

<http://rdcsupport.biogenidec.com>

## Getting Started in RDC

### Accessing the RDC Support Website

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

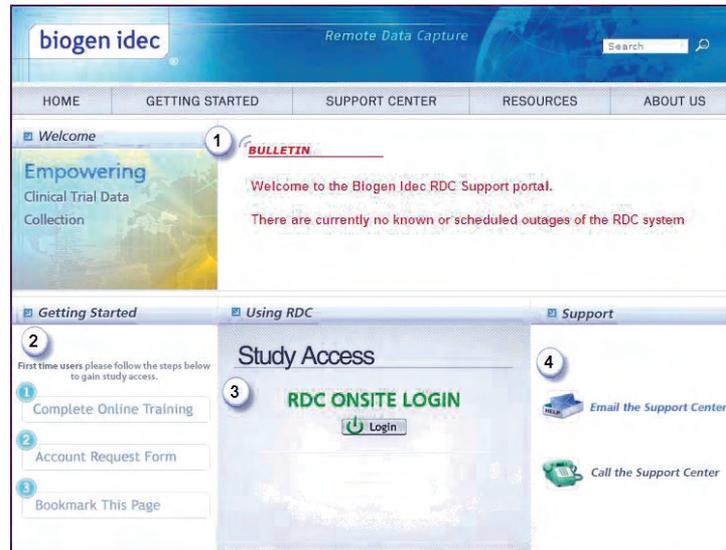
<http://rdcsupport.biogenidec.com>

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**  
Where to find information for contacting the RDC Support Center

Before subject data entry can take place site should complete:

- The RDC Site Assessment
- Completing RDC Training
- Getting an RDC account



### The RDC Site Assessment

All first time sites that are participating in an RDC study receive a Site Assessment call from the RDC Support Center.



The Site Assessment call takes place approximately two to three weeks prior to the Site Initiation Visit.



This call can take up to 30 minutes and is very important in helping the site get up and going in RDC.



The RDC Support Center will assess the site's technology to ensure that the available computer systems are capable of running RDC.



If the site has any difficulties in using RDC, the RDC Support Center works with the site and their IT group to remedy the issues.



If the RDC Support Center cannot solve the site's issues – Biogen Idec may provision wireless access cards and laptops.



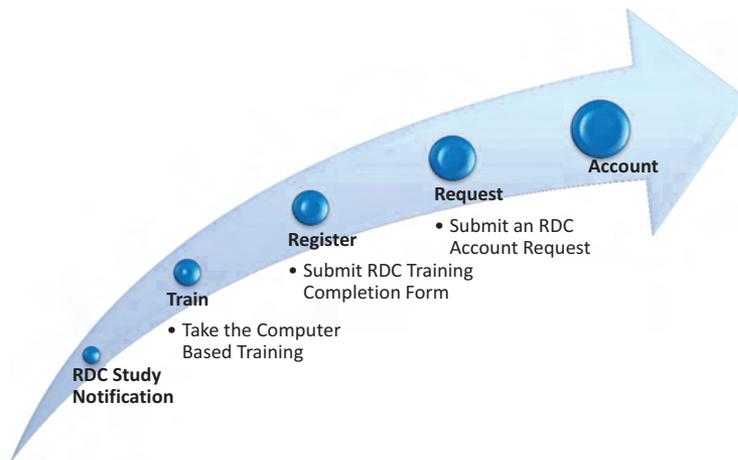
If a site finds that their equipment can no longer run RDC; the site can contact the RDC Support Center for another Site Assessment.

### Getting an RDC Account

To do work in RDC a potential user must get a user account. This is done by doing the following:

- 1) Site users should inform the site CRA that there are new users so that this information can be passed onto Biogen Idec.
- 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.



<http://rdcsupport.biogenidec.com>

## RDC Training Computer Based Training

Users wanting access must go to <http://rdcsupport.biogenidec.com> to complete the Computer Based Training.

The RDC website is a public website and no log-in is required to take the Computer Based Training.

Biogen Idec will not provide an email notification to take RDC training – it is up to the user to take this training when necessary.



<http://rdcsupport.biogenidec.com>

Once you are in the training environment you will select the role you want to train under.

Roles and responsibilities are defined in the "Roles and Responsibilities" section.

All users must complete a training that is appropriate to the type of access they need and are approved for by Biogen Idec.

If you are uncertain of what role to train under contact your CRA.

Note: If you are an investigator and would like to do data entry, you will need to train as a Site User as well as the PI training.

The screenshot shows the Biogen Idec Remote Data Capture website. At the top, there is a navigation bar with links for HOME, GETTING STARTED, SUPPORT CENTER, RESOURCES, and ABOUT US. Below the navigation bar, the text "Online Training:" is displayed. A large red-bordered box contains the instruction "Select your role from the options available". A red arrow points from this box to a section titled "TRAINING OPTIONS". This section contains five buttons: "Site User", "CRA", "PI", "CDM", and "Read-Only". Below the buttons, a note states: "Note: If you are unsure which DC RDC training you should complete for your study, please contact your CRA/Monitor or the study's Project Manager."



When completing the form users need to make sure the contact information is correct.

**SITE TRAINING COMPLETION FORM**

Complete this form for processing. An electronic or printable version of this form will be provided to you for your records

**Required Fields for submission \***

Date: 16 May 2011

**Contact Info:**

First/Given Name: \* Joe  
Middle Name: L  
Last/Sur Name: \* Smith  
Phone Number: \* 617-555-1234  
Email Address: \* JSmith@yoursite.com  
Day of Birth: \* 10

**Training Content:**

- Introduction to OC RDC  
Introduction to OC RDC
- How to Use this Training  
How to Use this Training
- Overview of the OC RDC Process  
Overview of the OC RDC Process
- Access and Navigation  
Access OC RDC  
Navigate OC RDC  
Navigate the eCRF
- Data Entry Functions  
Select Patient & Open eCRF  
Initial Data Entry  
Modify Saved Data  
Audit History Data  
Mark eCRF as Blank
- Discrepancy Management  
Discrepancy Overview  
Discrepancy Workflow  
During Data Capture  
After Saving Data  
After Validate
- Additional Features  
Open Multiple eCRFs  
Delete an eCRF  
Insert Additional eCRFs  
OC RDC Reporting

Training Completion Date: \* 16 May 2011

It is imperative that you keep a copy of this form as documentation of your training. Please choose your document delivery method below.

Email  Print

By submitting this form, I acknowledge my understanding of the material provided, and I confirm that I have completed OC RDC training.

Submit

<http://rdcsupport.biogenidec.com>

### Requesting RDC Study Access

Once training is complete and registered, study access can be requested by submitting the Access Request Form.

The Access Request Form is available through the RDC Support website.

Note: If you've already completed training for RDC using the Biogen Idec Computer Based Training for another Biogen Idec study you do not need to take the training again.

The screenshot shows the Biogen Idec RDC Support website. The header includes the Biogen Idec logo, the text "Remote Data Capture", and a search bar. The navigation menu contains links for HOME, GETTING STARTED, SUPPORT CENTER, RESOURCES, and ABOUT US. The main content area is divided into sections: "Welcome" with a "BULLETIN" banner, "Empowering Clinical Trial Data Collection", "Getting Started" with a "Study Access" section, and "Support". The "Study Access" section contains a list of steps for first-time users: "1 Complete Online Training", "2 Account Request Form" (highlighted with a red box and a red arrow), and "3 Bookmark This Page". To the right of the "Study Access" section are two login options: "RDC ONSITE LOGIN" and "RDC 4.5.1 LOGIN". On the far right, there are two support options: "Email the Support Center" and "Call the Support Center". A callout box with a red border and white background contains the text "Click here to complete the Account Request Form" with a red arrow pointing to the "Account Request Form" link.

<http://rdcsupport.biogenidec.com>

Users should include the study (or studies) they need access to and make sure that contact information is correct.

Users will also need to provide their initial password. This will be used the first time a user logs into RDC. If a user already has access to a Biogen Idec study in RDC the user can enter any value but the existing password will not be changed.

The screenshot shows a web form titled "Biogen Idec RDC Support - Oracle Clinical Account Access Request Form". The form is divided into several sections:

- Date:** 10 May 2014
- Protocol Access Requested:**
  - Study Sponsor: Biogen Idec
  - Protocols: A table with 6 columns for protocol numbers. The first cell contains "100BI301". A red note below the table states: "Use each position for which you need access. At least one protocol number is Required."
- Contact Information:**
  - First/Given Name: Joe
  - Middle Name: L
  - Last/Sur Name: Smith
  - Country: United States (dropdown menu)
  - Phone Number: 1 617-555-1234
  - Email Address: JSmith@yoursite.com
  - Day of Birth: 10 (dropdown menu)
- Role:**
  - Question: "Please select one of the following which best describes your role in this study?"
  - Options:  Investigator / Site Staff,  External Monitoring/CRA Staff,  Sponsor,  CDM
- Initial Password:**
  - Text: "Please enter an initial password 6 to 10 characters long in the box to the right. You may only use English alphanumeric characters. Biogen Idec will set your initial RDC password to what you enter here. When you log in to RDC for the first time using this password, you will be required to change it. Good password composition practice suggests using a combination of numbers and letters."
  - Input field: A password field with a masked password "\*\*\*\*\*".

### RDC Account Tips

- Users performing data entry must have accounts by time of subject data entry
- Investigators performing CRF approval must have accounts prior to approving CRFs

→→ Best Practice: Initiate accounts prior to Site Initiation Visit ←←

Once all the above steps are complete, users will receive a username for your study, generally within **5 business days**. The password will be the one chosen when submitting the Account Request Form.

It is very important that training completion forms and account requests contain information that is consistent with information already provided to Biogen Idec via your Site Monitor

- User Name
- User Contact Information
- Site Number
- User Role

If you have any problems during the training process contact the RDC Support Center.

**NOTE:** If this information is not consistent – Biogen Idec will not be able to verify user requests!

- Delays in account creation!
- Delays in user access to RDC!
- Delays in data entry!
- Delays in locking data!

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### **Training for New RDC Users after First Patient In**

It is not unusual for new RDC users to need access after the first subject has entered the study for the site.

When this happens, it is important that the site notifies their Site Monitor (who in turn will notify Biogen Idec) that new RDC users will be joining the study.

All new users should complete the online training and submit both a training completion form and an account request form.

### **Removing RDC Access**

When an RDC user leaves the study, the site should immediately notify their Site Monitor so that RDC access for this study can be removed.

If this is temporary, the Site Monitor should still be notified and RDC access is removed until the user returns.

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## Using RDC

### 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

The screenshot shows the biogen idec Remote Data Capture (RDC) Support website. The header includes the biogen idec logo, the text 'Remote Data Capture', and a search bar. The navigation menu contains links for HOME, GETTING STARTED, SUPPORT CENTER, RESOURCES, and ABOUT US. The main content area is divided into several sections: 'Welcome' with a 'Clinical Trial Data Collection' graphic, 'Getting Started' with a list of steps for first-time users (Complete Online Training, Account Request Form, Bookmark This Page), 'Using RDC' with a 'Study Access' section, and 'Support' with contact options. The 'Study Access' section features a red box around the 'RDC ONSITE LOGIN' button, which has a 'Login' sub-button. A red arrow points from a text box above that says 'Use this link to log-in to your study' to the 'RDC ONSITE LOGIN' button. Below this, there is an 'RDC 4.5.1 LOGIN' section with a 'Login' button and the text 'FOR USE WITH OP\$ PREFIXED ACCOUNTS ONLY'. The 'Support' section includes 'Email the Support Center' and 'Call the Support Center' options.

### Password Security



Your account information and access must be exclusive to your use.



Do not share your user name or password.



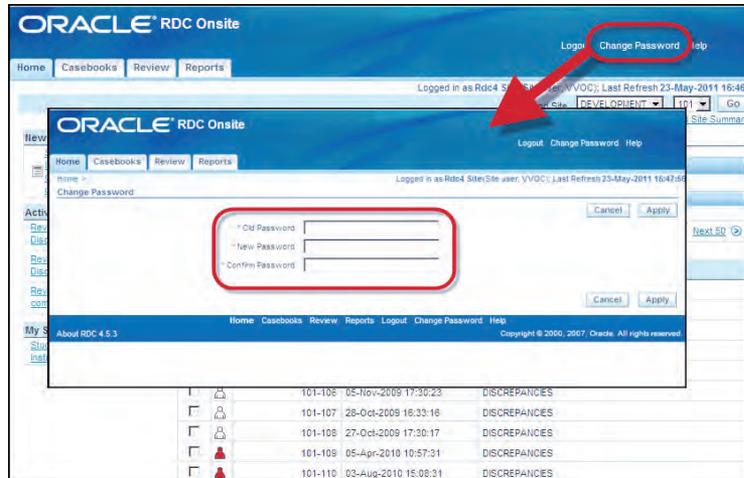
21 CFR part 11 – Electronic Signatures. Your information must also be secure. Do NOT post your login information on the computer or leave it where it can be viewed.

## Changing Your Password



Logging in to the application for the first time requires you to type your user name and password, which you requested after completing the Account Request Form.

You also have the option to manually change your password when necessary.



<http://rdcsupport.biogenidec.com>

## Logging out of RDC

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

Do not use the browser's 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.**

In order to log back in to the system, navigate back to the Login page using the Login button on the Biogen Idec RDC website.

The screenshot shows the Oracle RDC Onsite web application running in a Windows Internet Explorer browser. The browser's address bar shows the URL <http://rdcsupport.biogenidec.com>. The application header includes the Oracle logo and the text "RDC Onsite". A navigation menu contains "Home", "Casebooks", "Review", and "Reports". The user is logged in as "Kevin Stephenson" with a "Data management role" and a "Last Refresh" of "23-May-2011 17:03:56". The main content area displays a "Patient Selection List" with a table of patients. A red circle highlights the "Logout" link in the top navigation menu. Two red arrows point from text boxes to the "Logout" link and the browser's close button. The text boxes contain the following instructions:

- "Log-out of RDC using this link" (pointing to the Logout link)
- "Do not leave RDC by closing the browser" (pointing to the browser's close button)

Select	Patient Number	Last Modified	Casebook
<input type="checkbox"/>	T1		2010 TRAINING
<input type="checkbox"/>	T2		2010 TRAINING
<input type="checkbox"/>	T3		2010 TRAINING
<input type="checkbox"/>	T4		2010 TRAINING
<input type="checkbox"/>	T5		2010 TRAINING
<input type="checkbox"/>	T6		2010 TRAINING
<input type="checkbox"/>	T7		2010 TRAINING
<input type="checkbox"/>	T8		2010 TRAINING

**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

Many issues in RDC are in fact study related questions....

- How do I complete a CRF in RDC?
- Where do I find a CRF?
- Do I need to complete a CRF?
- What happens if a subject discontinues?
- In these cases the CRA and Clinical Team are the best points of contact!

***If in doubt....***

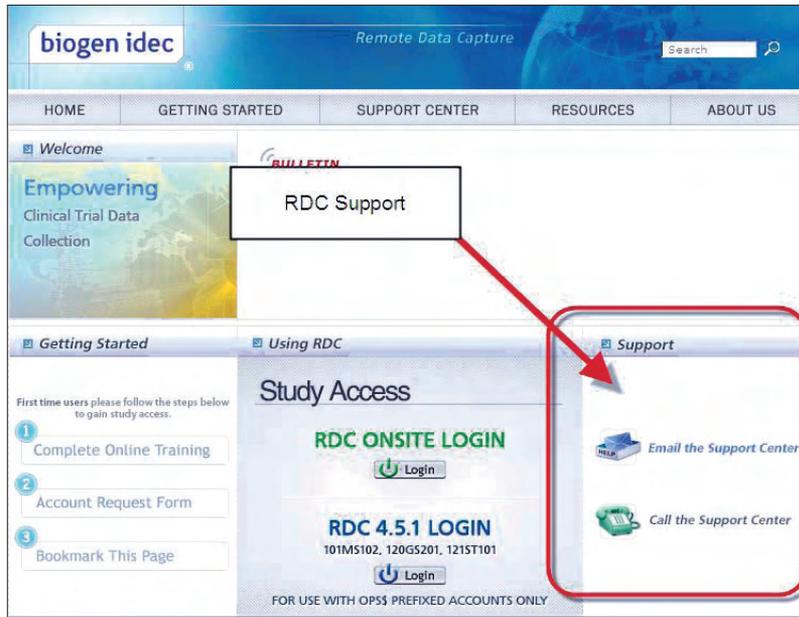
The RDC Support Center can still receive these calls but if they cannot answer a study related question they will make sure the issue is routed to the study team for further assistance.

<http://rdcsupport.biogenidec.com>

### Reaching the RDC Support Center

You can either call or email the support center. Contact information is available on the RDC Support Website.

Phone numbers are also available in appendix A: RDC Support Center Phone Numbers



#### RDC Support Center Hours

##### RDC Support Center Hours

- Sunday 6:00 PM EST to Friday 9:00 PM EST
- (Sunday 10:00 PM GMT to Saturday 2:00 AM GMT).

##### RDC Support Center Voicemail

- If you cannot reach the RDC Support Center leave a voicemail with the RDC Support Center so they can return your call.

##### Email support

- Email support is available at all times.

### Additional RDC Help

Besides your launch kit, there are several places to find help within RDC.

#### Online "Help"

- Online help guide available through RDC

#### Computer Based Training

- RDC Computer Based Training is always available as a reference and can be reviewed for any topic at any time

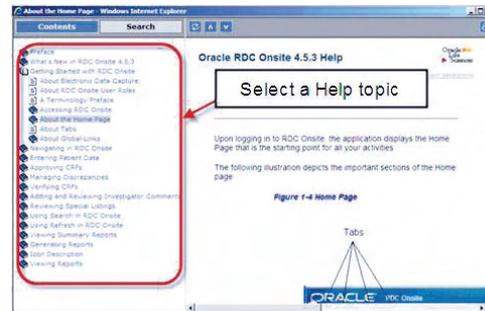
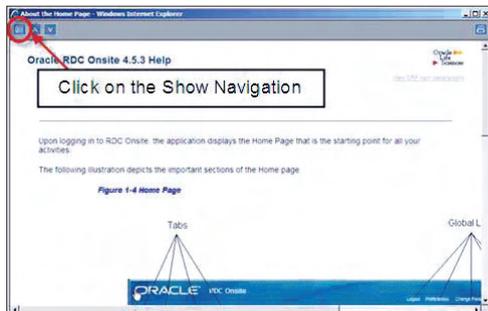
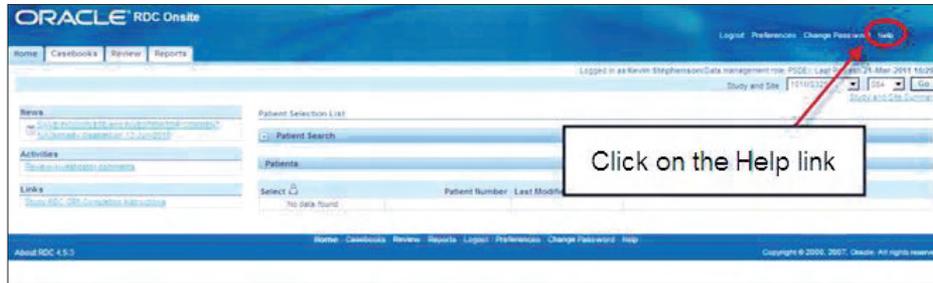
#### Current CRF Completion Instructions

- Entering and updating data
- Managing discrepancies
- Understanding colors and tabs
- Using reports
- Help in adding CRF pages
- How to blank and un-blank CRF pages
- How to approve or verify CRF pages

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## RDC Online Help

Online help is available in RDC by clicking on the **Help** link.



<http://rdcsupport.biogenidec.com>

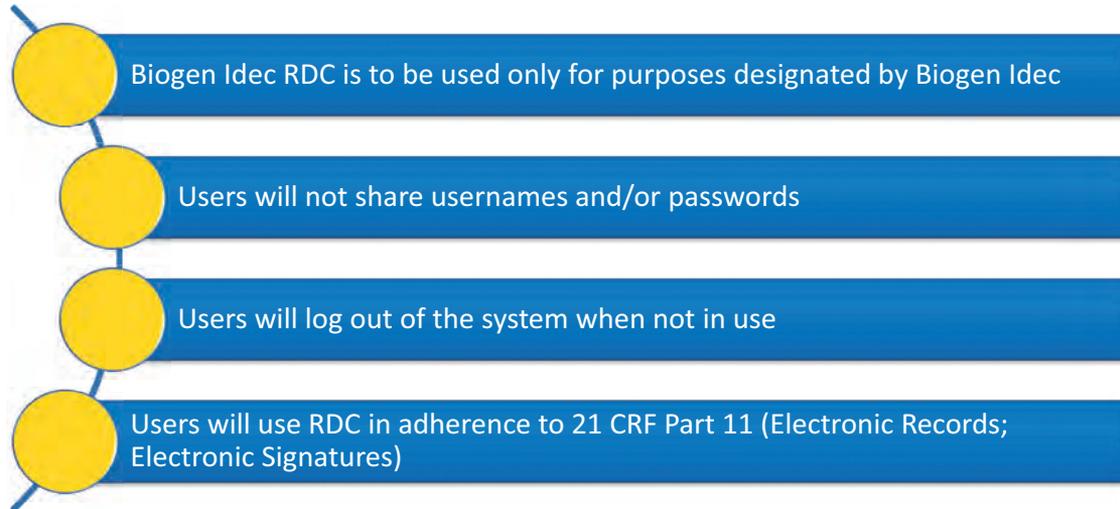
### RDC CRF Completion Instructions

The current version of study specific CRF Completion Instructions for an RDC study are available within RDC by clicking on the link on the study **Home** tab.

This will open a PDF file of the CRF Completion Instructions for your reference.



### RDC Compliance



**Violations of this agreement will result in:**

- Loss of RDC privileges
- A Remediation Plan