



## **Bringing the practice of pharmacy to clinical research and the role of community pharmacists in clinical trials**

# Clinical Research Problems

9 out of 10 drugs in clinical trials fail

**50%**

of trials **fail** to **recruit** enough **patients**



Slow recruitment + poor retention = **delays**

**40%**

of patients **fail** to **adhere** to the protocol



Lack of understanding = **failed study**

**85%**

of trials **fail** to **retain** enough **patients**



Delays = wasted resources and **lives lost**

**only 20%**

of **patients** are from **diverse** populations



Homogeneously enrolled trials = drugs that do not **adequately serve the whole population**



[https://www.sciencedirect.com/science/article/pii/S2211383522000521#:~:text=Analyses%20of%20clinical%20trial%20data,\(0%25\)2%2C4](https://www.sciencedirect.com/science/article/pii/S2211383522000521#:~:text=Analyses%20of%20clinical%20trial%20data,(0%25)2%2C4)  
<https://www.clinicalleader.com/doc/considerations-for-improving-patient-0001>  
<https://www.fda.gov/media/145718/download>

Patient



Clinical Research



Doctor



Pharmacist

Relationship | Trust | Patients Access  
Dispensing | Adherence | Counseling

## Root Cause

# Clinical Research Solution

Community Pharmacies working together with the industry to address:



Recruitment  
Diversity  
Patient Experience

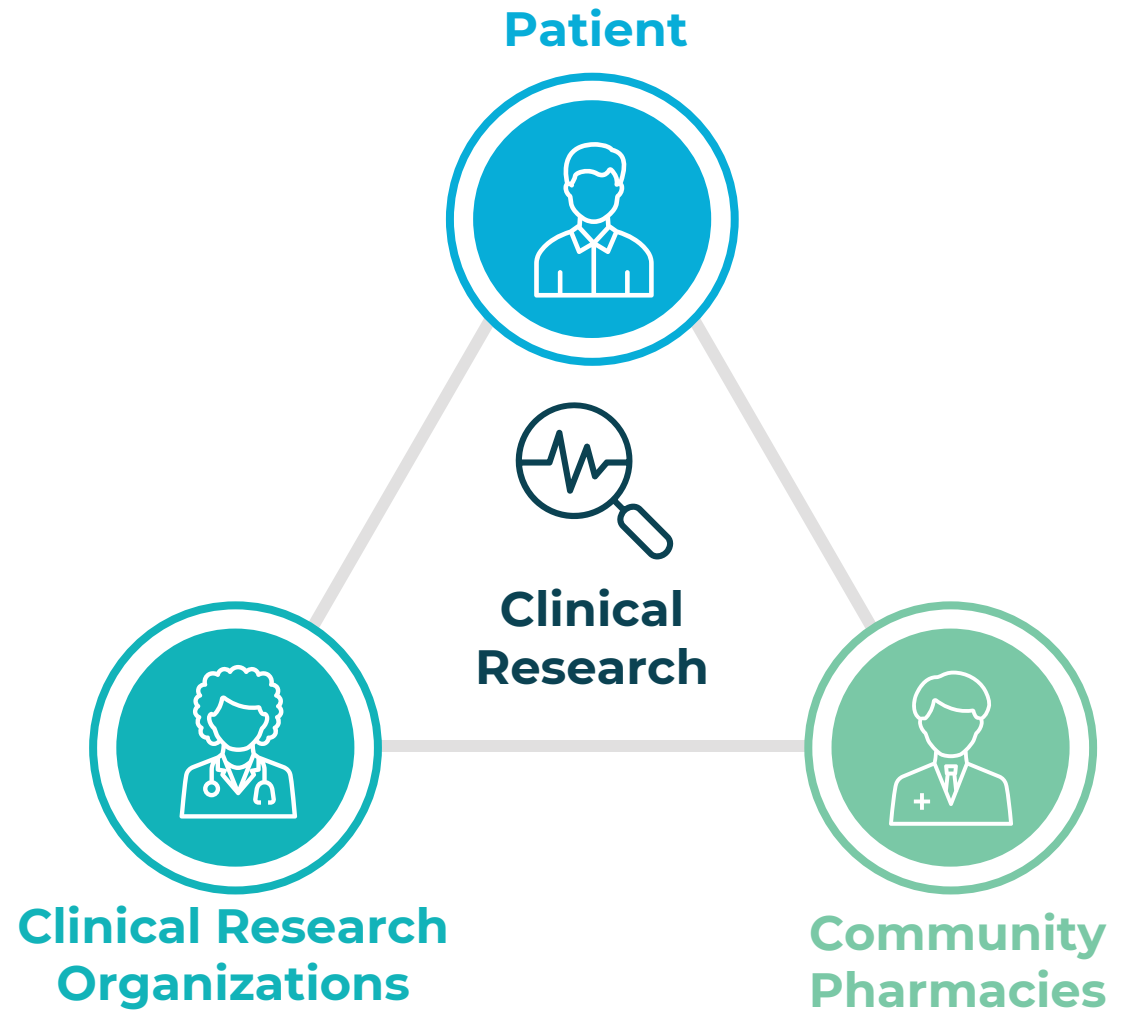
Patient Retention  
Patient Behavior  
RWD/RWE

Clinical Supplies  
Adherence  
Compliance

Site Burden  
Clinical Trial Oversight  
Patient Experience



# The Practice of Pharmacy







# Recruitment

## Community Pharmacists Disrupting Clinical Drug Trials

### TRADITIONAL PROCESS

Sponsors find clinical sites that have patients (Trust already established)

Sponsors/sites use social media and advertisements to find more patients (Trust not established)

Sponsor adds new clinical sites to find more patients (Trust already established)

#### Most patients don't enroll

- × Don't meet criteria
- × Aren't interested or are wary
- × Are unable to participate
- × Distance, time too much

### PHARMACY PROCESS

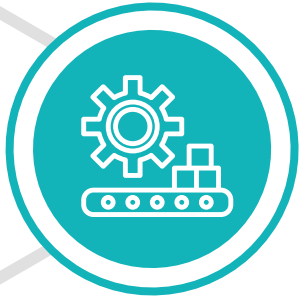
Sponsor hires pharmacies to find more patients using local community pharmacists (Trust already established)

Pharmacist refers patients to existing clinical sites (Maintaining trust)

#### More patients enroll

- ✓ They meet the criteria (confirmed in advance with EHR data)
- ✓ Relationships with trusted pharmacists increase interest and decrease wariness
- ✓ Reduced barriers to participation
- ✓ Supported by pharmacists throughout process





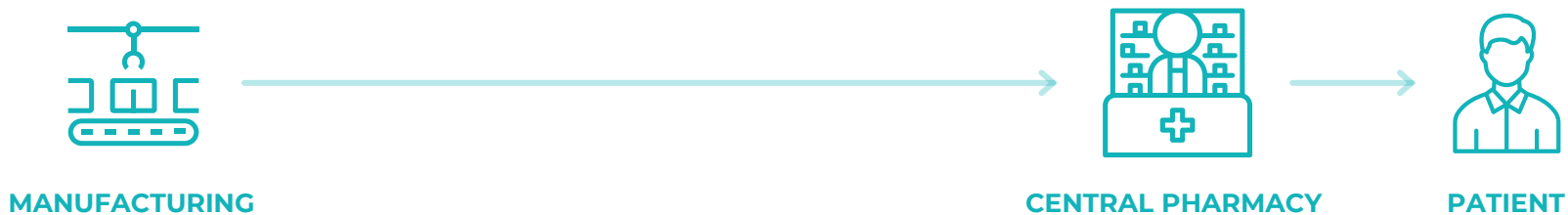
# Dispensing- Clinical Supplies Simplified

Community Pharmacists Disrupting Clinical Drug Trials

## CURRENT PROCESS



## PHARMACY DISPENSING PROCESS



- ✓ Alleviates clinical supply site burden and costs
- ✓ Centralizes packaging, labeling, dispensing, and distribution
- ✓ Enables DCT and hybrid trial models, cost effectively
- ✓ Improves quality and meets regulatory requirements
- ✓ Optimizes packaging & labeling and eliminates waste and excess shipping & handling
- ✓ Complete pharmacist oversight





# Counseling

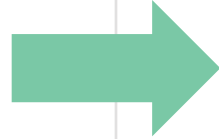
## Community Pharmacists Disrupting Clinical Drug Trials



### Pharmacist-provided medication and therapy management counseling

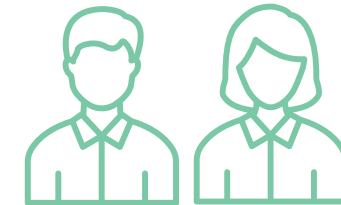
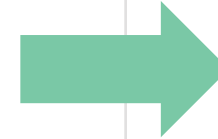
Increases compliance —  
better trial data

Increases retention —  
faster, more seamless trials



### Generates behavior trend reports, usage analytics, and progress metrics to optimize future trials

Pharmacist counselling data collected for first time



### Trial conduct and retention

Continuous and real-time clinical trial improvement



# Benefits for All Stakeholders



**Sponsor**

- Accelerated trial timelines
- Decreased drug development costs
- Addresses diversity



**Pharmacist**

- Increased revenue
- Augmented patient care
- Enhanced skill set and experience



**Patient**

- Clinical trial participation with minimal disruption to daily life
- Underrepresented populations have access to cutting-edge medicines



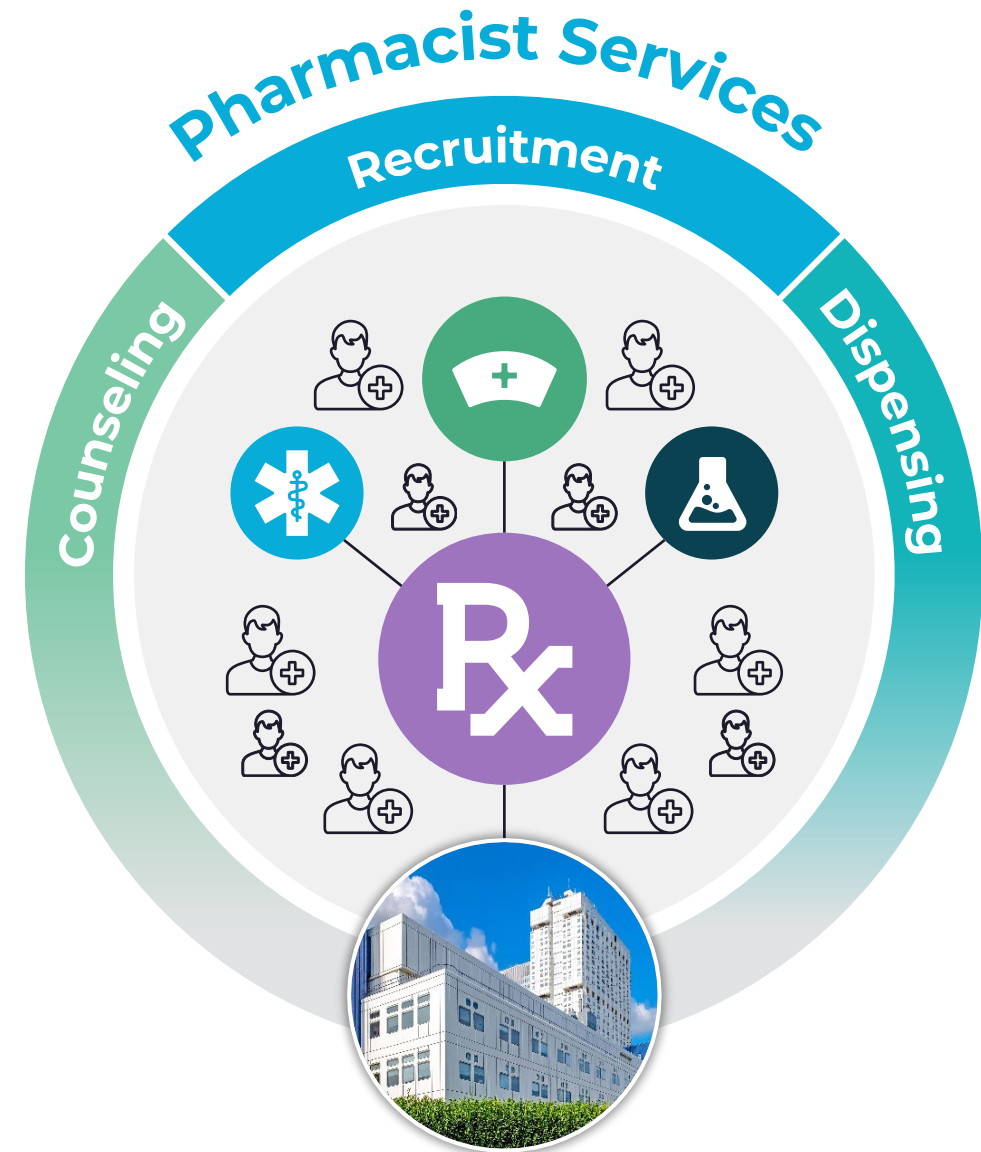


# Have you ever been invited to participate in a clinical trial?

Who do you think your patients would prefer to hear from about clinical trials?

- A. A doctor
- B. A nurse
- C. A text
- D. A call-center phone call
- E. A Facebook or other media add
- F. Their pharmacist

See HINTS® briefs handout - Clinical Trial Participation Among US Adults



# Can a pharmacist be an Investigator of a clinical trial?

## PART 312 -- INVESTIGATIONAL NEW DRUG APPLICATION

### Subpart A - General Provisions

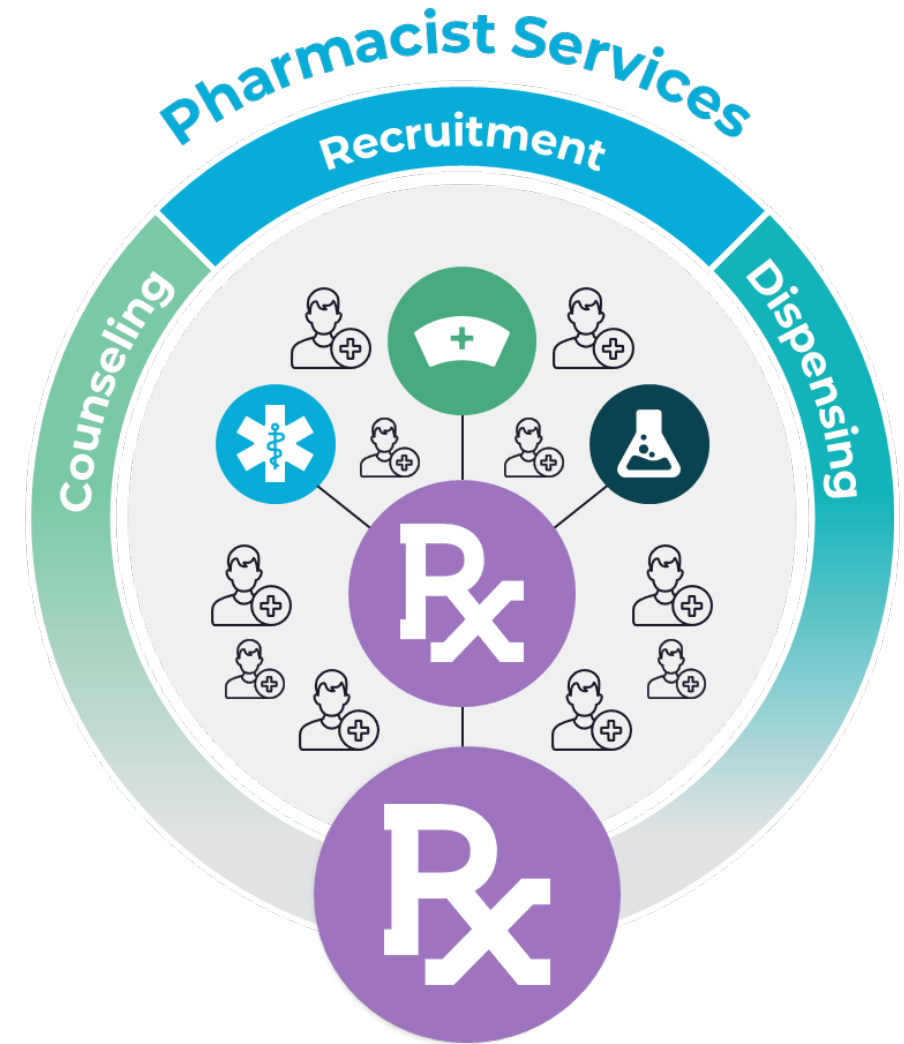
#### Sec. 312.3 Definitions and interpretations.

Investigator means an individual who actually conducts a clinical investigation (i.e., under whose immediate direction the drug is administered or dispensed to a subject).

### Subpart D - Responsibilities of Sponsors and Investigators

#### Sec. 312.60 General responsibilities of investigators.

An investigator is responsible for ensuring that an investigation is conducted according to the signed investigator statement, the investigational plan, and applicable regulations; for protecting the rights, safety, and welfare of subjects under the investigator's care; and for the control of drugs under investigation.



# In the News



## CVS Health Introduces Clinical Trial Services

The new business is uniquely positioned to continue delivering research solutions for COVID-19 and beyond with community presence, data capabilities and health care expertise

**CVS Health** 20 May, 2021, 09:00 ET



# In the News



Walgreens Launches Clinical Trial Business to Address Industrywide Access and Diversity Challenges and Redefine Patient Experience

*Clinical trials offering combines Walgreens established pharmacy presence and nationwide footprint with enterprise-wide health solutions and a legacy of delivering meaningful real-world evidence.*

June 16, 2022



# In the News



Kroger Health Establishes  
Clinical Trial Site Network to  
Increase Reach and Access to  
Research Studies

24 Jan, 2023, 14:55 ET



# In the News



RxE2 and Thrifty White Pharmacy Establish First E2 Dispensing Service for Clinical Drug Trials in the US  
25 Jun, 2020, 07:00 ET

How Learning and Persistence is Changing Clinical Trials for Better  
September 16, 2020

