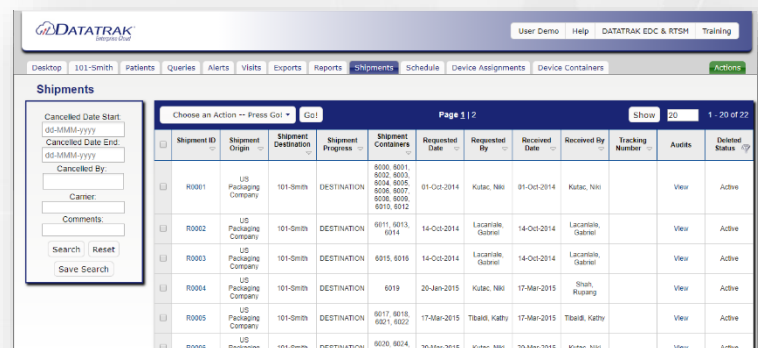


Randomize Patients and Automate Drug Supply

Datatrak's RTSM (Randomization & Trial Supply Management) product simplifies trial randomization and allows you to exert control over the randomization and supply process. RTSM supports a multitude of protocol schemes while dispensing, controlling and automating drug supply fulfillment. The robust Manager functionality allows users to view, filter, update and export information on drug containers, drug assignments, shipments and randomization schedules. This most advanced randomization and clinical supplies management product can be configured and maintained by you.

As a unified product within the Datatrak Enterprise Cloud clinical research platform, Datatrak's RTSM product provides users with the ability to:

- Easily randomize patients
 - Click to randomize
 - View a list of items to be completed
 - Get a receipt upon successful randomization
- Keep drug accountability visible
 - Track shipments, containers, vials
 - Know who has been assigned what drug
- Manage it all online
 - Randomization schedule generation
 - Initiating shipments and automate re-supply
 - Handling emergency unblinding and everything in between
- Perform randomization safer, better and faster
 - Reduce mistakes, not entering data twice
 - Works stand alone or together
 - Rapid deployments



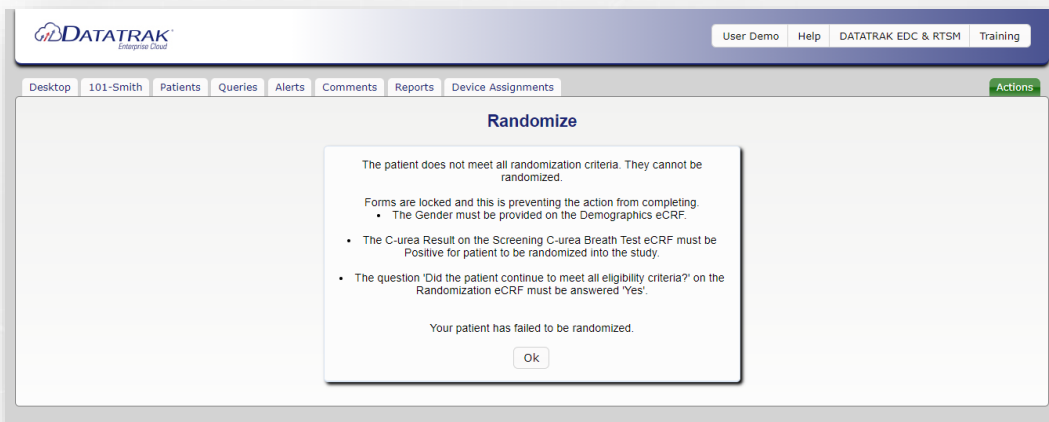
The screenshot shows the 'Shipments' management interface. It includes a search sidebar on the left with fields for 'Cancelled Date Start', 'Cancelled Date End', 'Cancelled By', 'Carrier', and 'Comments'. The main area displays a table of shipment records with columns for Shipment ID, Shipment Origin, Shipment Destination, Shipment Progress, Shipment Containers, Requested Date, Requested By, Received Date, Received By, Tracking Number, Audit, and Deleted Status. The table contains six rows of data for various shipments.

Shipment ID	Shipment Origin	Shipment Destination	Shipment Progress	Shipment Containers	Requested Date	Requested By	Received Date	Received By	Tracking Number	Audit	Deleted Status
R0001	US Packaging Company	101-Smith DESTINATION	DESTINATION	8000 8001, 8002 8003, 8004 8005, 8006 8007, 8008 8009, 8010 8011	01-Oct-2014	Kutac, Nilo	01-Oct-2014	Kutac, Nilo		View	Active
R0002	US Packaging Company	101-Smith DESTINATION	DESTINATION	8011 8013, 8014	14-Oct-2014	Lacarnile, Gabriel	14-Oct-2014	Lacarnile, Gabriel		View	Active
R0003	US Packaging Company	101-Smith DESTINATION	DESTINATION	8015 8016	14-Oct-2014	Lacarnile, Gabriel	14-Oct-2014	Lacarnile, Gabriel		View	Active
R0004	US Packaging Company	101-Smith DESTINATION	DESTINATION	8019	20-Mar-2015	Kutac, Nilo	17-Mar-2015	Shah, Rupang		View	Active
R0005	US Packaging Company	101-Smith DESTINATION	DESTINATION	8017 8018, 8021 8022	17-Mar-2015	Tibaki, Kathy	17-Mar-2015	Tibaki, Kathy		View	Active
R0006	US Packaging Company	101-Smith DESTINATION	DESTINATION	8020 8024, 8025 8026	20-Mar-2015	Kutac, Nilo	20-Mar-2015	Kutac, Nilo		View	Active

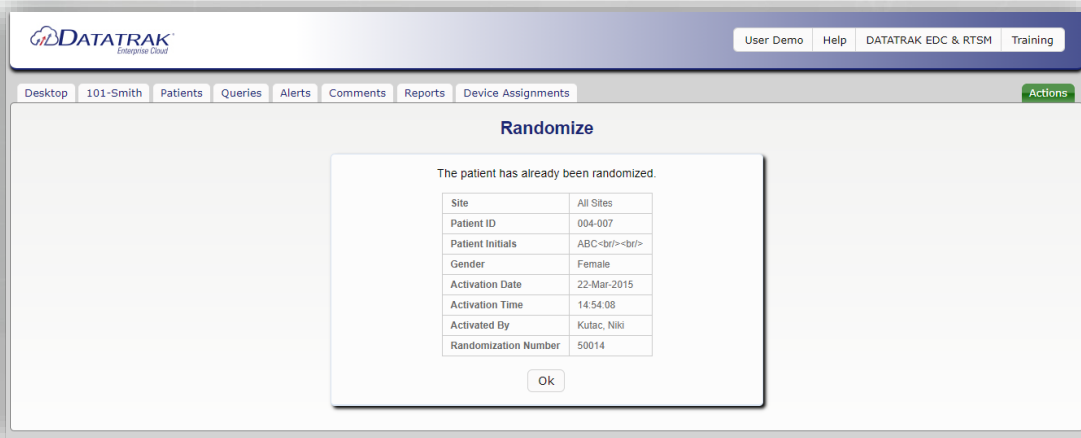
Unified technologies like Datatrak Enterprise Cloud aim to provide you with the greatest possible level of functionality in a single, streamlined product. If you're interested in discussing with us how we can simplify your lives, please reach out to us to schedule a demo today.

Randomization

RTSM can be programmed to randomize a patient based on client’s specifications. The system contains algorithms for stratification, institutional balancing, and minimization for randomization configuration. The system allows for real-time checks against the clinical data to ensure the patient meets entry criteria prior to allowing the randomization to occur. The checks can be applied to questions and forms and can be based on the data or metadata status as required.



Upon randomization a receipt, it displayed and email notifications are sent to team members notifying them of the randomization occurrence.



Blinding

RTSM can be programmed to have blinded and unblinded roles to allow management of inventory & randomization schedule.

Inventory Management

RTSM managers provide a real-time view into the supplies during a clinical trial, allowing users to efficiently plan and manage the clinical trial supplies.

RTSM allows defined shipping plans that will automatically request resupply amounts once site inventory reaches the resupply level. The resupply levels can be defined at a study level or site level depending on the drug supply specifications. RTSM also provides a manual process to request shipments which can be used in emergency situations; the system will automatically recommend the amount of inventory to send based on the inventory plan and this amount can be modified based on the situation.

Shipments request can be managed within RTSM:

- Automatic shipping request
- Manage multiple depots
- Track Couriers and Tracking Numbers
- Define Resupply Amounts per Study or Site
- Confirmation of Shipment Receipt, with ability to communicate issues with shipment

Requisition ID R0008

Required Fields *

This shipment request contains the following drug kits:

Kit ID	Total	<input type="checkbox"/> Received	<input type="checkbox"/> Missing	<input type="checkbox"/> Broken
1069	1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1072	1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1075	1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1076	1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Confirm Drug Kits (Please check the boxes next to the drug kits for confirmation of being received or missing.)

Date the shipment was documented as being received. (dd-MMM-yyyy) *

Please note any problems with your shipment.

Patient Assignments

RTSM can automatically assign drug at point of randomization or allow the site to assign drug when needed. The assignments can be made one time or across multiple visits as required by the protocol.

