISIT

BASELINE

29/04/2021 - 29/04/2021

- INCLUSION AND EXCLUSION CRITERIA
- DEMOGRAPHICS
- COMORBIDITY BURDENS
- FAMILY CANCER HISTORY
- INITIAL PRESENTATION AND DIAGNOSIS OF PROSTATE CANCER
- TREATMENTS AT INITIAL DIAGNOSIS OF PROSTATE CANCER
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.
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.
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 A if no data change is needed. The query will be updated.

Click B if data correction is needed. The query status will be updated.
Query Management in RWE Box – Query Reminder

From a user’s Inbox, all queries needing user’s actions are listed.
A user can navigate to all queries page under Data QC menu to export queries.
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
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.
Audit Trails – Study Level

• Navigate to Study Audit Trail page from Data QC menu.
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."
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.
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.
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.
Advanced Topics - Search (Simple and Advanced)
Advanced Topics - Cohort Builder

Search displaying 1 to 50 of 78

Create Cohort

Cohort List

COHORT LIST

<table>
<thead>
<tr>
<th>Cohort Name</th>
<th>Generated datetime</th>
<th>Patient Number</th>
<th>Encounter number</th>
<th>Status</th>
<th>Time cost</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALL Patients</td>
<td></td>
<td></td>
<td></td>
<td>Waiting</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IND-011-062</td>
<td>31/03/2021 19:30</td>
<td>1</td>
<td>1</td>
<td>Completed</td>
<td>00:06</td>
<td></td>
</tr>
</tbody>
</table>
Advanced Topics – Create Report and Export (restricted to Lead DM)

Download Excel, CSV, TSV or PDF
Advanced Topics – Study Specific Analytics Dashboard

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