



Pragmatic Trial Design Worksheet

If you have not already done so, we recommend that you start with completing the Prioritization Check-In [see Detailed Guidance] to help you and your team decide which of the 8 elements of pragmatic trials are most important for your project. After, review sections in the Detailed Guidance as needed corresponding to each issue below. These sections are noted at the beginning of each item.

1. Pragmatic INTERVENTIONS AND IMPLEMENTATION STRATEGIES: How will you assess the feasibility of your intervention and delivery strategies in your setting?

*Note: Consider assessing how your intervention and implementation strategies are compatible with workflow (sketch this out) and priorities of your intervention settings. We recommend using mixed methods to assess this and **all the issues below**.*

2. SETTINGS (CONTEXT) AND IMPLEMENTERS: What are the features of your intended setting that may help or hinder your implementation?

Note: Think about physical setting, available resources, staff burden, and history with similar interventions.

3. FIT TO CONTEXT (ADAPTATIONS): How will you permit tailoring or adapting activities to fit different situations and changes in context, while maintaining fidelity to the core goals or principles (functions) of your intervention? (i.e. How much can your intervention and/or strategies change to fit context?)

*Note: Review the Functions and Forms webpage ([url or link](#)) for examples and tools to help. While you will likely need to modify **forms** of the intervention or strategies, you should not modify the core **functions**.*

4. SELECTING A MODEL TO GUIDE PRAGMATIC STUDY: Briefly describe key features of your conceptual model and how you will assess how it is being implemented. (You may want to use your logic model to do this.)

Note: begin with an implementation logic model and consider context, implementation strategies, short- and long-term outcomes and how these fit together. We strongly recommend using the D&I Models Webtool [[dissemination-implementation.org](#)] to help (including creating a logic model) to select a framework, adapt if needed, and assess use of your model.

5. MULTI-LEVEL RECRUITMENT: List the key methods you will use to recruit real-world: 1) settings, 2) staff, and 3) patients to increase relevance for later, broad dissemination and scale-up.

Note- consider using more than one method, especially to ensure you are including different types of participants. Limit exclusions at all levels (settings, staff, patients) and keep in mind unintended consequences. We recommend reviewing the Expanded CONSORT figure and calculator ([url](#)).

6. EXPERIMENTAL DESIGN: Considering your project scope, budget and resources, what evaluation design will you use to be *feasible, rapid and rigorous*?

Note- consider what comparator (baseline or control condition) you will use to address the most likely alternative explanations a critic might raise of your results.

7. PRAGMATIC OUTCOMES: Summarize the key ways you will assess each of the pragmatic evaluation issues below:

a. What implementation outcomes are most important (e.g. reach, fidelity, costs) in your project and how will you pragmatically assess these?

b. What patient-centered outcomes are most important (e.g., perceived support, value concordance, quality of life) and how will you pragmatically assess these?

c. What other outcomes are most relevant for your study (e.g. *clinical outcomes, mechanisms or processes of change, unintended consequences, equity*) and how will you pragmatically assess these?

Note- we recommend reviewing the tables in section 6.7 on pragmatic measures and using the [iterative PRISM webtool for iterative assessment](#)