

Clinapps SmartSupplies

A company and systems overview

BSMA Oct 2015

About Clinapps

- Established in 1999 to provide software solutions and consulting services exclusively to the Biotech and Pharmaceutical industries
- Headquartered in San Diego, California
- Technology Center in Hyderabad, India
- Impressive market growth
- 100% of revenue is driven from our SmartSupplies software
- SmartSupplies software is well adopted in the industry and has been used in thousands of trials since its introduction
- Leaders in integration
- Track record of successful implementations
- Client driven organization

The Companies We Serve



Clinical Trial Trends

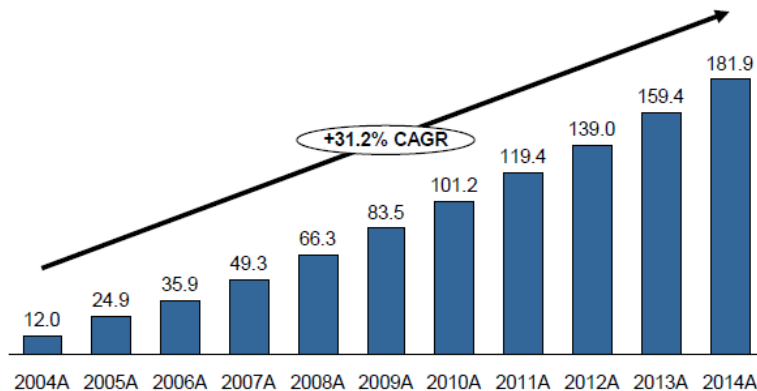
- The number of registered clinical trials has grown consistently from 2004 to 2014, at a CAGR of 31.2%
 - Trial complexity is increasing as companies expand to new geographies in order to complete trials
- Drug development costs have significantly increased from approximately \$140 million during the 1970's to \$2.6 billion in 2014
- Rising costs have largely been attributable to growing clinical trial protocols
 - Greater number of clinical trial protocols have increased to ensure efficacy
 - Rising patient interactions require timely kit shipments and seamless communication between sites and the clinical supply chain

Clinical Trial Protocol	
13 Endpoints	167 Procedures
35 Trial eligibility criteria	11 Required visits for study volunteers each 5-6 months

Source: Tufts Center for the Study of Drug Development

Registered Clinical Trials

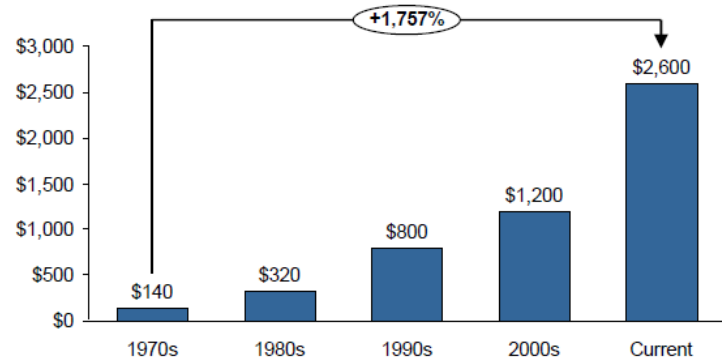
In Thousands



Source: clinicaltrials.gov

Drug Development Costs

\$ in Millions

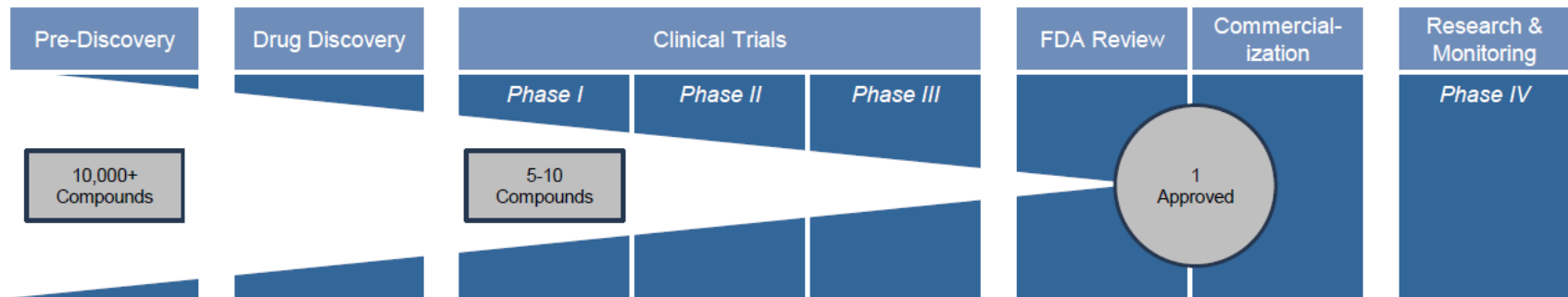


Source: PhRMA, Tufts Center for the Study of Drug Development

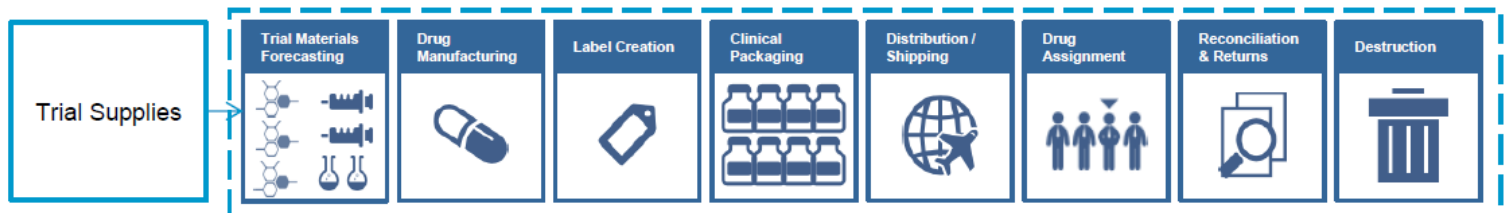
Drug Development Process

CLINapps' SmartSupplies solution suite plays a pivotal role in the clinical trial process, by managing inventory on a continual basis, helping to ensure that the right drug is given to the right patient at the right time, in a regulatory compliant and efficient manner.

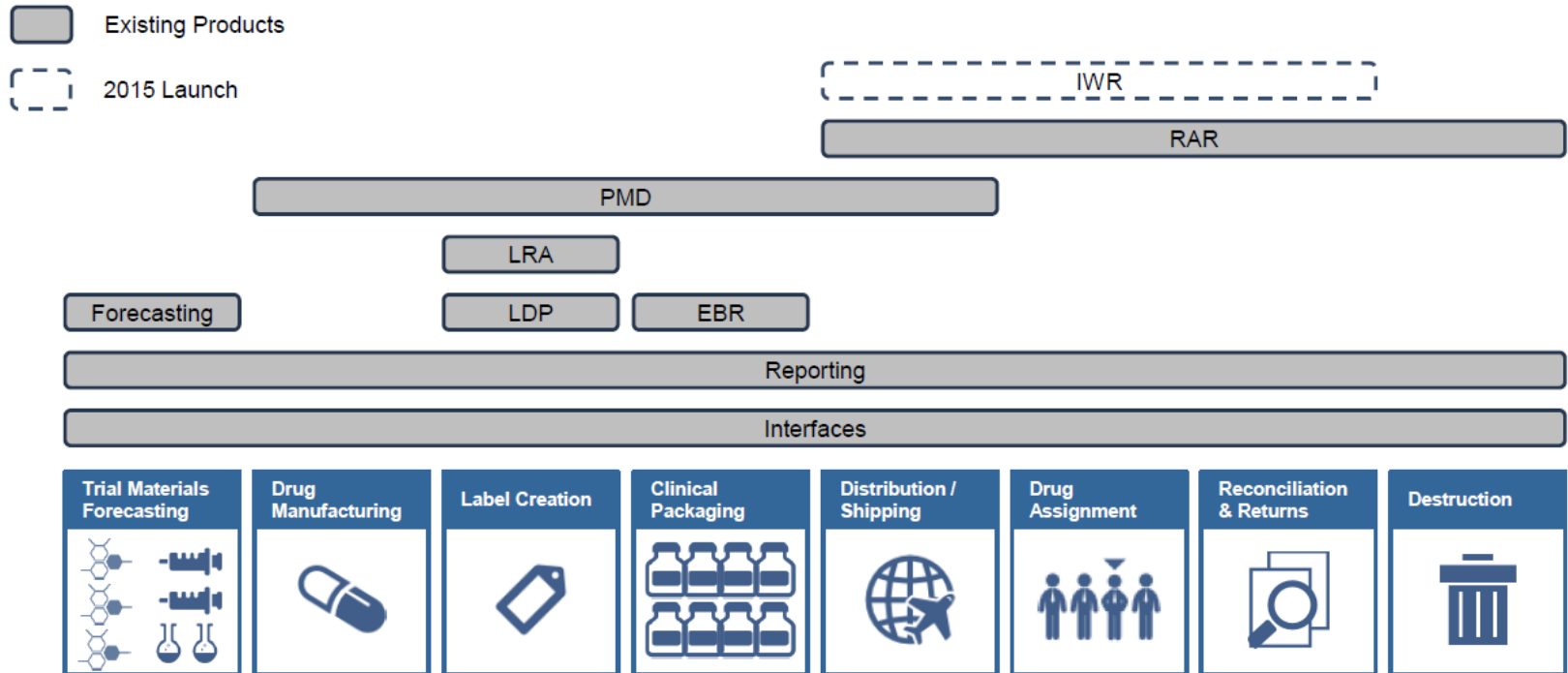
Macro Drug Development Processes



Micro Drug Development Processes



SmartSupplies Product Suite



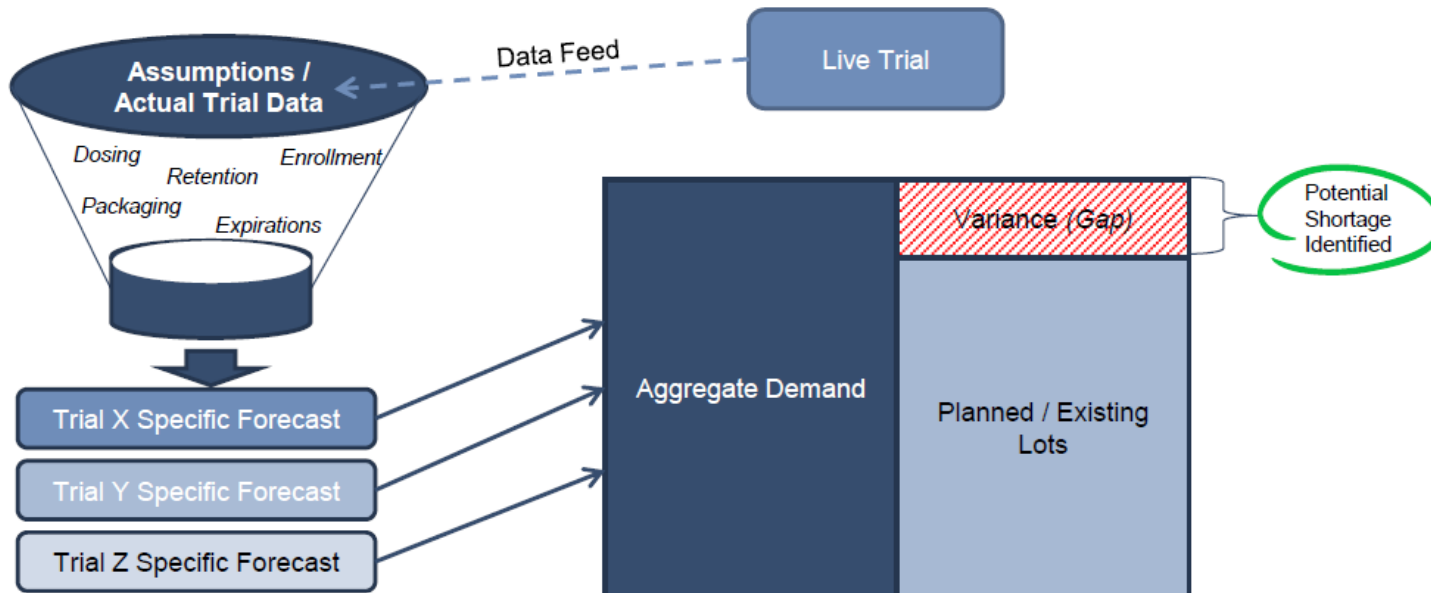
The SmartSupplies suite provides unmatched levels of integration when all modules are utilized

SmartSupplies Forecasting

SmartSupplies Forecasting assists in the creation of accurate and cost-effective clinical trial material forecasts. This solution is the most widely adopted point solution in the industry.

- Analyzes and plans for the clinical trial material requirements for each trial, based on

SmartSupplies Forecasting Framework



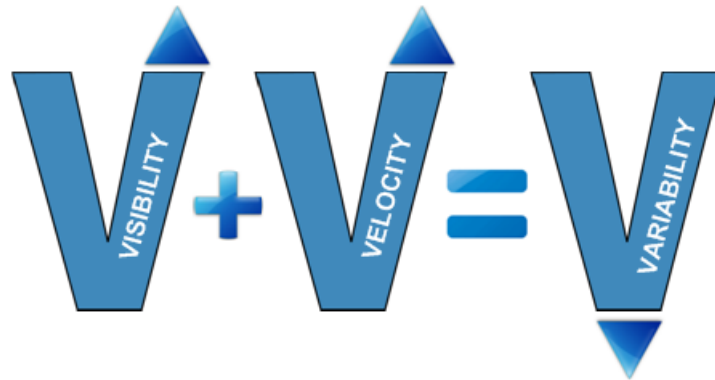
SmartSupplies Visibility Benefits

- Due to the variability in clinical demand, each study's drug requirements should be reviewed monthly to ensure optimal inventory levels
- For most companies due to the lack of systems and the manual nature of the activity, this cannot be done as frequently or accurately as required
- This is even true with a small number of studies, however as growth occurs it becomes nearly an impossible feat

The lack of adequate visibility increases the risk of stock outs, expiry dating issues, expedited shipments and production orders

- While it is difficult to quantify what this means in terms of both drug and operational costs, it is clearly not an insignificant number
- For most of our clients even a 5% savings in drug costs can provide millions of dollars annual savings

SmartSupplies Forecasting



VISIBILITY

- Everyone forecasting in the same easy to use, open and secure system
- Individual forecasts are aggregated (rolled up) into a corporate level for production planning

VELOCITY

- Less time spent creating new spreadsheets as the study changes
- Duplication/ learning from other similar forecasts
- Faster transfer of knowledge to other people and projects

VARIABILITY

- Reduction in forecast errors by using a fully validated system
- Reduction in obsolete/ excess stock
- Standardization of process reduces forecast variability as a whole

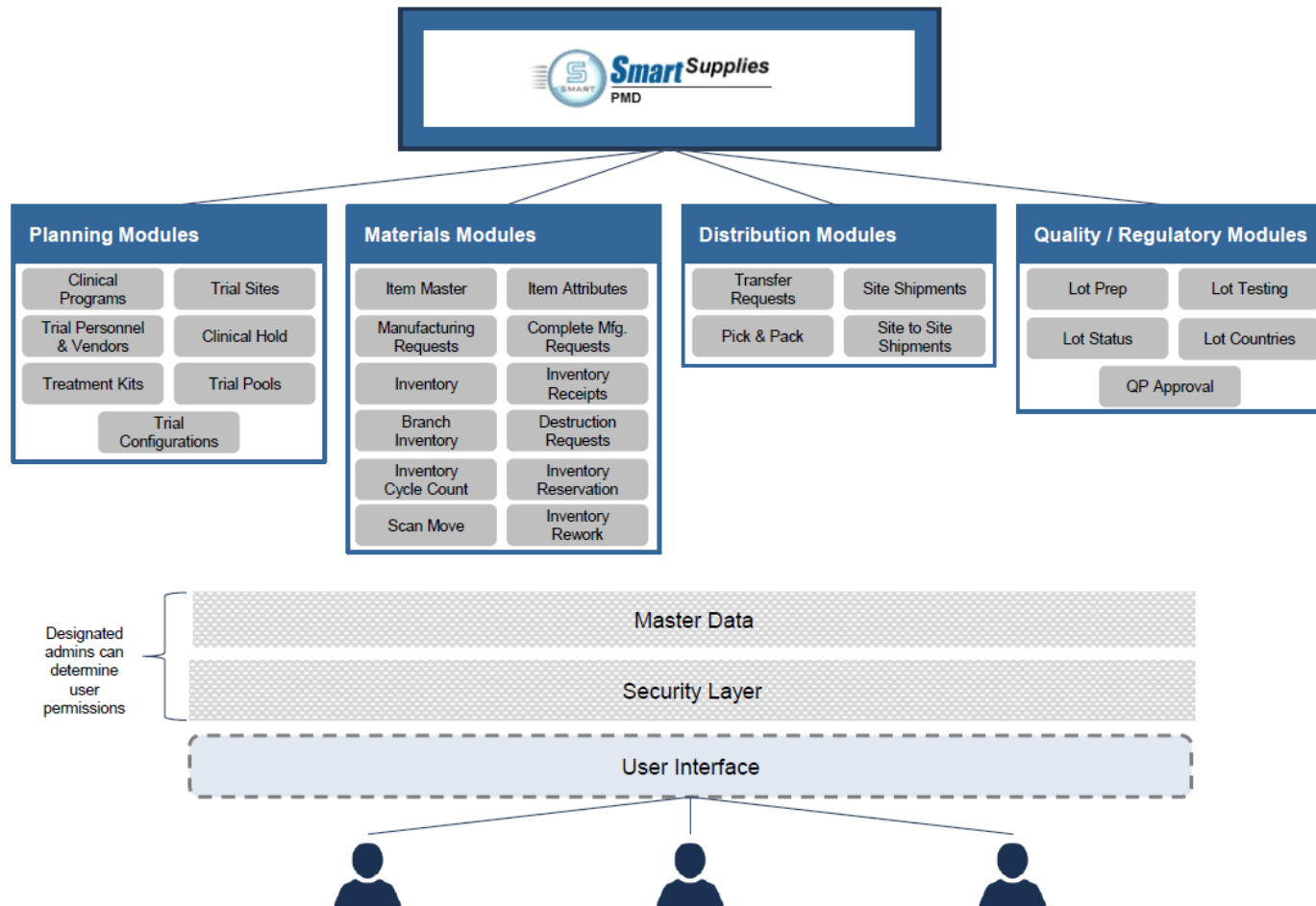
Industry Problem Statement

- For many companies the majority of their studies are packaged, labeled and distributed externally
- These organizations rely heavily on third party systems (IRT, depot web interfaces, etc.), as well as un-validated Excel spreadsheets, for planning and processing all clinical supply chain activities
- These processes require significant human effort to input and maintain the data and provide an opportunity for errors and compliance concerns
- Generally speaking the level of compliance is “debatable”

How can we solve these problems?

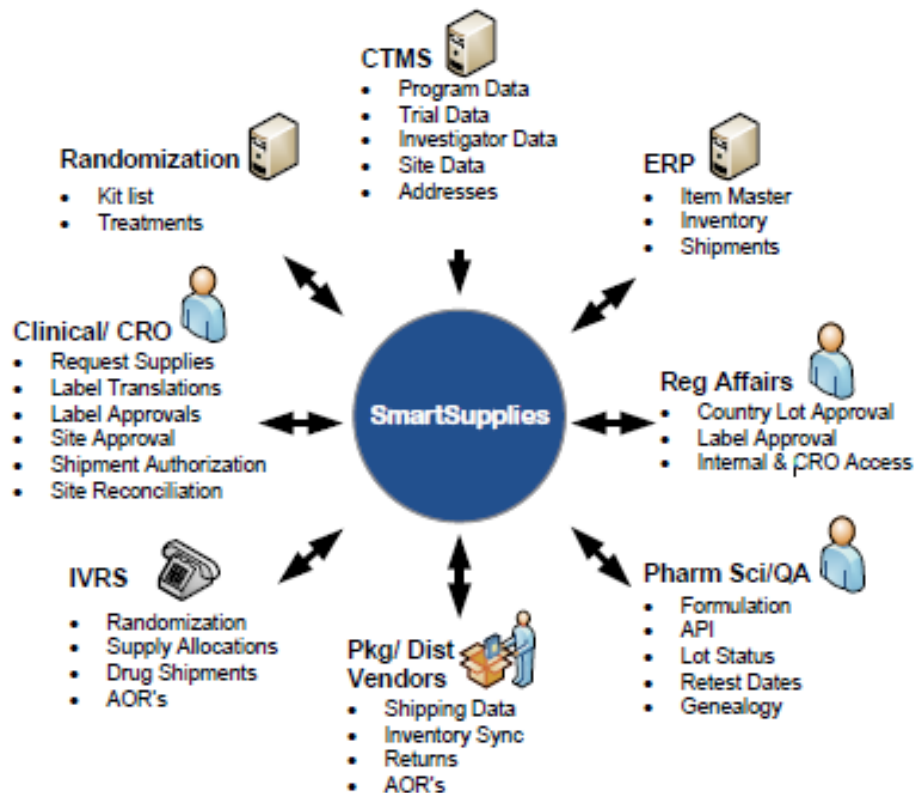


SmartSupplies PMD Overview



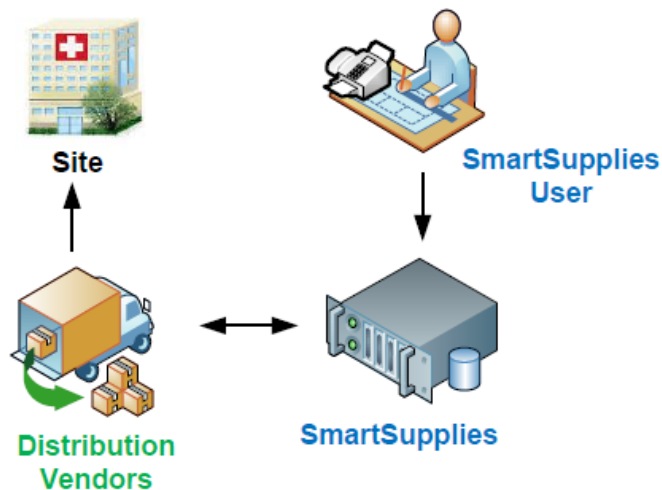
SmartSupplies Interfaces

SmartSupplies seamlessly integrates into the industry leading vendors and systems



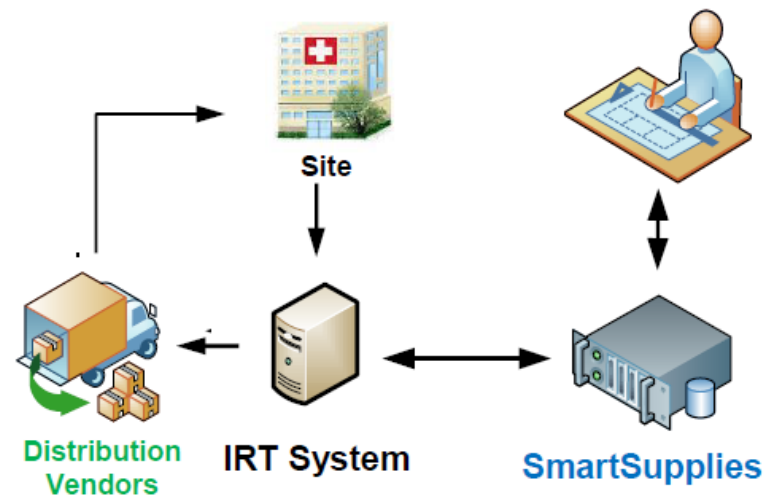
SmartSupplies PMD/RAR – Ordering Drug

Non-IRT Drug Ordering Process



- Not all clinical studies use IRT systems due to cost and duration
- Users can directly input order details into the SmartSupplies system

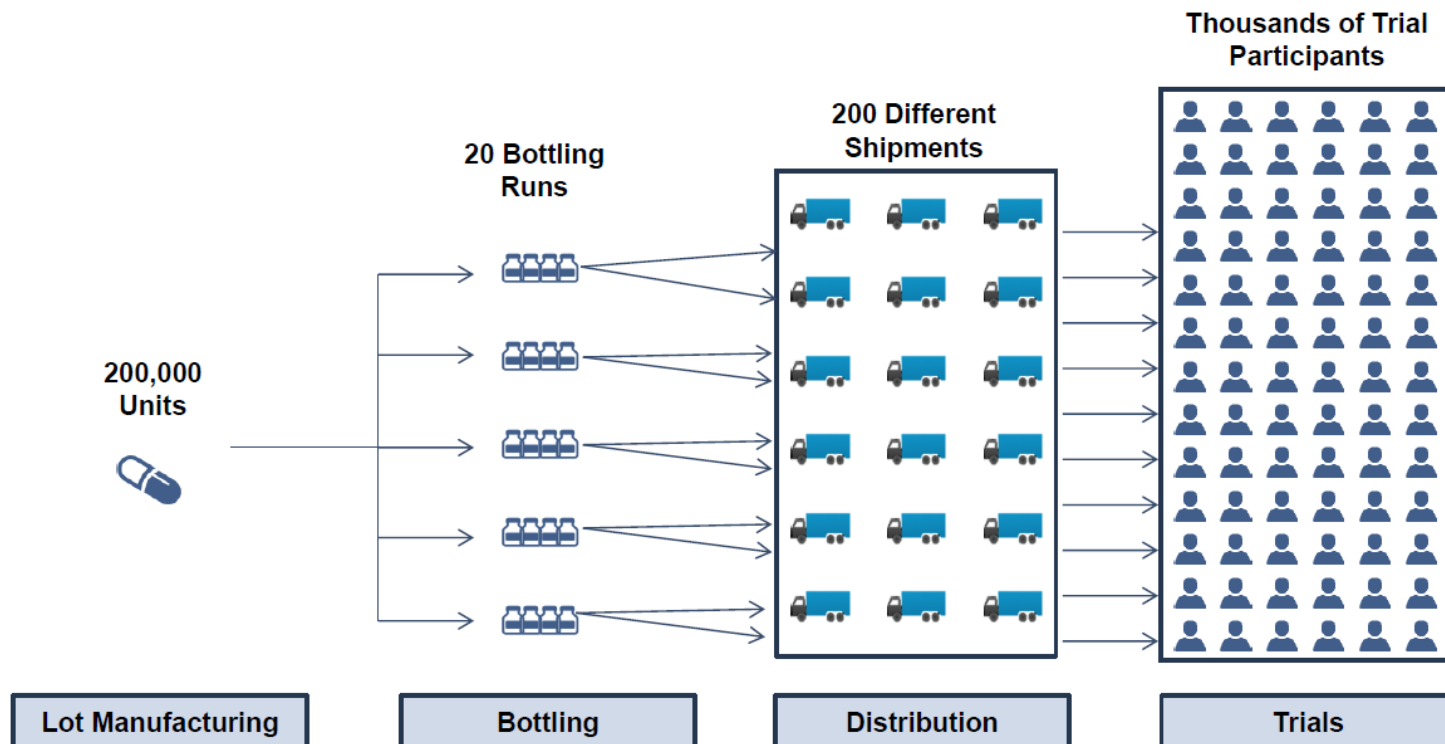
IRT Drug Ordering Process



- SmartSupplies' interfacing capabilities allow external IRT systems to place orders

SmartSupplies PMD/ RAR– Traceability Benefits

The benefits of being able to track materials down to the unit level within the SmartSupplies PMD solution multiply as materials move through the clinical trial supply chain.



Exceptional traceability and instant genealogy of units support rapid recalls

Clinapps Professional Services

Allow Clinapps to guide you through a smooth implementation

Validation Services



Project Management



Integration Services



Data Migration



Training



Remote Systems Administration



Premium Support



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