

Pain Program Translational Risk Checklist

Use this checklist to pressure-test translational logic before high-cost clinical and communication decisions.

1) Program framing

- Define the pain condition and subgroup precisely.
- State the intended mechanism-to-phenotype link in one sentence.
- Specify the near-term decision this work must support.

2) Biological rationale

- List supporting preclinical and human evidence separately.
- Flag where evidence is associative versus causal.
- Note key assumptions that still need validation.

3) Endpoint logic

- Define the primary endpoint and why it is decision-relevant.
- Confirm secondary endpoints support interpretation, not noise.
- Map timing of endpoint collection to expected biology and effect window.

4) Biomarker strategy

- Clarify biomarker role: enrichment, response monitoring, or mechanistic support.
- Identify interpretation risks for each biomarker candidate.
- Record operational feasibility constraints early.

5) Trial signal integrity

- List key confounders likely to dilute signal.
- Define minimum meaningful effect assumptions.
- Identify design choices most likely to create false negative outcomes.

6) Competitive and narrative risk

- Compare your claim set with publicly visible competitor claims.
- Flag claims that cannot yet be substantiated with current evidence.
- Prepare plain-language uncertainty statements for investor and partner use.

7) Decision readiness

- Rank top 3 unresolved risks by impact and urgency.
- Assign owner and deadline for each unresolved risk.
- Define go, no-go, and hold criteria before milestone meetings.

Quick scoring grid

Score each section 1-5 for readiness:

- 1 = weak, major unresolved risk
- 3 = partial, needs focused evidence work
- 5 = strong, decision-ready for current milestone

Use scores to prioritize where to run a short translation sprint first.

NociWise note: B2B consulting only. This checklist is for strategy planning, not patient care.