



# Top Takeaways

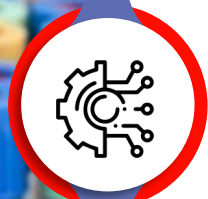
*from our webinar series addressing key challenges to reaching clinical trial milestones.*

## **Part 2: Clinical Sample Management – How to Avoid Losing a Sample**

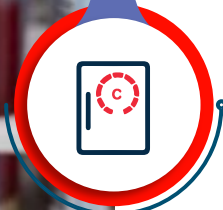
# Topics



Agile approaches to clinical sample shipping strategy



Digital technology options for ensuring a secure chain of custody



Best solutions for maintaining the integrity of clinical samples during storage

# Sample Life-Cycle

All samples have different journeys from

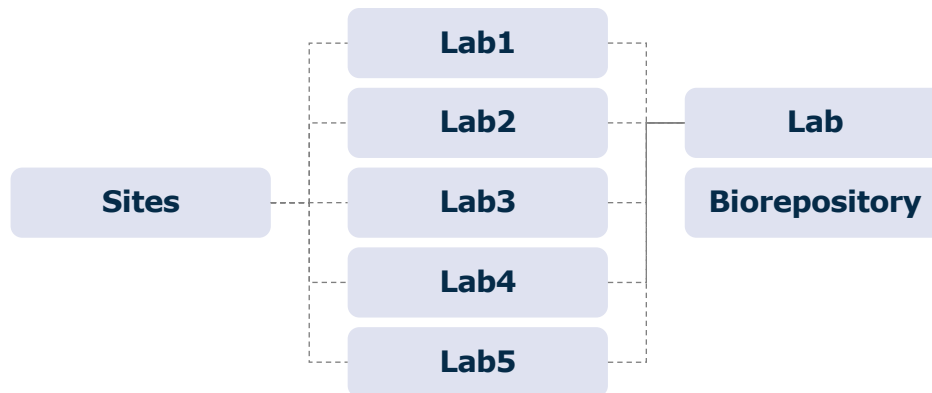


# Sample Life-Cycle – Overall Data and Sample Flows

## Complex Study Designs Advanced Therapy, Cell & Gene, and Early Phase Trials

### Multiple sample types

- Tumor
- Cell pellet
- Skin
- CTC
- Hair
- Blood
- Serum
- Plasma 16
- PG
- DNA
- RNA
- Bone Marrow
- PK
- Flow
- Safety
- Other



# How much more data is collected today for Phase II and Phase III studies compared to 10 years ago?

**Answer**

3X more data

**~20**

Endpoints in Phase II and III trials

**263**

Procedures per patient

**3.6<sub>MM</sub>**

Data points generated on average in Phase III trials

**3X**

Data from 10 years ago

Tufts Center for Drug Development. Rising Protocol Design Complexity Is Driving Rapid Growth in Clinical Trial Data Volume. January/February 2021. Vol. 23 No. 1.

# Importance of Sample Chain of Custody – Starting on the Day of Collection



Sample  
and data  
accountability



Proactive  
issue  
mitigation for  
future  
collection



Logistical  
planning prior  
to collection



Storage and  
Analysis  
Planning



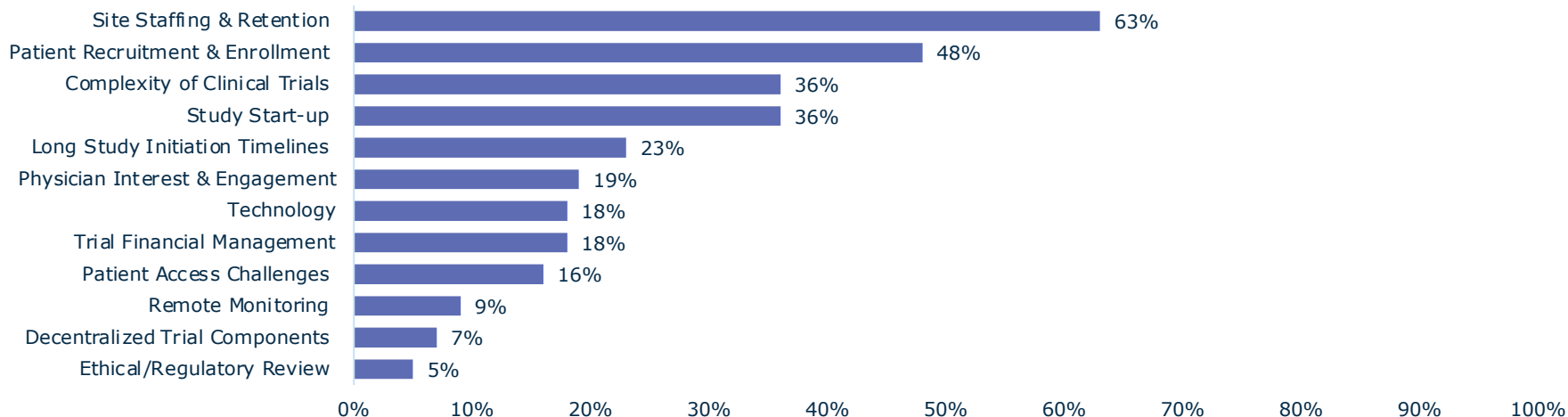
Patient  
care

# What Are the Top 3 Issues Impacting Sites Today?

## Answer

Below are the top 10 issues impacting sites today. However, **Staffing & Retention, Patient Recruitment, and Complexity of Clinical Trials** are the top three.

### Top Site Challenges in 2023 | What are the top issues impacting your site today?



Clinical Research Site Challenges Survey Report | © WCG Clinical 2023



# Challenges with Gathering Sample Information on Day of Collection



Every site has its own **systems, technology, methods, and workflows**

Sites are managing **one study** or **hundreds** of **studies**.

Sites are often working with **different laboratory kits/shippers**.

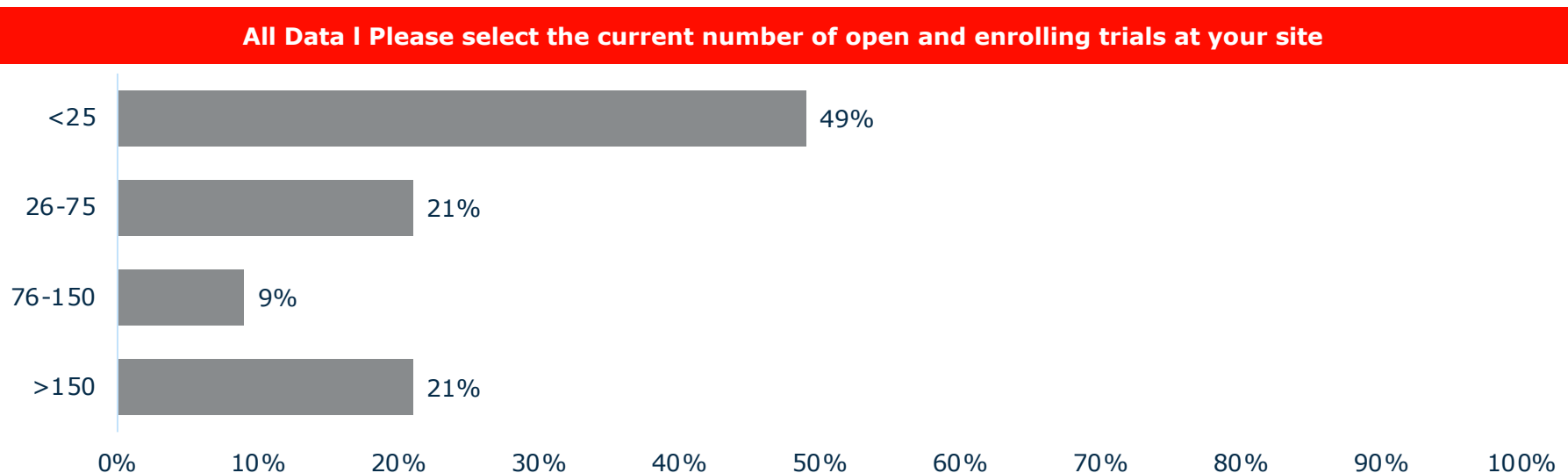
Sites are often booking couriers for **multiple shipments across different destinations** and **courier services**.

Sites are **BUSY**



# Sites Are BUSY

**From a Survey of 500 US Sites, 21% Responded as Being Currently Active in >150 Clinical Trials**

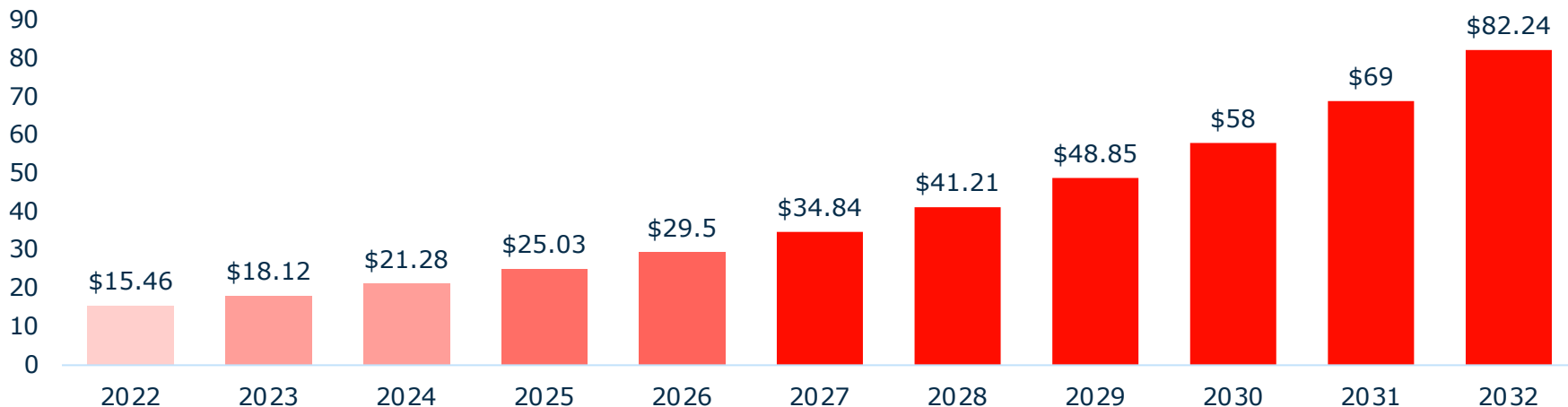


# What is the Compounded Annual Growth Rate of Global Cell and Gene Therapy Studies Projected Over the Next 9 Years?

## Answer

The global cell and gene therapy market size was exhibited at USD 15.46 billion in 2022 and is projected to hit around USD 82.24 billion by 2032, growing at a CAGR of 18.3% during the forecast period from 2023 to 2032

Cell & Gene therapy market size, 2022 to 2032 (USD Billion)



# Sample Life-Cycle – Overall Data and Sample Flows

## Advanced Therapy Trials - Example Tracking Flow Source Material and Product Tracking



- Vendor selection – kits on site
- Courier assessment (stability, customs, shippers, lane assessments)
- Scheduling visit, couriers, other
- Assay development?
- Regulatory requirements
  - Data collection and cleaning
  - Courier pick up

- Tracking in transit
- Logistical management – mitigation for delays

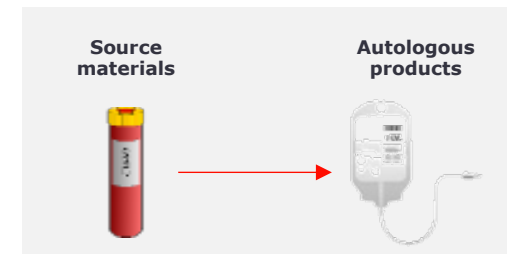
- Confirm receipt at lab
- Data cleaning

- Specialty processing
- Data cleaning

- Courier lane assessment
- Scheduling couriers, other

- Data collection and cleaning
- Courier pick up

- Confirm receipt at lab
- Data cleaning



Logistical challenges

Multiple vendors, systems, and people

Difficult for sites to manage

Continuous monitoring and visibility required

Multiple sample hand-offs

Timing is crucial

# Solutions – Site Centric Technology

**Provide site-centric day of collection and shipment options. Let the site choose. No single solution is 100%**

## Courier and lab/Storage integration options



Ease of use is the key to compliance in obtaining day-of-collection data (Collection and Shipment)



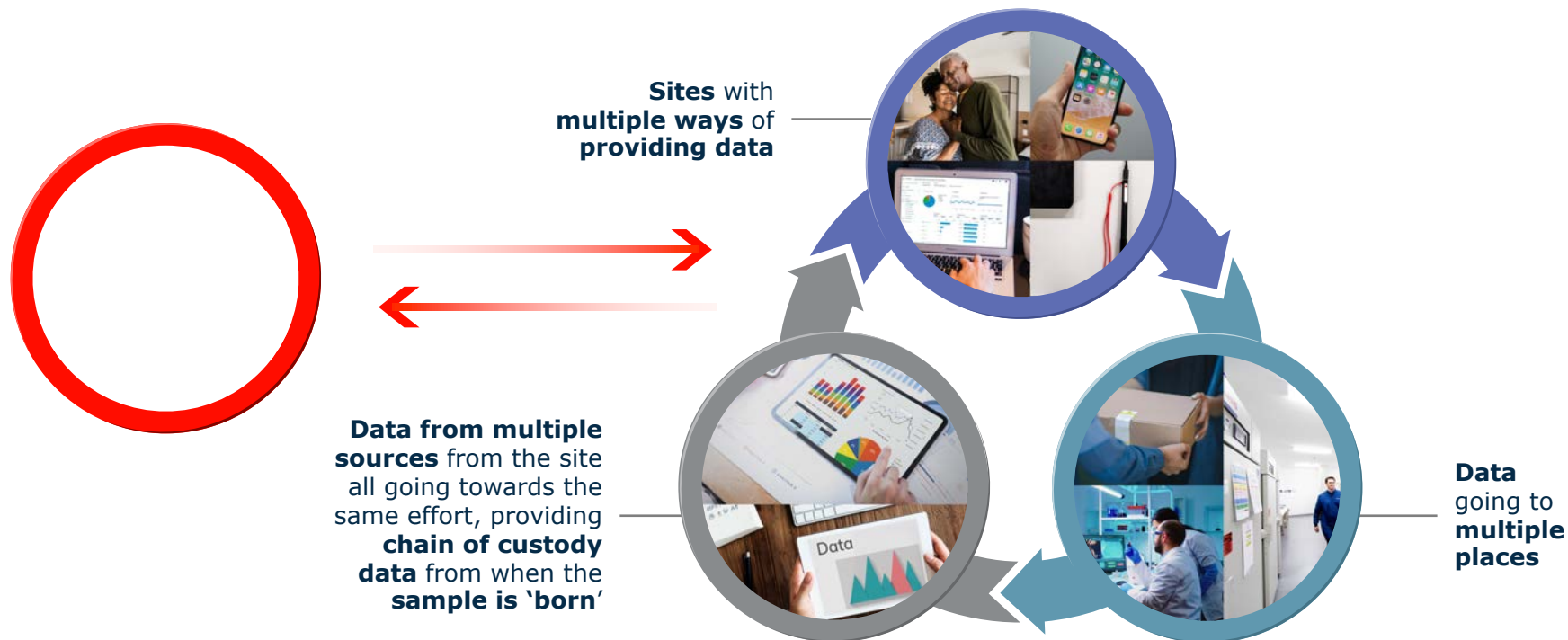
Courier Integration



Lab/Biorepository Data Integration

# Solutions – Chain of Custody Data

Acceleration through coordination



# Summary

**Planning and preparing for the unexpected from collection through transit to storage.**

## **Collection Integration**

Sample Collection, Data Submission and Tracking

## **Courier Integration**

Courier Collection, Transit and Receipt Tracking

## **Lab/Biorepository Integration**

Receiving, Processing, and Retrieving Samples for Storage

# Thank You!