

NIRMITEE HEALTH / KNOWLEDGE LIBRARY

THE MEDTECH EVIDENCE GAP TO PMCF DECISION KIT

A practical, audit-oriented toolkit to turn clinical claims and residual risks into defensible post-market evidence plans.

FROM CLAIM → EVIDENCE GAP → STUDY METHOD → DATA QUALITY → PMCF
REPORT → CER / RISK UPDATE

Who it is for | Regulatory Affairs, Clinical Affairs, Medical Affairs, Quality, RWE, and MedTech product leaders

2026 EDITION • Includes an editable evidence-gap register, method selector and 90-day implementation tracker.

An educational planning aid, not a substitute for device-specific regulatory, clinical, statistical or legal review.

Executive brief | The gap between evidence and assurance

A clinical evaluation report may summarize what is known about a device. A PMCF program should answer what must continue to be learned from its use in the real world. The critical planning step between the two is often missing: an explicit, traceable **claim-to-evidence gap register**.

Under the EU Medical Device Regulation (MDR), PMCF is a continuous process that updates clinical evaluation and is addressed within post-market surveillance. The manufacturer is expected to proactively collect and evaluate clinical data on the CE-marked device in its intended use, confirming safety and performance over its expected lifetime and identifying emerging risks [1,2].

The practical question is not “Should we run a survey?” It is “Which unresolved clinical question must we answer, what decision depends on it, and which data-collection design can credibly answer it?”

What this kit helps your team do

- Translate claims, intended purpose, residual risks and CER conclusions into **answerable evidence questions**.
- Prioritize evidence gaps without mistaking a numerical score for regulatory sufficiency.
- Select among literature surveillance, surveys, registries, observational studies, device follow-up and targeted clinical investigations.
- Define the minimum dataset, endpoints, follow-up, bias controls and decision thresholds before technology procurement.
- Connect PMCF outputs back into CER, risk management, PMS/PSUR and product decisions.

Important gate: a future PMCF activity does not automatically cure a present lack of clinical evidence needed to demonstrate conformity. Escalate critical premarket / conformity gaps separately [1,3].

Use with the companion spreadsheet: “Evidence Gap Register” for prioritization, “Method Selector” for design choices, “Study Brief” for protocol framing, and “90-Day Plan” for execution.

Regulatory signals that make this timely

EU | Clinical evidence and PMCF remain lifecycle obligations

MDR Annex XIV Part B describes PMCF as proactive clinical-data collection and evaluation. MDCG 2020-7 provides a PMCF plan template and expects an objective, appropriate method, justified sample size / timescale / endpoints, consideration of bias, known limitations and a reporting timeline [1,2]. MDCG 2020-8 provides a corresponding PMCF evaluation report template [4].

EU | PMS is not a disconnected quality report

The December 2025 MDCG 2025-10 guidance emphasizes a systematic PMS process embedded in the QMS, with post-market findings used to update technical documentation, clinical evaluation and risk management as appropriate [5]. PMCF should be planned as part of that feedback system, not as a one-off data exercise.

US | RWD suitability is an explicit design issue

On **18 December 2025**, FDA issued final guidance on using real-world evidence for medical-device regulatory decision-making, superseding its 2017 guidance. It clarifies FDA evaluation of whether real-world data are sufficiently relevant and reliable for the regulatory question [6]. This is a separate US regulatory pathway, not an automatic substitute for EU PMCF requirements.

FDA discussed implementation at a **18 February 2026** industry town hall and stated that, from 17 February 2026, it generally anticipated sponsors would be ready to include newly recommended information in submissions [7].

Planning implication: evidence generation should begin with a decision question and a data-quality argument, not with a platform demo.

Sources: EU MDR Annex XIV [1], MDCG 2020-7 [2], MDCG 2020-8 [4], MDCG 2025-10 [5], FDA final guidance [6] and FDA town hall [7].

The 7-step evidence decision workflow

01**DEFINE**

Capture device family, intended purpose, claims, patient population, variants and expected lifetime.

02**MAP**

For every claim and risk, link current evidence: CER, investigations, literature, complaints, registries, PMS.

03**TRIAGE**

Identify uncertainty, clinical consequence and decision urgency. Apply the critical sufficiency gate first.

04**DESIGN**

Select the lowest-burden credible method that answers the question; justify design, sample and follow-up.

05**SPECIFY**

Lock endpoints, data dictionary, sources, missing-data approach, bias controls and human review.

06**EXECUTE**

Operate site / participant workflows, data review, issue escalation, analysis and evidence versioning.

07**CLOSE LOOP**

Interpret results; update PMCF report, CER, risk file, PMS/PSUR and action owners.

Decision discipline: Every proposed PMCF activity should map to at least one named gap, objective, measurable endpoint and downstream decision.

Six types of evidence gaps worth finding

Use this taxonomy when reviewing the CER, risk management file, PMS data and claims. One device can have several gaps; a single activity may address more than one if the design genuinely supports it.

ID	Gap	Typical trigger	Evidence planning response
G1	CLAIM SUPPORT	A performance or clinical-benefit claim is supported only by indirect, weak or non-device-specific data.	Claim-to-endpoint mapping and source appraisal.
G2	POPULATION FIT	Evidence underrepresents a subgroup, care setting, geography, operator or indication.	Population distribution and subgroup plan.
G3	DURATION	Follow-up is too short to assess a clinically relevant durability, recurrence or late-event question.	Lifetime / event window and follow-up feasibility.
G4	RISK UNCERTAINTY	A residual risk, complication or use error has uncertain real-world frequency or severity.	Risk-file linkage and event definitions.
G5	DEVICE / PRACTICE CHANGE	Variants, workflow changes or state-of-the-art evolution may affect generalizability.	Version / variant / comparator traceability.
G6	EMERGING SIGNAL	Complaints, literature or PMS trends raise a question that needs systematic clinical evaluation.	Signal definition, escalation and confirmatory data.

The classification is an Nirmitee planning framework, not an official MDR gap taxonomy. The objective is to force specificity before choosing a method.

Prioritize gaps without hiding critical risks

The following is a practical team prioritization heuristic, not a regulatory scoring system. First apply the **critical evidence gate**. If evidence may be insufficient to demonstrate conformity, if an unresolved safety signal exists, or if a regulator / notified body has imposed a specific obligation, escalate immediately irrespective of score.

Step 1 | Rate each gap from 1 to 5

Dimension	1 - low	3 - moderate	5 - high
Clinical consequence	Minor decision impact	Could materially affect use or benefit-risk	Potential serious patient / user harm
Evidence uncertainty	Strong direct evidence; small limitation	Mixed evidence or material missingness	Little suitable device-specific evidence
Decision urgency	No near-term decision	Relevant within next review cycle	Active submission, safety or product decision

Step 2 | Add the three scores (3-15)

Priority	Total	Recommended response
HIGH	12-15	Named cross-functional owner; design / escalation immediately.
MEDIUM	8-11	Resolve through a time-bound evidence activity and review.
LOW	3-7	Document rationale, monitor and reassess at defined intervals.

Do not rank by score alone: a single severe safety issue or conformity shortfall may override the total. The manufacturer must justify evidence sufficiency for its specific device.

Companion spreadsheet automatically calculates the total and suggested priority once all three ratings are entered.

Worksheet 1 | Claim-to-evidence gap matrix

Complete one row per distinct claim, risk or clinical question. Link to controlled document IDs and versions, not just narrative descriptions.

Field	Example entry / question
Device & intended purpose	Which model, variant, patient population, user and indication?
Clinical claim or residual risk	What is claimed, or what uncertainty could alter benefit-risk?
Evidence available	CER section; device-specific study; literature; PMS; registry; complaints.
Evidence limitation	Why is the evidence not yet sufficient for the question?
Gap category	G1 claim / G2 population / G3 duration / G4 risk / G5 change / G6 signal.
Decision at stake	CER update, risk acceptance, claim maintenance, labeling or study design.
Data to collect	Endpoint, covariates, adverse events, denominator, follow-up.
Owner & due date	Regulatory / Clinical / Quality accountable person and decision date.

Three questions that prevent vague gaps

- **Specificity:** Can you write the gap as a question that a dataset could answer?
- **Traceability:** Can you point to the exact claim, risk item or CER section it affects?
- **Actionability:** What decision changes when the new evidence arrives?

Bad gap: “Need more RWE.” **Better gap:** “In the indicated chronic-wound subgroup, do 12-week clinical outcomes and device-related events remain consistent with the current benefit-risk conclusion?”

Worksheet 2 | Choose the right evidence method

These are design options, not a regulatory hierarchy. Suitability depends on the question, risk, endpoint, device, available data and bias control. A combination is often appropriate [2].

Method	Best-fit question	Main design risk
Targeted literature review	State of the art; known risks; external context	Limited ability to prove own-device performance; publication bias
HCP / patient survey	Use patterns, usability, patient-reported experience	Recall, selection and non-response bias; weak denominators
Device registry	Longitudinal own-device safety and performance	Site selection, follow-up loss, confounding, completeness
Retrospective RWD study	Existing EHR / registry data for a specified question	Coding quality, device identification, missing confounders
Prospective observational study	Predefined endpoints and follow-up in routine care	Operational burden, missing data, selection bias
Extended follow-up cohort	Late outcomes and durability for known recipients	Attrition and survivor bias
Comparative study / investigation	Relative effect or unresolved higher-stakes claim	Comparator selection, feasibility, ethics, cost

Selection rule: choose the method only after defining the clinical question, endpoint, expected event frequency, minimum meaningful difference / precision, required follow-up and credible analysis population.

The RWD fitness-for-purpose checklist

FDA's December 2025 guidance emphasizes the relevance and reliability of RWD for the specific regulatory question [6]. The following practical checks are useful for EU PMCF planning as well, without implying that the two frameworks are identical.

Check	Evidence needed before go-live
Device identification	Can every record be linked to the correct model, variant, lot / UDI where available?
Population match	Does the source represent intended users, indications, subgroups and care settings?
Endpoint capture	Are outcomes clinically meaningful, consistently defined and available at required times?
Exposure & denominator	Do you know who received the device, when and for how long?
Missingness	What is missing, why, and how will it affect interpretation?
Confounding & bias	Which baseline variables and comparator information can be captured?
Safety ascertainment	How are device events, complaints, serious events and reporting routes distinguished?
Data provenance	Can source, transformation, corrections and audit history be reconstructed?
Privacy / permissions	Are consent, lawful basis, agreements, access and transfer controls appropriate?
Analysis reproducibility	Can the dataset cut, protocol, code and output version be recreated?

A large dataset is not automatically decision-grade evidence. A smaller, well-characterized dataset may be more useful than a larger dataset that cannot identify the device or capture the endpoint.

Worksheet 3 | One-page PMCF study brief

Use this to align Regulatory, Clinical, Medical, Quality, Statistics and Digital before drafting a full protocol. The final protocol and documentation must meet applicable requirements [1,2].

Element	Write the decision-ready answer
Evidence question	What uncertainty will this activity resolve?
Device scope	Models / variants, intended purpose, indication, users and population.
Objective & hypothesis	What will be estimated or compared, and why does it matter?
Design / method	Registry, survey, prospective cohort, retrospective RWD, etc.; rationale.
Endpoints	Primary / secondary clinical outcomes and safety definitions.
Follow-up	Timepoints linked to clinical relevance and expected device lifetime.
Sample justification	Precision, expected event rate, statistical power or other rationale.
Eligibility & sites	Inclusion / exclusion criteria, representativeness, site mix.
Bias / missing data	Selection, confounding, attrition and missingness mitigation.
Data / digital workflow	eCRF, ePRO, EHR extraction, monitoring, query handling and audit trail.
Escalation	Safety signals, deviations, data quality thresholds and owners.
Outputs & decision	PMCF report date, CER / risk updates and claim / label implications.

Decision to record: Approve / Revise / Escalate. Include approver, date, document ID and version.

Worked example | Hypothetical wound-therapy device

Illustrative only. A manufacturer of a CE-marked wound-therapy device has a clinical claim supported by a controlled investigation and published evidence. PMS feedback suggests that outcomes in a subgroup treated in community settings may be less well characterized. This is a fictional teaching example, not a product claim or recommended protocol.

Step	Illustrative decision
Claim / risk	Clinical performance and tolerability within the stated intended use.
Evidence gap	Limited device-specific follow-up for the subgroup treated outside specialist centers.
Decision question	Are subgroup outcomes and device-related events consistent with the current clinical evaluation?
Gap classification	G2 population fit + G3 follow-up; check for G4 risk uncertainty.
Method choice	Prospective multicenter observational follow-up or fit-for-purpose registry.
Minimum dataset	Device identifier, indication, baseline severity, care setting, use duration, clinical endpoint, events, follow-up.
Bias controls	Consecutive enrollment where feasible, pre-specified covariates, missingness monitoring, site mix.
Success / escalation	Pre-specified clinical interpretation criteria; investigate unexpected safety or performance signals.
Close the loop	PMCF evaluation report → CER review → risk file and PMS actions where indicated.

Do not copy sample sizes, endpoints or acceptance thresholds from this example. These must be clinically and statistically justified for the actual device.

Design the evidence workflow before buying tools

A PMCF or RWE platform should implement a validated, controlled workflow; it should not define the clinical question. Consider the full operating model below.

Workflow stage	Minimum digital capability	Responsible role
Plan	Protocol, SoA, forms, versioned data dictionary, approvals	Clinical / Statistics / RA
Collect	eCRF, device ID, site / patient workflows, optional ePRO	Sites / Investigators
Control	Role-based access, edit checks, queries, deviations, audit trail	Data Management / Quality
Monitor	Completeness, visit adherence, event trends, risk-based review	Clinical Ops / Safety
Analyze	Locked extract, reproducible dataset, analysis traceability	Statistics / Medical
Report	PMCF report evidence package, version references, approvals	Clinical / RA / Quality
Update	CER, risk file, PMS/PSUR and product actions as appropriate	Regulatory / Quality / Product

Integration questions to ask

- Will device and patient identifiers be consistently linked across site systems and longitudinal follow-up?
- Can reviewers trace a figure in the PMCF report back to source data and a specific analysis version?
- How will a safety signal travel from study data into the established vigilance / PMS process?
- Who owns the decision to update the CER, risk controls, instructions for use or follow-up plan?

Technology is the connective tissue. Evidence credibility comes from clinical design, data quality, governance and traceable decisions.

Worksheet 4 | A realistic first 90 days

A 90-day program should produce a defensible plan and a controlled pilot, not promise mature long-term clinical evidence in three months.

Window	Deliverable	Exit criterion
Days 1-15	Device / claim inventory, CER and risk review, source mapping	Every priority claim / risk has a named evidence source and owner.
Days 16-30	Gap register, critical gate, cross-functional triage	High-priority gaps approved; conformity issues escalated.
Days 31-45	Method comparison, feasibility and data source assessment	Preferred design justified; known biases documented.
Days 46-60	Study brief, endpoints, data dictionary, governance / privacy review	Protocol-development inputs approved by relevant functions.
Days 61-75	eCRF / ePRO / registry workflow configuration, test and training	Controlled pilot environment; traceability and data checks tested.
Days 76-90	Pilot readiness review, first-site workflow rehearsal, reporting calendar	Go / no-go decision, owners, risks and monitoring cadence recorded.

Weekly management review

- New critical evidence gaps or emerging safety signals.
- Protocol decisions awaiting Clinical / Regulatory / Quality approval.
- Site readiness, data completeness and follow-up feasibility.
- Any change to scope, endpoint, model / variant or intended-use assumptions.

The companion 90-Day Plan sheet contains editable workstreams, owners, target dates, status and evidence of completion.

Close the loop | From PMCF findings to action

The most common operational failure is treating the PMCF evaluation report as the end of the process. Its value comes from decisions it enables and records it updates. EU MDR and MDCG guidance connect post-market clinical evidence to clinical evaluation, risk management and PMS [1,4,5].

Finding	Review / action	Controlled record
Performance consistent with expectations	Confirm benefit-risk position; continue planned surveillance	PMCF report + CER review
New subgroup limitation	Assess claims, labeling, clinical interpretation and follow-up	CER + PMCF plan + risk file
Unexpected adverse event pattern	Safety / vigilance assessment and escalation as applicable	PMS / vigilance + risk management
Data too incomplete to conclude	Assess root cause; revise data capture or study design	Data-quality CAPA / protocol amendment
New variant or usage pattern	Evaluate applicability of existing evidence and new questions	Change control + CER / PMCF review

The evidence traceability chain

**CLAIM / RISK ID → GAP ID → PMCF OBJECTIVE → METHOD / PROTOCOL →
DATASET / ANALYSIS → FINDING → APPROVAL → CER / RISK / PMS ACTION**

Maintain explicit document IDs, dates and versions at each link. This is a practical design recommendation, not a claim that a single software system is legally mandated.

12-point PMCF plan review checklist

Use this before approving a PMCF activity or engaging a data-platform partner. Check each item and retain the supporting reference.

#	Question to answer before approval
01	Is the intended purpose, device scope, variant and patient population unambiguous?
02	Does each objective trace to a CER conclusion, clinical claim, residual risk or PMS signal?
03	Have current evidence sources been critically appraised, including their limitations?
04	Have any gaps affecting present conformity or safety been escalated separately?
05	Is the selected method appropriate for the clinical question and risk?
06	Are endpoints, event definitions, comparator / context and follow-up pre-specified?
07	Is the sample / precision / power rationale defensible for the proposed inference?
08	Are selection bias, confounding, missingness and attrition addressed?
09	Can the data source identify the actual device and relevant patient population?
10	Are privacy, ethics, governance, safety escalation and data ownership defined?
11	Are analysis, PMCF report timing and review responsibilities documented?
12	Are CER, risk-management and PMS / PSUR feedback actions explicitly assigned?

Decision: ☐ Approved ☐ Revision required ☐ Escalate for clinical / regulatory review

Approver: _____ Date: _____ Document version: _____

Sources, scope and next step

Regulatory sources reviewed for this October 2026 edition. The EU MDCG documents are non-binding guidance; the applicable law, device classification, intended purpose, market, standards and notified-body expectations require device-specific interpretation.

Primary sources

[1] EU MDR 2017/745, Annex XIV

<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02017R0745-20250110>

[2] MDCG 2020-7 PMCF plan template, Apr 2020

https://health.ec.europa.eu/document/download/a5cdb303-c782-4010-8723-7d389af678f7_en?filename=md_mdcg_2020_7_guidance_pmcf_plan_template_en.pdf

[3] MDCG 2020-6 sufficient clinical evidence, Apr 2020

https://health.ec.europa.eu/system/files/2020-09/md_mdcg_2020_6_guidance_sufficient_clinical_evidence_en_0.pdf

[4] MDCG 2020-8 PMCF evaluation report template, Apr 2020

https://health.ec.europa.eu/system/files/2020-09/md_mdcg_2020_8_guidance_pmcf_evaluation_report_en_0.pdf

[5] MDCG 2025-10 PMS guidance, Dec 2025

https://health.ec.europa.eu/document/download/a9ad86b7-1b8e-4bae-beb4-48b2b3ed2f05_en?filename=mdcg_2025-10_en.pdf

[6] FDA RWE for medical devices final guidance, Dec 18 2025

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-real-world-evidence-support-regulatory-decision-making-medical-devices>

[7] FDA RWE town hall, Feb 18 2026

<https://www.fda.gov/medical-devices/medical-devices-news-and-events/town-hall-use-real-world-evidence-support-regulatory-decision-making-medical-devices-final-guidance>

NEXT STEP | Run a 60-minute evidence-gap mapping workshop with Clinical, Regulatory, Quality and Digital. Leave with one prioritized question, a method shortlist and a draft data map.

About Nirmitee Health Nirmitee Health supports Pharma and MedTech teams with digital evidence workflows, data infrastructure, interoperability and regulated product engineering. Clinera can support configured EDC, ePRO and registry workflows where appropriate; clinical and regulatory decisions remain with the manufacturer and qualified professionals.

Nirmitee Health • nirmitee.health • Educational material; not regulatory, medical, statistical or legal advice.