

RM01: From Oversight to Insight –

Rethinking Risk-Based Quality Management

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Disclaimer

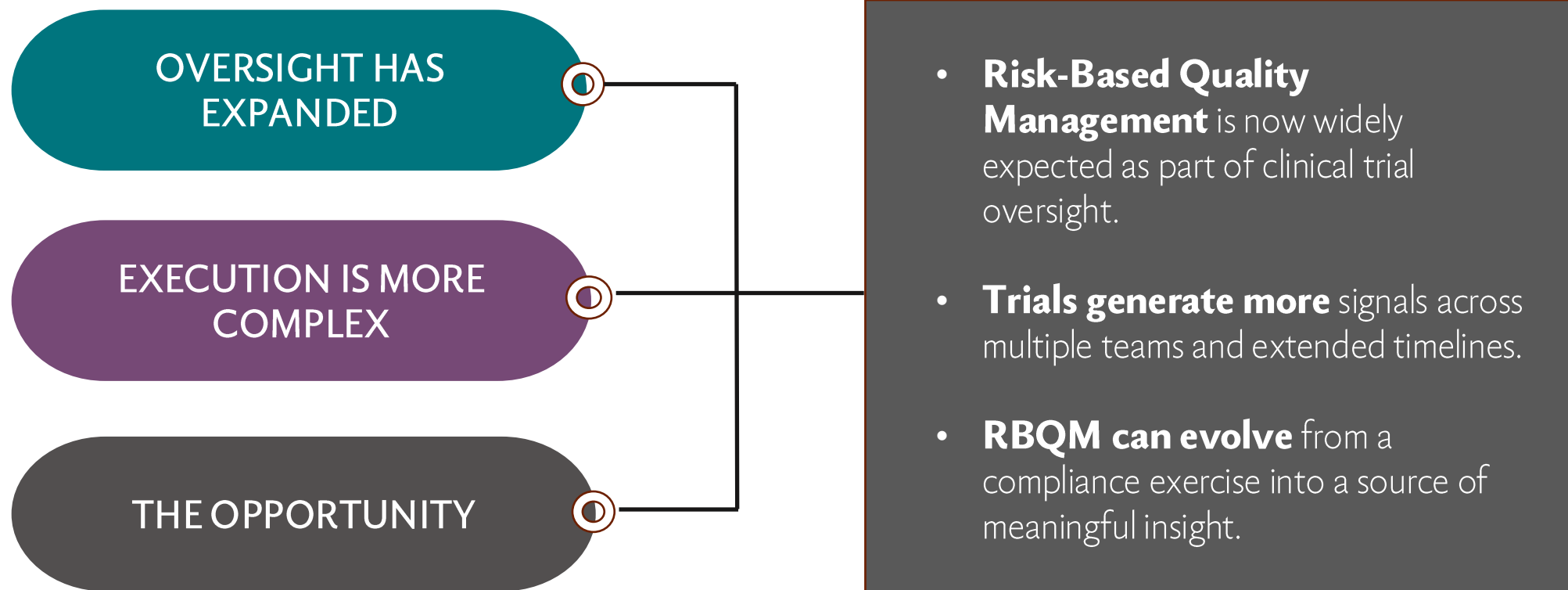
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WHY **RBQM** MATTERS NOW

As RBQM becomes standard practice, the complexity of trial execution continues to rise.



Where **RBQM** Breaks Down in practice

Execution realities can make it more challenging to see how signals connect.

A STRONG FRAMEWORK

- RBQM processes are well defined and widely implemented.

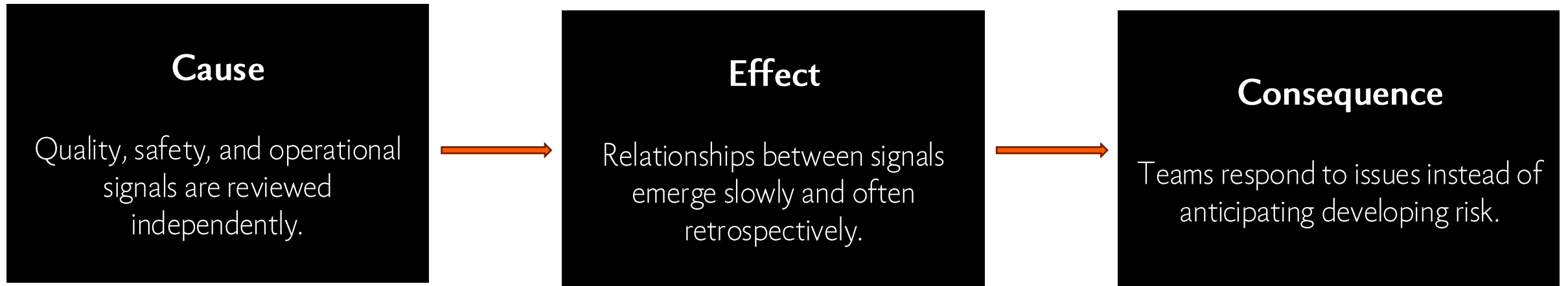
LIMITED VISIBILITY

- Signals are reviewed across separate views and review cycles.

THE RESULT

- Understanding risk often relies on experience rather than clarity.

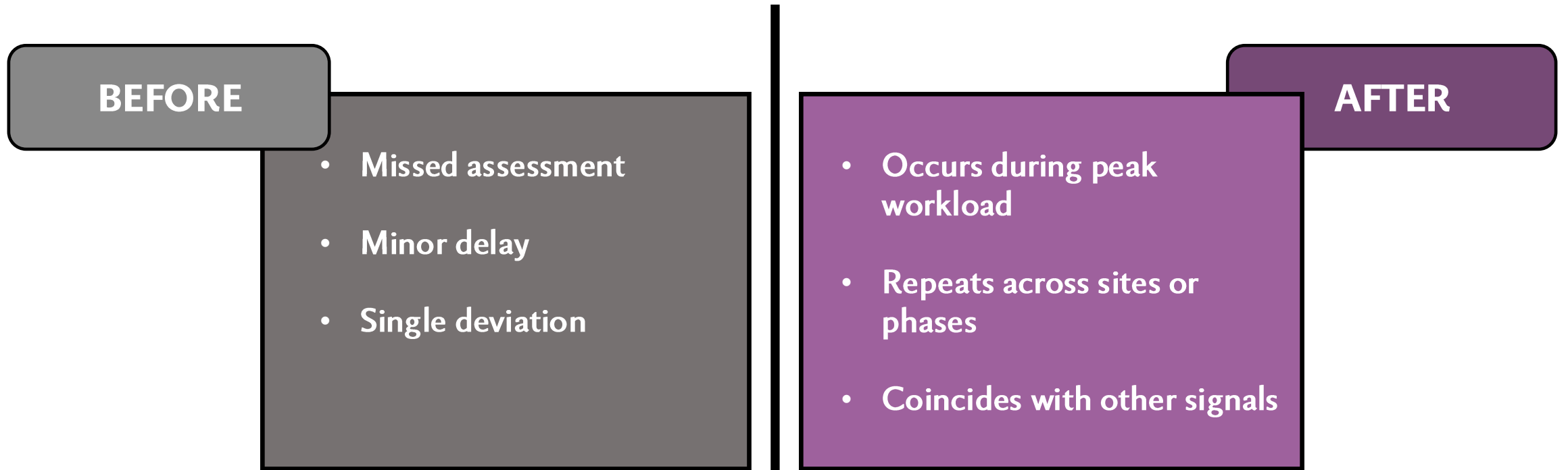
What Happens When Signals Stay Separate?



Understanding **Quality Signals** in Context

What's Observed	How Meaning Emerges	What Changes
Individual quality signals	Viewed together within the same trial activity or timeframe	Risk becomes clearer
Deviations, safety, operations	Interpreted in relation to workload and execution conditions	Patterns replace isolated findings
Trial activity over time	Reviewed as connected events	Earlier understanding develops

How **Context** Changes Interpretation

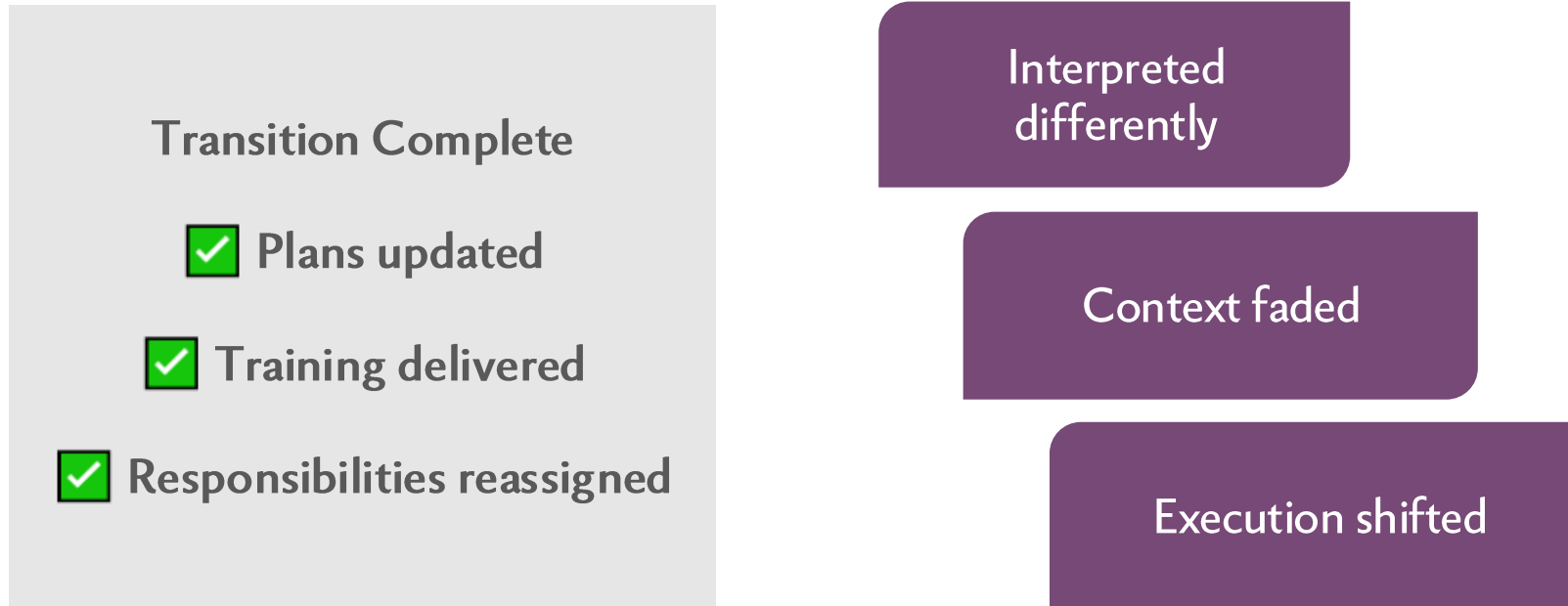


Context transforms individual findings into insight.

Aligning **RBQM** with Trial Flow

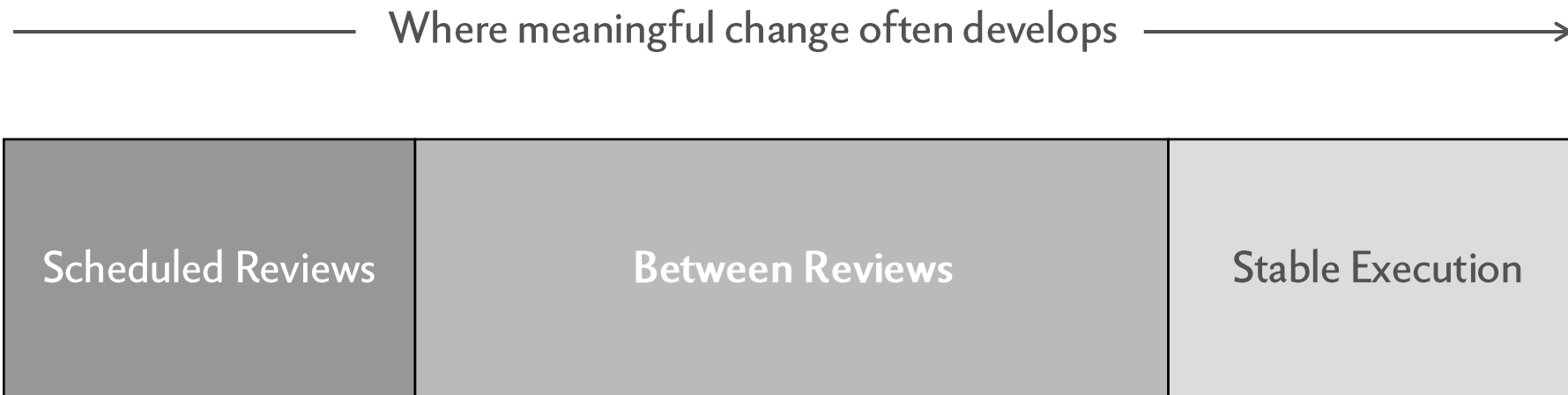


Why **Transitions** Deserve Attention



Transitions succeed when execution matches intent.

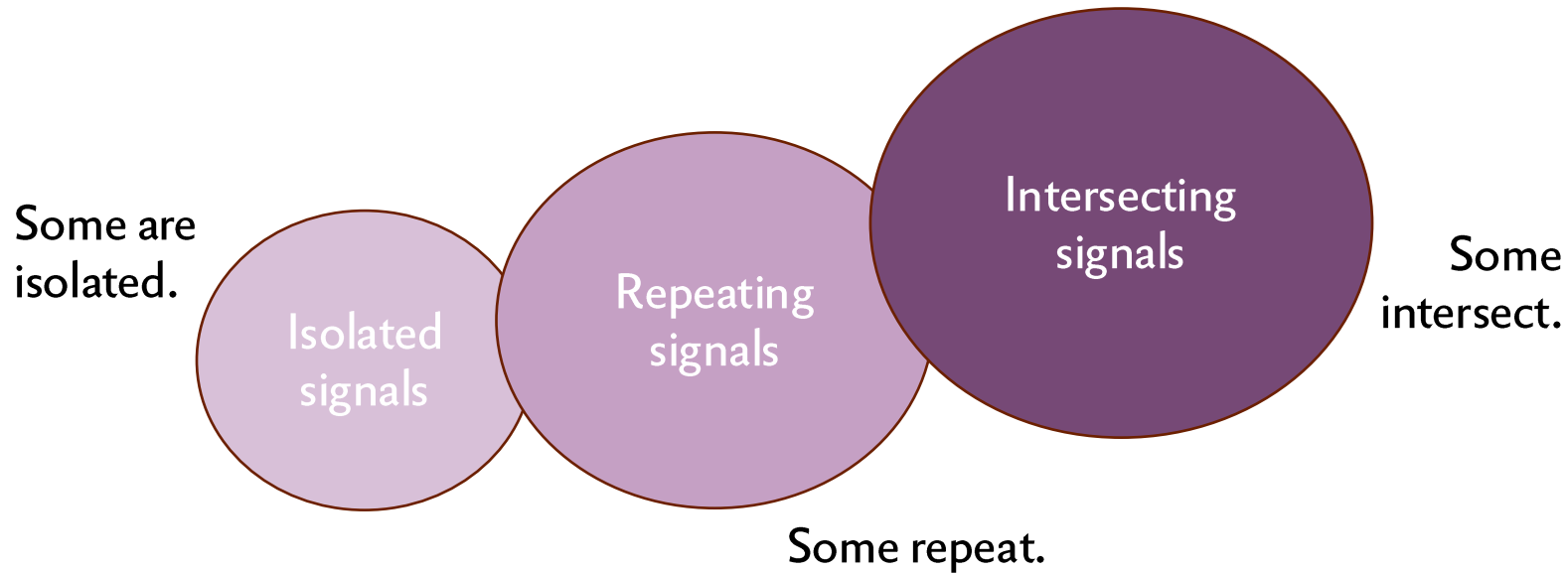
From Periodic Review to **Ongoing** Awareness



Many meaningful changes develop gradually, outside formal review moments.

Smarter Prioritization Through Connection

Not all signals carry the same weight.



Connected signals guide focus where it matters most!

From Querying Data to **Exploring Risk**

FROM STATIC Listings

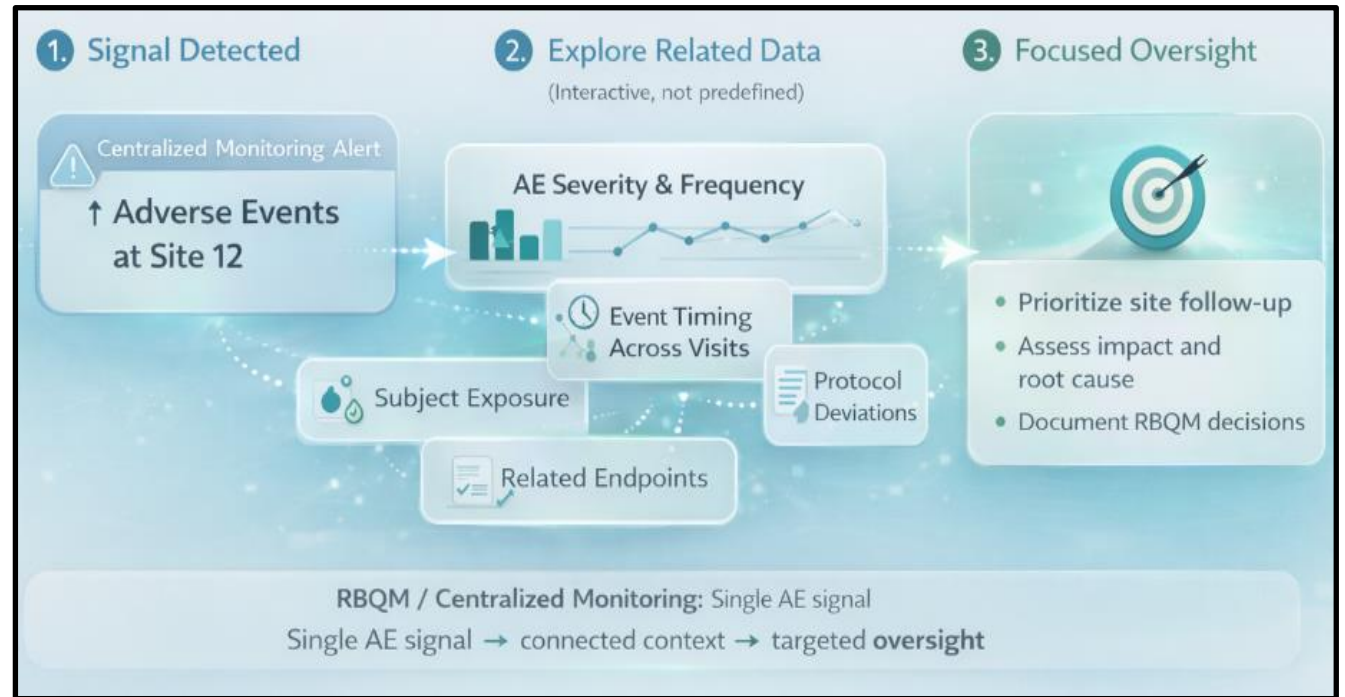
Traditional outputs and fixed listings limit the ability to detect emerging risks and patterns across study data.

TO RISK-FOCUSED EXPLORATION

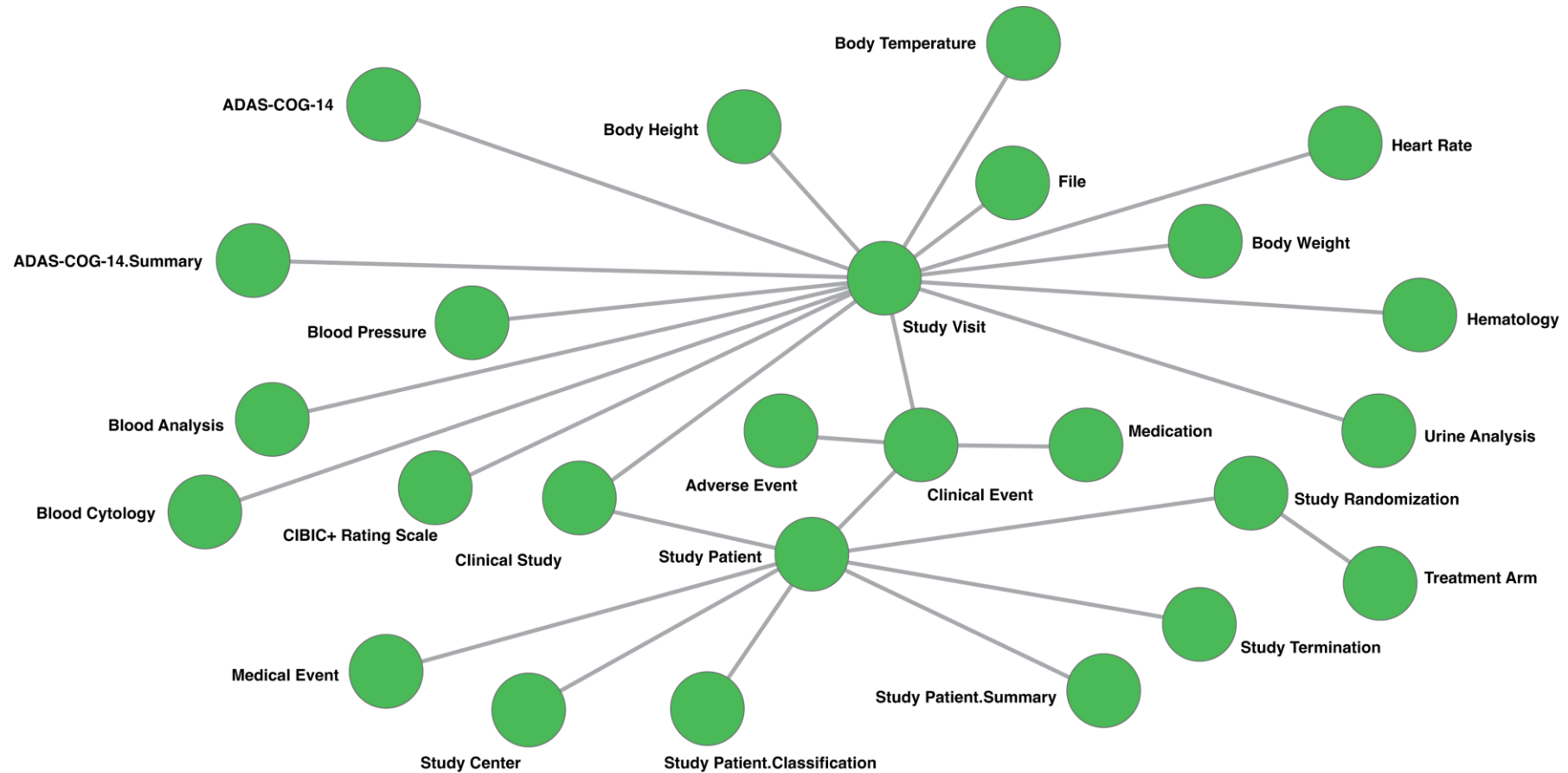
Reviewers dynamically explore key risk indicators, trends, timelines, and related data to continuously assess study quality and emerging issues.

EXAMPLE (Adverse Events)

An increase in AEs at a site prompts immediate exploration of severity, timing, and related data - enabling early, targeted oversight.



Data model



Demography

Study Patient Id	01-705-1393@CDISCPLOT01
Age	84.0 a
Sex	Female
Country	USA
Treatment Arm	Xanomeline Low Dose
Termination Type	DISCONTINUED
ComplWeek 8	Yes
ComplWeek 16	Yes
ComplWeek 24	No
Efficacy Group	Yes
Safety Group	Y
Intent-To-Treat Group	Y
Height(BL)	144.78 cm
Weight(BL)	54.89 kg
BMI(BL)	26.2 kg/m2

Medical History

ATRIAL HYPERTROPHY
BUNDLE BRANCH BLOCK RIGHT
OOPHORECTOMY PARTIAL
ALZHEIMER'S DISEASE

Relative Timeline - Med, AE & Lab (Time = Day in Study)

Legend:

- Meds - Classification: Study Drug (Green bar)
- AE - Seriousness: Seriousness (Green bar), Not Serious (Grey bar)
- BldAn - ALAT~Norma: LOW (Red square), NORMAL (Green square)
- Reference lines: ALAT UpRef (Green line), ALAT LowRef (Green line), ALAT (Grey line)
- BldAn - ASAT~Norma: NORMAL (Green square)
- Reference lines: ASAT UpRef (Green line), ASAT LowRef (Green line), ASAT (Grey line)
- BldAn - Bilirubin~Nor.: NORMAL (Green square), [None] (Black square)
- Reference lines: Bilirubin UpRef (Green line), Bilirubin LowRef (Green line), Bilirubin (Grey line)

Hard to demonstrate risk-based oversight?

Can you **compare data** from different studies?

Want to easily **share findings**?

Easy to share **RBQM** insights?

Which **CQFs** drive this study?

Are lab **trends triggering safety** signals?

Are **site data** patterns consistent?

Which **risk/KRI** version is current?

Can you compare **risk trends** across studies?

Can you spot **site or patient** outliers?



Waiting on **centralized monitoring** signals?

Catching **safety or deviation** signals early?

Need to handle many different **data sources**?

Ready for **RBQM inspection** questions?

24/7 access to RBQM insights?

The Impact

- **EARLIER VISIBILITY**

Key patterns and shifts surface sooner.

- **STRONGER DECISIONS**

Teams act with confidence, guided by context and timing.

- **MOMENTUM OVER TIME**

Quality becomes a living capability, not a one-time check.

Thank you!

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