PHARMATEMPLATE / RBQM WORKBENCH 2.1

RBQM Workbench
Complete user guide

From project setup to data loading, interpretation and documented follow-up.

ONCO-RBQM-001

Multicentre walkthrough with four indicators, manual measurements, derivation of ALL and Excel import.



English edition · 16 November 2026

All screenshots are from the implemented interface and contain fictional data.

Open RBQM Workbench

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Interface screenshots

01 / WORKFLOW

Start here: the complete workflow

RBQM Workbench supports risk-based quality review for a study team. Start from factors critical to quality, define risks and controls, select indicators, load an explicit data cutoff, review signals, document decisions and follow actions through effectiveness checks.

First session: choose the website language; click New study; set the study reference, review date and expected sites; click Update study. Add risks before indicators. Adapt definitions and limits, then download the project-specific Excel or enter measurements manually.

Every review cycle: save a JSON backup, update the review date, load new data, inspect the import preview, apply it explicitly, review both signals and data quality, document assessments, update actions and export the report plus the latest JSON.

The landing screen initially contains a fictional demo. It is not your study. The separate complete Excel training example uses its own matching project. See the training walkthrough later in this guide.

Section	Purpose
1 · Review signals	Prioritize current signals, missingness and overdue actions.
2 · Factors & risks	Describe critical factors, failures, controls and owners.
3 · Indicators & limits	Define formulas, scope, limits and review criteria.
4 · Data & coverage	Manual entry, Excel/CSV imports and measurement export.
5 · Decisions & actions	Retain assessments, ownership, evidence and effectiveness.
RBM impact	Review eight quality, timeliness and cost concepts.
Report / Method & sources	Export the review and inspect calculation rules and scope.

02 / WORKFLOW

Create, save and reopen a project

Study / reference identifies the project. **Review date** is the date used to assess freshness and whether actions are overdue; it is not automatically the computer date. **Expected sites** is a comma-separated list of technical codes. ALL is reserved for trial-level measurements and must not be entered as a site.

Click Update study to apply these fields. Save JSON also applies and saves changes still in these fields. A cutoff, baseline or recorded review cannot be after the review date. Removing sites that still have linked data can fail validation. When Excel adds sites from valid declared coverage, check the resulting site list against the intended study.

Save JSON downloads the complete project: risks, definitions, aggregated measurements, coverage, reviews with retained snapshots, actions and the editable change history. Use **Open JSON** to resume. Excel and CSV import measurements; they do not restore the complete project.

Continuity: there is no general autosave. Reloading or closing the page can lose the session. Save JSON regularly and before New study, Fictional example, loading another project or replacement imports. An explicit ES/EN switch carries the current project to the companion page for that switch; a JSON backup remains necessary.

Interface language does not translate your custom project text. Legacy version 1.0 JSON is migrated where supported; review detectability, metric definitions, coverage origins and old action closure evidence before use.

See figure 1

03 / WORKFLOW

Factors, risks and controls

In Factors & risks, add a risk for each relevant critical-to-quality factor. Describe the failure that could affect participant protection or reliable results, assign an owner, specify mitigation and set a next review date where useful.

Initial and residual assessments use probability (P), impact (I) and difficulty of detection (D) on illustrative 1-5 scales. Residual values represent the assessment after controls; documenting a control does not prove it is effective.

The displayed priority score is **P × I**, not P × I × D. Priority is high when I = 5 or P × I ≥ 15; medium when P × I ≥ 6 otherwise; low otherwise. Detection remains a separate flag: unassessed D or D ≥ 4 prompts a detection review. Higher D means harder detection.

Example: P = 4 and I = 3 gives 12, medium priority. Residual P = 2 and I = 3 gives 6, still medium. D = 4 separately highlights a detection gap. I = 5 makes priority high even with a smaller product.

These are tool conventions, not validated universal scales or prescribed regulatory thresholds. Apply your study team’s agreed interpretation. The next risk review date is a planning field; it does not create an email reminder.

See figure 2

04 / WORKFLOW

Configure indicators and limits

Use the library and Adapt to study, or Custom indicator. Link every metric to an existing risk and retain its technical ID when editing. Library definitions and demo limits are starting examples; approval remains pending until the study team adapts and reviews them.

KRI supports investigation and follow-up, often by site. **QTL** is trial-level and must use study scope and ALL. A QTL needs numerical limits. **KPI** describes performance or impact. The eight impact KPIs have no limits by default.

Define population, source, numerator/value, denominator/base, unit, scope, owner, rationale, planned response, minimum interpretive base and maximum data age. Rates calculate 100 × n/d; ratios calculate n/d; numeric indicators use the supplied value. A percentage needs integer counts and n ≤ d. A ratio can exceed 1; cost allows a decimal numerator.

Limit rules are inclusive. With high direction, value ≥ action is Action, else value ≥ warning is Warning. With low direction, value ≤ action is Action, else value ≤ warning is Warning. Set the direction to match the metric; higher reconciliation completeness is favourable.

Choose **Data acquisition method**. **Aggregate data / manual entry** accepts your defined counts or value/base. **Automatic calculation from query records** exposes **Calculation recipe**. Percentages and ratios show count recipes, with **X days (strictly older)** required only for **Unresolved > X days**. **Median to closure** requires a numeric site indicator. Changing the actual definition or recipe can make existing results require recalculation. A limits-only change re-evaluates existing values; retained historical decisions remain linked to their old snapshot. Re-download Excel after changing definitions or project reference.

See figure 4

05 / WORKFLOW

Manual entry and explicit missingness

In Data & coverage choose Manual measurement, or Enter measurement on an impact card. Select the metric and site. For additive trial indicators, use site codes for components or ALL for the direct trial measurement. Enter the cumulative coverage origin and cutoff, with origin ≤ cutoff ≤ review date.

For a percentage or ratio, fill numerator and denominator and leave value/base empty. Enter 5 and 29 for 17.24137931%, not 17.24 in the numerator. For a numeric metric, enter value and, where available, base; leave numerator/denominator empty. A median must already have been calculated from eligible individual records.

Choose Missing at this cutoff to record explicit unavailability. Blank does not mean zero. For zero confirmed events with a positive denominator, enter n = 0 and the correct d. A denominator of zero yields no percentage or ratio, not 0%. Numeric results without a sufficient base remain limited for interpretation.

Editing a measurement updates its metric/site/cutoff record. Other measurements at the same site/cutoff must share the same coverage origin. Coordinate a coverage correction across those records rather than creating conflicting origins.

Declare cutoff without data creates coverage without inventing measurements. The latest declared cutoff then determines current missingness. This is different from a complete zero-query snapshot: for that case, declare the site in Periods with queries_complete = YES and no eligible query rows.

See figure 9

06 / WORKFLOW

Excel: where the file goes and what each sheet does

Open Data & coverage. Click 1. Download Excel template (EN) after configuring your project, fill it and select 2. Import Excel (.xlsx). An import prepares a preview; selecting the file does not immediately change the study.

The workbook is English on both website languages. Preserve sheet names and technical headers. Enter custom indicator text in English in the website if you want an entirely English dictionary. The workbook is tied to the study reference and current definitions; changing either can make it incompatible.

You can use aggregates alone, Queries_Raw + Periods, or a mixed file. Do not supply an aggregate for a metric/site/cutoff already derived from raw rows. Indicators is a dictionary, not a way to change the website configuration. Configure in the tool, then download again.

Sheet	Use
Instructions	Read entry rules and field dictionary.
Measurements	One aggregate per metric/site/cutoff.
Queries_Raw	One query state per query and explicit snapshot.
Periods	Complete query coverage by site/cutoff, including zero-query sites.
Indicators	Current definitions; read-only reference for import.
Metadata	Technical project binding. Do not edit.
Example / Expected_Results	Reference only. Neither sheet is imported. Expected_Results is in the filled training workbook.

See figure 14

07 / WORKFLOW

Aggregate measurements: field dictionary

Use exactly these technical headers in Measurements or aggregate CSV. Each row represents a single metric/site/cutoff. Keep the same population and cumulative origin for comparable observations. Do not add participant fields or explanatory extra columns.

Example rate: K02, S01, 2026-01-01, 2026-09-30, 24, 25, blank, blank gives 96% completed reconciliation. **Example numeric:** IM06, S01, same origin/cutoff, blank, blank, 3, 60 means a median of 3 days based on 60 records.

For an explicit missing aggregate, keep ID, site and dates and leave all applicable numerical fields blank. For a rate/ratio, leaving only one of n and d blank is invalid. Optional base does not belong on a rate/ratio row. Use native Excel numbers, not numeric text or formulas; paste calculated values.

Header	Meaning / rule
metric_id	Exact technical ID from Indicators.
site_id	Technical site code; ALL for study-level metrics.
period_start	Inclusive origin of cumulative coverage.
period_end	Inclusive cutoff, no later than review date.
numerator	Count for rates/ratios; decimal cost if configured.
denominator	Non-negative integer for the same eligible population.
value	Precomputed numeric value or eligible-record median.
base	Eligible-record count for a numeric value; optional, but needed for qualified interpretation.

08 / WORKFLOW

Raw query snapshots: field dictionary

Raw input is a snapshot format, not an event-history format. Supply one row per query at each explicit cutoff, including its state on that date. The same ID may appear at different cutoffs; it must stay assigned to the same site. A query ID must be unique across the entire snapshot, not just within each site.

Periods is required for Excel raw input. Declare every complete site/cutoff, even when it has zero query rows. Use ALL only for trial aggregates, never for raw queries or query periods. YES is an explicit completeness assertion, not a way to bypass missing extraction.

Keep original opening dates across snapshots. A reopening is represented by a new explicit snapshot with OPEN or ANSWERED and blank closed_date; the tool does not reconstruct reopenings or absent cutoffs. Queries opened before the coverage origin are rejected: correct the origin or the documented population.

Queries_Raw header	Meaning / rule
query_id / site_id	Technical text IDs. No patient names or personal data.
opened_date	Original opening; within coverage and not after snapshot.
status	OPEN, ANSWERED, CLOSED or CANCELLED.
snapshot_date	Explicit state date, matching a Periods row.
closed_date	Required for CLOSED; opening ≤ closure ≤ snapshot. Blank for OPEN/ANSWERED.
Periods header	Meaning / rule
site_id	Individual site code, including zero-query sites.
period_start / period_end	Coverage origin and snapshot cutoff.
queries_complete	YES only if the eligible snapshot is complete.

09 / WORKFLOW

Raw calculations: a worked example

Only metrics mapped to query recipes are calculated from raw data. Other indicators, such as reconciliation, missing primary assessments, audit findings and costs, require authorized aggregates or manual measurements. The default demo has K01 and K03 raw recipes; the impact pack also adds IM07.

At the cutoff, OPEN and ANSWERED are both unresolved. CLOSED remains in the eligible denominator. CANCELLED is excluded from numerator, denominator and closure median. Query age uses calendar days since original opening. The overdue test is strictly > X days, not ≥ X.

Worked cutoff: 2026-09-30; complete cumulative coverage from 2026-01-01. Q001 opened 2026-08-30 and OPEN is 31 days old. Q002 opened 2026-08-31 and ANSWERED is exactly 30 days old. Q003 opened 2026-09-01 and CLOSED 2026-09-05 has a 4-day duration. Q004 is CANCELLED.

Eligible d = 3. Overdue unresolved n = 1 gives K01 = 33.33333333%. Unresolved n = 2 gives K03 = 66.66666667%. The closure median is 4 days, base = 1; if the configured minimum base is larger, it remains a small-base result. A complete zero-query site yields d = 0 and no percentage, and no closure median.

For multiple cutoffs, repeat each query’s state at each cutoff explicitly. A favourable closure median can coexist with a rising backlog: open queries never enter that median. Do not average site percentages or site medians to create a trial result.

Recipe	Calculation
query_overdue	100 × unresolved queries strictly older than age_days / all eligible queries.
query_open	100 × OPEN or ANSWERED / all eligible queries.
query_closure_days	Median of closure minus original opening among eligible CLOSED queries. Base = number closed.

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CSV: aggregates or one raw cutoff

In Data & coverage, choose Aggregate measurements or Query snapshots before selecting the CSV. Use the same technical headers as the corresponding Excel sheet. Aggregate CSV may contain multiple explicit cutoffs. Raw CSV supports one cutoff per import.

For raw CSV, enter Raw coverage origin and Raw cutoff, then confirm complete extraction including expected sites with zero queries. Every row’s snapshot_date must equal the chosen cutoff. The tool declares coverage for all currently expected sites plus sites found in the CSV; review that list before asserting completeness.

Raw CSV has no separate Periods sheet. The on-screen dates and completeness checkbox supply its context. To import multiple snapshots together, use Excel with explicit Periods instead, or import separate complete CSV cuts sequentially.

CSV supports comma-separated or semicolon-separated fields, detected from the header. Use ISO dates YYYY-MM-DD and dot decimal numbers, such as 1234.50. Do not use localized thousands separators, percent symbols or decimal commas for numeric input. Quote text fields containing the chosen separator; keep the same number of columns on every row.

Export measurements CSV downloads aggregates only. It can be reimported as aggregate CSV, but does not contain raw query records, indicator definitions, risks, decisions or actions. Older compatible aggregate CSV using metricId/site/date is supported; new files should use the current schema.

Aggregate CSV header	metric_id, site_id, period_start, period_end, numerator, denominator, value, base
Raw CSV header	query_id, site_id, opened_date, status, snapshot_date, closed_date

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Import preview: validate, inspect, apply

After selecting a file, inspect the preview counts: derived/aggregate measurements, declared coverage, raw query snapshot rows and cancelled rows excluded. Repeated query IDs at different snapshots count as separate input rows. Coverage counts are not participant counts.

Issues identify sheet, row, column and cause. Any ERROR blocks the complete import. No valid subset is silently applied. Fix the source file and import it again. Only the first 100 issues and first 20 measurement previews are displayed; this display limit does not mean the remaining rows were ignored.

Append new cutoffs retains existing measurements and coverage. An existing metric/site/cutoff or conflicting coverage origin blocks application: append is not an upsert. For a newer cutoff, supply a new cutoff with consistent definitions and origin.

Replace all measurements and coverage removes the project’s complete previous measurement and coverage collections and substitutes the input, not just the selected site or cutoff. Risks, definitions, recorded reviews and actions remain. Historical decisions retain their snapshots; the latest panel may require new assessment. Save JSON before replacement.

Check the confirmation that you reviewed population, cutoffs and results, then click Apply import. A preview is bound to the study, definitions and review date; if these change, prepare the preview again. Verify results after application and save the updated JSON. Raw files are not retained as full query datasets in the project; keep the authorized extraction separately.

Before applying	Check
Identity	Correct study and project-specific template.
Population / origin	Same eligibility and cumulative origin for each site/cutoff.
Completeness	Full raw snapshots, including zero-query sites.
Counts / values	Expected input rows, exclusions, units and derived results.
Strategy / backup	Append versus complete replacement; JSON backup saved.

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Complete fictional training walkthrough

1. Save any working project JSON. **2.** Open Data & coverage and click 1. Load example project. This loads RBQM-TRAINING-001 | Fictional study with matching English definitions, a review date of 2026-09-30, three sites and 12 metrics; it has no measurements yet.

3. Download RBQM_Fictional_Example_EN.xlsx from the example link. **4.** Select it through 2. Import Excel (.xlsx). **5.** Confirm the preview, normally Append new cutoffs into this empty training project, then Apply import.

The example contains 34 aggregate rows, 162 raw snapshot rows and six complete site cutoffs across 2026-08-31 and 2026-09-30. The import derives 52 measurements; six cancelled snapshot rows are excluded. Eight project coverages include the two ALL aggregate cuts. The 162 rows are not 162 distinct queries.

Expected_Results contains 52 independently calculated fixed reference results. It is not imported and does not update if you change the inputs. The blank standalone RBQM_Template_EN.xlsx is bound to the same training project; for a real study, use the template downloaded from your own configured project.

Impact baselines and comparability in this package are explicit fictional training assumptions. Definitions remain pending review. These values are test examples, not performance targets or evidence of RBM effectiveness.

Latest cutoff / S01 unless ALL	Expected value
K01 overdue queries	5/29 = 17.24137931%
K03 unresolved backlog	8/29 = 27.58620690%
K02 safety reconciliation	24/25 = 96%
Q01 missing primary assessment / ALL	4/120 = 3.33333333%
IM05 visit interval	135/3 = 45 days per interval
IM06 eCRF entry median	3 days; base 60
IM08 issue closure median	9 days; base 12

13 / WORKFLOW

Review signals: reading the current board

Each row is one metric at one site, or ALL for trial scope. Cutoff is the latest declared coverage for that site. Result shows the calculated value plus counts or base. Signal and data quality are separate columns; both matter.

The four summary cards count warning/action rows, results with data gaps, QTL action-limit exceedances and overdue actions. They count result rows or actions, not patients or unique sites. A row may appear in both signal and data-gap counts. Impact metrics with no limits have no agreed limit status; they are not automatically within limit.

Use All, Signals, Data gaps or QTL to focus the board. Click an indicator row to inspect its definition and history, or Evaluate to document the current assessment. When there is no cutoff, Declare cutoff opens the coverage form first. A missing latest measurement is not filled using an older value.

In the built-in demo, K01/S01 is 25% (25/100), Action and Usable data. K01/S02 is 20% (1/5), Action and Small base. K01/S03 is Missing at the current cutoff despite an earlier measurement. K02/S01 at 95% is Warning because lower completeness is unfavourable and the warning rule includes equality.

See figure 13

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What every signal and quality label means

Signal evaluates configured limits; quality evaluates availability, definition compatibility, denominator/base and freshness. Read the numerical value and context before deciding. A colour is not a clinical conclusion, compliance verdict or automated instruction.

Quality is a primary displayed label, not a complete list of all possible limitations. For example, a stale result can also have a small base; inspect base and cutoff even when the displayed quality says Stale. Definition pending team review is another independent warning.

For a rate, base means denominator. For a numeric result, base is the count supporting that value. Data age is calendar days from cutoff to review date; a result becomes Stale only when age is greater than max_age_days, not equal. Data freshness is different from the age threshold used to count overdue queries.

Label	Meaning / response
Within limit	Below/above applicable limit in its configured direction; still review quality and context.
Warning / Action	Inclusive warning/action rule met; verify data and assess proportionate follow-up.
No agreed limits	No numerical threshold evaluation configured; descriptive result only.
Missing	No applicable current measurement, or explicit missing observation. Never interpret as zero.
No denominator	Rate/ratio denominator is zero. No computable rate or ratio.
Small base	Supporting base absent or below the configured minimum; judgment needed.
Stale	Cutoff older than the configured maximum relative to review date.
Definition changed: recalculate	Stored data meaning no longer matches current metric; prepare compatible measurements again.
Usable data	Passes these tool checks; not a certification that the source data are correct.

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History, assessments and retained decisions

Click a metric row to see population, numerator/value, denominator/base, limits, coverage origin, minimum base, freshness and the planned response. Its chart displays historical values against the current limits; it is not a statistical control chart.

The simple observed change uses the earlier valid observation only when the cumulative origin and time basis match. A percentage change in this clinical detail is a difference in percentage points, not a relative percentage. This basic trend is not the same as the stricter explicit-baseline comparison on RBM impact.

Use Evaluate or Document review. Enter a review owner, decision, assessment/cause/rationale and optional next review date. Review the extraction and context first. For a QTL exceedance, assess whether a systemic issue could affect participant protection or reliability of results; do not equate exceedance automatically with non-compliance.

Saving retains the metric definition, value, signal, data quality and coverage used at that moment. If the definition revision or current assessment changes, the current row may need another assessment; the old decision remains in Documented reviews and in JSON. A missing result may still be assessed once a coverage cutoff is declared.

Decision	Typical use, with documented rationale
Monitor	Follow a trend or limited result with an explicit review plan.
Investigate	Check source, process and likely cause; consider an action.
No action, with rationale	Explain why no action is proportionate and what was checked.
Possible systemic issue	Assess broader implications and coordinated response.

See figure 15

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Actions, due dates and effectiveness

In Decisions & actions, use Add action, or Create action from a documented review to carry its risk/review link. Specify an ID, risk, optional related review, owner, proportionate action/goal and due date. A linked review must refer to the same risk.

Action states are Open, In progress and Closed. An action is overdue when it is not closed and its due date is before the project review date. This is a date-based flag, not an email notification. A due date equal to review date is not yet flagged overdue.

Closing requires both Execution evidence and Effectiveness check. Evidence describes what was done and its supporting record. Effectiveness describes what was reviewed, when, and whether the intended effect occurred or remains uncertain. A favourable percentage alone may not establish effectiveness.

Example: investigate critical-data backlog, assign the DM lead and agree a due date. Record the site follow-up and listing reference as execution evidence. At the next cutoff, assess query age, backlog, missing data and recurrence, then document what supports or limits the conclusion.

Updating an action records an editable project event. The tool does not provide electronic signatures, automatic escalation, an immutable audit trail or a validated CAPA approval workflow. Keep official records and evidence in your organization’s designated process.

See figure 16

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RBM impact: quality and cost metrics

RBM impact separates descriptive quality, timeliness and cost concepts from clinical KRI/QTL assessment. Add all 8 metrics adds missing library concepts and an associated risk without creating measurements or overwriting existing customizations. Adapt each definition to the study before use.

No impact KPI has agreed limits by default. Expected reading is an interpretation hypothesis, not a success threshold or causal conclusion. Review Alternative reading and the study’s complexity, maturity, population and extraction changes.

IM01-IM04 are study-level in the supplied pack and use ALL. Query raw input cannot generate these metrics; prepare authorized aggregates from their sources. The identifiers below are the default pack IDs and may differ after customization or ID collision.

Metric	Calculation and interpretation
IM01 · Major/critical findings per audit	Findings / completed site audits. Denominator is audits, not unique sites. A rise may reflect better detection; review severity and recurrence.
IM02 · Unreported confirmed SAEs	100 × confirmed unreported SAEs / all confirmed SAEs discovered by any method. This is not the late-reporting KRI and its denominator is not participants. Improved discovery can affect the observed proportion.
IM03 · Significant deviations per treated participant	Deviation events / unique treated participants. Repeated events can make the ratio > 1. It differs from the library percentage of participants with at least one deviation.
IM04 · Average monitoring cost per site	Allocated cost across central, remote and on-site modes / included sites. Use one ISO currency and consistent allocation. Cost reduction must be interpreted with retained quality coverage.

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RBM impact: timeliness metrics

IM05-IM08 are site-level in the supplied pack. Use an individual site code, never ALL unless you deliberately redefine scope with a justified valid method. These metrics are calendar-day summaries, not survival estimates or exposure-adjusted rates.

Only IM07 can be generated directly from supported query snapshots. IM05 needs sums and interval counts from visit records. IM06 and IM08 require precomputed medians from matched eligible individual records, with supporting bases. The tool does not take visit, eCRF-entry or issue raw listings as inputs.

For a median, enter value and base and leave n/d blank. Never average site medians to make a global median. Open/unmatched records fall outside these completed-record medians, so review their backlog and age separately.

Metric	Calculation and interpretation
IM05 · On-site visit interval	Sum of calendar days between consecutive on-site visit pairs / number of valid intervals at that site. One visit yields no interval. Longer spacing does not demonstrate better quality; check safety, backlog and data entry.
IM06 · Visit-to-eCRF entry	Median of first valid entry date minus visit date. Base = matched records. Outstanding entries are excluded and need separate follow-up. No fixed causal expectation.
IM07 · Query open-to-close	Median closure minus original opening among non-cancelled CLOSED queries. Base = closed queries. A shorter median with worsening backlog can mislead. No fixed causal expectation.
IM08 · Significant/major issue closure	Median closure minus opening among eligible closed issues. Base = closed issues. Follow unresolved/overdue issues and recurrence separately; a new process can initially change detection or timing.

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Baseline, observed change and comparability

On an impact card click Configure / baseline. Select an explicit earlier cutoff with a measurement for that same metric and site. Document comparability in the rationale and set Comparability reviewed to Yes only after review of population, definitions, source, coverage, currency and study context.

A comparison is calculated only when baseline and current observations exist, baseline precedes current cutoff, cumulative origin and time basis match, both results have usable data, and comparability is explicitly confirmed. A stale/small current result, missing baseline, changed definition or zero denominator prevents qualification.

Absolute change = current - baseline. For rates this is percentage points; otherwise it uses the metric’s units. **Relative change = 100 × (current - baseline) / |baseline|.** A zero baseline gives no relative percentage, although a qualified absolute difference can still be available.

Example: 20% to 15% is -5 percentage points and -25% relative. A median from 6 to 3 days is -3 days and -50% relative. Increase, Decrease and No change describe the numerical direction; they do not automatically mean success, failure or causation.

Not comparable asks you to check baseline, population, coverage and data quality. The baseline value may still be displayed for context when the change is unavailable. Comparisons are descriptive; there is no adjustment for case mix, trial maturity or confounding.

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Reports, exports and project handover

Report assembles current result rows, coverage/origins, signal and quality, current assessments, impact comparisons, risks and controls, definitions/rationale, retained decisions, actions/effectiveness and the editable event history. Different sites can have different latest cutoffs; check this before presenting a cross-site review.

Print / save PDF opens the browser print dialog. Choose a PDF destination, review page breaks and save. **Download HTML report** creates a standalone readable snapshot; it does not reopen the working project. **Save project JSON** preserves the editable project for later work.

CSV provides aggregate measurements only. JSON includes aggregates and raw source-row references but not the full raw query extraction. Keep the original extraction, applicable definitions and official supporting evidence separately where your organization requires them.

A practical handover includes the dated report, current JSON, source extraction reference and any unresolved issues or limitations. Treat the report as a supporting review record, not an electronic signature or a validated official record by itself. The downloadable user guide describes the tool; it is different from your study’s generated review report.

See figure 17

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Troubleshooting: imports and unexpected outputs

If a file is rejected, correct it as a whole and upload again. Do not edit Metadata to force compatibility. Save JSON before changing definitions or replacing data. Review the exact sheet/row/column in the preview.

When a number looks plausible but unexpected, verify the configured unit, eligible population, denominator, snapshot state, original opening, cancelled exclusions and current cutoff. Displayed counts are often enough to identify a scope or extraction mismatch.

Problem	Likely cause and correction
Study or definitions changed	Wrong project/template or revised definitions. Open the matching JSON or download a fresh current template.
Unknown metric / scope conflict	Use exact metric_id. Use site codes for site indicators and eligible ALL components, and ALL for a direct trial measurement.
Duplicate measurement	Repeated metric/site/cutoff, mixed raw and aggregate result, or append to an existing key. Remove duplication or choose complete replacement after backup.
Invalid date / coverage	Use valid ISO/Excel dates, common origin, cutoff ≤ review date and opening within coverage. No time-of-day inputs.
Missing Periods / completeness	Declare every raw site/cutoff, queries_complete = YES only if complete, and include zero-query sites.
Closure / state error	CLOSED requires a valid closure; OPEN/ANSWERED require blank closure.
Number / formula / column error	Paste native numerical values; use correct unit fields and supported headers only. CSV decimals use dot.
Empty input sheets	Example and Expected_Results are not imported; fill the actual input sheets.
Missing / Small base / Stale	Check current declared cutoff, denominator/base and review date versus data cutoff. Missing is not zero.
Change unavailable	Set explicit earlier baseline, confirm comparability, use matching origins and qualified measurements.
Action will not close	Provide execution evidence and an effectiveness conclusion; check review-risk linkage.

22 / WORKFLOW

Standard library: formulas and scope

The library offers eight clinical/query concepts in addition to the eight impact KPIs. Only selected concepts become project indicators. Technical project IDs such as K01 are assigned by the project; library code describes the concept. Adapt classification, eligibility and applicable deadline before interpreting.

All built-in temporal definitions use cumulative snapshots from an explicit origin. The tool does not automatically create exposure-adjusted rates, rolling-window indicators, case-mix-adjusted comparisons or subject-level longitudinal analyses.

Concept / default scope	Formula / required source
Open queries >30 days / site	100 × unresolved strictly older than configured days / eligible non-cancelled queries. Raw supported.
Unresolved query backlog / site	100 × OPEN or ANSWERED / eligible non-cancelled queries. Raw supported.
Median query closure days / site	Median closure-opening among CLOSED; base = closed. Raw supported.
Missing primary assessment / study QTL	100 × eligible participants without valid primary assessment / participants whose assessment is due. Aggregate.
Consent issues / site	Number of reviewed participants with a relevant issue; numeric value and reviewed-participant base. Aggregate.
Late SAE reporting / site	100 × reportable SAEs beyond defined deadline / reportable SAEs with deadline elapsed. Aggregate.
Completed safety reconciliation / site	100 × completed cases / cases requiring reconciliation; low direction. Aggregate.
Important protocol deviations / site	100 × reviewed participants with at least one important deviation / reviewed participants, counted once. Aggregate.

23 / WORKFLOW

Operating limits, glossary and final checklist

File limits: uploads up to 5 MB. XLSX input supports up to 20,000 aggregate measurements, 50,000 raw query rows and 1,000 raw Periods rows, subject to total project limits. No input formulas, macros, external links, encrypted workbooks or 1904 date system. Use YYYY-MM-DD or supported native midnight/serial Excel dates.

Display versus storage: the Data table shows at most 200 measurement rows, while JSON retains all project measurements within its limits. The project is capped at 500 sites, 100 metrics and 20,000 observations; raw-derived outputs also count toward that observation limit. Larger extractions can exceed aggregate capacity.

Local processing: study data are processed in the browser and are not automatically saved to a server. Downloads may be stored or synchronized by your own device settings. Use only technical IDs and authorized aggregates; keep participant identifiers out of this workspace.

Scope: this is an editable decision-support workspace, not a validated GxP system, immutable audit trail, electronic-signature service, EDC integration or automated clinical decision system.
Team-reviewed means the selected field is Yes, not a signed approval. Method & sources links to the methodological material; study-specific judgment remains necessary.

Term	Meaning
CtQ / RBQM / RBM	Critical to quality / risk-based quality management / risk-based monitoring.
KRI / QTL / KPI	Risk indicator / trial-level quality tolerance limit / performance or impact indicator.
Cutoff / origin / baseline	State date / start of cumulative coverage / explicit earlier comparison cutoff.
Base / snapshot	Support count / state explicitly represented at a cutoff.
Final check	Correct project, reviewed definitions, complete population, compatible origin, signal plus quality checked, decisions/actions documented, report and JSON saved.

24 / WORKFLOW

Data acquisition and automatic ALL

Use **Aggregate data / manual entry** for any supported KRI, QTL or KPI definition, including pharmacovigilance or clinical evaluability. Automated import from individual records is available for implemented query recipes. Choose the recipe only if its eligibility, states, numerator or value, and denominator or base match the agreed definition.

Percentages always require integer counts. **Ratio numerator** is available for ratios, which may use an integer count or a decimal amount. **Unit label** gives context to numeric or ratio outcomes. **Limit evaluation** exposes direction and both thresholds when enabled. QTL requires trial scope and limits.

Under **ALL source**, **Direct ALL entry** uses a global measurement. **Derive ALL from sites** is available for additive trial percentages and ratios, including compatible query counts. Choose the official source once per indicator. Medians, other numbers and RBM impact KPIs cannot be pooled from sites here.

Before confirming a derived cutoff, check the expected site list, compatible origin and definition, sufficient global base and absence of overlap. Do not mix source types across components of the same derived result. Source references, coverage and confirmations are kept in the JSON. Later or incompatible cutoffs do not borrow contributions from earlier dates.

A recipe change retains earlier measurements. If the data definition changes, the tool marks prior data for recalculation. Changing the displayed labels in this release alone preserves the calculation and the Excel binding. Reimport from the appropriate source for a genuine definition change.

25 / WORKFLOW

ONCO-RBQM-001 · Create the study

This fictional multicentre example uses three sites and four indicators. The limits are for training. In a real study, agree populations, cutoffs, controls, thresholds and escalation with the team before drawing conclusions.

1. Set up the project. Click **New study**. Set **Study / reference** to ONCO-RBQM-001, **Review date** to 2026-10-02 and **Expected sites (comma)** to S01, S02, S03. Click **Update study**. All examples use origin 2026-09-01 and cutoff 2026-09-30.

2. Define risks. In **2 · Factors & risks**, click **Add risk** for each row. Use the factor and failure columns to fill the fields, enter the proposed controls, and select the initial and residual P/I/D values. Set **Next review** to 2026-10-07 and click **Save record**.

ID · factor / failure	Owner · planned control · initial → residual P/I/D
R01 · Critical data reliability / unresolved discrepancies	Data Manager · weekly query review and site escalation · 4/3/3 → 2/3/2
R02 · Participant safety / delayed SAE reconciliation	Safety Manager · safety–EDC reconciliation and discrepancy review · 2/5/2 → 2/5/1
R03 · Primary endpoint integrity / missed assessments	Clinical Lead · review due visits before cutoff · 3/5/3 → 2/5/2

See figure 1

26 / WORKFLOW

ONCO-RBQM-001 · Configure the four indicators

3. Configure definitions. In **3 · Indicators & limits**, use **Custom indicator**, or select a library definition and click **Adapt to study**. Set **ID**, **Name**, **Related risk**, **Type**, **Scope**, **Calculation / unit** and **Data acquisition method** as shown below.

Fill **Eligible population**, **Numerator / value definition**, **Denominator / base definition** and **Source & extraction** from the next page. Set **Owner assignment** to **Use risk owner** and verify **Effective owner**. To override it, choose **Use custom owner**. Set **Maximum data age (days)** to 30 for all four.

Choose **Apply warning / action** for the KRIs and QTL, then enter **Exceedance direction**, **Warning limit**, **Action / QTL limit** and each minimum base. Enter 20 for 20%. Enter a rationale such as “Fictional limits, weekly review” and a planned response such as “Check source and investigate”. Set **Reviewed by study team** to **Yes: definition and review plan agreed** for this exercise. Save each record.

Indicator	Settings, warning/action and minimum interpretive base
K01 · Open queries (%) · KRI · R01	By site · Percentage: 100 × n/d · Aggregate data / manual entry · Greater than or equal: 20 / 40 · base 10
K02 · SAE reconciliation completed (%) · KRI · R02	By site · percentage · aggregate/manual · Less than or equal: 95 / 85 · base 10
Q01 · Missing primary assessments (%) · QTL · R03	Trial (ALL) · Derive ALL from sites · percentage · aggregate/manual · Greater than or equal: 5 / 10 · base 30
P01 · Median query resolution time · KPI · R01	By site · Number / aggregate median · days · Automatic calculation from query records · Median to closure · No limits: value and context · base 2

27 / WORKFLOW

ONCO-RBQM-001 · Align population and source

For K01, match the source definition before choosing a query recipe. Use **Unresolved backlog** only if all eligible OPEN and ANSWERED queries are counted and the denominator includes eligible closed queries. If the source counts only OPEN or uses a different denominator or population, keep the aggregated method and describe that definition.

For P01, **Unit label** is days. **Median to closure** uses elapsed calendar days between original opening and closure for eligible CLOSED queries. Unresolved and cancelled queries do not contribute to the median. Keep a descriptive KPI without numerical thresholds in this exercise.

ID	Eligible population · numerator/value · denominator/base · source
K01	Non-cancelled queries opened in coverage · OPEN or ANSWERED at cutoff · all eligible queries including CLOSED · EDC listing with status at cutoff.
K02	SAEs requiring reconciliation at cutoff · reconciliations completed · all cases requiring reconciliation · safety database and EDC reconciliation listing.
Q01	Participants due for primary assessment at cutoff · due assessments missing or unusable · all due participants counted once · due-assessment listing.
P01	Queries opened in coverage and CLOSED by cutoff · median elapsed days · number of eligible closed queries · Queries_Raw and Periods.

See figure 8

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ONCO-RBQM-001 · Manual entry and results

4. Enter data. In **4 · Data & coverage**, click **Manual measurement**. Choose the indicator and site, set **Cumulative coverage origin** to 2026-09-01 and **Cutoff date** to 2026-09-30. Leave **Availability** at **Data available**, enter the counts or value/base, then click **Save record**. Repeat for the table.

Enter Q01 for S01 and S02 first, then follow the incomplete-coverage check on the next page before entering S03. Use the P01 numeric rows to validate a manual calculation from the same closed queries used in the Excel exercise. Manual entry records the value and base you provide.

On **1 · Review signals**, read **Signal** and **Data quality** separately. The example is two days old at review, within 30 days, and all listed site bases meet the thresholds. P01 is descriptive and has **No agreed limits**.

ID	S01 · S02 · S03
K01	2/10 = 20% Warning · 4/10 = 40% Action · 1/10 = 10% Within limit
K02	19/20 = 95% Warning · 17/20 = 85% Action · 20/20 = 100% Within limit
Q01	2/40 = 5.00% · 7/45 = 15.56% · 3/35 = 8.57%; contributions only
P01	Value 4 / base 2 · value 7 / base 3 · value 7 / base 2 (days)

29 / WORKFLOW

ONCO-RBQM-001 · Derive and confirm Q01

5. Derive ALL. In **Data & coverage → Trial ALL results**, open Q01 **Site breakdown**. With only S01 and S02, it shows **Incomplete coverage** and a provisional 9/85 ≈ 10.59%. S03 is missing at this cutoff, so there is no official signal. Enter 3/35 for S03 at the same origin and cutoff. The provisional row becomes 12/120 = 10%.

6. Confirm. Click **Confirm coverage and source**. Set **Source reference** to ONCO-0930. Under **Populations and definitions checked** choose **Yes, counts are additive, consistent and non-overlapping**, and save. Q01 · ALL now reaches **Action** at the inclusive 10% QTL. This calls for assessment of a possible systemic issue and its implications for participants and outcomes.

Pooling counts gives 100 × (2 + 7 + 3)/(40 + 45 + 35) = 10%. The simple mean is about 9.71% and gives sites equal weight despite different bases. Each eligible participant should contribute once to the overall denominator.

7. Correct a component. Under **Measurements & coverage**, **Edit** Q01/S02 and change 7 to 4, keeping 45 and the same dates. The result becomes 9/120 = 7.50% and **Warning**. Restore 7 before comparing with Excel. A numeric correction within the same compatible coverage recalculates ALL. Changes to origin, site set or definition can invalidate confirmation.

30 / WORKFLOW

ONCO-RBQM-001 · Reproduce the results with Excel

8. Prepare the workbook. Save the manual project as JSON. Use a separate session with an equivalent project saved before any measurements. In **Data & coverage**, use **1. Download Excel template (EN)** from that project. Keep the headers and Metadata. In Measurements, enter the nine K01/K02/Q01 rows from the manual table (metric, site, origin, cutoff, numerator, denominator). Leave value and base blank. Use site codes for Q01 components.

The seven raw rows are the complete fictional extraction for the selected P01 resolution workflow. K01 uses a separate, broader EDC listing. Keep K01 aggregated for this file. In Periods use three rows with site_id S01/S02/S03, period_start 2026-09-01, period_end 2026-09-30 and queries_complete YES. In Queries_Raw use the rows below. All have opened_date 2026-09-01, status CLOSED and snapshot_date 2026-09-30. Add no P01 rows to Measurements for these keys.

9. Compare. Use **2. Import Excel (.xlsx)**. In **Import preview**, expect 12 measurements, 3 coverage records and 7 queries. Inspect issues and results, select **Append new cutoffs**, tick the review confirmation and click **Apply import**. Reconfirm Q01 coverage. Compare with the manual table; the P01 medians are 4 = (2+6)/2, 7 and 7 = (5+9)/2 days. Their bases are 2, 3 and 2.

site_id	query_id → closed_date (one row per ID)
S01	S01-Q1 → 2026-09-03 · S01-Q2 → 2026-09-07
S02	S02-Q1 → 2026-09-04 · S02-Q2 → 2026-09-08 · S02-Q3 → 2026-09-11
S03	S03-Q1 → 2026-09-06 · S03-Q2 → 2026-09-10

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ONCO-RBQM-001 · Document and hand over

10. Evaluate and follow up. Under **Review signals**, click **Evaluate** for Q01 · ALL. In **Review signal / data quality**, select **Investigate**. Record that 12 of 120 due participants lack a usable assessment. Note that you will verify the due-assessment listing and investigate missing assessments across the three sites. Set **Next review** to 2026-10-09 and save. Review K01/S02 and K02/S02 separately using the same workflow.

Go to **5 · Decisions & actions** and click **Create action** in the documented review row. Record “Reconcile visit listings and review the next cutoff”, with Clinical Lead and due date 2026-10-09. Keep it open until evidence is available. Update status, evidence and effectiveness after the follow-up. The QTL result itself does not determine whether the trial is invalid.

11. Export. Open **Report** to inspect inputs, cutoff, signal, quality, ALL components and review/action records. Choose **Download HTML report** or **Print / save PDF**. Use **Save project JSON** or **Save JSON** for the editable project, including coverage confirmation and historical evaluations.

Interface screenshots

01 · Study settings

02 · Critical factors, controls and assigned owners

03 · Initial and residual risk ratings

04 · Indicator definition · identification, owner and method

05 · Indicator definition · population, numerator, denominator and source

06 · Indicator definition · limits, minimum base and team review

07 · Automatic query recipe and strict age threshold

08 · Numeric KPI with Median to closure

09 · Manual measurement · Q01 contribution for S01

10 · Q01 · Derive ALL from sites

11 · Site breakdown and provisional ALL

12 · Confirmation of ALL coverage and source

13 · Current values, threshold signals and data quality

14 · Excel import preview before applying

15 · Human assessment of the Q01 signal

16 · Documented assessment and linked action

17 · Review report and export controls

FIGURE 01 / ONCO-RBQM-001

Study settings



FIGURE 02 / ONCO-RBQM-001

Critical factors, controls and assigned owners

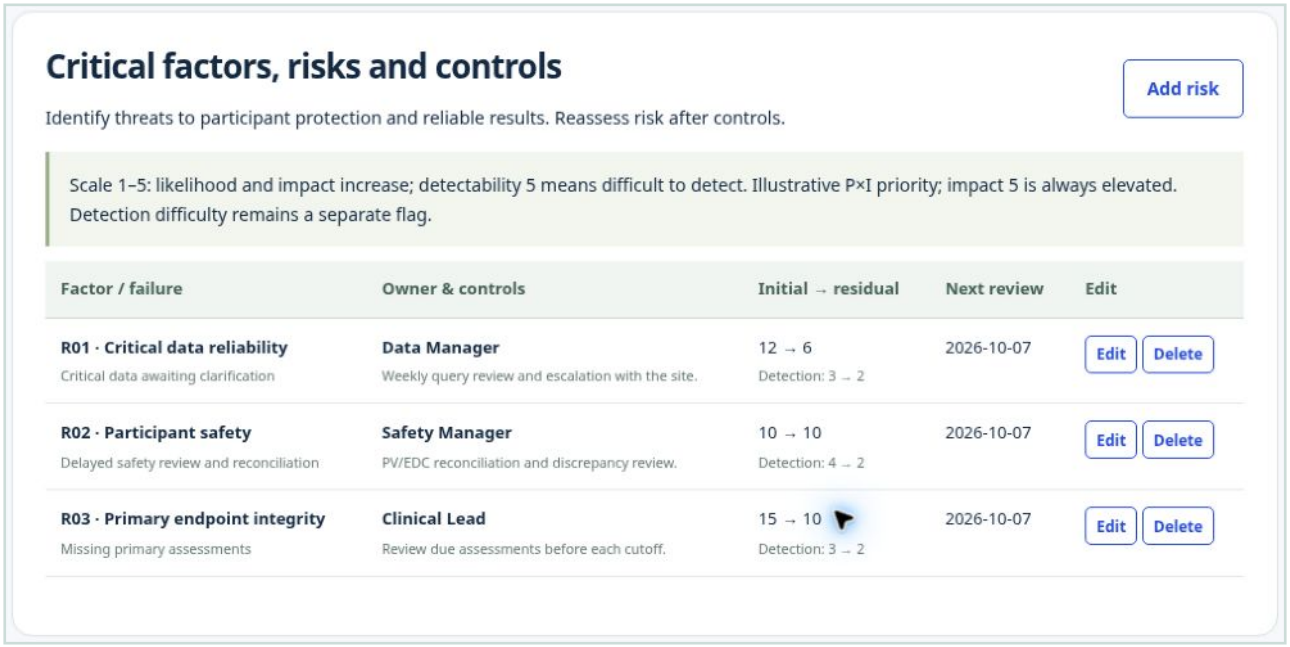


FIGURE 03 / ONCO-RBQM-001

Initial and residual risk ratings

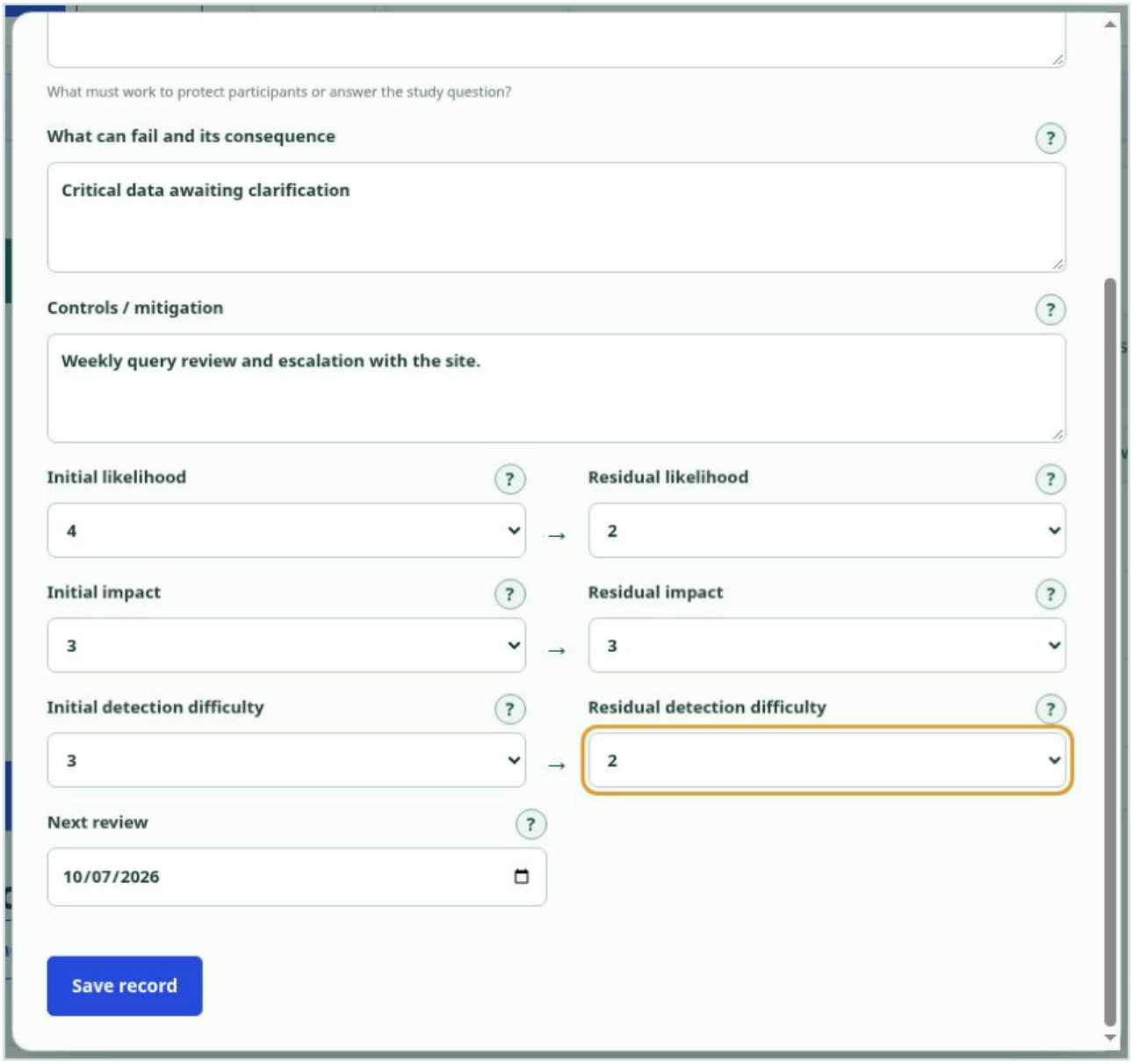


FIGURE 04 / ONCO-RBQM-001

Indicator definition · identification, owner and method



FIGURE 05 / ONCO-RBQM-001

Indicator definition · population, numerator, denominator and source

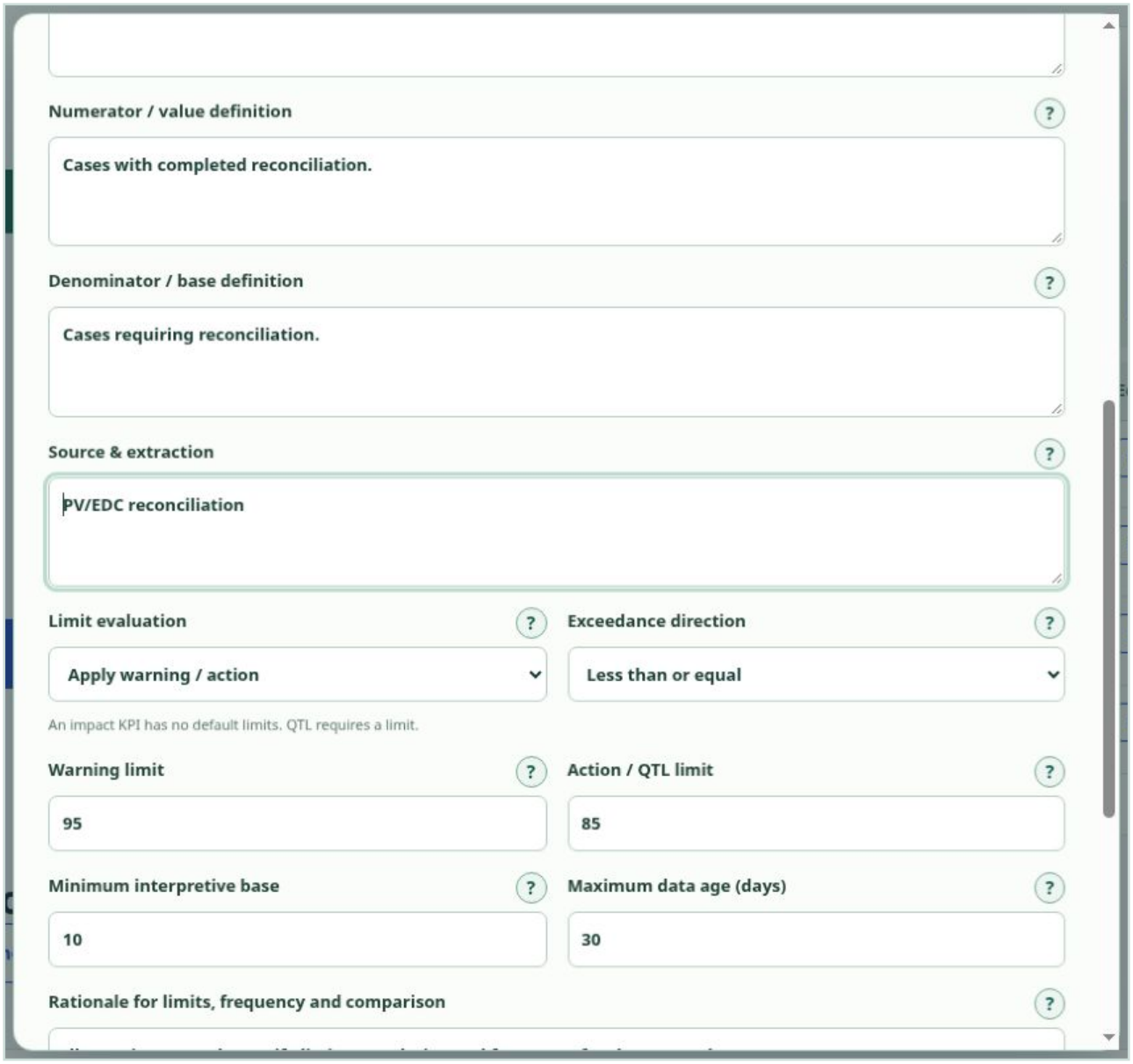


FIGURE 06 / ONCO-RBQM-001

Indicator definition · limits, minimum base and team review

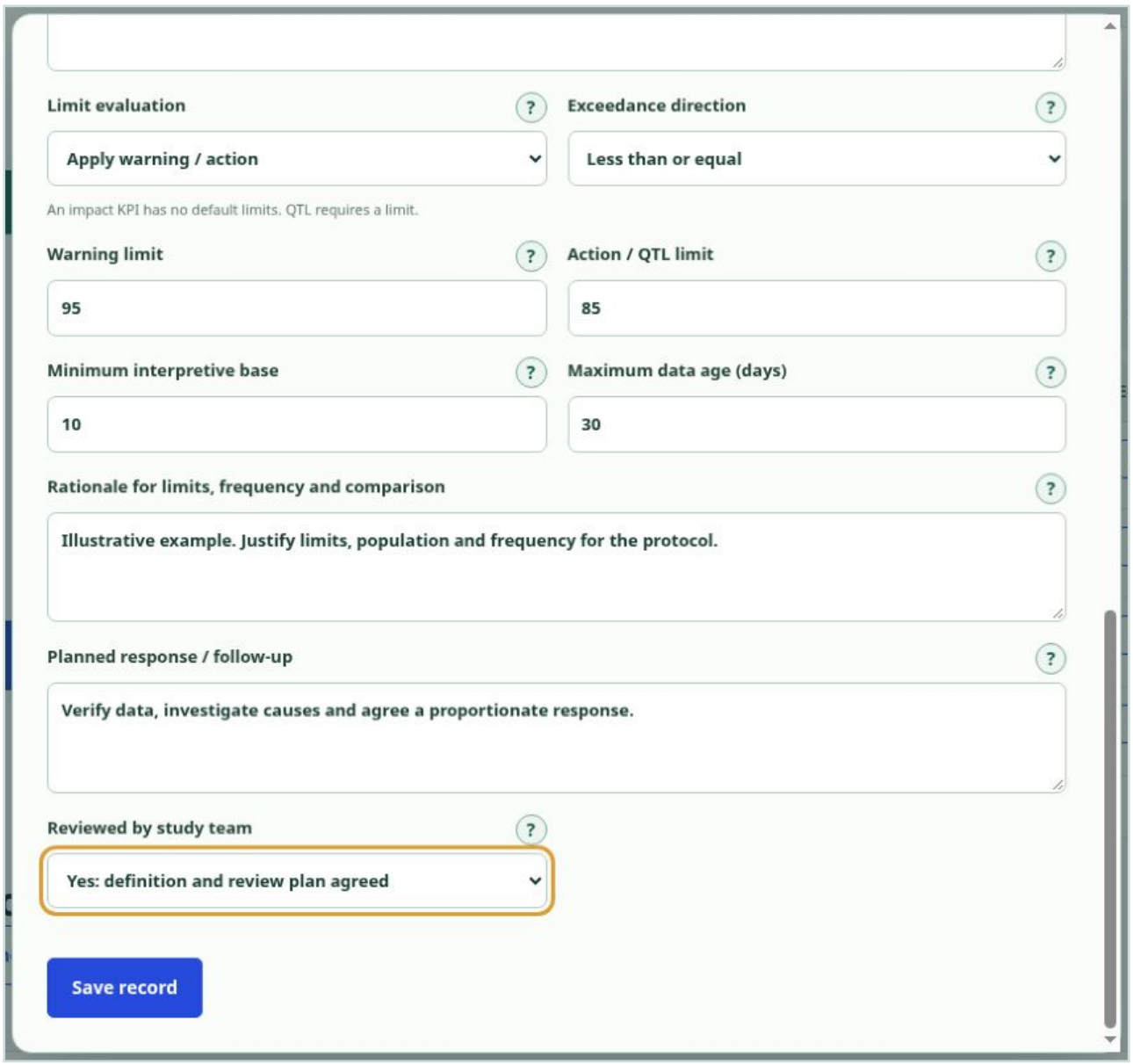


FIGURE 07 / ONCO-RBQM-001

Automatic query recipe and strict age threshold

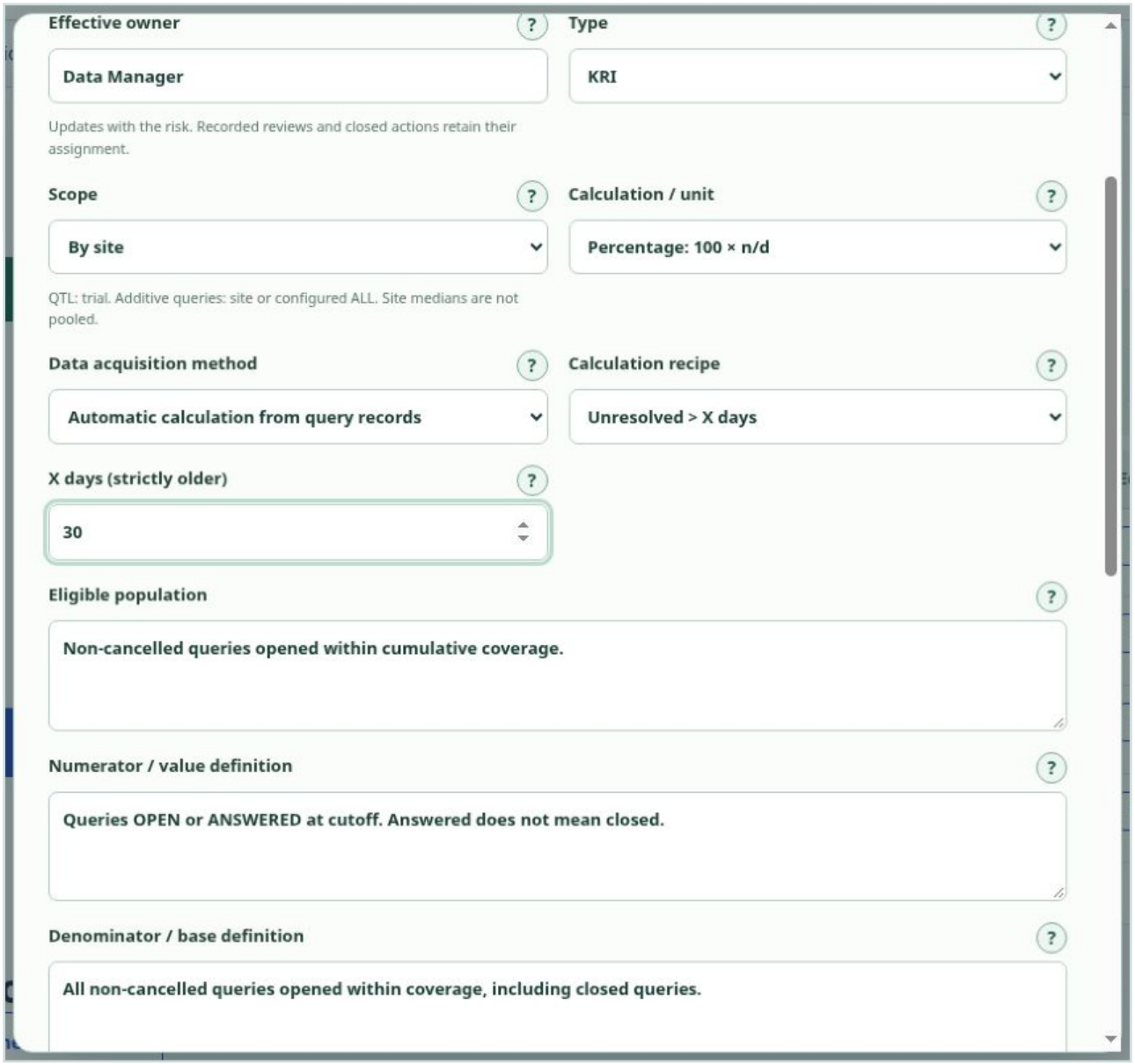


FIGURE 08 / ONCO-RBQM-001

Numeric KPI with Median to closure

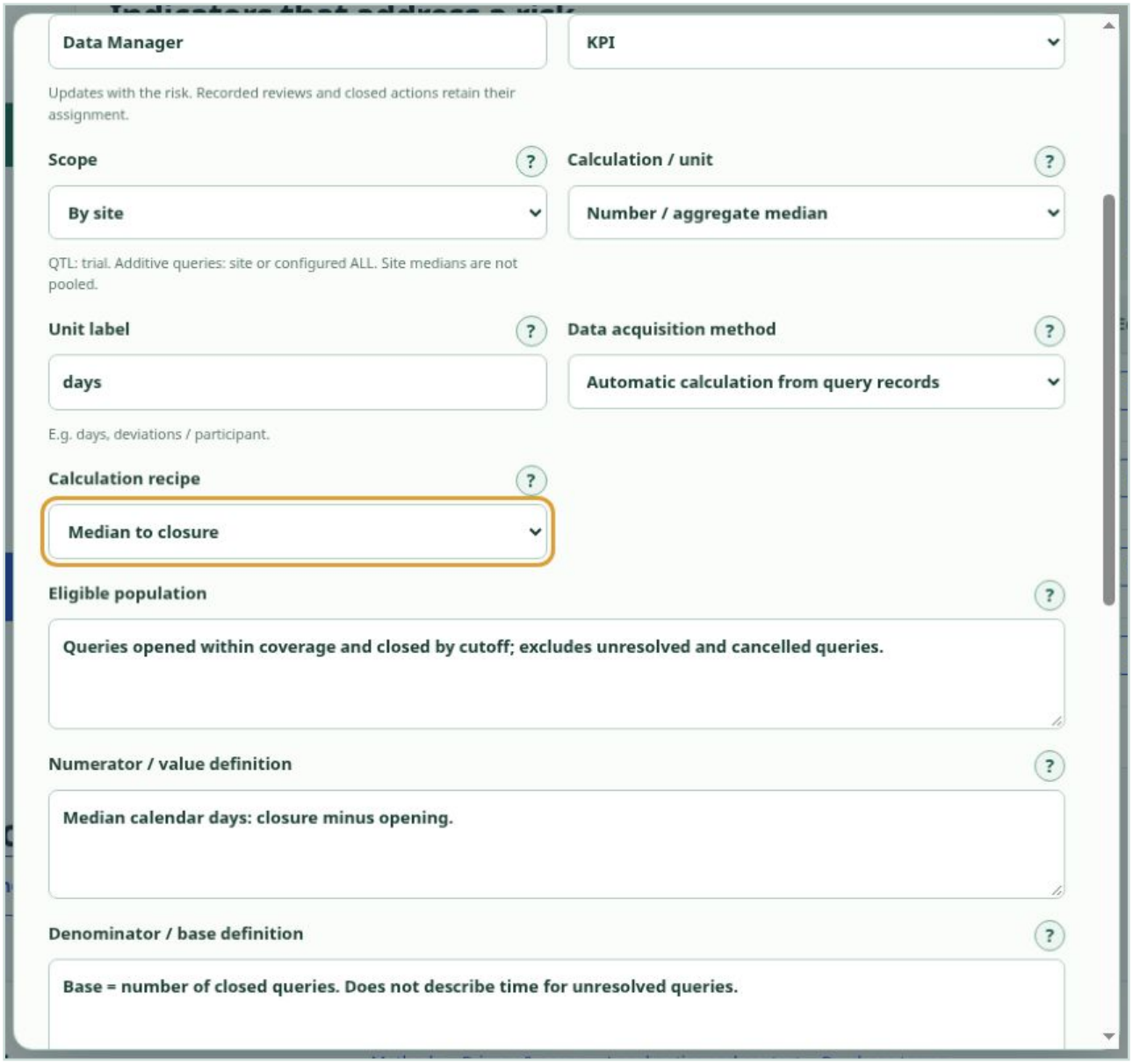


FIGURE 09 / ONCO-RBQM-001

Manual measurement · Q01 contribution for S01

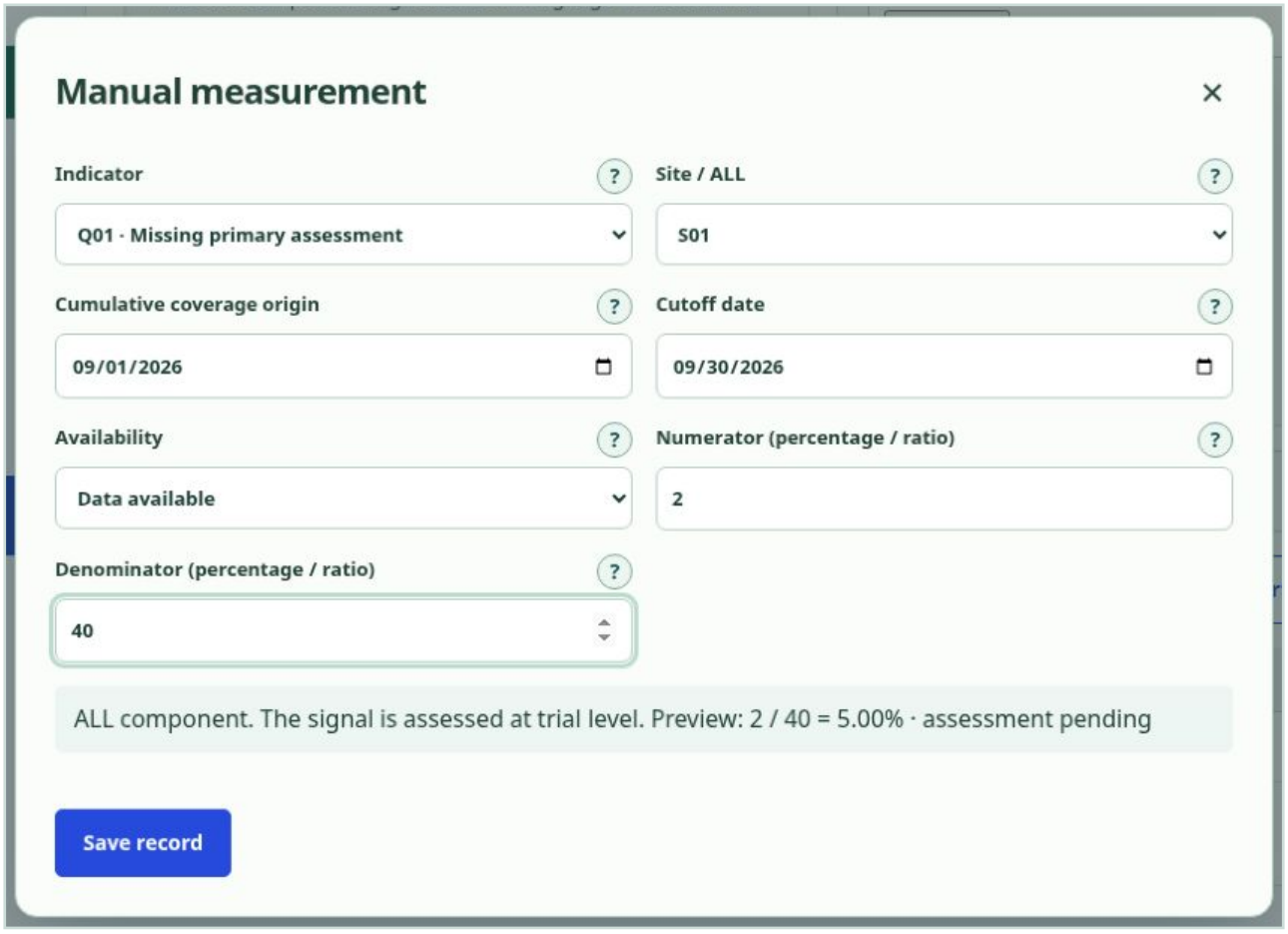


FIGURE 10 / ONCO-RBQM-001

Q01 · Derive ALL from sites

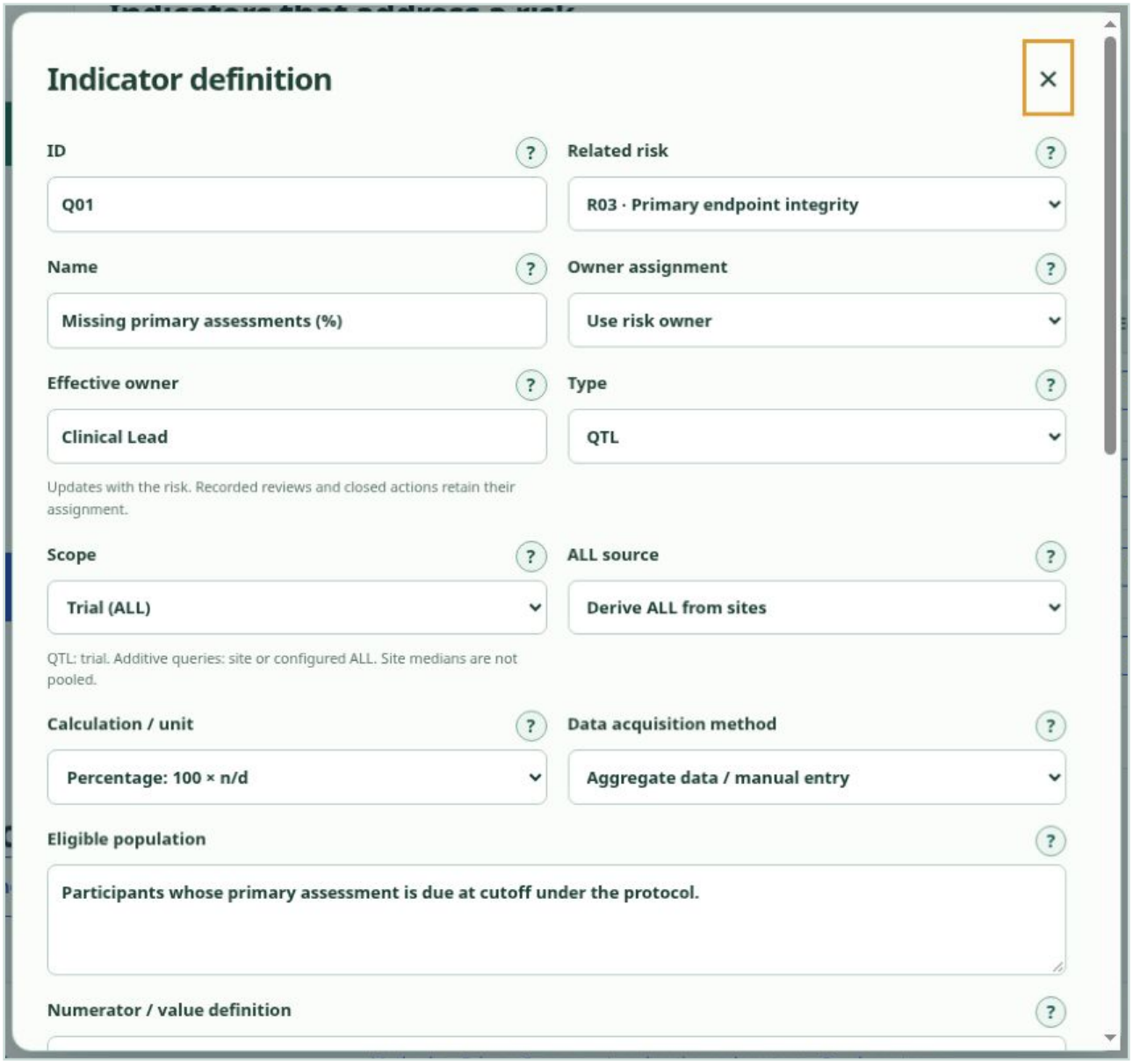
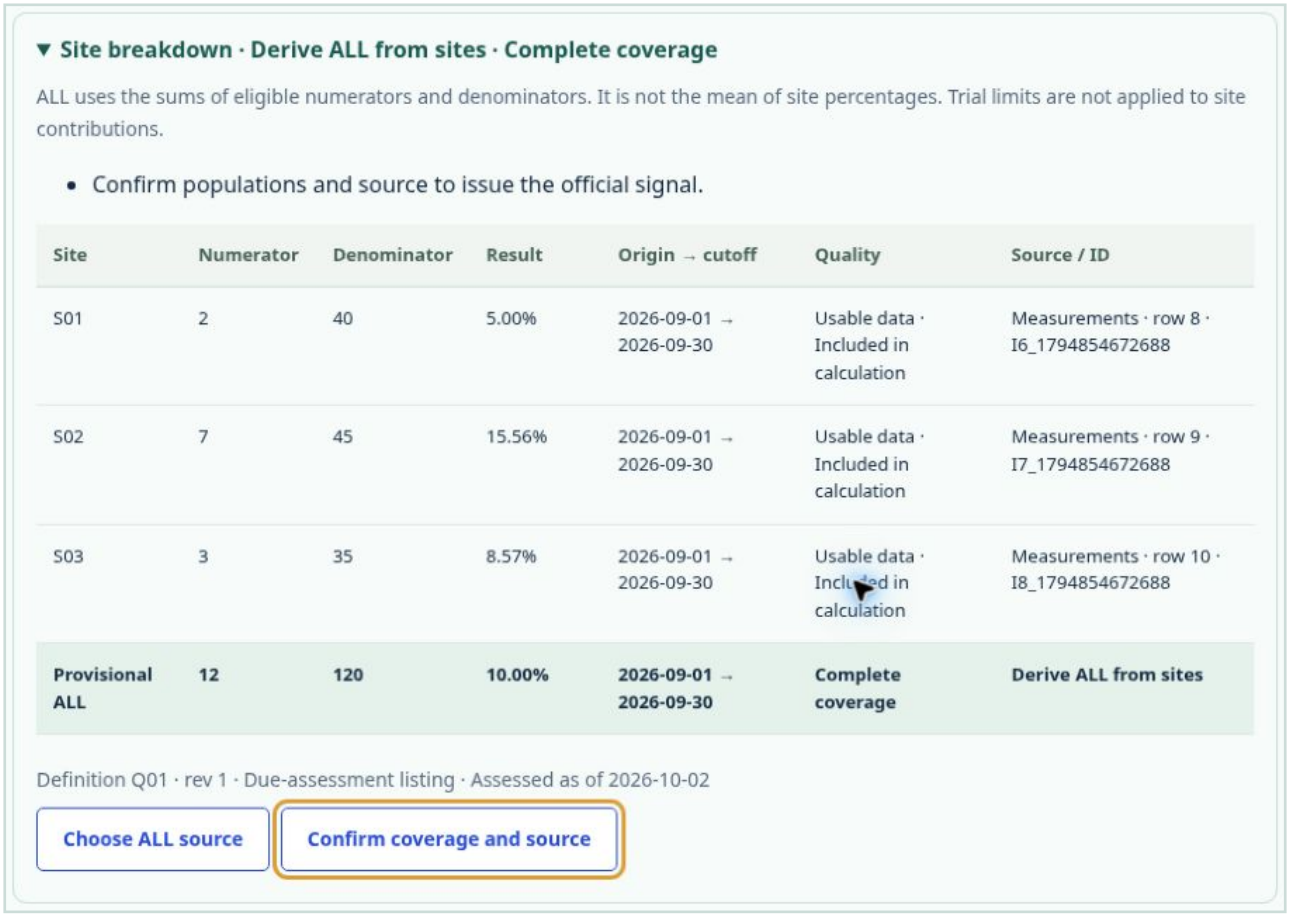


FIGURE 11 / ONCO-RBQM-001

Site breakdown and provisional ALL



▼ Site breakdown · Derive ALL from sites · Complete coverage

ALL uses the sums of eligible numerators and denominators. It is not the mean of site percentages. Trial limits are not applied to site contributions.

- Confirm populations and source to issue the official signal.

Site	Numerator	Denominator	Result	Origin → cutoff	Quality	Source / ID
S01	2	40	5.00%	2026-09-01 → 2026-09-30	Usable data · Included in calculation	Measurements · row 8 · I6_1794854672688
S02	7	45	15.56%	2026-09-01 → 2026-09-30	Usable data · Included in calculation	Measurements · row 9 · I7_1794854672688
S03	3	35	8.57%	2026-09-01 → 2026-09-30	Usable data · Included in calculation	Measurements · row 10 · I8_1794854672688
Provisional ALL	**12**	**120**	**10.00%**	**2026-09-01 → 2026-09-30**	**Complete coverage**	**Derive ALL from sites**

Definition Q01 · rev 1 · Due-assessment listing · Assessed as of 2026-10-02

Choose ALL source | Confirm coverage and source

FIGURE 12 / ONCO-RBQM-001

Confirmation of ALL coverage and source

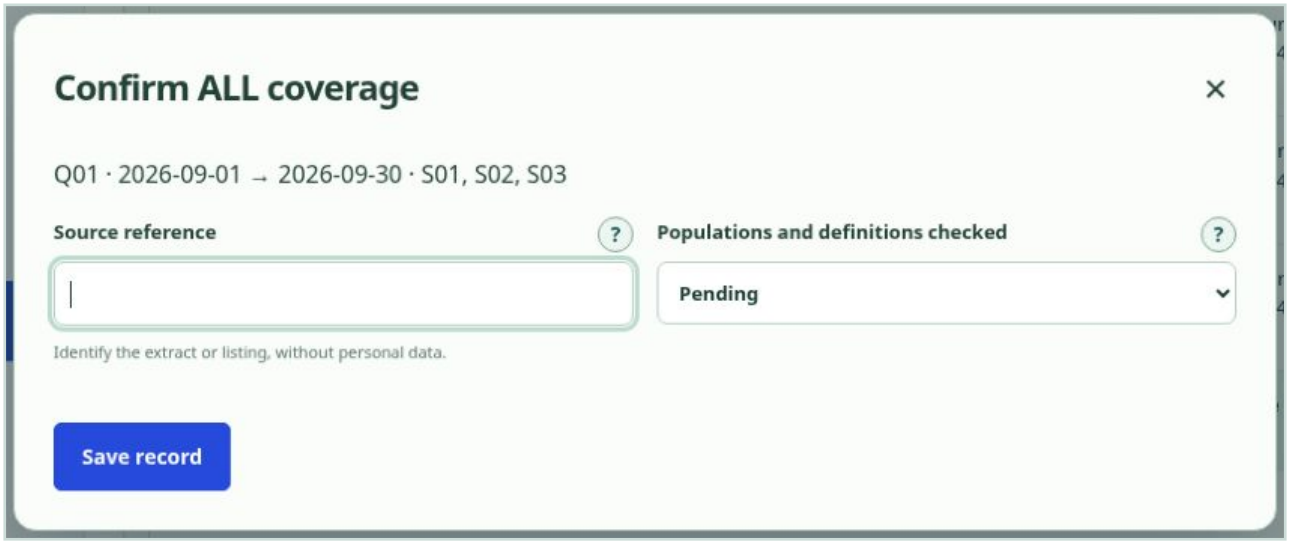


FIGURE 13 / ONCO-RBQM-001

Current values, threshold signals and data quality

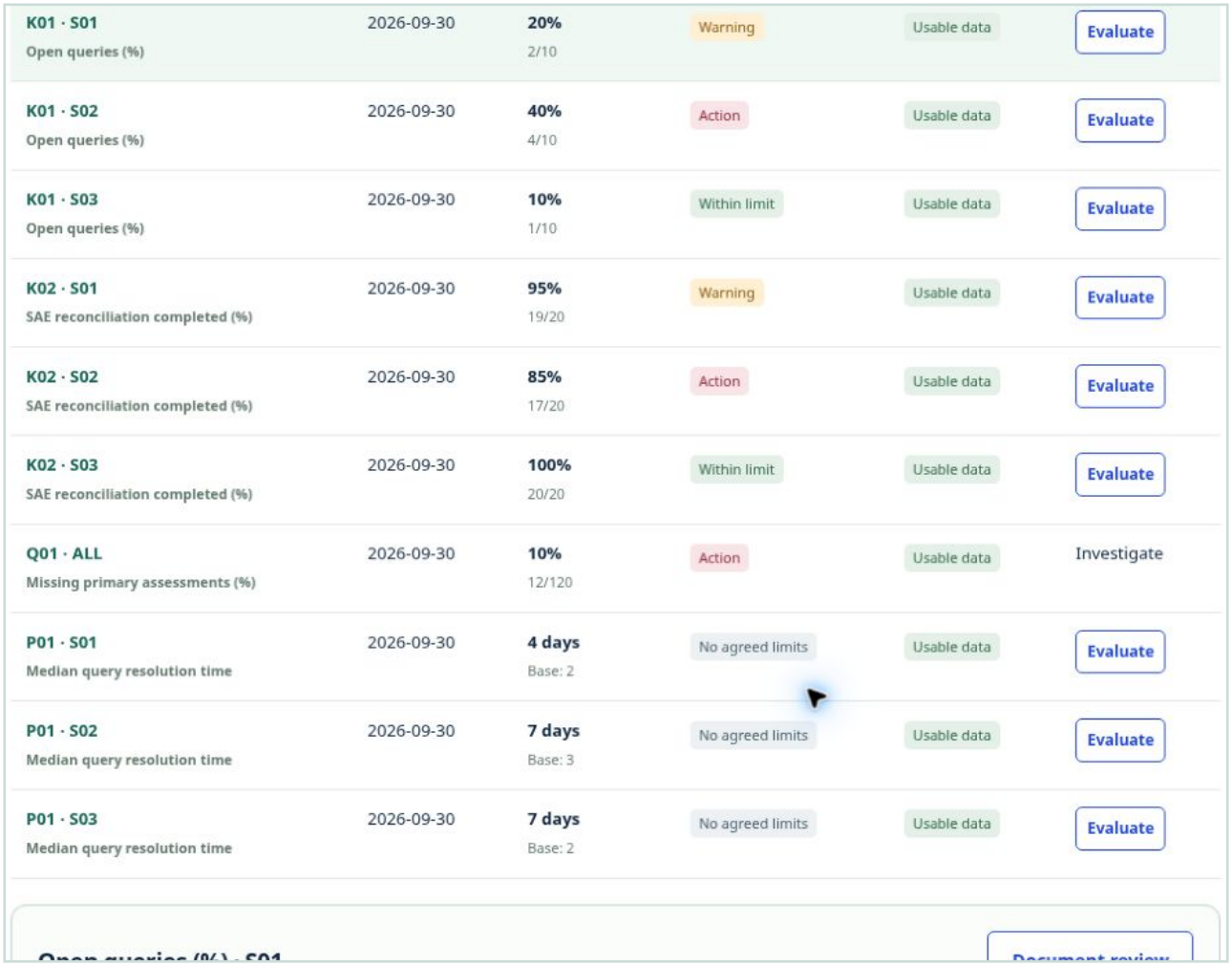
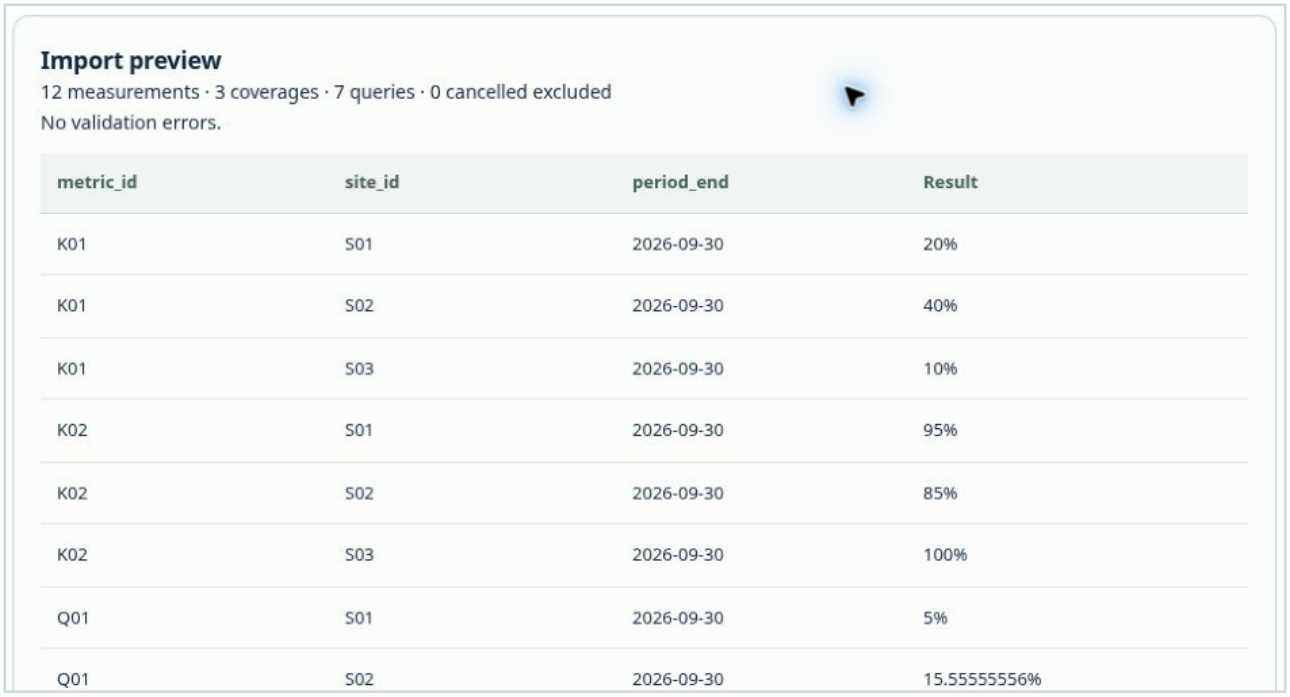


FIGURE 14 / ONCO-RBQM-001

Excel import preview before applying



Import preview

12 measurements · 3 coverages · 7 queries · 0 cancelled excluded

No validation errors.

metric_id	site_id	period_end	Result
K01	S01	2026-09-30	20%
K01	S02	2026-09-30	40%
K01	S03	2026-09-30	10%
K02	S01	2026-09-30	95%
K02	S02	2026-09-30	85%
K02	S03	2026-09-30	100%
Q01	S01	2026-09-30	5%
Q01	S02	2026-09-30	15.55555556%

FIGURE 15 / ONCO-RBQM-001

Human assessment of the Q01 signal

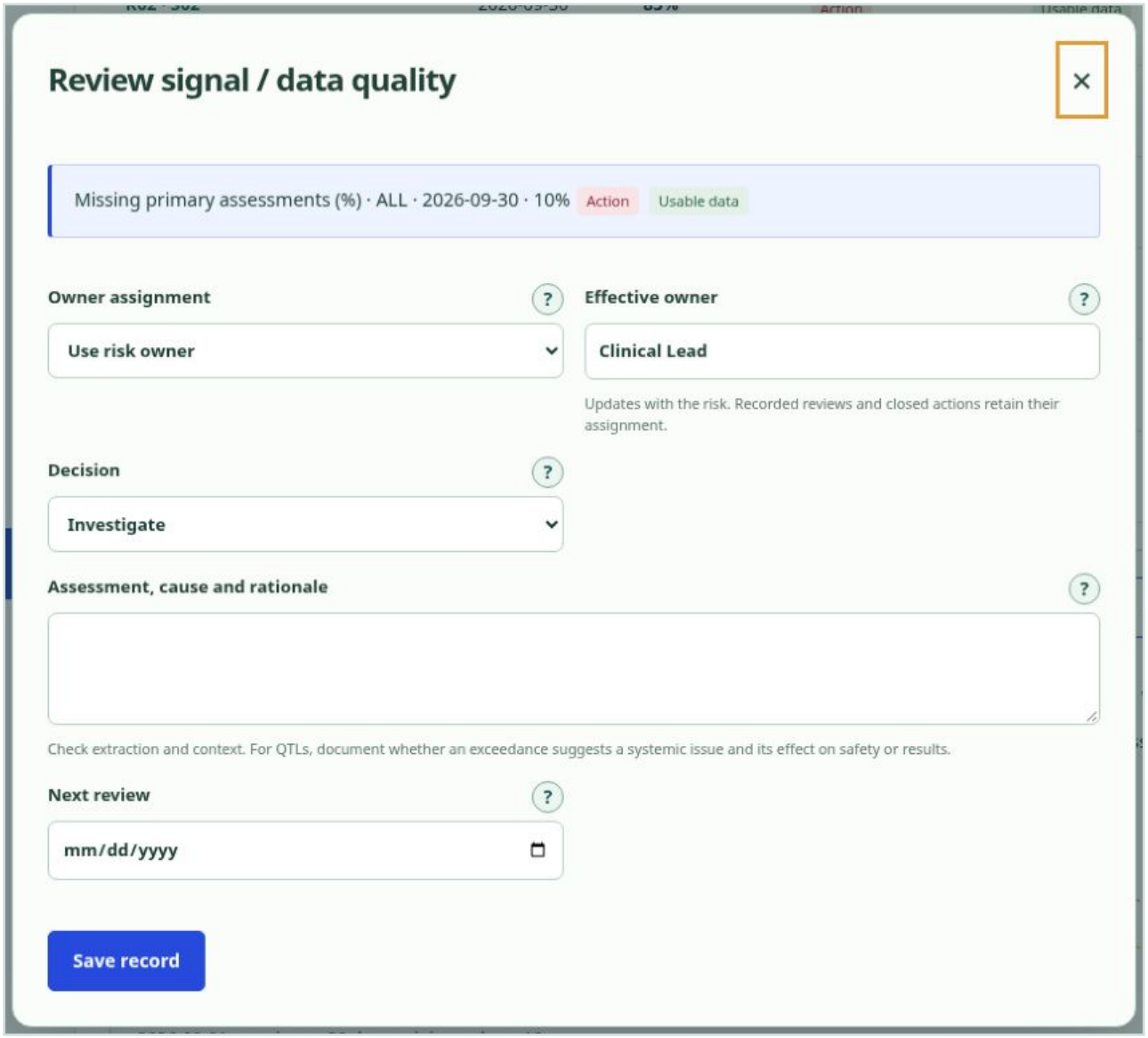


FIGURE 16 / ONCO-RBQM-001

Documented assessment and linked action

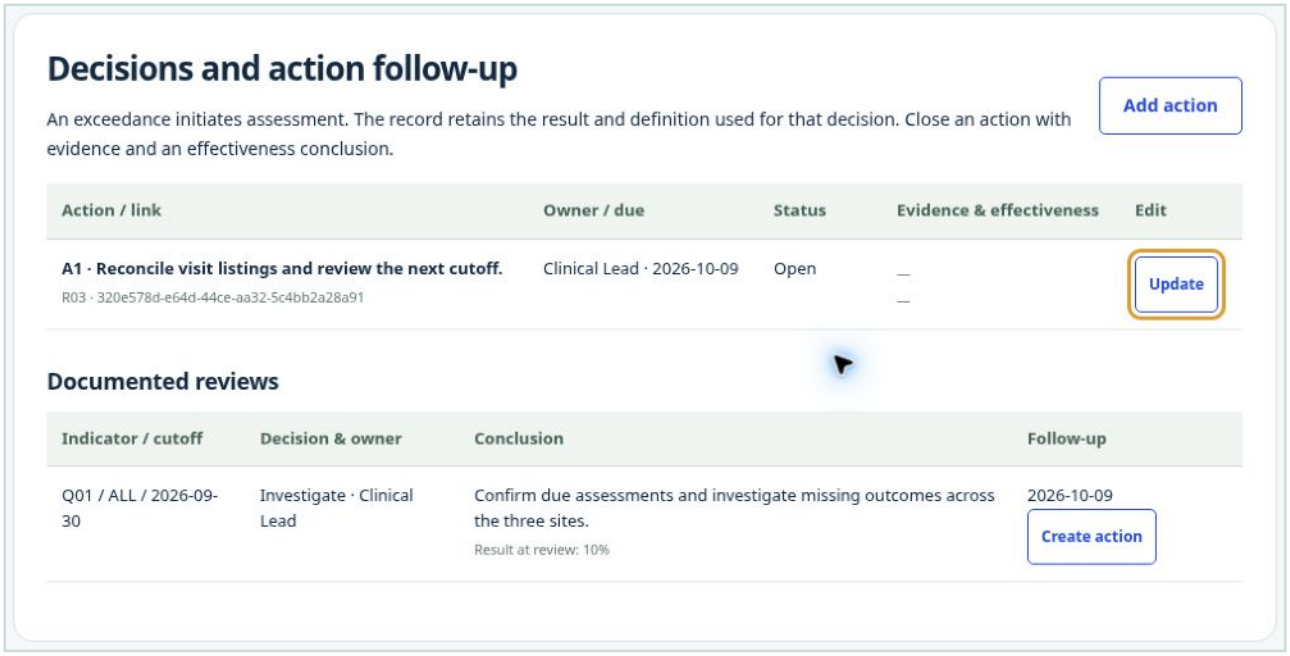


FIGURE 17 / ONCO-RBQM-001

Review report and export controls

