
Medidata Rave D2d Electronic Data Capture (EDC) System

Investigators



Objective

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

EDC System Goals

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

Medidata Rave EDC system

- Web-based, browser and platform (operating system) independent
- No requirement for additional software
- Ability to calculate and populate data fields based on data entered (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
- Generates 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

Investigators

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

Research Coordinators

- Enter patient data into eCRF
- Manage and resolve queries
- Run reports

Research Assistants

- Enter patient data into various eCRF

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
- Preliminary access granted for training
- Full system access granted after training completed



Account Activation Training Form			
To Be Completed by the user			
Sponsor	NIDDK / Tufts Medical Center	Protocol #	D2d study
User Account Information			
First Name		Last Name	
Email			
Telephone		Fax	
Principal Investigator Name:			
Investigator Site Number			
Training Information			
Have you completed any RAVE/Medidata related eLearning, Webinar, or Instructor Led training courses?			<input type="checkbox"/> Yes <input type="checkbox"/> No
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).			
Statement of Understanding			
<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)	
Authorized Sponsor Personnel		Authorized Signature	Date (dd-MMM-yyyy)
Name	Patricia R. Sheehan		
E-mail	Psheehan1@tuftsmedicalcenter.org		
Title/Project Role	Project Manager	Phone#	

Email from Medidata

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. For more information please visit <http://www.imedidata.com>. Thank you for using iMedidata.

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- 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

- 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

Sign In

Username


Password

 Log in

[I forgot my username or password](#)

[Trouble logging in?](#)

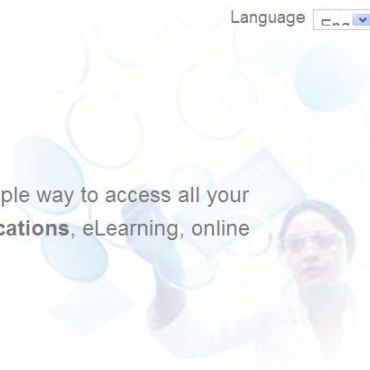
Welcome to iMedidata - the fast, simple way to access all your Medidata Rave® EDC studies, **Medidata applications**, eLearning, online discussions and more... in one place.

 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](#)

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Coordinating Center at Tufts Medical Center
www.d2dstudy.org | d2d@tuftsmedicalcenter.org

Apps



My Information

Ellen Vickery (evickery)
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

el evickery (1)

[Rave EDC Essentials for Investigators](#)

e-Learning module

Medidata® Training Program - Mozilla Firefox

https://www.imedidata.com/public/courses/47078554/init.htm?course_id=9

Rave EDC Essentials for Investigators

medidata University®

RESOURCES TRANSCRIPT HELP EXIT

Welcome to Medidata Rave® EDC Essentials for Investigators

Medidata Rave® provides an industry-leading user experience for electronic data capturing, management, and reporting of clinical research data. This course will show you in detail how to use Rave to perform your specific responsibilities during the data collection and management process.

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 0:08 -0:13 AUDIO PREVIOUS NEXT



EDC support

- System issues:
 - Slowness, website problems

MEDIDATA SOLUTIONS, INC.

helpdesk@mdsol.com

(866) 633-4328

- D2d specific questions
 - Forms
 - Data entry

Coordinating Center

D2d@tuftsmedicalcenter.org

(617)-636-D2d2 (3232)



System Navigation



Language English ▾

Sign In

Username

Password

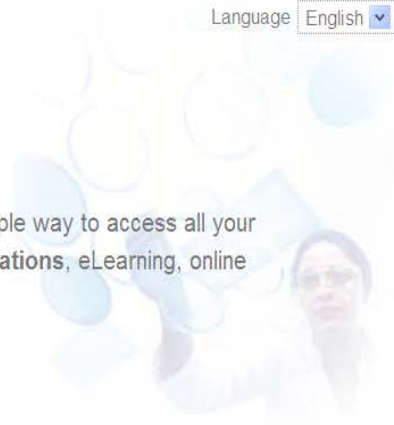
 Log in

[I forgot my username or password](#)

[Trouble logging in?](#)

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 Take a Tour



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Welcome to iMedidata! You successfully logged in.

Apps




My Information

Patricia Sheehan (psheehan)
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 (3)

[Rave Query Management](#)

[Rave Reporter](#)

[Foundations of JReview 9.0](#)

Site Home Page

Home - Medidata Rave

https://hdcvcd08-107.mdsol.com/MedidataRave/(S(s3kd20sua3swi5v4mwnlfzq0))/HomePage.aspx?LD_StudyID=3

D2d **SCRATCH**

iMedidata Messages My Profile Help Home Logout
User: Ellen Vickery Research Associate

D2d-Study ABC Medical Center

Search for participant

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

Subject	Subjects
10001	12
10002	3
10004	5
10008	7
10011	
10012	
10014	
10016	
10017	
10019	
10020	
10021	

List of the site's enrolled participants

Task Summary: Site

- Requiring Signature 12
- NonConformant Data 3
- Open Queries 5
- Overdue Data 7

Page 1 << Page 1 of 1 >>

[Icon Key](#)









































Reports

medidata Rave

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ICONS in Medidata

 Site	 Never Touched	 Incomplete
 Studies	 <u>Complete</u>	 Requires Verification
 Study	 Locked	 Requires Review
 Subject	 Entry Lock	 Query Open
 Subject in doubt	 <u>Not Conformant</u>	 Answered Query
 Form	 Inactive	 Requires Coding
 Site Group	 <u>Overdue</u>	 <u>Requires Signature</u>
 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		

Site Home Page

Home - Medidata Rave

https://hdcvd08-107.mdsol.com/MedidataRave/(S(s3kd20sua3swi5v4mwnlfzq0))/HomePage.aspx?LD_StudyID=3

D2d **SCRATCH** iMedidata Messages My Profile Help Home Logout
User: Ellen Vickery Research Associate

D2d-Study ABC Medical Center

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

Subject	Subjects
▼ Task Summary: Site	
▶ Requiring Signature	12
▶ NonConformant Data	3
▶ Open Queries	5
▶ Overdue Data	7
10001	
10002	
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10008	
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10014	
10016	
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10019	
10020	
10021	

Page 1 << < Page 1 of 1 > >>

[Icon Key](#)

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Site Home Page

Subject

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

Subject

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

Page 1

[Icon Key](#)

Reports

▼ **Task Summary: Site**

▼ Requiring Signature

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

Subjects

12

▶ NonConformant Data

3

▶ Open Queries

5

▶ Overdue Data

7

Participant Home Page

Navigation Bar: D2d-Study | ABC Medical Center | **10021**

Left Navigation Menu: 10021, Screening, 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), Call Log (1)

Subject: Subject

Grid View

Visit	Date
Screening	01 Jan 2000
Baseline	15 Jan 2000
Randomization	25 Jan 2000
Month 3 (1)	22 Apr 2000
Month 6 (1)	09 Jul 2000
Month 9 (1)	07 Oct 2000
Month 12 (1)	05 Jan 2001
Month 15 (1)	05 Apr 2001
Month 18 (1)	04 Jul 2001
Month 21 (1)	02 Oct 2001
Month 24 (1)	31 Dec 2001
Month 27 (1)	31 Mar 2002
Month 30 (1)	29 Jun 2002
Month 33 (1)	27 Sep 2002
Month 36 (1)	26 Dec 2002
Month 39 (1)	26 Mar 2003
Month 42 (1)	24 Jun 2003
Month 45 (1)	23 Sep 2003

Task Summary: Subject

Task	Pages
Requiring Signature	3
Screening-Screening Inclusion Exclusion Criteria	
Screening-Local Laboratory	
Month 3 (1)-Safety Local Laboratory	
1	
NonConformant Data	0
Open Queries	0
Overdue Data	45

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URL: https://hdcvd08-107.mdsol.com/MedidataRave/(S(33kd20sua3swi5v4mwnlfzq0))/Modules/EDC/CRFPage.aspx?DP=2494

Investigator Review






















Home | D2d-Study | ABC Medical Center | 10021 | Month 3 (1) | Safety Local Laboratory




Month 3 (1)
Visit Date
M03 Visit Summary
Safety Local Laboratory
M03 Central Laboratory

CRF History
10021 - Safety Local Laboratory
10021 - Visit Date
10021 - Local Laboratory
10021 - Visit Date

Inactivate Page

Subject: 10021
Page: Safety Local Laboratory - Month 3 (1)

Were safety specimens collected for analysis at the local laboratory?	Yes	  
Date of laboratory specimens collection?	22/Apr/2000	  
Time of laboratory specimens collection (24 hour clock 00:00-23:59)?	08:00	  
Serum calcium	12.0	  
Serum creatinine	23.0	  
Estimated creatinine clearance (GFR)	1.6	  
Was a pregnancy test done?	No	  
If Yes, please record results		

Sign and Save

Save Cancel

[Printable Version](#) [View PDF](#) [Icon Key](#)
CRF Version 4 - Page Generated: 07 Jul 2013 14:54:31 Eastern Daylight Time

Data Entry

- No data are saved until SIGN and 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. For example: the Central Laboratory Forms must be entered to ship specimens.
- Performance-based payments to sites will be determined by the visits entered in the system.

A few remaining comments

- Webinars to review the system 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.