RTSM Drug Pooling Advantages of Drug Pooling in Clinical Trials

Investigational Drug (IP) manufacturing is very expensive and can take long periods of time to complete. So it is important to reduce waste, ensure efficient assignment of treatments, and reduce the administrative burden associated with tracking IP. Drug pooling reduces drug supply overage and maintains adequate supplies for patients.

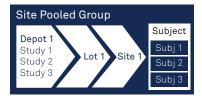
What is "Pooled Supplies"?

Non-Sharing Study Supplies are associated to a trial at the time a packlist is uploaded.

Non-Sharing Study		
Study 1	Study 2	Study 3
Depot 1	Depot 2	Depot 3
Lot 1	Lot 2	Lot 3
Site 1	Site 2	Site 3



Depot Pooled Group Supplies are associated to a trial at the time of shipping. **Site Pooled Group** Supplies are associated to a trial at time of dispendation.



<u>Rave RTSM's</u> drug pooling feature addresses the need to make efficient use of trial supply across multiple studies. There are two approaches that can be utilized - a Depot Pooled Group and Site Pooled Group. Drug pooling at the depot and site-level enables the sharing of a drug where a depot and/or site may be participating in multiple studies utilizing the same compound. This revolutionary approach to trial supply management realizes enormous cost savings and simplifies trial supply storage at sites and depots.

Rave RTSM Drug Pooling Benefits

Drug pooling streamlines workflows and improves efficiencies in drug supply

Reduced Inventory

- Pooling supplies across studies reduces total inventory needed
- Simplifies logistics management
- Significant IP cost savings

Reduced Shipments

- Fewer shipments to manage
- System flexibility that enables control of shipment size
- Reduced shipment costs amplified with multiple studies

Reduced Site Storage

- Pooling across studies at site reduces supply need at site
- Simplifies supply and inventory management at site

Cross-Study and Site Reporting

- Inventory reporting across studies
- Drill down capability on site inventory
- Single source of data for reporting



FACT SHEET RTSM DRUG POOLING

There are inherent value and benefits to pooling clinical supplies- especially as IP becomes more expensive and trial design complexity continues to increase. Advancements in RTSM technology enable the operational complexity to be addressed, allowing sponsors to realize the true value of implementing drug pooling strategies.

Challenges

Burden for the site

• Receive multiple shipments of drug into different databases

Burden for depots

• Pick, pack and shipments of drug into different databases

Burden for sponsor

 Pay for multiple shipments instead of one: increase drug overage for each database: increase in drug waste

Solution via Pooling Approach

Solution for the site

Receive one shipment

Solution for depots

• Pick, pack and ship one combine shipment to the site

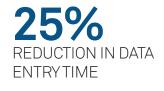
Solution for sponsor

- Run multiple indication databases with less inventory
- Decrease costs by sharing supplies across studies and sites

Benefits of Pooled Supplies

Sponsor results seen across multiple studies

40% REDUCTION IN PACKAGING WASTE **34%** REDUCTION IN SHIPPING COSTS



The Medidata Advantage

There is no more efficient way to save on inventory than drug pooling and no more advanced solution than Rave RTSM. Rave RTSM's drug pooling can be enabled at any time prior to a study or during an existing study and the set-up is simple with no system downtime. Real-time data visibility and reporting at the depot and site level across studies promote more informed decision-making.

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