



# Site User and Investigator User Guide

Cenduit Interactive Response Technology  
(C.I.R.T.)

System Instructions for

**Regeneron  
RECOVERY**

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# 1. General Information

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**Regeneron** has contracted Cenduit, LLC to provide clinical trial management support in three key areas:

1. Subject Management
2. Drug Supply Management
3. Reporting

## IWRS

Cenduit's Interactive Response Technology, or C.I.R.T., is deployed on a study-by-study basis to provide:

- **I**nteractive **W**eb **R**esponse **S**ystem (**IWRS**) – System transactions occur over the internet.\*

\*Based on testing and validation, Cenduit strongly recommends that IWRS users access C.I.R.T.'s web interface using Internet Explorer 9.0 or higher. Other browsers will work with C.I.R.T. however, Cenduit cannot be certain of how the system will interact on an on-going basis.

## 2. Global Helpdesk

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### **Cenduit's Global Helpdesk is available:**

- ✓ 24 hours a day, 365 days a year.
- ✓ by telephone or e-mail.
- ✓ in English, but live translation is available.

A complete listing of [CENDUIT CONTACT INFORMATION](#) for this study is at the end of this guide. Do not hesitate to contact us with **any** questions regarding:

- Login difficulties
- Failed or rejected transactions
- Incorrect data entry
- Assistance performing a transaction
- Unknown transaction status

**Never repeat** a transaction as it may cause duplicate entries in the system. Please call the Global Helpdesk first.

### **Keep the following information available when contacting Cenduit:**

Protocol: RECOVERY

Study ID Number (XXXX): 8030

Site Number:

C.I.R.T. User's 8-Digit Account Number:

Your **Direct\*** Telephone Number:

\*If your call is disconnected, Cenduit will call you back at the direct telephone number specified above.

## 3. Getting Started

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### User Credentials



When the study begins, Cenduit will send an email with user account information to all C.I.R.T. users.

Each user will receive a:

1. 8-digit Account Number
2. Temporary Password

When you receive a temporary password, you must change this credential immediately when you access C.I.R.T. for the first time. Once you have established a password, it must remain **confidential**.

### Login - Internet Passwords

1. If you are accessing C.I.R.T. via internet, go to <https://iwr.cenduitsolutions.com/IRT>.



en | fr | es | de | zh | ja | ru |

Account Number

Password

LOG IN

Having trouble logging in?

Enter your 8-digit account number.

Enter your temporary password.

2. Configure your email address.

It is important to enter your email address at the first login in order to be able to use the “Forget Password” functionality and reset the password by yourself when needed.

**USER NOTICE**

TO PROVIDE BETTER CUSTOMER SERVICE TO OUR USERS, CENDUIT NOW REQUIRES AN EMAIL ADDRESS AND SECURITY QUESTIONS FOR ALL USERS. THIS WILL PROVIDE AN ADDITIONAL LAYER OF SYSTEM SECURITY AND ALLOW USER TO RESET THEIR PASSWORD THROUGH THE AUTOMATED "FORGET PASSWORD" FEATURE.

+ **CONFIGURE YOUR EMAIL ADDRESS**

❖ Enter your email address and confirm your entry

**USER NOTICE**

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← **CONFIGURE YOUR EMAIL ADDRESS**

Please provide your email address.

Enter your email address.

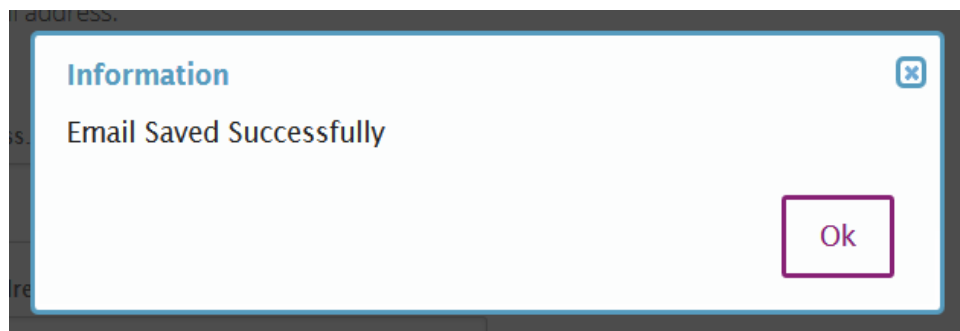
  

Confirm your email address.

**Submit**

❖ Your email will be saved in the system



3. Enter you security question to help in case you forget your password.

**USER NOTICE**

TO PROVIDE BETTER CUSTOMER SERVICE TO OUR USERS, CENDUIT NOW REQUIRES AN EMAIL ADDRESS AND SECURITY QUESTIONS FOR ALL USERS. THIS WILL PROVIDE AN ADDITIONAL LAYER OF SYSTEM SECURITY AND ALLOW USER TO RESET THEIR PASSWORD THROUGH THE AUTOMATED "FORGOT PASSWORD" FEATURE.

**— CONFIGURE YOUR QUESTION AND ANSWER PROFILE**

Provide answer for any one of the questions and make sure you remember your answer, because the question will be used later to allow you to reset your forgotten password and unlock your account

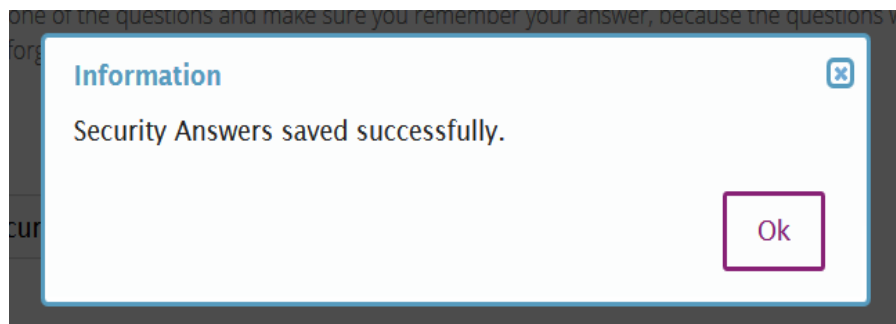
Security Question

Security Answer

Confirm Answer

Select a question  
Enter your answer  
Confirm your answer

The system will display once the security question has been saved successfully.



4. Configure your new password

**— CONFIGURE YOUR PASSWORD**

Password length should be between 8 and 10. Password should contain the following combinations. 1 character(s) from [a-z], 1 character (s) from [A-Z], 2 character(s) from [0-9].

Password:

New Password:

Confirm Password:

Enter old password

Enter New Password

Confirm New Password

**Passwords must contain at least 8 to characters and include:**

- ✓ 1 uppercase letter characters
- ✓ 1 lowercase letter
- ✓ 2 numbers
- ✓ 1 uppercase letter
- ✓ 1 lowercase letter

5. Log in again using your new password. The Main Menu will appear. Move your mouse over the word **STUDIES** and select the protocol number.

Action

Select Action

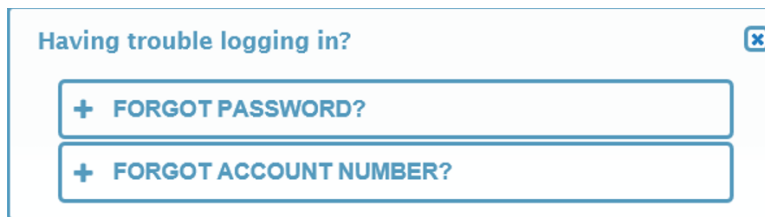


## Remember!!

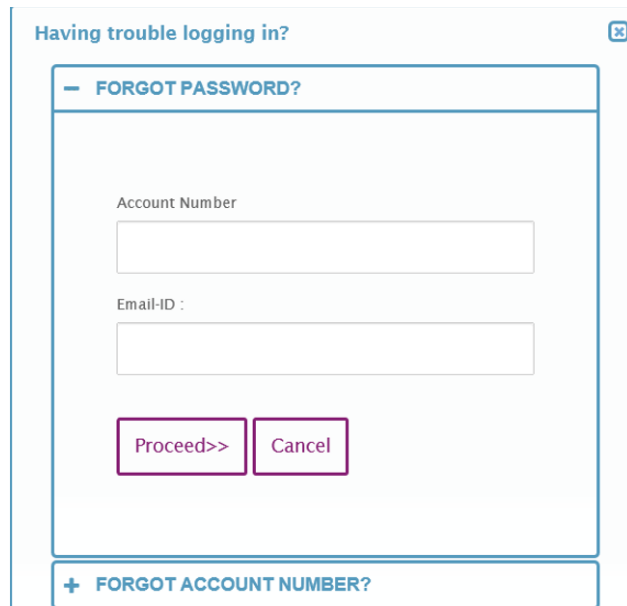
- ❖ If you forget your password, click on “Having trouble logging in”



The following screen will appear. Click on the issue that you are facing:

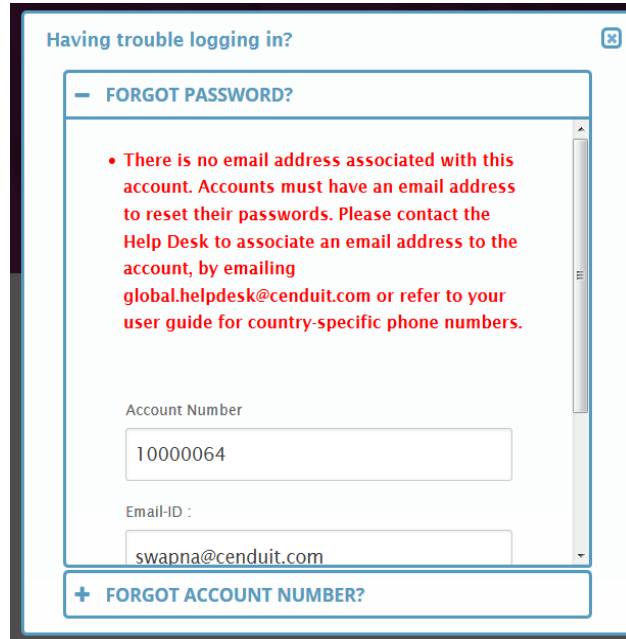


- ❖ If you forget your password, the following screen will appear

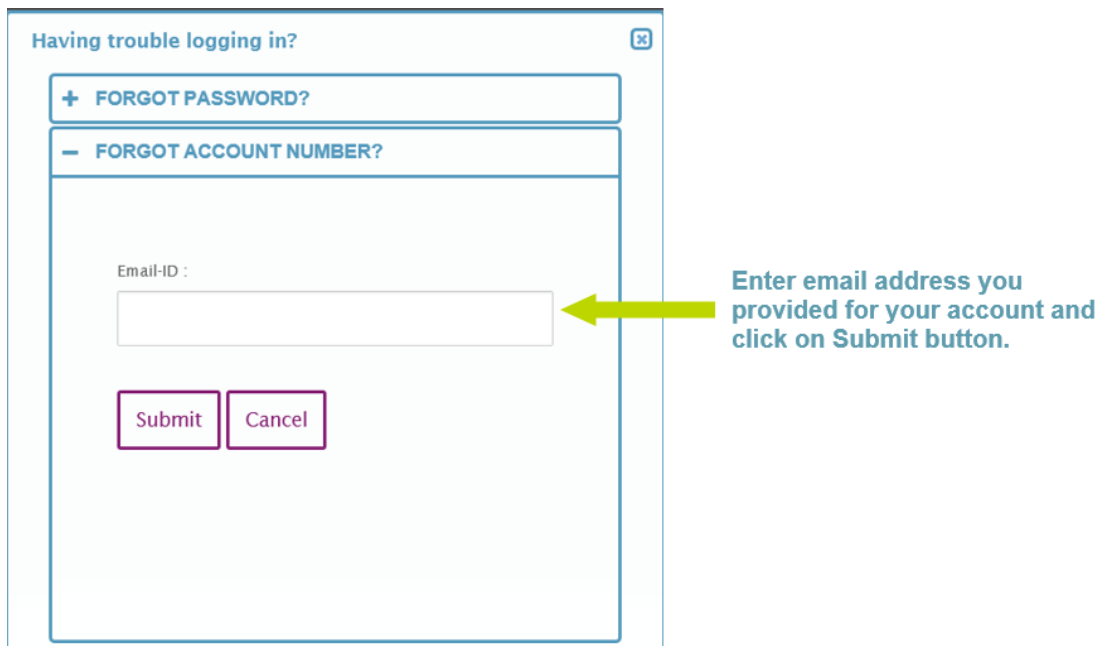


Your password will be emailed to the recovery email address provided by you to Cenduit.

**IMPORTANT:** Ensure that you enter your email address at your first login in. Otherwise you will receive the below error message (in red). In this case, please contact the HelpDesk in order to reset your password



❖ If you forget your account number, the following screen will appear



**IMPORTANT:** Ensure that you enter your email address at your first login in. Otherwise you will receive the below error message (in red). In this case, please contact the Helpdesk in order to reset your password

Having trouble logging in?

+ FORGOT PASSWORD?

- FORGOT ACCOUNT NUMBER?

- The email address is incorrect or there is no account associated with this email address. Accounts must have an email address to reset their passwords. Please contact the Help Desk to associate an email address to the account, by emailing [global.helpdesk@cenduit.com](mailto:global.helpdesk@cenduit.com) or refer to your user guide for country-specific phone numbers.

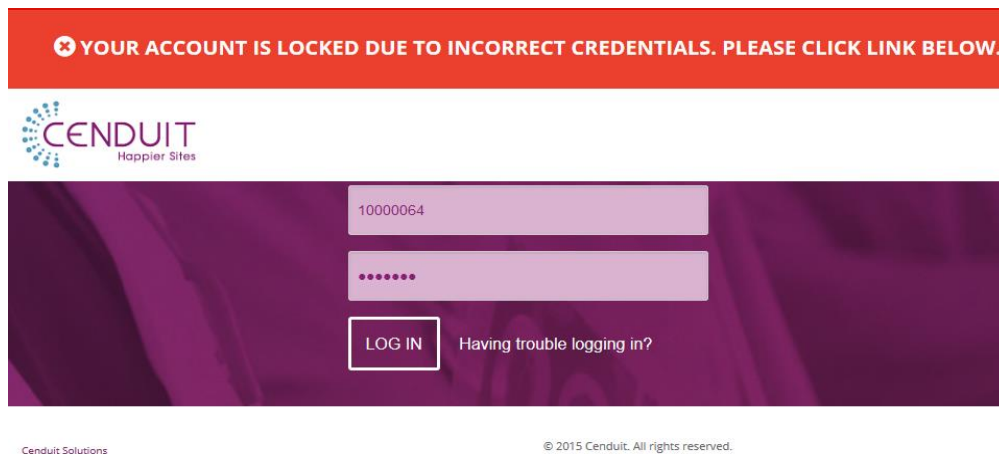
Email-ID :

xxxxx@cenduit.com

Submit Cancel

Your account number will be emailed to the recovery email provided by you to Cenduit

- ❖ If you enter your password incorrectly **3** times, your account will be **locked**.



- ❖ If this happens, an email will be sent to the email address recorded with your account number. You can do one of the following to have your password reset.
  - 1) Follow the instructions on the previous page for “Forgot Password”

2) Contact the Global Helpdesk in order to unlock your account. Then a temporary password will be emailed to you.

- ❖ Passwords Expire every 90 days
- ❖ If password expires, your account will be locked. If this happens, you will need to contact the Global Helpdesk in order to **RESET** your account. Then a temporary password will then be emailed to you.
- ❖ You can also change your password using the feature shown on the Website, roll the mouse over your username in the top right corner of the page.

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+ CONFIGURE YOUR QUESTIONS AND ANSWER PROFILE

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+ CONFIGURE YOUR PASSWORD

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## 4. System Basics

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### Web Data Entry

The web-based interface for C.I.R.T., IWRS, is a question and answer format. Answer each question, one at a time, then press **NEXT PAGE**. If, at any time during form entry, you make a mistake, press the **PREVIOUS PAGE** button to return to the error and correct it.

Responses will be requested in one of the following formats:

- **Drop-down Lists** – Select an item from the drop-down list.
- **Calendars** – Select a date such as a date of birth by selecting the YEAR first, the MONTH next, and the DAY last. Dates may only be entered in this order.
- **Text Entry** – Enter the information into the text box.

When all of the answers for a form have been provided, you will be required to review all of the information. If correct, select **SUBMIT** and the transaction will be posted to the system's database. If incorrect, select **PREVIOUS PAGE** to return to the error and correct it.

Users should open the CIRT2 system in a unique web page (not in several web tabs) and transactions should be performed one at the time.

You will receive a confirmation of all transactions on-screen and by email (from [noreply@cenduitsolutions.com](mailto:noreply@cenduitsolutions.com)) or fax within 5 minutes of submission. **Please keep printed confirmations with your source documentation.** If you do NOT receive a confirmation, please ensure your fax machine is turned on and operational, check your spam and junk/bulk email folders or contact the Global Helpdesk. A Global Helpdesk Associate can send the confirmation again.

## Site Material Status Update Form

This form is to be used to manage the kit statuses available at site. The below are the possible questions contained within the form.

QUESTION	RESPONSE OPTIONS
<p>What would you like to do? (One or more options can be selected)</p>	<ul style="list-style-type: none"> <li>• Record Allocated to Subject kit(s) from Site stock</li> <li>• Record Site stock temperature excursion</li> <li>• Record damaged kit(s) from Site stock</li> <li>• Record lost kit(s) from Site stock</li> </ul>
<p>Please select the kit number(s) that were allocated to the subject: (Only applicable if allocated to subject was selected in the first question)</p>	<p>Choose one or more kit numbers from the list</p>
<p>Please select the kit number(s) under temperature excursion: (Only applicable if temperature excursion was selected in the first question)</p>	<p>Choose one or more kit numbers from the list</p>
<p>Please select the damaged kit number(s): (Only applicable if damage kits was selected in the first question)</p>	<p>Choose one or more kit numbers from the list</p>
<p>Please select the kit number(s) that were lost: (Only applicable if damage kits was selected in the first question)</p>	<p>Choose one or more kit numbers from the list</p>

## Web Errors

If you discover an error after pressing **SUBMIT**, please use the **printed confirmation** to communicate the error to the Global Helpdesk:

1. Cross through the error with a single line and initial and date the crossed-out information.
2. Write the correct data on the confirmation.

3. Fax or e-mail the corrected confirmation to the Global Helpdesk using the [CENDUIT CONTACT INFORMATION](#) at the end of this guide.

## System Transaction Responses

For each transaction entered in the C.I.R.T. system, you will receive a confirmation on-screen for transactions completed via the web, over the phone for transactions completed via the phone, and via email and/or fax for all transactions. This confirmation will indicate that the transaction was either SUCCESSFUL or REJECTED.

SUCCESSFUL response indicates that the transaction was successfully recorded in the C.I.R.T.

- Example1: a successful response, which reads, "SITE MATERIAL UPDATE STATUS SUCCESSFUL" only indicates that the Site Material Update Status transaction was successfully recorded in the C.I.R.T.

REJECTED response indicates that the transaction was NOT successfully recorded in the C.I.R.T.

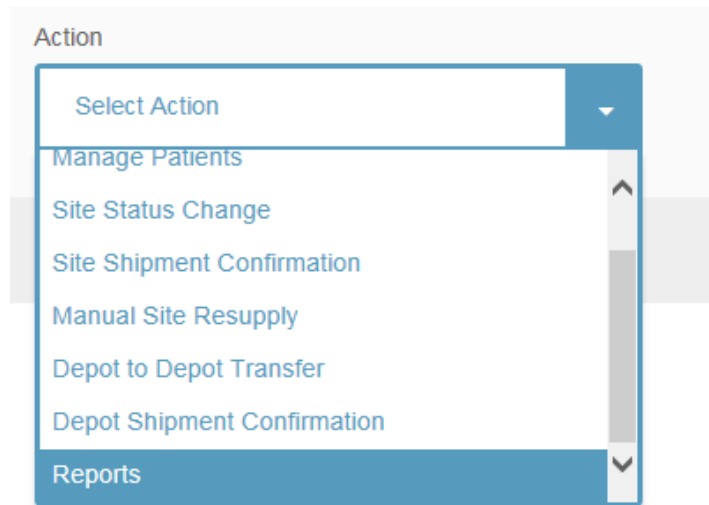
- Example: a rejection response, which reads, "SITE MATERIAL UPDATE STATUS SUCCESSFUL" only indicates that the Site Material Update Status transaction was not successfully recorded in the C.I.R.T.

# 5. Reports

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## Accessing Reports

1. Select Reports from the Home screen





2. Select the Report that you would like to view

Site Status Detail Report

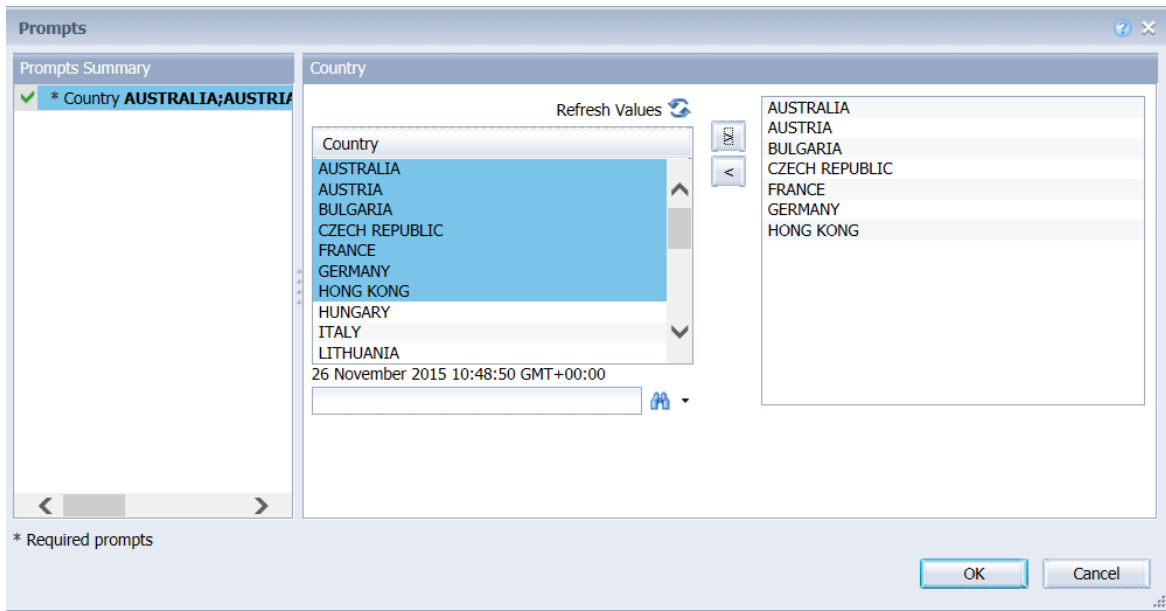
View

Patient Overview Report

View


3. If the report contains filtering parameters, a dialog box will appear.
  - ✓ Select the values from the list box on the left and move them to the list box on the right by pressing the  button. You can also double-click on the values.
  - ✓ You can also search for a specific value using by typing it in the text box and then clicking on the  button.
  - ✓ Select "OK".

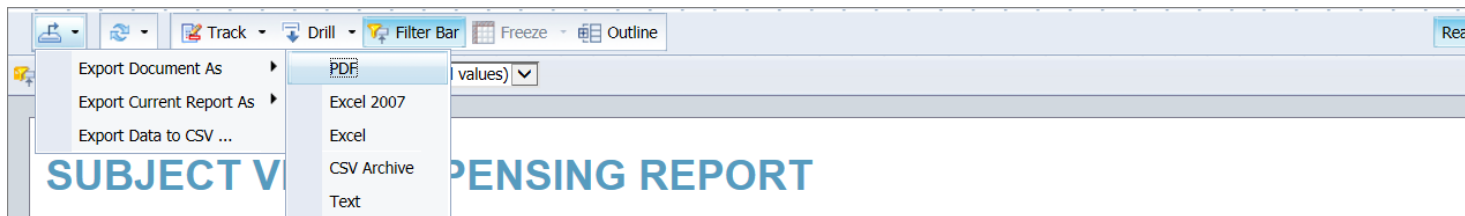




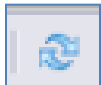
## Exporting Reports

Reports can be exported to PDF, Excel or CSV format:

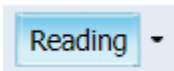
1. Click on the  icon located in the top left corner above the report.
2. Select, "Export Document As" → PDF, Excel 2007, Excel, CSV Archive or Text as shown below.



## Reporting Tools




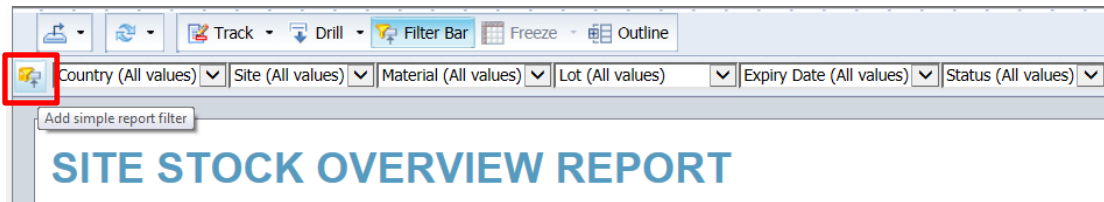
In the report view, select this icon at the top right to return the latest results from the database.



By clicking on the 'Reading' drop down list you will be able to view the report in PDF format without having to save it. This will allow you to print the report for instance. Selecting HTML format will bring you back to the original view.

## Adding Filters

For some reports filters will already be available but if it is not the case or if you would like to add additional filters; simply click on the  icon that is located in the top left corner above the report. These filters will allow only you to see the data you are interested in and to export only these data.



## Report Descriptions

At the Main Menu Screen, select the **'Reports'** option in the menu and a list of reports will appear. The following reports (with examples) will be available.

### Unblinded Site Stock Overview

#### Site User, Investigator

COUNTRY	SITE NUMBER	MATERIAL	LOT NUMBER	EXPIRY DATE	ON SITE	QUARANTINED	IN TRANSIT	DISPENSED	DAMAGED	EXPIRED	OTHER
CANADA	12345	REGN109 33 20R Vial	203548/1	31- Dec- 2021	10	4	6	12	3	0	1

## 6. Cenduit Contact Information

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### Cenduit International Telephone List – IWRS

Country	Toll-free Global Helpdesk	IVRS
United Kingdom	00-800 1012 1960	00-800 0809 1995

### Corrections Fax Numbers

International	US Direct	Toll-free US and Canada
+44 140 334 2317	1-610-871-0700	1-866-443-3228

### E-mail Address

[global.helpdesk@cenduit.com](mailto:global.helpdesk@cenduit.com)

### Website for Transactions

<https://iwr.cenduitsolutions.com/IRT>.

### Direct Global Helpdesk

Toll-Free United States and Canada: 1-877-253-3080

Universal Free EU: 00-800-1012-1960

Direct-Dial United States and Canada: 1-610-871-0150

Direct-Dial United Kingdom: +44 140 334 2316

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English	21-Sep-2020	0.2	Benjamin Davis	Removal of subject management, updated studyID Code
English	22-Sep-2020	0.3	Benjamin Davis	Added Site Material Status Update questions/answers; Removed references to screening
English	23-Sep-2020	1.0	Benjamin Davis	Versioned for approval