ETMF RISK SCORING CONFIGURATION, MIGRATION & ADOPTION GUIDE

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2. Overview

The Risk Scoring feature provides configurable, hierarchical risk visibility across the eTMF.

Risk can be enabled at two levels for the 'Master Feature Toggles' which can be enabled independently.

- Document Level Risk (Document-level scoring)
- Document/Site/Country/Trial Risk (Aggregate roll-up scoring)

This allows end users to:

- Use only document type-level risk
- Use full hierarchical roll-up risk
- Disable the features entirely

3. Risk Architecture

A. TOGGLE 1: DOCUMENT TYPE RISK

When this toggle is enabled, every document is assigned a risk score between 0-100.

The Document Risk consists of the following:

Document Type Risk

Each document type has a predefined risk value between 0–100.

Example:

- ICF – 95
- Safety Report – 90
- CV – 60
- Training Log – 40

A script exists to populate out-of-the-box (OOTB) document type risk values which represents inherent regulatory criticality.

Dynamic Document Risk

The dynamic risk adjusts the baseline risk using the following operational factors:

Factor	Description	Configurable?
Status	Lifecycle status	✖ Always enabled
Open Query	Active query present	☑ Enable/Disable
In Audit	Included in audit	☑ Enable/Disable
AI Flag	AI-detected issue	☑ Enable/Disable

Note: Each factor has a configurable weighting and follows a default hierarchy i.e., Status > Query > Audit > AI Flag.

B. TOGGLE 2: SITE, COUNTRY AND TRIAL RISK

If the toggle is ON for site, country or trial, document risks roll up hierarchically as follows:

Document → Site → Country → Trial

In addition to aggregated document risk, the following risk factors may be included:

Factor	Configurable?
Missing Document Rate	☑ Enable/Disable
Document Rejection Rate	☑ Enable/Disable

Aggregated Document Risk	✖ Always included when roll-up is enabled

If the toggle is OFF:

- Site, country, and trial risk are not calculated
- Document-level risk remains functional (if enabled)

4. Configuration Options Summary

Master Toggles

Feature	Can Enable/Disable?
Document Type Risk	☑ Yes
Document/Site/Country/Trial Risk	☑ Yes

Document Type Risk

Item	Configurable?
Risk score per document type (0-100)	☑ Yes

Note: It is recommended to use the OOTB values initially.

Dynamic Document Risk

Enable Disable Factors

Factors	Can Disable?
Status	✖ No
Query	☑ Yes
Audit	☑ Yes
AI Flag	☑ Yes

Adjust Factor Weights

Weights are configurable with the default weighting priority being as follows:

Status > Query > Audit > AI Flag

Note: It is recommended to not modify at initial go-live**.**

Site, Country and Trial Risk Factors

If the roll-up toggle is enabled, the following factors can be enabled or disabled.

Factors	Can Disable?
Missing Document Rate	☑ Yes
Document Rejection Rate	☑ Yes
Aggregated Document Risk	✖ No

Note: It is recommended to keep both missing document rate and rejection rate enabled for accurate oversight.

5. Recommended Default Configuration

It is strongly recommended to launch customers with full feature enabled and OOTB configuration.

Recommended Setup

Setting	Recommendation
Document Type Risk	ON
Document/Site/Country/Trial Risk	ON
Document Type Risk Values	OOTB
Status Factor	Enabled
Query Factor	Enabled
Audit Factor	Enabled
AI Flag	Enabled (if AI used)
Dynamic Weights	Default
Missing Document Rate	Enabled
Rejection Rate	Enabled

6. Implementation Steps for Configuration Team

STEP 1: CONFIRM THE SCOPE WITH CUSTOMER

Clarify whether:

- Document risk only?
- Full hierarchical risk?
- AI in use?
- Audit module in use?

STEP 2: RUN DOCUMENT TYPE RISK SCRIPT

Populate the OOTB baseline risk values.

STEP 3: CONFIGURE TOGGLES

- Enable/Disable Document Risk
- Enable/Disable Site/Country/Trial Risk

STEP 4: CONFIRM DYNAMIC RISK FACTORS

- Enable or disable the following:
  - Query
  - Audit
  - AI Flag
- Confirm weights (default recommended

STEP 5: CONFIGURE ROLL-UP RISK FACTORS

Enable or disable the following

- Missing Document Rate
- Rejection Rate

STEP 6: VALIDATE UI COMPONENTS

Ensure the following UI components are validated:

- Risk column visible in document view
- Risk-based dashlets added
- Site/Country/Trial dashboards configured (if roll-up enabled)

7. Migration Considerations

A. BACKFILL

- Run document type population script before enabling risk.
- Risk scores calculate dynamically from current state.

B. HISTORICAL DATA

- No historical data changes.
- Risk is calculated based on current document attributes.

C. ROLLOUT RECOMMENDATION

Phased adoption recommended:

- Enable with defaults.
- Monitor for 4–8 weeks.
- Adjust configuration only if operationally necessary.

8. Adoption Strategy Guidance

Encourage clients/customers to use risk scoring for:

- Inspection Readiness
- Risk based monitoring
- Site oversight prioritization
- Executive reporting
- Quality trending

9.   Key Design Principles

The two-toggle model allows flexibility while preserving simplicity

Risk Scoring

- Optional at aggregate level
- Configurable
- Hierarchial
- Data Driven
- Backward Compatible

10. Final Recommendation

For most customers enable both **Document Risk** and **Site/Country/Trial** Risk using default configuration.

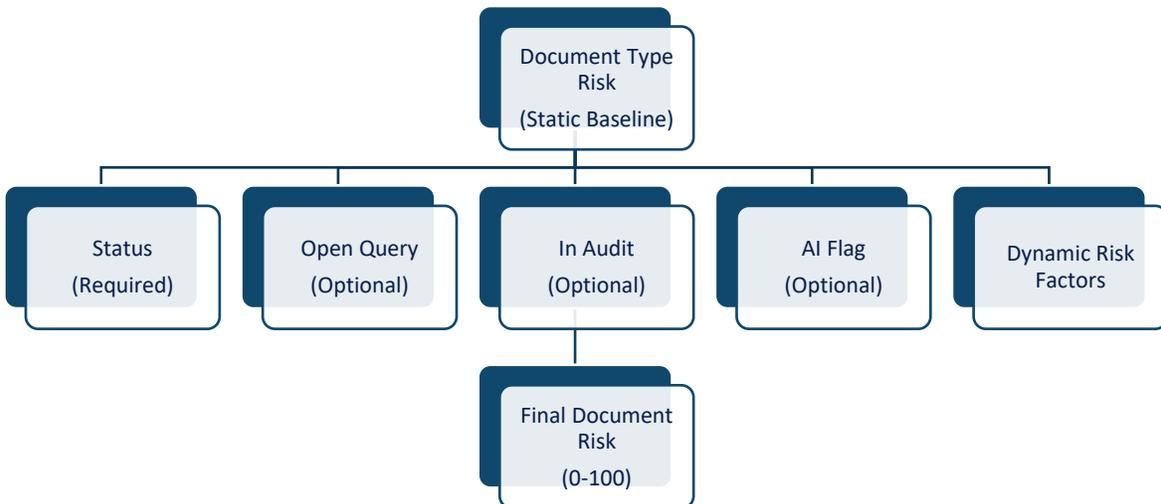Customization should follow operational experience, not precede it.

11. Visual Risk Architecture Diagram

A. TWO-TOGGLE FEATURE STRUCTURE

Toggle 1 can be ON independently
Toggle 2 required Toggle 1 to be ON

```
                    ┌─────────────────┐
                    │  Risk Scoring   │
                    └────────┬────────┘
              ┌──────────────┴──────────────┐
    ┌──────────────────┐        ┌──────────────────────────┐
    │     Toggle 1     │        │        Toggle 2          │
    │  Document Risk   │        │ Site/Country/Trial Risk  │
    └──────────────────┘        └──────────────────────────┘
```

B. DOCUMENT RISK CALCULATION

```
                        ┌──────────────────┐
                        │ Document Type    │
                        │ Risk             │
                        │ (Static Baseline)│
                        └────────┬─────────┘
     ┌───────────┬───────────────┼───────────────┬───────────────┐
 ┌─────────┐ ┌──────────┐ ┌────────────┐ ┌──────────┐ ┌──────────────┐
 │ Status  │ │Open Query│ │  In Audit  │ │ AI Flag  │ │ Dynamic Risk │
 │(Required)│ │(Optional)│ │ (Optional) │ │(Optional)│ │   Factors    │
 └─────────┘ └──────────┘ └─────┬──────┘ └──────────┘ └──────────────┘
                          ┌────────────┐
                          │Final Document│
                          │   Risk      │
                          │  (0-100)    │
                          └────────────┘
```

Note: Weighting is configurable with the default priority being **Status** > **Query** > **Audit** > **AI Flag.**

C. RISK ROLL-UP MODEL

When the Toggle 2 i.e., Site/Country/Trial Risk is enabled:

Document Risk (All Documents at Site)

Site Risk Score

Country Risk Score

Trial Risk Score

D. ROLL-UP RISK INPUT

At the Site/Country/Trial level:

Inputs	Required/Optional
Aggregated Document Risk	Required
Missing Document Rate	Optional Toggle
Document Rejection Rate	Optional Toggle

E. END TO END VISUAL SUMMARY

DOCUMENT TYPE RISK
+
DYNAMIC DOCUMENT SIGNALS
=
DOCUMENT RISK
↓
SITE RISK
↓
COUNTRY RISK
↓
TRIAL RISK

Optional Contributors

- Missing document rate
- Rejection rate
- AI signals
- Audit inclusion

12. Sales Positioning Brief

A. 🎯 CORE VALUE PROPOSITION

Risk Scoring transforms the eTMF from a document repository into a proactive inspection readiness and oversight engine.
It answers:

- Where are we most exposed?
- Which sites need attention?
- Which documents are likely inspection risks?
- Where should QA focus

B. 🧠 THE STRATEGIC NARRATIVE

Traditional eTMFs are reactive. The Risk Scoring makes the eTMF:

- Predictive
- Prioritized
- Actionable
- Executive-ready

Instead of reviewing everything, teams review what matters most.

C. 💡 BUSINESS PROBLEMS IT SOLVES

- **Inspection Anxiety**: Sponsors don't know their true inspection posture. The Risk scoring surfaces high-risk documents and sites immediately.
- **Inefficient QA Review**: QA reviews evenly instead of risk-based. Risk enables targeted oversight.
- **Hidden Stack Risk**: Missing documents and rejections aren't contextualized. Roll-up risk highlights problematic countries or sites early.
- **Executive Blind Spots**: Leadership sees completeness metrics, not exposure risk. Trial-level risk provides board-ready insight.

D. HOW TO POSITION THE TWO TOGGLES

Conservative Customer

"We can enable document-level risk only — no roll-up — so your team gets comfortable with it."

Low disruption entry point.

If Customer Is Advanced / Risk-Based Monitoring Focused

Position full roll-up:

"This allows you to prioritize sites the same way RBQM prioritizes patient safety."

Connect to ICH E6(R2) risk-based oversight language.