



Industry gaps in sample tracking, learn about what technologies and services are essential for end-to-end clinical trial sample tracking.

Presented by:

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LabConnect

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Today's Agenda

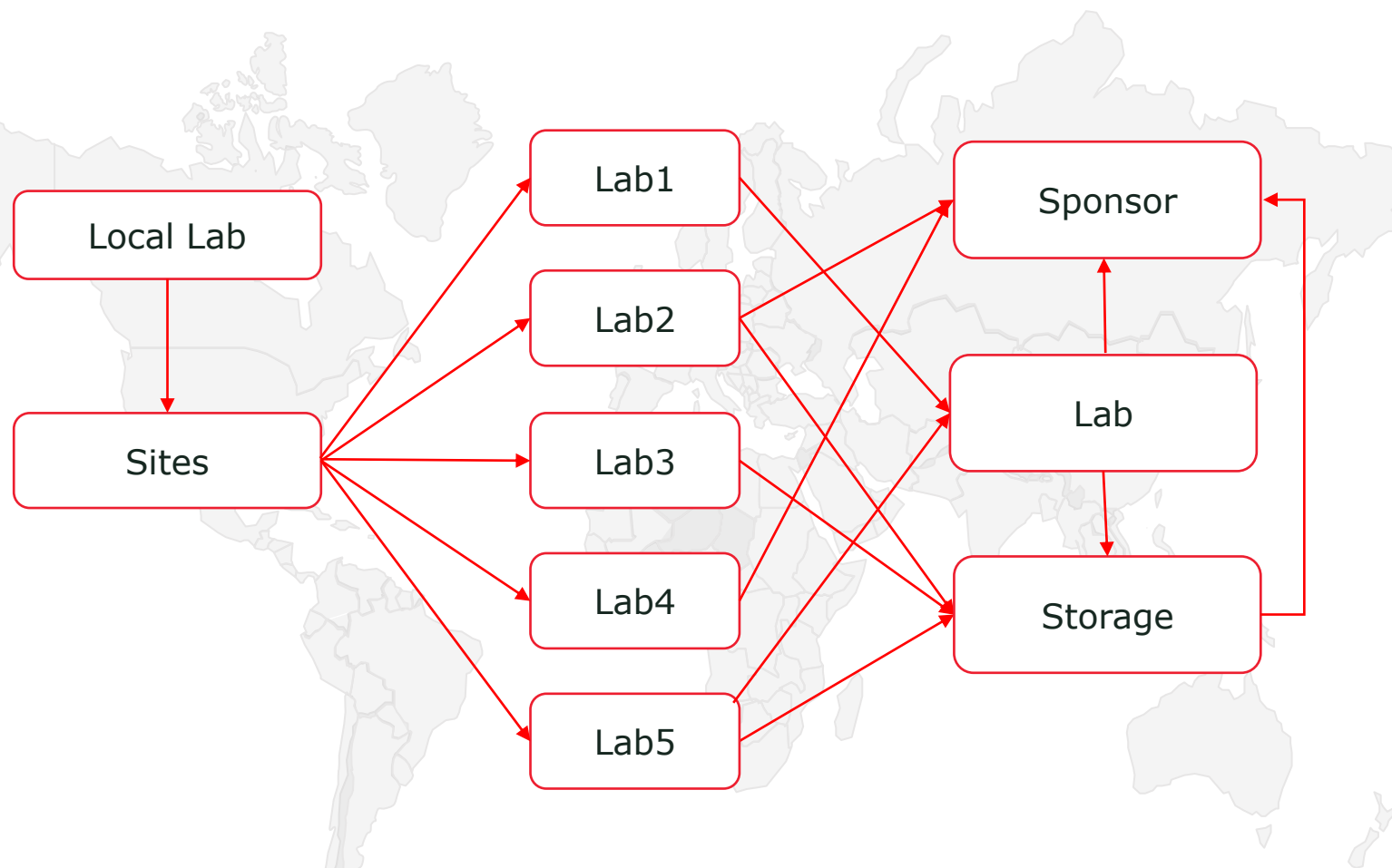
- What is Sample Tracking?
- Current Industry Challenges
- Solutions and Considerations
- Tracking Beyond the Central Lab
- End to End Tracking Summary



What is Sample Tracking?

What does sample tracking mean to you? What does it mean in the industry?

Do You Know Where Your Samples Are?



Package Tracking VS Sample Tracking

SAMPLE TRACKING

- Information 1-48 hours from collection
- Scheduled Collection Confirmation Options
- Forecasting Tools
- Missed Visits/Collections Monitoring
- Data Collection/Integration Technologies
- Subject/sample detail
- Courier Integration and Escalation
- Logistical Oversight

PACKAGE TRACKING

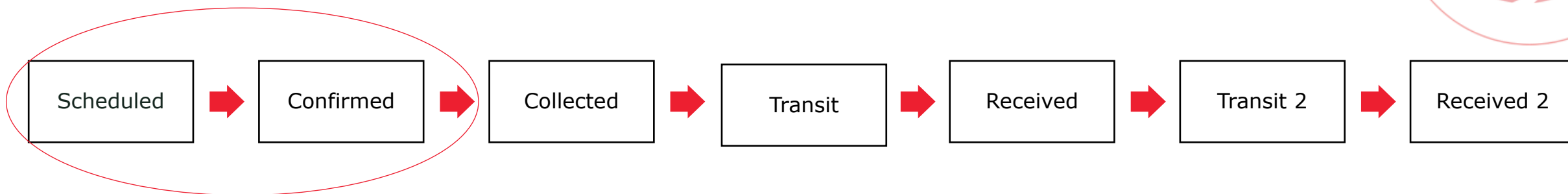
- 24+ hours from collection
- No LIVE monitoring
- Reaction tracking
- AWB detail



Current Industry Challenges

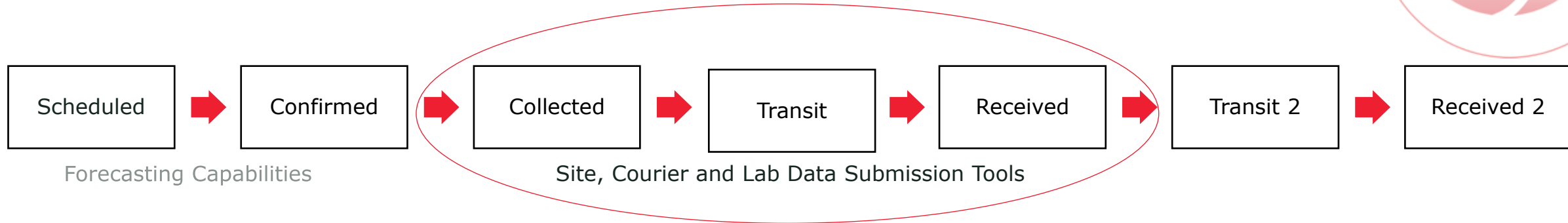
Where are the gaps in sample tracking from the moment of collection through its entire life-cycle

Sample Flow and Challenges in Tracking



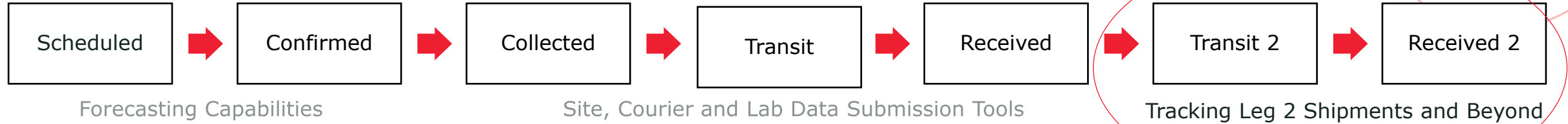
- Forecasting
 - Need detailed information of visit/sample collections
 - Missing vs. expected reconciliation real-time

Sample Flow and Challenges in Tracking



- Forecasting
 - Need detailed information of visit/sample collections
 - Missing vs. expected reconciliation real-time
- Site, Courier and Lab Data Submission Tools (Day of)
 - Need **increased compliance** in data submission
 - Courier integration and oversight
 - Laboratory confirmation of shipment/receipt

Sample Flow and Challenges in Tracking



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- Tracking Beyond the Central Lab
 - Ability to see where samples are post Central Lab.

Solutions and Considerations

What are the current technology solutions available today and what technology solutions to consider for tomorrow

Solutions - Forecasting

Need to know when a sample is to be collected in order to track

View Forecast Summary

Schedule: DEMO From: 1Oct2011 To: 30Oct2011 Forecast: Both Go

26481585-MMY-1001 Forecast from Visit 1 R: Rolling Schedule, F: Fixed Schedule

Visit Name		Day 1	Day 2	Day 7	Day 14	Week 4
Visits		Visit 1	Visit 2	Visit 3	Visit 4	Visit 5
Subject 001	F	9/1/2011	9/2/2011	9/7/2011	9/14/2011	9/28/2011
	R	9/1/2011	9/3/2011	9/8/2011	9/15/2011	9/29/2011
Subject 002	F	10/5/2011	10/1/2011	10/11/2011	10/18/2011	11/1/2011
	R	10/5/2011	10/1/2011	10/11/2011	10/18/2011	11/1/2011
Subject 003	F	3/4/2011	3/5/2011	3/10/2011	3/17/2011	3/31/2011
	R	3/4/2011	3/5/2011	3/10/2011	3/17/2011	3/31/2011

01-Oct-2011 + 7 days 8 - 14 days 15 - 30 days

Flags when current date or entered date outside the alert date
Flags when current date or entered date within the alert date

Customized alerts for visits that appear outside of the forecasted date/time.

- Confirm collection/date time for tracking activities
 - Booking courier and courier services
 - Ensuring courier pick up
- Ability for multiple schedules
- Ability to modify/switch schedules anytime

Solutions – Site Centric Technology

Real-time data submission -
Unlocking the key to compliance



Unique Sheet ID

Digital Verification

Specimen Level Coding
Linked to Visit Coding

Collected

Shipped

Received

Comments Regarding
Sample

81.2138.8.199

Cycle 1 Day 1
Kit 2

DEMO

SEND TO LabConnect the Day of Collection by docking your PEN
Alternate: Fax: 360.210.5499 Email: sgrant@labconnectllc.com

1. FILL IN SUBJECT INFO

SITE: 033-003-3
SUBJECT ID: 033-003-3
(033-SSS-##, S=site, # = subject ID)
INITIALS: Please use pre-assigned dummy initials
AAC
GENDER: Male or Female
M
Write M or F

DATE OF BIRTH: 19-APR-1946
(DD - MMM - YYYY)
COLLECTION DATE: 20-FEB-2012
(DD - MMM - YYYY)
COLLECTION TIME PRE-DOSE: CMMC, PBMC, PG
09-55 (24 hour clock)
COLLECTION TIME 3-6 hours POST-DOSE: PBMC
13-00 (24 hour clock)

2. COLLECTION INSTRUCTIONS – See Lab Manual for complete instructions on collection, storage, and shipment of samples.

CMMC – Collect 7.5 mL of blood in a room temperature CellSave tube. Store tube upright at room temperature. Do not refrigerate. Ship ambient on the day of collection.
PBMC – Collect 4 mL of blood in a room temperature CPT Sodium Citrate tube. Centrifuge immediately. Remix by gently inverting 8 to 10 times. Ship ambient on the day of collection.
PG – Fill tube Lavender top tube COMPLETELY, as far as the vacuum will allow. Mix immediately by gently inverting 10-15 times. Ship ambient on the day of collection.

SAMPLES	SAMPLE ID LABEL	3. Collected SITE	4. Shipped SITE	SHIP TO	5. Received BERLIN	6. Received
CMMC 1 - 10ml CellSave Predose	*4240593300101*	QTY: 1	QTY: 1	VERIDEX	NA	QTY Veridex:
PBMC 1- 4 mL CPT Sodium Citrate Predose	*4240593300201*	QTY: 1	QTY: 1	LabConnect BERLIN	QTY: 1	QTY Radnor:
PG (optional) 1 - 10 mL Lavender Predose	*4240593300501*	QTY: 1	QTY: 1	LabConnect BERLIN	QTY: 1	QTY Radnor:
PBMC 1- 4 mL CPT Sodium Citrate 3-6 hours Post dose	*4240593400201*	QTY: 1	QTY: 1	LabConnect BERLIN	QTY: 1	QTY Radnor:

Enter Quantity of samples collected. If samples were not collected please enter 0 in the comments section.

Always write on the top white copy. Keep the bottom copy for your records and ship the other copies with the samples.

Initials: FT
Date: 20-FEB-2012

Initials: FT
Date: 20-FEB-2012

Initials: 30
Date: 21-FEB-2012

Initials: 30
Date: 21-FEB-2012

COMMENTS (Initial and date all comments):
CANARY FORM MISSING!
Canary form missing!
PBMC Pre and Post Dose not Centrifuged.
PBMC pre- and postdose not centrifuged.

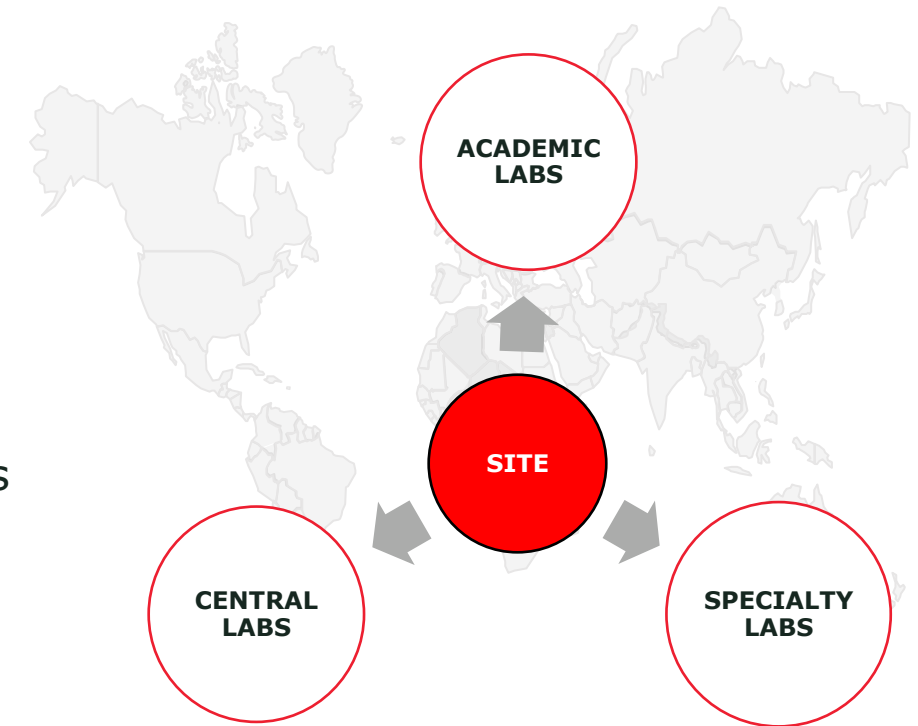
WHITE - LAB1 CANARY - LAB2 PINK - LAB3 GOLD -

SITE

Solutions – Courier Integration and Oversight



- Logistical Integration and Technologies
 - Lane verification, dry runs, and early collaboration with your shipping partner
 - Evaluate Sample **Stability** with Shipping Options
 - Evaluate Lab and Site **Locations**
 - Strategic Shipping – **Time/Cost** Analysis
 - Documentation - Commercial Invoices
 - IATA Compliance
 - Availability of monitoring technologies for high value samples
 - Track shipments in real-time from origin to destination
 - Real-time temperature monitoring devices and services
 - Replenishes Dry-Ice/Customs Clearance
 - Assist/Maintains Sample Integrity



Solutions – One System



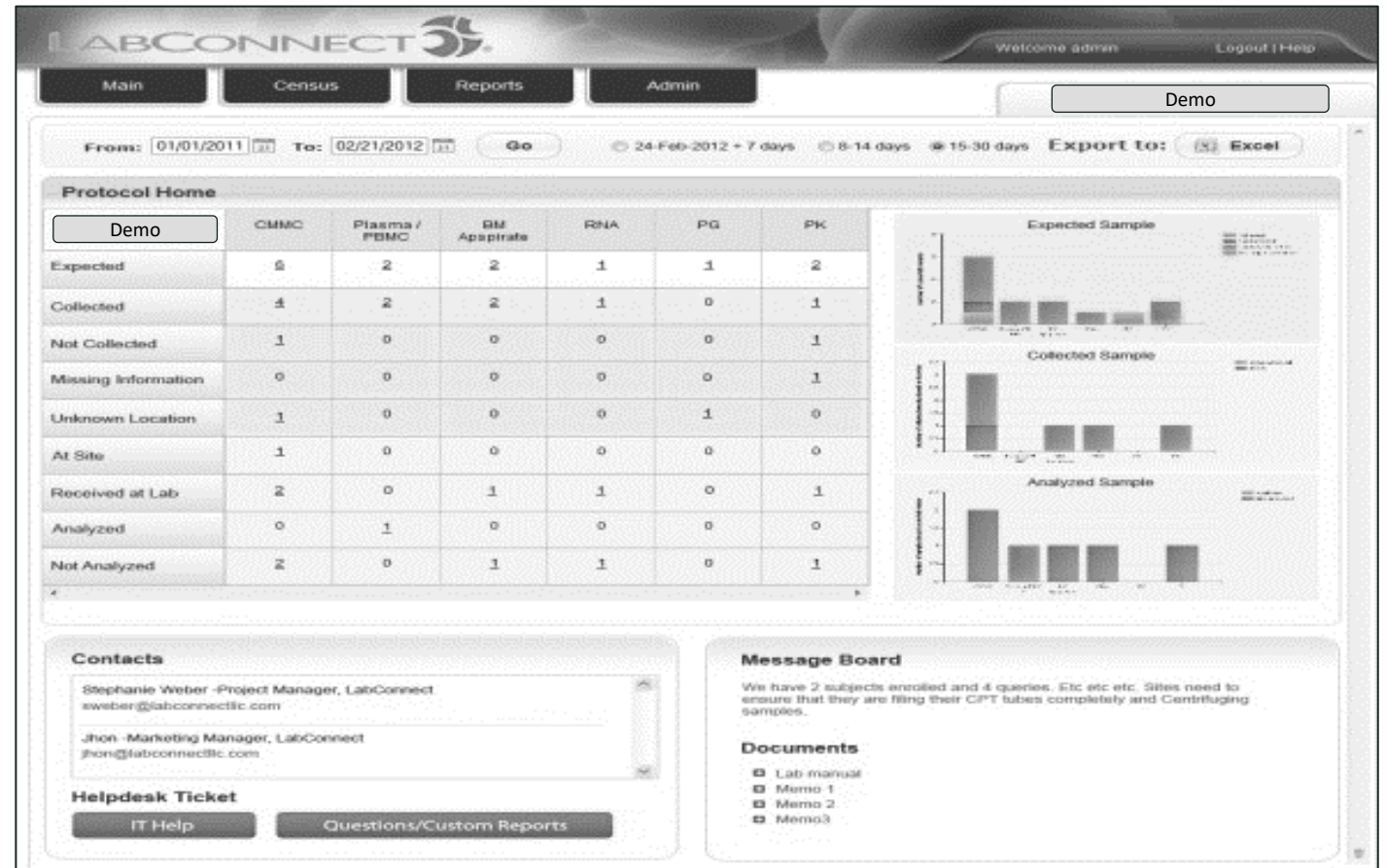
SampleREACH™ Web Portal



Virtual Accessioning

- Form review
- Queries generated
- Data submission

Virtual Accessioning - Real-Time Visibility



Solutions – Sample Tracking Plan

- Developing a comprehensive end to end Sample Tracking Plan
 - Sample flow with stabilities and temperature requirements
 - Outline of Milestones and sample touchpoints
 - Stakeholders' roles and responsibilities
 - Visit forecast planning and alerts
 - Logistics Pre-Assessment details



Solutions – Sample Tracking Team

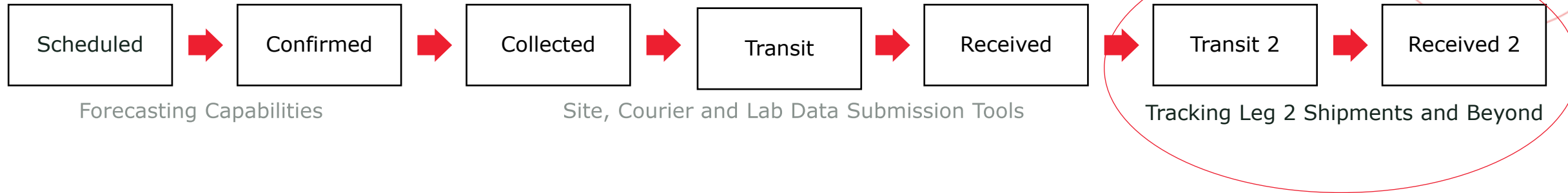
- Digital Pen/Scan set up and monitoring
- Forecasting for subject visits
- Confirming subject visit date and time
- Book any applicable couriers
- **Monitor for collection, shipment, receipt and other status changes per the sample tracking plan**
- Virtually accession and track samples
- Open queries on accession and tracking
- Escalate open queries or other issues to PM



Tracking Beyond The Central Lab

Who is tracking Leg 2 and 3 shipments and beyond?

Solutions – Electronic Manifest Tacking



- Tracking Beyond the Central Lab
 - Ability to see where samples are post Central Lab.
 - Electronic Manifest Tracking
 - Upload manifest into system to change the location and status of a sample
 - In transit
 - Received
 - One System Access

End to End Tracking

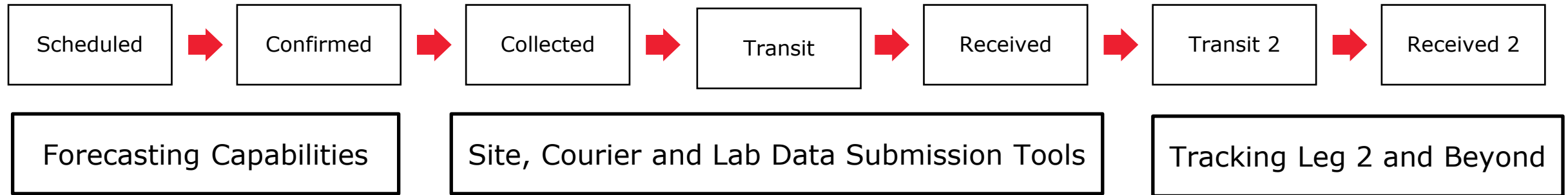
Summary of key points to take home from this presentation

Summary – Necessities in Tracking

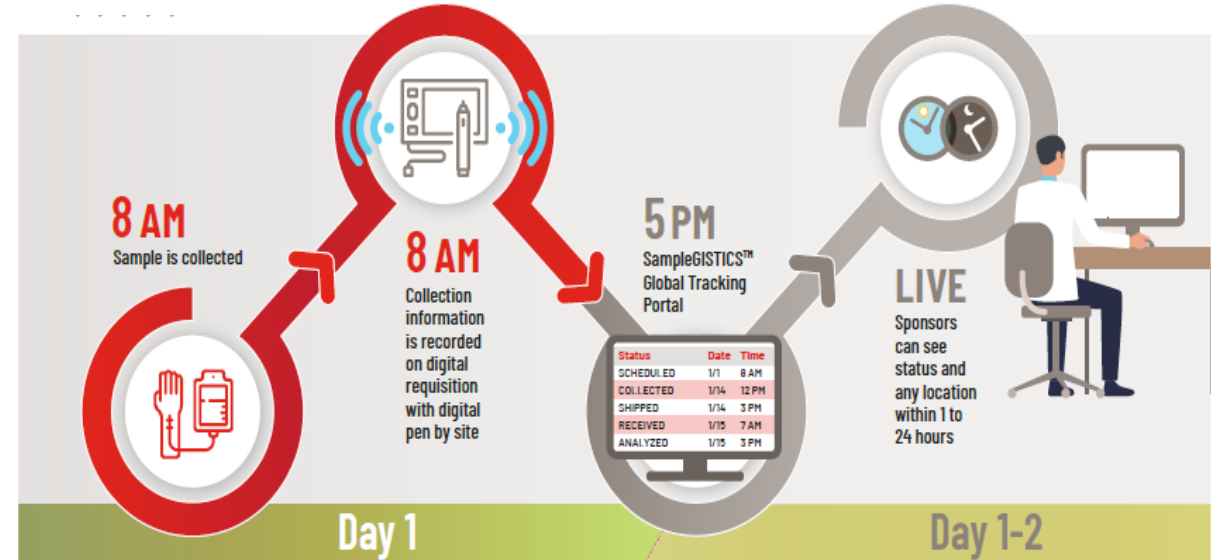
- Forecasting collections and shipment
- Site/lab data submission compliance
- Courier integration and oversight
- Missing vs. expected reconciliations
- Ability to track beyond the central lab



Summary – Solutions



- End to End Tracking Plan
- Dedicated Tracking Team
- Tracking Tools (Compliance)
- One System Visibility





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