



Clinical Ink®

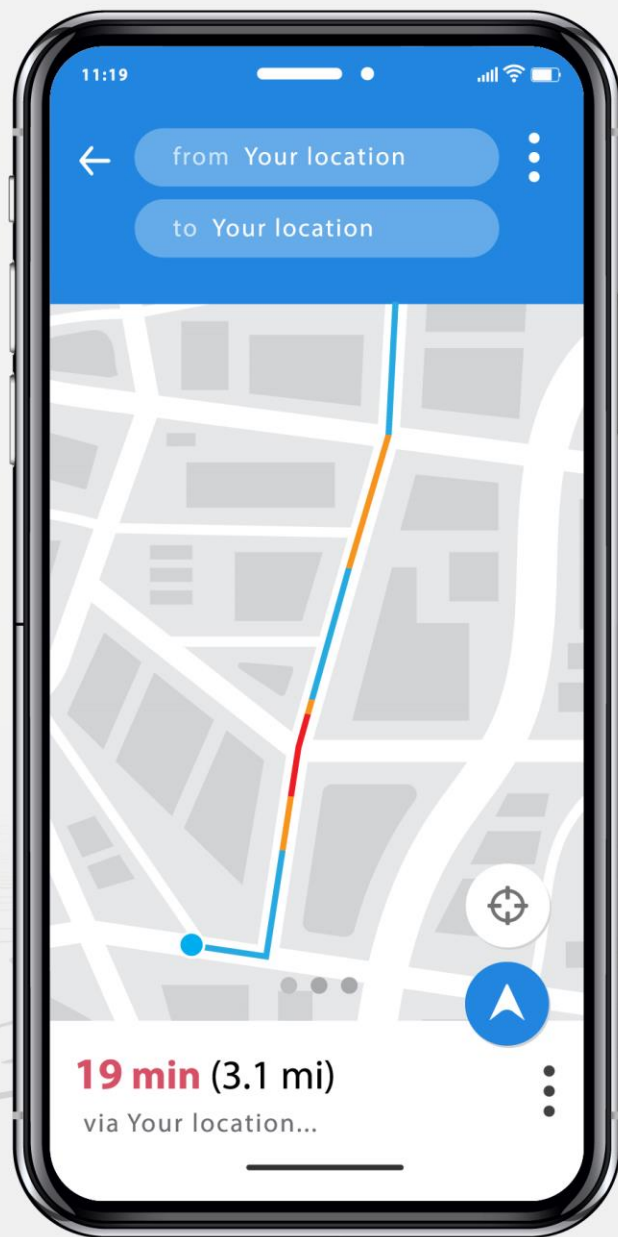
eSource | eCOA | ePRO

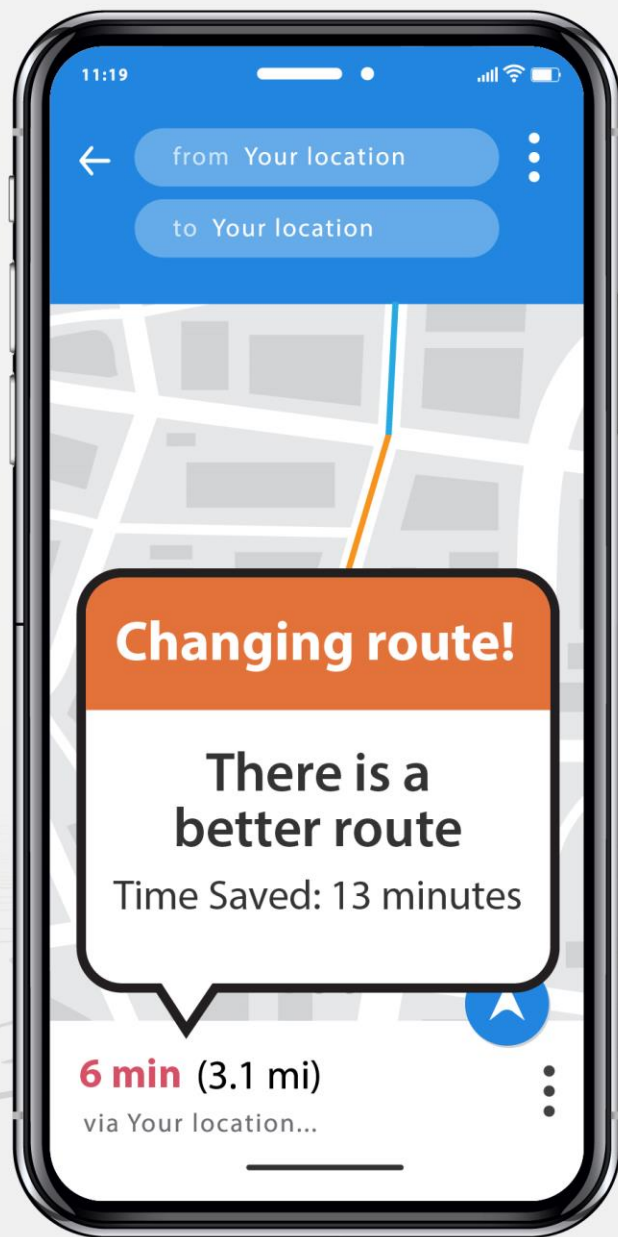
REROUTING YOUR RISK-BASED MONITORING (RBM) STRATEGY

OVERCOMING IMPLEMENTATION ROADBLOCKS WITH NEW TECHNOLOGIES AND APPROACHES

Jonathan Andrus, M.S., CQA, CCDM

Chief Business Officer | Clinical Ink





Changing route!

**There is a
better route**

Time Saved: 13 minutes

6 min (3.1 mi)

via Your location...

AREAS OF DISCUSSION

- RBM strategy considerations
- The current state of RBM
- Streamlining RBM with tools and technologies

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- **RBM strategy considerations**
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RBM STRATEGY CONSIDERATIONS: RACT

Documentation of Critical Data & Processes

- Team alignment on “what matters”
- Focused risk assessment

Consistent Approach to Assessment

- Each category* has a series of questions
- Examples of high, medium, and low risk

Impact & Probability

- Determines the impact to the study if the risk becomes an issue
- Determines the probability of the risk occurring

Output

- Provides direction on where the most attention is needed for monitoring and mitigation
- Determines the overall risk level (high, medium, or low) for monitoring activities

Program Level RACT

Protocol Level RACT

Categories

- Safety
- Endpoints
- IP
- Technology
- Operational Experience

- Study phase
- Subject population
- Endpoints
- Technology
- Data collection & CRF source
- Study medication/IP
- Blinding
- Clinical supply chain
- Protocol complexity
- Operational complexity
- Geography

RBM STRATEGY CONSIDERATIONS: REAL-TIME DATA REVIEW

From: support@clinicalink.com <support@clinicalink.com>
Sent: Tuesday, January 22, 2019 6:00 AM
To: Smith, Sue <sue.smith@hospital.com>
Subject: Engage Non-compliance- Action Required

Hello Sue,

The following participants in the Engage Demo study have not had **Daily Asthma Symptom Diary** data captured for **two consecutive days** since 21 January at 5:00 AM:

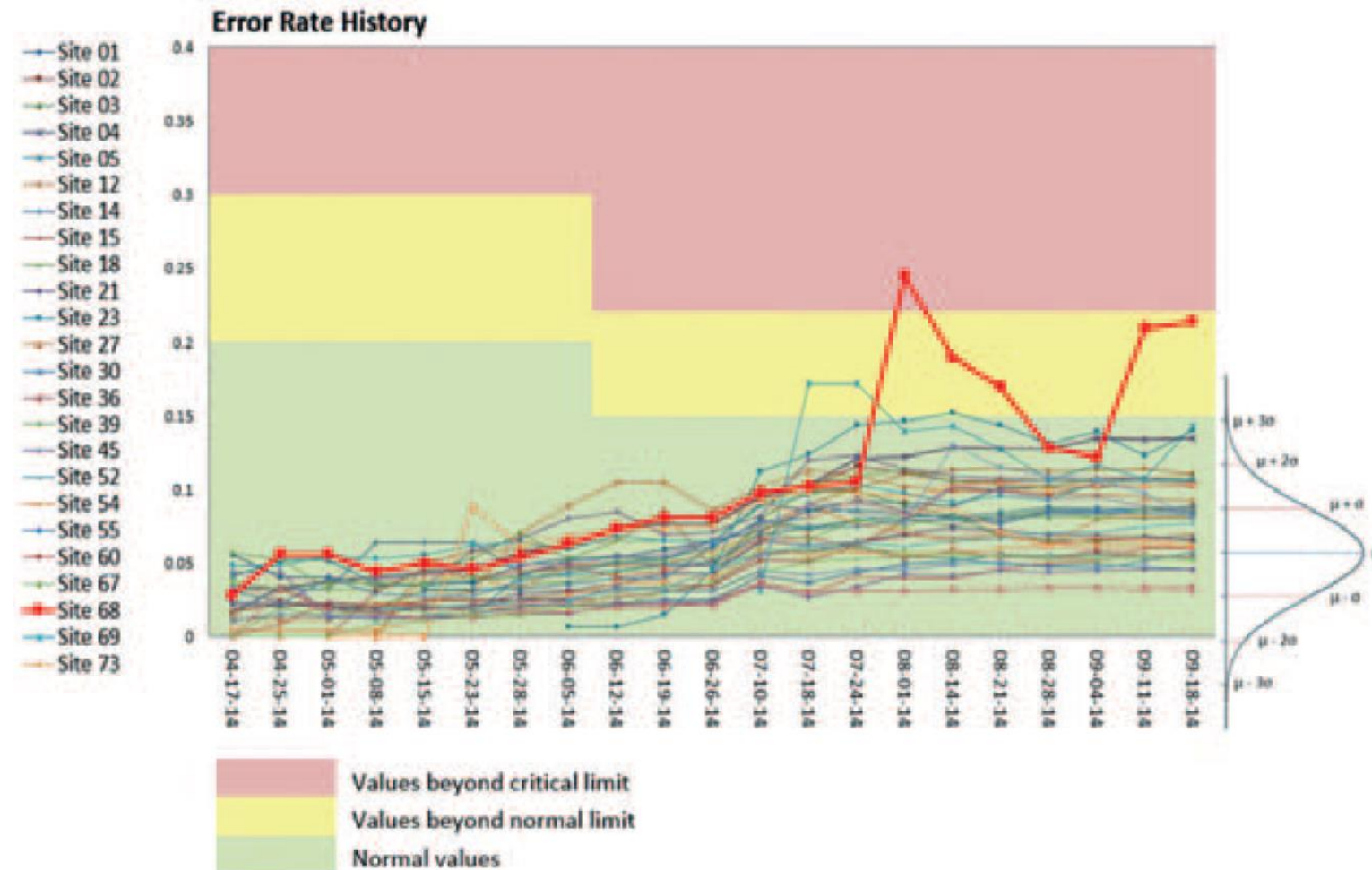
- 001-109

The following participants in the Engage Demo study have submitted a new **Asthma Event Diary** since 21 January at 5:00 AM:

- 001-108

Please follow up with these participants as necessary.
Regards,
Your Clinical Ink Engage Team

RBM STRATEGY CONSIDERATIONS: REPORTS/ANALYTICS



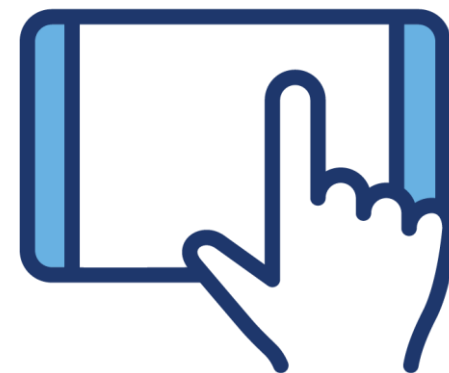
RBM STRATEGY CONSIDERATIONS: PARTNERSHIPS



STATISTICS



CLINICAL



VENDORS

AREAS OF DISCUSSION

- RBM strategy considerations
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INFORMAL SURVEY OF DM LEADERS

Are your organizations using a risk-based approach to data and clinical review on a regular basis?

INFORMAL SURVEY OF DM LEADERS

Are your organizations using a risk-based approach to data and clinical review on a regular basis?

Top 3 Pharma



Getting started

Fully adopted

INFORMAL SURVEY OF DM LEADERS

Are your organizations using a risk-based approach to data and clinical review on a regular basis?

Top 3 Pharma



Medium Sized Pharma



Getting started

Fully adopted

INFORMAL SURVEY OF DM LEADERS

Are your organizations using a risk-based approach to data and clinical review on a regular basis?

Top 3 Pharma



Small, Specialty CRO



RACT

Medium Sized Pharma



Getting started

Fully adopted

INFORMAL SURVEY OF DM LEADERS

Are your organizations using a risk-based approach to data and clinical review on a regular basis?

Top 3 Pharma



Small, Specialty CRO



RACT

Medium Sized Pharma



RACT

Getting started

Fully adopted

INFORMAL SURVEY OF DM LEADERS

What about the review of audit trail data?

Top 3 Pharma



Small, Specialty CRO



RACT

Medium Sized Pharma



RACT

Getting started

Fully adopted

INFORMAL SURVEY OF DM LEADERS

Why have your organizations been slow to adopt?

Top 3 Pharma



Small, Specialty CRO



RACT

Medium Sized Pharma



RACT

Getting started

Fully adopted

FDA



“The advent of precision medicine is challenging the entire medical research ecosystem to develop more efficient approaches to testing and developing diagnostics and therapeutics... including frameworks that are more carefully suited to the kinds of precision technologies that underpin new treatments.”

- Scott Gottlieb
23rd Commissioner of the FDA

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TOOLS AND METHODS TO DRIVE RBM: DIRECT DATA CAPTURE



Central and remote monitoring



Travel costs



Lag between patient visit
and monitoring data

TOOLS AND METHODS TO DRIVE RBM: TARGETED SDV/SDR



TOOLS AND METHODS TO DRIVE RBM: AUDIO, VIDEO, PHOTOGRAPHY



TOOLS AND METHODS TO DRIVE RBM TARGETED SDV/SDR REVIEW

Manage Sites - All ▼

Site		Subjects		Visit Forms				Queries		
Site ^	Status	All	Unsigned	All	Incomplete	Complete	Required	All	Open	Responded
	All ▼									
001	Active	156	155	336	268	68	6	1139	1130	3

Showing 1 to 1 of 1 entries

TOOLS AND METHODS TO DRIVE RBM

< Subject: 0976 >

Print

< Form A >

Page 1

Screening Number: 333333
Week 3 Visit
Week 3 Visit Form

Visit Information Transcribed

Baseline Visit date:

Date of visit: 22 / May / 2019 22

☐ Yes ☒ No Is there a new version of the Informed Consent that needs to be signed?

Adverse Event and Concomitant Medication Review Transcribed

☐ Yes ☒ No Are there any changes in health to be reported?

☐ Yes ☒ No Are there any changes in concomitant medications to be reported?

☐ Yes ☒ No Have there been any dose changes in concomitant medications?

Reason for concomitant medication dose adjustment:

Prohibited Medication

Query History Validations **Review** Compare Audio

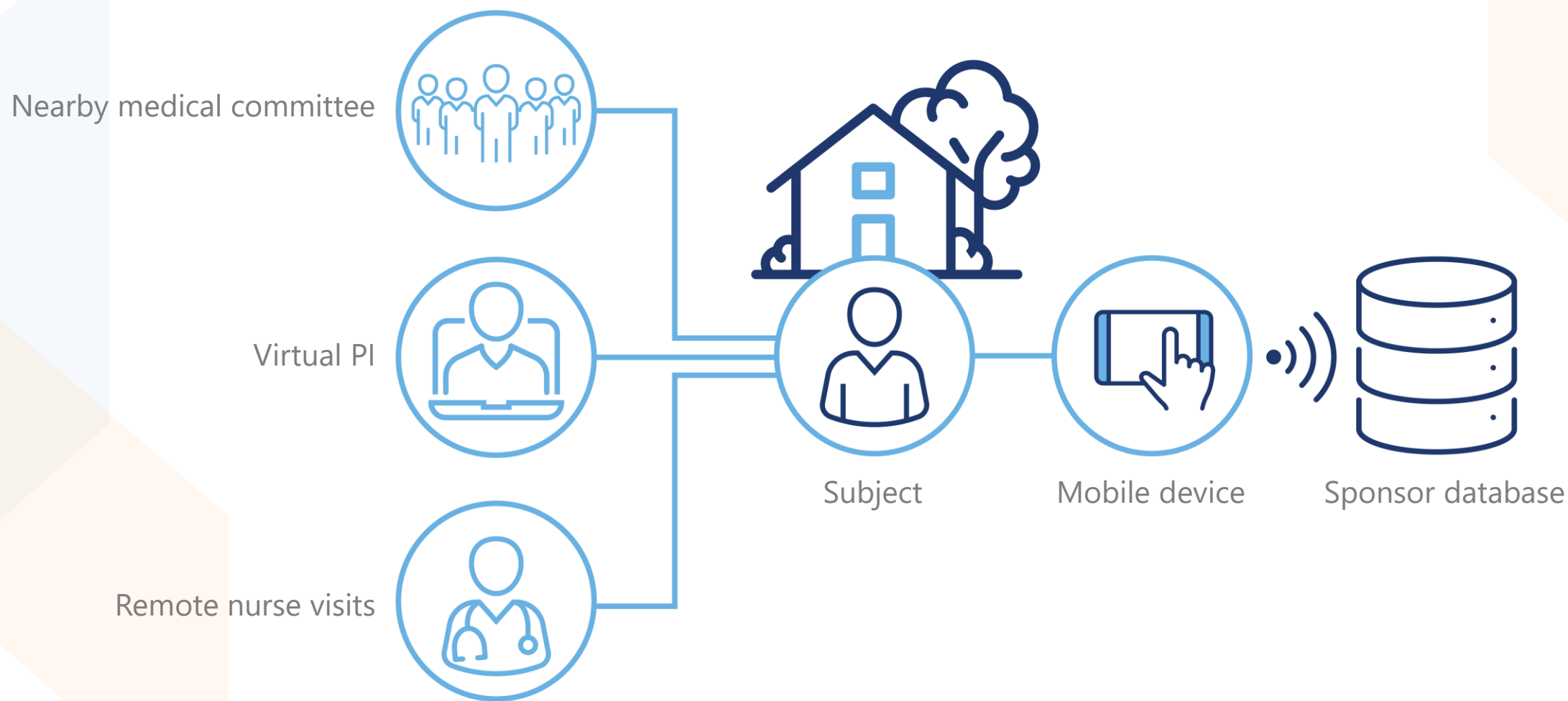
Previous Reviews

Monitor Review - Current

Review Type	Status	Reviewed By	Review Date	
Monitor	Reviewed	Matt Johnson	13-Aug-2019 10:44:03 -04:00	View ✓

Field	Reviewed By	Review Date
Date of Visit	Matt Johnson	13-Aug-2019 10:44:03 -04:00
Changes in Health	Matt Johnson	13-Aug-2019 10:44:03 -04:00

TOOLS AND METHODS TO DRIVE RBM: VIRTUAL/SITE LESS TRIALS



TOOLS AND METHODS TO DRIVE RBM: HYBRID STUDIES



RECENT WHITE PAPER

The Evolution of Clinical Data Management to Clinical Data Science

A Reflection Paper on the impact of the Clinical Research industry trends on Clinical Data Management

4 June 2019



Society for Clinical Data Management

© Society for Clinical Data Management

Our Vision

"Leading innovative clinical data science to advance global health research and development"

Our Mission

"Connect and inspire professionals managing global health data with global education, certification and advocacy"

The Evolution of Clinical Data Management to Clinical Data Science:
A Reflection Paper on the Impact of the Clinical Research Industry Trends on Clinical Data Management



SUMMARY

- Partnership across all of the project/program teams is critical
 - DM is poised to be the center of enabling an effective RBM strategy
- Tools, Technologies, and Styles
 - Must look at how the data are collected (both from a source standpoint and method chosen (traditional sites, virtual study, etc.)
 - What does that mean to the collective RBM approach and the techniques provided based on the tools/style selected?
 - Consider the cost reductions that can be achieved through reduced on-site monitoring and immediate access to data to identify data issues/problems