

Risk Based Monitoring in eCOA

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eCOAforum

Introduction



Pre-conference Survey Highlights:

Experienced & current Risks

- Missing assessments
- Reporting Compliance
- Site Entry and Response Delays
- Protocol Compliance
- Data integrity
- Deanonimizing data / patient id disclosure
- Data Security.
- 21 Part 11 Compliance

Issues that existing monitoring failed to identify

- “Trends”
- “Signals”
- “Performance”
- “Incorrect use”

Can RBM help ?



Primarily Prevention



Agenda



1) Introduction	2) eCOA Risks	3) Workshop	4) Recommendations & Summary
10min	25 min	40 min	55 min
<ul style="list-style-type: none">➤ RBM in 1 slide,➤ RBM and eCOA,➤ eCOA for RBM	<ul style="list-style-type: none">➤ Common Risks➤ 1 step more➤ Methodology	<ul style="list-style-type: none">➤ Risk, Data, Visuals	<ul style="list-style-type: none">➤ Data and Tools➤ Q&Discussion➤ Cases from survey(?)



Introduction

eCOA and RBM



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RBM in 1 slide



Why?

We have a problem



Cost ↑
Quality ↓
Throughput ↓
Timelines ↑
Patient safety ?
Compliance ?
Complexity ↑
Shortcuts, tweak, fraud ?



What?

Proactively Manage Risk

Regulatory Focus

Patient
Safety

Data
Integrity

Trial
Conduct

Trial
Results

Company Focus

Quality By Design
Prevent issues by:
Design, Set-up,
Preparations etc




How?

Structured, analytical

1  Focus on *Key Risks*

2  Data driven,
structured,
analytical

3  Take action
And Document

RBM in eCOA – A Case?



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Any Problems ?

Any Risks ?

RBM in eCOA – Key Risks?




How?



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eCOA Features

- Data Source → No going back.
- High data volume & frequency → 1 problem generates a massive number of issues.
- Behaviour dependent → Impact on protocol and assumption compliance.
- (Often) Endpoint → Critical impact on trial results
- Challenging – Many and diverse data collectors.
- Complex → Difficult task for sites and patients.
- Expensive

RBM in eCOA – Data suitable? ✓



How?

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eCOA Specific Data Features



Pros

- Direct → Immediate indicator
- Sensitive → Good indicator
- High volume/frequency → Strong indicator
- Rich in meta-data and behavioural information → Sharp indicator



Cons

- Individual → Can be difficult to use for corrective actions.
- Event driven → What is expected ?

RBM - Case in eCOA ?



Why



What?



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Focus on *Key* Risks

2



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Take action
And Document



eCOA Risks

eCOA and RBM





eCOA Risks – 1st Step

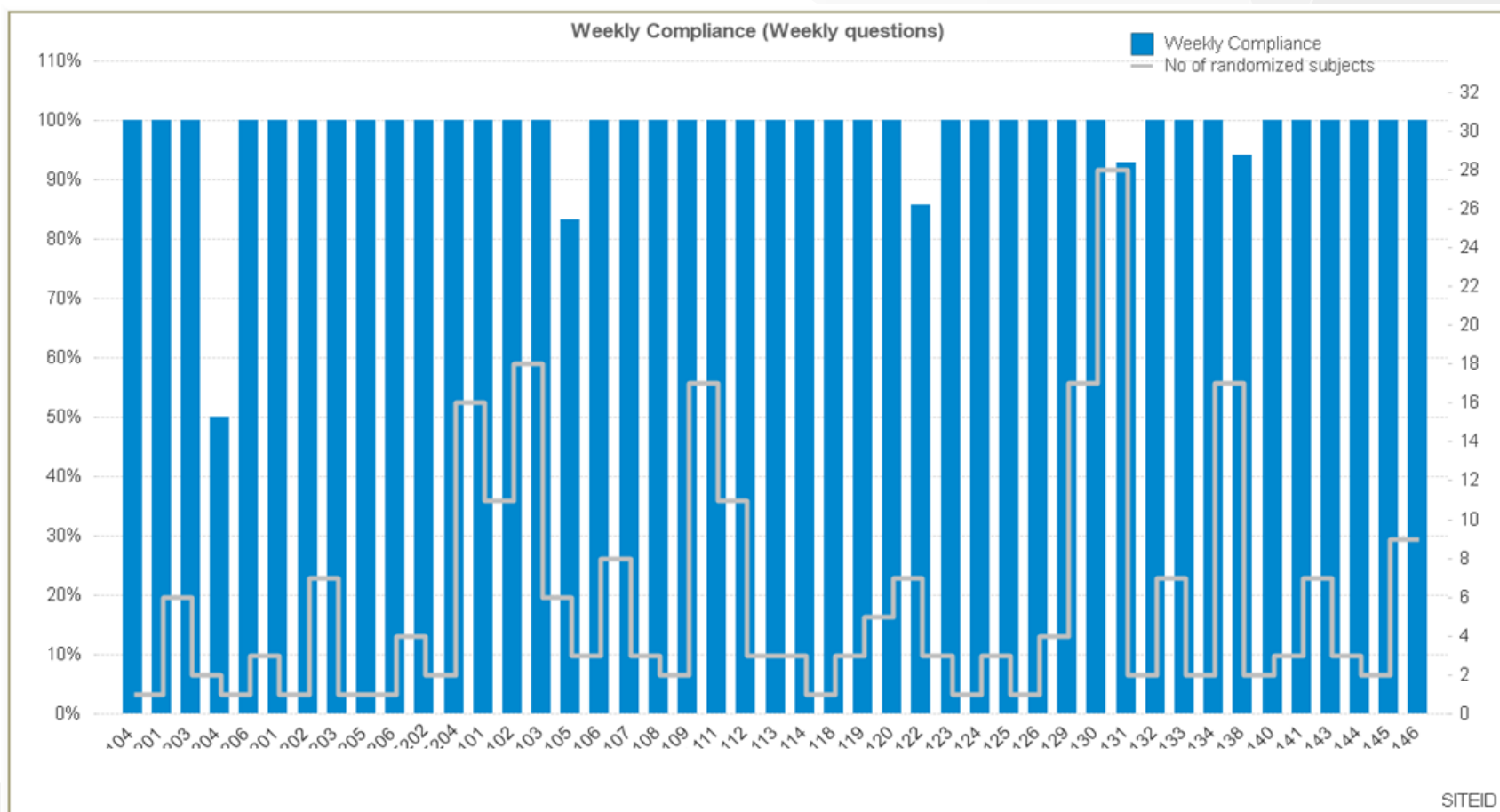


Risk	Example
Compliance	Daily question not answered
Patient behaviour not as assumed	Patient entering data in retrospect
Misunderstanding / Incorrect use	Patient enter rescue medication as IMP
Incomplete Data	Time of IMP missing
Inconsistent Data	Entered data inconsistent with device data
Technical Issues	Timestamps, device-link, broken devices
Influenced Data	Patient influenced to “tweak” data
Invented Data	Invented patients, invented data

eCOA Risks – 1st step



Example – Compliance by site





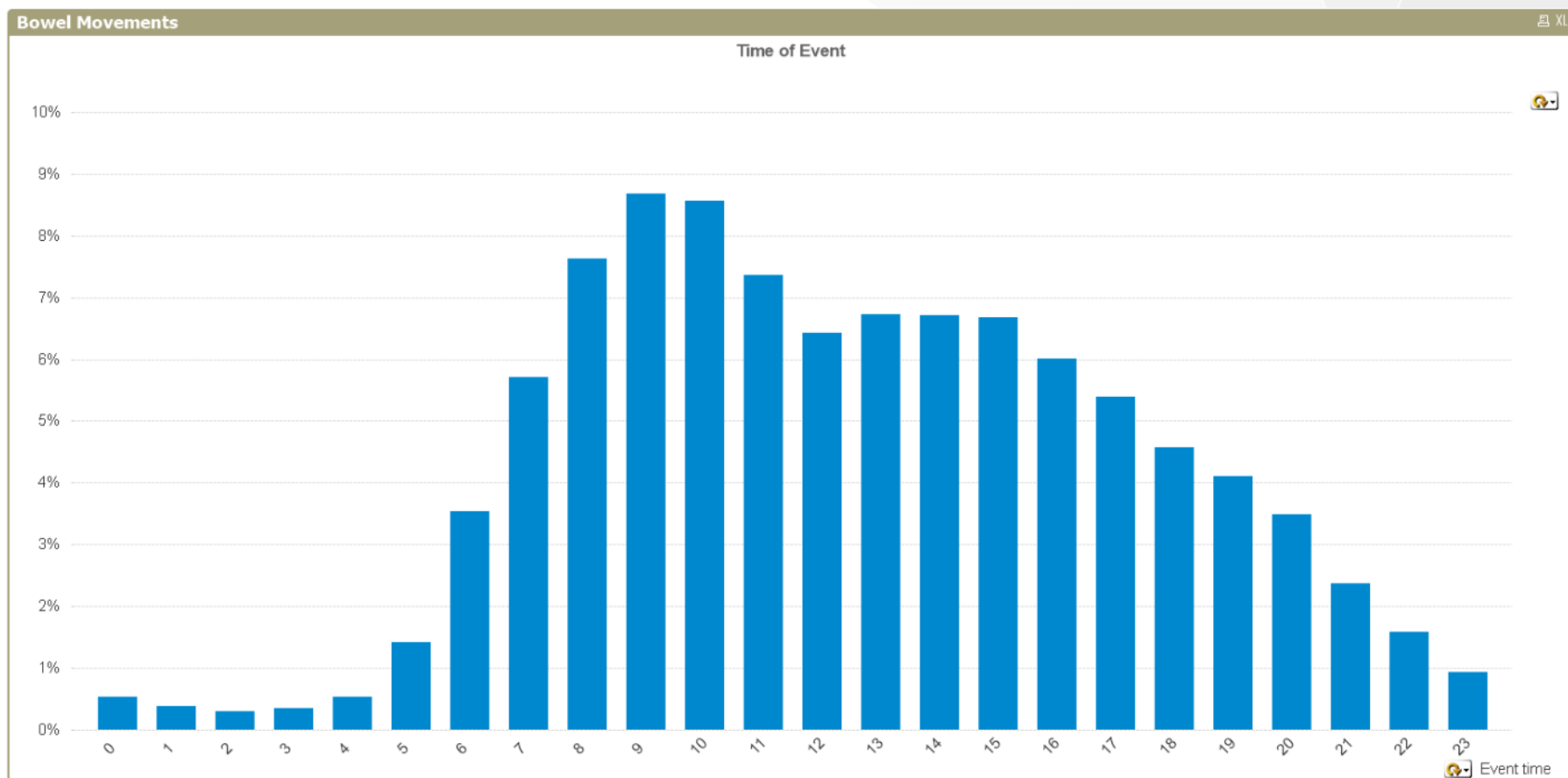
eCOA Risks – One more step

Example – Compliance by study visit schedule



eCOA Risks – 1st step

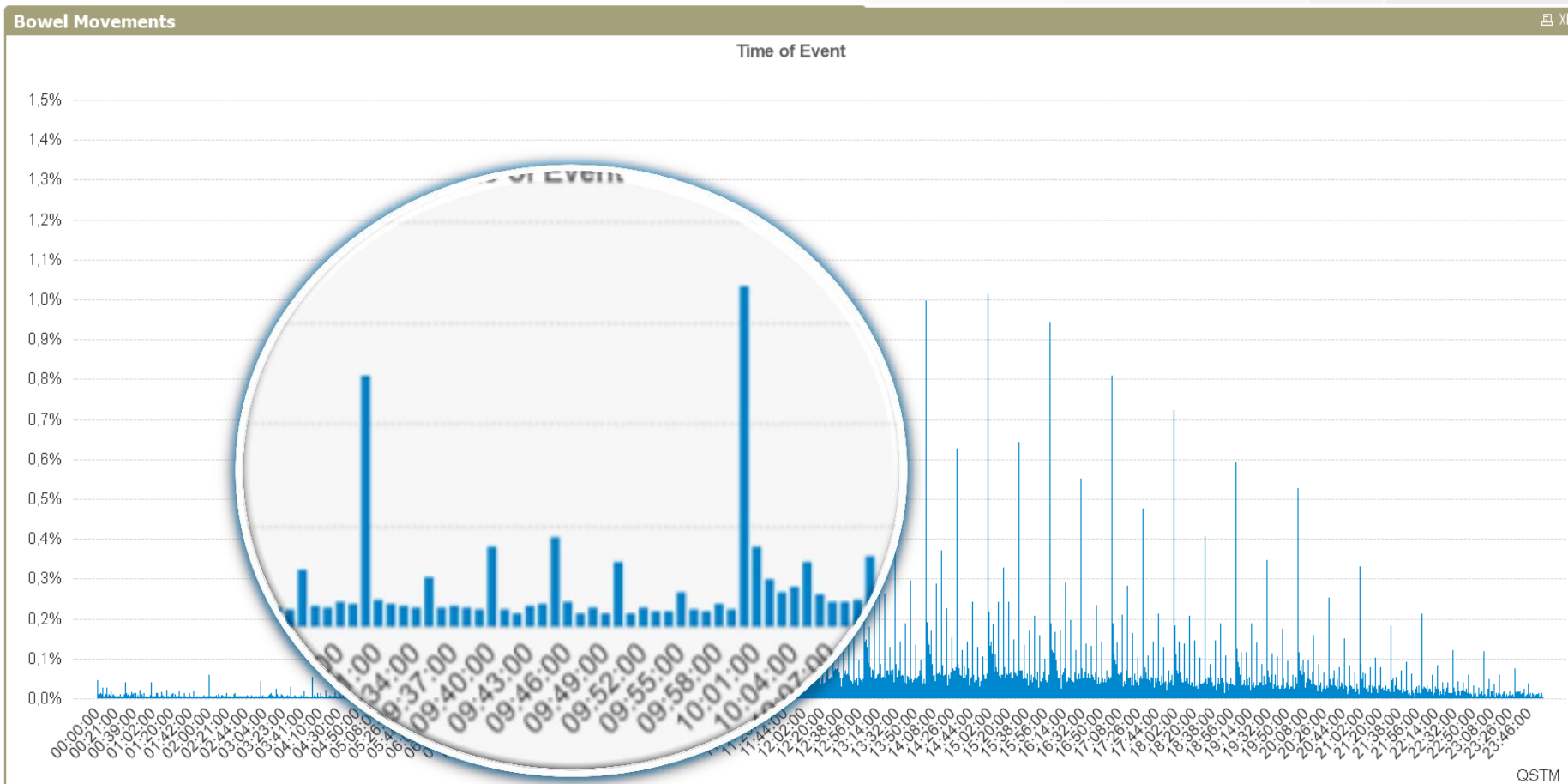
Example – Patient reported time by hour





eCOA Risks – One more step

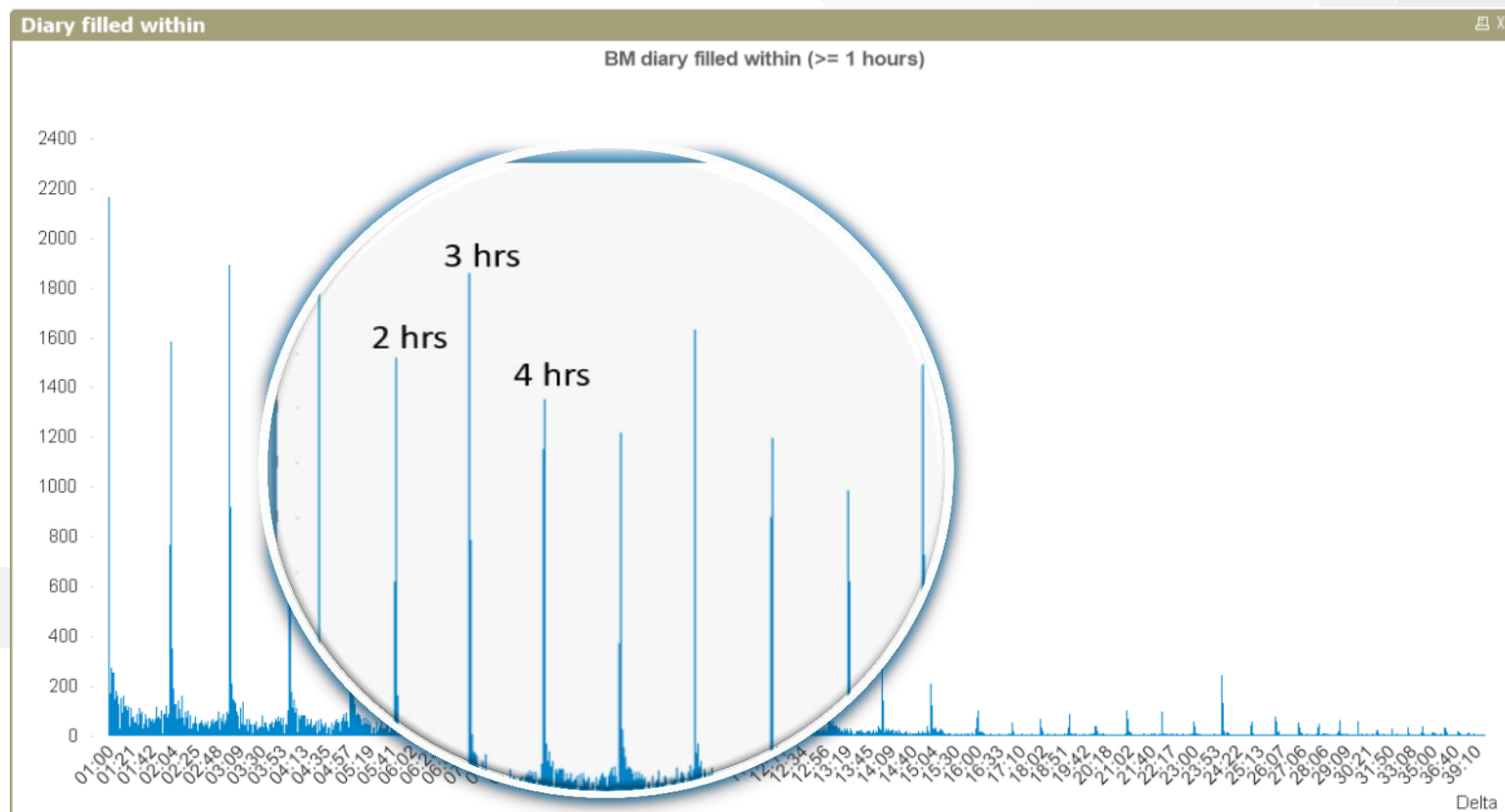
Example – Patient reported time by minute





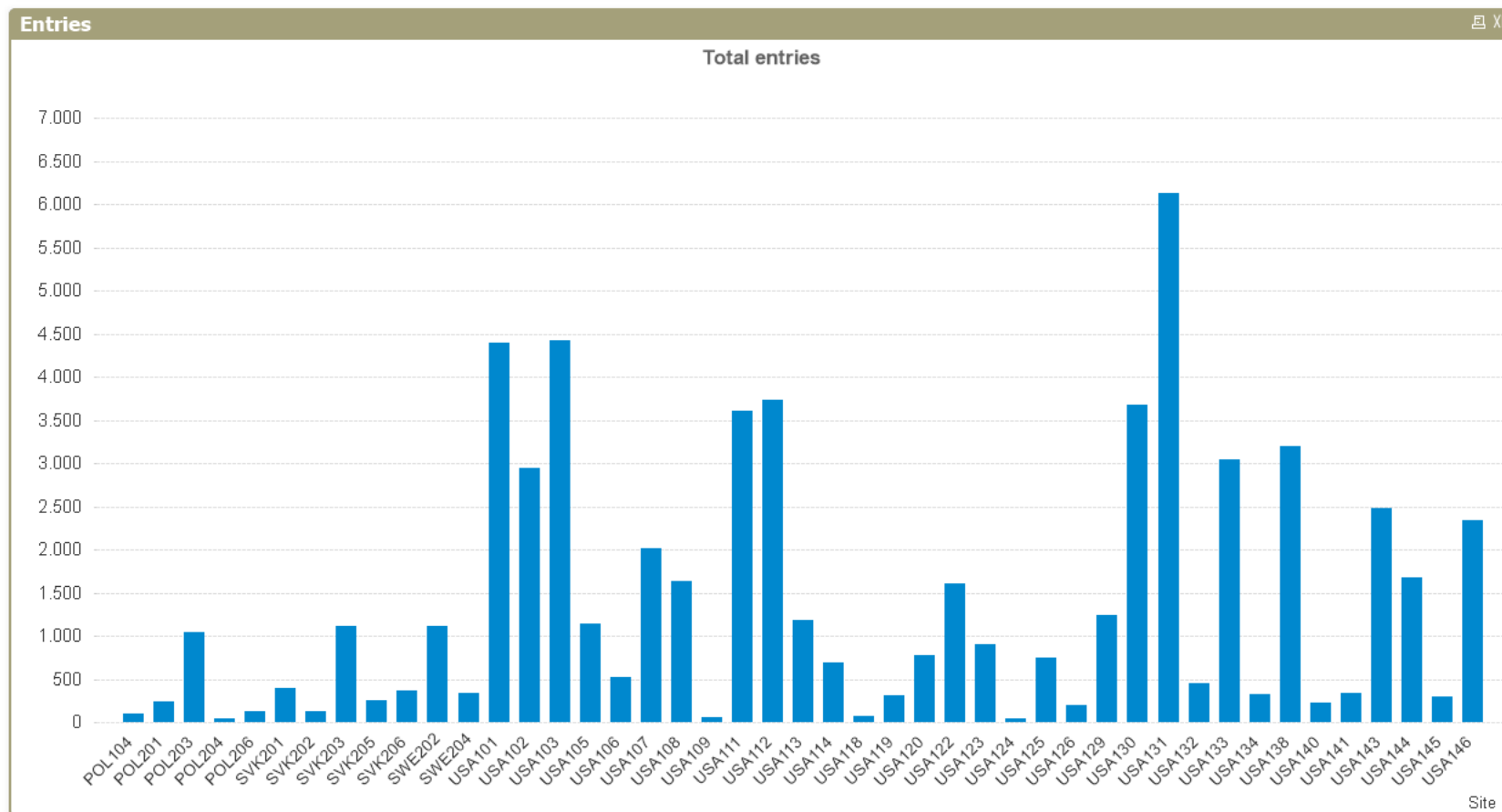
eCOA Risks – One more step

Example – Patient reported time vs entry time



eCOA Risks – 1st step

Example – Diary entries

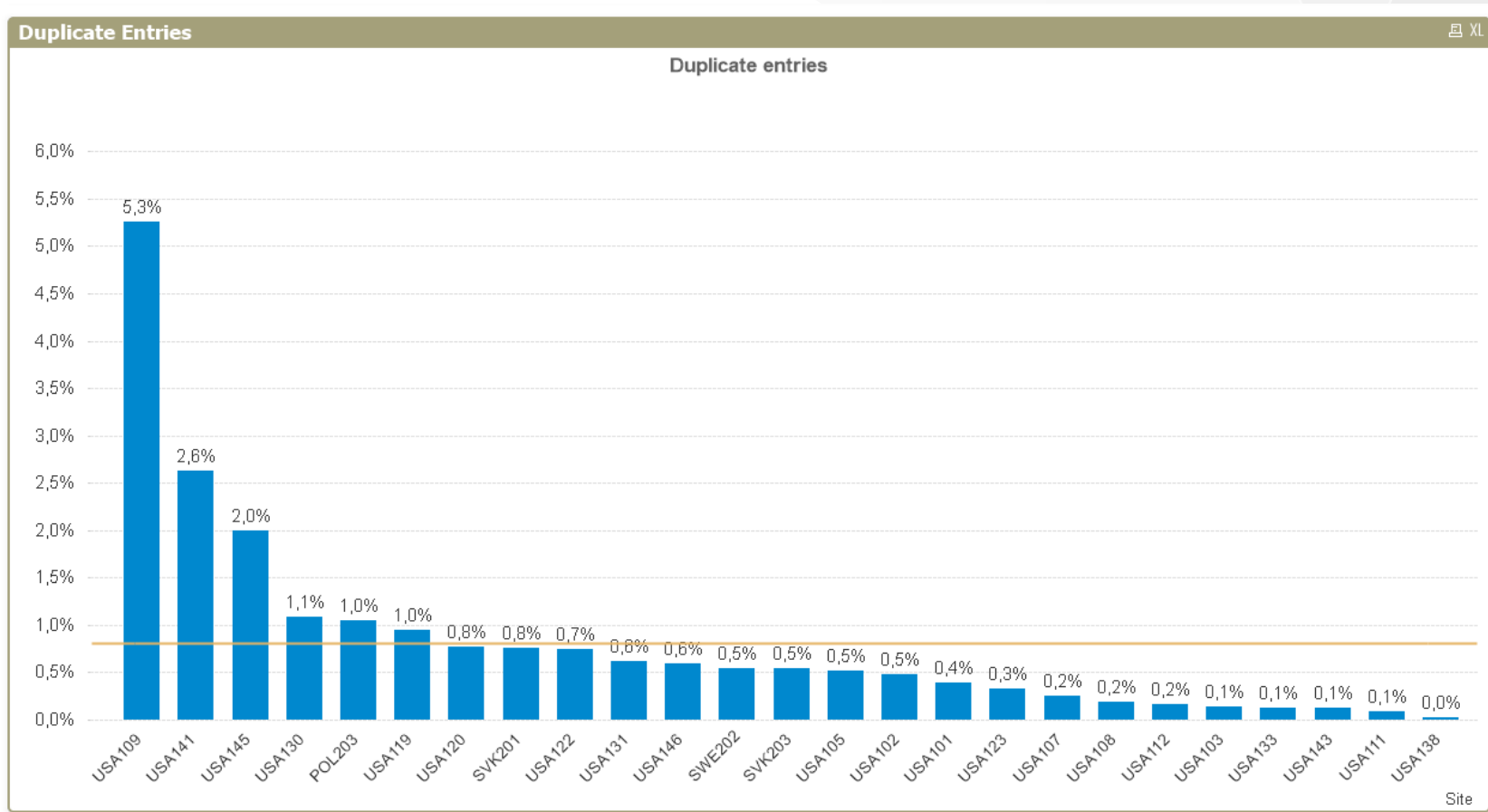




eCOA Risks – One more step



Example – Duplicate entries





eCOA RBM Methodology

eCOA and RBM



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eCOA Risks – 1st Level Challenges



Risk	KRI	Site 1	Site 2	Site 3	Site 4	Site 5	Site 6
Compliance with daily question							
Patient entering in retrospect							
Patient entering rescue med as IMP							
Patient not reporting meal							
Timepoint not matching glucometer							
Technical Issues – Device failure							
Influenced Data ?							
Compliance with dose reporting							
Device phase not changed correctly							
Patient rounding important timepoints							
Incomplete Data in another way							
Inconsistent Data with 3 rd source							
Technical Issues of another kind							
Influenced Data as well							
Invented Data Other aspect							
Compliance with weekly questions							

RBM - Methodology – One more step

Structured, analytical

1



focus Focus on ! Risks

2



Data driven,
structured,
analytical

3



Take action
And Document

One more step

1 Actual Risk (Consequence!)

2 Right data to identify issue

3 Efficient visual / analysis

<Identify and Understand>

4 Action with impact



Work-shop – Table Relay

eCOA and RBM




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RBM Workshop – One more step

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2  Data driven,
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One more step

1 Actual Risk (Consequence!)

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<Identify and Understand>

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Table Relay




	 Risk	 Data	 Visual/Analysis
Table1	Risk 1	Data for Risk n	...
Table2	Risk 2	Data for Risk 1	Visual for Risk n
	Risk 3	Dara for Risk 2	Visual for Risk 1
	Visual for Risk 2
			...
	Risk n



Table Risk Relay

Preparations: Find (at your table):

a) Someone with legible handwriting, b) A messenger, c) Pen and the form (Yes, apologies, pen & paper)

1) 5 minutes to define a ! Risk

- Shift - : Table 1 → Table 2, Table 2 → Table 3 etc

2) 5 minutes to suggest data for monitoring the received risk

- Shift - : Table 1 → Table 2, Table 2 → Table 3 etc (Hand over Risk AND Data Notes)

3) 5 minutes to suggest a visual (draw?) to monitor the received risk, using the received data.

- Collect all the notes and give them to me, I will type it up and share with everyone.

Listen & Discuss



RBM for eCOA – Data & Tools



Data Considerations

Clinical data (Vs Assumptions, Realistic, Completeness)

Issue-data (Protocol Deviations, DCFs)

Metadata (Timestamps, log-ons, variation)

Data relations (Duration, sequence, time-differences, distribution)



Tool and Analytics Recommendations

- Visual** – To show the trend, pattern, correlation: “What is going on”
- Interactive** – To allow for efficient investigation of a signal: “Why?”
- Agile** – To look at the right thing in each study: “Sharp on the risks”
- Statistics** – Efficient in detecting irregularities and abnormal patterns
- KRIs** – Are good; But limited in trend, root cause analysis, and risk to aggregate out signals.
- Listings** – Are sometimes needed; But are typically displaying consequences, not root cause. For addressing , not to understand and act.

RBM for eCOA - Summary

We do have problems



There is a case for RBM in eCOA



There are risks

focus

..with a consequence



The data is there..

Mind the methodology

1



Be sharp in identifying risks – 1 step more

2



Use the right data...

...and efficient visuals/analytics

3

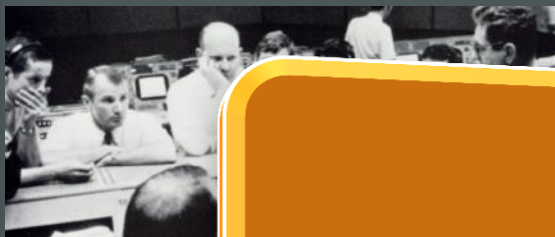


Identify the actual issue to take the appropriate action.
And Document

RBM for eCOA - Summary



We do have problems



Mind the methodology

1

There is identifying risks – 1 step more

But remember:

First

Prevent issues by:

Design, Set-up, Preparations etc

Then

RBM

There is a



focus



The data is there..

Take the

Thank You!

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