
# Ask the Project Manager: Scott Smith, using micro.P3.express in a Clinical Coordinating Center

Scott Smith is a certified micro.P3.express and P3.express practitioner with extensive experience in clinical research administration. In this interview, he reflects on his work establishing a structured project management approach within a newly created clinical coordinating center at a large academic medical institution in the Midwestern United States.

**Scott, thank you for joining us. Can you tell us about the organization you worked for and your role there?**

I worked for a major academic medical center in the Midwest. It is one of a small number of nationally recognized cancer centers in the United States and serves a large regional patient population. In terms of scale, it is an enterprise-level organization with well over a thousand employees and thousands of patients.

I was part of the research administration team, specifically within a newly launched clinical coordinating center. The center was created to build the operational infrastructure required to support multi-center, grant-funded clinical research trials. When I joined, I was the third person hired and the first brought in specifically to manage multi-center research activities.

By the time I left, the team had grown to five people, working across regulatory affairs, safety monitoring, clinical operations, and project management.

**Before we go further, could you explain what a clinical coordinating center is?**

The purpose of the clinical coordinating center is to establish the operational infrastructure needed to support multicenter, grant-funded clinical research studies., Rather than focusing on delivering care at a single site, the center's role is to design and manage a framework that enables multiple participating sites to conduct research consistently and compliantly.

In clinical research, where trials can be operationally demanding and highly regulated, this level of coordination is critical. The clinical coordinating center is responsible for laying that groundwork, standardizing processes such as feasibility assessments, and ensuring that multi-center trials can be conducted safely, consistently, and in alignment with funding and regulatory requirements.

**What types of projects were you responsible for?**

One of the main projects I led was developing a standardized feasibility assessment process for prospective research sites.

In multicenter clinical trials, participating sites must demonstrate that they have qualified physicians, research nurses, support staff, and systems and processes in place. Interest alone is not enough. Even if a physician is clinically qualified, the surrounding infrastructure may not be sufficient to support a trial. This frequently leads to challenges or failures in clinical research.

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The project focused on developing a structured feasibility questionnaire to be incorporated into a standing assessment process. Instead of evaluating sites informally or inconsistently, we developed a defined and repeatable approach to gather demographic data, personnel qualifications, review systems and processes, and assess operational readiness.

**Why did you choose to use micro.P3.express for this work?**

There were several reasons. First, simplicity and ease of use were essential. At the time, we had no formal project management office or established methodology. Our team was small, and it was possible that individuals without formal project management backgrounds would need to manage projects.

I wanted a framework that was practitioner-oriented, simple to teach, and straightforward to implement. It needed to be something I could tailor to our context and provide to colleagues in a usable format.

Second, micro.P3.express supported rotating leadership within a small, expert team. During the feasibility questionnaire project, different subject matter experts led at different stages. For example, our director, with strong expertise in quality assurance and audit readiness, led specific phases. Our safety monitor led other phases because of their specific expertise. Using the micro.P3.express approach enabled us to shift leadership based on subject-matter expertise while maintaining structure. That flexibility improved the quality of the final deliverable.

In my view, the feasibility assessment tool we produced was one of the strongest I have seen in my field. The structured and methodical approach contributed significantly to that outcome.

**How did this differ from how projects are typically managed in clinical research?**

Clinical research is highly regulated, and rightly so. Regulatory processes are in place to ensure patient safety. However, the level of oversight can create tension when organizations need to respond quickly.

In many environments, project management becomes inconsistent. Workarounds are common, and approaches vary by project. Some organizations require project managers to hold advanced clinical degrees. Others have formal methodologies documented but not consistently applied.

In this case, I understood that large-scale institutional change was unlikely within a state-funded institution. Instead, we focused on implementing a practical framework locally within our division. The goal was to establish documentation, structure, and repeatable processes before launching multi-center trials.
Many frameworks in the research environment are heavily theoretical and encounter significant difficulties in real-world situations. The approach we adopted emphasized execution bydoing the work clearly and systematically.

**How did you implement the framework in practice?**

Because I was the first person in a dedicated project management role within the division, implementation began with documentation.
We were required to develop standard operating procedures that formalized our general research operations. Beneath those, we developed detailed work instructions that described how tasks would be carried out. I embedded the project framework within those documents.

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I approached this from the perspective of colleagues who were not trained project managers but might be assigned projects. Earlier in my career, I served as a de facto project manager while negotiating budgets and contracts without formal project management tools. I wanted to ensure others would not face the same situation.
The objective was to create a practical guide. If someone was assigned a project, they could open the documentation and follow a defined roadmap rather than starting from scratch.

**What challenges did you face during implementation?**

There were three main challenges. The first was internal policy constraints. We addressed this by drafting our standard operating procedures broadly and using detailed work instructions to define operational specifics. This provided flexibility while remaining compliant.
The second was the institutional mindset. Research administrations frequently operate within rigid, siloed structures. Encouraging engagement across those boundaries required effort and persistence.

The third was cross-functional buy-in, particularly from clinicians and practitioners in the hospital and the school of medicine. Internal negotiations could be more complex than external ones. Introducing structured workflows added value, but it also required navigating internal politics and differing priorities.

**What lessons did you take away from this experience?**

The central lesson is that having a framework is preferable to having none. Even if an organization eventually needs a more complex methodology as it grows, starting with a practical, usable structure helps prevent many problems. Without a framework, documentation suffers, lessons go unrecorded, and burnout becomes more likely.

With a roadmap in place, teams can assess projects before starting, document decisions, and maintain clarity on what they are doing and why. It does not eliminate every challenge, but it resolves many issues simply by avoiding ad hoc management.

Having structure means you do not have to reinvent the wheel each time.

**Thanks a lot for your time, Scott!**