RAPID TRIAL ACTIVATION IN ONCOLOGY:

IMPLICATIONS & OPPORTUNITIES FOR INVESTIGATIONAL DRUG SERVICE OPERATIONS

By Alex Vondracek, PharmD, BCPS, BCOP

The timeline for launching an oncology clinical trial is more than an administrative metric — it is a measure of how quickly patients gain access to potentially lifesaving therapies. Extended start-up periods delay care, reduce trial competitiveness and can undermine accrual goals.

For many years, activation followed a slow, step-by-step path: contracts negotiated, budgets finalized, ethics approved and operational preparations completed, each step beginning only when the previous one ended.[1]

Alex Vondracek

For Investigational Drug Service (IDS) pharmacies, these lengthy timelines provided predictable windows to prepare, but their readiness rarely influenced overall activation speed.

That paradigm is changing. With the rise of rapid trial activation models, pharmacy operations are no longer a downstream function. They are a critical determinant of whether a trial opens on time.

DEFINING RAPID TRIAL ACTIVATION

In its traditional form, trial activation was a linear sequence. Site selection led to contract negotiations, followed by budget development, regulatory submissions and institutional review board (IRB) approval. Only after those milestones were reached did the final operational steps begin.

This approach ensured a clear order of operations but created cumulative delays. Evidence shows that under this model, the time from site selection to first patient enrollment often exceeded six months and, for complex oncology protocols, could extend close to eight months.[1]

Rapid trial activation transforms this process into one built on parallel readiness. Instead of moving step by step, essential activities — contracting, budgeting, regulatory review, IRB submission — advance at the same time. Many programs shorten timelines further by using pre-negotiated master agreements, standardized budget templates and centralized IRB approval.[1] From the earliest feasibility discussions, operational regulatory, and scientific considerations are addressed together to identify and remove barriers before they slow progress.

The shift from sequential to concurrent workflows has been linked to substantial gains in efficiency. Reports have documented reductions of more than 100 days across contracting, review and site launch phases compared with traditional approaches.[2,3] Trials that once took a half-year or longer to activate can now, in some cases, open within weeks of site selection — and in certain circumstances, within days of identifying an eligible participant.

IMPACT ON IDS OPERATIONS

Embedding IDS pharmacies earlier in the activation process changes both the timing and nature of their work. Pharmacy is now engaged during feasibility, working alongside regulatory, contracting and clinical colleagues from the onset.

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This integration compresses work that once spanned months into periods of days or weeks. Building electronic order sets, creating accountability records and preparing staff training all occur in parallel with other start-up tasks. This approach requires clear budgeting to account for labor performed before a trial is fully approved.[4]

The pace leaves little margin for error. Mistakes in medication handling, storage, orders, dosing schedules or compounding instructions can cause costly delays when timelines are tight. Close coordination with other departments is essential to keep readiness activities aligned and IDS teams may need to start preparations "at risk," initiating work before the trial has full approval to proceed.

CHALLENGES IN THE RAPID ACTIVATION ENVIRONMENT

While the benefits of faster activation are clear, compressed timelines create operational pressures. Concentrating multiple complex tasks into shorter periods can strain resources and increase the likelihood of bottlenecks.[1,4] Workforce shortages and high turnover among research pharmacy staff are persistent challenges that can disrupt even well-designed workflows.[1]

Institutional practices can also limit efficiency. In some organizations, policy still dictates that certain steps must be completed sequentially — for example, requiring a finalized budget before initiating IRB submission — which reduces the potential for parallel processes.[1] Without coordinated workflows, defined responsibilities and institutional support for certain at risk activities, the advantages of rapid activation can be diminished.

EVIDENCE-BASED STRATEGIES TO SUPPORT IDS IN RAPID ACTIVATION

Adapting successfully to rapid activation requires aligning resources, processes and infrastructure to the demands of accelerated timelines. Assigning pharmacists specifically to trial start-up ensures these activities receive focused attention and are not delayed by competing operational duties.[4,5] Cross-training pharmacists and technicians to perform readiness tasks creates flexibility, enabling teams to absorb workload peaks and maintain progress even during staffing gaps.[4,6]

By engaging early, working in parallel with other functions and aligning resources with the realities of compressed timelines, pharmacy operations can directly influence patient access, trial competitiveness and enrollment performance.

Standardization can be a powerful accelerant. Using validated, predeveloped order sets, compounding protocols and accountability templates streamlines preparation while promoting consistent practice.[4] Integrating pharmacy systems with regulatory and trial management platforms improves information flow and reduces duplication of work.[4]

Infrastructure modernization also supports sustained readiness. Automated dispensing technology, barcode-based inventory systems and expanded cold storage capacity improve efficiency and safety under tight timelines.[4] Positioning IDS pharmacists in clinical care areas strengthens communication with healthcare teams, supporting readiness for timely patient care.[5]

Finally, establishing a culture of continuous process improvement is critical. Tracking activation milestones, holding post-activation reviews and adjusting workflows to address recurring issues are practices shown to help organizations maintain and build on efficiency gains.[1,4]

CONCLUSION

Rapid trial activation is more than a scheduling improvement — it is a strategic evolution that places IDS at the center of a trial's success. By engaging early, working in parallel with other functions, and aligning resources with the realities of compressed timelines, pharmacy operations can directly influence patient access, trial competitiveness and enrollment performance.

Institutions that invest in IDS capacity, technology and authority will be best positioned to meet the demands of modern oncology research. In a setting where every day matters, IDS readiness is not a background task — it is a core measure of a site's ability to deliver innovative therapies to patients without unnecessary delay.

▲ **Alex Vondracek**, PharmD, BCPS, BCOP, is an Investigational Drug Clinical Pharmacy Specialist – in the Blood and Marrow Transplant and Cellular Immunotherapy Program at Moffitt Cancer Center in Tampa, Fla.

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