DECISION MATURITY

The RBQM Decision Maturity Model

Most organizations measure RBQM maturity by which components they have in place. That measures capability, not decisions. This model measures how an organization turns risk into action.

5 maturity levels, from Traditional to Learning	**7** links in the decision chain	**3** components of the Decision Gap	**24** point self-assessment to find your level

01 — WHAT THE MODEL MEASURES

The Decision Gap

The elapsed time between the point at which a risk to trial quality becomes knowable and the point at which the organization acts on it, with a recorded rationale.

Risk becomes knowable — **Organization acts, with a recorded rationale**

COMPONENT 1
Time to Know
How long a risk that was visible in the protocol or data goes unrecognized.

COMPONENT 2
Time to Understand
How long it takes to interpret a signal and decide it matters.

COMPONENT 3
Time to Act
How long it takes to choose, carry out, and record the response.

THE DECISION CHAIN: WHERE CAPABILITY-FIRST TOOLING STOPS

Know	Detect	Interpret	Prioritize	Decide	Act	Evidence and Learn

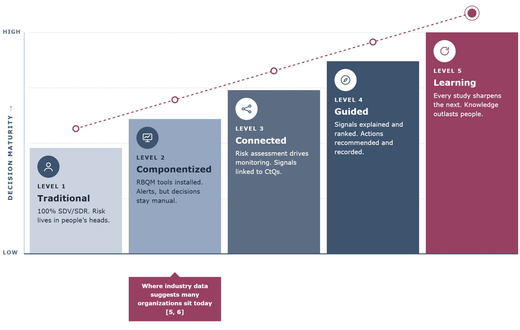
Typically covered by capability-first tools

Left to people: manual, variable, and rarely recorded at the time

02 — THE MODEL

Five Levels of Decision Maturity

Each level up the model moves more of the decision chain from people's heads into a connected, explained, and recorded process, and narrows the Decision Gap.



TYPICAL DECISION GAP BY LEVEL — Relative, illustrative scale

Very wide	Wide	Narrowing	Narrow	Closing

Figure 4. The RBQM Decision Maturity Model. Bar heights and gap lengths show direction of change, not measured values.

03 — LEVEL BY LEVEL

What Each Level Looks Like

LEVEL	WHAT IT LOOKS LIKE	TYPICAL DECISION GAP	SCORE (0–24)
LEVEL 1 **Traditional**	100% SDV/SDR. Risk assessment is informal and depends on individuals.	**Very wide.** Most risks found in conduct or at inspection.	0–6
LEVEL 2 **Componentized**	Risk assessment, KRIs, and central monitoring in place. Tools produce alerts, but interpretation and decisions stay manual and inconsistent. Many teams keep 100% SDV as a fallback [5].	**Wide.** Detection is faster, but understanding and action are not.	7–12
LEVEL 3 **Connected**	Risk assessment drives the monitoring plan. The team links signals to CtQs and changes the monitoring plan in response.	**Narrowing.** Teams watch known risks in the right places.	13–17
LEVEL 4 **Guided**	Signals arrive explained and ranked. Teams review, decide, and record recommended actions at the time.	**Narrow.** Decisions are faster, consistent, and evidenced.	18–21
LEVEL 5 **Learning**	Outcomes feed back into the next study. Thresholds and risk content improve over time, and knowledge outlasts people.	**Closing.** Each study starts ahead.	22–24

04 — THE EVIDENCE

Why Many Organizations Sit at Level 2

Most have installed RBQM components, but 100% SDR/SDV remains common and adoption is lowest during execution, where teams make day-to-day decisions [5, 6].

90% of trials in 2025 included at least one RBQM component [5]

Most studies still ran 100% source data review and verification [5]

57% of trials, on average, in which companies implement RBQM [6]

48% the same measure at companies running fewer than 25 trials a year [6]

Why teams hold back. Hesitancy to move away from 100% SDR/SDV stems from risk aversion, lack of trust, and fear of missing events [5]. The main barriers are a lack of organizational knowledge, mixed perceptions of RBQM's value, and poor change management [6].

Capability-first RBQM has given the industry more to look at without making it easier to decide. The problem is not data volume. It is decision making.

05 — SELF-ASSESSMENT

Find Your Level

Score 12 statements from 0 (not true) to 2 (consistently true) for your organization. This TRI-designed diagnostic supports discussion and gives a total out of 24.

STATEMENTS 1–3
Time to Know
Consistent baselines, risks traced to the protocol, and burden assessed before approval.

STATEMENTS 4–8
Understand and Act
Focus on critical data, signals with context, consistent conclusions, and ranked actions.

STATEMENTS 9–10
Evidence
Decisions traced to a name, date, and reason, with records created at the time.

STATEMENTS 11–12
Learning
Lessons change the next study, and knowledge survives when people leave.

TOTAL SCORE TO INDICATIVE LEVEL

0–6	7–12	13–17	18–21	22–24
Level 1 · Traditional	Level 2 · Componentized	Level 3 · Connected	Level 4 · Guided	Level 5 · Learning

0 — Total score — 24

Where to start. The lowest-scoring group is usually the best place to start a pilot.

See Where Your Organization Stands
Book a 30-minute session, or send TRI a protocol and compare the results.

www.tritrials.com/trial-os

Making RBQM simple for all clinical trials

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REFERENCES

[5] Association of Clinical Research Organizations (ACRO). RBQM Survey Summary Report: findings from data reported for 2025. 2026.

[6] Tufts CSDD. Comprehensive Assessment of Risk-Based Quality Management Adoption in Clinical Trials. Therapeutic Innovation and Regulatory Science. 2024.