



Global **Virtual** Clinical Trial Supplies

Benefits of Implementing a
Virtual Supply Process
for Commercially Available Medications
and Ancillary Supplies

Tom Gottschalk
Vice President, Business Development



I am sorry to disappoint you –

I am NOT this
Tom Gottschalk



Defining **Virtual Supply**



My goal is for this presentation to be educational and not a sales pitch, so I am intentionally not using a **Product Name**

In place of a **Product Name** I am using the general term **Virtual Supply** that embraces the philosophy of this clinical supply strategy



Virtual Supply Concept



Provide Trials Commercially Available Medications and Ancillary Supplies

- ✓ **Optimize Employee Effort**
- ✓ **Minimize Waste and Risk**
- ✓ **Appreciate Significant Savings**
- ✓ **Sustainably Friendly**





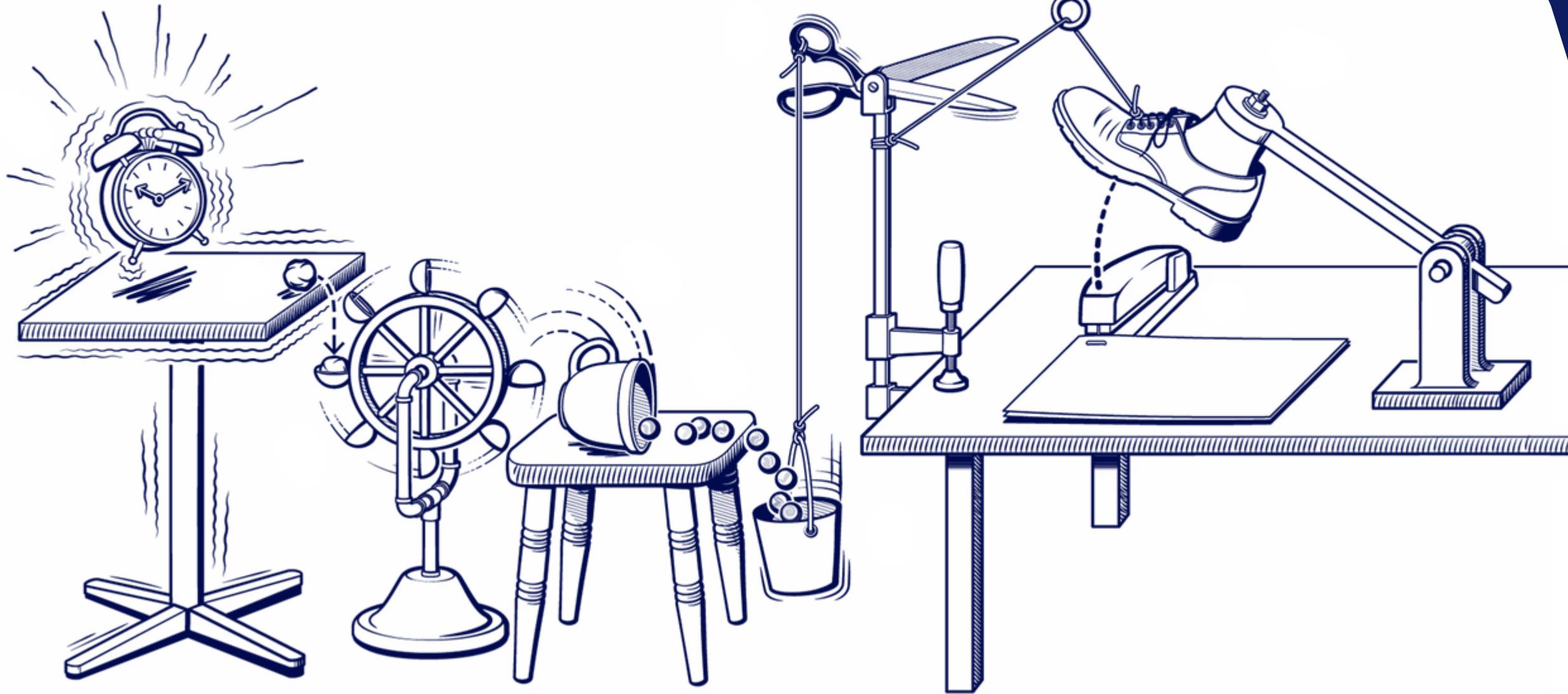
Open Your Mind
TO CHANGE

*Virtual Clinical
Trial Supplies*

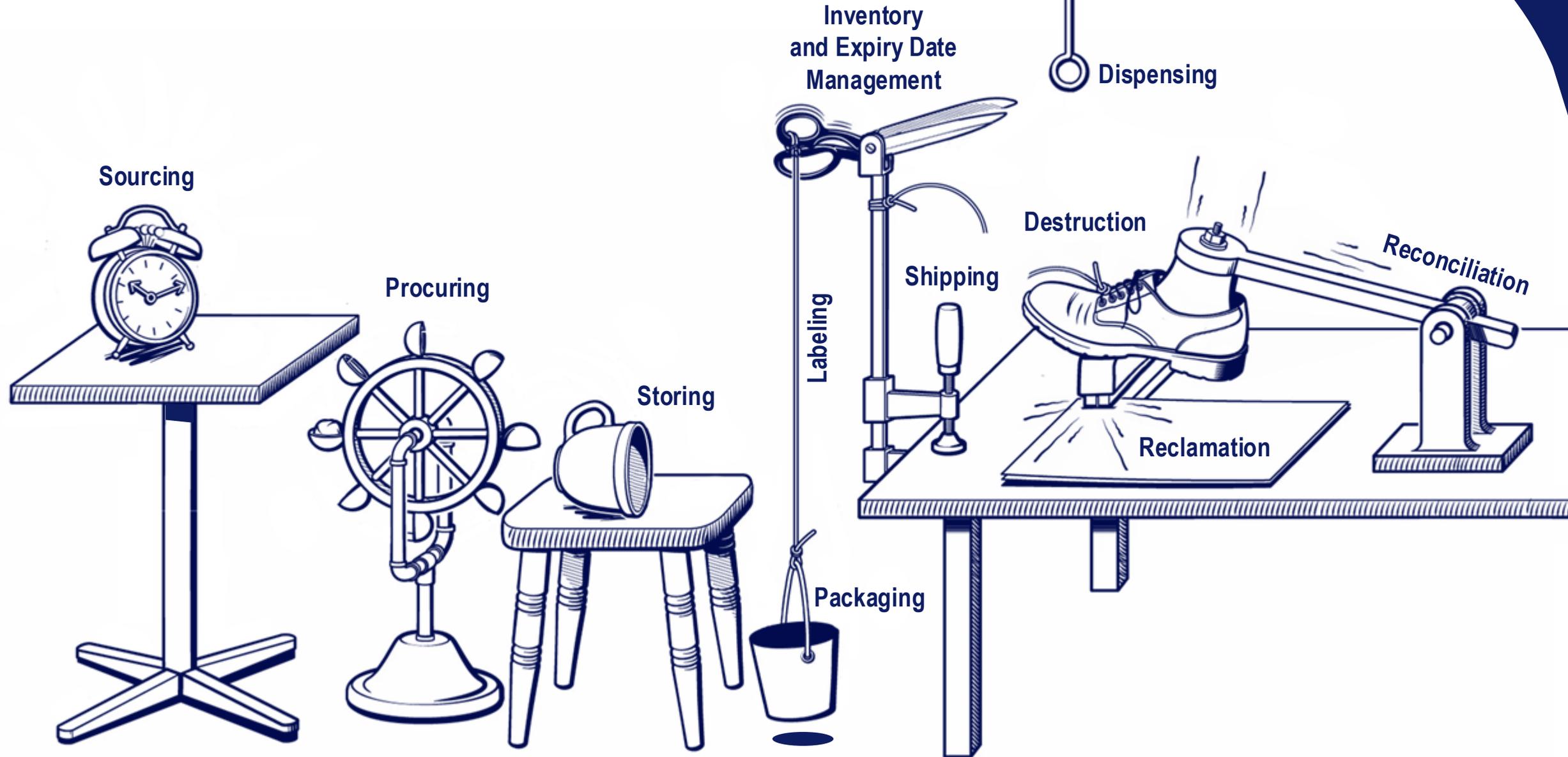
Traditional Bulk Supply Process



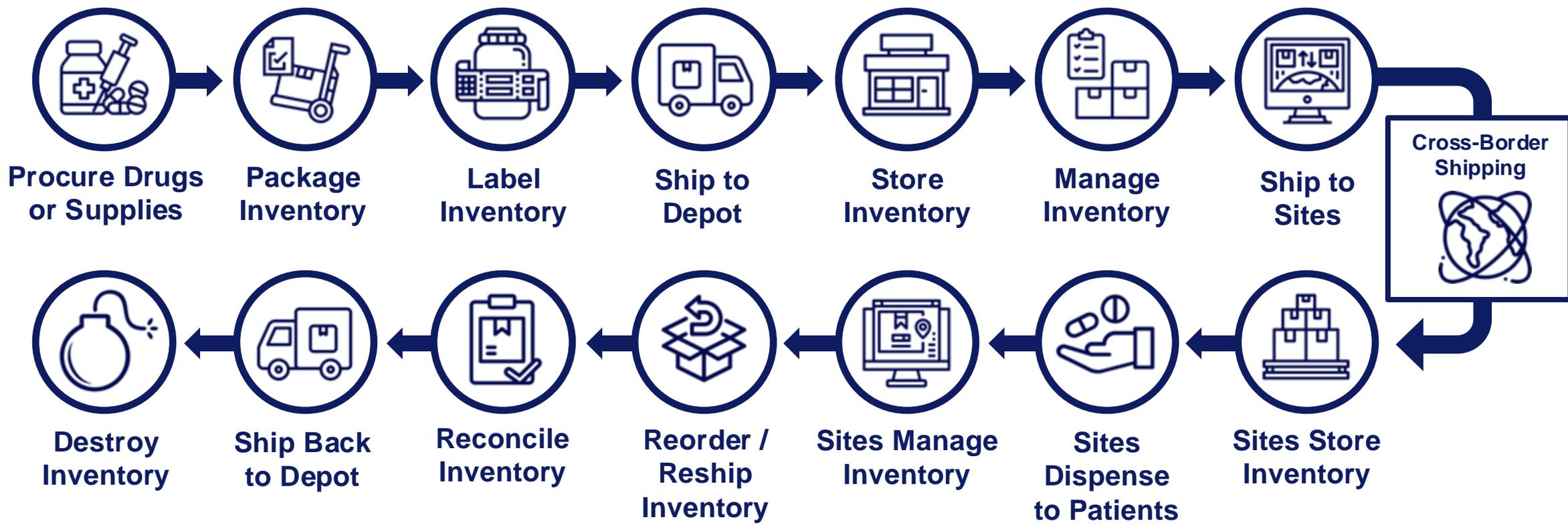
Rube Goldberg – Automatic Stapler



Clinical Trial Supply World



Traditional Bulk Supply Process



Understanding the **Virtual Supply** Strategy and Process



How does the **Virtual Supply** Strategy Differ from the Traditional Bulk Supply Strategy

Minimizes, and in some cases eliminates:

- the up-front purchase of a large physical inventory of medication and ancillary supplies
- the effort and expense of repacking, clinical labeling, and storing large physical inventory of medication and ancillary supplies
- the need for a central depot that serves multiple countries
- the hassle, time and expense of cross-border shipping
- overages and waste



Quality

Utilize a vendor that:

- Is licensed and follows regulatory directives and guidelines, complying with Good Distribution Practice (GDP) for Medicines for Human Use, 2013/C 343/01
- Maintains the quality and integrity of products through a comprehensive Quality Management System
- Measures performance through KPI's

Goals

Implement the most appropriate and efficient supply strategy and tactics to:

- **Maintain continuity of supply**
- **Manage batch & expiry requirements**
- **Maintain temperature conditions**
- **Provide supporting documentation**
- **Maintain integrity & compliance**
- **Minimize import & export challenges**
- **Reduce waste**
- **Control costs**



Strategy

- **Challenge the norms and adapt to each trial's specific needs**
- **Implement the most appropriate and efficient supply process for each unique trial using one or more tactics**
- **Reduce complexity and burden**
- **Maximize value**

Tactics

“Pull” versus “Push”

- Actual demand versus forecasted demand
- Provide quantities specific to each site and patients' needs

“Just In Time” / “On Demand”

- Provide only as needed
- Order close to when the medication or ancillary supply is needed

“In country” sourcing and distribution

- Avoid cross-border shipping when possible



Process Step 1

Assess the clinical trial supply need

All scenarios are not created equal

- Protocol requirements
- Participating countries
- Medication and ancillary supplies needed
- Medication requirements (REMS)
- Country specific regulations
- Other requirement(s)

Utilize expertise to formulate a trial specific supply strategy

- Market Intelligence
- Supply Chain Planning
- Risk Management
- Documentation Management
- Sourcing
- Storage & Distribution
- Waste Management
- Returns
- Destruction Services
- Reconciliation



Process Step 2

Put together the most efficient clinical trial supply strategy

In country sourcing

- For medication that is available in the countries in which there will be sites
- With or without a depot

Central sourcing

- When medication is not available in a country
- Mitigate shortages
- Unique protocol needs
 - *Difficult to access items*
 - *Single lot requirement*
- With or without a depot

A hybrid approach



Operational Flow



Leverage the supplier network to provide clinical trials a physical inventory of commercially available medication and supplies

- Manufacturers
- Wholesaler network
- Secondary sourcing, procurement and logistics vendors



Portal Dashboard



Test Pharma 1

TC



CTS Gateway



Order Procurement →

- Place orders
- Access tracking information
- View order history



Study Team Settings →

- Add, deactivate and edit Study Team users



Resources →

- View and download program collateral such as Site Instructions, Order Forms and Program Specific Training Presentations
- View and download the formulary

New Order



CTS Gateway

Test Pharma 1

TC



Order Procurement

[Export](#) [New Order](#)

View submitted order statuses in the table below. To view more details click on the actions icon. To create a new order click on the "New Order" button in the top right.

Order ID	Patient ID	Site Name	Date of Submission	Order Status	Actions
006Pu00000J3ge5IAB		test Site	Feb 19, 2025	submitted	
006Pu00000J1dMEIAZ		test Site	Feb 18, 2025	submitted	
006Pu00000J1dAtIAJ		test Site	Feb 18, 2025	submitted	
006Pu00000J1dm2IAB		test Site	Feb 18, 2025	submitted	
006Pu00000J1gTiIAJ		test Site	Feb 18, 2025	submitted	
006Pu00000IuyGslAJ		test Site	Feb 13, 2025	submitted	
006Pu00000IYKLOIA5		test Site	Jan 30, 2025	submitted	
006Pu00000ItojpIAD		test Site	Jan 27, 2025	submitted	
006Pu00000ITjIIIAD		test Site	Jan 27, 2025	submitted	
006Pu00000ITiBOIA1		test Site	Jan 27, 2025	submitted	

Order Details

Order ID: 006Pu00000J3ge5IAB
Status: submitted

Site Info

Site Name: test Site
Address: 123 test street, Liverpool, STF, GB

Items (1)

Created: Feb 19, 2025
Name: Test Framework 1 Abilify Asimtufii - 1 - 720mg/2.4ml - Prefilled Syringe - Otsuka America Pharmaceutical Inc NDC: 59148-102-80 - United States - Store at 25C. Excursions permitted at 15C-30C
Quantities Ordered: 5

Enter Order



CTS Gateway Test Pharma 1 TC

Order Procurement

View submitted order statuses in the table below. For more information, see the top right.

Export New Order

Order Details

Order ID: 006Pu00000J3ge5IAB

Street, Liverpool, STF, GB

025
work 1 Abilify Asimtufii - 1 - 720mg/2.4ml -
Otsuka America Pharmaceutical Inc NDC: 59148-
ates - Store at 25C. Excursions permitted at 15C-
ed: 5

Add New Order Request

Site Delivery Address * **4** Patient ID

test Site testid

Product Order Information * Quantity * Add to Order

Test Framework 1 Abilify Asimtufii - 1 - ' 10 +

SUBMIT Cancel

Order ID	Pat			
006Pu00000J3ge5IAB				
006Pu00000J1dMEIAZ				
006Pu00000J1dAtIAJ				
006Pu00000J1dm2IAB				
006Pu00000J1gTIIAJ				
006Pu00000IuyGsIAJ	test Site	Feb 13, 2025	submitted	
006Pu00000IYKLOIA5	test Site	Jan 30, 2025	submitted	
006Pu00000ITojplAD	test Site	Jan 27, 2025	submitted	
006Pu00000ITjIIAD	test Site	Jan 27, 2025	submitted	
006Pu00000ITiBOIA1	test Site	Jan 27, 2025	submitted	

View Cart



CTS Gateway

Test Pharma 1

Add New Order Request

Site Delivery Address * Patient ID

test Site testid

Product Order Information * Quantity * Add to Order

Product Order Information +

Items Added to Cart (1) ★ 5

Product	Quantity	Actions
Test Framework 1 Abilify Asimtufii - 1 - 720mg/2.4ml - Prefilled Syringe - Otsuka America Pharmaceutical Inc NDC: 59148-102-80 - United States - Store at 25C. Excursions permitted at 15C-30C	10	

Rows per page: 10 1-1 of 1

By checking this box I confirm that all of the above order details are correct.

SUBMIT Cancel

Order Procurement

View submitted order statuses in the table top right.

Search

Order ID	Pat
006Pu00000J3ge5IAB	
006Pu00000J1dMEIAZ	
006Pu00000J1dAtIAJ	
006Pu00000J1dm2IAB	
006Pu00000J1gTIIAJ	
006Pu00000IuyGsIAJ	
006Pu00000IYKLOIA5	
006Pu00000ITojplAD	
006Pu00000ITjIIAD	
006Pu00000ITiBOIAI	

test Site Jan 27, 2025 submitted

Confirm Order



CTS Gateway Test Pharma 1 TC

Order Procurement

View submitted order statuses in the table top right.

Search

Order ID	Pat
006Pu00000J3ge5IAB	
006Pu00000J1dMEIAZ	
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006Pu00000ITajplAD	
006Pu00000ITjllIAD	
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Site Delivery Address * Patient ID

test Site testid

Product Order Information * Quantity * Add to Order

Product Order Information +

Items Added to Cart (1)

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Rows per page: 10 1-1 of 1

By checking this box I confirm that all of the above order details are correct.

Submit **Cancel**

test Site Jan 27, 2025 submitted



Submit Order



CTS Gateway

Your order was successfully created! Close this window to track your order status or submit a new order request

Test Pharma 1

Order Procurement

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Quantities Ordered: 5

Order History



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Dashboard

Order Procurement

Study Team Settings

Site Settings

Resources

Program Settings

Mercalis Users

Clinical Study Settings

Order Procurement Setup

Logout

Order Procurement

Export

New Order

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006Pu00000FgMEpIAN		test Site	Sep 25, 2024	submitted	
006Pu00000FiZavIAF		test Site	Sep 27, 2024	submitted	
006Pu00000FihVWIAZ		test Site	Sep 30, 2024	submitted	
006Pu00000FIm70IAB		test Site	Sep 30, 2024	submitted	
006Pu00000FimesIAB		test Site	Sep 30, 2024	submitted	
006Pu00000FImi5IAB		test Site	Sep 30, 2024	submitted	
006Pu00000FmtMYIAZ		test Site	Oct 1, 2024	submitted	
006Pu00000FmuDIIAJ		test Site	Oct 1, 2024	submitted	
006Pu00000Fno6BIAR		test Site	Oct 2, 2024	submitted	

Order Details

Order ID: 006Pu00000J3oerIAB

Status: submitted

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Site Name: test Site

Address: 123 test street, Liverpool, STF, GB

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Quantities Ordered: 10

Order Details



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006Pu00000FImesIAB		test Site	Sep 30, 2024	submitted	
006Pu00000FIImi5IAB		test Site	Sep 30, 2024	submitted	
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Order Details

Order ID: 006Pu00000FIhVWIAZ

Status: submitted

Site Info

Site Name: test Site

Address: 123 test street, Liverpool, STF, GB

Items (1)

Created: Sep 30, 2024

Name: Test Framework 1 Abilify Asimtufii - 1 - 720mg/2.4ml - Prefilled Syringe - Otsuka America Pharmaceutical Inc NDC: 59148-102-80 - United States - Store at 25C. Excursions permitted at 15C-30C

Quantities Ordered: 2

Tracking Number



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006Pu00000FIIm70IAB		test Site	Sep 30, 2024	submitted	
006Pu00000FImesIAB		test Site	Sep 30, 2024	submitted	
006Pu00000FIImi5IAB		test Site	Sep 30, 2024	submitted	
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006Pu00000FmuDIIAJ		test Site	Oct 1, 2024	submitted	
006Pu00000Fno6BIAR		test Site	Oct 2, 2024	submitted	

Order Details



Order ID: 006Pu00000FIhVWIAZ

Status: submitted

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Site Name: test Site

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Quantities Ordered: 2

Functionality



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Optimize Employee Effort



Sponsor Benefits



Consultative Strategic Planning

Less activities and employee effort required to provide sites/patients with medication and ancillary supplies

Reduced shipping cost by minimizing shipping across borders

Reduced waste

Reduced activities support sustainability goals and a reduced carbon footprint

Site Benefits



Not required to store large quantities of medication

Providing the ability to order medication when it is needed and in the appropriate quantity

Simplified “Site Sourcing” – eliminate site burden to source, procure, utilize their capital and wait for reimbursement

Less Hassles

Large and Complex Supply Requirements

Minimize Or Eliminate Sourcing, Purchasing, And Manipulating Large Physical Inventories

Specialty and Limited Distribution Drugs

Access Through Existing Commercial Distribution Channels As Opposed To The Secondary Market

High-Priced Items

Minimize Or Eliminate Expensive Carrying Costs

Special Handling

Cold Chain Managed by Authorized Distributors

Short Expiry Windows

Expiry Managed by Authorized Distributors



**Minimize
Waste
and Risk**



Why is Supply Chain Efficiency Needed?

- ✓ Contingency stock for known factors
- ✓ Overage for unknown factors
- ✓ Delayed start, pause, or early stop
- ✓ Enrollment challenges
- ✓ Impact of real-world events
- ✓ Actual use differs from forecast

**30-50%
Waste**



Minimal (and in some cases, no) up-front purchase of physical inventory or cost to maintain the inventory

Spend Management – Pay For What is Ordered

Minimal (and in some cases, no) inventory management

Expiry dating, temperature excursions, loss, damage, diversion

Minimal (and in some cases, no) impact resulting from “real life”

Slow/no enrollment, protocol changes, trial holds, trial ends early, natural disasters, war in Ukraine, other unforeseen events (i.e., COVID)

Forecasting is based on “consumed demand” not “assumed demand”

Minimizes adding in overages, contingency stock, and other variables

Minimal (and in some cases, no) waste

Due to overage, contingency stock, and other factors

Favorable and consistent pricing

Leverage contracts with Manufacturers and Authorized Distributors

Less Risk



**Appreciate
Significant
Savings**



One Sponsor's 16 Year Experience Implementing a **Virtual Supply** Strategy in the United States and Canada

Sponsor

Top pharmaceutical manufacturer

Duration

16 years of utilization

Volume

Over 100 programs

Therapeutic Areas Of Study

Primarily oncology and respiratory, other areas secondarily





One Sponsor's 16 Year Experience Implementing a Virtual Supply Strategy in the United States and Canada

Mercalis Service History (Through October 28, 2024)										
Sponsor	2016	2017	2018	2019	2020	2021	2022	2023	2024	Total
Estimates										
Requested					17	26	21	22		86
Awarded					11	20	19	13		63
Declined					6	6	2	7		21
Activity										
Active Programs		6	12	16	33	44	62			107
Total Programs (2009 to Present)										
Program Type										83
Pharmacy Channel										24
										56
										50
										1
Country Of Service										95
										12
Therapeutic Category										53
										54
Contracting Party										12
										95
Financial										
Set Up		\$90,000	\$138,000	\$72,500	\$232,876	\$261,750	\$156,250			\$951,376
Monthly Management		\$638,250	\$926,900	\$1,158,500	\$1,455,756	\$1,800,378	\$1,794,971			\$7,774,755
Rebate		\$0	-\$53,438	-\$114,650	-\$144,173	-\$179,078	-\$156,007			-\$647,346
Medication Dispensation										
Prescriptions Dispensed	22,067	11,248	1,908	5,541	6,061	2,938	2,597	2,669	2,976	75,200
Medication Value Dispensed	\$4,515,270	\$2,404,124	\$1,595,817	\$9,361,829	\$18,299,020	\$10,431,947	\$11,133,429	\$12,001,643	\$16,108,522	\$85,270,892
Total Spend Per Year										
Set Up		\$90,000	\$138,000	\$72,500	\$232,876	\$261,750	\$156,250			\$951,376
Monthly Management		\$638,250	\$926,900	\$1,158,500	\$1,455,756	\$1,800,378	\$1,794,971			\$7,774,755
Rebate		\$0	-\$53,438	-\$114,650	-\$144,173	-\$179,078	-\$156,007			-\$647,346
Prescriptions Dispensed		5,541	6,061	2,938	2,597	2,669	2,976			75,200
Medication Value Dispensed		\$9,361,829	\$18,299,020	\$10,431,947	\$11,133,429	\$12,001,643	\$16,108,522			\$85,270,892
TOTAL		\$10,095,620	\$19,316,543	\$11,551,235	\$12,680,485	\$13,887,362	\$17,906,712			\$93,424,877
Savings										
										\$14,491,568
										\$70,779,324
										\$89,941,587
										\$329,306
										\$85,129,115
										\$141,777
Savings										
Sponsor has saved over \$46M and 87 labor years									Supply	\$36,666,483.74
									Labor	\$9,057,196.46
									Rebate	\$647,345.19
									TOTAL	\$46,381,025.39

Savings

Sponsor has saved over \$46M and 87 labor years

Supply	\$36,666,483.74
Labor	\$9,057,196.46
Rebate	\$647,345.19
TOTAL	\$46,381,025.39

**Sustainably
Friendly**



Clinical Trials Generate a Significant Amount of Waste

- The most substantial expenses in clinical supply chain operations do not pertain to the drugs themselves but rather revolve around ensuring the safe and efficient delivery of these drugs to patients
 - *Oncology & Rare Disease may be an exception*
- The focus should be on responsible resource management and waste reduction in clinical trial supply chains
- While complete waste elimination is not realistic, **the aim should be to promote sustainable and eco-friendly processes**



Implement Clinical Supply Tactics That Align with Sustainability Goals

Pull vs Push

Just In Time vs Just In Case

Ordering small batches in specific geographies instead of centralizing a larger stockpile

On Demand Distribution

Provide medication only as needed
Sites order in advance of each patient's immediate need

Virtual Supply Model

Medication is provided through existing commercial distribution channels

Direct To Site

Skip the depot (when appropriate)

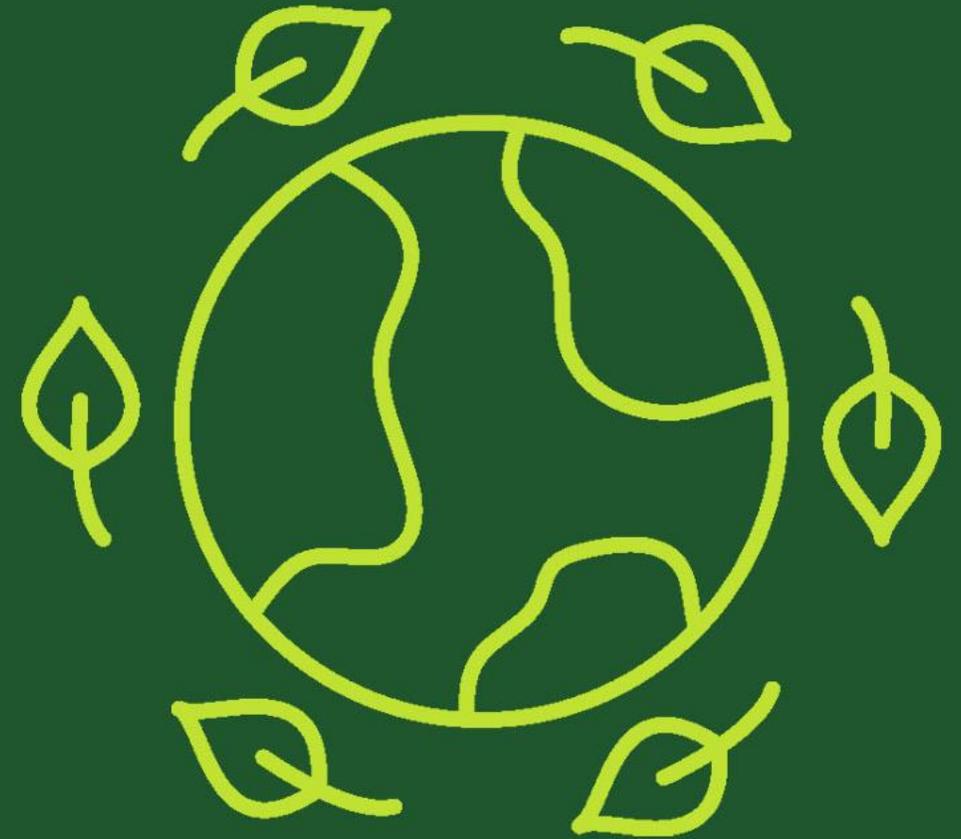
Less shipping

Less idle inventory that requires storage and inventory management resources

Carbon Footprint Impact

Less everything

- **Employees**
- **Employee hours**
- **Processes and resources**
 - *source, procure, pack, label, store, inventory manage, reconcile, reclaim, destroy*
 - *efforts and materials associated with the above*
- **Shipping**
 - *same item is shipped many times*
- **Overage and waste**



Carbon Footprint Analysis

Please Come See Me to Ask Questions and Learn More



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End-to-End Partnership Commercial Solutions Industry Resources **Connect**

Global Clinical Supply

RxStudy Card™ by Mercalis is the trusted global clinical trial supply partner that offers a more efficient and reliable way to procure commercially available clinical trial supplies. Mercalis pioneered the virtual supply process that minimizes the cost, time, and waste associated with the traditional bulk supply procurement method. RxStudy Card™ provides a streamlined and sustainable solution to supply commercially available medications and supplies.



CP

ABOUT WHAT WE DO OUR GLOBAL SERVICES NEWS GET IN TOUCH

Home > What we do

>>> WHAT WE DO

Global Clinical Trial Supply Services and Solutions

As one of the leading global clinical trial supply companies, ClientPharma's extensive experience and expertise in clinical trial services means we provide both comprehensive and pragmatic supply solutions

- > Overview
- > Our clinical trial services and solutions
- > Get in touch with us

Case Study

Global Local Sourcing



RxStudy Card

Mercialis Clinical Trial Supply

Case Study: Optimizing Supply Efficiency by Implementing a Local Sourcing Strategy

This case study showcases a strategy to address specific challenges in sourcing and supplying pharmaceutical drugs to multiple sites across different countries. The solution offered customized approaches and showcased the advantages of localized logistics and skilled project management.

BACKGROUND

A sponsor needed support to source and supply infliximab (cold chain) and mycophenolate (controlled ambient) to 20 sites across the United Kingdom (9), Poland (6), and Spain (5).

CHALLENGES

- Infliximab shortages in certain countries posed a risk to supply continuity.
- Difficulty in sourcing mycophenolate locally in large enough quantities for labeling.
- Short lead times to target FPI for some sites added pressure to the supply chain.

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CASE STUDY

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MAY 2024

SOLUTIONS

Local Sourcing through Audited Vendors:

Infliximab and mycophenolate were locally sourced (in country), on-demand, through audited vendors in the United Kingdom, Poland, and Spain.

Providing Appropriate Infliximab Options Locally:

Local sourcing ensured that the most appropriate infliximab options were provided to meet the specific needs of each site.

Direct Delivery to Sites with Local Logistics:

Qualified vendors delivered the drug directly to the sites via an on-demand basis, leveraging local logistics networks.

Shorter Lead Times and Smaller Project Scope:

With local sourcing and direct delivery to sites, the program operated with shorter lead times to provide supply, reducing overall project timelines and scope.

Maintained Compliance:

Despite the challenges and complex logistics involved, compliance with regulatory requirements was maintained throughout the program, ensuring the safety and efficacy of the drug delivered to each site.

Expert Project Management:

The program was managed by supply chain experts who oversaw the sourcing, procurement, and delivery processes, providing a smooth execution and timely delivery of drug to each site.

BENEFITS

Reduced Procurement Efforts, Logistics, Costs, and Risk:

Local sourcing and leveraging local logistics ensured a steady and reliable supply while significantly reducing procurement efforts, logistics, and costs. This also mitigated the risks associated with international shipping and import/export procedures.

Elimination of Labeling and Storage Issues:

Local sourcing eliminated the need for labeling or storage of the drug minimizing regulatory compliance risks and simplifying supply chain operations.

CONCLUSION

By adopting a localized sourcing and delivery approach, the sponsor successfully overcame the challenges associated with international supply chain logistics, ensuring timely and reliable access to infliximab and mycophenolate for patients across the United Kingdom, Poland, and Spain. The program's success highlights the importance of strategic supply chain management and collaboration with audited vendors to optimize efficiency, reduce costs, and maintain compliance in pharmaceutical supply chain operations.

Mercialis has a suite of Clinical Trial Support services designed to provide time and cost efficiencies.

RxStudy Card – Pharmacy provides commercially available medications and supplies through retail and specialty pharmacies. This supply strategy reduces supply process steps, requires less employee time, eliminates supply waste, and has fewer risks resulting in an 80% reduction in labor and a 50% reduction in costs.

RxStudy Card – Provider provides reimbursement for site sourced and administered medication and is essential for studies requiring biologics and oncolytics, which are more frequently being sourced directly by a provider and not through a pharmacy.

RxStudy Card – Procurement is an innovative GLOBAL clinical trial supply process that more efficiently provides commercially available medications and supplies. RxStudy Card – Procurement leverages "in country" sourcing and distribution, provides study teams and sites a simple online ordering experience for "just in time" "as needed" delivery, in quantities specific to each site and patients need with direct to site shipments and real time order and shipment status.

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CASE STUDY

Case Study

Global Direct Sourcing



RxStudy Card

Mercialis Clinical Trial Supply

Case Study: Optimizing Efficiency by Streamlining Access to Iressa (Gefitinib) for a Multiple Country Study

This case study demonstrates how strategic collaboration with a manufacturer and authorized distributors, coupled with a localized approach to procurement and supply chain management, can effectively address challenges related to accessing pharmaceutical products in diverse global markets.

BACKGROUND

A leading global sponsor sought support in accessing Iressa (gefitinib) as a standard-of-care product in South America, North America, Australia, and New Zealand. The program aimed to address challenges in managing the sourcing and import requirements for several countries and controlling costs, particularly in countries where the price of gefitinib was high.

CHALLENGES

Complex Sourcing and Import Requirements:

Managing sourcing and import requirements separately for multiple countries, including Argentina, Brazil, Chile, Colombia, Mexico, and Peru posed logistical challenges and increased administrative burdens.

Cost Control in High-Priced Markets:

Controlling costs, especially in markets like the USA and Canada where the price of gefitinib was high, presented a significant challenge to the program's success.

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MAY 2024

SOLUTIONS

Direct Collaboration with the Manufacturer:

Collaboration directly with the manufacturer of Iressa established access continuity.

Direct Collaboration with Authorized Distributors:

Collaboration with manufacturers and authorized distributors, utilizing local logistics networks, enabled the direct and on-demand delivery of Iressa to sites, effectively shortening the supply chain.

BENEFITS

Mitigation of Customs and Import Delays:

A streamlined approach of sourcing gefitinib in country for South and Central America enabled the program to avoid the logistical complexities and risks of delays during customs and import procedures.

Reduction in Sourcing Volumes and Waste:

By implementing an on-demand, just-in-time approach, the program successfully reduced sourcing volumes and minimized waste by procuring gefitinib only for sites guaranteed to come online.

Significant Reduction in Logistics Efforts and Costs:

Direct sourcing and delivery to sites minimized transportation costs and simplified supply chain

operations. Efforts and costs associated with logistics were significantly reduced compared to traditional methods of sending materials to regional depots.

Competitive Material Costs

By sourcing directly from the manufacturer or their authorized distributors, the program ensured that material costs remained competitive in all countries, including high-priced markets like the USA and Canada.

Supply Chain Optimization:

Embracing a strategy of local sourcing and supply chain optimization allowed the program to enhance agility, reduce lead times, and maintain control over costs, ultimately improving the overall efficiency of the supply chain.

CONCLUSION

Through strategic collaboration with the manufacturer and authorized distributors, the study successfully overcame challenges related to sourcing and accessing Iressa (gefitinib) across multiple countries. By adopting a localized approach to procurement and supply chain management, the program achieved significant cost savings, minimized logistical complexities, and ensured timely access to medication for patients in South America, North America, Australia, and New Zealand.

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Thank You!

Tom Gottschalk | 336-471-6638
tom.gottschalk@mercalis.com

