

# Aligning Clinical Supply Strategies With Sustainability Goals

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# Introduction

Increasingly pharmaceutical companies are committing to reduce their carbon footprints in the execution of clinical trials.

I will discuss how implementing innovative **clinical trial supply** technologies and sustainable processes can

- result in a more efficient use of human resources
- reduce the number of logistical resources required
- reduce waste
- save money
- lower the carbon footprint impact



# When was the first Earth Day?

**April 22, 1970**

**54 years ago!!!**

# Sustainable supply chains: Clinical trials in a new era of limited resources

Industry leaders are undertaking efforts to reduce drug waste and building clinical trials with ESG in mind, writes **William Newton**.

At the [Clinical Trial Supply \(CTS\) East Coast 2022](#) conference on October 19–20, sustainable drug development was a common refrain. Speakers said the environmental goals of Environmental, Social, Governance (ESG) have shifted from a lofty ideal to an economic imperative if pharma is to maintain its current pace of innovation. Panellists discussed data-driven solutions to drug supply optimization, new supply-side contract strategies, and the growing industry-wide push to minimize waste.

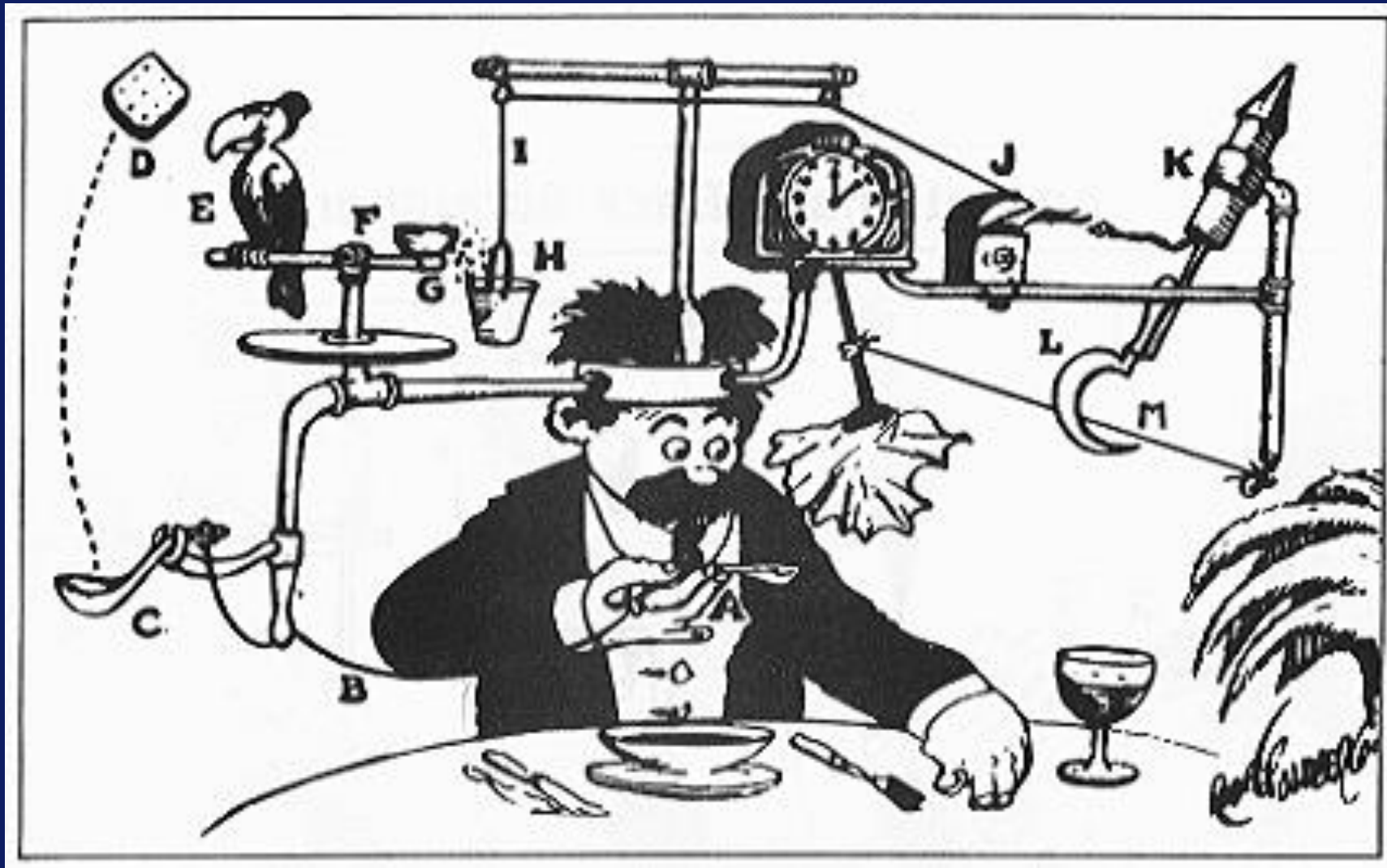
“There has never been more competition for limited resources in the pharma industry than there is right now,” N-Side’s Amaury Jeandrain told *Clinical Trials Arena* on the sideline of CTS. “Sustainability means less costs, less drug waste, less transport, less CO2 emissions, and, ultimately, more drugs to patients.”

## New clinical trial supply chain models

To eliminate waste in clinical trials, [sponsors should diversify their supply chains](#) rather than consolidate them, explained TrialCard’s Tom Gottschalk in a CTS presentation. “Our industry is yearning for a ‘one size fits all’ approach to clinical trial supply, but that’s simply not the best option,” Gottschalk said. “There is great global diversity in documentation requirements, quality procedures, healthcare systems, cultures, and patients.”

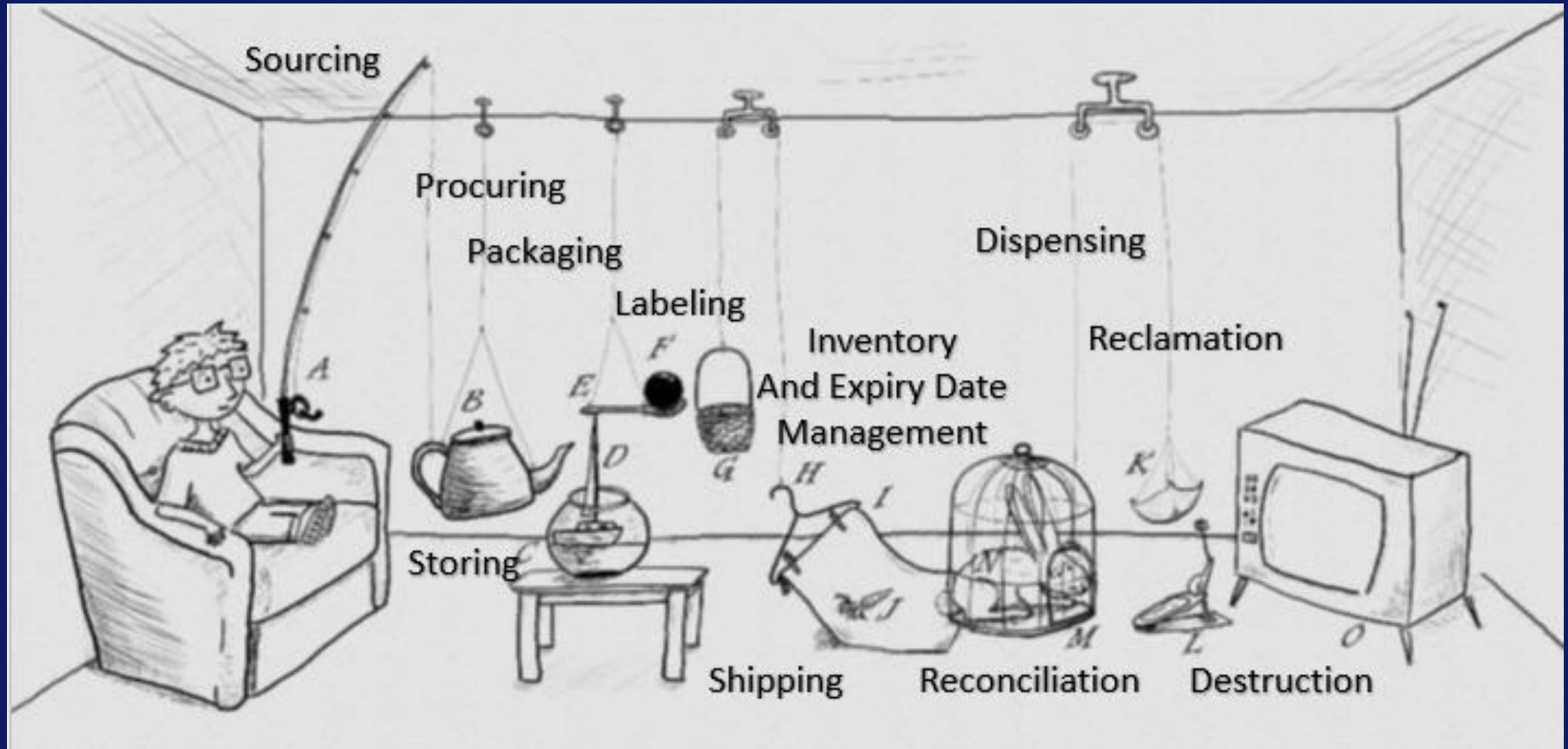
<https://www.clinicaltrialsarena.com/features/sustainable-clinical-trial-supply-chains/>

# Rube Goldberg – Self Operating Napkin





# Clinical Supply



# Clinical Supply **Strategies** That Align With Sustainability Goals



# 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.





# Clinical Supply **Strategies** That Align with Sustainability Goals



## Pull versus Push

- **Just In Time versus 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 retail and specialty pharmacy trade channels.

## Direct To Site/Patient Delivery

- Skip the depot (DTS/DTP).
- Skip the site (DTP).
- 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



**Recycling one aluminum can save  
enough energy to run a TV for how  
many hours?**

**Three  
also the equivalent of a half gallon  
of gasoline**

# Clinical Supply **Tactics** That Align With Sustainability Goals

RxStudy Card – **Pharmacy**

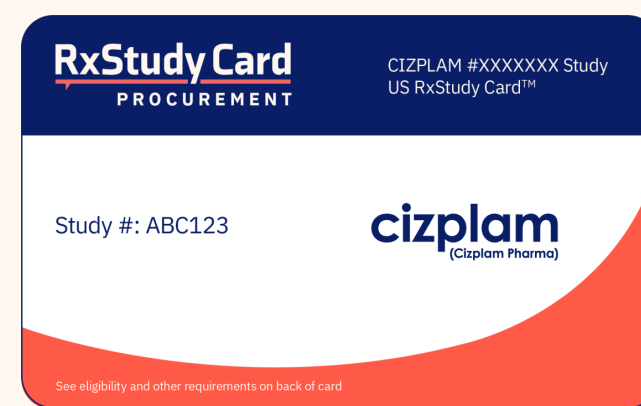
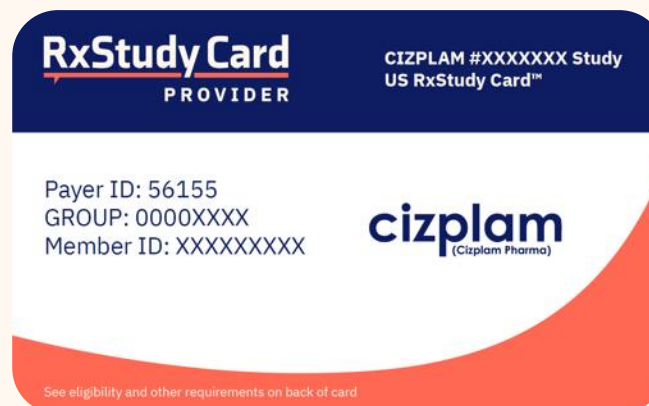
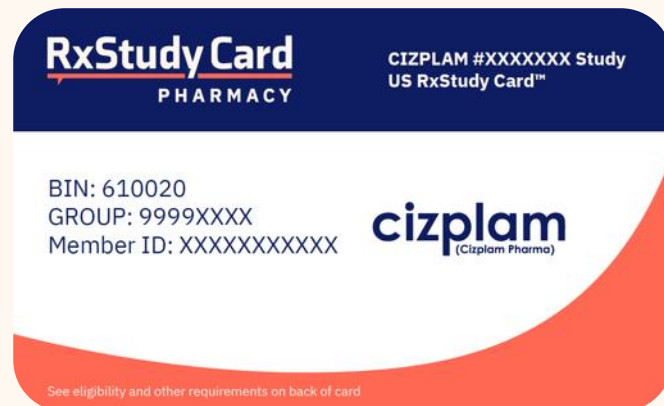
RxStudy Card – **Provider**

RxStudy Card - **Procurement**





# When To Consider An Alternative And Diverse Clinical Supply Process



When *any phase study* requires *commercially available medication*

# RxStudy Card - Pharmacy Process



- A pharmacy benefit-based clinical supply service provides commercially available medications and supplies for any phase trial involving all therapeutic areas of study, dispensed through existing retail and specialty pharmacy networks.
- Provides comparators, standard of care, adjuvant, concomitant, rescue medications, placebo's, ancillary products, and medical devices. Especially helpful in providing access to limited distribution and allocated medications
- Reduces supply process steps, requires less employee time, eliminates supply waste, has fewer risks, and saves money.
- Is available in the United States, Canada, and Puerto Rico.
- **Foundation of a most efficient supply strategy.**
- **Greatest time and cost efficiency.**
- **Least hassle and risk.**

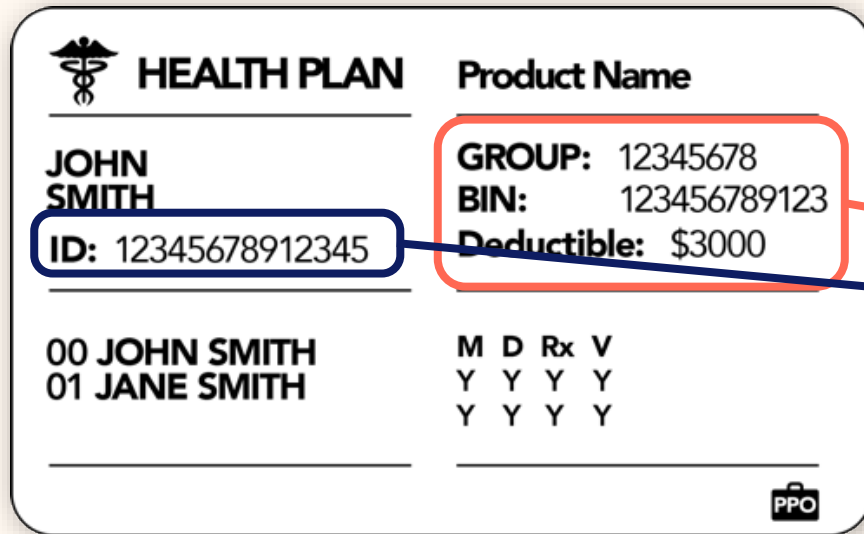
# RxStudy Card - Provider Process



- A medical benefit-based payment service that provides reimbursement to clinical trial sites and outsourced providers for site sourced and administered medication and/or medical services rendered.
- Is essential for studies that have formularies containing biologics and oncolytics, which are more frequently being covered through the medical benefit platform and not the pharmacy benefit platform.
- Facilitates electronic claims reimbursement utilizing the same trusted platform used by providers to submit claims to insurance companies, enabling payments within 6–18 business days.
- Is available in the United States and Puerto Rico.
- **Fills gaps that the pharmacy benefit-based program does not cover:**
  - **Medications that are not covered under the pharmacy benefit (buy and bill).**
  - **Reimburse for site sourced medications, supplies and services rendered.**
  - **Sites that are unable or unwilling to use the pharmacy benefit-based process.**

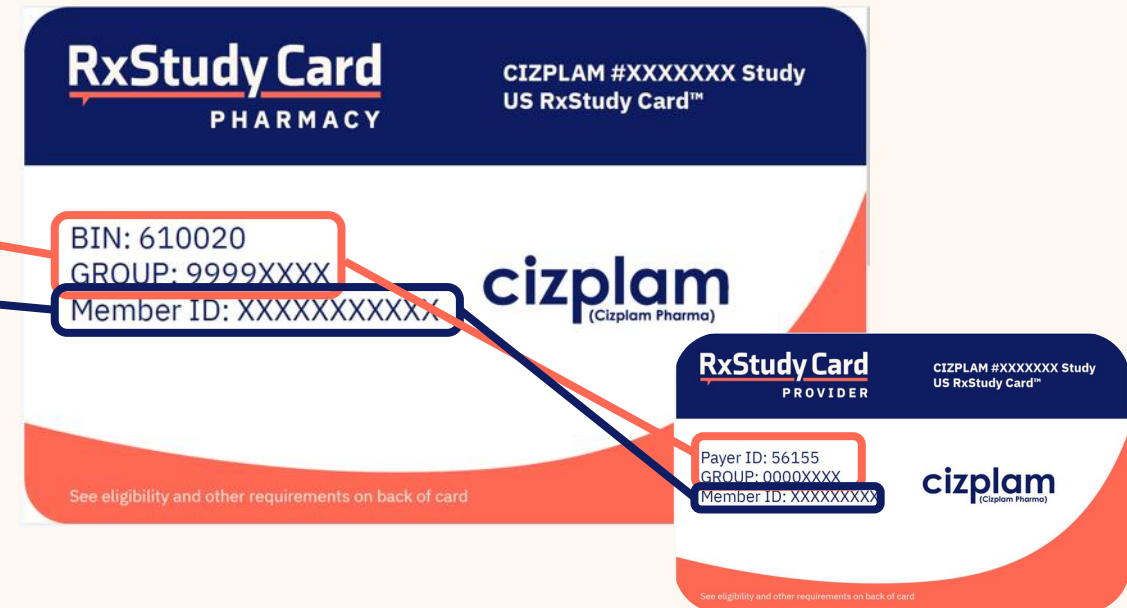
# How Does The RxStudy Card Process Work?

## Insurance Card



*The Group Number controls the business rules*

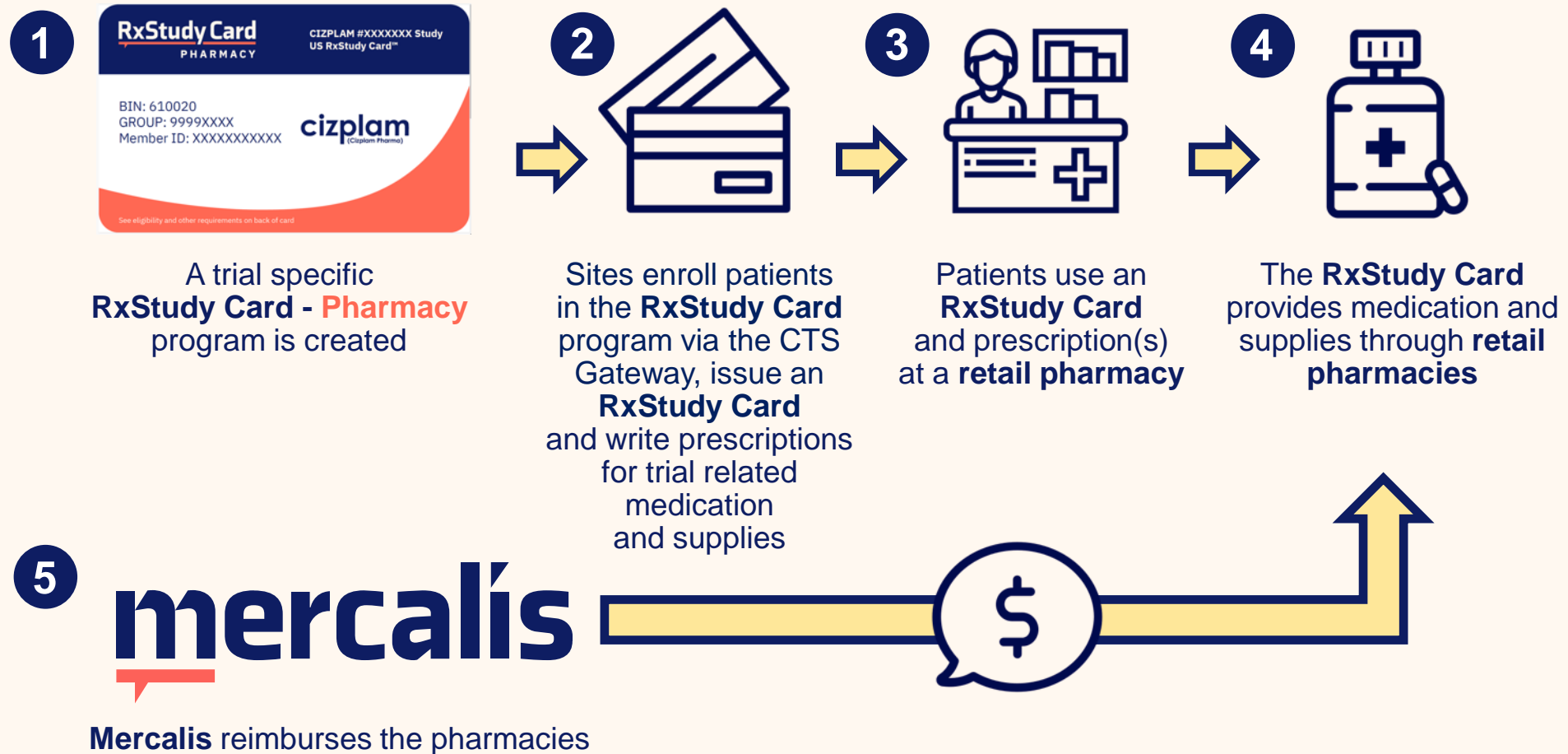
## RxStudy Card



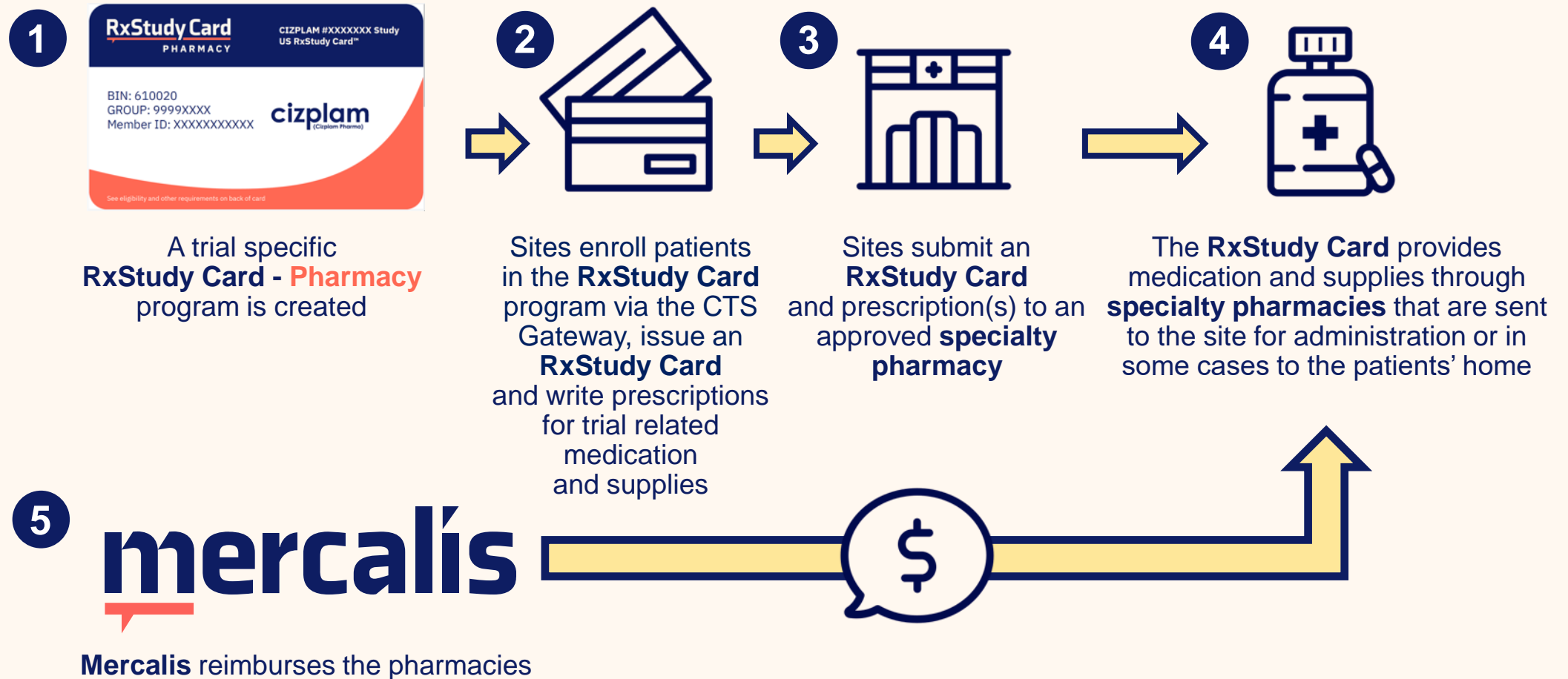
*The Member ID Number tracks the use of the card*



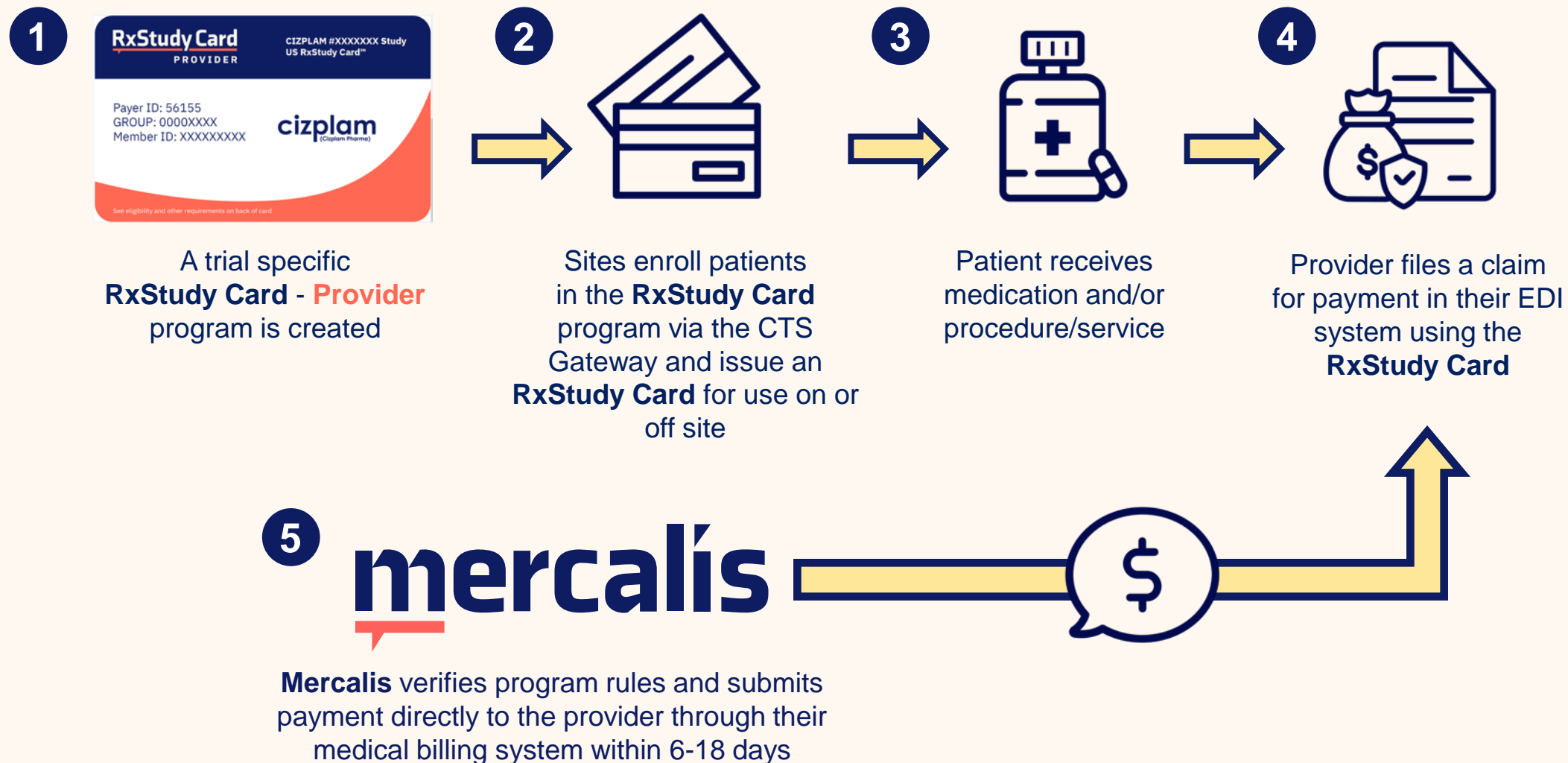
# RxStudy Card - Pharmacy **Retail Pharmacy** Process



# RxStudy Card - Pharmacy **Specialty Pharmacy** Process



# RxStudy Card - **Provider** Process



# Benefits Of A Virtual Supply Process





# Less Hassles

## Specialty and Limited Distribution Drugs

Commercial Inventory Takes Stocking Priority

## Large and Complex Formularies

Eliminate Sourcing + Purchasing Large Physical Inventories

## High-Priced Items

Eliminate Expensive Carrying Costs

## Special Handling

i.e., Cold Chain Left to Pharmacies

## Controlled Substances

Managed by State and Federal Pharmacy Regulations

## Short Expiry Windows

Expiry Managed by Pharmacies



# Less Risk

**No outlay of money made up front for physical inventory or carrying cost to maintain the inventory**

Spend Management – Pay As You Go

**No impact related to inventory control**

Expiry dating, temperature excursions, loss, damage, diversion

**No impact resulting from “real life”**

Slow/no enrollment, protocol changes, trial holds, trial ends early, COVID-19 complications

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

No factoring in overages, contingency stock, and other variables

**No waste**

Due to overage, contingency stock, and other factors

**Favorable and consistent pricing**

Leverage contracts with PBMs and Specialty Pharmacies



# Proven Time and Money Savings

The virtual supply process has demonstrated two areas of savings versus the traditional process:

1. Time Savings Case Study – 1 trial, 1 medication on formulary, 3-year duration, 1 employee

**A net time savings of 80%**

2. Process And Supply Savings Case Studies

**An average monetary savings of 48%**



## TIME & MONEY



**RxStudy Card**  
PHARMACY

CIZPLAM #XXXXXXX Study  
US RxStudy Card™

BIN: 610020  
GROUP: 9999XXXX  
Member ID: XXXXXXXXXXXX

**cizplam**  
(Cizplam Pharma)

See eligibility and other requirements on back of card

# Case Study 1: Virtual Supply Process

- The virtual supply process has been used by a top 5 pharmaceutical sponsor client since 2009 in support over 100 clinical trials
- The sponsor has **saved over 76 labor years** through more efficient processes
- The sponsor has **saved over \$38M** through favorable pricing and waste elimination



## TIME & MONEY



**RxStudy Card**  
PHARMACY

CIZPLAM #XXXXXXX Study  
US RxStudy Card™

BIN: 610020  
GROUP: 9999XXXX  
Member ID: XXXXXXXXXXXX

**cizplam**  
(Cizplam Pharma)

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# What country has the highest recycling rate?

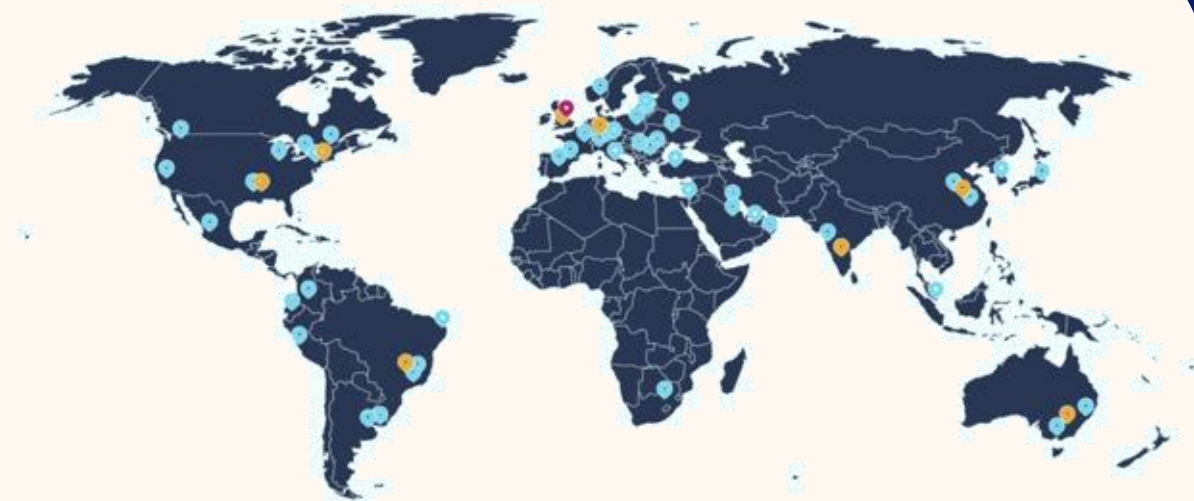
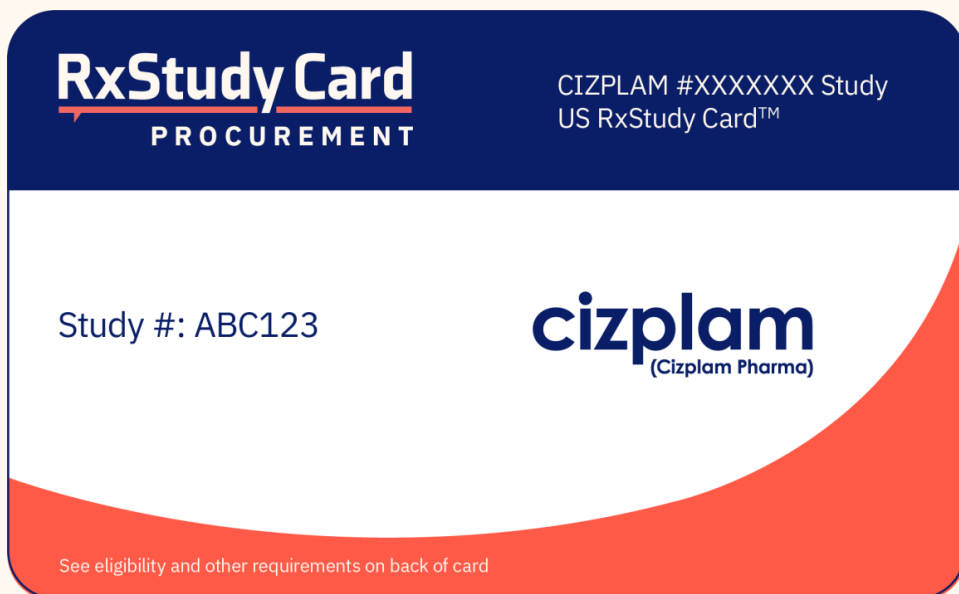
**Germany**  
**which recycles 66.1% of its waste**

# RxStudy Card – Procurement

## Enhanced Bulk Supply Process



An innovative global clinical trial supply process that provides sites around the world a physical inventory of commercially available medications and supplies.



# Proven Process

The **RxStudy Card – Procurement** process mirrors the same process as the **RxStudy Card – Pharmacy Specialty Pharmacy** process.

The **RxStudy Card – Pharmacy Specialty Pharmacy** process has proven to be effective and efficient in the United States.

## Pull versus Push

- Just in time
- On demand
- Site and patient specific

## Parallels

- In country local source = Specialty Pharmacy
- Orders = Prescriptions
- Medication is shipped directly to the site
  - *No middle step of a depot for storage, inventory management and additional shipping*
- Sites submit request for medication 1 – 2 weeks in advance of a patient needing it
  - *No site seeding step and effort*
  - *No site inventory storage and management responsibilities*



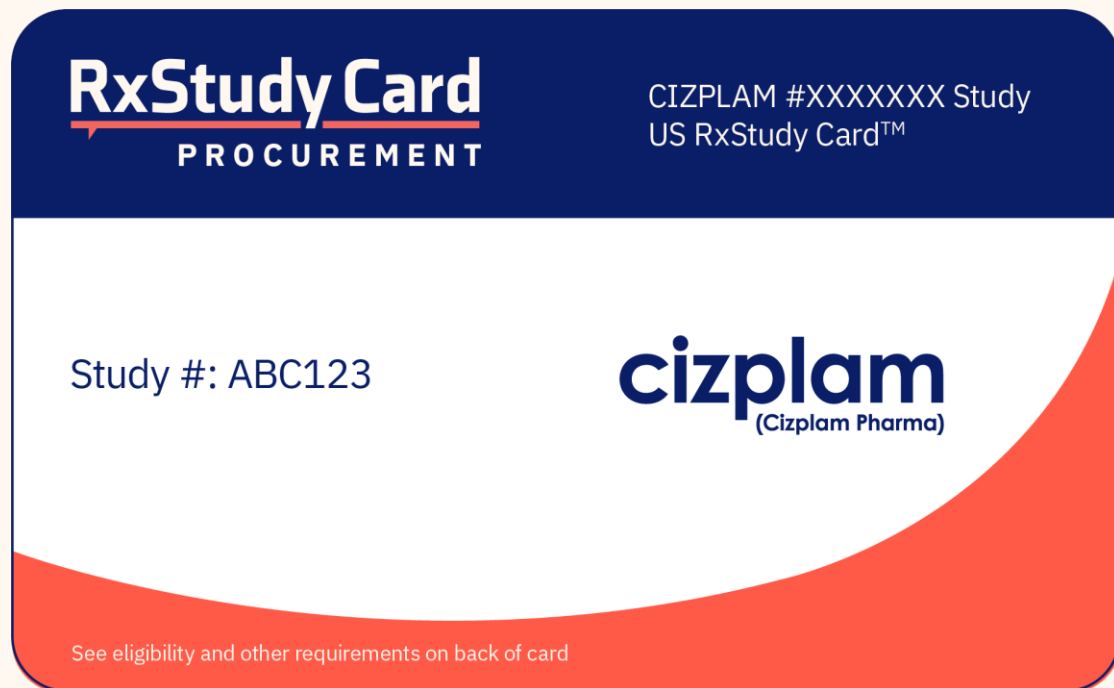
# RxStudy Card - Procurement

- An enhanced bulk supply process that meets the needs of studies requiring a physical inventory of medications and supplies.
- **A true global clinical supply offering.**
- In the US it fills in the gaps that pharmacy-based or medical benefit-based programs do not cover.
  - Need for immediate dosing.
  - Sites that are unable or unwilling to use the pharmacy or medical benefit-based processes.





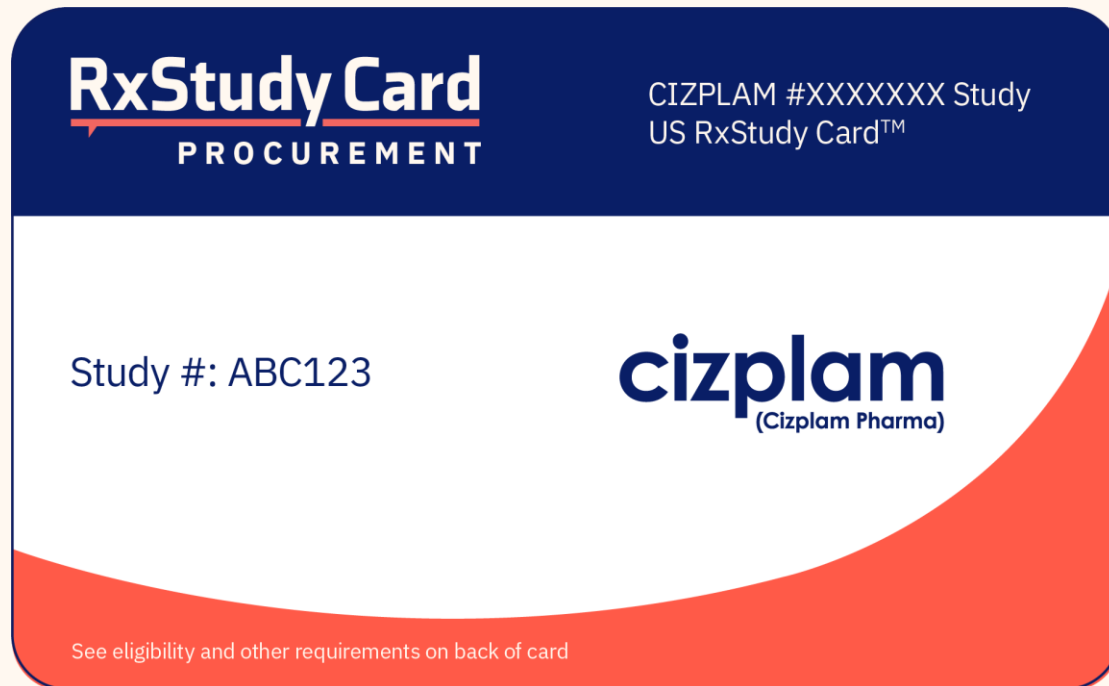
# How Does the RxStudy Card - **Procurement** Process work?



- Leverages “in country” sourcing.
- Provides study teams and sites a simple ordering experience through an online portal called the Mercalis Clinical Trial Support Gateway:
  - *just in time*
  - *on demand*
  - *quantities specific to each site and patients' needs*
  - *direct-to-site shipments*
  - *real-time order and shipment status*

# RxStudy Card – Procurement

## Sourcing and distribution options



### In country

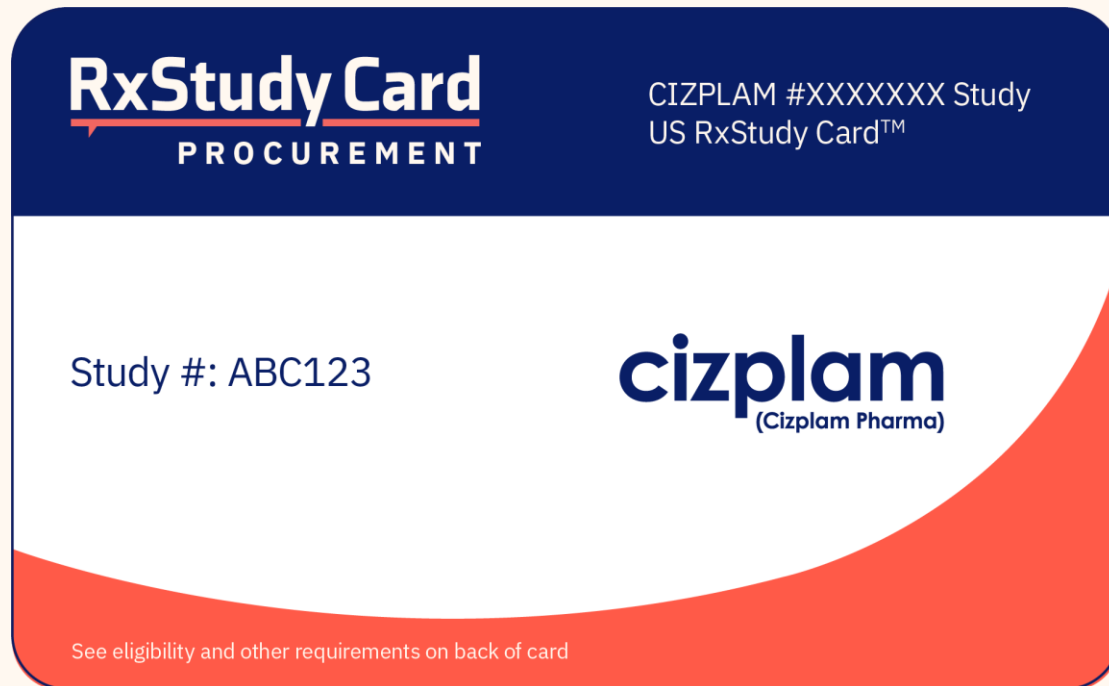
- Used when the medication is available in countries where there will be sites.

### Central location

- When medication is not available in a country where there will be sites.
- Hard to get medication.
- Mitigate shortages.
- Unique protocol needs.
  - One lot number required.

# RxStudy Card – Procurement

## Differs from the traditional bulk supply process



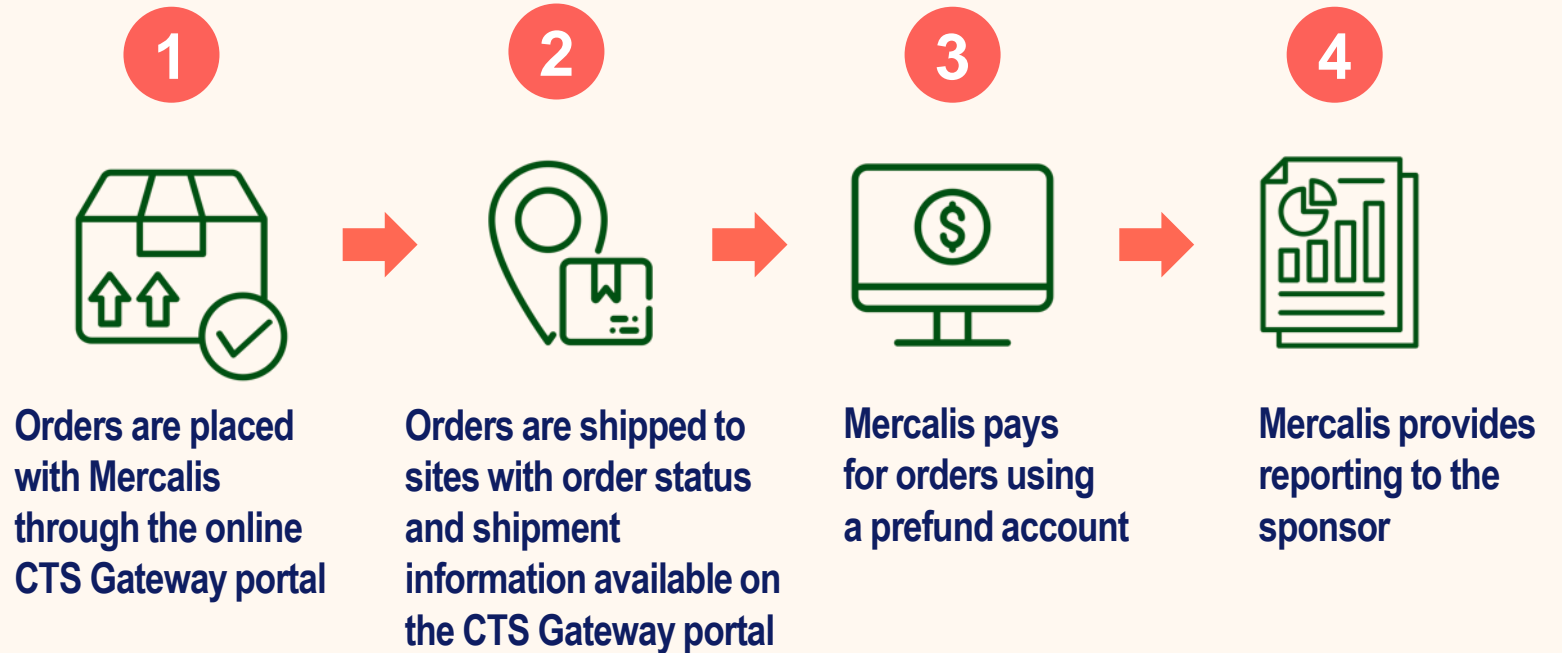
- Often does not require an up-front purchase of a large physical inventory of medication and supplies.
- Avoids the effort and expense of repacking, labeling, and storing medication and supplies.
- Eliminates the need for a central depot that serves multiple countries.
- Eliminates the expense and complexity of cross boarder shipping.
- Reduces overages and waste.

# RxStudy Card - Procurement Process



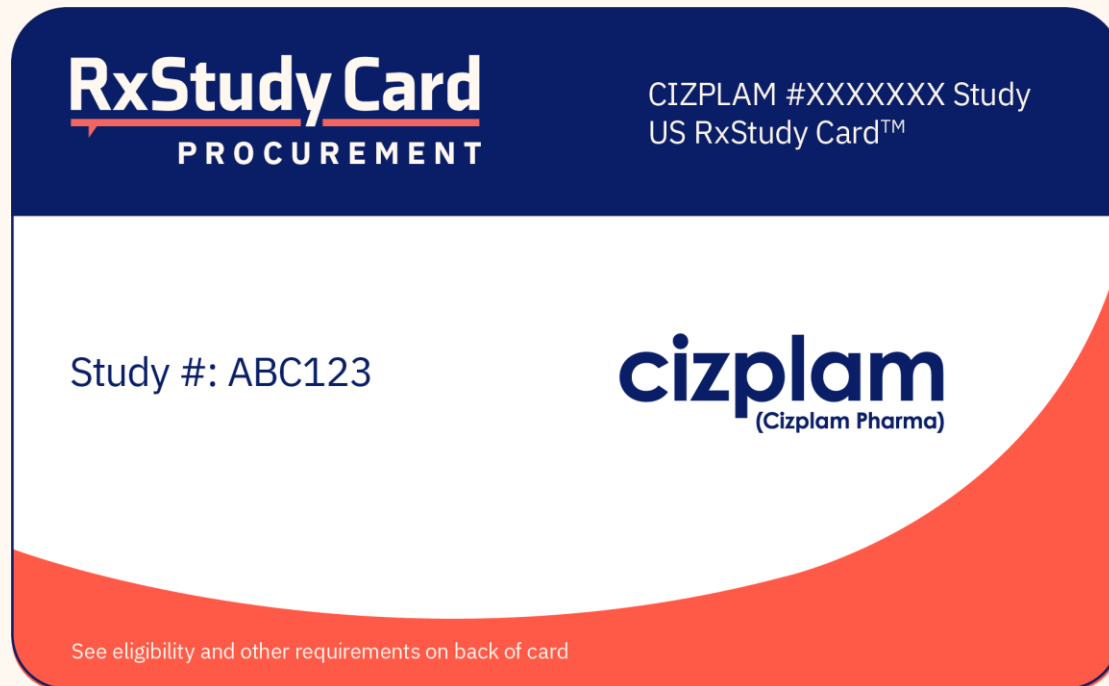
**Leverages the supplier network to provide sites a physical inventory of commercially available medication and supplies**

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



# RxStudy Card – Procurement

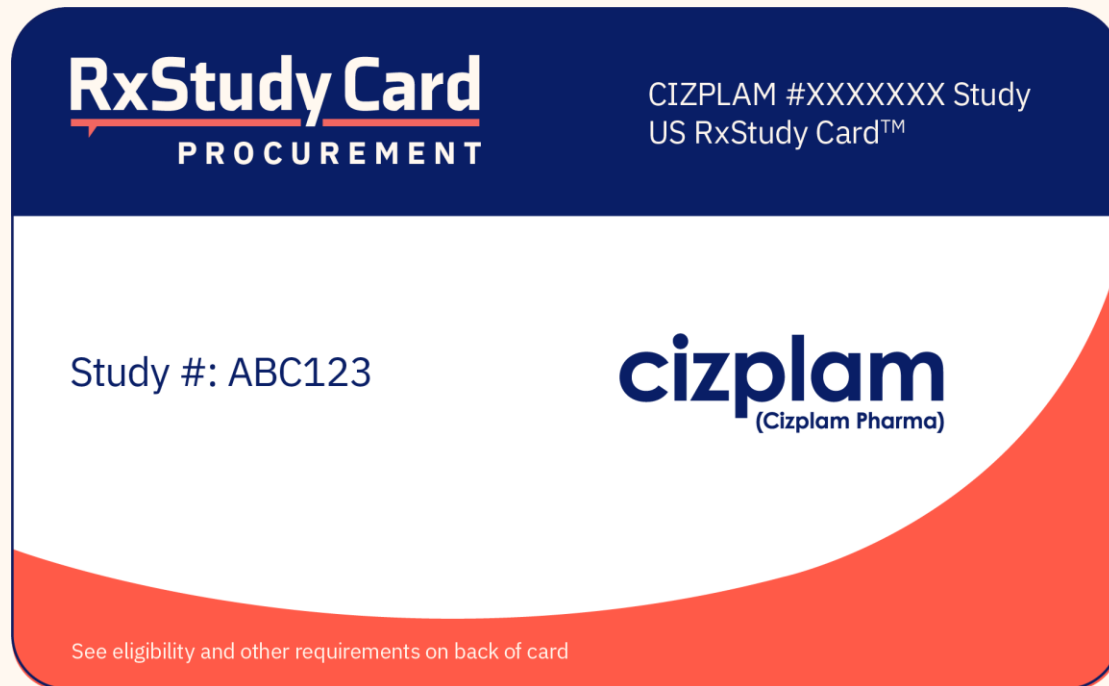
## Site benefits:



- Does not require sites to store large quantities of medications.
- Provides the ability to order medications when it is needed and in the appropriate quantity.



# RxStudy Card – Procurement Sponsor benefits:



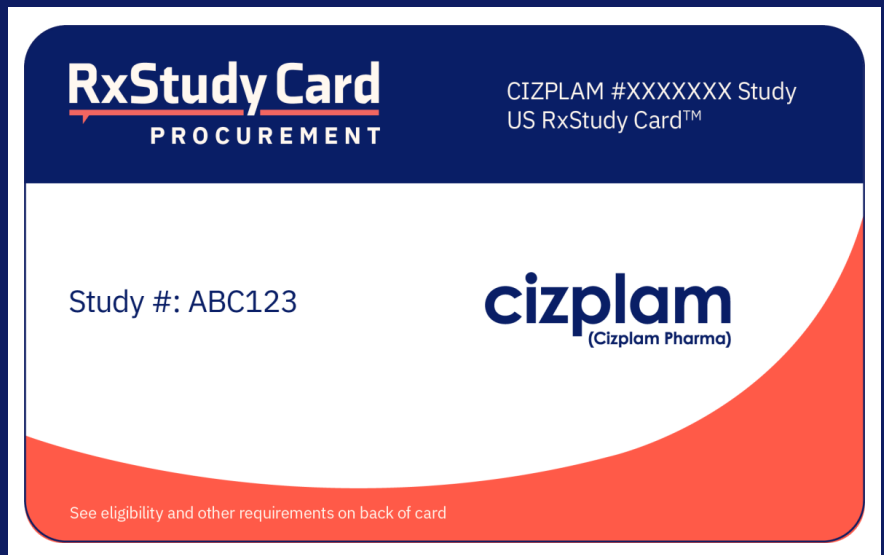
- **Provides efficiencies that result in time and cost savings:**
  - Fewer activities and less employee effort required.
  - Reduced waste.
  - Reduced shipping cost (not shipping across borders).
  - Reduced activities.
- **Supports sustainability goals and a reduced carbon footprint.**

# Case Study 2: Multi-country Local Sourcing Process

- Study needed infliximab and mycophenolate for 20 sites in three countries (UK, Poland and Spain)
- **Challenges** - an infliximab shortage, long labeling timelines and FPI fast approaching
- **Solutions** - local sourcing, just in time/on demand ordering and direct to site delivery through audited in country vendors
- **Benefits** - 1) reduced procurement efforts, logistics, costs and risk, 2) elimination of labeling and storage, 3) shorter lead times and 4) smaller project scope



## TIME & MONEY

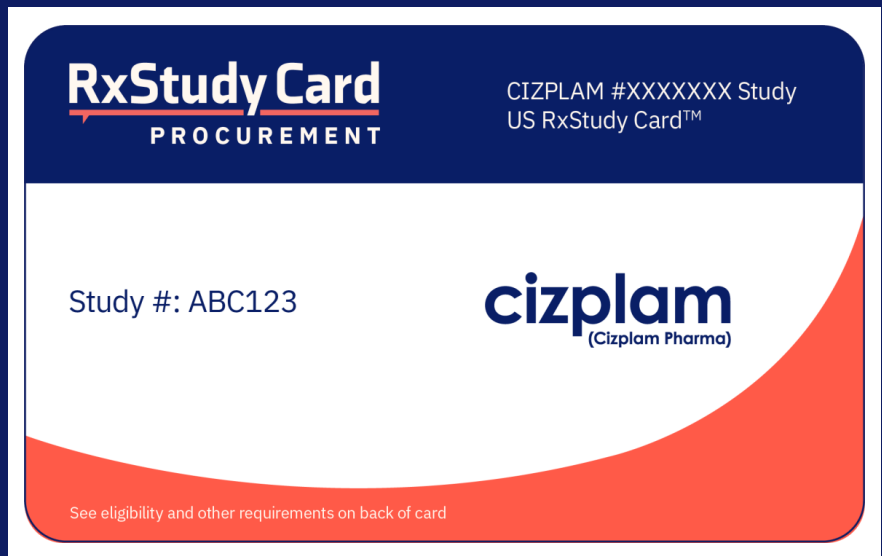


# Case Study 3:

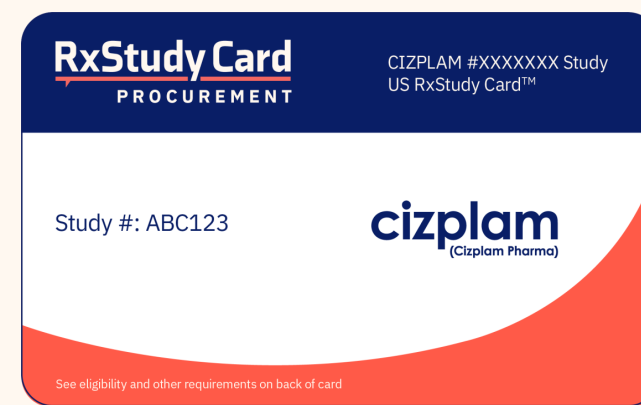
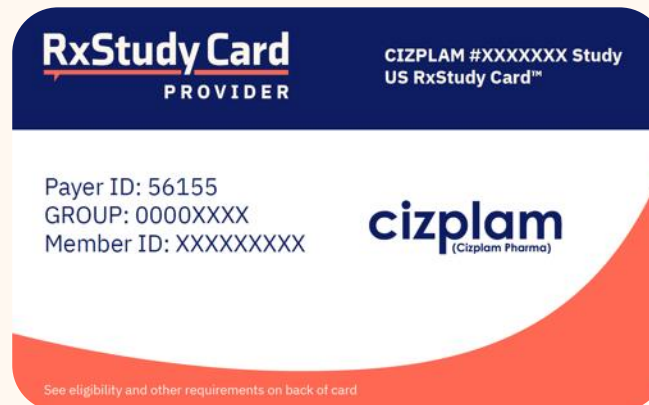
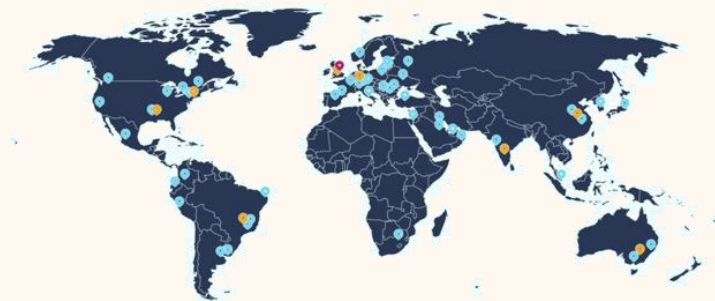
## Multi-country Direct Sourcing Process

- Study needed IRESSA (gefitinib) for standard of care in North America, South America, Australia and New Zealand
- Challenges - complex sourcing, importation logistics and high pricing in North America
- Solutions - sourcing directly through the manufacturer and authorized distributors, on demand/just in time ordering and direct to site delivery through local logistics networks
- Benefits - 1) reduced procurement efforts, logistics, and risk, 2) elimination of importation, 3) reduction in sourcing volumes and waste, 4) cost control

## TIME & MONEY



# Clinical Supply Processes That Align With **Sustainability** Goals



When *any phase study* requires *commercially available medication*



# Sustainability Partnership



- Mercalis is committed to help our clients reach their sustainability goals.
- Mercalis has a dedicated point of contact to coordinate these efforts:

Latrinda Williams

Sr. Director of Diversity, Equity, Inclusion, and Culture

919.717.8355

[Lriley@mercalis.com](mailto:Lriley@mercalis.com)

- Mercalis shows our commitment to sustainability by using third partner vendors to aid in assessing our sustainability initiatives:
  - *These partners include CDP (Carbon Disclosure Project) and EcoVadis.*
- Mercalis signed a commitment to SBTI (Science Based Target Initiatives) to establish our near-term target within 24 month of signing the commitment, December 2025.





# Thank You!

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