Accessing the RDC Support Website

Study access and support for RDC is through the RDC Support Website:

http://rdcsupport.biogenidec.com

The website provides:

1) **Bulletins**
   Informational Updates for RDC Onsite

2) **Getting Started**
   Where to go for
   a. **Training**
   b. **Requesting Accounts**

3) **RDC Onsite Login**
   Where to log into RDC Onsite studies

4) **RDC Support**
RDC Support Center

The RDC Support Center can help with...

- Difficulty logging in to RDC
- Account password resets
- Trouble with network connections
- RDC performance problems
- RDC messages

Report RDC issues right away to receive help for...

- Equipment needs
- Technical problems
- Data Entry problems

RDC Support Center supports only RDC and not...

- IVRS
- Clinical Portals
- Non-Biogen Idec Studies
- Clinical Site IT structure
Getting an RDC Account

To do work in RDC a potential user must get a user account.

1) **Notify**
   Site users should inform the site CRA that there are new users

2) **Train**
   Complete the RDC Computer Based Training

3) **Register**
   Register training by submitting a Training Completion Form

4) **Request**
   Request access to the study by submitting an Account Request Form

Once an account is requested it will take up to **FIVE business days** for the user to receive their account information.
RDC Compliance

- Biogen Idec RDC is to be used only for purposes designated by Biogen Idec
- Users will not share usernames and/or passwords
- Users will log out of the system when not in use
- Users will use RDC in adherence to 21 CRF Part 11 (Electronic Records; Electronic Signatures)

Violations of this agreement will result in:
- Loss of RDC privileges
- A Remediation Plan
Changing Your Password

How to manually change your password:

- Click in the **Old Password** box and enter the old password.
- In the **New Password** box, enter the new password.
- In the **Confirm Password** box, re-enter the new password.
- Click **Apply**.
Accessing your study

You will access your study through the RDC Support website. When logging in to RDC, there are a few things to remember:

- Passwords are not case sensitive, but must start with a letter and may include numbers.
- Your password should be 6-10 characters in length.
- You are prompted to change the initial password upon first time login.
- Passwords will expire every 90 days and cannot be reused.
- Your account will be locked after three unsuccessful log-in attempts due to erroneous username or password entries.

Contact the RDC Support Center for any account or technical issues.
Logging out of RDC

**Important:** Always use the OC RDC Logout option.

**Do not use the browser's standard close button** as this only closes the browser window but does not properly log you out of RDC.

Before logging out ensure that you save your work and close any open eCRFs.

**NOTE:** RDC will automatically log you out after **30 minutes** of inactivity. Any data that has not been saved will be lost.
The Blank Casebook Report creates a hard copy of the casebook. The report output is similar to the PDR, but no patient data is included.

**Note:** A generic report is generated when the patient number is left blank.
Navigating the RDC Environment

On the RDC home page you will see four navigation tabs:
- Home
- Casebook
- Review
- Reports

These global links also allow you to log out of the system, change your password and access online RDC help.

The Global Links are found at the top and bottom of each tab window. These links allow you the flexibility to access information via the tabs or via the hyperlinks.
Finding Your Study and Site

If you have access to more than one study or site in the application, you need to select the appropriate study and site from the drop-down lists located at the top right of the screen.
Marking a CRF as Blank

The Blank Flag tool is used to intentionally mark a CRF, or a section of a CRF, as blank.

This is used when an assessment or visit was expected but not performed.

Marking the CRF blank notifies others that this page was not missed but intentionally left blank.

**NOTE:** If an entire visit is missed, each individual CRF within that visit must be marked as blank.
Unmarking a CRF as Blank

Once a CRF, or field(s), is grayed out (marked blank) you will need to click the Blank Flag tool and remove the check from the selected box in order to make these fields available for data entry.

Click the Blank Flag tool and the CRF Blank Selection(s) Processing window will open.

To enable the data entry fields on this eCRF, all the checks must be removed.

The Change Reason area displays and you are required to provide a reason for the change by selecting the appropriate reason from the drop down list.
Data Field Colors

On a CRF page you have the following color scheme:

- A **red** field contains a discrepancy actionable to you
- A **yellow** field contains a discrepancy actionable to someone in another user role
- A **green** field indicates that there was a discrepancy on that field that has been manually closed
CRF Icons

CRF Icons will appear with different colors and symbols depending on the actions that have been performed or are needed.
Data Entry Short Cuts – TODAY’S DATE
Enter a “T” into the date field and when leaving the field will populate with the current date.

Data Entry Short Cuts – YESTERDAY’S DATE
Enter a “Y” into the date field and leaving the field will populate the date field with yesterday’s date.
Data Entry Short Cuts – LAST DATE ENTERED VALUE

Enter “L” into a date field and leaving the field will populate the date field with the last date entered.
The **Add Visit Page** button allows you to insert an unplanned CRF if you have completed data entry on all available CRF pages, but still have additional data to enter.

**NOTE:** The **Add Other Page** button should only be used if specifically indicated in the CRF Completion Instructions.

**Important:** Confirm that you are on the correct visit prior to adding a visit page.
Insert Additional CRFs (continued)

The Add Visit Page dialog box displays. Select the CRF that you wish to add to this visit using the radio button next to the CRF Name.

A second Add Visit Page dialog window displays. Leave the default value in the Select Sub-visit drop down list and click Apply.

A new, unplanned Visit Page is added to the Casebook Spreadsheet for the selected visit with a U next to the icon denoting this is an additional/unplanned visit page.

NOTE: The new visit page must be completed and saved immediately, or it will not be retained by the system.
Delete a CRF

There may be times when you need to delete a CRF that was created in error.

Click the **Delete** button.

Open the CRF you want to delete and click on the "Delete CRF" icon.
Delete a CRF (continued)

The Delete CRF dialog box displays. Accept the default Change Reason. If necessary, type an optional comment in the Change Comment text box.

Tip: You may also check the box Remember comment... for subsequent Delete CRF operations if you want to use the same comment for subsequent actions within the same session. The comment will only be retained until you log out of RDC.

A dialog box will display to confirm you want to perform the deletion.
Reviewing Discrepancies (Queries)

You can review discrepancies (queries) for your patient by using the Activities link on the Home tab or by navigating to the Review tab.
Finding Your Discrepancies (Queries) in RDC

Use the **Review – Discrepancies Sub-Tab** to quickly find discrepancies actioned to you.

Queries that are actionable to you are red. Click on the CRF icon to open the CRF and address.