



Entity : REVA

Content Type: Detailed Design Specification

Document Title: REVA\_DDS

Doc. No.: DDS-GLB-COMP-2022-0030-00001.003

## Approval

**Document Title :REVA\_DDS**

**Doc. No. :DDS-GLB-COMP-2022-0030-00001.003**

## **Approval**

Approver	Functional Role	Approved On	Reason For Esign
Rose Sanchez-Sonn [rose.sanchez-sonn@otsuka-us.com]	System Owner	20-Sep-2024 12:05:53 PM Time Zone: (EDT)	Approval



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# **Detailed Design Specification For Remote Electronic Virtual Assessment (REVA), Version 1.0**

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Release Reference Number: [RLSE0011768](#)



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## Signature Page

### Author

Name	Title/Department
Ian Quinn	Data Scientist / Think Team, ODS, OPDC

Note: Author(s) section is used to capture the details of first version of the document only. The version number in 'Revision History' section should be in sync with version of the document in ALVIS, after approval.

### Reviewed by

Printed Name	Title/Department
Rose Sanchez-Sonn	Associate Director, Senior Platform Lead, OIT – Global R&D OAPI

### Approved by

Meaning of Signature — Approvers		
Printed Name	Title/Department	Signatures & Date
Rose Sanchez-Sonn	Associate Director, Senior Platform Lead, OIT – Global R&D OAPI	<Electronic signature in ALVIS>



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## Revision History

<b>Version No.</b>	<b>Date</b>	<b>Change Description</b>	<b>Name/Title/Department</b>
1.0	8-Nov-2018	New Document, (Final) for Project Reference Number DMND0004859	Ian Quinn / Data Scientist / Think Team. OIT - Global R&D, OPDC
2.0	01-Feb-2019	Updated section 10 to include current screenshots for Project Reference Number DMND0004859	Ian Quinn / Data Scientist / The AIPI (ODS) – Global R&D, OPDC
3.0	13-May-2019	Updates as authorized by Change Request CHG0006903: 1. Updated Section 4 References to update the Version for URS and FRS and add Service Now Change Request due to which this document is currently being updated. 2. Updated Screenshot to match to Latest Screen changes made from Section 10.1.1 to 10.1.33 and added Field details for additional information. 3. Added new screenshot for 10.1.34 Informational Landing Screen and 10.1.35 FAQ Screens	Ian Quinn / Data Scientist / Think Team. OIT - Global R&D, OPDC
4.0	08-June-2020	Updates as authorized by Change Request CHG0012146: 1. Added section 10.1.36 describing the statistics dashboard	Ian Quinn / Data Scientist / Think Team, Early Phase and Translational Sciences, OPDC
5.0	03-Mar-2022	Updates as authorized by Change Request RLSE0010266: 1. Reviewers/Approvers table updated to list current roles. 2. Updated section 4 for Project References 3. Section 10.1.30 and 10.1.31 for updated fields and screenshots	Ajay Dhiman, Application Developer, OIT – Global, R&D, OAPI
6.0	13-May-2022	Following sections have been updated to incorporate the changes for RPA as authorized by: <b>RLSE0010345</b> . <ul style="list-style-type: none"> <li>• Updated Reviewers and Approvers list to reflect current responsibilities.</li> <li>• Updated Section 12 to list Mongo DB version 5.0</li> <li>• Updated Section 5.2 for Beehive Server connection details</li> </ul>	Ajay Dhiman, Application Developer, OIT – Global, R&D, OAPI



Version No.	Date	Change Description	Name/Title/Department
<b>ALVIS Revision History</b>			
001	22-Dec-2022	<p>Resetting the document revision history to version 001 as part of managing the document in ALVIS. No content changes within the body and no changes to Author/Reviewer/Approver sections are made. This revision is QC approved by GQS Validation Analyst acknowledging the document establishment in ALVIS.</p> <p>Legacy document ID from GQ-EDMS is VAL-0031413.</p>	Aamod Dixit, Validation Analyst (Manage Service Provider (MSP), Cognizant), GQS, OPDC.
002	21-Jul-2023	<p>Following sections have been updated to incorporate the changes for release reference no. <b>RLSE0010963</b>.</p> <ul style="list-style-type: none"><li>When a Trial is updated for a subject in the Web application if the subject has a rash case, the rash case should be transferred to the new trial. This will allow the transition of data of subjects to another trial through the application functionality. (Sec 9.1.23 and 10.1.30)</li><li>Added new “Download Patient Report” Button in Subject History and Report tab for all users. (Sec 9.1.22 and 10.1.31)</li><li>Translate to Spanish when the Spanish language option is selected for the convenience of Spanish users. (Sec 10.2.14)</li><li>Improve the checkbox's faint "x" appearance on the Subject History and Report tab. (Sec 10.1.31)</li><li>Added timestamps to the checkboxes and comments field in Subject Interactive view tab. (Sec 10.1.30)</li><li>Email body description is updated for Telederm/ Central Dermatologist and Medical Monitor when they make any update in Subject Interactive View tab. (Sec 10.2.15)</li><li>Updated to include SMTP server. (Sec 5.1)</li></ul>	Ajay Dhiman, Application Developer, OIT – Global, R&D, OAPI



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Version No.	Date	Change Description	Name/Title/Department
003	16-Sep-2024	<p>Following sections have been updated to incorporate the changes for release reference no. <b>RLSE0011768</b>.</p> <ul style="list-style-type: none"><li>• Updated Section 12 to list: Mongo DB version 7.0, Node JS version 20.17.0, Angular version 16.2.0</li><li>• Updated Section 5.1 for System Architecture Diagram. Figure 1.</li></ul>	Ajay Dhiman, Application Developer, OIT – Global, R&D, OAPI

Note: The version number in 'Revision History' section should be in sync with version of the document in ALVIS after approval.

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## 1 Introduction

### 1.1 Purpose

The purpose of this Detailed Design Specification (DDS) is to document the architecture and detailed design for all components of the Remote Electronic Virtual Assessment (REVA) system.

## 2 System Overview

REVA is a system for capturing rashes that occur during clinical trials. It collects and stores images of rashes and allows for centralized reviews by dermatologists to determine if rash-occurrences are related to a given study drug. This does not replace established systems of adverse event reporting, but rather provides additional context.

Using smart phones, subjects can complete questionnaires evaluating their rash conditions, and securely transmit that information along with photographs of rash locations to the trial's clinicians.

## 3 Scope

### 3.1 In Scope

The architecture and detailed design for all components of the REVA system.

### 3.2 Out of Scope

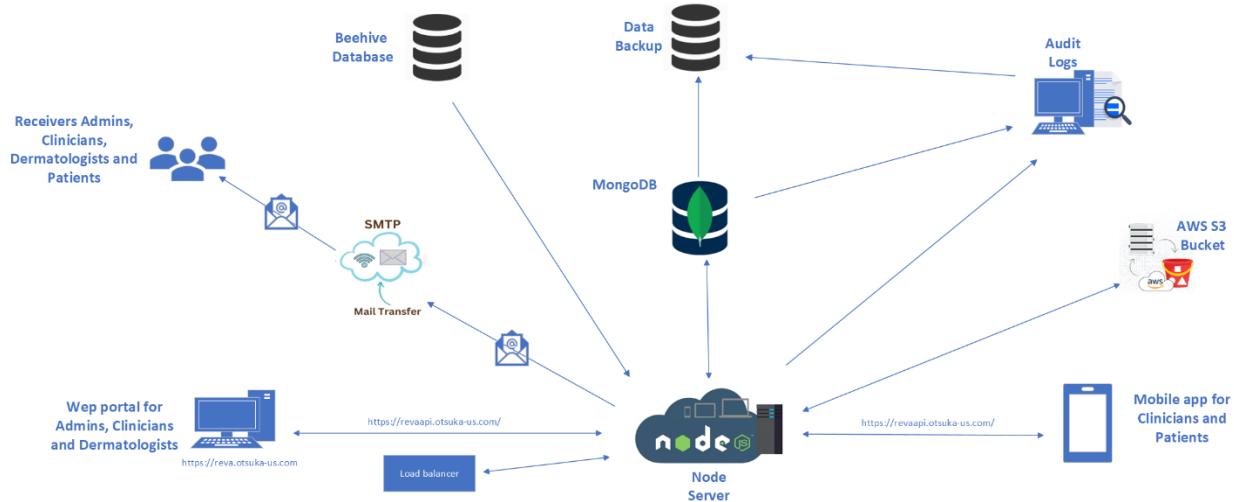
User and functional requirements for the REVA system.

## 4 References

Val Number	Name & Title	Version
PRC-0001783	GQ-1100-WP-001 "Computerized System Validation and Qualification Activities"	4.0
SRD-0004663	GQ-1100-ATT-001 "Good Documentation Guidelines"	2.0
FRS-GLB-COMP-2022-0030-00001.002	REVA_v2.0_FRS	2.0

## 5 Design overview

### 5.1 System Architecture



**Figure 1 - Architecture Overview**

The REVA system will comprise the following high-level components:

- A mobile client application
- A web-based client application
- A node.js server
- A MongoDB database
- An audit log system
- A backup/disaster-recovery system
- Otsuka's Beehive EMR database
- SMTP Server

Both the mobile and web-based applications will send data to and pull data from the node.js server. The node.js server will send data to and pull data from the MongoDB database and pull data from the Beehive database. The MongoDB database will provide data to and ingest data from the node.js server. The audit log system will ingest activity data from both the node.js server and the MongoDB database. Finally, the backup/disaster-recovery system will ingest data from both the MongoDB database and the audit log system.

Reva application is using the “**Nodemailer**” node package for email sending. For email sending host Z1EXCHA1310.mocr-nt1.otsuka-us.com (**10.45.61.253**) server used as a destination server and port 25 is using for this. Above host address is used as SMTP relay server. This server is set up for internal communication only, and it is relaying to M365 Smart Host which is encrypted.



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## 5.2 System Interfaces

The REVA system will pull data from an electronic medical record database on Otsuka's Beehive server.

HOST: j1cdhedge01.ams.otsukamalziad.com

PORT: 25004

USERNAME: svc\_reva

AUTH: LDAP

## 6 Assumptions, Limitations and Exclusions

There are no assumption, limitations and exclusions for the REVA system.

## 7 Instructions

The system components described in this DDS facilitate the functionality described in the URS & FRS. In other words, this DDS describes the specific implementation of higher-level requirements described in the URS & FRS.

## 8 Database Structure

REVA uses the NoSQL database MongoDB.

### 8.1 Database/ File System Space Requirements

Space utilized by the MongoDB database and S3 bucket file system must expand according to usage.

### 8.2 Table/ Layouts Details

#### 8.2.1 users

The following will describe the data structures of records stored in the REVA system.

**Subject:**

```

_id: {
  type: String,
  lowercase: true,
  trim: true
},
password: String,
resetPasswordToken: {
  type: String,
},
resetPasswordExpires: String,
last_login: String,
login_dateTime: String,

```



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```

dateTime_registered: String,
added_by: String,
isActive: {
    type: Boolean,
    default: true
},
isPasswordSet: {
    type: Boolean,
    default: false
},
subject_id: String,
cases: Number,
trial: String,
sites: [String],
updatedAt: Date
createdAt: Date

```

**Clinician:**

```

_id: {
    type: String,
    lowercase: true,
    trim: true
},
password: String,
resetPasswordToken: {
    type: String,
},
resetPasswordExpires: String,
last_login: String,
login_dateTime: String,
dateTime_registered: String,
added_by: String,
isActive: {

```



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```

    type: Boolean,
    default: true
  },
  isPasswordSet: {
    type: Boolean,
    default: false
  },
  id: String,
  sites: [String],
  trials: [String],
  local_dermatologists: [String],
  email: {
    type: String,
    required: true
  },
  name: {
    type: String,
    required: true
  },
  phone: {
    type: String,
    required: false
  }
}

updatedAt: Date
createdAt: Date
  
```

#### **System Administrator:**

```

_id: {
  type: String,
  lowercase: true,
  trim: true
},
password: String,
  
```



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```

resetPasswordToken: {
    type: String,
},
resetPasswordExpires: String,
last_login: String,
login_dateTime: String,
dateTime_registered: String,
added_by: String,
isActive: {
    type: Boolean,
    default: true
},
isPasswordSet: {
    type: Boolean,
    default: false
},
id: String,
email: {
    type: String,
    required: true
},
name: {
    type: String,
    required: true
},
phone: {
    type: String,
    required: false
}
updatedAt: Date
createdAt: Date

```

**Local Administrator:**



```
_id: {
    type: String,
    lowercase: true,
    trim: true
},
password: String,
resetPasswordToken: {
    type: String,
},
resetPasswordExpires: String,
last_login: String,
login_dateTime: String,
dateTime_registered: String,
added_by: String,
isActive: {
    type: Boolean,
    default: true
},
isPasswordSet: {
    type: Boolean,
    default: false
},
id: String,
email: {
    type: String,
    required: true
},
name: {
    type: String,
    required: true
},
phone: {
    type: String,
```



	<p style="text-align: right;">Entity : REVA  Content Type: Detailed Design Specification  Document Title: REVA_DDS  Doc. No.: DDS-GLB-COMP-2022-0030-00001.003</p>
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```

    required: false
}
updatedAt: Date
createdAt: Date

```

#### **Central Administrator:**

```

_id: {
  type: String,
  lowercase: true,
  trim: true
},
password: String,
resetPasswordToken: {
  type: String,
},
resetPasswordExpires: String,
last_login: String,
login_dateTime: String,
dateTime_registered: String,
added_by: String,
isActive: {
  type: Boolean,
  default: true
},
isPasswordSet: {
  type: Boolean,
  default: false
},
id: String,
email: {
  type: String,
  required: true
},

```



	<p style="text-align: right;">Entity : REVA  Content Type: Detailed Design Specification  Document Title: REVA_DDS  Doc. No.: DDS-GLB-COMP-2022-0030-00001.003</p>
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```

name: {
    type: String,
    required: true
},
phone: {
    type: String,
    required: false
}
updatedAt: Date
createdAt: Date

```

#### **Telederm:**

```

_id: {
    type: String,
    lowercase: true,
    trim: true
},
password: String,
resetPasswordToken: {
    type: String,
},
resetPasswordExpires: String,
last_login: String,
login_dateTime: String,
dateTime_registered: String,
added_by: String,
isActive: {
    type: Boolean,
    default: true
},
isPasswordSet: {
    type: Boolean,
    default: false
}

```



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```

},
id: String,
email: {
    type: String,
    required: true
},
name: {
    type: String,
    required: true
},
phone: {
    type: String,
    required: false
}
updatedAt: Date
createdAt: Date

```

**CRA:**

```

_id: {
    type: String,
    lowercase: true,
    trim: true
},
password: String,
resetPasswordToken: {
    type: String,
},
resetPasswordExpires: String,
last_login: String,
login_dateTime: String,
dateTime_registered: String,
added_by: String,
isActive: {

```



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```

type: Boolean,
default: true
},
isPasswordSet: {
    type: Boolean,
    default: false
},
id: String,
email: {
    type: String,
    required: true
},
name: {
    type: String,
    required: true
},
phone: {
    type: String,
    required: false
}
updatedAt: Date
createdAt: Date

```

#### **Monitor:**

```

_id: {
    type: String,
    lowercase: true,
    trim: true
},
password: String,
resetPasswordToken: {
    type: String,
}

```



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```

resetPasswordExpires: String,
last_login: String,
login_dateTime: String,
dateTime_registered: String,
added_by: String,
isActive: {
  type: Boolean,
  default: true
},
isPasswordSet: {
  type: Boolean,
  default: false
},
id: String,
email: {
  type: String,
  required: true
},
name: {
  type: String,
  required: true
},
phone: {
  type: String,
  required: false
}
updatedAt: Date
createdAt: Date

```

#### **Central Dermatologist:**

```

_id: {
  type: String,
  lowercase: true,
  trim: true
}

```



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```

    },
password: String,
resetPasswordToken: {
    type: String,
},
resetPasswordExpires: String,
last_login: String,
login_dateTime: String,
dateTime_registered: String,
added_by: String,
isActive: {
    type: Boolean,
    default: true
},
isPasswordSet: {
    type: Boolean,
    default: false
},
id: String,
email: {
    type: String,
    required: true
},
name: {
    type: String,
    required: true
},
phone: {
    type: String,
    required: false
},
address: String
updatedAt: Date
createdAt: Date

```



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### **Local Dermatologist:**

```

_id: {
    type: String,
    lowercase: true,
    trim: true
},
password: String,
resetPasswordToken: {
    type: String,
},
resetPasswordExpires: String,
last_login: String,
login_dateTime: String,
dateTime_registered: String,
added_by: String,
isActive: {
    type: Boolean,
    default: true
},
isPasswordSet: {
    type: Boolean,
    default: false
},
id: String,
email: {
    type: String,
    required: true
},
name: {
    type: String,
    required: true
},

```



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```

phone: {
    type: String,
    required: false
},
address: String
updatedAt: Date
createdAt: Date

```

### **8.2.2 trials**

```

_id: String,
name: {
    type: String,
    unique: true,
    dropDups: true
},
administrators: [String],
central_dermatologists: [String],
added_by: String,
dateTime_start: String,
dateTime_end: String,
sites: [String],
cras: [String],
monitors: [String],
telederms: [String]
updatedAt: Date
createdAt: Date

```

### **8.2.3 sites**

```

_id: String,
id: String,
name: {
    type: String,
    unique: true,
    dropDups: true
},

```



	Entity : REVA Content Type: Detailed Design Specification Document Title: REVA_DDS Doc. No.: DDS-GLB-COMP-2022-0030-00001.003
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administrators: [String],  
 local\_dermatologists: [String],  
 added\_by: String,  
 country: String,  
 state: String,  
 city: String,  
 street\_address: String,  
 zipCode: String  
 updatedAt: Date  
 createdAt: Date

#### **8.2.4 rash\_reports**

id: String,  
 subject\_id: String,  
 sites: [String],  
 trial: String,  
 resolved: Boolean,  
 needs\_review: Boolean,  
 dateTime\_resolved: String,  
 last\_observed: String,  
 dateTime\_created: String,  
 submitted\_by: String,  
 clinician\_submitted: Boolean,  
 sent\_to\_local\_dermatologist: Boolean,  
 case\_number: String,  
 telederm\_comments: String,  
 localDermVisitRequested: Boolean,  
 localDermVisitRequestorId: String,  
 reviewedByTelederm: Boolean,  
 teledermId: String,  
 reviewedByMonitor: Boolean,  
 monitorId: String,  
 eruption: String,  
 teledrem\_Comment\_Eruption\_Last\_Updated: String,



	<p style="text-align: right;">Entity : REVA  Content Type: Detailed Design Specification  Document Title: REVA_DDS  Doc. No.: DDS-GLB-COMP-2022-0030-00001.003</p>
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Monitor\_Last\_Updated: String,  
Id\_Suggested\_Date\_Last\_Updated: String,  
instances:  
[ **PatientReportInstanceSchema** ],  
updatedAt: Date  
createdAt: Date

**PatientReportInstanceSchema:**

instanceId: String,  
dateTime\_captured: String,  
submitted\_by: String,  
clinician\_submitted: Boolean,  
form:  
{  
first\_noticed: String,  
recent\_contact\_with\_other\_rash: Boolean,  
recent\_exposure\_to\_dyes\_or\_toxins: Boolean,  
changes: [String],  
itching: Number,  
burning: Number,  
tenderness: Number,  
rash\_is: [String],  
color: String,  
texture: String,  
size\_in\_cm: Number,  
symptoms: [String]  
},  
bodyPart\_images: [**ImageDataSchema**]

**ImageDataSchema:**

bodyPart: String,  
image: String,  
date\_time: Date



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## 8.2.5 dermatology\_reports

\_id: String,  
subject\_id: String,  
trial: String,  
clinician: ReportReviewItemSchema,  
localDermatologist: [ ReportReviewItemSchema ],  
centralDermatologist: ReportReviewItemSchema,  
dateTime\_created: Date,  
reportName: String

### ReportReviewItemSchema:

revid: String,  
reviewed: Boolean,  
dateTime\_reviewed: Date,  
reportName: String

## 8.3 Other Database Objects

NA

## 8.4 Administration and Access Control Details

A designated group of system administrators, architects, and developers will have read and write access on the system server, except for audit logs, to which they will only have read access. The expansion and retraction of this group's membership will be jointly determined by REVA business and system owners.

## 9 Component Level Design

### 9.1.1 Classes / Objects / Modules

This section comprises middle-layer functional modules that must mediate communication between the user-interface and the MongoDB database. These modules must reside on the node.js server.

#### 9.1.2 Register User

This module must take form inputs from the Register User screen on the web app, convert them into a JSON object, and insert this object into the user's collection.

#### 9.1.3 Register Site

This module must take form inputs from the Register Site screen on the web app, convert them into a JSON object, and insert this object into the sites collection.

#### 9.1.4 Register Trial

This module must take form inputs from the Register Trial screen on the web app, convert them into a JSON object, and insert this object into the trials collection.



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### **9.1.5 Report Rash**

This module must take form inputs from the Rash Details screen on the mobile app and image inputs from the Take Photo screen on the mobile app, convert the form inputs into a JSON object, insert this object into the patient\_reports collection, and upload the image inputs to a directory on the server.

### **9.1.6 Generate Report**

This module must pull records from the patient\_reports collection in the MongoDB database and medical history records corresponding to the patient about whom the report must be generated from the EMR database on the Beehive, generate a pdf displaying these records, upload this pdf to a directory on the server, and insert a record into the dermatology\_reports collection.

### **9.1.7 Upload Report**

This module must take form inputs and a file input from the Upload Dermatology Report screen on the web app, convert the form inputs into a JSON object, upload the file input to a directory on the server, and insert the JSON object into the dermatology\_reports collection.

### **9.1.8 Edit User**

This module must take form inputs from the User Details screen on the web app, convert them into a JSON object, and use this object to modify the corresponding record in the users collection.

### **9.1.9 Edit Site**

This module must take form inputs from the Site Details screen on the web app, convert them into a JSON object, and use this object to modify the corresponding record in the sites collection.

### **9.1.10 Edit Trial**

This module must take form inputs from the Trial Details screen on the web app, convert them into a JSON object, and use this object to modify the corresponding record in the trials collection.

### **9.1.11 Update Rash**

This module must take form inputs from the Rash Details screen on the mobile app and image inputs from the Take Photo screen on the mobile app, upload the image inputs to a directory on the server, convert the form inputs into a JSON object, and insert the JSON object into the snapshots field of the record corresponding to the updated rash in the patient\_reports collection.

### **9.1.12 View Users**

This module must pull records from the user's collection to be displayed on the Users screen on the web app and the Clinician Home screen on the mobile app. It must use different query parameters depending on the role of the user viewing the screen.

### **9.1.13 View Sites**

This module must pull records from the sites collection to be displayed on the Sites screen on the web app. It must use different query parameters depending on the role of the user viewing the screen.

### **9.1.14 View Trials**

This module must pull records from the trials collection to be displayed on the Trials screen on the web app. It must use different query parameters depending on the role of the user viewing the screen.

### **9.1.15 View Rash History**

This module must pull records from the patient\_reports collection to be displayed on the Patient History screen on the web app. It must use different query parameters depending on the role of the user viewing the screen.



	Entity : REVA Content Type: Detailed Design Specification Document Title: REVA_DDS Doc. No.: DDS-GLB-COMP-2022-0030-00001.003
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### **9.1.16 View Dermatology Reports**

This module must pull records from the dermatology\_reports collection to be displayed on the Dermatology Reports screen on the web app. It must use different query parameters depending on the role of the user viewing the screen.

### **9.1.17 View Dermatology Report**

This module must pull a record from the dermatology\_reports collection and open the corresponding pdf in a new browser tab from the web app. The specific record pulled must depend on which record was clicked by the user. The specific report opened must depend on which report was clicked by the user.

### **9.1.18 View User Details**

This module must pull a record from the user's collection to be displayed on the User Details screen on the web app. The specific record pulled must depend on which record was clicked by the user.

### **9.1.19 View Site Details**

This module must pull a record from the sites collection to be displayed on the Site Details screen on the web app. The specific record pulled must depend on which record was clicked by the user.

### **9.1.20 View Trial Details**

This module must pull a record from the trials collection to be displayed on the Trial Details screen on the web app. The specific record pulled must depend on which record was clicked by the user.

### **9.1.21 Download Report**

This module must pull a pdf report stored in a directory on the server and download it through the user's web browser. The specific report downloaded must depend on the report clicked by the user.

### **9.1.22 Download Patient Report**

This module must download a patient report in pdf format from subject history and report tab by clicked on "Download Patient Report" button. The specific downloaded pdf record is saved in user local machine. this button is visible for all the users roles.

### **9.1.23 Edit Subject**

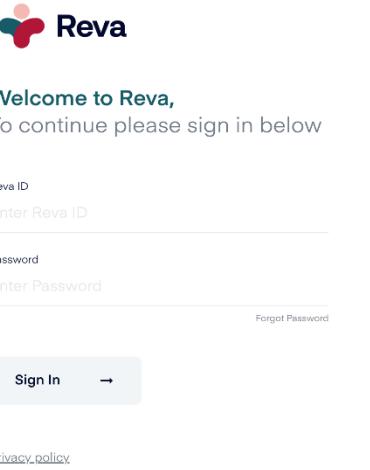
This module takes the input from user like Subject ID, Trial, and Sites which user wants to edit and after clicked on submit button all the cases and dermatologist reports which were associated with that subject is transferred to the new Trail and Sites.

	<p style="margin: 0;">Entity : REVA</p> <p style="margin: 0;">Content Type: Detailed Design Specification</p> <p style="margin: 0;">Document Title: REVA_DDS</p> <p style="margin: 0;">Doc. No.: DDS-GLB-COMP-2022-0030-00001.001</p>
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## 10 Application Interface Design

### 10.1 Web Dashboard

#### 10.1.1 Login



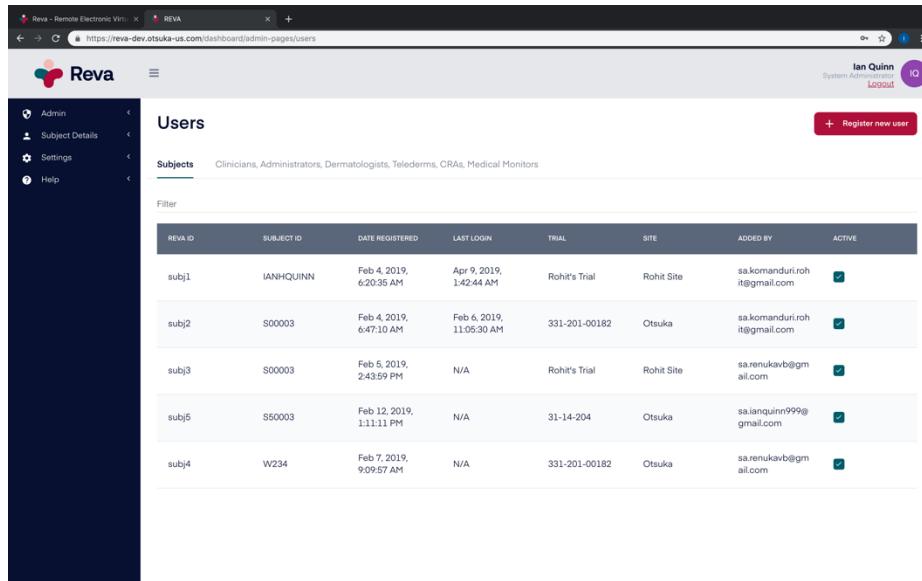
The screenshot shows the Reva login interface. At the top center is the Reva logo, which consists of three overlapping colored shapes (blue, red, and green) followed by the word "Reva". Below the logo is the text "Welcome to Reva," and a sub-instruction "To continue please sign in below". There are two input fields: "Reva ID" with placeholder text "Enter Reva ID" and "Password" with placeholder text "Enter Password". To the right of the password field is a "Forgot Password" link. Below the fields is a "Sign In" button with a right-pointing arrow. At the bottom left is a link to "Privacy policy".

REVA ID:      *users -> \_id*

Password:      *users -> password*

	Entity : REVA
	Content Type: Detailed Design Specification
	Document Title: REVA_DDS
	Doc. No.: DDS-GLB-COMP-2022-0030-00001.001

## 10.1.2 System Administrator Home



REVA ID	SUBJECT ID	DATE REGISTERED	LAST LOGIN	TRIAL	SITE	ADDED BY	ACTIVE
subj1	IANHQUINN	Feb 4, 2019, 6:20:35 AM	Apr 9, 2019, 1:42:44 AM	Rohit's Trial	Rohit Site	sa.komanduri.rohit@gmail.com	<input checked="" type="checkbox"/>
subj2	S00003	Feb 4, 2019, 6:47:10 AM	Feb 6, 2019, 11:05:30 AM	331-201-00182	Otsuka	sa.komanduri.rohit@gmail.com	<input checked="" type="checkbox"/>
subj3	S00003	Feb 5, 2019, 2:43:59 PM	N/A	Rohit's Trial	Rohit Site	sa.renukavb@gmail.com	<input checked="" type="checkbox"/>
subj5	S50003	Feb 12, 2019, 1:11:11 PM	N/A	31-14-204	Otsuka	sa.lanquinn999@gmail.com	<input checked="" type="checkbox"/>
subj4	W234	Feb 7, 2019, 9:09:57 AM	N/A	331-201-00182	Otsuka	sa.renukavb@gmail.com	<input checked="" type="checkbox"/>

REVA ID: users -> \_id

SUBJECT ID: users -> subject\_id

DATE REGISTERED: users -> dateTime\_registered

LAST LOGIN: users -> last\_login

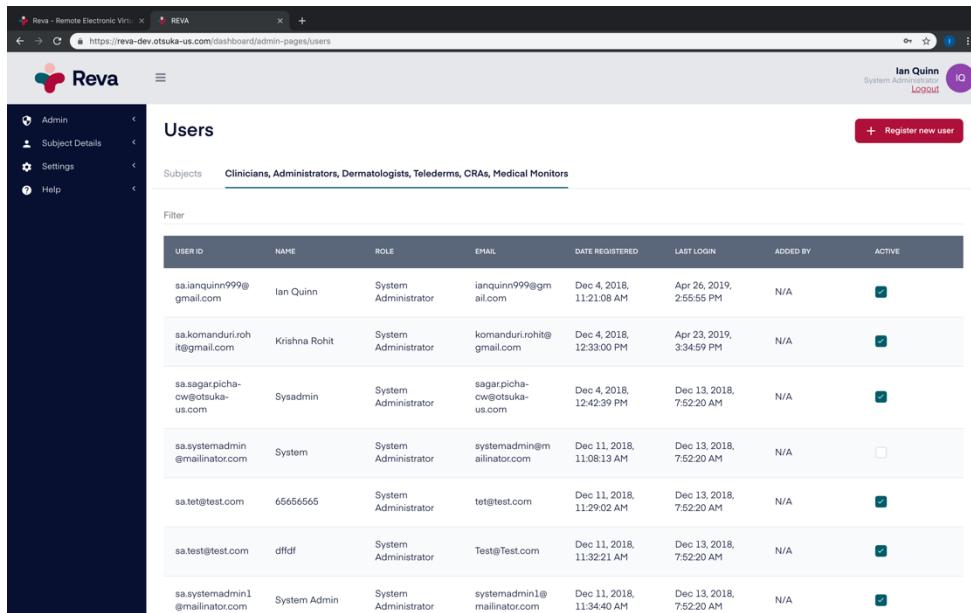
TRIAL: users -> trial

SITE: users -> site

ADDED BY: users -> added\_by

ACTIVE: users-> added\_by

	Entity : REVA
	Content Type: Detailed Design Specification
	Document Title: REVA_DDS
	Doc. No.: DDS-GLB-COMP-2022-0030-00001.001



User ID	Name	Role	Email	Date Registered	Last Login	Added By	Active
sa.ianquinn999@gmail.com	Ian Quinn	System Administrator	ianquinn999@gmail.com	Dec 4, 2018, 11:21:08 AM	Apr 26, 2019, 2:55:55 PM	N/A	<input checked="" type="checkbox"/>
sa.komanduri.rohit@gmail.com	Krishna Rohit	System Administrator	komanduri.rohit@gmail.com	Dec 4, 2018, 12:33:00 PM	Apr 23, 2019, 3:34:59 PM	N/A	<input checked="" type="checkbox"/>
sa.sagar.pichav@otsuka-us.com	Sysadmin	System Administrator	sagar.pichav@otsuka-us.com	Dec 4, 2018, 12:42:39 PM	Dec 13, 2018, 7:52:20 AM	N/A	<input checked="" type="checkbox"/>
sa.systemadmin@mailinator.com	System	System Administrator	systemadmin@mailinator.com	Dec 11, 2018, 11:08:13 AM	Dec 13, 2018, 7:52:20 AM	N/A	<input type="checkbox"/>
sa.tet@test.com	65656565	System Administrator	tet@test.com	Dec 11, 2018, 11:29:02 AM	Dec 13, 2018, 7:52:20 AM	N/A	<input checked="" type="checkbox"/>
sa.test@test.com	dfdf	System Administrator	Test@Test.com	Dec 11, 2018, 11:32:21 AM	Dec 13, 2018, 7:52:20 AM	N/A	<input checked="" type="checkbox"/>
sa.systemadmin1@mailinator.com	System Admin	System Administrator	systemadmin1@mailinator.com	Dec 11, 2018, 11:34:40 AM	Dec 13, 2018, 7:52:20 AM	N/A	<input checked="" type="checkbox"/>

USER ID: *users -> \_id*

NAME: *users -> name*

ROLE: *users -> role*

EMAIL: *users -> email*

DATE REGISTERED: *users -> dateTime\_registered*

LAST LOGIN: *users -> last\_login*

ADDED BY: *users -> added\_by*

ACTIVE: *users -> active*



Entity : REVA

Content Type: Detailed Design Specification

Document Title: REVA\_DDS

Doc. No.: DDS-GLB-COMP-2022-0030-00001.001

### 10.1.3 Central Administrator Home

REVA ID: users -> \_id

SUBJECT ID: users -> subject\_id

DATE REGISTERED: users -> dateTime\_registered

LAST LOGIN: users -> last\_login

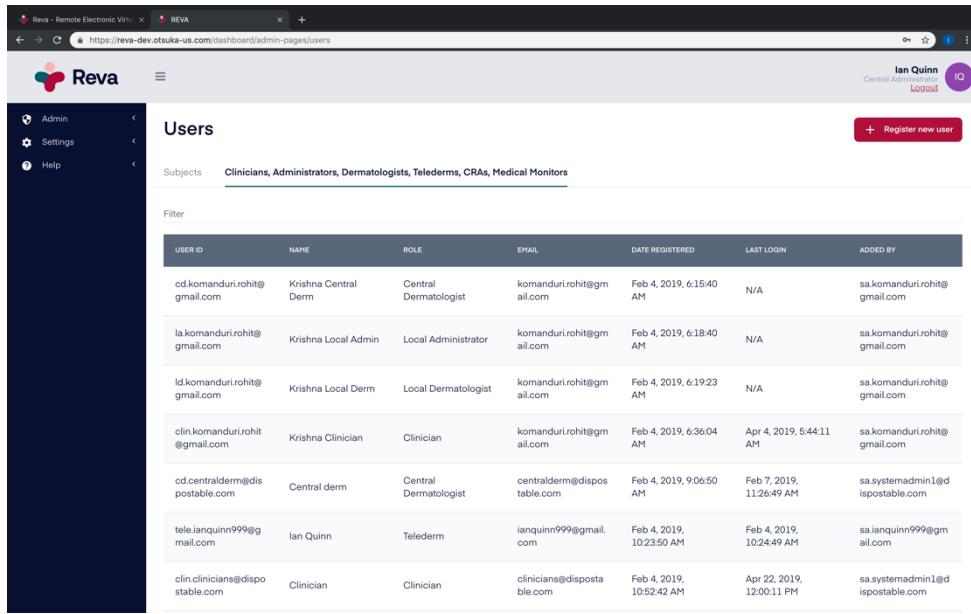
TRIAL: users -> trial

SITE: users -> site

ADDED BY: users -> added\_by

ACTIVE: users-> added\_by

	Entity : REVA
	Content Type: Detailed Design Specification
	Document Title: REVA_DDS
	Doc. No.: DDS-GLB-COMP-2022-0030-00001.001



User ID	Name	Role	Email	Date Registered	Last Login	Added By
cd.komanduri.rohit@gmail.com	Krishna Central Derm	Central Dermatologist	komanduri.rohit@gmail.com	Feb 4, 2019, 6:15:40 AM	N/A	sa.komanduri.rohit@gmail.com
la.komanduri.rohit@gmail.com	Krishna Local Admin	Local Administrator	komanduri.rohit@gmail.com	Feb 4, 2019, 6:18:40 AM	N/A	sa.komanduri.rohit@gmail.com
ld.komanduri.rohit@gmail.com	Krishna Local Derm	Local Dermatologist	komanduri.rohit@gmail.com	Feb 4, 2019, 6:19:23 AM	N/A	sa.komanduri.rohit@gmail.com
clin.komanduri.rohit@gmail.com	Krishna Clinician	Clinician	komanduri.rohit@gmail.com	Feb 4, 2019, 6:36:04 AM	Apr 4, 2019, 5:44:11 AM	sa.komanduri.rohit@gmail.com
cd.centralderm@dispostable.com	Central derm	Central Dermatologist	centralderm@dispostable.com	Feb 4, 2019, 9:06:50 AM	Feb 7, 2019, 11:26:49 AM	sa.systemadmin1@dispostable.com
tele.ianquinn999@gmail.com	Ian Quinn	Telederm	ianquinn999@gmail.com	Feb 4, 2019, 10:23:50 AM	Feb 4, 2019, 10:24:49 AM	sa.ianquinn999@gmail.com
clin.clinicians@dispostable.com	Clinician	Clinician	clinicians@dispostable.com	Feb 4, 2019, 10:52:42 AM	Apr 22, 2019, 12:00:11 PM	sa.systemadmin1@dispostable.com

USER ID: *users -> \_id*

NAME: *users -> name*

ROLE: *users -> role*

EMAIL: *users -> email*

DATE REGISTERED: *users -> dateTime\_registered*

LAST LOGIN: *users -> last\_login*

ADDED BY: *users -> added\_by*

ACTIVE: *users -> active*



Entity : REVA

Content Type: Detailed Design Specification

Document Title: REVA\_DDS

Doc. No.: DDS-GLB-COMP-2022-0030-00001.001

#### 10.1.4 Local Administrator Home

REVA ID: users -> `_id`

SUBJECT ID: users -> `subject_id`

DATE REGISTERED: users -> `dateTime_registered`

LAST LOGIN: users -> `last_login`

TRIAL: users -> `trial`

SITE: users -> `site`

ADDED BY: users -> `added_by`



Entity : REVA

Content Type: Detailed Design Specification

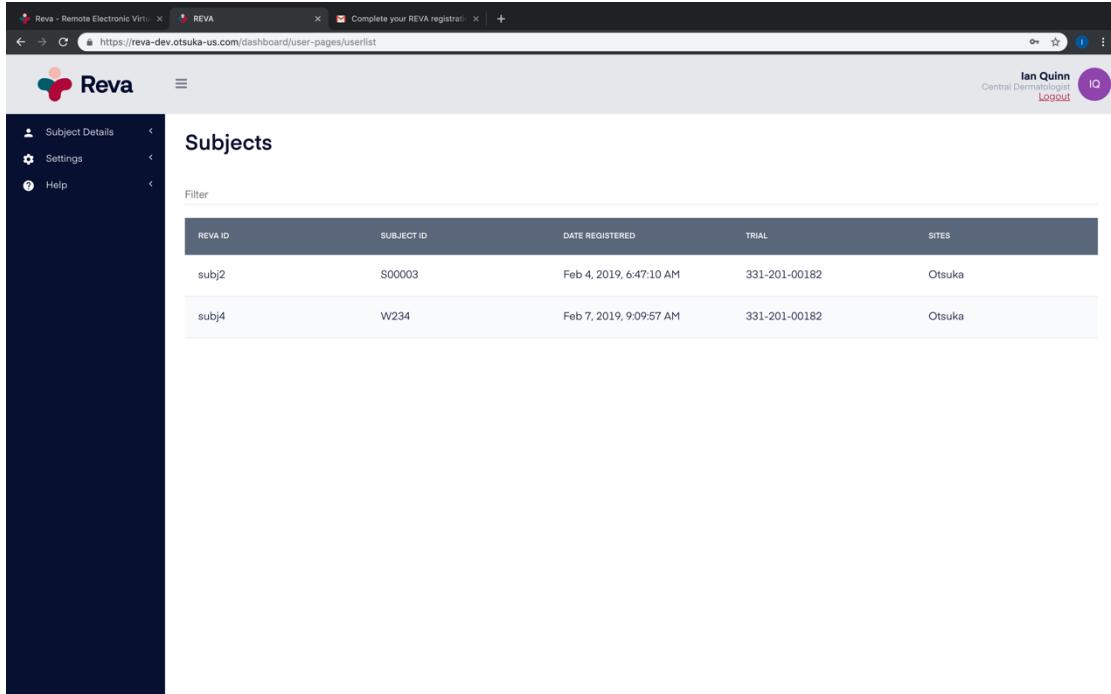
Document Title: REVA\_DDS

Doc. No.: DDS-GLB-COMP-2022-0030-00001.001

USER ID: *users -> \_id*NAME: *users -> name*ROLE: *users -> role*EMAIL: *users -> email*DATE REGISTERED: *users -> dateTime\_registered*LAST LOGIN: *users -> last\_login*ADDED BY: *users -> added\_by*

	<p style="margin: 0;">Entity : REVA</p> <p style="margin: 0;">Content Type: Detailed Design Specification</p> <p style="margin: 0;">Document Title: REVA_DDS</p> <p style="margin: 0;">Doc. No.: DDS-GLB-COMP-2022-0030-00001.001</p>
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### 10.1.5 Central Dermatologist Home



REVA ID	SUBJECT ID	DATE REGISTERED	TRIAL	SITES
subj2	S00003	Feb 4, 2019, 6:47:10 AM	331-201-00182	Otsuka
subj4	W234	Feb 7, 2019, 9:09:57 AM	331-201-00182	Otsuka

REVA ID: *users -> \_id*

SUBJECT ID: *users -> subject\_id*

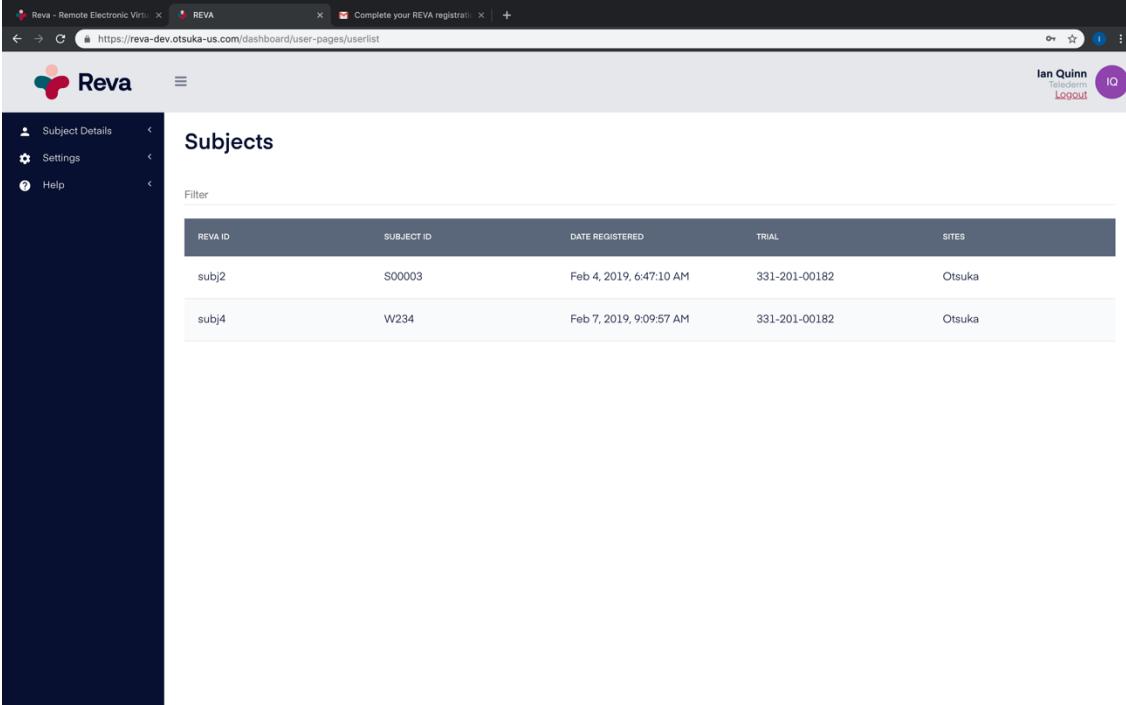
DATE REGISTERED: *users -> dateTime\_registered*

TRIAL: *users -> trial*

SITES: *users -> sites*

	<p style="text-align: right;">Entity : REVA  Content Type: Detailed Design Specification  Document Title: REVA_DDS  Doc. No.: DDS-GLB-COMP-2022-0030-00001.001</p>
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### 10.1.6 Tele-Dermatologist Home



REVA ID	SUBJECT ID	DATE REGISTERED	TRIAL	SITES
subj2	S00003	Feb 4, 2019, 6:47:10 AM	331-201-00182	Otsuka
subj4	W234	Feb 7, 2019, 9:09:57 AM	331-201-00182	Otsuka

REVA ID: *users -> \_id*

SUBJECT ID: *users -> subject\_id*

DATE REGISTERED: *users -> dateTime\_registered*

TRIAL: *users -> trial*

SITE: *users -> sites*



Entity : REVA

Content Type: Detailed Design Specification

Document Title: REVA\_DDS

Doc. No.: DDS-GLB-COMP-2022-0030-00001.001

### 10.1.7 Monitor Home

The screenshot shows a web browser window with the URL <https://reva-dev.otsuka-us.com/dashboard/user-pages/userlist>. The page title is "Subjects". On the left, there is a sidebar with navigation links: "Subject Details", "Settings", and "Help". The main content area displays a table with two rows of data:

REVA ID	SUBJECT ID	DATE REGISTERED	TRIAL	SITES
subj2	S00003	Feb 4, 2019, 6:47:10 AM	331-201-00182	Otsuka
subj4	W234	Feb 7, 2019, 9:09:57 AM	331-201-00182	Otsuka

REVA ID: *users -> \_id*

SUBJECT ID: *users -> subject\_id*

DATE REGISTERED: *users -> dateTime\_registered*

TRIAL: *users -> trial*

SITES: *users -> site*



Entity : REVA

Content Type: Detailed Design Specification

Document Title: REVA\_DDS

Doc. No.: DDS-GLB-COMP-2022-0030-00001.001

### 10.1.8 CRA Home

The screenshot shows a web browser window with three tabs: 'Reva - Remote Electronic Virtual', 'REVA', and 'Complete your REVA registration'. The main content area is titled 'Subjects' and displays a table with two rows of data. The columns are labeled 'REVA ID', 'SUBJECT ID', 'DATE REGISTERED', 'TRIAL', and 'SITES'. The data is as follows:

REVA ID	SUBJECT ID	DATE REGISTERED	TRIAL	SITES
subj2	S00003	Feb 4, 2019, 6:47:10 AM	331-201-00182	Otsuka
subj4	W234	Feb 7, 2019, 9:09:57 AM	331-201-00182	Otsuka

REVA ID: *users -> \_id*

SUBJECT ID: *users -> subject\_id*

DATE REGISTERED: *users -> dateTime\_registered*

TRIAL: *users -> trial*

SITES: *users -> site*



Entity : REVA

Content Type: Detailed Design Specification

Document Title: REVA\_DDS

Doc. No.: DDS-GLB-COMP-2022-0030-00001.001

### 10.1.9 Local Dermatologist Home

The screenshot shows a web browser window with the URL https://reva-dev.otsuka-us.com/dashboard/user-pages/dermatologyreports. The page title is "Dermatology Reports". On the left, there is a sidebar with options: "Subject Details", "Settings", and "Help". On the right, there is a user profile for "Ian Quinn" and a "Logout" button. Below the title, there is a "Download rash work-up sheet" button. A "Filter" section is present above a table. The table has columns: TRIAL, SUBJECT, CLINICIAN, LOCAL DERMATOLOGIST, CREATED, SUBJECT REPORT, LOCAL DERM REPORT, CENTRAL DERMATOLOGIST, and CD REVIEWED. One row is visible in the table:

TRIAL	SUBJECT	CLINICIAN	LOCAL DERMATOLOGIST	CREATED	SUBJECT REPORT	LOCAL DERM REPORT	CENTRAL DERMATOLOGIST	CD REVIEWED
331-201-00182	S00003	clin.ian_clin@dispostable.com	Id:lanquinn999@gmail.com	Apr 26, 2019, 3:18:12 PM	<a href="#">View Report</a>	<a href="#">Upload</a>		<input type="checkbox"/>

TRIAL:

*dermatology\_reports -> trial*

SUBJECT:

*dermatology\_reports -> subject*

CLINICIAN:

*dermatology\_reports -> clinician*

LOCAL DERMATOLOGIST:

*dermatology\_reports -> localDermatologist -> [object] -> id*

CREATED:

*dermatology\_reports -> dateTime\_created*

SUBJECT REPORT:

*dermatology\_reports -> localDermatologist -> [object] -> reportName*

LOCAL DERM REPORT:

*dermatology\_reports -> localDermatologist -> [object] -> reportName*

CENTRAL DERMATOLOGIST:

*dermatology\_reports -> centralDermatologist -> id*

CD REVIEWED

*dermatology\_reports -> centralDermatologist -> reviewed*



Entity : REVA

Content Type: Detailed Design Specification

Document Title: REVA\_DDS

Doc. No.: DDS-GLB-COMP-2022-0030-00001.001

### 10.1.10 Clinician Home

The screenshot shows a web-based clinician dashboard for the REVA system. The top navigation bar includes tabs for 'REVA' and 'Complete your REVA registration'. The main content area is titled 'Subjects' and displays a table of registered subjects. The table columns are: REVA ID, SUBJECT ID, DATE REGISTERED, TRIAL, and SITES. Two rows of data are visible:

REVA ID	SUBJECT ID	DATE REGISTERED	TRIAL	SITES
subj2	S00003	Feb 4, 2019, 6:47:10 AM	331-201-00182	Otsuka
subj4	W234	Feb 7, 2019, 9:09:57 AM	331-201-00182	Otsuka

REVA ID: *users -> \_id*

SUBJECT ID: *users -> subject\_id*

DATE REGISTERED: *users -> dateTime\_registered*

TRIAL: *users -> trial*

SITES: *users -> site*

Otsuka	Entity : REVA
	Content Type: Detailed Design Specification
	Document Title: REVA_DDS
	Doc. No.: DDS-GLB-COMP-2022-0030-00001.001

### 10.1.11 Register User

REVA User Registration Form

Role:

Please select user role from list



Entity : REVA

Content Type: Detailed Design Specification

Document Title: REVA\_DDS

Doc. No.: DDS-GLB-COMP-2022-0030-00001.001

### 10.1.12 Register System Administrator

The screenshot shows a web browser window with the URL <https://reva-dev.otsuka-us.com/dashboard/admin-pages/register>. The page title is "REVA User Registration Form". On the left, there is a sidebar with navigation links: Admin, Subject Details, Settings, and Help. The main content area has a heading "Role:" followed by a dropdown menu set to "System Administrator". Below this, there are three input fields: "Email address", "Name", and "Phone". At the bottom right are "Submit" and "Cancel" buttons. In the top right corner, there is a user profile section for "Ian Quinn" (System Administrator) with a "Logout" button.

Email address: *users -> email*  
Name: *users -> name*  
Phone: *users -> phone*



Entity : REVA

Content Type: Detailed Design Specification

Document Title: REVA\_DDS

Doc. No.: DDS-GLB-COMP-2022-0030-00001.001

### 10.1.13 Register Central Administrator

The screenshot shows the 'REVA User Registration Form'. On the left, a sidebar menu includes 'Admin', 'Subject Details', 'Settings', and 'Help'. The main form area has a heading 'REVA User Registration Form'. A dropdown menu under 'Role:' shows 'Central Administrator' selected. Below the dropdown is a note: 'Please select user role from list'. There are three input fields: 'Email address', 'Name', and 'Phone'. At the bottom right are 'Submit' and 'Cancel' buttons.

Email address:           *users -> email*  
Name:                   *users -> name*  
Phone:                  *users -> phone*



Entity : REVA

Content Type: Detailed Design Specification

Document Title: REVA\_DDS

Doc. No.: DDS-GLB-COMP-2022-0030-00001.001

#### 10.1.14 Register Local Administrator

The screenshot shows a web browser window with the URL <https://reva-dev.otsuka-us.com/dashboard/admin-pages/register>. The page title is "REVA User Registration Form". On the left, there is a sidebar with navigation links: Admin, Subject Details, Settings, and Help. The main content area has a heading "Role:" followed by a dropdown menu showing "Local Administrator" is selected. Below the role selection, there are three input fields: "Email address", "Name", and "Phone". At the bottom right, there are "Submit" and "Cancel" buttons.

Email address:            *users -> email*  
Name:                    *users -> name*  
Phone:                   *users -> phone*



Entity : REVA

Content Type: Detailed Design Specification

Document Title: REVA\_DDS

Doc. No.: DDS-GLB-COMP-2022-0030-00001.001

### 10.1.15 Register Central Dermatologist

The screenshot shows a user registration interface for 'REVA User Registration Form'. On the left, a sidebar navigation includes 'Admin', 'Subject Details', 'Settings', and 'Help'. The main area displays a dropdown menu for 'Role' with 'Central Dermatologist' selected. Below the role selection are input fields for 'Email address', 'Name', 'Phone', and 'Address'. At the bottom right are 'Submit' and 'Cancel' buttons.

Email address: *users -> email*  
Name: *users -> name*  
Address: *users -> address*  
Phone: *users -> phone*



Entity : REVA

Content Type: Detailed Design Specification

Document Title: REVA\_DDS

Doc. No.: DDS-GLB-COMP-2022-0030-00001.001

### 10.1.16 Register Tele-Dermatologist

The screenshot shows a web-based user registration interface for the REVA system. At the top, there's a header bar with the REVA logo and a navigation menu. On the left, a sidebar menu includes 'Admin', 'Subject Details', 'Settings', and 'Help'. The main content area is titled 'REVA User Registration Form'. It features a dropdown menu for 'Role' with 'Telederm' selected. Below it are three input fields: 'Email address', 'Name', and 'Phone'. At the bottom right are 'Submit' and 'Cancel' buttons.

Email address:                   *users -> email*  
Name:                           *users -> name*  
Phone                           *users -> phone*



Entity : REVA

Content Type: Detailed Design Specification

Document Title: REVA\_DDS

Doc. No.: DDS-GLB-COMP-2022-0030-00001.001

### 10.1.17 Register Monitor

The screenshot shows a web browser window with three tabs: 'Reva - Remote Electronic Virt...', 'REVA', and 'Complete your REVA registrati...'. The main content area is titled 'REVA User Registration Form'. On the left, there's a sidebar with navigation links: Admin, Subject Details, Settings, and Help. Under 'Role:', the 'Monitor' option is selected, with a note below it saying 'Please select user role from list'. Below the role selection are fields for 'Email address', 'Name', and 'Phone'. At the bottom right are 'Submit' and 'Cancel' buttons.

Email address: *users -> email*

Name: *users -> name*

Phone *users -> phone*



Entity : REVA

Content Type: Detailed Design Specification

Document Title: REVA\_DDS

Doc. No.: DDS-GLB-COMP-2022-0030-00001.001

### 10.1.18 Register CRA

The screenshot shows a web browser window with the URL <https://reva-dev.otsuka-us.com/dashboard/admin-pages/register>. The page title is "REVA User Registration Form". On the left, there is a sidebar with navigation links: Admin, Subject Details, Settings, and Help. The main content area has a heading "Role:" followed by a dropdown menu with the option "CRA" selected. A placeholder text "Please select user role from list" is visible below the dropdown. Below the role selection are three input fields: "Email address", "Name", and "Phone". At the bottom right are "Submit" and "Cancel" buttons.

Email address:                   *users -> email*  
Name:                           *users -> name*  
Phone:                          *users -> phone*



Entity : REVA

Content Type: Detailed Design Specification

Document Title: REVA\_DDS

Doc. No.: DDS-GLB-COMP-2022-0030-00001.001

### 10.1.19 Register Local Dermatologist

The screenshot shows a web-based user registration form for 'REVA User Registration Form'. On the left, there is a sidebar with navigation links: Admin, Subject Details, Settings, and Help. The main content area displays a dropdown menu for 'Role' with 'Local Dermatologist' selected. Below this, there are four input fields: 'Email address', 'Name', 'Phone', and 'Address'. At the bottom right of the form are two buttons: 'Submit' and 'Cancel'.

Email address: *users -> email*  
Name: *users -> name*  
Address: *users -> address*  
Phone: *users -> phone*



Entity : REVA

Content Type: Detailed Design Specification

Document Title: REVA\_DDS

Doc. No.: DDS-GLB-COMP-2022-0030-00001.001

### 10.1.20 Register Clinician

The screenshot shows the 'REVA User Registration Form' interface. The form fields include:

- Email address: [Input field]
- Name: [Input field]
- Phone: [Input field]
- Trials: [Dropdown menu set to 'Trial']
- Sites: [Dropdown menu set to 'Site']
- Local Dermatologists: [Dropdown menu set to 'Local Dermatologists']

At the bottom right are 'Submit' and 'Cancel' buttons. The top right shows a user profile for 'Ian Quinn' (System Administrator) with a 'Logout' link. The top bar shows the browser title 'Reva - Remote Electronic V... REVA' and the URL 'https://reva-dev.otsuka-us.com/dashboard/admin-pages/register'.

Email address:

*users -> email*

Name:

*users -> name*

Sites:

*users -> sites*

Trials:

*users -> trials*

Local Dermatologists:

*users -> local\_dermatologists*

Phone:

*users -> phone*



Entity : REVA

Content Type: Detailed Design Specification

Document Title: REVA\_DDS

Doc. No.: DDS-GLB-COMP-2022-0030-00001.001

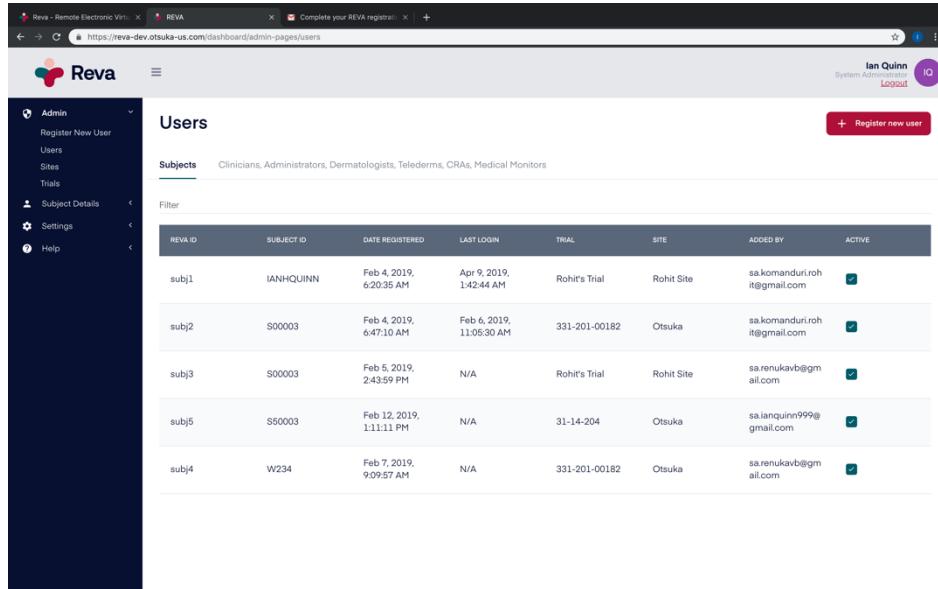
### 10.1.21 Register Subject

The screenshot shows the 'REVA User Registration Form'. On the left is a sidebar with navigation links: Admin, Subject Details, Settings, and Help. The main area has a heading 'REVA User Registration Form'. A 'Role' section contains a dropdown menu labeled 'Subject'. Below it is a 'Subject ID' field. To the right, there's a 'Trial' section with a dropdown menu set to 'Trial', and a 'Sites' section with a dropdown menu set to 'Site'. At the bottom right are 'Submit' and 'Cancel' buttons.

ID: *users -> \_id*  
Sites: *users -> sites*  
Trial: *users -> trial*

	<p style="margin: 0;">Entity : REVA</p> <p style="margin: 0;">Content Type: Detailed Design Specification</p> <p style="margin: 0;">Document Title: REVA_DDS</p> <p style="margin: 0;">Doc. No.: DDS-GLB-COMP-2022-0030-00001.001</p>
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### 10.1.22 User List



REVA ID	SUBJECT ID	DATE REGISTERED	LAST LOGIN	TRIAL	SITE	ADDED BY	ACTIVE
subj1	IANHQUINN	Feb 4, 2019, 6:20:35 AM	Apr 9, 2019, 1:42:44 AM	Rohit's Trial	Rohit Site	sa.komanduri.rohit@gmail.com	<input checked="" type="checkbox"/>
subj2	S00003	Feb 4, 2019, 6:47:10 AM	Feb 6, 2019, 11:05:30 AM	331-201-00182	Otsuka	sa.komanduri.rohit@gmail.com	<input checked="" type="checkbox"/>
subj3	S00003	Feb 5, 2019, 2:43:59 PM	N/A	Rohit's Trial	Rohit Site	sa.renukavb@gmail.com	<input checked="" type="checkbox"/>
subj5	S50003	Feb 12, 2019, 1:11:11 PM	N/A	31-14-204	Otsuka	sa.ianquinn999@gmail.com	<input checked="" type="checkbox"/>
subj4	W234	Feb 7, 2019, 9:09:57 AM	N/A	331-201-00182	Otsuka	sa.renukavb@gmail.com	<input checked="" type="checkbox"/>

REVA ID: users -> \_id

SUBJECT ID: users -> subject\_id

DATE REGISTERED: users -> dateTime\_registered

LAST LOGIN: users -> last\_login

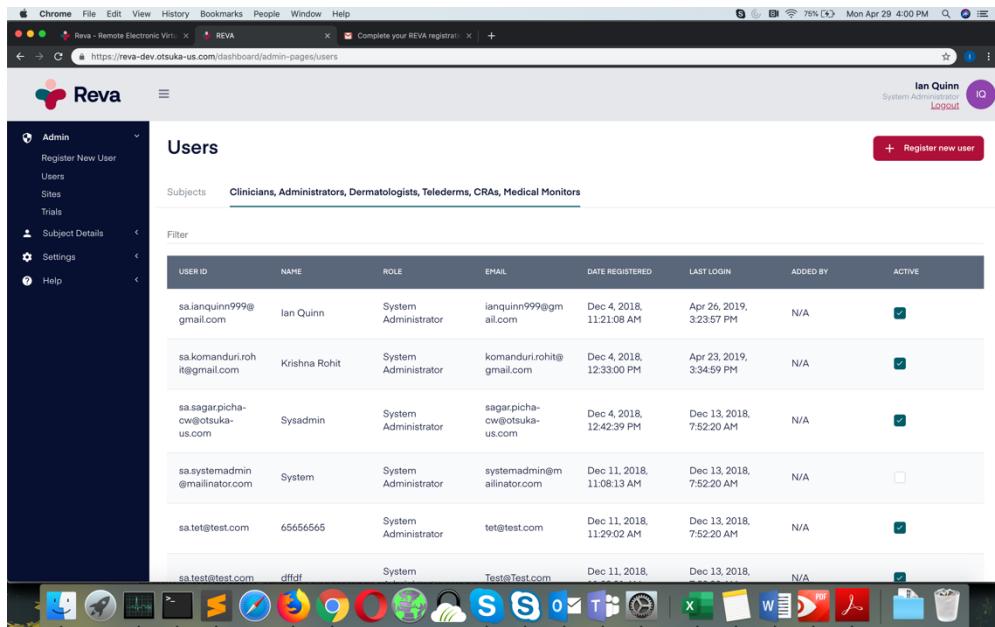
TRIAL: users -> trial

SITE: users -> site

ADDED BY: users -> added\_by

ACTIVE: users-> added\_by

	<p style="text-align: right;">Entity : REVA</p> <p style="text-align: right;">Content Type: Detailed Design Specification</p> <p style="text-align: right;">Document Title: REVA_DDS</p> <p style="text-align: right;">Doc. No.: DDS-GLB-COMP-2022-0030-00001.001</p>
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User ID	Name	Role	Email	Date Registered	Last Login	Added By	Active
sa.ianquinn999@gmail.com	Ian Quinn	System Administrator	ianquinn999@gmail.com	Dec 4, 2018, 11:21:08 AM	Apr 26, 2019, 3:23:57 PM	N/A	<input checked="" type="checkbox"/>
sa.komanduri.rohit@gmail.com	Krishna Rohit	System Administrator	komanduri.rohit@gmail.com	Dec 4, 2018, 12:33:00 PM	Apr 23, 2019, 3:34:59 PM	N/A	<input checked="" type="checkbox"/>
sa.sagar.pichav@otsuka-us.com	Sysadmin	System Administrator	sagar.pichav@otsuka-us.com	Dec 4, 2018, 12:42:39 PM	Dec 13, 2018, 7:52:20 AM	N/A	<input checked="" type="checkbox"/>
sa.systemadmin@mailinator.com	System	System Administrator	systemadmin@mailinator.com	Dec 11, 2018, 11:08:13 AM	Dec 13, 2018, 7:52:20 AM	N/A	<input type="checkbox"/>
sa.tet@test.com	65656565	System Administrator	tet@test.com	Dec 11, 2018, 11:29:02 AM	Dec 13, 2018, 7:52:20 AM	N/A	<input checked="" type="checkbox"/>
sa.test@test.com	dffdf	System	Test@Test.com	Dec 11, 2018,	Dec 13, 2018,	N/A	<input checked="" type="checkbox"/>

USER ID: *users -> \_id*

NAME: *users -> name*

ROLE: *users -> role*

EMAIL: *users -> email*

DATE REGISTERED: *users -> dateTime\_registered*

LAST LOGIN: *users -> last\_login*

ADDED BY: *users -> added\_by*

ACTIVE: *users -> active*



Entity : REVA

Content Type: Detailed Design Specification

Document Title: REVA\_DDS

Doc. No.: DDS-GLB-COMP-2022-0030-00001.001

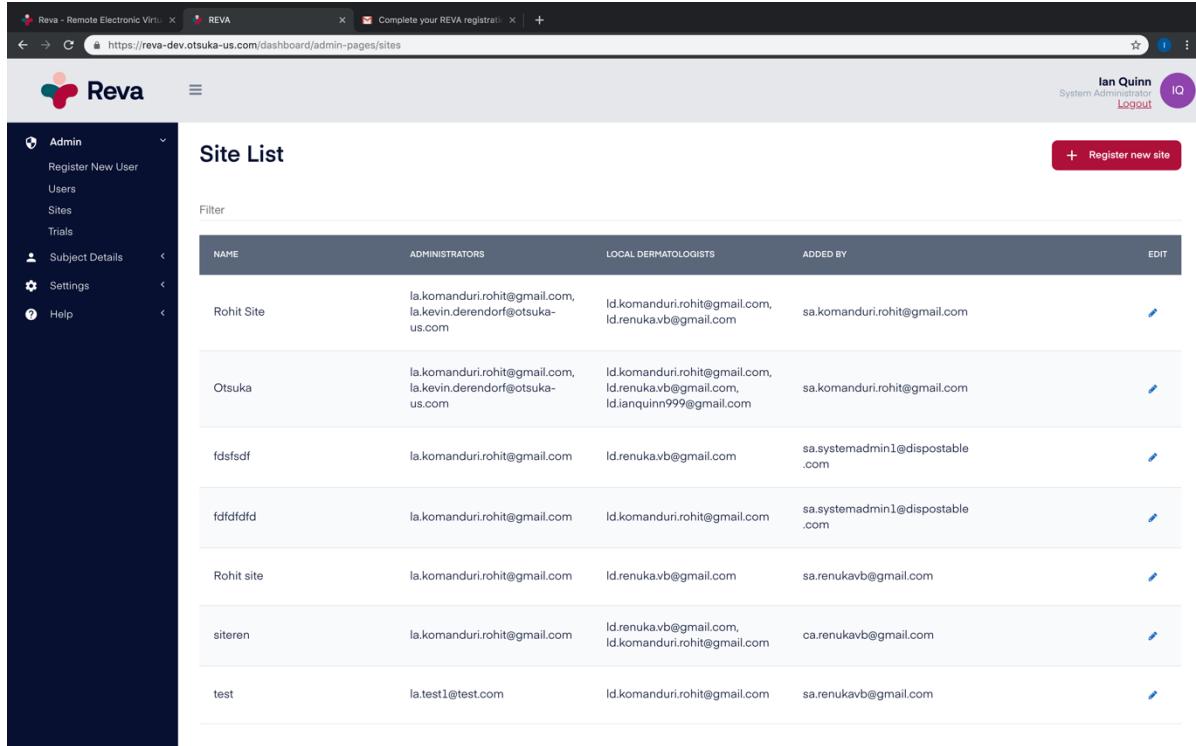
### 10.1.23 User Details

The screenshot shows the 'REVA User Update Form' interface. On the left is a sidebar with navigation links: Admin (selected), Register New User, Users, Sites, Trials, Subject Details (expanded), Settings, and Help. The main content area has a title 'REVA User Update Form'. It includes a 'Role:' dropdown set to 'Clinician', a note 'Please select user role from list', and input fields for 'Email address' (komanduri.rohit@gmail.com), 'Name' (Krishna Clinician), and 'Phone' (1111). To the right, there are sections for 'Added By' (sa.komanduri.rohit@gmail.com), 'Trials' (Rohit's Trial, 331-201-00182), 'Sites' (Rohit Site, Otsuka), and 'Local Dermatologists' (ld.komanduri.rohit@gmail.com). At the bottom are 'Submit' and 'Cancel' buttons.

For each role, the fields that appear on the user registration screen should also appear here.

	Entity : REVA Content Type: Detailed Design Specification Document Title: REVA_DDS Doc. No.: DDS-GLB-COMP-2022-0030-00001.001
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### 10.1.24 Site List



NAME	ADMINISTRATORS	LOCAL DERMATOLOGISTS	ADDED BY	EDIT
Rohit Site	la.komanduri.rohit@gmail.com, la.kevin.derendorf@otsuka-us.com	ld.komanduri.rohit@gmail.com, ld.renukavb@gmail.com	sa.komanduri.rohit@gmail.com	
Otsuka	la.komanduri.rohit@gmail.com, la.kevin.derendorf@otsuka-us.com	ld.komanduri.rohit@gmail.com, ld.renukavb@gmail.com, ld.ianquinn999@gmail.com	sa.komanduri.rohit@gmail.com	
fdsfsdf	la.komanduri.rohit@gmail.com	ld.renukavb@gmail.com	sa.systemadmin1@dispostable.com	
fdfdfdfd	la.komanduri.rohit@gmail.com	ld.komanduri.rohit@gmail.com	sa.systemadmin1@dispostable.com	
Rohit site	la.komanduri.rohit@gmail.com	ld.renukavb@gmail.com	sa.renukavb@gmail.com	
siteren	la.komanduri.rohit@gmail.com	ld.renukavb@gmail.com, ld.komanduri.rohit@gmail.com	ca.renukavb@gmail.com	
test	la.test1@test.com	ld.komanduri.rohit@gmail.com	sa.renukavb@gmail.com	

NAME:

*sites -> name*

ADMINISTRATORS:

*sites -> administrators*

LOCAL DERMATOLOGISTS:

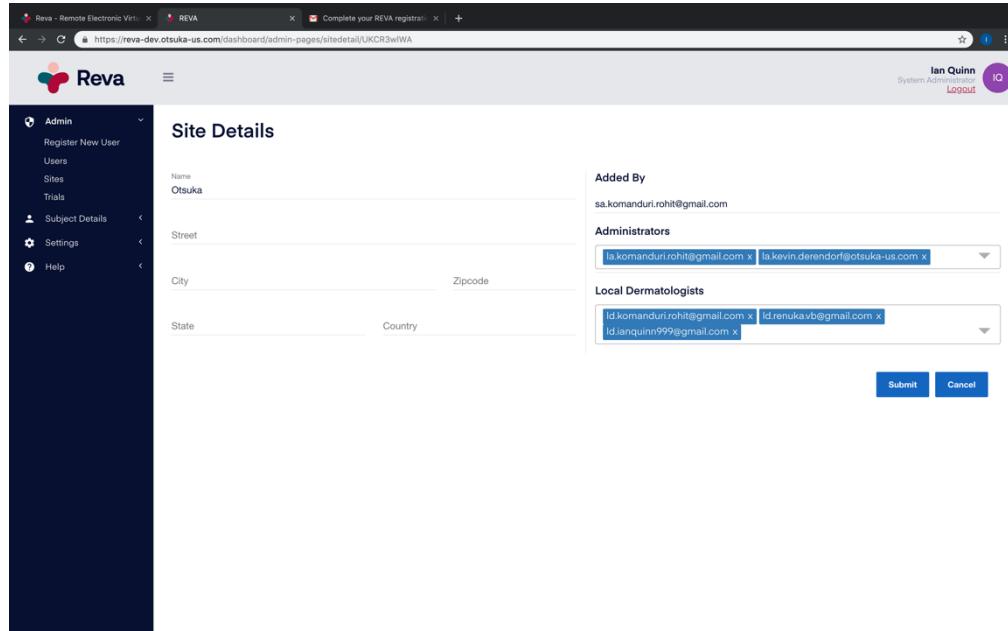
*sites -> local\_dermatologists*

ADDED BY:

*sites -> added\_by*

	<p style="text-align: right;">Entity : REVA Content Type: Detailed Design Specification Document Title: REVA_DDS Doc. No.: DDS-GLB-COMP-2022-0030-00001.001</p>
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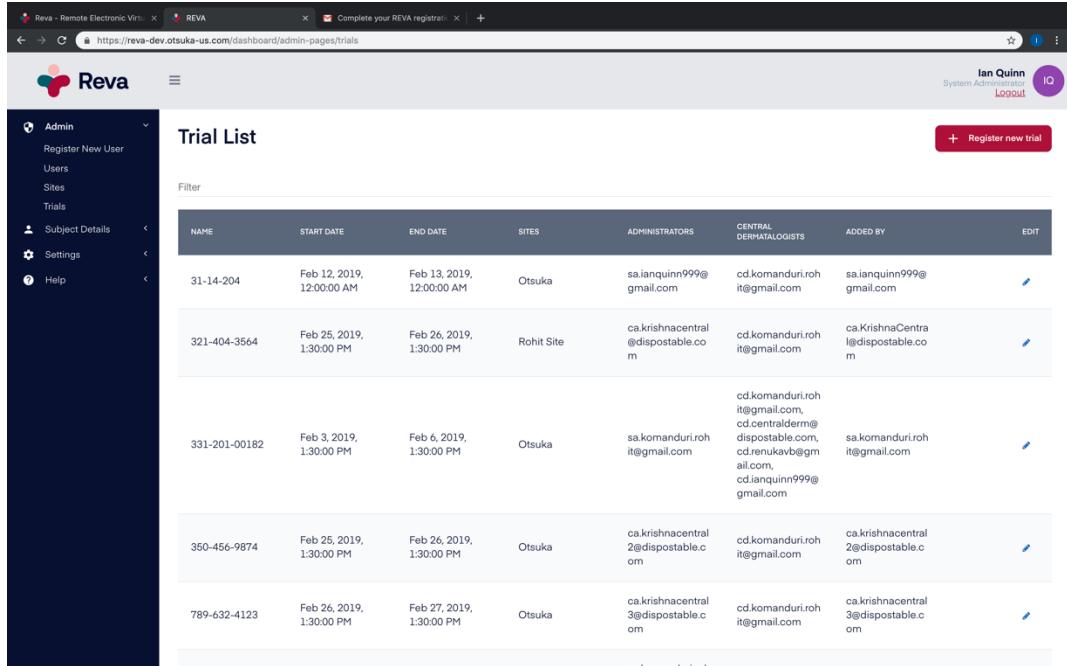
### 10.1.25 Register Site / Site Details



Name:	<i>sites -&gt; name</i>
City:	<i>sites -&gt; city</i>
Country:	<i>sites -&gt; country</i>
Administrators:	<i>sites -&gt; administrators</i>
Local Dermatologists:	<i>sites -&gt; local_dermatologists</i>
Street:	<i>sites -&gt; street_address</i>
State:	<i>sites -&gt; state</i>
Zipcode:	<i>sites -&gt; zipCode</i>
Added By:	<i>sites -&gt; added_by</i>

	Entity : REVA
	Content Type: Detailed Design Specification
	Document Title: REVA_DDS
	Doc. No.: DDS-GLB-COMP-2022-0030-00001.001

## 10.1.26 Trial List



NAME	START DATE	END DATE	SITES	ADMINISTRATORS	CENTRAL DERMATOLOGISTS	ADDED BY	EDIT
31-14-204	Feb 12, 2019, 12:00:00 AM	Feb 13, 2019, 12:00:00 AM	Otsuka	sa.ianquinn999@gmail.com	cd.komanduri.rohit@gmail.com	sa.ianquinn999@gmail.com	<a href="#">Edit</a>
321-404-3564	Feb 25, 2019, 1:30:00 PM	Feb 26, 2019, 1:30:00 PM	Rohit Site	ca.krishnacentral@dispostable.com	cd.komanduri.rohit@gmail.com	ca.KrishnaCentral@dispostable.com	<a href="#">Edit</a>
331-201-00182	Feb 3, 2019, 1:30:00 PM	Feb 6, 2019, 1:30:00 PM	Otsuka	sa.komanduri.rohit@gmail.com	cd.komanduri.rohit@gmail.com, cd.centralderm@dispostable.com, cd.renukav@gmail.com, cd.ianquinn999@gmail.com	sa.komanduri.rohit@gmail.com	<a href="#">Edit</a>
350-456-9874	Feb 25, 2019, 1:30:00 PM	Feb 26, 2019, 1:30:00 PM	Otsuka	ca.krishnacentral2@dispostable.com	cd.komanduri.rohit@gmail.com	ca.krishnacentral2@dispostable.com	<a href="#">Edit</a>
789-632-4123	Feb 26, 2019, 1:30:00 PM	Feb 27, 2019, 1:30:00 PM	Otsuka	ca.krishnacentral3@dispostable.com	cd.komanduri.rohit@gmail.com	ca.krishnacentral3@dispostable.com	<a href="#">Edit</a>

NAME:

*trials -> name*

START DATE:

*trials -> dateTime\_start*

END DATE:

*trials -> dateTime\_end*

SITES:

*trials -> sites*

ADMINISTRATORS:

*trials -> administrators*

CENTRAL DERMATOLOGISTS:

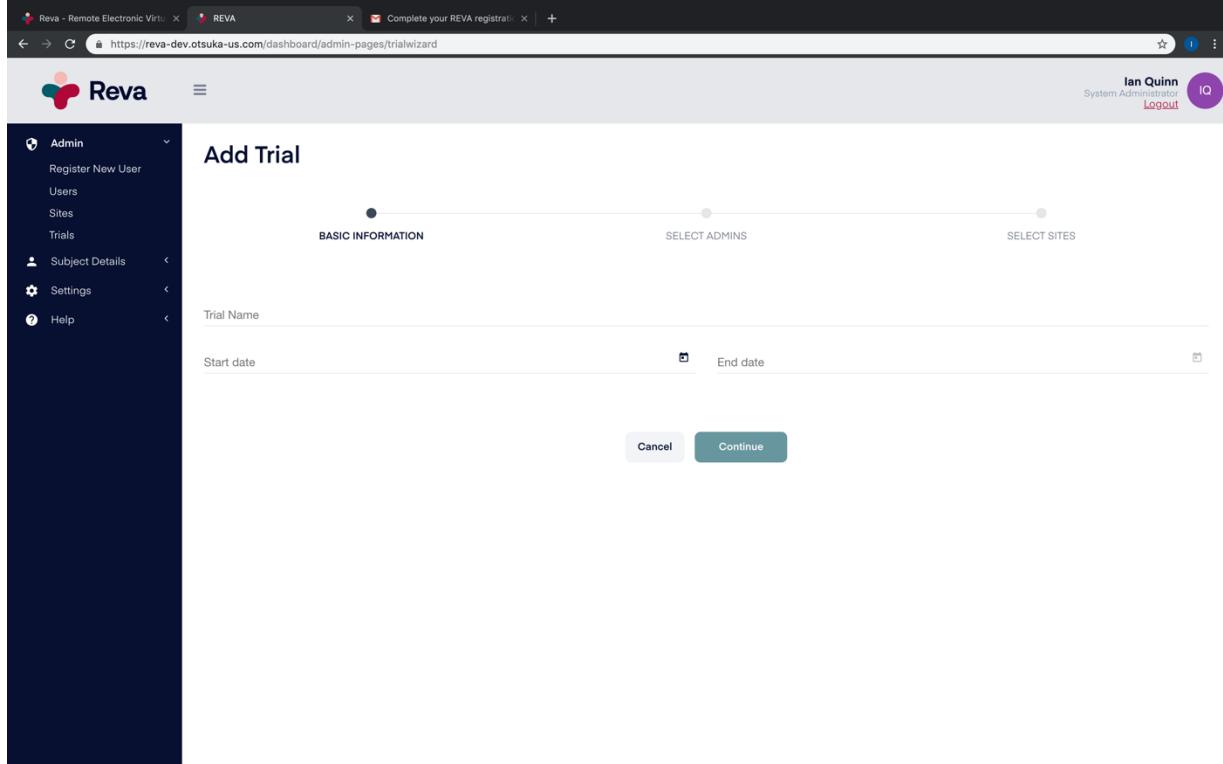
*trials -> central\_dermatologists*

ADDED BY:

*trials -> added\_by*

	<p style="margin: 0;">Entity : REVA</p> <p style="margin: 0;">Content Type: Detailed Design Specification</p> <p style="margin: 0;">Document Title: REVA_DDS</p> <p style="margin: 0;">Doc. No.: DDS-GLB-COMP-2022-0030-00001.001</p>
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### 10.1.27 Register Trial



The screenshot shows the REVA software's 'Add Trial' wizard. The left sidebar has a dark theme with a 'Admin' dropdown menu. The main area is titled 'Add Trial' and is currently on the 'BASIC INFORMATION' step. It contains fields for 'Trial Name' and date ranges ('Start date' and 'End date'). At the bottom are 'Cancel' and 'Continue' buttons.

Trial Name: *trials -> name*  
 Start date: *trials -> dateTime\_start*  
 End date: *trials -> dateTime\_end*



Entity : REVA

Content Type: Detailed Design Specification

Document Title: REVA\_DDS

Doc. No.: DDS-GLB-COMP-2022-0030-00001.001

The screenshot shows the 'Add Trial' wizard in the Reva software. The current step is 'BASIC INFORMATION'. The interface includes a sidebar with navigation links such as Admin, Register New User, Users, Sites, Trials, Subject Details, Settings, and Help. On the right, there are four dropdown menus for selecting staff roles: 'Please select Central Dermatologists' (Dermatologists List), 'Please select CRAs' (CRA List), 'Please select Medical Monitors' (Medical Monitor List), and 'Please select Teledermes' (Telederms List). At the bottom, there are 'Cancel', 'Back', and 'Continue' buttons.

Please select Central Dermatologists:

*trials -> central\_dermatologists*

Please select CRAs:

*trials -> cras*

Please select Monitors:

*trials -> monitors*

Please select Telederms:

*trials -> telederms*



Entity : REVA

Content Type: Detailed Design Specification

Document Title: REVA\_DDS

Doc. No.: DDS-GLB-COMP-2022-0030-00001.001

The screenshot shows a web-based application for managing trials. On the left, there's a dark sidebar with navigation links: Admin (Register New User, Users, Sites, Trials), Subject Details, Settings, and Help. The main area has a title 'Add Trial' and a progress bar with three steps: 'BASIC INFORMATION' (green dot), 'SELECT ADMINS' (green dot), and 'SELECT SITES' (black dot). A message 'Please select sites for the trial' is displayed above a dropdown menu labeled 'Sites List'. At the bottom are buttons for 'Cancel', 'Back', and 'Finish'.

Please select sites for the trial: *trials -> sites*



Entity : REVA

Content Type: Detailed Design Specification

Document Title: REVA\_DDS

Doc. No.: DDS-GLB-COMP-2022-0030-00001.001

### 10.1.28 Trial Details

The screenshot shows the 'Trial Details' page in the Reva application. The page has a left sidebar with navigation links: Admin, Register New User, Users, Sites, Trials, Subject Details, Settings, and Help. The main content area is titled 'Trial Details'. It shows the following data:

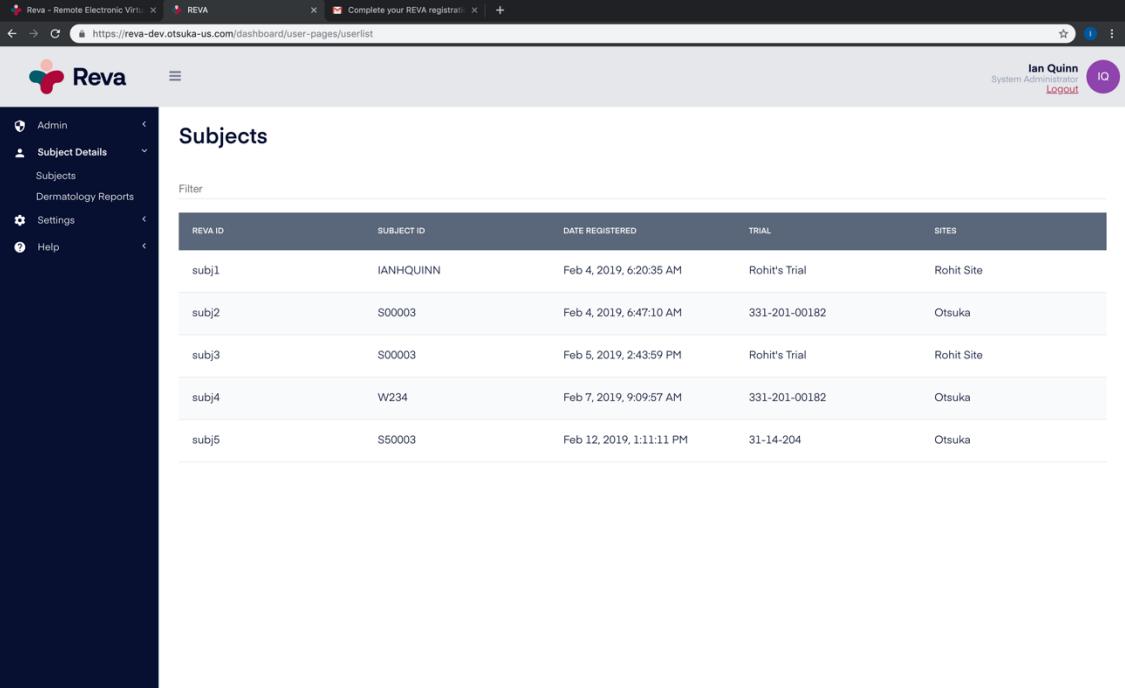
- Name: 331-201-00182
- Added By: sa.komanduri.rohit@gmail.com
- Start date: 2/3/2019
- End date: 2/6/2019
- Sites: Otsuka
- Central Dermatologists: cd.komanduri.rohit@gmail.com, cd.centralderm@dispostable.com, cd.renukavb@gmail.com, cd.lanquin999@gmail.com
- CRAs: cra.cra@dispostable.com, cra.lanquin999@gmail.com
- Administrators: sa.komanduri.rohit@gmail.com, tele.lanquin999@gmail.com, tele.komanduri.rohit@gmail.com
- Telederms: tele.lanquin999@gmail.com, tele.komanduri.rohit@gmail.com
- Medical Monitor: mon.monitor@dispostable.com, mon.renukavb@gmail.com, mon.lanquin999@gmail.com

At the bottom right are 'Submit' and 'Cancel' buttons.

Name:	trials -> name
Start date:	trials -> dateTime_start
Added By:	trials -> added_by
End date:	trials -> dateTime_end
Sites:	trials -> sites
Administrators:	trials -> administrators
Central Dermatologists:	trials -> central_dermatologists
Telederms:	trials -> telederms
CRAs:	trials -> cras
Monitors:	trials -> monitors

	<p style="text-align: right;">Entity : REVA Content Type: Detailed Design Specification Document Title: REVA_DDS Doc. No.: DDS-GLB-COMP-2022-0030-00001.001</p>
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### 10.1.29 Subject List



REVA ID	SUBJECT ID	DATE REGISTERED	TRIAL	SITES
subj1	IANHQUINN	Feb 4, 2019, 6:20:35 AM	Rohit's Trial	Rohit Site
subj2	S00003	Feb 4, 2019, 6:47:10 AM	331-201-00182	Otsuka
subj3	S00003	Feb 5, 2019, 2:43:59 PM	Rohit's Trial	Rohit Site
subj4	W234	Feb 7, 2019, 9:09:57 AM	331-201-00182	Otsuka
subj5	S50003	Feb 12, 2019, 1:11:11 PM	31-14-204	Otsuka

REVA ID: *users -> \_id*

SUBJECT ID: *users -> subject\_id*

DATE REGISTERED: *users -> dateTime\_registered*

TRIAL: *users -> trial*

SITES: *users -> site*



Entity : REVA

Content Type: Detailed Design Specification

Document Title: REVA\_DDS

Doc. No.: DDS-GLB-COMP-2022-0030-00001.001

### 10.1.30 Trial Update for Subject / Subject Interactive View

The screenshot shows a web-based application interface for managing users. On the left, there is a dark sidebar with navigation links: Admin (Register New User, Users, Sites, Trials), Subject Details (Subject ID: subj1, Subject ID: TEST 2023), Statistics, Settings, and Help. The main content area is titled "REVA User Update Form". It contains fields for "Role" (set to "Subject") and "Subject ID" (set to "subj1"). Below these, there are dropdown menus for "Added By" (set to "sa.komanduri.rohit@gmail.com"), "Trial" (set to "31-14-204"), and "Sites" (set to "Otsuka"). At the bottom right are buttons for "Submit", "Cancel", and "Reset Password". The top of the screen shows browser tabs for "ValGenesis 4.1", "REVA", "REVA", "Mail - Dhiman-CW, Ajay 189", and the current page "reva-dev.otsuka-us.com/dashboard/admin-pages/users/subj1?role=Subject". The status bar at the bottom indicates the time as "6:18 AM" and the date as "7/25/2023".



Entity : REVA

Content Type: Detailed Design Specification

Document Title: REVA\_DDS

Doc. No.: DDS-GLB-COMP-2022-0030-00001.001

The screenshot shows the Reva software interface. At the top, there is a navigation bar with the Reva logo, user information (Ajay, System Administrator), and a logout button. On the left, a sidebar menu includes Admin, Subject Details (selected), Subjects, Dermatology Reports, Statistics, Settings, and Help. The main content area has tabs for Subject Interactive View, Subject History and Reports, and Dermatology Reports. Under Subject Interactive View, it shows a subject named TEST 2023 with sites Otsuka and trial 31-14-204. It also displays registration and login details. A RASH HISTORY section shows 3 cases. Below that, there are tabs for Case 1, Case 2, and Case 3. A section for Local Dermatologist includes fields for report generation and clinician submission status.

SUBJECT: TEST 2023

SITES: Otsuka

TRIAL: 31-14-204

REGISTERED ON: Feb 4, 2019, 4:50:35 PM

LAST LOGIN: Apr 28, 2020, 8:16:31 PM

RASH HISTORY: 3 cases

Case 1 Case 2 Case 3

LAST OBSERVED: Feb 02, 2023

RESOLVED:

SITES: Otsuka

SUBMITTED BY: clin.komanduri.rohit@gmail.com

CLINICIAN SUBMITTED: true

Local Dermatologist

Report generated for Local Dermatologist:

(ACTION FOR TELEDERM/CENTRAL DERMATOLOGISTS & MEDICAL MONITORS)

Local Dermatologist visit suggested:

Last Updated: Jun 13, 2023, 2:27:35 PM



Entity : REVA

Content Type: Detailed Design Specification

Document Title: REVA\_DDS

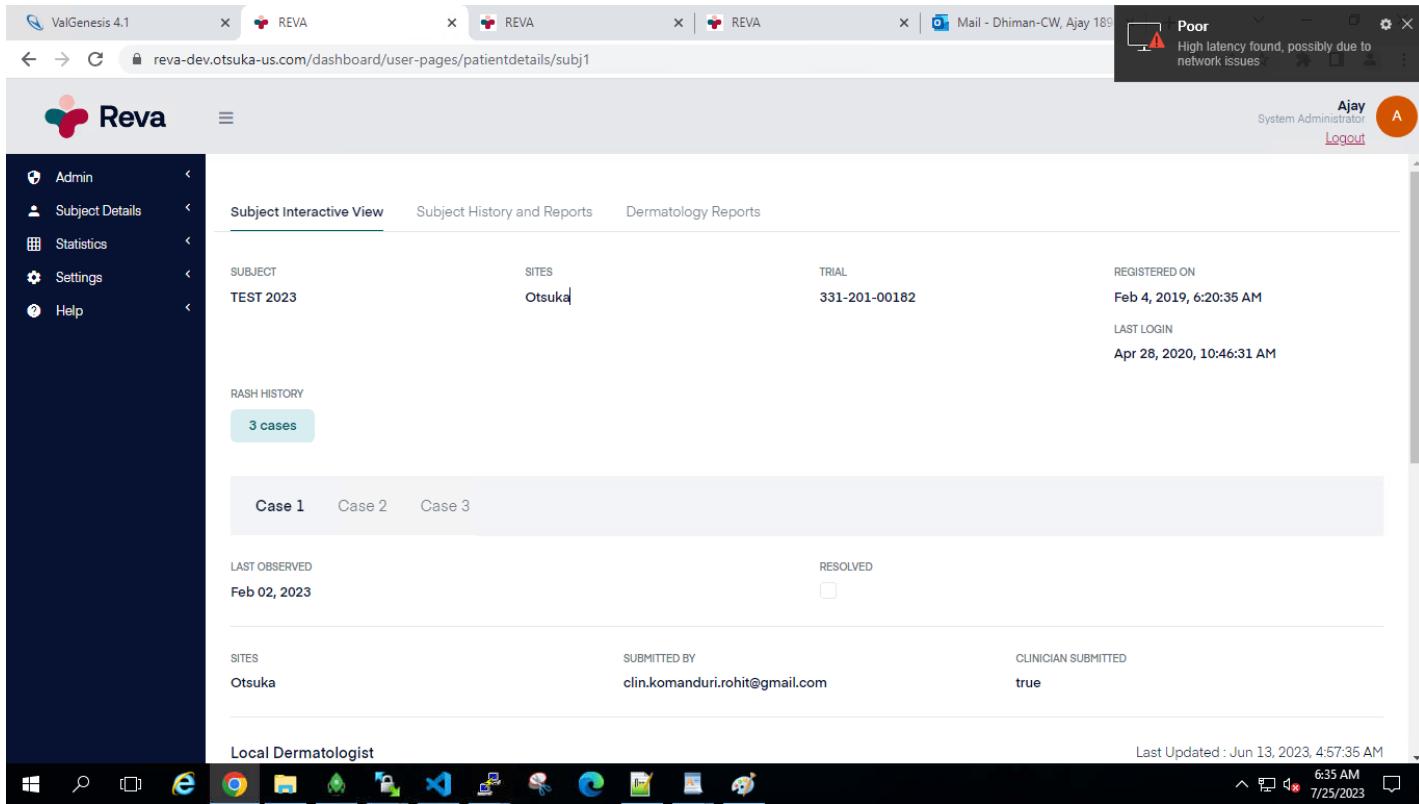
Doc. No.: DDS-GLB-COMP-2022-0030-00001.001

The screenshot shows a web-based application titled "REVA User Update Form". The left sidebar has a dark theme with white text and includes links for Admin (Register New User, Users, Sites, Trials), Subject Details (selected), Statistics, Settings, and Help. The main content area has a light gray background and contains the following fields:

- Role:** A dropdown menu labeled "Please select user role from list".
- Subject:** A dropdown menu labeled "subj1".
- REVA ID:** A dropdown menu labeled "TEST 2023".
- Added By:** A text field containing "sa.komanduri.rohit@gmail.com".
- Trial:** A dropdown menu containing "331-201-00182".
- Sites:** A dropdown menu containing "Otsuka".

At the bottom right of the form are three buttons: "Submit", "Cancel", and "Reset Password". The status bar at the bottom of the screen shows the date and time: "6:35 AM 7/25/2023".

	<p style="text-align: right;">Entity : REVA  Content Type: Detailed Design Specification  Document Title: REVA_DDS  Doc. No.: DDS-GLB-COMP-2022-0030-00001.001</p>
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The screenshot shows the Reva software interface. At the top, there are four browser tabs: ValGenesis 4.1, REVA, REVA, and Mail - Dhiman-CW, Ajay 189. A system status bar indicates "Poor" performance due to network issues.

The main window displays the "Subject Interactive View" for subject TEST 2023. The subject details are as follows:

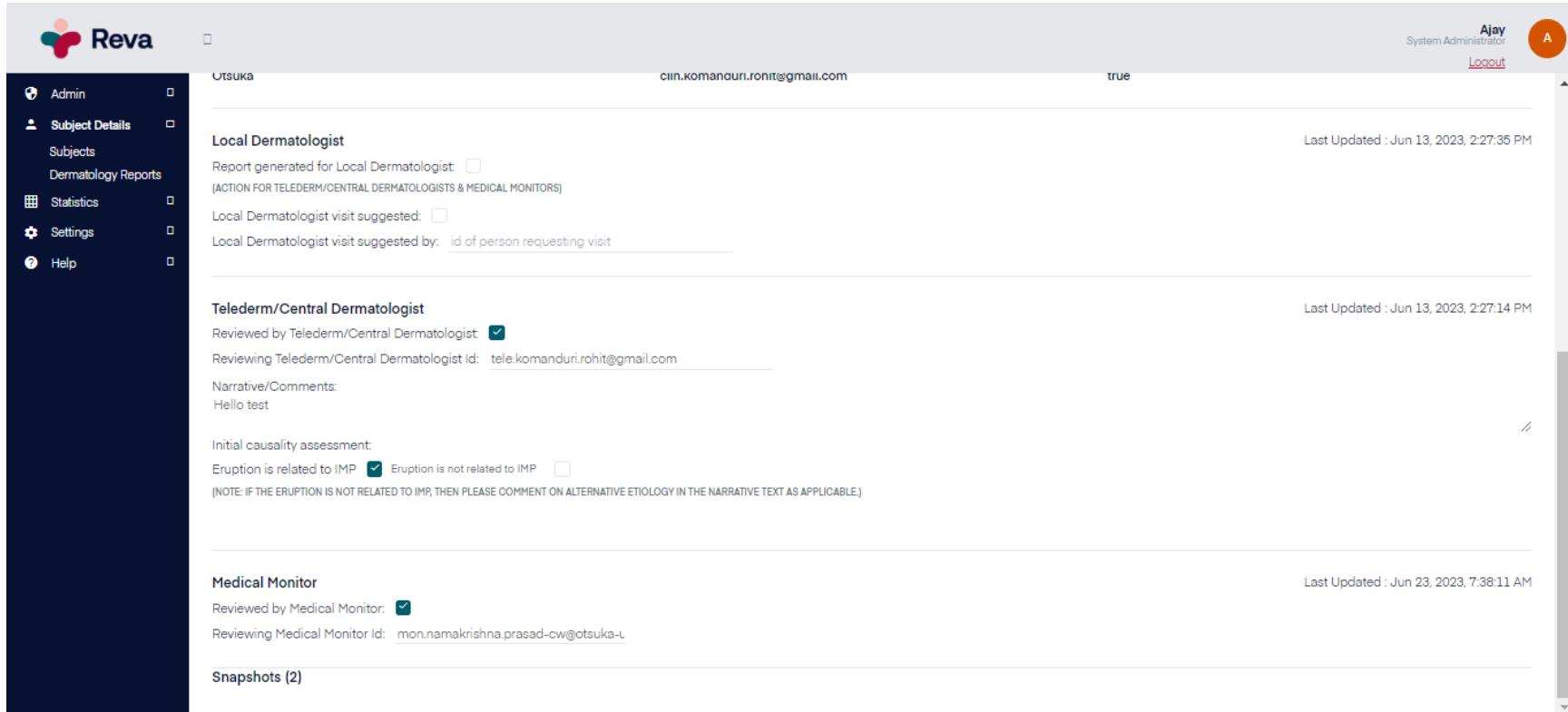
- SUBJECT: TEST 2023
- SITES: Otsuka
- TRIAL: 331-201-00182
- REGISTERED ON: Feb 4, 2019, 6:20:35 AM
- LAST LOGIN: Apr 28, 2020, 10:46:31 AM

Under "RASH HISTORY", it shows "3 cases". Below that, under "Case 1", the details are:

- LAST OBSERVED: Feb 02, 2023
- RESOLVED: (checkbox)

At the bottom, it shows "Local Dermatologist" and the last update time: Jun 13, 2023, 4:57:35 AM. The system status bar also shows the date: 7/25/2023.

	<p style="margin: 0;">Entity : REVA</p> <p style="margin: 0;">Content Type: Detailed Design Specification</p> <p style="margin: 0;">Document Title: REVA_DDS</p> <p style="margin: 0;">Doc. No.: DDS-GLB-COMP-2022-0030-00001.001</p>
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The screenshot shows a web-based application interface for managing patient data. On the left is a dark sidebar menu with options like Admin, Subject Details (selected), Statistics, Settings, and Help. The main content area displays a patient record for 'Otsuka'.

**Subject Details:** Shows the patient's name 'Otsuka', email 'ciin.komanduri.ronit@gmail.com', and a status indicator 'true'. The last update was on Jun 13, 2023, at 2:27:35 PM.

**Local Dermatologist:** Report generated for Local Dermatologist:  (ACTION FOR TELEDERM/CENTRAL DERMATOLOGISTS & MEDICAL MONITORS). Local Dermatologist visit suggested:  Local Dermatologist visit suggested by: id of person requesting visit.

**Telederm/Central Dermatologist:** Reviewed by Telederm/Central Dermatologist:  Reviewing Telederm/Central Dermatologist Id: tele.komanduri.rohit@gmail.com. Narrative/Comments: Hello test. Initial causality assessment: Eruption is related to IMP  Eruption is not related to IMP  (NOTE: IF THE ERUPTION IS NOT RELATED TO IMP, THEN PLEASE COMMENT ON ALTERNATIVE ETIOLOGY IN THE NARRATIVE TEXT AS APPLICABLE).

**Medical Monitor:** Reviewed by Medical Monitor:  Reviewing Medical Monitor Id: mon.namakrishna.prasad-cw@otsuka-l.

**Snapshots (2)**: Shows two image attachments.

Subject: *users -> subject\_id*  
 Trial: *users -> trial*  
 Registered on: *users -> dateTime\_registered*  
 Last Login: *users -> last\_login*  
 Sites: *users -> sites*

**Confidential and Proprietary**

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Template No.: GLB-CSVDDS-00011.002



Entity : REVA

Content Type: Detailed Design Specification

Document Title: REVA\_DDS

Doc. No.: DDS-GLB-COMP-2022-0030-00001.001

Sites:	<i>rash_reports -&gt; sites</i>
Date Resolved:	<i>rash_reports -&gt; dateTime_resolved</i>
Submitted By:	<i>rash_reports -&gt; submitted_by</i>
Clinician Submitted:	<i>rash_reports -&gt; clinician_submitted</i>
Report generated for local dermatologist:	<i>rash_reports -&gt; sent_to_local_dermatologist</i>
Local dermatologist visit suggested:	<i>rash_reports -&gt; localDermVisitRequested</i>
Local dermatologist visit suggested by:	<i>rash_reports -&gt; localDermVisitRequestorId</i>
Reviewed by telederm/central dermatologist:	<i>rash_reports -&gt; reviewedByTelederm</i>
Reviewing telederm/central dermatologist id:	<i>rash_reports -&gt; teledermId</i>
Reviewed by monitor:	<i>rash_reports -&gt; reviewedByMonitor</i>
Reviewing monitor id:	<i>rash_reports -&gt; monitorId</i>
Narrative/Comments:	<i>rash_reports -&gt; telederm_comments</i>
Eruption is related to IMP:	<i>rash_reports -&gt; eruption</i>
telederm_Comment_Eruption_Last_Updated:	<i>Rash_reports -&gt; teledrem / CD last updated date</i>
monitor_Last_Updated:	<i>Rash_reports -&gt; monitor last updated date</i>
Id_Suggested_Date_Last_Updated:	<i>Rash_reports -&gt; local dermatologist last updated date</i>



Entity : REVA

Content Type: Detailed Design Specification

Document Title: REVA\_DDS

Doc. No.: DDS-GLB-COMP-2022-0030-00001.001

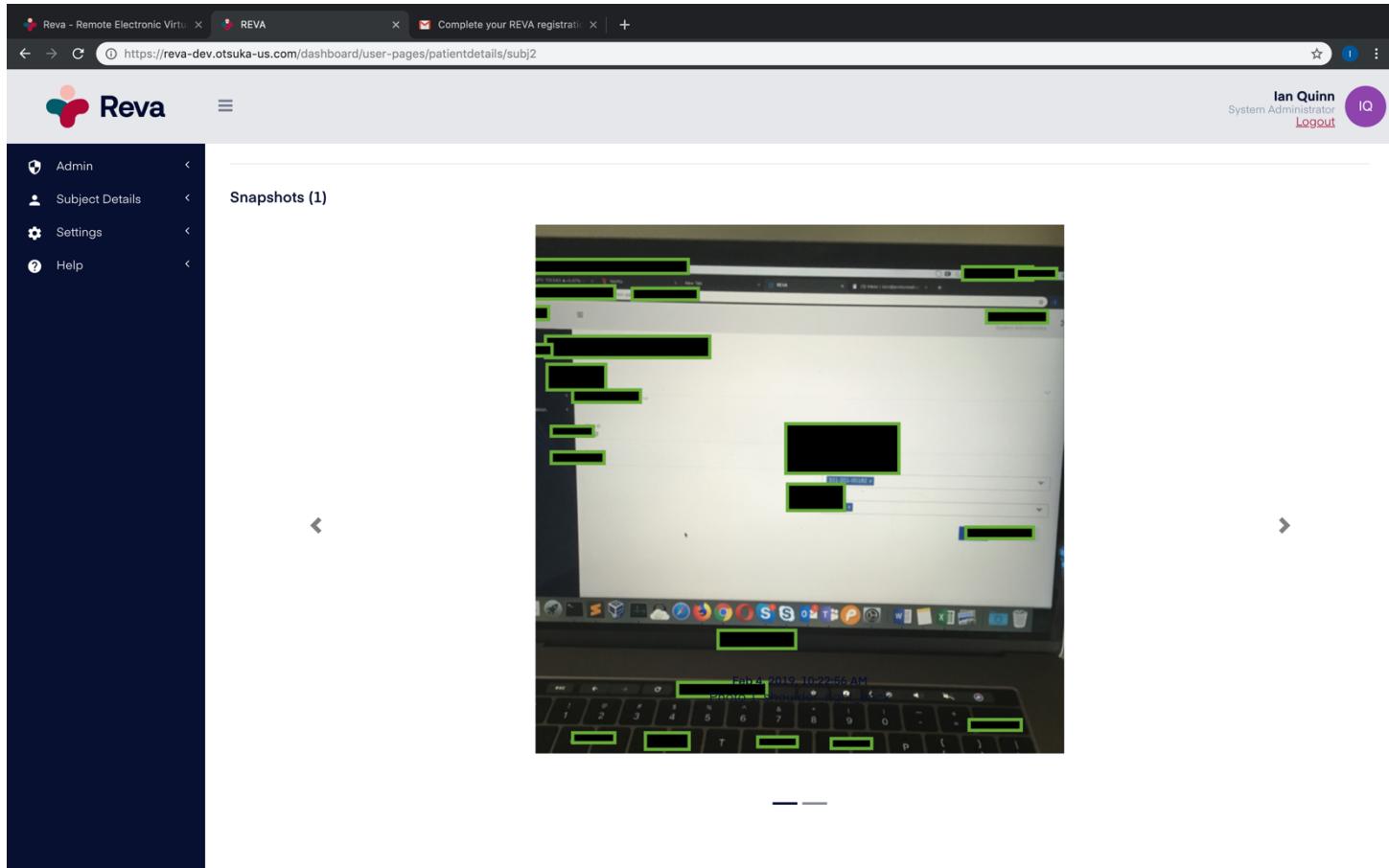


Image:

*rash\_reports -> instances -> [object] -> bodyPart\_images -> [object] -> image*

Confidential and Proprietary

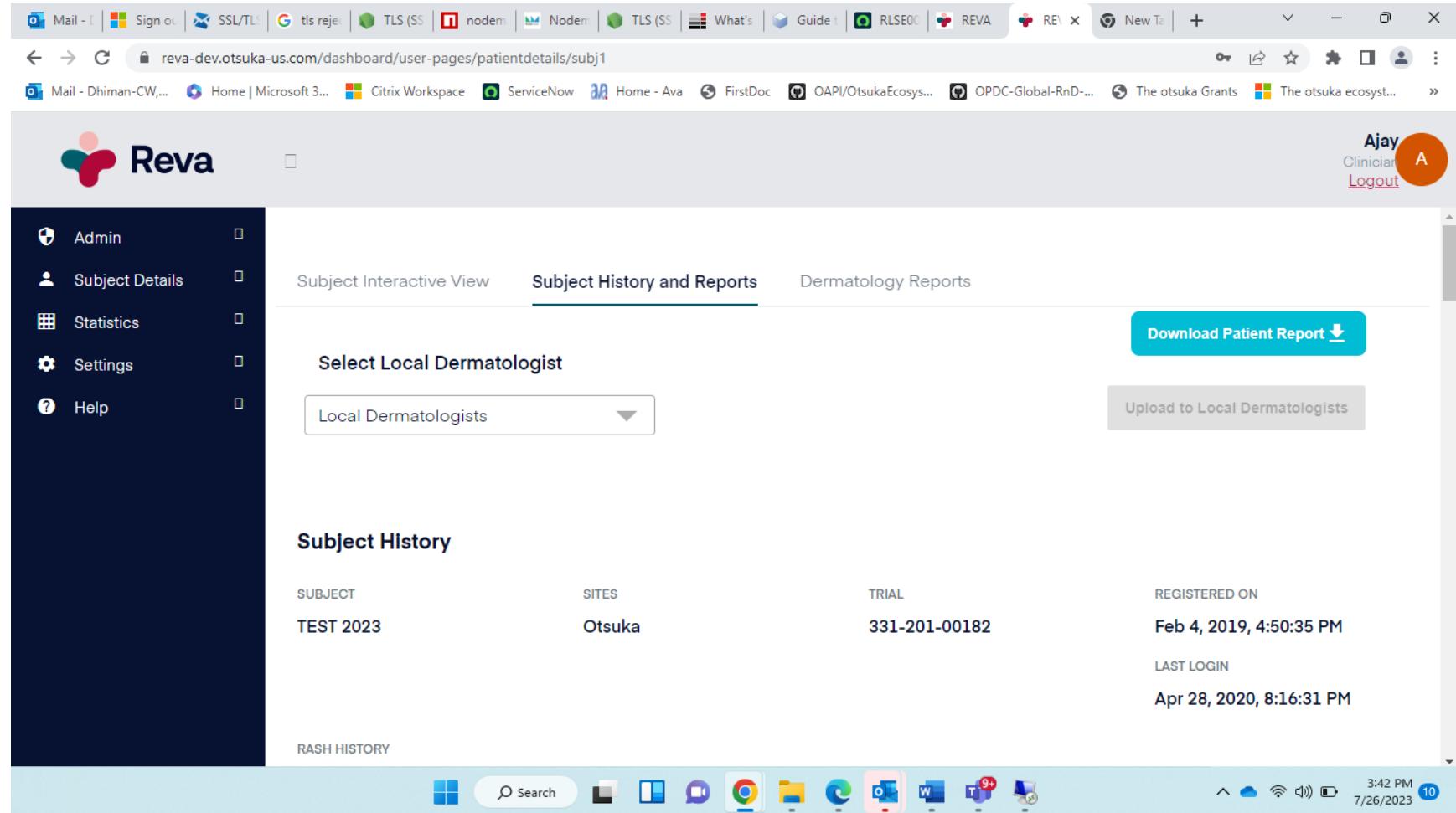
Template No.: GLB-CSVDDS-00011.002

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Doc.No. DDS-GLB-COMP-2022-0030-00001.003 Approved On 20-Sep-2024 12:05:53 PM (EDT)

	<p style="text-align: right;">Entity : REVA</p> <p style="text-align: right;">Content Type: Detailed Design Specification</p> <p style="text-align: right;">Document Title: REVA_DDS</p> <p style="text-align: right;">Doc. No.: DDS-GLB-COMP-2022-0030-00001.001</p>
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### 10.1.31 Subject History and Reports



The screenshot shows the Reva software interface. At the top, there is a navigation bar with various links like Mail, Sign on, SSL/TLS, TLS (SS), nodem, Nodem, What's, Guide, RLSEOC, REVA, New Tab, and a search bar. Below the navigation bar is a toolbar with icons for Mail - Dhiman-CW..., Home | Microsoft 3..., Citrix Workspace, ServiceNow, Home - Ava, FirstDoc, OAPI/OtsukaEcosys..., OPDC-Global-RnD..., The otsuka Grants, and The otsuka ecosystem... . On the far right of the top bar, there is a user profile for 'Ajay' with a clinician badge and a logout button.

The main content area has a header with three tabs: 'Subject Interactive View', 'Subject History and Reports' (which is underlined, indicating it is active), and 'Dermatology Reports'. To the right of these tabs is a blue button labeled 'Download Patient Report' with a download icon. Below the tabs, there is a section titled 'Select Local Dermatologist' with a dropdown menu set to 'Local Dermatologists' and a button to 'Upload to Local Dermatologists'.

The central part of the screen is titled 'Subject History' and displays the following information:

SUBJECT	SITES	TRIAL	REGISTERED ON
TEST 2023	Otsuka	331-201-00182	Feb 4, 2019, 4:50:35 PM

Below this, there is a section titled 'RASH HISTORY'.

At the bottom of the screen, there is a taskbar with icons for various applications like File Explorer, Search, Task View, Edge, Google Chrome, File Manager, Outlook, Word, and Teams. On the far right of the taskbar, there is a system tray showing the date and time (3:42 PM 7/26/2023) and battery status (10).



Entity : REVA

Content Type: Detailed Design Specification

Document Title: REVA\_DDS

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Subject Interactive View    Subject History and Reports    Dermatology Reports

**Subject History**

SUBJECT: TEST 2023    SITES: Otsuka    TRIAL: 31-14-204

REGISTERED ON: Feb 4, 2019, 4:50:35 PM    LAST LOGIN: Apr 28, 2020, 8:16:31 PM

RASH HISTORY: 3 cases

**Case 1**    Last Observed: Feb 02, 2023     Resolved

SITES: Otsuka    SUBMITTED BY: clin.komanduri.rohit@gmail.com    CLINICIAN SUBMITTED: true

LOCAL DERMATOLOGIST: Report generated for Local Dermatologist:   
Local Dermatologist visit suggested:   
Local Dermatologist visit suggested by:

TELEDERM/CENTRAL DERMATOLOGIST: Reviewed by Telederm/Central Dermatologist:   
Reviewing Telederm/Central Dermatologist Id: tele.komanduri.rohit@gmail.com  
Telederm/Central Dermatologist comments:

MEDICAL MONITOR: Reviewed by Medical Monitor:   
Reviewing Medical Monitor Id: mon.namakrishna.prasad-cw@otsuka-us.com

Select Local Dermatologist: *dermatology\_reports -> localDermatologist -> [object] -> id*

Subject: *users -> subject\_id*

Trial: *users -> trial*

Registered on: *users -> dateTime\_registered*

Last Login: *users -> last\_login*

Sites: *users -> sites*

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Template No.: GLB-CSVDDS-00011.002

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Entity : REVA

Content Type: Detailed Design Specification

Document Title: REVA\_DDS

Doc. No.: DDS-GLB-COMP-2022-0030-00001.001

Rash History:	<i>rash_reports</i>
Case [X]:	<i>rash_reports -&gt; case_number</i>
Observed [X]:	<i>rash_reports -&gt; last_observed</i>
Snapshots [X]:	<i>rash_reports -&gt; instances</i>
Resolved:	<i>rash_reports -&gt; resolved</i>
Sites:	<i>rash_reports -&gt; sites</i>
Date Resolved:	<i>rash_reports -&gt; date_time_resolved</i>
Submitted By:	<i>rash_reports -&gt; submitted_by</i>
Clinician Submitted:	<i>rash_reports -&gt; clinician_submitted</i>
Report generated for local dermatologist:	<i>rash_reports -&gt; sent_to_local_dermatologist?</i>
Local dermatologist visit suggested:	<i>rash_reports -&gt; localDermVisitRequested?</i>
Local dermatologist visit suggested by:	<i>rash_reports -&gt; localDermVisitRequestorId?</i>
Reviewed by telederm/central dermatologist:	<i>rash_reports -&gt; reviewedByTelederm?</i>
Reviewing telederm//central dermatologist id:	<i>rash_reports -&gt; teledermId?</i>
Narrative/Comments:	<i>rash_reports -&gt; telederm_comments?</i>
<i>Eruption is related to IMP:</i>	<i>rash_reports -&gt; eruption</i>
<i>Last Updated:</i>	<i>rash_reports -&gt; telederm_Comment_Eruption_Last_Updated</i>
<i>Suggestion Date Last Updated:</i>	<i>rash_reports -&gt; Id_Suggested_Date_Last_Updated</i>



Entity : REVA

Content Type: Detailed Design Specification

Document Title: REVA\_DDS

Doc. No.: DDS-GLB-COMP-2022-0030-00001.001

The screenshot shows a web-based application interface for 'Reva - Remote Electronic Virtu...' at 'REVA'. The user is 'Ian Quinn' (System Administrator) who has logged out. The main content area displays a 'Snapshot captured Feb 4, 2019, 10:22:56 AM' with various symptoms and exposure details. Below this is a large image of a skin rash with several green rectangular highlights indicating specific areas of interest or analysis.

Snapshot captured Feb 4, 2019, 10:22:56 AM	
Taken:	Feb 4, 2019, 10:22:56 AM
By:	S00003
Recent Contact With Other Rash:	true
First Noticed:	Feb 4, 2019, 12:00:00 AM
Itching:	2
Texture:	Raised
Tenderness:	2
Symptoms:	sore throat
Recent Exposure to Dyes or Toxins:	true
Changes:	skin care products
Burning:	2
Rash Is:	peeling
Color:	Red

Snapshot captured [X]:

Taken:

Recent Contact With Other Rash:

rash\_reports -> instances -> [object] -> date\_time\_captured

rash\_reports -> instances -> [object] -> date\_time\_captured

rash\_reports -> instances -> [object] -> form -> recent\_contact\_with\_other\_rash

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Entity : REVA

Content Type: Detailed Design Specification

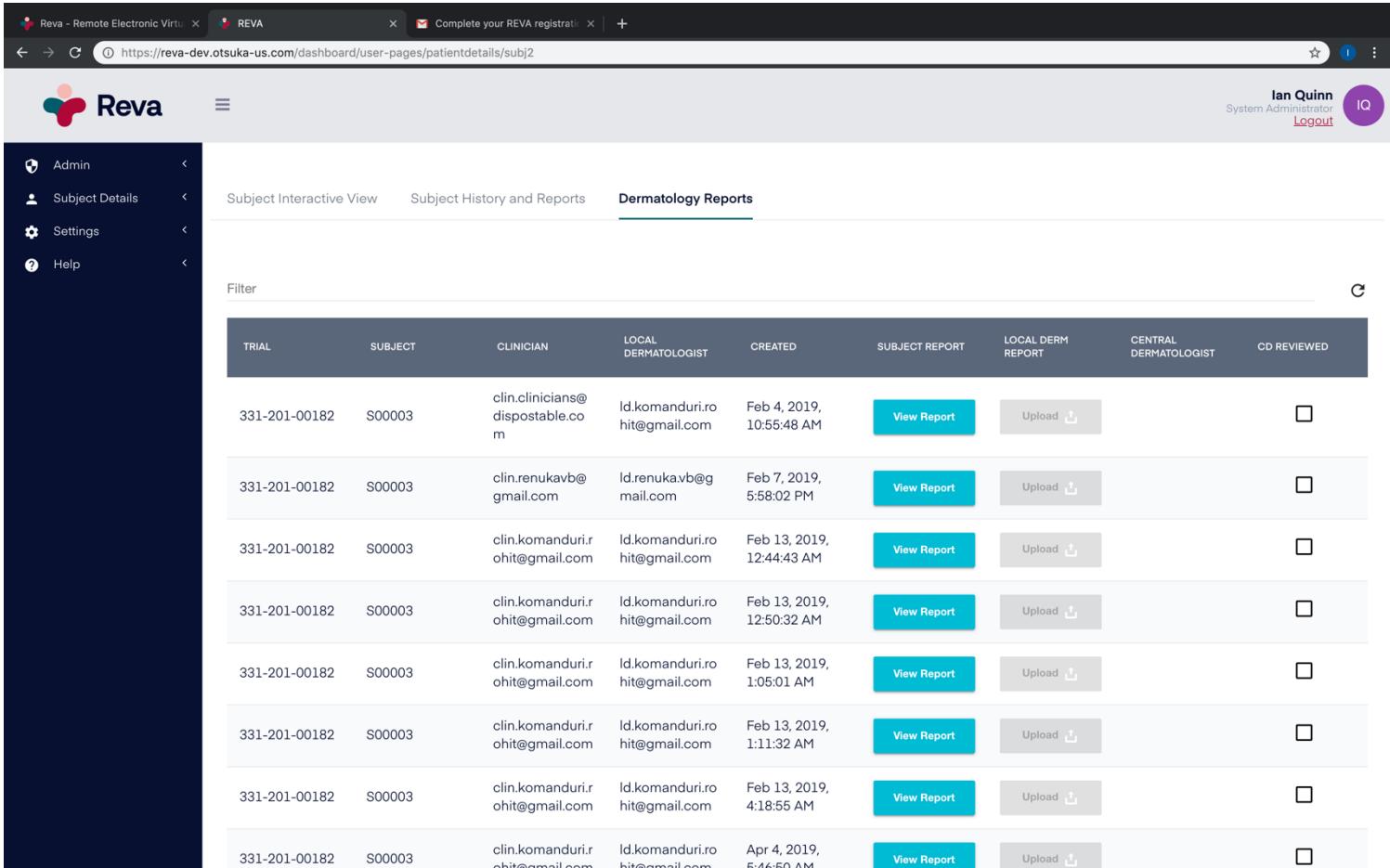
Document Title: REVA\_DDS

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Recent Exposure to Dyes or Toxins:	<i>rash_reports -&gt; instances -&gt; [object] -&gt; form -&gt; recent_exposure_to_dyes_or_toxins</i>
First Noticed:	<i>rash_reports -&gt; instances -&gt; [object] -&gt; form -&gt; first_noticed</i>
Changes:	<i>rash_reports -&gt; instances -&gt; [object] -&gt; form -&gt; changes</i>
Itching:	<i>rash_reports -&gt; instances -&gt; [object] -&gt; form -&gt; itching</i>
Burning:	<i>rash_reports -&gt; instances -&gt; [object] -&gt; form -&gt; burning</i>
Texture:	<i>rash_reports -&gt; instances -&gt; [object] -&gt; form -&gt; texture</i>
Rash Is:	<i>rash_reports -&gt; instances -&gt; [object] -&gt; form -&gt; rash_is</i>
Tenderness:	<i>rash_reports -&gt; instances -&gt; [object] -&gt; form -&gt; tenderness</i>
Color:	<i>rash_reports -&gt; instances -&gt; [object] -&gt; form -&gt; color</i>
Image:	<i>rash_reports -&gt; instances -&gt; [object] -&gt; bodyPart_images -&gt; [object] -&gt; image</i>

	<p style="text-align: right;">Entity : REVA</p> <p style="text-align: right;">Content Type: Detailed Design Specification</p> <p style="text-align: right;">Document Title: REVA_DDS</p> <p style="text-align: right;">Doc. No.: DDS-GLB-COMP-2022-0030-00001.001</p>
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### 10.1.32 Dermatology Reports



TRIAL	SUBJECT	CLINICIAN	LOCAL DERMATOLOGIST	CREATED	SUBJECT REPORT	LOCAL DERM REPORT	CENTRAL DERMATOLOGIST	CD REVIEWED
331-201-00182	S00003	clin.clinicians@dispostable.com	ld.komanduri.rohit@gmail.com	Feb 4, 2019, 10:55:48 AM	<a href="#">View Report</a>	<a href="#">Upload</a>	<input type="checkbox"/>	
331-201-00182	S00003	clin.renukavb@gmail.com	ld.renuka.vb@gmail.com	Feb 7, 2019, 5:58:02 PM	<a href="#">View Report</a>	<a href="#">Upload</a>	<input type="checkbox"/>	
331-201-00182	S00003	clin.komanduri.rohit@gmail.com	ld.komanduri.rohit@gmail.com	Feb 13, 2019, 12:44:43 AM	<a href="#">View Report</a>	<a href="#">Upload</a>	<input type="checkbox"/>	
331-201-00182	S00003	clin.komanduri.rohit@gmail.com	ld.komanduri.rohit@gmail.com	Feb 13, 2019, 12:50:32 AM	<a href="#">View Report</a>	<a href="#">Upload</a>	<input type="checkbox"/>	
331-201-00182	S00003	clin.komanduri.rohit@gmail.com	ld.komanduri.rohit@gmail.com	Feb 13, 2019, 1:05:01 AM	<a href="#">View Report</a>	<a href="#">Upload</a>	<input type="checkbox"/>	
331-201-00182	S00003	clin.komanduri.rohit@gmail.com	ld.komanduri.rohit@gmail.com	Feb 13, 2019, 1:11:32 AM	<a href="#">View Report</a>	<a href="#">Upload</a>	<input type="checkbox"/>	
331-201-00182	S00003	clin.komanduri.rohit@gmail.com	ld.komanduri.rohit@gmail.com	Feb 13, 2019, 4:18:55 AM	<a href="#">View Report</a>	<a href="#">Upload</a>	<input type="checkbox"/>	
331-201-00182	S00003	clin.komanduri.rohit@gmail.com	ld.komanduri.rohit@gmail.com	Apr 4, 2019, 5:46:50 AM	<a href="#">View Report</a>	<a href="#">Upload</a>	<input type="checkbox"/>	

TRIAL: *dermatology\_reports -> trial*  
 SUBJECT: *dermatology\_reports -> subject*  
 CLINICIAN: *dermatology\_reports -> clinician*

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LOCAL DERMATOLOGIST:	<i>dermatology_reports -&gt; localDermatologist -&gt; [object] -&gt; id</i>
REVIEW REQUESTED:	<i>dermatology_reports -&gt; localDermReviewRequested?</i>
CREATED:	<i>dermatology_reports -&gt; dateTime_created</i>
SUBJECT REPORT:	<i>dermatology_reports -&gt; localDermatologist -&gt; [object] -&gt; reportName</i>
LOCAL DERM REPORT:	<i>dermatology_reports -&gt; localDermatologist -&gt; [object] -&gt; reportName</i>
CENTRAL DERMATOLOGIST:	<i>dermatology_reports -&gt; centralDermatologist -&gt; id</i>
CD REVIEWED	<i>dermatology_reports -&gt; centralDermatologist -&gt; reviewed</i>



Entity : REVA

Content Type: Detailed Design Specification

Document Title: REVA\_DDS

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### 10.1.33 Subject Rash Report

The screenshot shows a web-based application for managing clinical data. At the top, there's a header with tabs like 'REVA' and a URL indicating the report is for a subject registered on Feb 4, 2019. Below the header, the 'Subject History' section shows details such as SUBJECT ID (S00003), SITE (Otsuka), TRIAL (331-201-00182), and registration and login dates. The 'RASH HISTORY' section indicates 7 cases. A detailed 'Case 1' view is shown, including fields for SITE (Otsuka), SUBMITTED BY (S00003), and CLINICIAN SUBMITTED (false). It also includes sections for LOCAL DERMATOLOGIST, TELEDERM, and MEDICAL MONITOR. A 'Snapshot captured Feb 4, 2019, 10:22:56 AM' is displayed at the bottom, showing a close-up image of a rash and its associated symptoms and history.

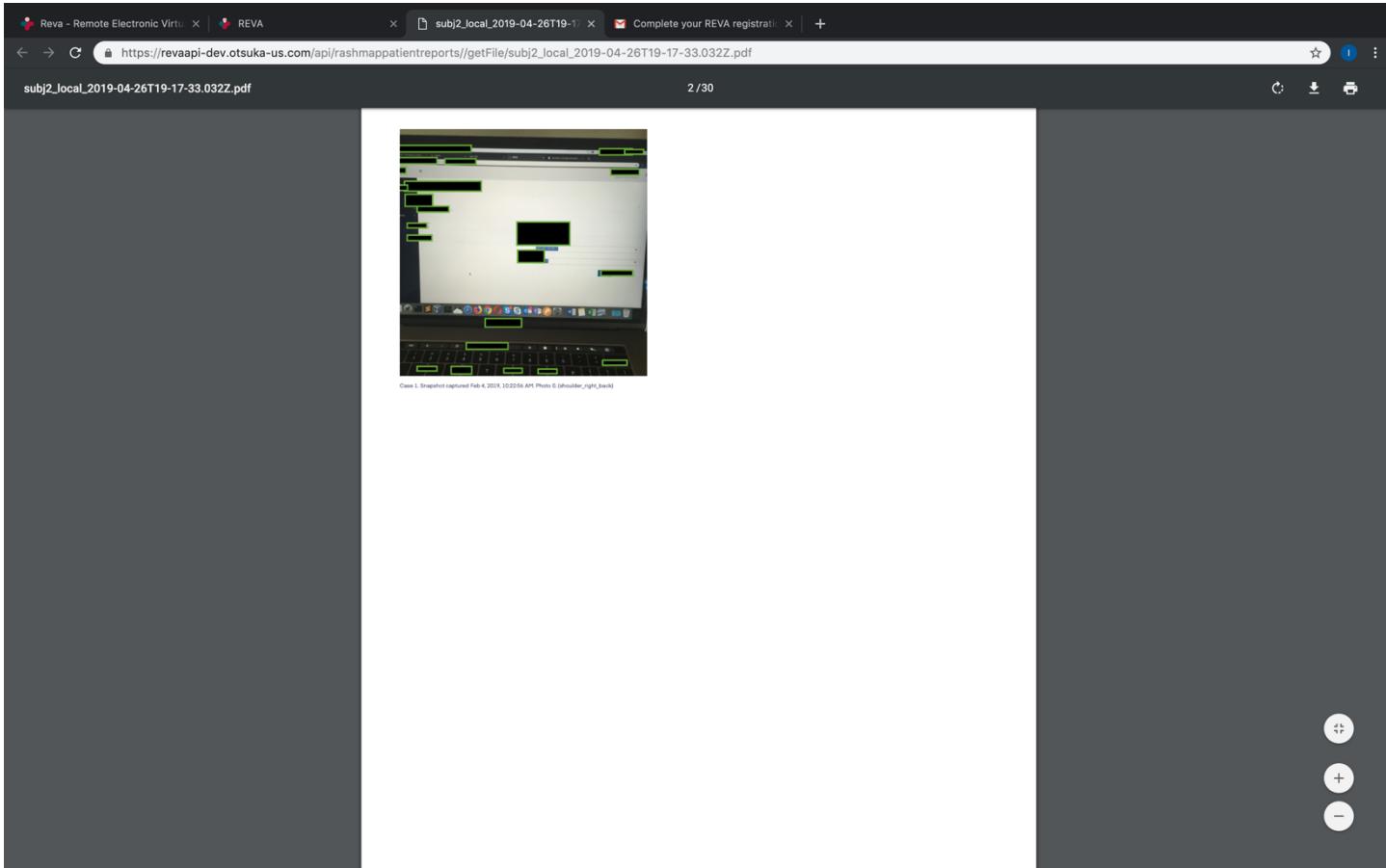


Entity : REVA

Content Type: Detailed Design Specification

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Entity : REVA

Content Type: Detailed Design Specification

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### 10.1.34 Informational Landing Screen

Reva - Remote Electronic Virtu × REVA × Complete your REVA registratio × + https://reva-dev.otsuka-us.com

Reva

— Remote Electronic Virtual Assessment

## Otsuka is committed to bringing novel products to market.

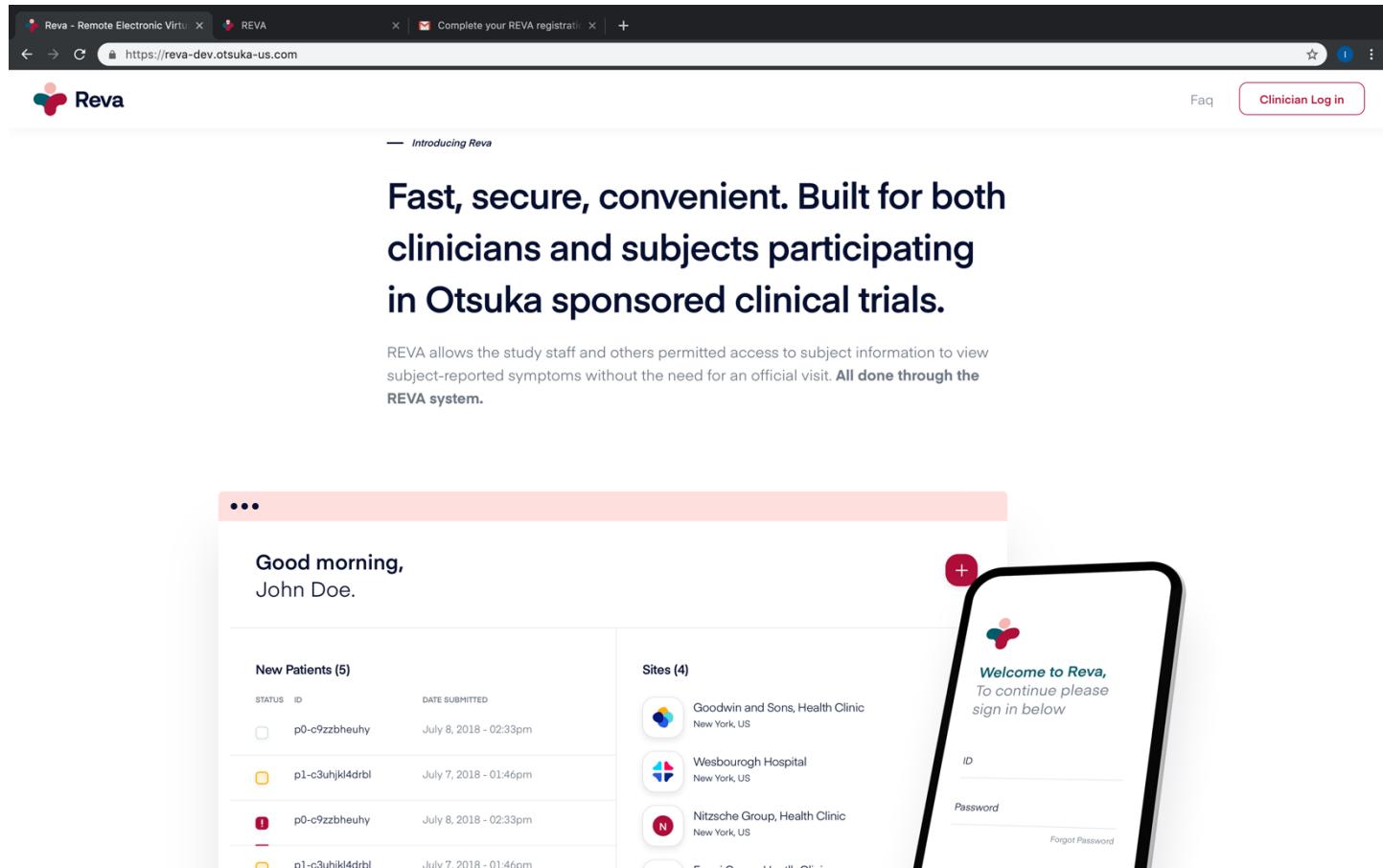
Introducing **Reva**, a virtual clinic model allowing subjects participating in Otsuka-sponsored clinical trials to report symptoms to study staff using a smart phone.

App Store Play Store

Need Help or have Questions? ⓘ

Built by the Think Team Otsuka Pharmaceutical Development & Commercialization, Inc. "Otsuka – people creating new products for better health worldwide."

	<p style="margin: 0;">Entity : REVA</p> <p style="margin: 0;">Content Type: Detailed Design Specification</p> <p style="margin: 0;">Document Title: REVA_DDS</p> <p style="margin: 0;">Doc. No.: DDS-GLB-COMP-2022-0030-00001.001</p>
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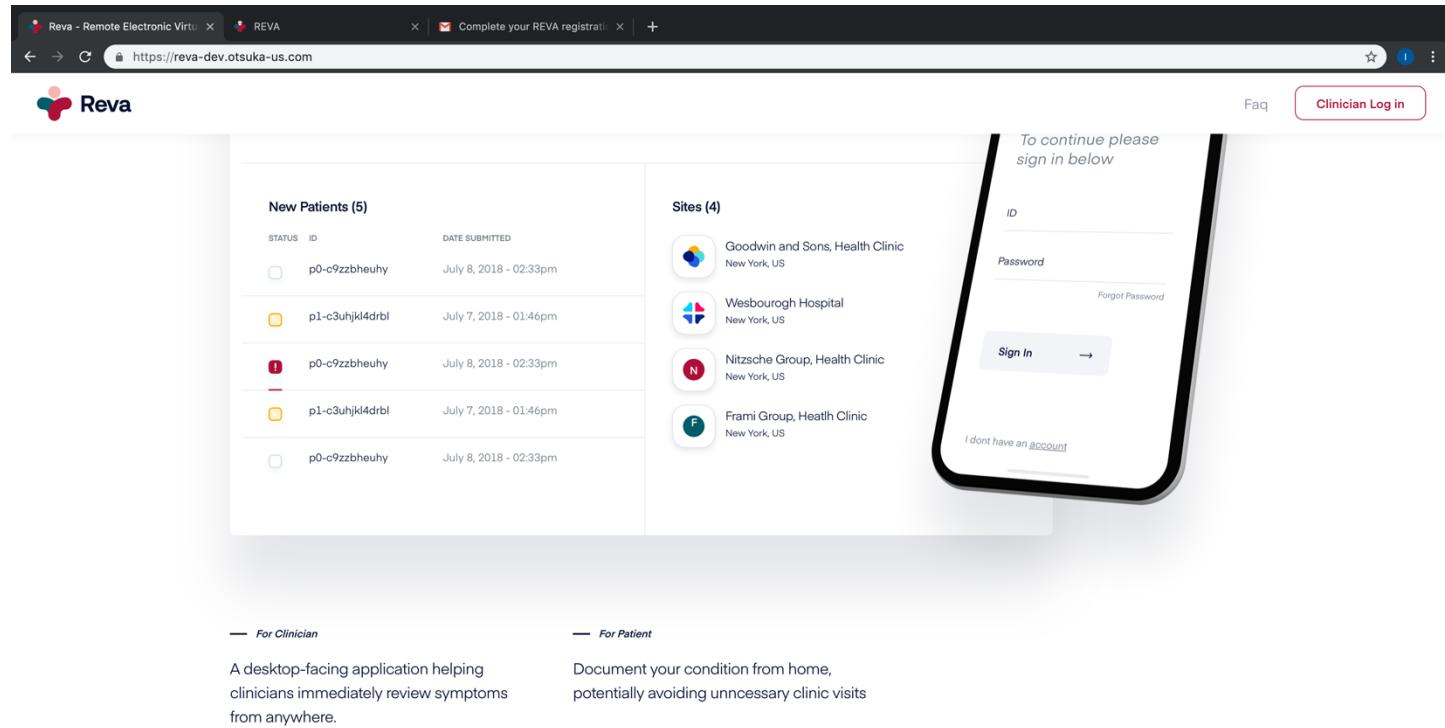


The screenshot shows the Reva system interface. At the top, there are two browser tabs: 'Reva - Remote Electronic Virtu' and 'REVA'. The main content area displays the 'Introducing Reva' page with the heading: 'Fast, secure, convenient. Built for both clinicians and subjects participating in Otsuka sponsored clinical trials.' Below this, a paragraph explains that REVA allows study staff and others permitted access to view subject-reported symptoms without an official visit, all done through the REVA system. To the right, there is a 'Clinician Log in' button. Below the introduction, there are two main sections: 'New Patients (5)' and 'Sites (4)'. The 'New Patients' section lists five entries with columns for STATUS, ID, and DATE SUBMITTED. The 'Sites' section lists four sites with their names and locations. To the right, a smartphone displays the 'Welcome to Reva' screen with fields for 'ID' and 'Password'.

New Patients (5)		
STATUS	ID	DATE SUBMITTED
<span style="color: #ccc;">□</span>	p0-c9zzbheuhy	July 8, 2018 - 02:33pm
<span style="color: orange;">□</span>	p1-c3uhjkl4drbl	July 7, 2018 - 01:46pm
<span style="color: red;">□</span>	p0-c9zzbheuhy	July 8, 2018 - 02:33pm
<span style="color: yellow;">□</span>	p1-c3uhjkl4drbl	July 7, 2018 - 01:46pm

Sites (4)	
	Goodwin and Sons, Health Clinic New York, US
	Wesbourne Hospital New York, US
	Nitsche Group, Health Clinic New York, US

	<p style="text-align: right;">Entity : REVA  Content Type: Detailed Design Specification  Document Title: REVA_DDS  Doc. No.: DDS-GLB-COMP-2022-0030-00001.001</p>
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The screenshot displays the Reva application interface. On the left, there are two main sections: 'New Patients (5)' and 'Sites (4)'. The 'New Patients' section lists five entries with columns for STATUS, ID, and DATE SUBMITTED. The 'Sites' section lists four health clinics with their names and locations. On the right, a smartphone screen shows a 'Clinician Log in' overlay with fields for 'ID' and 'Password', a 'Forgot Password' link, and a 'Sign In' button. Below the phone is a link 'I dont have an account'.

STATUS	ID	DATE SUBMITTED
<input type="checkbox"/>	p0-c9zzbheuhy	July 8, 2018 - 02:33pm
<input checked="" type="checkbox"/>	p1-c3uhjkl4drbl	July 7, 2018 - 01:46pm
<input type="checkbox"/>	p0-c9zzbheuhy	July 8, 2018 - 02:33pm
<input checked="" type="checkbox"/>	p1-c3uhjkl4drbl	July 7, 2018 - 01:46pm
<input type="checkbox"/>	p0-c9zzbheuhy	July 8, 2018 - 02:33pm

Sites (4)	
	Goodwin and Sons, Health Clinic New York, US
	Wesbourne Hospital New York, US
	Nitzsche Group, Health Clinic New York, US
	Frami Group, Health Clinic New York, US

*To continue please sign in below*

ID

Password

[Forgot Password](#)

**Sign In** →

*I don't have an account*

**For Clinician**  
A desktop-facing application helping clinicians immediately review symptoms from anywhere.

**For Patient**  
Document your condition from home, potentially avoiding unnecessary clinic visits

	<p style="margin: 0;">Entity : REVA</p> <p style="margin: 0;">Content Type: Detailed Design Specification</p> <p style="margin: 0;">Document Title: REVA_DDS</p> <p style="margin: 0;">Doc. No.: DDS-GLB-COMP-2022-0030-00001.001</p>
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The screenshot shows the homepage of the Reva website. At the top, there's a navigation bar with tabs for "Reva - Remote Electronic Virtu...", "REVA", and "Complete your REVA registrati...". Below the navigation is a search bar with the URL "https://reva-dev.otsuka-us.com". On the left, the Otsuka logo is displayed. On the right, there are links for "iOS App", "Android App", "Clinician Log in", "Terms of Use", "Privacy Policy", "Disclaimer", and "Visit Otsuka". In the bottom left corner, there's a note: "Built by the Think Team. Otsuka Pharmaceutical Development & Commercialization, Inc. 'Otsuka - People creating new products for better health worldwide'".

### 10.1.35 FAQ

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Entity : REVA

Content Type: Detailed Design Specification

Document Title: REVA\_DDS

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The screenshot shows a web browser window for the REVA platform. The address bar displays the URL <https://reva-dev.otsuka-us.com/faq.html>. The page title is "How can we help you?". Below the title, there is a sub-instruction: "To help you find answers quicker, pick a category below". Three categories are listed in boxes:

- Subject**: Represented by a person icon. Description: "Learn how to manage patient requests with ease."
- Clinician**: Represented by a stethoscope icon. Description: "Learn how to manage patient requests with ease."
- Administrator**: Represented by a gear icon. Description: "Learn how to manage patient requests with ease."

On the right side of the page, there are two buttons: "Faq" and "Clinician Log in".

Otsuka	<p>Entity : REVA  Content Type: Detailed Design Specification  Document Title: REVA_DDS  Doc. No.: DDS-GLB-COMP-2022-0030-00001.001</p>
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## Subject

Subject Taking Photos and Submitting Update →

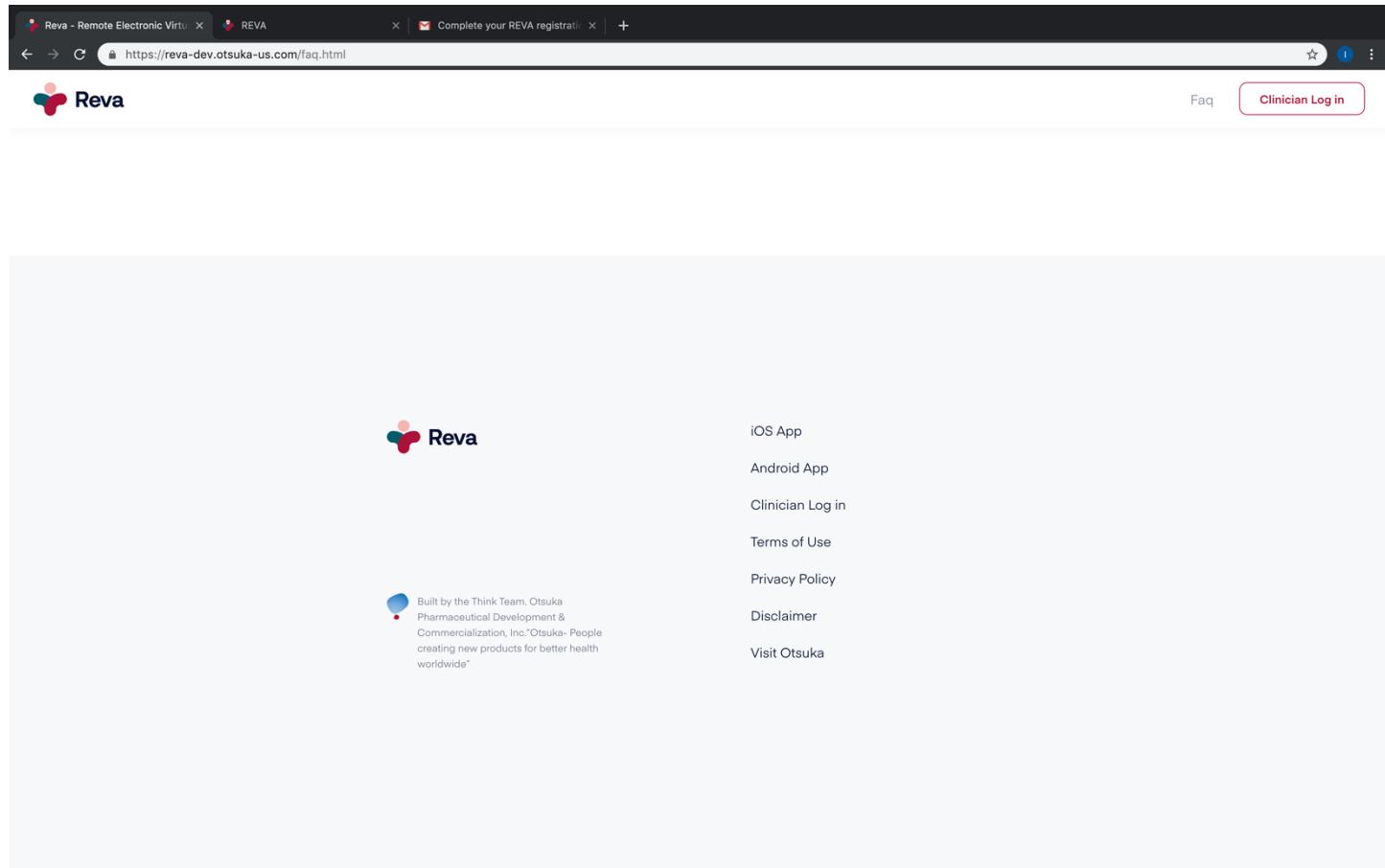
Subject Using Body Map →

Subject Answering Question →

Subject Documenting a Rash →

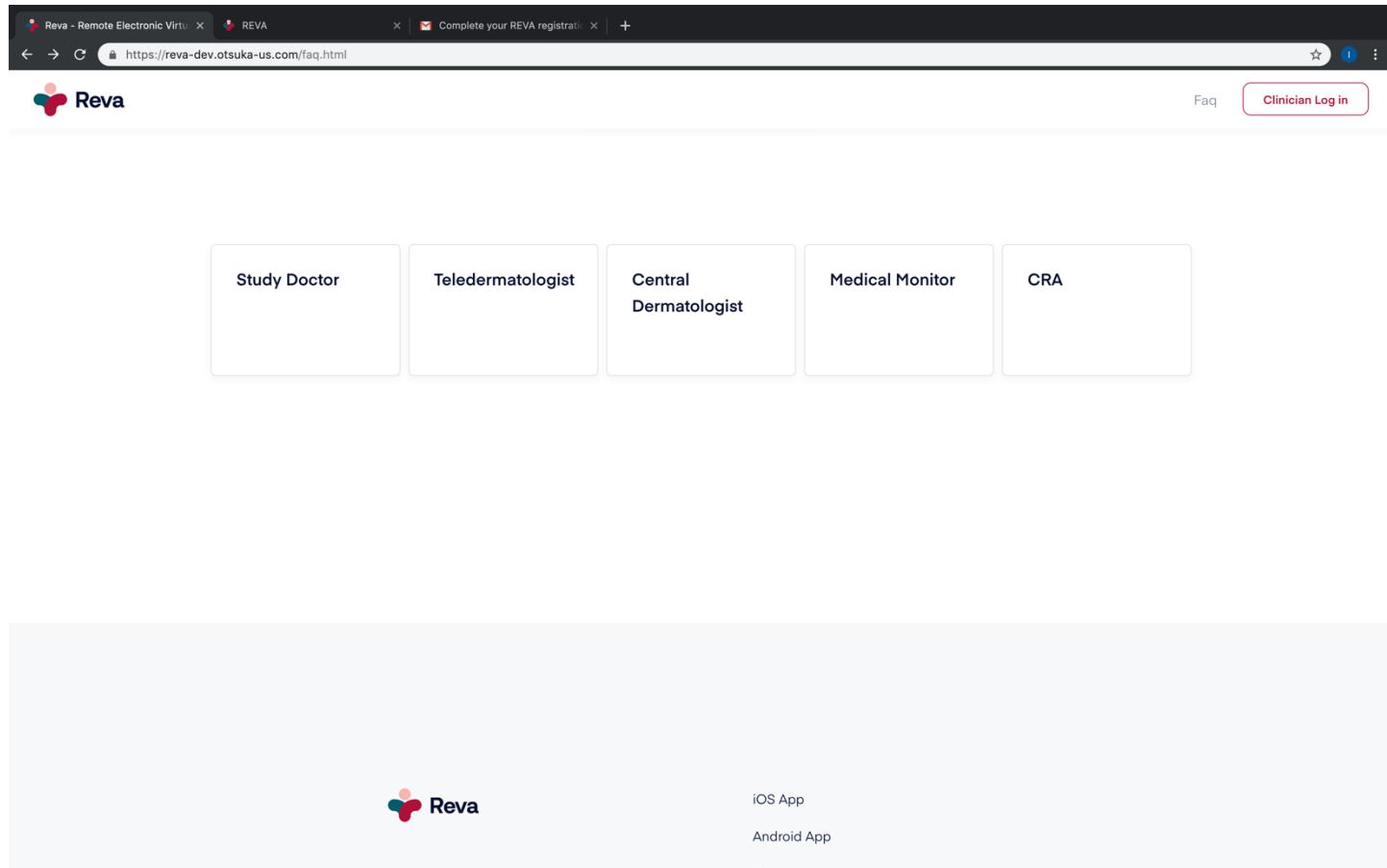
Subject Logging In →

	<p style="text-align: right;">Entity : REVA  Content Type: Detailed Design Specification  Document Title: REVA_DDS  Doc. No.: DDS-GLB-COMP-2022-0030-00001.001</p>
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The screenshot shows the Reva website at https://reva-dev.otsuka-us.com/faq.html. The page has a dark header with tabs for "Reva - Remote Electronic Virtu", "REVA", "Complete your REVA registrati...", and a "+" button. Below the header is a search bar and a "Faq" link. The main content area is mostly blank. At the bottom is a footer with the Reva logo, a paragraph about Otsuka, and links to "iOS App", "Android App", "Clinician Log in", "Terms of Use", "Privacy Policy", "Disclaimer", and "Visit Otsuka".

	<p style="text-align: right;">Entity : REVA  Content Type: Detailed Design Specification  Document Title: REVA_DDS  Doc. No.: DDS-GLB-COMP-2022-0030-00001.001</p>
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Note: In future versions of the application, the button that reads "Study Doctor" will read "Clinician".

Otsuka	Entity : REVA Content Type: Detailed Design Specification Document Title: REVA_DDS Doc. No.: DDS-GLB-COMP-2022-0030-00001.001
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## ← Administrator Hierarchy

Administrator

### Logging in

Go to the web dashboard portal at <https://reva.otsuka-us.com/admin-pages/users>. Enter your username and password. If you cannot remember your password, you can choose to reset it by following the prompts on the "Forgot password?" link on the login page

There are three levels of administrators in REVA:

- Local Administrators, associated with a given site
- Central Administrators, associated with a given trial
- System Administrators, associated with the REVA system

Duties of administrators depend on the level to which they are assigned.

1. System Administrators create each trial's record and the records of Central Administrators.
2. Central Administrators create records for the study sites, the Central Dermatologists, Tele-dermatologists, Medical Monitors, Clinical Research Associates (CRAs), and Local Administrators.
3. Local administrators create records for Study Doctors, Local Dermatologists, and Subjects, and

### 10.1.36 Statistics Dashboard

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The screenshot shows the Reva application's Statistics page. The left sidebar has a dark theme with the following navigation items:

- Admin
- Subject Details
- Statistics (selected)
- Usage Statistics
- Settings
- Help

The main content area has a light gray header with the Reva logo and a user profile for Ian Quinn. Below the header, the title "Statistics" is displayed. A red disclaimer message "Disclaimer: this feature is currently in its beta phase." is shown. A "SELECT A TRIAL" dropdown menu contains several trial names, with "Rohit's Trial" selected. A "Submit" button is next to the dropdown, and a "Export Rash reports to excel" button is to the right. The main data table is titled "All trials" and contains the following data:

SUBJECTS REGISTERED THIS WEEK	SUBJECTS REGISTERED THIS MONTH	SUBJECTS LOGGED IN RECENTLY	TOTAL SUBJECTS FOR THE TRIAL
0	0	0	10
RASH CASES REFERRED THIS MONTH	NEW RASH UPDATES THIS MONTH	RASH SUBJECTS FOR THE TRIAL	TOTAL RASH CASES
0 ▾	0 ▾	4 (40%)	19
RASH CASES WITHOUT TELEDERM REVIEW	REPORTED RASH CASES BY SUBJECT VS. CLINICIAN	SITES INVOLVED WITH THIS TRIAL	LOCAL ADMINS IN THIS TRIAL
13 ▾	17 (89%)	4 ▾	3
CLINICIANS LOGGED IN RECENTLY			
0			

SUBJECTS REGISTERED THIS WEEK:

users

RASH CASES REFERRED THIS MONTH:

rash\_reports

RASH CASES WITHOUT TELEDERM REVIEW:

rash\_reports

CLINICIANS LOGGED IN RECENTLY:

users

SUBJECTS REGISTERED THIS MONTH:

users

NEW RASH UPDATES THIS MONTH:

rash\_reports

REPORTED RASH CASES BY SUBJECT VS. CLINICIAN:

rash\_reports

SUBJECTS LOGGED IN RECENTLY:

users



Entity : REVA

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RASH SUBJECTS FOR THE TRIAL:

*rash\_reports*

SITES INVOLVED WITH THE TRIAL

*trials*

TOTAL SUBJECTS FOR THE TRIAL:

*users*

TOTAL RASH CASES:

*rash\_reports*

LOCAL ADMINS IN THIS TRIAL:

*users / sites / trials*

	<p style="margin: 0;">Entity : REVA</p> <p style="margin: 0;">Content Type: Detailed Design Specification</p> <p style="margin: 0;">Document Title: REVA_DDS</p> <p style="margin: 0;">Doc.No.: DDS-GLB-COMP-2022-0030-00001.003</p>
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## 10.2 Mobile App

### 10.2.1 Login

EN | ES | FR



#### Welcome to Reva,

To continue please  
sign in below

ID

Password

**Login**

[Forgot Password?](#)  
Call the clinic to reset it.

ID:

*users -> \_id*

Password:

*users -> password*



Entity : REVA

Content Type: Detailed Design Specification

Document Title: REVA\_DDS

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### 10.2.2 Set Password



## Set Password

Please enter a new password.

Password

Password must contain :

A lowercase letter,  
A captial(uppercase) letter,  
A number and Mininum 8 characters.

Confirm Password

Password and Confirm Password fields must ...

**Submit**

Password:

*users -> password*

Confirm Password:

*users -> password*



### 10.2.3 Consent

## Welcome

---

Welcome!

This app is a digital version  
of the traditional paper-  
based clinical workflow for  
submitting updates on rash  
condition.

As the rash changes, you  
can use the app to take  
photos and fill out  
questionnaire about it.

---

Cancel

Continue



Entity : REVA

Content Type: Detailed Design Specification

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## Disclaimer

**The APP does not give  
medical advice**

NO COMMUNICATION FROM THE APP TO YOU WILL INCLUDE OR CONSTITUTE MEDICAL ADVICE.

DO NOT IGNORE OR DELAY OBTAINING PROFESSIONAL MEDICAL ADVICE BECAUSE OF INFORMATION GATHERED THROUGH USE OF THE APP.

IN CASE OF A HEALTH EMERGENCY, CALL FOR EMERGENCY SERVICES (911) OR GO TO YOUR LOCAL EMERGENCY ROOM.

IF YOU HAVE TECHNICAL ISSUES REGARDING THE APP PLEASE CONTACT THE STUDY DOCTOR

IMMEDIATELY

Cancel

Continue



Entity : REVA

Content Type: Detailed Design Specification

Document Title: REVA\_DDS

Doc.No.: DDS-GLB-COMP-2022-0030-00001.003

Doc.No. DDS-GLB-COMP-2022-0030-00001.003 Approved On 20-Sep-2024 12:05:53 PM (EDT)

## Disclaimer

INFORMATION GATHERED  
THROUGH USE OF THE APP.

IN CASE OF A HEALTH  
EMERGENCY, CALL FOR  
EMERGENCY SERVICES (911) OR  
GO TO YOUR LOCAL EMERGENCY  
ROOM.

IF YOU HAVE TECHNICAL ISSUES  
REGARDING THE APP PLEASE  
CONTACT THE STUDY DOCTOR  
IMMEDIATELY.

IN ORDER TO BETTER PROTECT  
YOUR PRIVACY, AVOID  
INCLUDING IDENTIFYING IMAGES  
IN THE BACKGROUND OF YOUR  
PICTURE (E.G., PHOTOGRAPHS  
OF YOURSELF OR FAMILY  
MEMBERS IN THE BACKGROUND,  
DOCUMENTS WITH IDENTIFYING  
INFORMATION, TATTOOS, ETC).

Cancel

Continue



#### 10.2.4 Grant Consent

## CONFIRMATION OF CONSENT

I confirm that I have read, understood and agree to the Informed Consent for an Otsuka sponsored Clinical Trial and have signed the Consent Form. I further confirm that I have read and understood the informed consent's explanation of how my personal information will be collected by the REVA APP and used for the clinical study. I understand that to the extent there is any conflict between the Otsuka Privacy Policy (provided below) and the Informed

**Cancel**

**Agree**



Entity : REVA

Content Type: Detailed Design Specification

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## CONFIRMATION OF CONSENT

below) and the Informed Consent the Informed Consent shall control.

By selecting Accept and Continue, you agree to these terms.

If you have not signed an Informed Consent for an Otsuka Sponsored Clinical Trial or you do not agree to these terms, please click Cancel and Exit.

If you decide not to accept the above terms of use for the App you should contact the Study Doctor immediately.

**Cancel**

**Agree**

	Entity : REVA Content Type: Detailed Design Specification Document Title: REVA_DDS Doc.No.: DDS-GLB-COMP-2022-0030-00001.003
---	---

#### 10.2.5 Rash List

## Rash List

[?](#) [Logout](#)

**Rash started on:**  
**01/17/2019**  
First Noticed on: 1/16/2019





Rash Started on:

*rash\_reports -> dateTime\_created*

Instances: [X]:

*rash\_reports -> instances*



#### 10.2.6 Rash Details



## Rash Details

When did you first notice the rash?

Pick Date



Please select a Date

Before your rash started, did you have contact with someone else with a rash?

Yes

No

Exposure to dyes or toxins?

Yes

No

Any changes to (check all that apply)



Diet

**Continue**



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## Rash Details

- Diet
- Skin care products
- Clothing
- Detergent

---

On a scale of 0 to 5, with 0 being "none", 1 being "mild" and 5 being "severe", how would you describe the rash?

Itching



Burning



Tenderness



**Continue**



## Rash Details

Tenderness ▾

Is the rash (check all that apply)

- Scaly
- Peeling
- Spotty
- Bleeding
- Oozing

Color

**Continue**



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## Rash Details

Color

Red

Not Red

Texture

Raised

Flat

Any of the following symptoms?

Fever

Sore throat

Weight loss

**Continue**



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## Rash Details

- Weight loss
- Yellow eyes or skin
- Chest pain
- Dark urine
- Low energy
- Streaking
- Blistering

**Continue**

When did you first notice the rash?:

*rash\_reports -> instances -> [object] -> form -> first\_noticed*

 <b>Otsuka</b>	Entity : REVA Content Type: Detailed Design Specification Document Title: REVA_DDS Doc.No.: DDS-GLB-COMP-2022-0030-00001.003
--	---

Before your rash started...:	<i>rash_reports -&gt; instances -&gt; [object] -&gt; form -&gt; recent_contact_with_other_rash</i>
Recent exposure to dyes or toxins?:	<i>rash_reports -&gt; instances -&gt; [object] -&gt; form -&gt; recent_exposure_to_dyes_or_toxins</i>
Any changes to...:	<i>rash_reports -&gt; instances -&gt; [object] -&gt; form -&gt; changes</i>
On a scale of 1 to 5...:	<i>rash_reports -&gt; instances -&gt; [object] -&gt; form -&gt; itching</i> <i>rash_reports -&gt; instances -&gt; [object] -&gt; form -&gt; burning</i> <i>rash_reports -&gt; instances -&gt; [object] -&gt; form -&gt; tenderness</i>
Is the rash...:	<i>rash_reports -&gt; instances -&gt; [object] -&gt; form -&gt; rash_is</i>
Color:	<i>rash_reports -&gt; instances -&gt; [object] -&gt; form -&gt; color</i>
Texture:	<i>rash_reports -&gt; instances -&gt; [object] -&gt; form -&gt; texture</i>
Any of the following...:	<i>rash_reports -&gt; instances -&gt; [object] -&gt; form -&gt; symptoms</i>



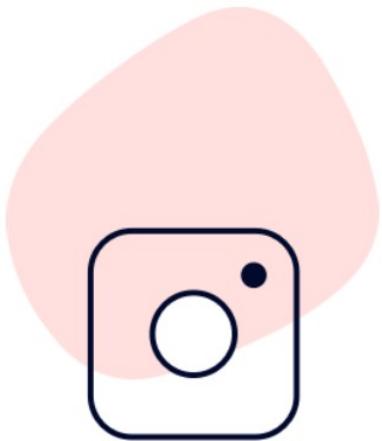
#### 10.2.7 Body Map

## Body Map



Select Body Part:

head\_front



No Photos uploaded.  
Please click on the  
"camera" icon to start  
taking photos.

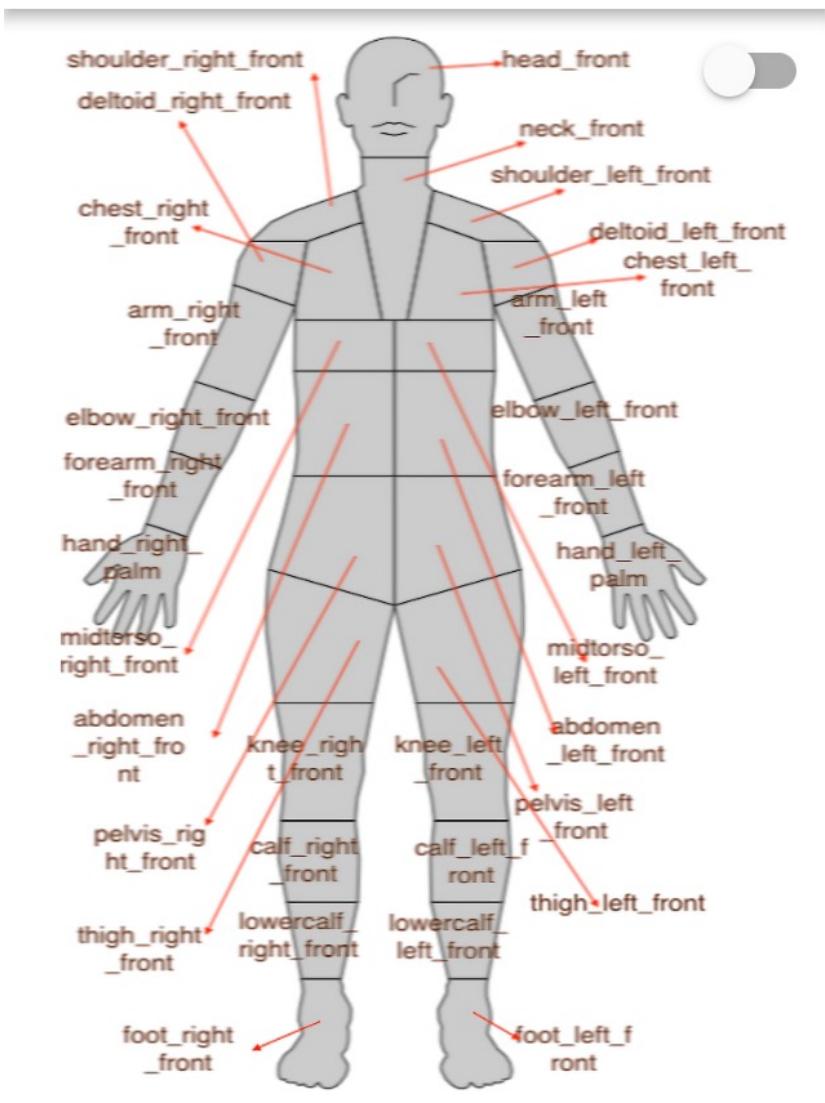


Submit

Image: rash\_reports -> instances -> [object] -> bodyPart\_images -> [object] -> image

#### 10.2.8 Body Map Help

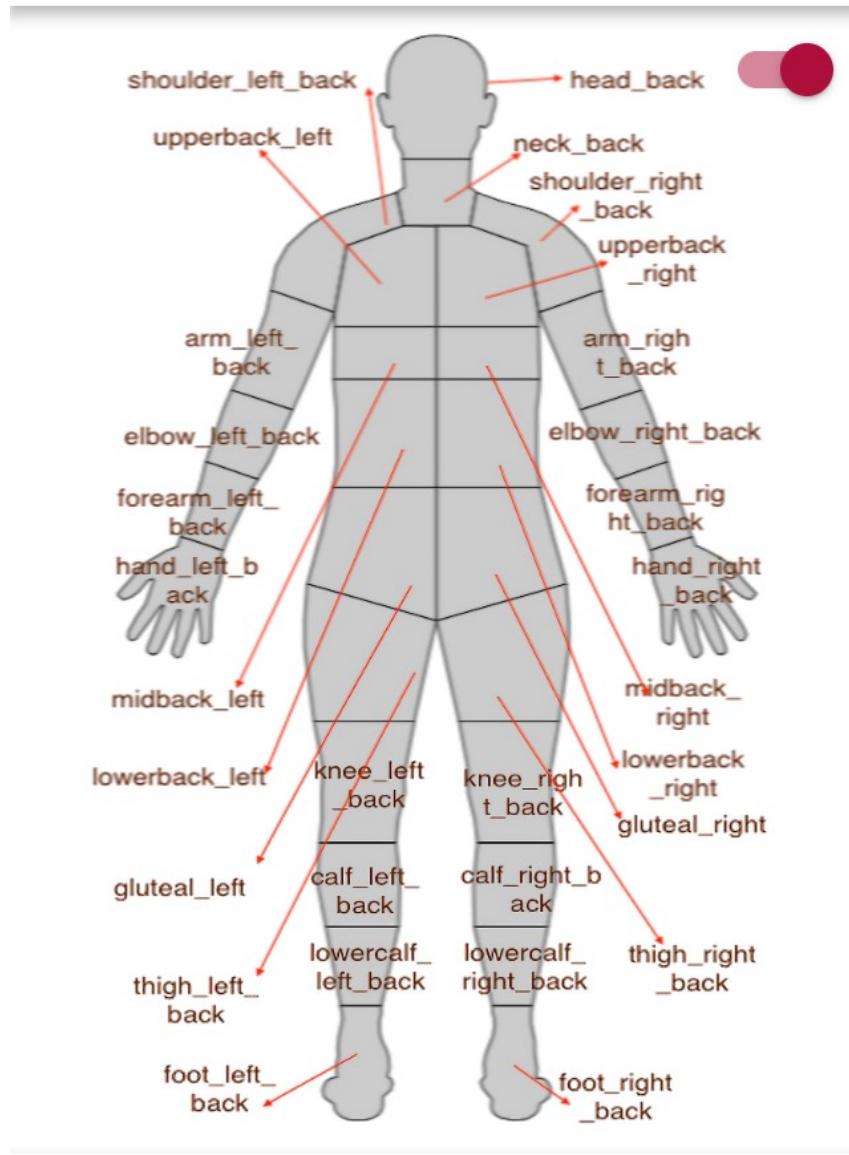
## Body Map Help



# Front

Toggle button to change view

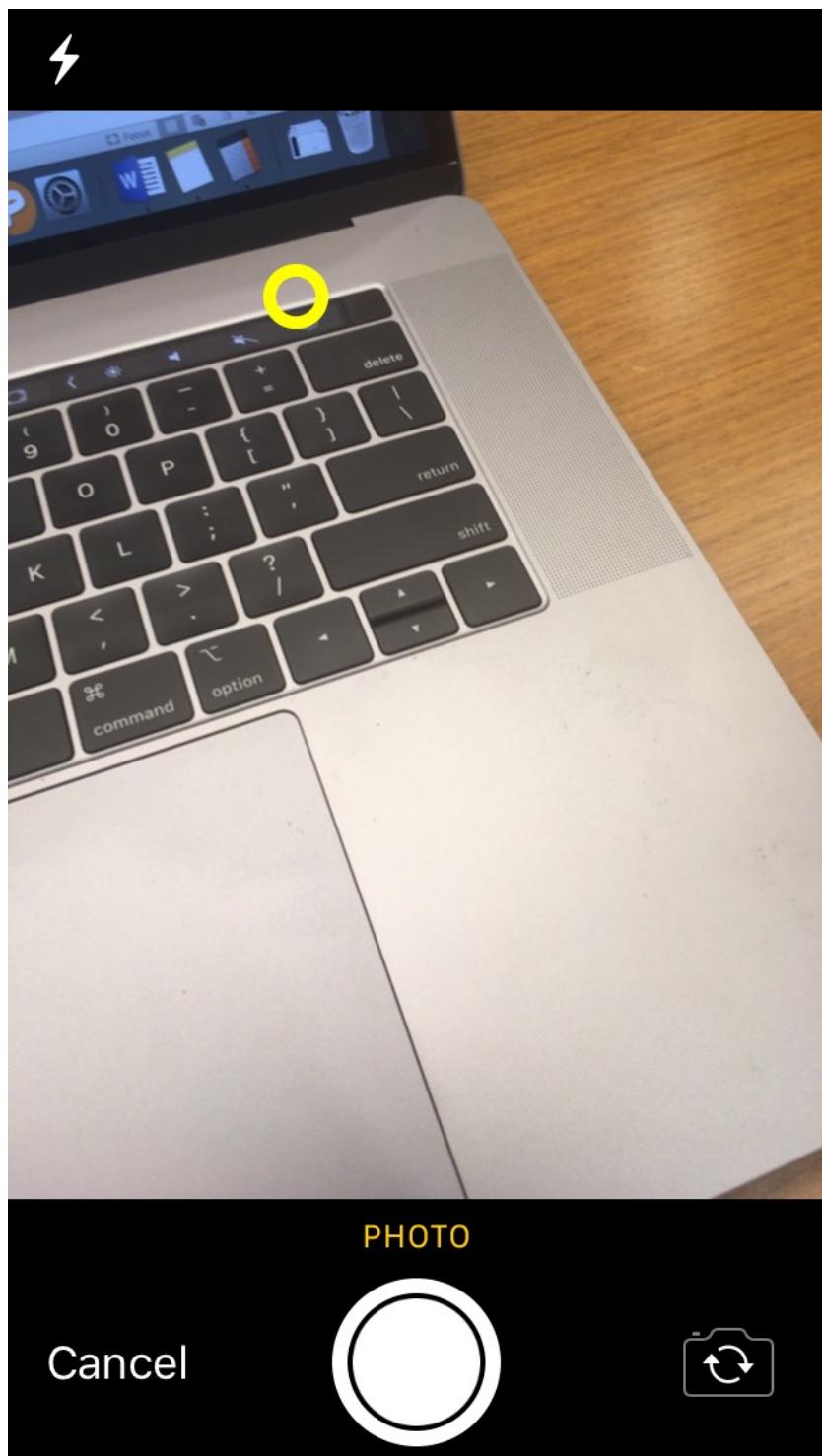
## < Body Map Help



## Back

Toggle button to change view

#### 10.2.9 Take Photo





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#### 10.2.10 Help

##### Reference Help

**Help**

←      **Body Map**      ?      ✓

Select Body Part:

head\_front

The "reference" drop-down contains several common objects.

Select one from the list and place it on your skin.

This object is for scale.

It's fine to hold it in place with your fingers, so long as the rash is visible.

Do not put the object over the center of the rash.

Submit

<      >

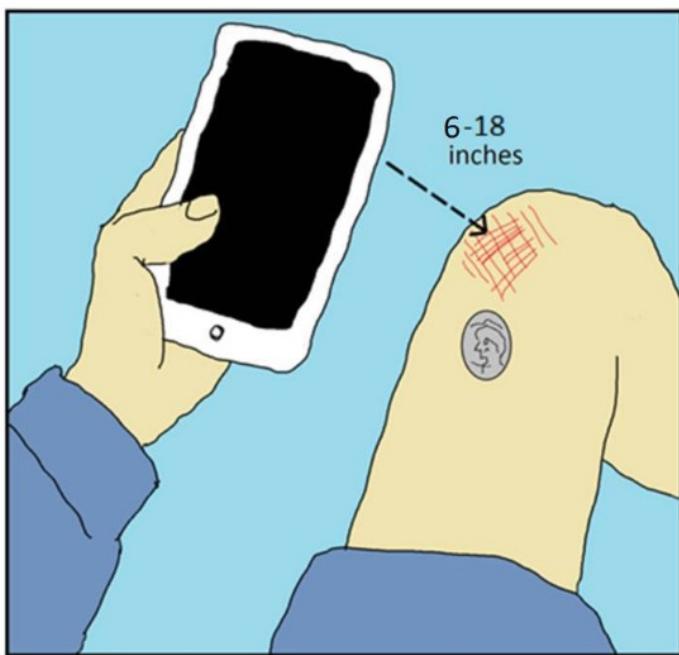
##### Distance Help



## Help

Hold the phone so that your rash is in frame. For your first photo, the phone should be about 18 inches from your skin, and about 6 inches for a close-up.

Use natural light if possible.



Position Reference Outline Help

<

## Help

Using your touchscreen, drag the outline so that it is on top of your reference object.



<

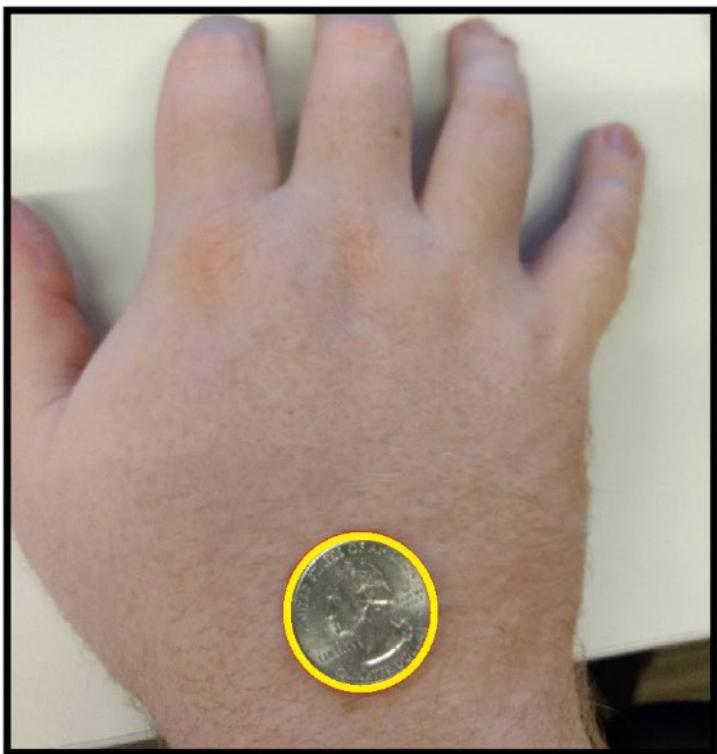
>

**Position Reference Outline Help II**

&lt;

## Help

Move the phone closer or farther away until the outline and the reference object appear to be the same size.



&lt;

&gt;

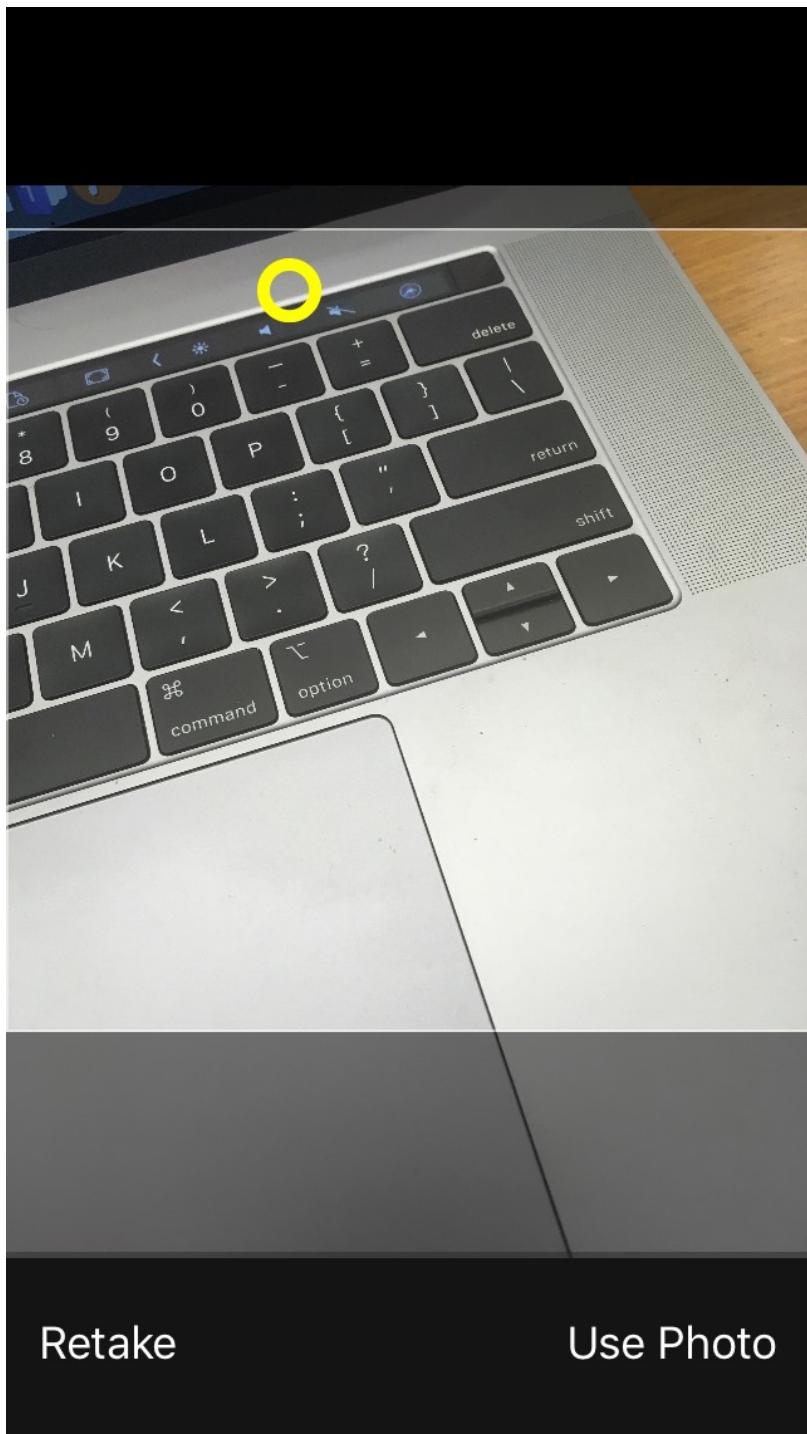
**Take Photo with Reference Object Help**



## Help



### 10.2.11 Photo Options





#### 10.2.12 Update Rash



## Update Rash

Is the rash spreading or getting more severe? For example, does the rash have new bumps, worse itching, or darker color?

Yes

No

**Continue**



## Update Rash

Is the rash spreading or getting more severe? For example, does the rash have new bumps, worse itching, or darker color?

Yes

No

Has the rash resolved?

Yes

No

**Continue**

Has the rash resolved?:

rash\_reports -> resolved



## Update Rash

Is the rash spreading or getting more severe? For example, does the rash have new bumps, worse itching, or darker color?

Yes

No

Has the rash resolved?

Yes

No

When did you last notice the rash?

Pick Date



Submit

When did you last notice the rash?:

*rash\_reports -> last\_observed*

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## 10.2.13 Clinician Home

Logout

**Clinician Home**

---

2

**subj9**  
Trial: 331-201-00182

---

0

**subj11**  
Trial: 31-14-204

---

Subject header:                   *users -> \_id*  
Trial:                              *users -> trial*



Entity : REVA

Content Type: Detailed Design Specification

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#### 10.2.14 Spanish screens

← Mapa del cuerpo ? ✓

Elegir parte corporal:  
cabeza\_anterior ▾

El menú desplegable "referencia" contiene varios objetos comunes.  
Seleccione uno de la lista y colóquelo sobre la piel.  
Este objeto sirve para determinar la escala.  
Está bien sostenerlo en posición con los dedos, siempre y cuando el sarpullido quede visible.  
No coloque el objeto sobre el centro del sarpullido.

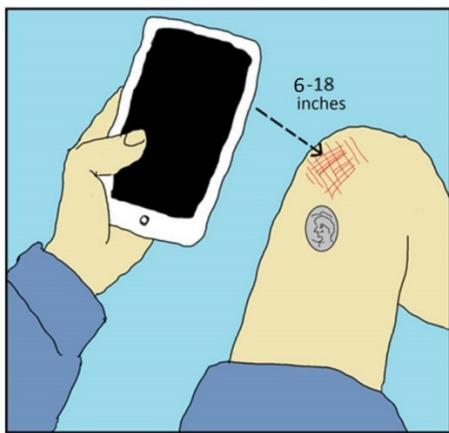
?

X

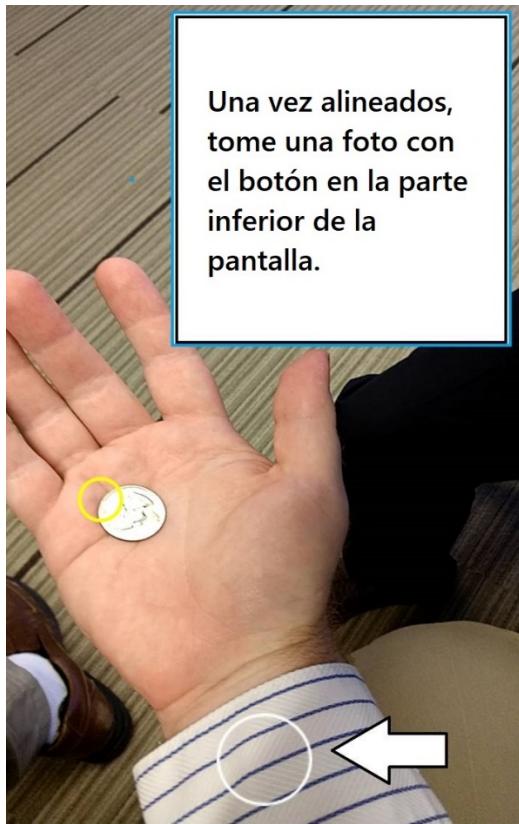
Submit

Sostenga el teléfono para que el sarpullido quede enmarcado. Para su primera foto, el teléfono debe estar a una distancia de unas 18 pulgadas de la piel y a unas 6 pulgadas para un primer plano.

Utilice luz natural si es posible.



Usando su pantalla táctil, arrastre el contorno para que quede encima de su objeto de referencia.





### 10.2.15 Email Description Medical Monitor and Telederm/Central Dermatologist.

REVA Rash Update for Subject TEST 2023 - Dhiman-CW, Ajay 18987 - Outlook - Google Chrome  
① about:blank

REVA Rash Update for Subject TEST 2023

revva@otsuka-us.com  
To: Dhiman-CW, Ajay 18987  
Wed 7/26/2023 12:22 PM

A review of the rash report has been submitted by the Medical Monitor.

To review, please log into the REVA web dashboard at: <https://jpn01.safelinks.protection.outlook.com/?url=https%3A%2F%2Freva-dev.otsuka-us.com%2F&data=05%7C01%7Cajay.dhiman-cw%40otsuka-us.com%7C4ba5ca46690f42171ef308cb8da4e5b7%7C34ddb3397fd04f009041c2e47fbcc9f4%7C0%7C638259511593423267%7CUnknown%7CTWFpbGZsb3d8eyJWljojMC4wLjAwMDAiLCJQjoiV2luMzliLCBTii6lk1haWwiLCJXVCi6Mn0%3D%7C3000%7C%7C%7C&sdata=%2FjkZAnKp7TbYG0s8iLeV71uoyAsOTuOjtPg7Mxwwr1Y%3D&reserved=0>.

Submitted for: TEST 2023  
Submitted by: clin.komanduri.rohit@gmail.com  
Case: 1

Reply Forward

REVA Rash Update for Subject TEST 2023 - Dhiman-CW, Ajay 18987 - Outlook - Google Chrome  
① about:blank

REVA Rash Update for Subject TEST 2023

revva@otsuka-us.com  
To: Dhiman-CW, Ajay 18987  
Wed 7/26/2023 12:18 PM

A review of the rash report has been submitted by the Telederm/Central Dermatologist..

To review, please log into the REVA web dashboard at: <https://jpn01.safelinks.protection.outlook.com/?url=https%3A%2F%2Freva-dev.otsuka-us.com%2F&data=05%7C01%7Cajay.dhiman-cw%40otsuka-us.com%7C5c19d1e046f4ec84b4008db8da458db%7C34ddb3397fd04f009041c2e47fbcc9f4%7C0%7C638259509232489934%7CUnknown%7CTWFpbGZsb3d8eyJWljojMC4wLjAwMDAiLCJQjoiV2luMzliLCBTii6lk1haWwiLCJXVCi6Mn0%3D%7C3000%7C%7C%7C&sdata=0u8ldDEUC3vfZFXohQkL%2FohEqDH6mvDJFmxUeNogNg%3D&reserved=0>.

Submitted for: TEST 2023  
Submitted by: clin.komanduri.rohit@gmail.com  
Case: 2

Reply Forward



	<p style="margin: 0;">Entity : REVA</p> <p style="margin: 0;">Content Type: Detailed Design Specification</p> <p style="margin: 0;">Document Title: REVA_DDS</p> <p style="margin: 0;">Doc.No.: DDS-GLB-COMP-2022-0030-00001.003</p>
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## 11 Code Management / Configuration Management

Source code will be developed, managed, and maintained through a git repository residing on Haldane. Code will be maintained in two main versions: development and production. The development version will comprise the merged contributions of all developers. The production version will be used to run the live application. A development version will become the production version after changes in the development version have been reviewed, approved, tested, and validated.

## 12 Coding Standards

Naming conventions:

1. Variable and function names will be written in camel case: *thisVariableName*
2. Module names will be written as follows: *ThisModuleName*
3. For other standards followed during development, refer to the Code Review Checklist

Technology used to build system:

1. RHEL: The operating system of the server
2. MongoDB version 7.0: The database software
3. NodeJS v20.17.0: The server-side REST API framework
4. AngularJS v16.2: The web application development framework
5. Flutter: The mobile application development framework

## 13 Acronyms, Abbreviations and Definitions

Acronym or Abbreviation	Expansion or Definition
DDS	Detailed Design Specification
FRS	Functional Requirements Specification
GQS	Global Quality System
ODS	Otsuka Data Sciences
OPDC	Otsuka Pharmaceutical Development & Commercialization Inc.
REVA	Remote Electronic Virtual Assessment
R&D	Research & Development
URS	User Requirements Specification
VP	Validation Plan

**\*END OF DOCUMENT\***