

Endpoint and Biomarker Starter Map for Pain Trials

A practical starter framework to align endpoint hierarchy and biomarker logic with decision milestones.

Step 1 - Define decision context

- Milestone: IND, Phase 1 readout, Phase 2 design, or payer evidence package.
- Decision owner: clinical lead, translational lead, BD, or mixed group.
- Decision question: what must be true to move forward?

Step 2 - Build endpoint hierarchy

Primary endpoint

- One endpoint tightly linked to the key clinical decision.
- Timepoint aligned to expected onset and durability.

Key secondary endpoints

- Support interpretation of the primary result.
- Capture clinically meaningful dimensions without overloading protocol risk.

Exploratory endpoints

- Inform next design iteration.
- Avoid mixing exploratory signals into primary claim language.

Step 3 - Map biomarker use-cases

For each biomarker candidate, define:

- Mechanistic relevance: why this signal should move.
- Decision utility: what decision changes if it moves.
- Feasibility: sample timing, assay reliability, and operational burden.
- Failure mode: how a null or noisy result should be interpreted.

Step 4 - Create interpretation matrix

For each endpoint and biomarker pair, predefine:

- Expected direction of effect.
- Minimum signal threshold for confidence.
- Possible discordant outcomes and likely explanations.

Step 5 - Stress-test design

- Are endpoints sensitive to placebo/context effects?

- Is measurement frequency appropriate for expected dynamics?
- Are inclusion criteria aligned with mechanism and endpoint sensitivity?
- Is missing data risk addressed in protocol logic?

Step 6 - Translate to communication

- Draft one evidence-backed claim statement per major endpoint.
- Add confidence level and uncertainty notes.
- Separate "supported now" from "hypothesis for follow-up" language.

One-page output template

Include five blocks:

- Program goal and milestone
- Endpoint hierarchy table
- Biomarker use-case table
- Interpretation matrix
- Risks and next actions

NociWise note: B2B consulting only. This framework supports research strategy decisions and scientific communication.