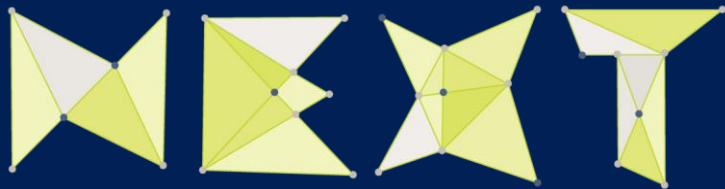
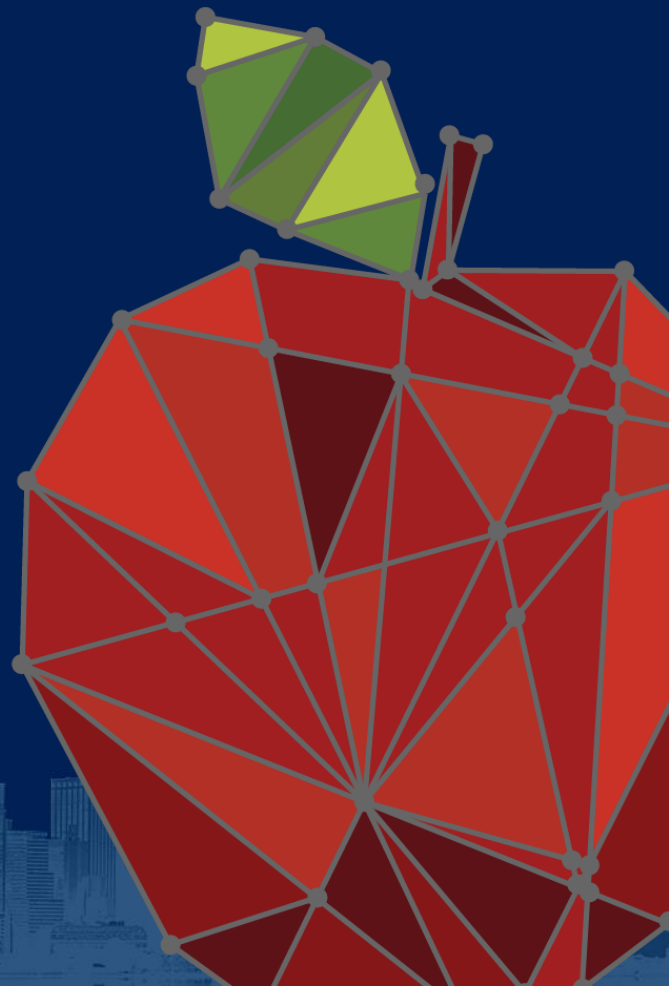


medidata



WHERE SCIENCE
MEETS TECHNOLOGY
MEETS THE FUTURE





Innovative Clinical Development Solutions

Why Rave EDC?

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October 24, 2018

Background

PROMETRIKA is an accredited Medidata Rave EDC CRO partner



Transitioned from “Classic” Rave to Rave EDC in 2018



Our most recent experiences with Rave EDC demonstrate the significant improvements in the UAT workflow

Overview

User Account Management

Simplified Icons

Automatic Upgrades

UAT Workflow

User Account Management

Platform Roles

- Available in Cloud Administration, required for Rave EDC
- Comprehensive roles that bring together multiple components

Roles and Permissions are defined at Client Division startup

- Simplifies access-granting activities
- Reduces possibility of granting inconsistent access to the same types of end-users

Simplified Icons

New features in Rave EDC




Self-evident visual indicators of outstanding tasks

Entering data

Addressing queries

Signing a form



Icons are more directly informative to the end-user

New Rave EDC Icons

Importance (1 = Highest, 10 = Least)	Icon	Description
1		Open Query
2		Read Only Opened Query
3		Non-Conformant Data
4		Requires Review
5		Requires Translation
6		Requires Verification
7		Overdue
8		Requires Coding
9		eSignature Required
10		Entered
11		Entering
12		Unsubmitted Form
13		Requires Data Freeze
14		Requires Data Lock
15		Data entry complete Locked

Move to next task after save

Save and Add Another Line

Importance (1 = Highest, 10 = Least)	Icon
1	
2	
3	
4	
5	
6	
7	
8	
9	

Rave EDC Subject Grid

	Subject	Demographics	Screening - VISIT 1	Pretreatment - VISIT 2	Randomization - VISIT 3	Week 4 - VISIT 4	Week 8 - VISIT 5
Patient Enrollment	🚩						
Visit Date			🗓️🚩	○	🚩	🕒	🕒
Informed Consent			○				
Demographics		🚩					
Inclusion Exclusion Criteria					○		
Randomization					○		

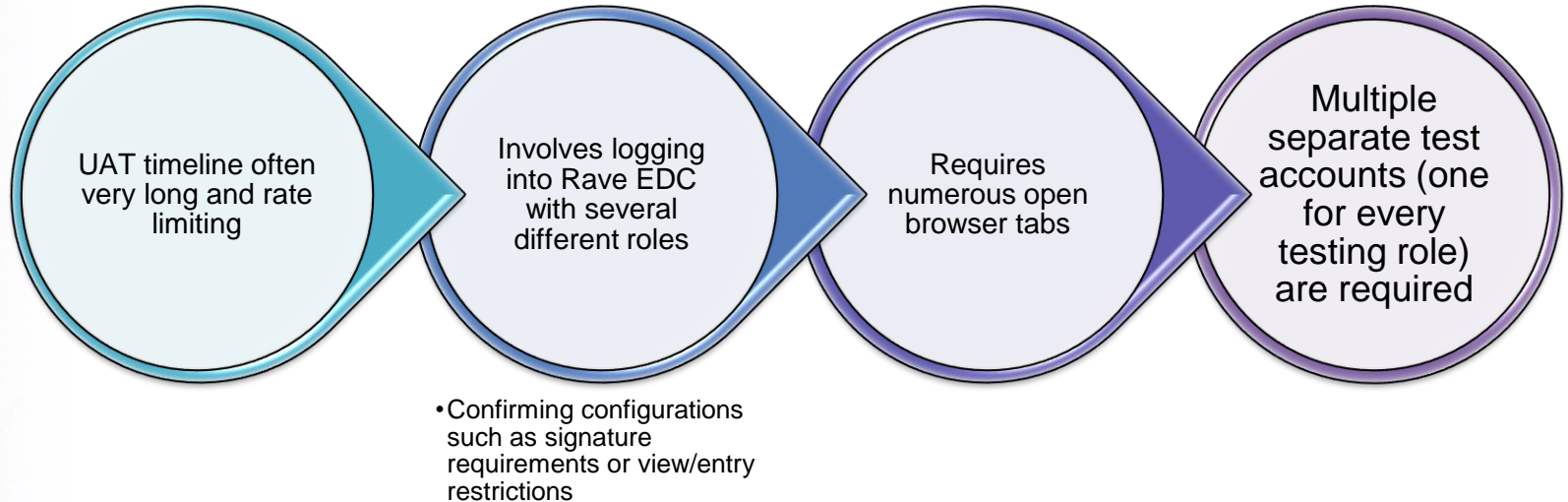
Automatic Upgrades



Rave EDC updates are applied in real time

New features available immediately, including those for integrated products

Rave Classic UAT Workflow



Rave EDC UAT Workflow

- Toggle between roles within the same browser window

The screenshot displays the Rave EDC UAT Workflow interface. The top navigation bar includes the 'medidata' logo and several menu items: 'STUDIES' (Prometrikax-Innovate), 'ACTIONS' (DENA TESTX), 'ENVIRONMENTS' (EDC), 'SITES' (Development), and '9998-9998 - Rusty Clinic'. A user profile dropdown menu is open, showing the user's name 'Kathy Zhe' and a list of roles. The role 'TEST - Clinical Research Coordinator' is highlighted in bold. A red circle is drawn around the dropdown menu to emphasize the role selection process.

Rusty Clinic - Subjects

Enrollment Target 0 Enrolled 0 Completed 0

Filter By Subject Status Find Subject

All Statuses Reset

Subject Information	Subject Status	Screening Visit	Pretreatment Visit	Randomization
001	Screened			
002	Screened			
111 Female	Screened	●	○	

3 Total

Per page 10 25 50 100

Rave EDC UAT Time Saving Benefits

Calendar control

- Streamlines testing for date fields

Field level edit checks / dynamics fire prior to saving

Efficiencies for database builders and system administrators

- New dropdown navigation menus allowing the user to switch environments
- Go from working in EDC to accessing the system administration screens with a single click



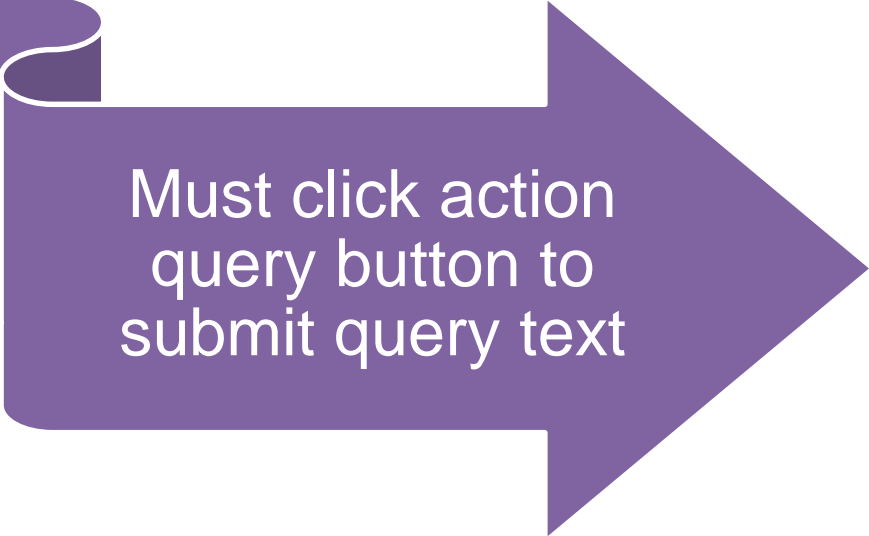
Rave EDC Considerations

- 1. Toggling between roles during testing brings you back to site-level view
- 2. Review of update release notes more crucial and time-sensitive given automatic application
- 3. “Pending Tasks” for all roles is shown as a single flag. Visibility of icon between roles depends on core configuration
- 4. Renaming site mid-study not possible

Rave EDC Considerations – User Interface



New e-Learning
team for pre-
production
training



Must click action
query button to
submit query text

ANY
QUESTIONS



Thank You