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# Medidata Rave D2d Electronic Data Capture (EDC) System

Research Coordinators



# Objective

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- To provide background knowledge and introduction to the D2d RAVE Electronic Data Capture (EDC) system

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- The goals of the electronic data capture (EDC) system are
    - Insure high quality and accurate data
    - Provide consistent data across multiple sites
    - Provide efficient methods for data checking and confirmation
    - Provide timely tracking and reporting on patient enrollment

# Medidata Rave EDC system

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- Web-based, browser and platform (operating system) independent
- No requirement for additional software
- Ability to calculate and populate data fields (BMI, eGFR)
- Role-based access control: system allows for users to have specified data entry access and viewing access at the site, form and question and field level
- Automatic programmed edit checks
  - Within questions
  - Across questions
  - Across forms and visits
- Allows for ongoing data management activities including:
  - Posting, responding and closing queries
- Generate clear audit trail
- Ability to set-up automatic e-mail notification of triggers (SAE, UAP), enrollment.
- Real-time report generation to extract and analyze data, create custom reports or ad hoc reports.
- Help desk availability for extended day (7A-9P ET)

# Roles and Activities

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## Investigators

- Review data entered
- Required to sign-off on certain forms confirming review:
  - Inclusion/exclusion
  - Safety labs
  - Adverse events
  - Diabetes outcome
- Enter data
- Run reports

## Research Coordinators

- Enter patient data into all eCRFs
- Manage and resolve queries
- Run reports

## Research Assistants

- Enter patient data into various eCRFs

# System Access

- Complete the Account Activation Training Form
  - User must be listed on the site Contact information spreadsheet at the CC to be granted any access.
- Download form from web-portal
- E-mail completed form to [D2d@tuftsmedicalcenter.org](mailto:D2d@tuftsmedicalcenter.org)
- Preliminary access granted for training
- Full system access granted after training completed



Account Activation Training Form			
<b>To Be Completed by the user</b>			
Sponsor	NIDDK / Tufts Medical Center	Protocol #	D2d study
<b>User Account Information</b>			
First Name		Last Name	
Email			
Telephone		Fax	
Principal Investigator Name:			
Investigator Site Number			
<b>Training Information</b>			
Have you completed any RAVE/Medidata related eLearning, Webinar, or Instructor Led training courses?			<input type="checkbox"/> Yes <input type="checkbox"/> No
<b>If yes, please attach the certification of all the courses you have taken and/or your training record (instructor's name, signature, and training date are required on the training record).</b>			
<b>Statement of Understanding</b>			
<i>I understand that execution of this form constitutes my acknowledgement that I am being provided with an account name and password, which constitute an electronic signature. I accept that my electronic signature is legally binding and equivalent to my written signature. I understand that I am responsible for data entered into the Medidata Solutions Clinical Research Application under my account name and password. I understand that sharing of passwords is illegal, and agree to keep my password secret. I agree to report any suspected fraudulent use of electronic systems to the sponsor immediately.</i>			
User Name	Signature	Date	
Print Name & Title	Authorized Signature	(dd-MMM-yyyy)	
<i>Please forward the completed and signed form to the D2d Coordinating Center (D2d@tuftsmedicalcenter.org). Upon Sponsor approval, you will receive an email from a generic Medidata account with user information.</i>			

To be Completed by Authorized Sponsor Personnel			
<i>I have verified above information is accurate and have indicated the role user should be granted as follows:</i>			
Environment (Prod, Dev, Training, etc)		Access Role to be granted (CRC, RA, RA-2, RA-3, PI, CRA, PM, DM, Safety)	
<b>Authorized Sponsor Personnel</b>		<b>Authorized Signature</b>	<b>Date (dd-MMM-yyyy)</b>
Name	Patricia R. Sheehan		
E-mail	Psheehan1@tuftsmedicalcenter.org		
Title/Project Role	Project Manager	Phone#	

# Email from Medidata

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Email not displaying correctly? [Click here](#) to see it in your browser.



Welcome to iMedidata.com - a faster, simpler way to access all of your iMedidata studies, training, and applications.

Greetings,

Meei-Jan Lee would like you to join the Study D2d-Study (SCRATCH) on iMedidata.

✔ Take me to iMedidata to activate my account.

A red arrow points from the right side of the image towards the button text.

For support with your new account, please email [helpdesk@mdsol.com](mailto:helpdesk@mdsol.com). For more information please visit <http://www.imedidata.com>. Thank you for using iMedidata.

This is a post-only mailing. Replies to this message are not monitored or answered.

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### Welcome to iMedidata!

iMedidata is a faster, simpler way to provide access to all your studies and applications.

To become an iMedidata member, follow the three steps below:

- Step 1: Fill out the fields on this page and click save.
- Step 2: Log in to your new account.
- Step 3: Accept the Terms of Use.

You're Done!

Please fill in the following information to create your iMedidata account

#### Fields marked with an asterisk (\*) are required.

Tip: your username must be at least 8 characters in length, and may contain alphanumeric characters, underscore, period, hyphen, and "@".

Username \*  Email \*

First Name \*  Middle Name

Last Name \*  Institution

Title  Department

Address Line 1  State

Address Line 2  Country

Address Line 3  Time Zone \*

City  Locale \*

Postal Code

Tip: your password must be at least moderate strength, which is minimum 8 characters, at least one capital letter, one lowercase letter, and one number.

Password \*  Password Confirmation \*

Password Strength

PIN Code

May be used in certain applications to recover your password or apply your eSignature.

Phone \*  Mobile Phone

Fax  Pager

Site Email Newsletter

Check here to receive emails iMedidata sends from time to time to clinical site staff to keep you aware of new offerings, events, surveys and other industry-relevant content.

Security Question \*

Answer \*

Activate

# Passwords and Security

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- **Passwords must contain at least 1 capital letter, 1 lowercase letter, 1 number, and be 8 characters in length**
- **Passwords cannot be used more than once per year**
- **Passwords expire after 90 days of initial creation**
- **Passwords should never be shared!**
- **Passwords will need to be re-entered after the system has been left unattended for 30 minutes**
- **Complete login information will need to be re-entered after the system has been left unattended for 60 minutes**



# Initial Log-in

✔ You have completed the first part of your iMedidata account activation. For security purposes, please log in again to complete the activation process.



Language EN

## Sign In

Username


Password

 Log in

[I forgot my username or password](#)

[Trouble logging in?](#)

Welcome to iMedidata - the fast, simple way to access all your Medidata Rave® EDC studies, **Medidata applications**, eLearning, online discussions and more... in one place.

 Take a Tour



Our mission is to put innovative technology and insightful data into your hands, to help you plan and manage clinical trials, and safely bring life enhancing treatments to market [Learn More](#)

 ██████████ with username ██████████ is now activated. Remember your username and password to log in to iMedidata.  
Welcome. You successfully created your iMedidata account.

**Apps**


You have zero (0) apps. Look here for apps linked to Studies, Sites, or Teams that you work in.

**My Information**

Name (Username)  
Locale eng  
Eastern Time (US & Canada)

[Account Details](#)  
[MyMedidata](#)

**Studies (0)**



You are involved with zero (0) studies.  
These are studies that you work on with their data and associated applications. Launch an application from this pane or view a required course.

**Sites (0)**



You are a member of zero (0) sites.  
View your sites here, and edit your site profile.

**Teams (0)**



You are a member of zero (0) teams.  
View your teams and team member information here. Teams can organize your clinical professionals into teams by interest, specialty, or study role.

**Tasks**

Invitations (1)

**Join D2d-Study (SCRATCH)** [accept](#) [decline](#)

eLearning (0)

No Pending eLearning

✔ Welcome to iMedidata! You successfully logged in.

## Apps




## My Information

Name (Username)  
Locale eng  
Eastern Time (US & Canada)

[Account Details](#)  
[MyMedidata](#)

Studies (1)

  
**D2d-Study (SCRATCH)**  
[Rave EDC](#)

Sites (0)

  
*You are a member of zero (0) sites.*  
*[View your sites here, and edit your site profile.](#)*

Teams (0)

  
*You are a member of zero (0) teams.*  
*[View your teams and team member information here. Teams can organize your clinical professionals into teams by interest, specialty, or study role.](#)*

## Tasks

Invitations (0)

*No Pending Invitations*

eLearning (1)

[Rave EDC Essentials for Clinical Research Coordinators](#)

# e-Learning module

## Rave EDC Essentials for Clinical Research Coordinators



RESOURCES TRANSCRIPT HELP EXIT



### Welcome to the Medidata Rave<sup>®</sup> Training Program

Rave provides industry-leading user experience and functionality for Electronic Data Capture (EDC), management, and reporting of clinical research data. The system is flexible and can meet sponsor clinical process requirements as well as the unique aspects of individual clinical trials.

This training course is intended for clinical site personnel as well as sponsor staff who work on clinical trials. This course will provide you with a thorough understanding of how to use Rave to carry out your specific responsibilities during the data collection and management process.

Some of the features included in this training may not be utilized by individual sponsors and others may be customized to meet unique study requirements. After completing and passing the final assessment, you will be granted full access to Rave.

**Note:** Please be sure to turn on your speakers as this course is fully narrated. If you do not have speakers, please click the **Transcript** to follow along.

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COURSE MENU 0:00 -0:54 AUDIO PREVIOUS NEXT

# EDC support

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- System issues:
  - Slowness, website
  - Username and password

MEDIDATA SOLUTIONS, INC.

[helpdesk@mdsol.com](mailto:helpdesk@mdsol.com)

(866) 633-4328

- D2d specific questions
  - Forms
  - Data entry

Coordinating Center

[D2d@tuftsmedicalcenter.org](mailto:D2d@tuftsmedicalcenter.org)

(617)-636-D2d2 (3232)



# System Navigation



Language English ▾

## Sign In

Username


Password

 Log in

[I forgot my username or password](#)

[Trouble logging in?](#)

Welcome to iMedidata - the fast, simple way to access all your Medidata Rave® EDC studies, **Medidata applications**, eLearning, online discussions and more... in one place.

 Take a Tour



Our mission is to put innovative technology and insightful data into your hands, to help you plan and manage clinical trials, and safely bring life enhancing treatments to market [Learn More](#)


iMedidata - Windows Internet Explorer  
https://www.medidata.com/?ticket=ST-1373055261r5C578E40B4830E9F31

File Edit View Favorites Tools Help

medidata  
Help Logout  
Patricia Sheehan (psheehan)

Welcome to iMedidata! You successfully logged in.


**Apps**

  
tufts-prometrika

**My Information**

**Patricia Sheehan (psheehan)**  
Locale eng  
Eastern Time (US & Canada)  
Account Details  
MyMedidata

**Studies (1)**


  
**D2d-Study (SCRATCH)**  
Rave EDC

**Tasks**


Invitations (0)  
No Pending Invitations

eLearning (3)  
**Rave Query Management**  
Rave Reporter  
Foundations of JReview 9.0

**Sites (0)**

  
You are a member of zero (0) sites.  
View your sites here, and edit your site profile.

**Teams (0)**

  
You are a member of zero (0) teams.  
View your teams and team member information here. Teams can organize your clinical professionals into teams by interest, specialty, or study role.

start Deleted Items - Micro... Screen Shots - Messa... Project Planning and ... Presentation1 EDC Training - Modul... Microsoft Excel Medidata - Windows ... Internet 125% 4:15 PM

# Site Home Page

**SCRATCH**

Home - Medidata Rave

iMedidata Messages My Profile Help Home Logout  
User: Patricia Sheehan Project manager

D2d-Study ABC Medical Center

Subject  [Advanced Search](#) [Add Subject](#)

**Search for participant**

**List of the site's enrolled participants**

**Add new participant**

Task Summary: Site		Subjects
NonConformant Data	3	
Open Queries	5	
Overdue Data	7	

Subject

- 10001
- 10002
- 10004
- 10008
- 10011
- 10012
- 10014
- 10016
- 10017
- 10019
- 10020
- 10021

Page 1 << Page 1 of 1 >>

Icon Key

Reports

- Query Summary - Query Summary Report
- Enrollment - Enrollment Report
- 360 Enrollment Tracking Report - Track Subject Enrollment Performance
- 360 Query Management - Manage Queries









































medidata Rave

Click Here for Customer Support Information

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# ICONS in Medidata

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 Site	 Never Touched	 Incomplete
 Studies	 Complete	 Requires Verification
 Study	 Locked	 Requires Review
 Subject	 Entry Lock	 Query Open
 Subject in doubt	 Not Conformant	 Answered Query
 Form	 Inactive	 Requires Coding
 Site Group	 Overdue	 Requires Signature
 Home	 Sticky Notes	 Out of Range High
 Comments	 Data Changed	 Out of Range Low
 Edit	 Protocol Deviation	 Requires Translation
 Study Status Deferred	 Site Status Deferred	 Requires First Pass DDE
 Folder not available to the user	 Add Marking	 Requires Second Pass DDE
 Task Summary Pop Up	 Folder	 Requires Reconciliation DDE
 Requires Coder Coding		

# Participant Home Page



SCRATCH

D2d-Study XYZ Medical Center 10015 [Grid View](#)

10015  
Screening  
Eligibility  
Baseline  
Randomization  
Month 3 (1)  
Month 6 (1)  
Month 9 (1)  
Month 12 (1)  
Month 15 (1)  
Month 18 (1)  
Month 21 (1)  
Month 24 (1)  
Month 27 (1)  
Month 30 (1)  
Month 33 (1)  
Month 36 (1)  
Month 39 (1)  
Month 42 (1)  
Month 45 (1)  
Month 48 (1)  
End of Study (1)  
End of Medication (1)

Visit	Date
Screening	11 Feb 2008
Eligibility	25 Feb 2008
Baseline	20 Feb 2008
Randomization	25 Feb 2008
Month 3 (1)	22 May 2008
Month 6 (1)	26 Aug 2008
Month 9 (1)	07 Nov 2008
Month 12 (1)	22 Feb 2009
Month 15 (1)	06 May 2009
Month 18 (1)	26 Aug 2009
Month 21 (1)	02 Nov 2009
Month 24 (1)	22 Feb 2010
Month 27 (1)	01 May 2010
Month 30 (1)	26 Aug 2010
Month 33 (1)	28 Oct 2010
Month 36 (1)	26 Jan 2011
Month 39 (1)	26 Apr 2011

**Task Summary: Subject**

	Pages
NonConformant Data	0
Open Queries	0
Overdue Data	1

medidata [Help for Customers Support Information](#) Medidata Rave® Version 5.6.4.157

# Data Entry

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- New forms will appear on the left panel as they become available for a given participant
- No data are saved until SAVE is pressed
- The data should be reviewed after the SAVE is pressed for any data entry errors. Queries will appear in pink.
- Data entry is expected as soon as possible after collection, typically within 48 hours. Note the Central Laboratory Forms must be entered to ship specimens.
- Site per participant payments will be determined by the visits entered in the system.

# A few remaining comments

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- We will have a few webinars to review forms prior to the initiation of enrollment.
  - Prior to the webinar attendees should complete the on-line e-learning module.
  - A training site will be available for users to add test data and become accustomed to the system.