

Specialty Pharmacy Outcomes Research Overview and Pearls

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Practitioners (SSPP)

[Advisory Group on Outcomes and Value](#)

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- 1. Generate/Identify Research Idea**
 - a. Ideas may come from strategic goals, gaps (or successes) in patient care, or collaborations with internal and external stakeholders.
 - b. Develop a research question using [PICOT method](#) (Population, Intervention/Exposure, Comparison, Outcome, and Time).
- 2. Define the Scope and the Scale of the Project**
 - a. Perform a literature search to discover existing state of understanding.
 - i. Refer to the [ASHP HSSP Outcomes Literature Library](#) for articles.
 - b. Determine initial outcomes to evaluate.
 - c. Evaluate project feasibility and resource requirement.
- 3. Engage Stakeholders**
 - a. Develop research team and outline responsibilities and timeline
 - b. Engage with other stakeholders that may need to be involved (will vary - managers, non-IRB research review boards, compliance, office of intellectual property, etc.)
- 4. Finalize Study Protocol**
 - a. Finalize primary and secondary outcomes.
 - b. Meet with statistician or create stats plan.
 - c. Develop data dictionary listing all data needed to perform the study that clearly defines each metric and how it is collected.
 - d. Establish study timeline.
 - e. Determine initial plan on how results will be disseminated.
 - i. Consider multiple deliverables if the project can support them.
- 5. Obtain IRB approval**
 - a. Requirements may vary between institutions. Work with local IRB for details.
- 6. Project Kickoff**
 - a. Set target deadlines for each remaining step of the research process.
 - b. Review team responsibilities.
 - c. Before kickoff, review the checklist below to ensure that you are ready.
- 7. Data Collection**
 - a. Request discrete data that will be extracted by analyst (if applicable).
 - b. Thoroughly train all data collectors and perform regular data quality checks.
 - c. Document discrepancies, deviations, or other changes that may occur.
- 8. Data Analysis**
 - a. Review and clean data. Organize data for analysis.
 - b. Perform statistical analysis.
 - c. Review data and determine key points from the findings.
- 9. Dissemination of Knowledge Gained**
 - a. Present and publish using scientific platforms (e.g., posters, presentations, publications).
 - b. Develop public mediums for dissemination (e.g., online magazines, social media).
- 10. Reflect on Study Methods and Findings**
 - a. Determine if further practice changes are needed.
 - b. Review ways to improve study design moving forward (e.g., better method of data documentation).
 - c. Develop subsequent research questions.



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