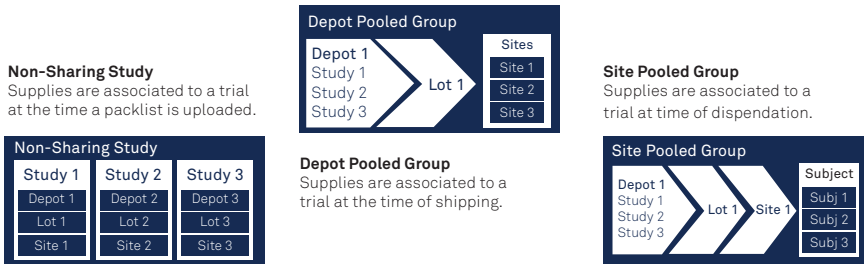
Advantages of Using Drug Pooling in Clinical Trials

Investigational Drugs (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. Furthermore, in cases where studies share similar characteristics, reducing duplication of effort in managing drug supply enables improved efficiency.

Currently most trials are independent consumption-based supply chain models. Whereas, drug pooling, or Pooled Supply, is the practice of sharing the same drug lot across multiple clinical trials. Companies are looking at drug pooling as a means to reduce expenses associated with drug supply and as a way to reduce the site burden when handling large quantities of IP. Drug pooling reduces drug supply overage and maintains adequate supplies for patients. There are two approaches that can be utilized - a Depot Pooled Group and Site Pooled Group. **Figure 1** below illustrates how pooled supplies work.

Figure 1

What is "Pooled Supplies?"



In the Depot Pooled Group, the drug supplies are associated to a trial at time of shipping. At the depot level multiple studies can make use of a batch of drug kits. In the Site Pooled Group, the drug supplies are associated to a trial at the time of dispendation. Sites can share the kits at their location across multiple studies.

Remove Technology as a Barrier

Technology can help foster adoption:

Operational and Regulartory Oppositions

- *Foreknowledge of trials*
- *Cost and effort of pooling systems*
- *Drug Accountability*
- *Labeling (US vs ex-US)*
- *Ability to map sites across trials*
- *Lack of transparency to inventory levels*
- *Un-numbered supplies work around?*

New Technology Paradigm

- *Pooling benefits determined after trial/program is live with Rave RTSM*
- *Rave RTSM, being a configurable solution reduces the cost and effort versus a customized solution*
- *Site's drug accountability activites are transparent across trials with Rave RTSM*
- *Rave RTSM shares at the lot level rather than the study level*
- *Inventory transparency in system and reporting using the Medidata platform*

Trial Supply Management has become increasingly challenging as investigational products (IP) become more complex, costly, and in some cases, less abundant. Coupled with these complexities are challenges associated with labeling, packaging, managing waste, and shipping. All the while, pharmaceutical companies are interested in controlling costs through reduction in waste of clinical supplies when conducting a trial.

Real-world Use Case

Case 1:
Challenge: A growing mid sized biotech had an aggressive program studies and was looking to control costs on numerous levels.

Approach: Using packaging and study designs that would benefit from using a drug pooling strategy on multiple studies.

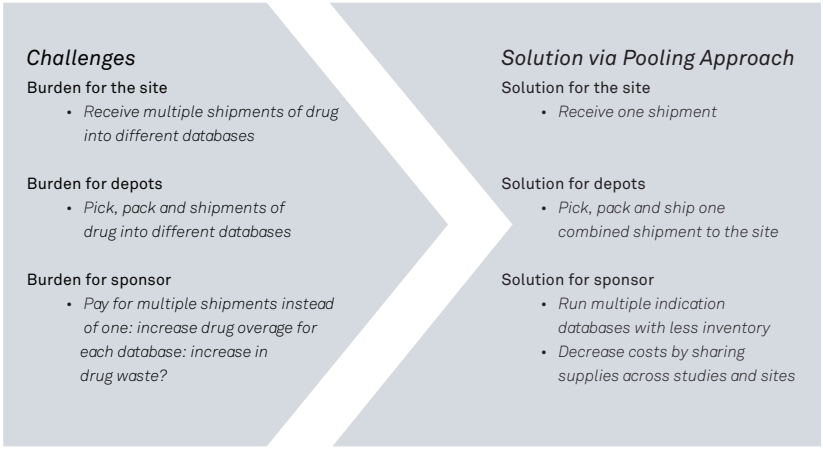
Results: They saw 39% less packaging waste and a 34% reduction in shipping costs by applying the pooling strategy. This was achieved without making compromises to the complex study objectives which utilized an adaptive dose escalation design. These studies are ongoing and operating smoothly.

Case 2:
Challenge: Sponsor wished to conduct two identical Phase III dermatological studies with a long-term extension that used a topical formulation. The program was being conducted in the US and Canada. Topical formulations create uncertainty with the amount of drug required per subject. Calculations for supply need are based on above average severity and rounding, resulting in over supply.

Approach: Pooling all supplies for two identical Phase III studies and a long-term extension allowed for a single label.

Results: With pooling there was no need for separate inventory allotments for each study and no need to re-seed sites for the extension study. It was easier to manage supply with a single source of inventory across all studies with the flexibility to move IP from one study to another without re-labeling. The rounding errors are gained back and this reduced the total number of tubes required to supply all studies. The sponsor was able to make optimal use of the supply and achieve maximum flexibility with planned inventory. They also reduced study drug overages and the cost of packaging and labeling.

Logistical challenges in today's clinical studies can be daunting for sites and the sponsor team. Medidata's Drug Pooling approach solves these challenges and provides the ability for savings and efficiency gains in a number of areas.



There is 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 now enable the operational complexity to be addressed, allowing sponsors to realize the true value of implementing drug pooling strategies.

Platform of Choice for Clinical Research

The Medidata Rave Clinical Cloud™ is the cutting-edge platform that transforms the clinical trial experience for patients, sponsors, CROs, and research sites. Designed with a unified data platform, the Rave Clinical Cloud creates a single source of truth for all study-related data. Simply put, enter data once and let the platform master and populate it throughout the end-to-end suite of Rave applications. Optimize operational execution, decrease the data entry and maintenance burden, and reduce the number of clinical systems across your study teams. Throw away your list of passwords, you are now on a truly unified platform.

About Medidata

Medidata is leading the digital transformation of life sciences, creating hope for millions of patients. Medidata helps generate the evidence and insights to help pharmaceutical, biotech, medical device and diagnostics companies, and academic researchers accelerate value, minimize risk, and optimize outcomes. More than one million registered users across 1,400 customers and partners access the world's most-used platform for clinical development, commercial, and real-world data.

Medidata, a Dassault Systèmes company (Euronext Paris: #13065, DSY.PA), is headquartered in New York City and has offices around the world to meet the needs of its customers.

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