

# Strategic Fit & Resource Capacity Checklist for Innovators

For evaluating PCP and PPI opportunities

## 1) Strategic Alignment

### 1.1 Corporate Strategy Fit

- Does the tender align with our company's long-term strategic priorities?
- Does it target a therapeutic area / clinical domain within our focus portfolio?
- Does it strengthen our positioning in a priority EU market?
- Does participation enhance credibility with HTA bodies, payors, or reference sites?
- Does it align with our innovation positioning (first-in-class vs incremental improvement)?

### Decision Flag:

- Strong strategic fit
- Opportunistic fit
- Outside core strategy

## 2) Technology Readiness & Product Maturity

### 2.1 TRL Compatibility

- Is our current Technology Readiness Level (TRL) aligned with the call requirements?

PCP:  Early TRL (3–6) acceptable

PPI:  Near-market (TRL 7–9) required

- Can required TRL milestones be realistically achieved within tender timelines?
- Are required validation steps technically feasible?

### 2.2 Product Development Roadmap

- Does the PCP/PPI fit into our existing development roadmap?
- Does it accelerate planned validation or create roadmap diversion?
- Are requested features already planned or would they require major pivot?
- Does participation create technical debt or complexity?

**Risk Indicator:**

- High roadmap disruption
- Moderate adaptation
- Fully aligned

**3) Scientific & Evidence Generation Value****3.1 Clinical Evidence**

- Does the opportunity support structured clinical validation?
- Does it provide access to reference clinical sites?
- Will generated data support CE marking / MDR compliance?
- Does it support HTA-relevant outcomes (cost-effectiveness, real-world data)?

**3.2 Publication & Credibility**

- Is co-publication possible?
- Does it enable real-world evidence (RWE) generation?
- Does it strengthen discussions with payors?

**Strategic Value Rating:**

- High evidence leverage
- Moderate validation value
- Limited added evidence benefit

**4) Regulatory & Compliance Alignment**

- Does the tender support regulatory validation (e.g., MDR / IVDR conformity)?
- Are regulatory expectations clearly defined?
- Are there additional certification requirements?
- Are IP ownership and foreground/background IP terms acceptable?
- Are data governance and GDPR obligations manageable?

Red Flags:

- Unclear IP ownership
- Excessive data-sharing obligations
- Regulatory ambiguity

**5) Market Access & Commercial Strategy Fit**

- Does this opportunity allow for commercialization (in a new market / indication)?
- Does it strengthen relationships with payors or health systems?
- Is there a credible path from pilot to scale?
- Does the PPI imply committed procurement volume?
- Does it improve reimbursement positioning?

Commercial Leverage:

- High market entry acceleration
- Moderate signal value
- Limited commercialization pathway

**6) Eligibility & Legal Requirements**

6.1 Legal Entity & Geographic Criteria

- Are we eligible as a legal entity (SME, large enterprise, EU-based, etc.)?
- Is EU or associated country establishment required?
- Are there restrictions on subcontracting?

6.2 Consortium Requirements

- Is consortium participation mandatory?
- Do we have suitable partners identified?
- Are roles and responsibilities clearly defined?
- Are consortium governance and liability terms acceptable?

### 6.3 Financial & Administrative Compliance

- Do we meet financial capacity requirements?
- Are reporting obligations manageable?
- Do we have internal resources for EU grant administration?

#### Eligibility Status:

- Fully eligible
- Eligible with partners
- Not eligible

## 7) Resource Capacity Assessment

### 7.1 R&D Capacity

- Do we have sufficient engineering capacity?
- Is clinical affairs bandwidth available?
- Do we have regulatory resources allocated?
- Does this conflict with other strategic projects?

### 7.2 Financial Capacity

- Can we pre-finance required activities?
- Is co-funding required?
- Is cash flow impact acceptable?

### 7.3 Management Attention

- Is executive sponsorship available?
- Is project leadership identified?

#### Capacity Assessment:

- Fully resourced
- Requires reallocation
- Capacity gap

### 8) Risk Assessment

- Timeline feasibility risk
- Consortium dependency risk
- Regulatory uncertainty
- Technical feasibility risk
- Reputational risk
- Opportunity cost (what must be deprioritized?)

Overall Risk Level:

- Low
- Moderate
- High

### Final Go / No-Go Matrix

Dimension	High	Medium	Low
Strategic Fit	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
TRL Alignment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Evidence Value	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Market Impact	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Resource Capacity	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Risk Level	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

### Final Decision:

- Go (Proactive engagement)
- Conditional Go (Mitigate gaps)
- No-Go (Document rationale)