



Comprehensive Capabilities Comparison

Key

Included, no added cost ✓

Add-on/Low cost \$

Not Available X

Add-on/High cost \$\$\$

General

Item	TrialKit	Clinical Studio	Medidata Rave	Oracle Clinical/RDC
Cost	\$	\$	\$\$\$	\$\$\$
Complete cross-functionality between native mobile app and web-based system	✓	✓	X	X
Complete Web API for external integrations, including native support for wearables and activity tests	✓	✓	X	X
Ability to create host accounts and studies quickly and freely.	✓	✓	\$\$\$	\$\$\$
Free training with a qualified instructor	✓	✓	X	X
Certification training	✓	\$	\$\$\$	\$\$\$
System-wide branding and customization to create your own internal solution	N/A	✓	X	X
Full Study Enterprise Management within a single system for departments, divisions, affiliated companies and investigators	✓	✓	X	X
Site and patient recruiting capabilities	✓	X	X	X
Search TrialKit database of other published studies by therapeutic area	✓	X	X	X
Real-time reporting	✓	✓	\$\$\$	\$\$\$

Host Account Functionality

Item	TrialKit	Clinical Studio	Medidata Rave	Oracle Clinical/RDC
Switch between multiple accounts and studies housed on any number of geographically-placed servers in one tap	✓	✓	X	X
Webpage Builder for customized content	N/A	✓	X	X
User Controlled Intra-Host Transferable Studies, including sites, users, data and files	✓	✓	\$\$\$	X
Ability to create a study from a template at any time	✓	✓	✓	X
Manage all studies from a single account	✓	✓	X	X
Publish study visibility by therapeutic area for subjects and sites to request participation	✓	X	X	X
Archive and unarchive studies with a single tap	✓	✓	X	X
Manage users across an entire account and individually per study	✓	✓	X	X



Create custom web pages to portray information to users	✓	✓	X	X
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Study Security and Data Access

Item	TrialKit	Clinical Studio	Medidata Rave	Oracle Clinical/RDC
Ability to create and manage unlimited roles with Advanced Role Security	✓	✓	✓	✓
Grant or revoke any role or right in the system with a single checkbox	✓	✓	✓	✓
Manage multiple sites per study	✓	✓	✓	✓
Assign multiple users per site	✓	✓	✓	✓
Assign a single user to multiple sites	✓	✓	✓	✓
Grant or revoke view and insert rights to any role for any form	✓	✓	✓	✓
Grant view and editing rights to all roles with a single tap	✓	✓	X	X
Assign a hierarchy of role access levels	✓	✓	✓	✓
Hook into events through Restful web service	✓	✓	\$\$\$	\$\$\$
Comprehensive Documented Web API	✓	✓	X	X

Study Workflow

Item	TrialKit	Clinical Studio	Medidata Rave	Oracle Clinical/RDC
Ability to define multiple review levels by role and program and order of completion	✓	✓	X	X
Define each level to review by form or field, including Risk-Based Monitoring support	✓	✓	\$	\$
Define each level to review as requiring an electronic signature	✓	✓	✓	✓
Touchscreen signing	✓	X	X	X
Individual locking and unlocking	✓	✓	✓	✓
CEC Adjudication	✓	✓	\$	\$

Query Management

Item	TrialKit	Clinical Studio	Medidata Rave	Oracle Clinical/RDC
Fully integrated Query Management at no additional charge	✓	✓	✓	✓
Form-based Queries	✓	✓	✓	✓
Field-based Queries	✓	✓	✓	✓
Interval-based Queries	✓	✓	✓	X
My Queries Report by role	✓	✓	✓	✓
Filter Report based on any criteria	✓	✓	✓	X
System Generated Queries (via failed edit checks)	✓	✓	✓	✓



Ability to define user role deployment by System-generated Query	✓	✓	✓	✓
Ability to override role deployment by edit check for System Queries	✓	✓	✓	X
Manual Queries for user with appropriate right	✓	✓	✓	✓
Set default roles for Manual Query Deployment	✓	✓	✓	✓
Override default roles for Manual Query Deployment	✓	✓	X	X
Redeploy existing Query to any role or revoke role rights to any Query	✓	✓	X	X
Code each Query type for effective reporting and exportation	✓	✓	✓	✓
Automatic close of System Query upon data correction	✓	✓	✓	✓
Manual close of System Query, with Protocol Deviation option	✓	✓	✓	✓
Send notification emails by site, Query, Query type	✓	✓	✓	X

Version Control

Item	TrialKit	Clinical Studio	Medidata Rave	Oracle Clinical/RDC
Study Versioning for controlled study/protocol changes	✓	✓	✓	X
Publish multiple Versions	✓	✓	✓	X
Set Version by site	✓	✓	✓	X
Migrate subject to any Version from any Version	✓	✓	X	X
Published Versions prevent any changes to study build criteria	✓	✓	✓	✓
View all changes made between Versions	✓	✓	✓	X
Define Development Version for testing through administrative sites	✓	✓	✓	X
Run multiple sites and subjects on multiple Versions simultaneously	✓	✓	✓	X
Capacity for an unlimited number of Versions	✓	✓	✓	X
Automatically break record locks on subject migration if data has changed or Query generated on new Version	✓	✓	✓	X

Regulatory Auditing

Item	TrialKit	Clinical Studio	Medidata Rave	Oracle Clinical/RDC
All forms are saved entirely; existing data is archived and can be retrieved at any time	✓	✓	X	X
Time, user, and changes stamped to every transaction	✓	✓	✓	✓
Require reason for changes to field data	✓	✓	✓	✓
Report on CRFs with missing reasons	✓	✓	X	X



Code reason fields or use free text by study	✓	✓	X	X
Copy reason from one field to another	✓	✓	X	X
Log every transaction to a subject record and optionally view on CRF or Audit Report	✓	✓	X	X
Report on all changed fields with the reason for change	✓	✓	X	X
Report on record origination (Mobile App or Website)	✓	✓	X	X
Report on data origination (GPS - Mobile App) and user logins	✓	✓	X	X
Plot data origination on Map	✓	✓	X	X
Extract all records - including archived and deleted	✓	✓	X	X
Undelete records	✓	✓	✓	X
Site/user auditing for tracking the site and user permission changes	✓	✓	✓	✓
Report on every action taken by users with drill-down capabilities	✓	✓	X	X

eCRF Building

Item	TrialKit	Clinical Studio	Medidata Rave	Oracle Clinical/RDC
Drag and Drop Form Builder with ability to drop field controls anywhere on canvas	✓	✓	X	X
Integrated Conditional Action Builder for creating edit checks, hiding fields, disabling fields, creating popup messages, populating field values, computing fields and sending both email and push notifications	✓	✓	X	X
No programming required	✓	✓	X	X
Access data from other forms when building Conditional Actions	✓	✓	✓	✓
Support for multiple, tabbed pages on a single form	✓	✓	X	X
Cut, copy and paste any field	✓	✓	X	X
Target the same form for multiple devices (iPhone, iPad, Web Browser)	✓	✓	X	X
Manage a complete library of private and public forms	✓	✓	X	X
Export form and all attributes from any account and study	✓	✓	X	X
Import form and all attributes, from any account and study	✓	✓	X	X
Annotated Case Report Forms	✓	✓	X	X
Export Metadata to Excel, XML or ODM	✓	✓	✓	X
Automatically validate CRFs and edit checks	✓	✓	X	X
Tag forms as validated by Version with stored logs	✓	✓	X	X



Create custom notifications with Mail Merge (email and push)	✓	✓	X	X
Create Distribution Lists for Conditional Action Notifications	✓	✓	X	X
Capture any type of data imaginable	✓	✓	X	X
Extend any eCRF with any programming language	✓	✓	✓	✓
Preview rendered forms within Form Builder with Conditional Actions	✓	✓	X	X

Subject Visits

Item	TrialKit	Clinical Studio	Medidata Rave	Oracle Clinical/RDC
Intuitive user-friendly navigation for simple data entry	✓	✓	X	X
Scheduled Visits by Visit Interval	✓	✓	X	X
Visit Intervals relative to other Visit Intervals	✓	✓	✓	✓
Interval Date Entry (enter one visit date for an entire Interval)	✓	✓	✓	X
Unscheduled Visits by required form	✓	✓	✓	X
Cyclical Unscheduled Visits for oncology and other cyclical treatment studies	✓	✓	✓	X
Longitudinal Log Forms for events that cannot be scheduled like medications, adverse events, etc.	✓	✓	X	X
Drop Apple ResearchKit tests into a visit	✓	X	X	X

Randomization and Local Labs

Item	TrialKit	Clinical Studio	Medidata Rave	Oracle Clinical/RDC
Randomization by visit	✓	✓	X	X
Multiple Randomizations per study	✓	✓	X	X
Randomize after any visit	✓	✓	X	X
Stratify Randomizations on any field(s) in system	✓	✓	X	X
Centralized or Site Stratified Randomization	✓	✓	X	X
Import Randomization from Excel	✓	✓	✓	X
Return Subject Profile ID with Allocation	✓	✓	✓	X
Blinded or Unblinded Randomization	✓	✓	✓	X
Decode Randomization Arms	✓	✓	X	X
Use Randomization Arms in Conditional Actions to hide fields, forms and intervals	✓	✓	✓	X
Run studies within a study	✓	✓	X	X
Randomization Schedule app by site and subject	✓	✓	X	X
Local Lab range support	X	✓	\$\$\$	\$\$\$
Multi-stratified auto-population of lab units by site	X	✓	\$\$\$	\$\$\$



Medical Coding

Item	TrialKit	Clinical Studio	Medidata Rave	Oracle Clinical/RDC
Cost	\$	\$	\$\$\$	\$\$\$
Certified WHODrug and MedDRA coding tool	✓	✓	✓	✓
Auto-code single record	✓	✓	\$\$\$	\$\$\$
Rapid Auto-coding of large datasets in bulk	✓	✓	X	X
Filter coding lists by all criteria	✓	✓	X	X
Independent review levels	✓	✓	\$\$\$	X
Auto-code on native mobile app (iOS)	✓	✓	X	X
Synonym Dictionary importing and support	✓	✓	\$\$\$	\$\$\$
Batch Processes for autocode, save and review	✓	✓	\$\$\$	\$\$\$

Inventory Control

Item	TrialKit	Clinical Studio	Medidata Rave	Oracle Clinical/RDC
Track drugs, devices and other products from manufacturing through treatment/explant	✓	✓	X	X
Create and print barcodes for products	✓	✓	X	X
Directly scan any product using the device camera and update inventory instantly	✓	X	X	X
Inventory Disposition Report (shows all product and their current whereabouts)	✓	✓	X	X
Track products by supplier, site and patient	✓	✓	X	X
Set reorder levels by site	✓	✓	X	X
Automatic site reordering	✓	✓	X	X
Product return to supply	✓	✓	X	X
Custom workflow configurability to include manufacturer, supplier, depot, site, and subject	✓	X	X	X

Study Documents/File Management

Item	TrialKit	Clinical Studio	Medidata Rave	Oracle Clinical/RDC
Centralized Study Document Manager	X	✓	X	X
Upload documents to any CRF	✓	✓	X	X
Document Viewer	✓	✓	X	X
Annotate documents by user	X	✓	X	X
Redact documents by user	X	✓	X	X
Document Manipulation	X	✓	X	X

Site Regulatory Documents

Item	TrialKit	Clinical Studio	Medidata Rave	Oracle Clinical/RDC
Centralized Site Regulatory Document Manager	✓	✓	X	X



Create forms to track regulatory documents and assign to each site	✓	✓	✗	✗
Tie enrollment to regulatory document completion	✗	✓	✗	✗
Show status, by site, of regulatory document completion	✗	✓	✗	✗
Set approved to enroll	✗	✓	✗	✗
Choose from three site enrollment rules	✗	✓	✗	✗
Site payment tracking based on CRF and visit completion rules	✓	✓	✗	✗

Study Branding and Customizable Themes

Item	TrialKit	Clinical Studio	Medidata Rave	Oracle Clinical/RDC
Upload complete Theme on a per study basis	N/A	✓	✗	✗
All users in that study view that Theme	N/A	✓	✗	✗
Build four landing pages to customize messaging for study	N/A	✓	✗	✗
No programmer required	N/A	✓	✗	✗

Subject Manager

Item	TrialKit	Clinical Studio	Medidata Rave	Oracle Clinical/RDC
Subject registration through customizable form	✓	✓	✓	✗
100% customizable Subject Profile ID's	✓	✓	✓	✓
Subject view by site	✓	✓	✓	✓
Active Version Control by Subject View	✓	✓	✗	✗
Choose the fields to be displayed in view	✓	✓	✗	✗
Automatic generation of Subject Profile ID	✓	✓	✓	✓
Print completed Subject Registration Record	✓	✓	✓	✓
Deleting of Subject Record can be undone	✓	✓	✗	✗
Batch Registration for receiving batches of Subjects (i.e., pre-clinical lab)	✓	✓	✗	✗
Subject Record Page - displays all Subject CRFs on a single page	✓	✓	✓	✓
Show status or Statuses of Subject	✓	✓	✓	✓
Customizable Subject View	✓	✓	✓	✓
View Unblinded Randomizations	✓	✓	✓	✓
View Location on Map of where record was captured on mobile device	✓	✓	✗	✗
Hide and disable fields and forms based on Subject Events in real-time	✓	✓	✓	✗
Hover over or tap on field to reveal all Queries and Statuses	✓	✓	✗	✗
Query Icon provides quick access to the current field/form/ Interval query	✓	✓	✗	✗



Save draft CRF lists error messages but does not generate Queries until saved final	Coming Soon	✓	✓	✓
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Study-Related Forms

Item	TrialKit	Clinical Studio	Medidata Rave	Oracle Clinical/RDC
Capture data related directly to the study such as protocol or study materials/inventory	✓	✓	X	X
Build and deploy study-related forms to web	✓	✓	X	X

Reporting

Item	TrialKit	Clinical Studio	Medidata Rave	Oracle Clinical/RDC
AdHoc Report Builder	Coming Soon	✓	✓	X
Dashboard Report reveals dozens of study metrics on a single page and allows drill-down capabilities into Report and Relevant Subject Records	✓	✓	X	X
Action Item Report by Role - lists items that require immediate Attention	✓	✓	✓	✓
My Queries Report that filters by site, form, field, status, subject and type	✓	✓	X	X
Full Subject Audit Report that displays all transactions made to any Subject Record and allows drill-down capabilities into the transaction	✓	✓	X	X
CRF Export / Study Closeout - exports all relevant data by site, subject and form. Displays Queries, changes to Record, review locks and the CRF in an annotated style, all exported to PDF	X	✓	X	X
Export all Report data to Excel with single tap	Coming Soon	✓	X	X
Seamless integration with JReview	✓	✓	✓	X
Extract entire data set <i>by form</i> to SAS, ODM, XML, SPSS and Excel with single mouse click at any time	Coming Soon	✓	X	X
Extract entire data set to SAS, ODM, XML, SPSS and Excel with single mouse click at any time	Coming Soon	✓	X	X

Mobile App Functions

Item	TrialKit	Clinical Studio	Medidata Rave	Oracle Clinical/RDC
Full native resolution support on all iOS devices – both portrait and landscape viewing	✓	✓	X	X
Randomize subjects from App	✓	✓	X	X
Deploy CRFs created on Clinical Studio to both TrialKit and Clinical Studio	✓	✓	X	X
Deploy CRFs created on TrialKit to both TrialKit and Clinical Studio	✓	✓	X	X
Scan barcodes directly into a CRF and autofill data from FDA device registry	✓	X	X	X
Add images to CRFs for users to sketch on simply for referencing	✓	X	X	X



Allow users to upload images, video, and audio directly to a CRF.	✓	X	X	X
Multiple tab/pages for effective use of limited screen space, allowing for easier navigation on a form.	✓	✓	X	X
Target CRFs for multiple devices (iPhone, iPad, Web Browser)	✓	✓	X	X
Stamp location of user to each completed Subject Record (must be enabled by users)	✓	✓	X	X
Send Group Notifications (role, site, user, etc.)	✓	✓	X	X
Send notification by event in data (AE, SAE, or any combination of data) to any role in system	✓	✓	X	X
Manage users' mobile devices	✓	✓	X	X
Customizable and automated notifications (push and email)	✓	✓	X	X

Patients - ePRO & eDiary

Item	TrialKit	Clinical Studio	Medidata Rave	Oracle Clinical/RDC
Cost	✓	✓	X	X
Automatic notification to device when form is due	✓	✓	X	X
Simple tap user interface to complete forms	✓	✓	X	X
Forms designed in Website and easily deployed to App	✓	✓	X	X
Patient Portal on Website for patients to sign in and access survey forms if they don't use the TrialKit app	✓	✓	X	X
Icon Badges that show number of forms currently due	✓	N/A	X	X
Ability to schedule push notifications to inform subjects that forms are due	✓	✓	X	X
Full Help available from App and Patient Portal Website	✓	✓	X	X
Mobile ePRO Device Manager enables direct communication with subjects via the App or email	✓	✓	X	X
Clinician handoff capability - allows patients to complete forms without the need to separately log in.	✓	N/A	X	X

Disclaimer: This document was created based knowledge of certified developers on each of the platforms compared above. Crucial Data Solutions, Inc. must not be held responsible for potential inaccuracies due to ever-changing software features on each of the cited systems. The objective of this comparison is to provide a comprehensive list of functions to consider when making comparisons with other platforms. To provide feedback or information for improving the accuracy of comparisons made on this document, please contact info@clsds.com.