Most Essential RbM Pitfalls and a Way to Fix Them

Artem Andrianov, PhD, MBA
CEO
Cyntegrity Germany GmbH

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Duality of RBM definition: EMA vs FDA

RBM - is an important part of a preventive clinical trial management.

RBM - is the adequate mix of strategies including centralized and on-site monitoring practices

„Both show the target, but do not describe the way“

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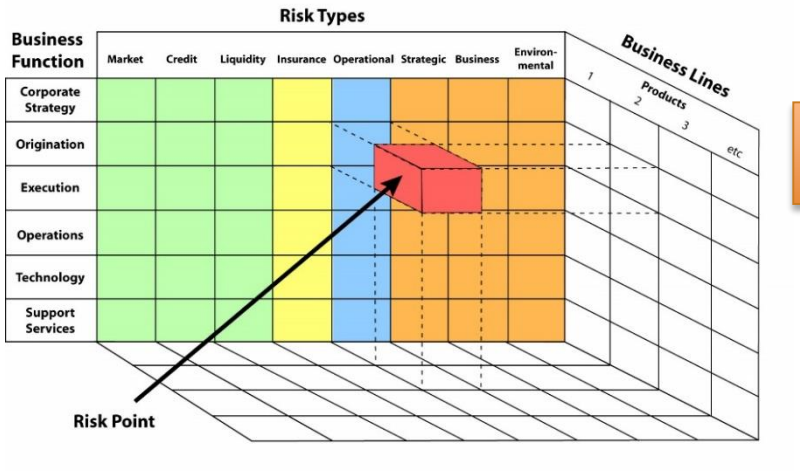
Can RbM influence the data quality and patient safety inversely?

Pitfall 1. SDV is reduced without any other action

RBM systems should look into not making a monitoring visit redundant, but **optimize the time spend by a site monitor on-site.**

Site Risk Profile from Data analysis



Expectations

28%

2%

Reality

?

4%

On Site Visit SDV

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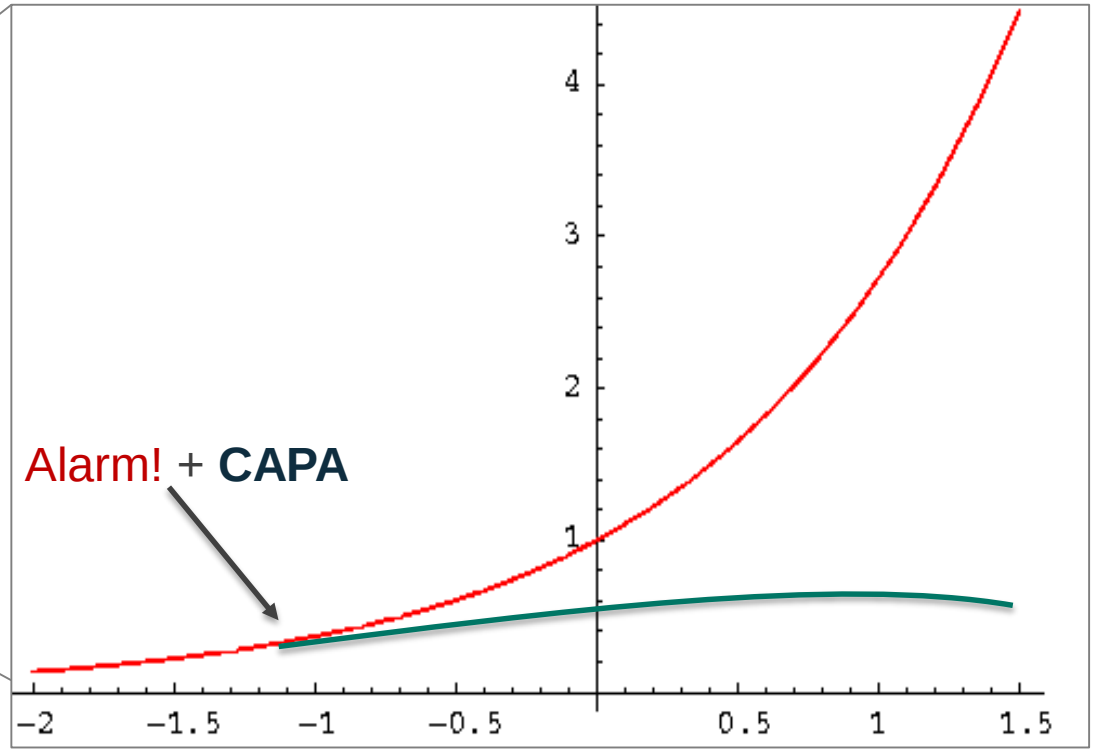
Pitfall 2. Risk evaluation is not objective

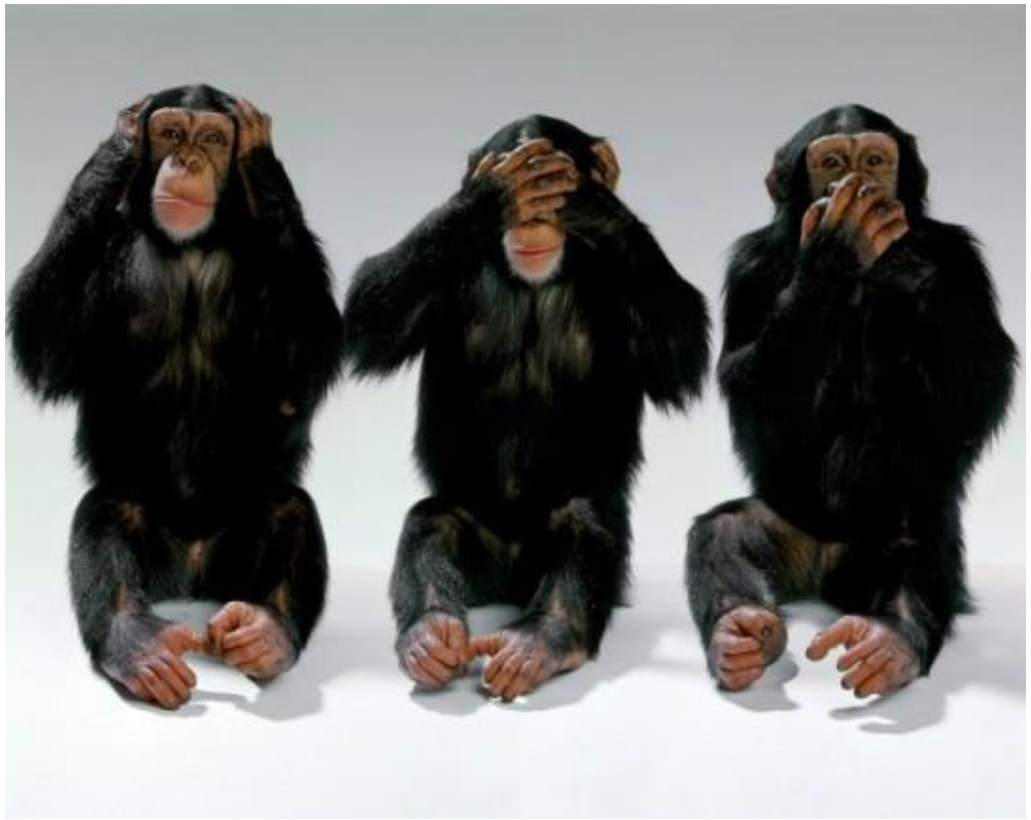


Key Risk Indicator is effective only if it is:

- **Reliable**
- **Pro-active** (so called “leading indicator”)

Pitfall 3. Risk evaluation is biased

Vs.



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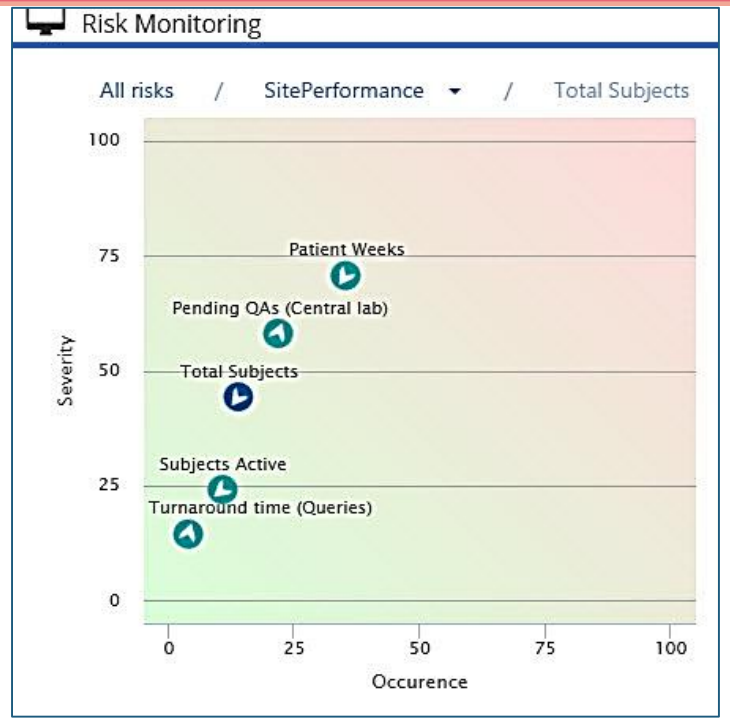
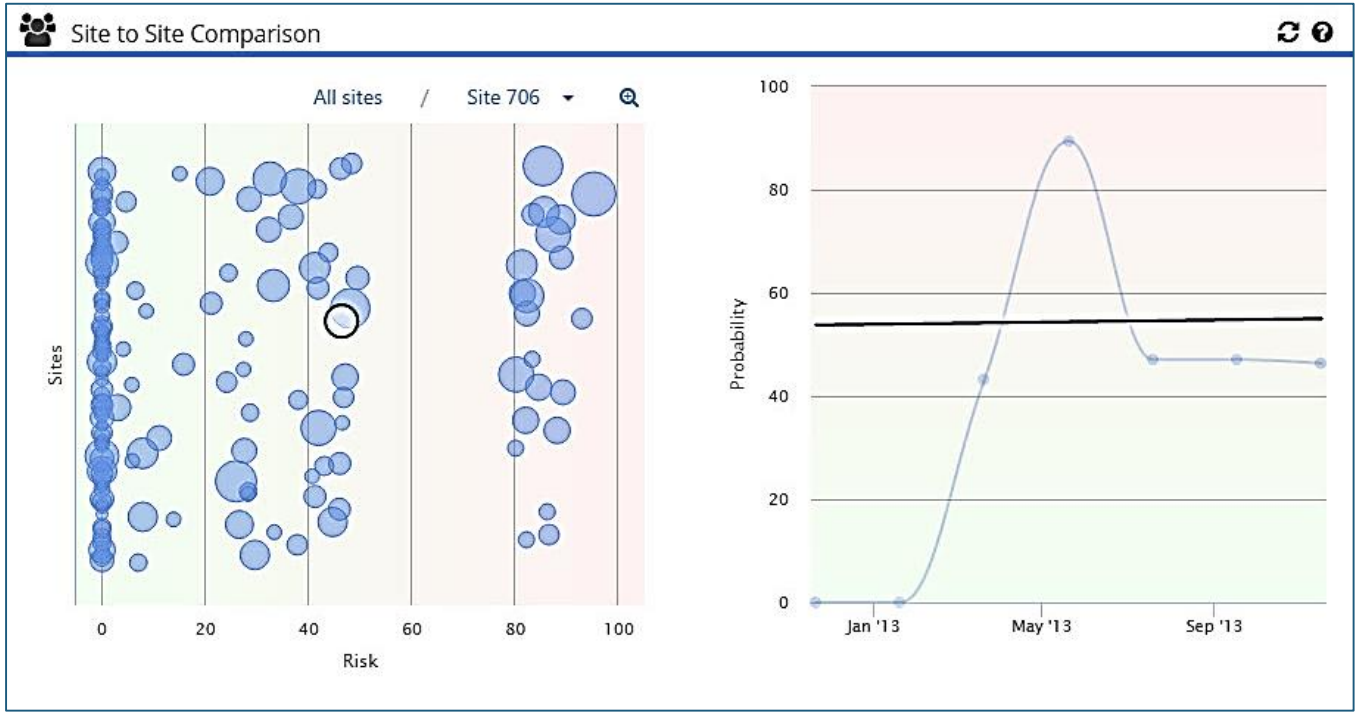
Pitfall 4. Risk evaluation becomes outdated





Source: Cyntegrity Internal

"Risks are like water, sometimes calm,
sometimes rough, but they flow, develop and change."

How to avoid?

Make risk evaluation on regular basis, monthly, weekly or even daily.

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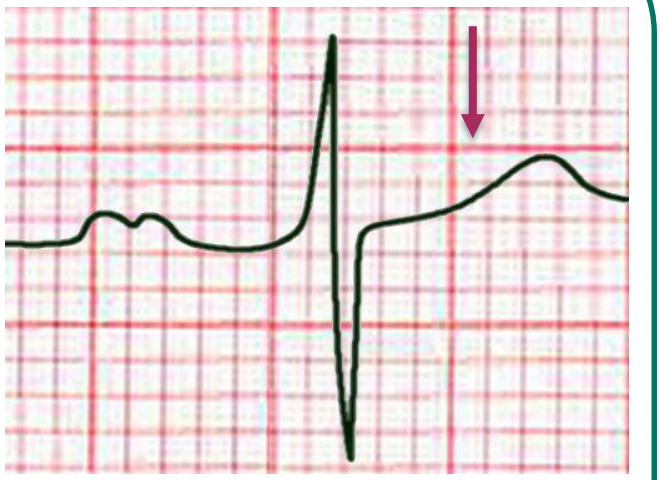
Pitfall 5. The late arrival of data



Signal

How to avoid?

- It is absolutely essential to motivate sites to send data as quickly as possible.
- The best practice: 5 to 9 day turn-around.

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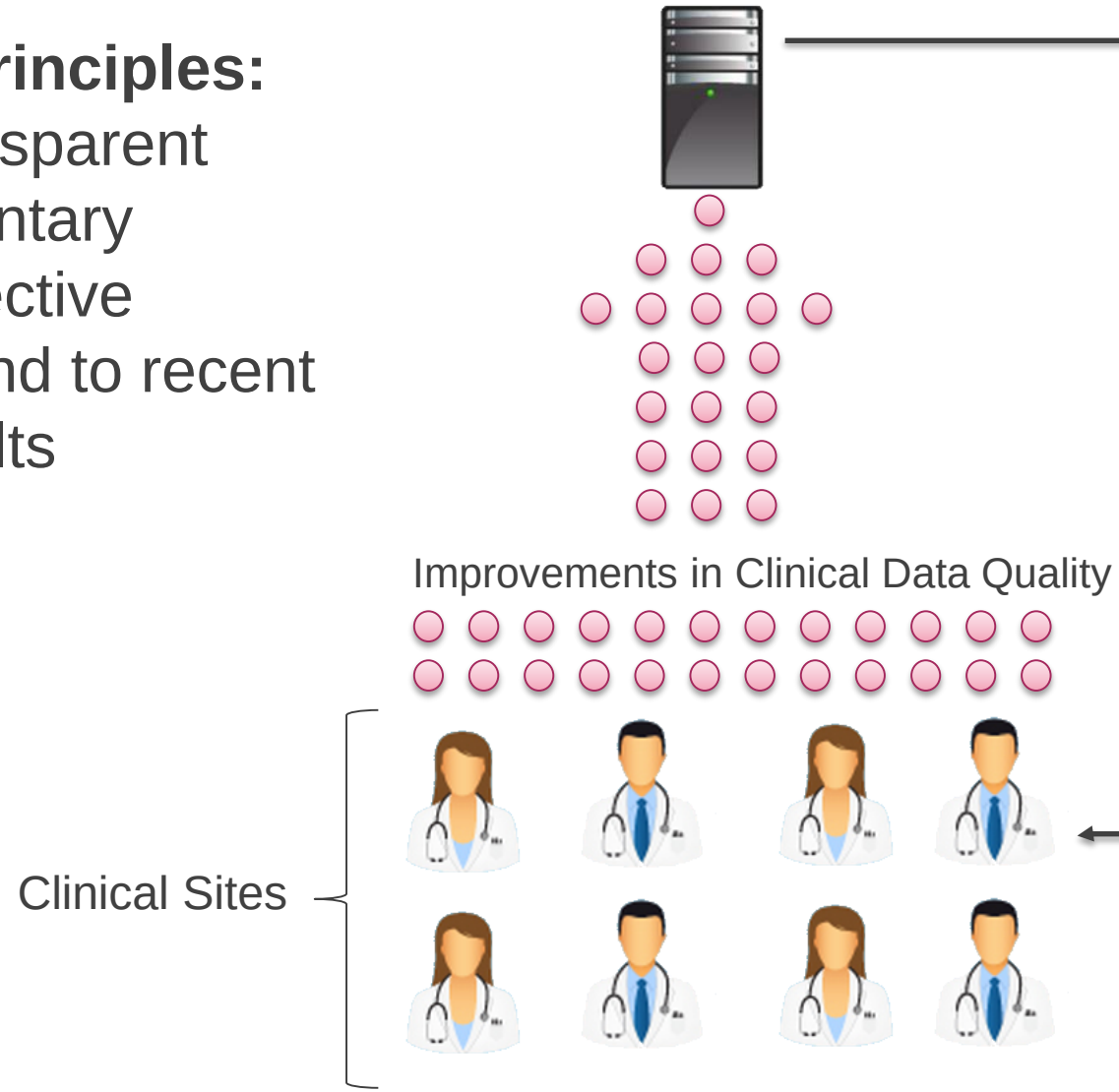
Pitfall 6. Sites ignore RbM and do not improve

Key Principles:

- ✓ Transparent
- ✓ Voluntary
- ✓ Objective
- ✓ Bound to recent results



Automatic Site RBM Report

- Development of Data Quality provided
- Key Risk Indicators Dynamics
- Major issues in the recent time
- Major Risk Assessment & Ranking

Main Advantages:

- Self-improvement
- “Observer” effect
- Reduction of Monitoring efforts

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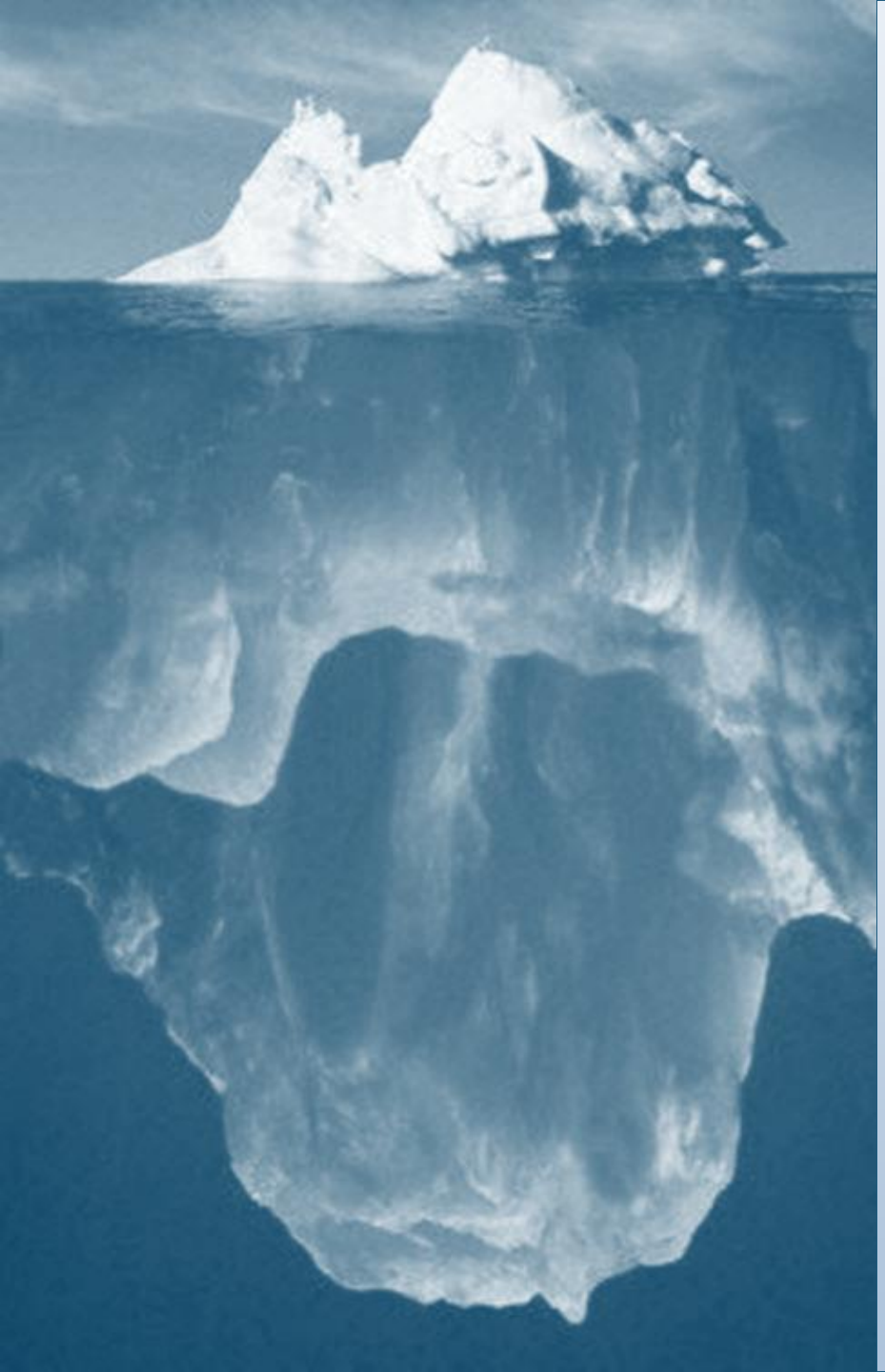


Pitfall 7. Monitoring team does not accept the new procedure?

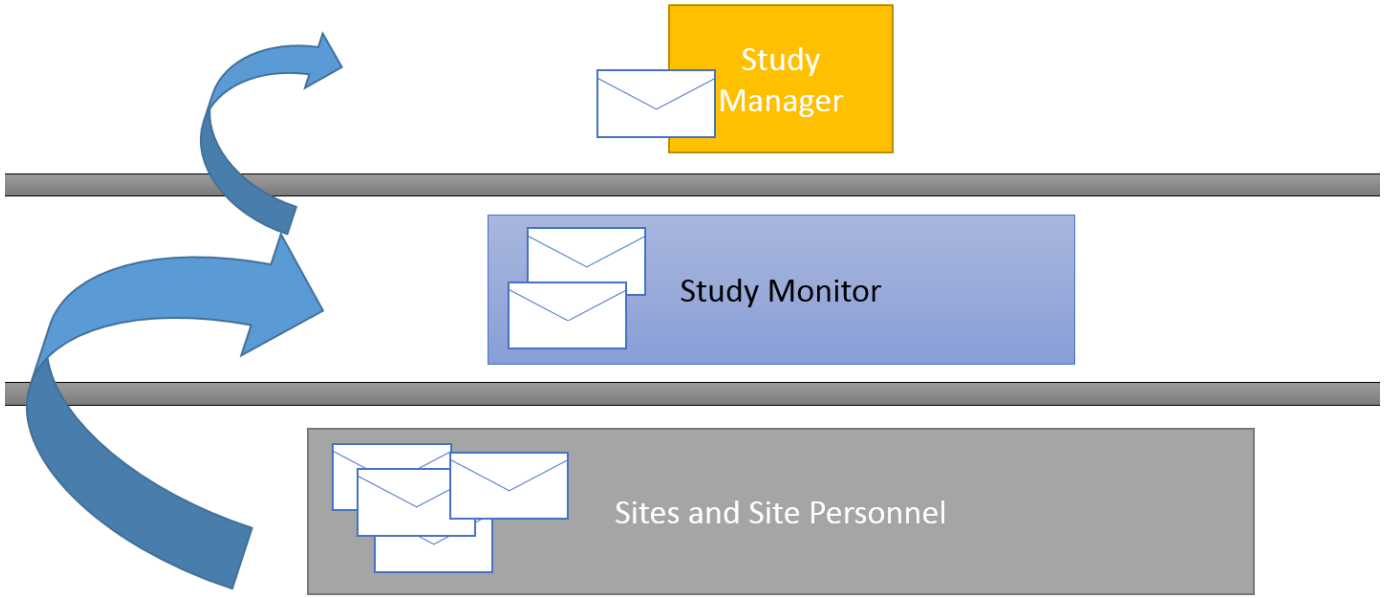
Dealing with Resistance

Education	Communication the desired switch to RBM
Participation	Involve CRAs in designing the change, offer a new position: Central monitor
Facilitation	Provide Skills Training and emotional support
Negotiation	Offer Incentives for study-management team and CRAs
Coercion	Threaten loss of job or promotion opportunities

Pitfall 8. The RbM IT system produces too many messages for monitoring team

FROM:

TO:



How to avoid?

- Apply certain prioritization and escalation logic.
- Generate a message only for group of events

Key “take-aways”

- Yes, RBM can influence the DQ and patient safety inversely.
- Technology plays a critical role in effective RBM. However, the **monitoring team** is more important.
- RBM is not a “formula” to configure and forget.
- Are we sure we are looking at all relevant risks within a trial?”
- Trial demands **well-trained monitors**. Even more now.

“Even if something appears as obvious, it is not true yet.”

Ask