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W303: Cracking the Code: Optimizing Clinical Trial Startups for Rapid Success

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Focus for Today's Session:
A practical, outcomes-driven approach to redesigning clinical trial startup.

Learning Objectives

1. Analyze
Identify structural and operational bottlenecks that delay clinical trial startup and impact timelines, financial performance, and compliance.

2. Apply
Implement practical strategies to redesign startup processes, including governance models, parallel workflows, feasibility triage, and budgeting practices.

3. Measure
Develop an outcomes-driven approach to track performance, improve activation timelines, and strengthen sponsor and investigator engagement.

What is your current average startup timeline?

Startup Challenge

- 3-9 + month activation timeline
  - Academic Medical Centers (AMCs) and hospitals: 9.4 months.
  - Independent sites and physician practices: 4.8 months.
  - Average time for contract and budget finalization: 177.6 days (nearly 6 months).
- Contract & budget cycles often exceed 150+ days
- IRB approvals
- Multiple handoffs across departments
- Limited visibility into progress

Trial startup remains one of the least predictable phases in research operations!

The Hidden Problem

Startup delays are structural, not transactional!

- Fragmented ownership
- Sequential workflows
- Unclear decision authority
- Limited performance accountability

Most improvement efforts focus on fixing steps: forms, templates, or workflows.

Why It Matters

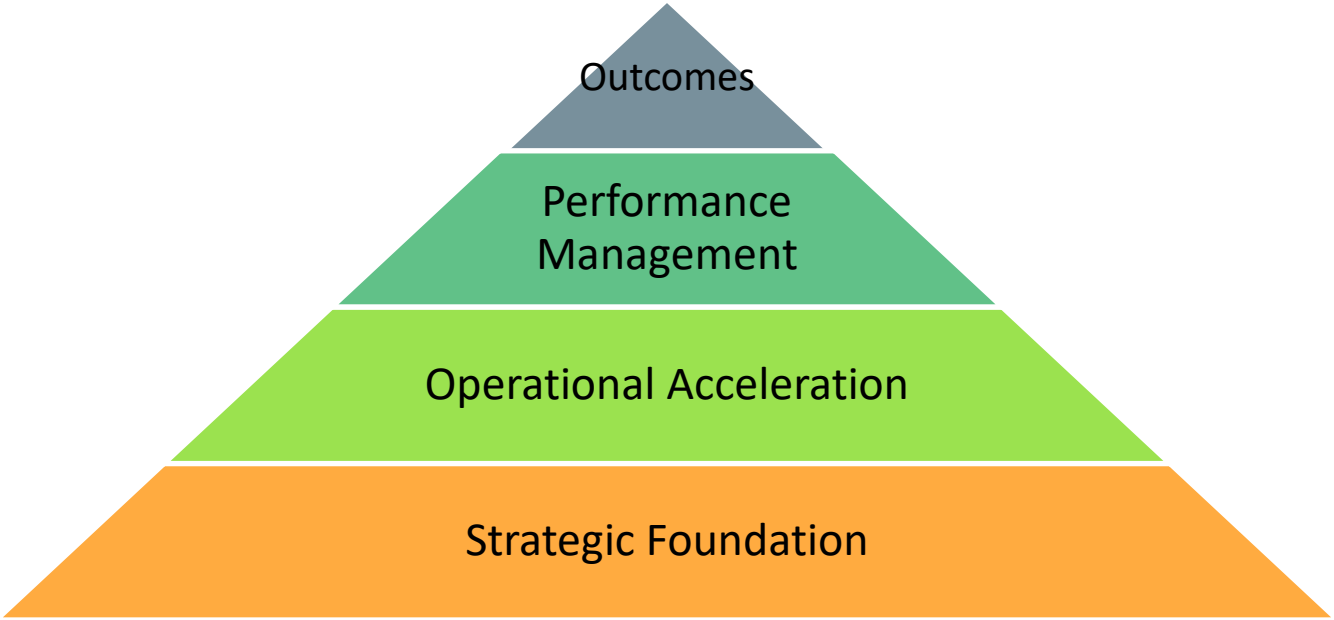
- Delays in patient access to clinical trials
- Lost or delayed revenue
- Reduced investigator engagement
- Sponsor confidence and site selection impact
- Staff burnout

What Actually Moves the Needle?

- Not more effort
- Not more meetings

A redesigned startup model.

Clinical Trial Startup: Institutional Capability



Strategic Alignment

- Executive sponsorship & research prioritization
- Defined governance & activation decision authority
- Portfolio strategy & feasibility triage
- Alignment with financial and clinical growth goals

Speed begins with institutional intent.

Governance in Practice: Who Owns Activation?

Common State:

- Multiple Stakeholders
- No clear decision owner
- Delayed approvals

Practice:

- Assign activation owner
- Define decision service level agreements (e.g., 5 business days)
- Create escalation pathway

Outcomes:

- Reduced approval delays
- Fewer stalled studies
- Clear accountability

Examples: SLA

Step	SLA
Feasibility Review	5 business days
Budget Review	5-7 business days
Contract redlines	7-10 business days
PI response	3-5 business days

- Define SLA
- Communicate to all teams
- Track (on time vs delayed)
- Escalate (if no response by x, escalate to director)

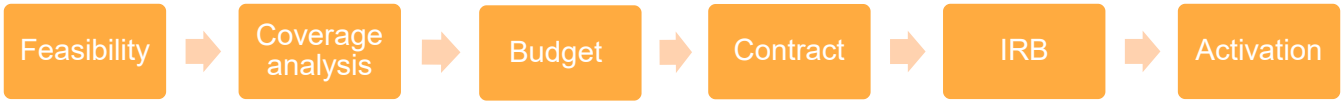
Operational Acceleration

- Standardized feasibility & intake infrastructure
- Parallel activation workflow (budget, regulatory, coverage analysis)
- Contracting and budget negotiation playbooks
- Dedicated activation ownership model

Acceleration is achieved through workflow architecture.

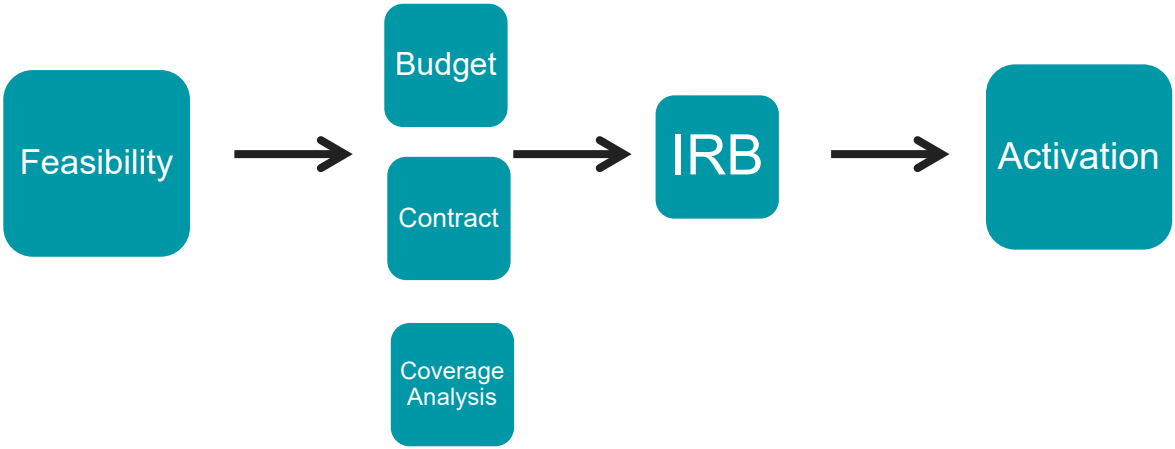
Sequential vs Parallel Startup

Traditional Model - Sequential



Sequential vs Parallel Startup

Accelerated Model - Parallel



Feasibility that Actually Filters

Problem:

- We say yes to everything
- Poor-fit studies move forward
- Staffing

Practice:

- Patient population
- PI bandwidth
- Staff bandwidth
- Financial viability

Outcomes:

- Higher activation success rate
- Less wasted startup effort

Define Thresholds:

Go

Conditional

No-Go

Feasibility in Practice: Using Workload Data (OPAL)

Problem: Feasibility decisions often rely on PI interest and estimated patient populations.

Practice: Use tools to assess:

- Coordinator capacity
- Study complexity
- Competing study demands

Example:

- Assign workload score per study
- Define capacity thresholds per coordinator
- Evaluate

Outcomes:

- More realistic feasibility decisions
- Reduced staff burnout
- Improved study execution and enrollment

Feasibility Decision Tool: Capacity Based

Feasibility = Capacity + Complexity + Prioritization

OPAL: a standard score is based on 1-8
Monthly Hours = OPAL Score × 4
Capacity % = (OPAL × 4) ÷ 160

Coordinator	Current Load	New Study Impact (OPAL 6)	Total Load	Decision
CRC A	70% (112 hrs)	+ 15% (24 hrs)	85%	Go
CRC B	85% (136 hrs)	+ 15% (24 hrs)	100%	Conditional
CRC C	100% (160 hrs)	+ 15% (24 hrs)	115%	No-Go

Tyson, C., Black, K., et al. Clinical Research Coordinator Workload Assessment Using an Adapted Ontario Protocol Assessment Level Score. Journal of Clinical and Translational Science, 2024.

Budgeting Reality, Not Hope

Practice:

- Benchmark against prior studies
- Develop a budget play blook
- Use fully loaded cost model, include:
  - Screen failures
  - Reconsent, rescreening
  - Long-term follow-up
  - Amendments (about 60-70% of protocols)
  - Monitoring prep

Outcomes:

- Improved trial margin
- Fewer mid-study financial issues
- Fewer missed budget opportunities
- Increased ROI

Performance Management

- Startup timeline dashboards & transparency
- Investigator engagement and activation metrics
- Sponsor experience as a performance indicator
- Continues process refinement

Sustainable speed requires visibility and accountability.

Startup Metrics that Matter

Metrics:

- Days from feasibility → activation
- Contract cycle time
- Budget approval time
- Feasibility → activation conversion rate

Practice:

- Build simple dashboard (Excel/Power BI, Loop)
- Review monthly

Outcomes:

- Visibility bottlenecks
- Faster course correction

Sponsor Experience = Future Pipeline

Practice:

- Define response time expectations
- Standardize communication cadence
- Share startup timelines proactively

Outcomes:

- Repeat studies
- Preferred site status
- Increased trial volume

Outcomes

- Reduced activation timelines
- Increased clinical trial portfolio growth
- Stronger sponsor confidence
- Expanded patient access to innovation
- Improved financial sustainability

Startup efficiency is a strategic advantage.

Clinical Trial Startup Redesign: Mid-sized Hospital

Metric	Before	After
Startup Timeline	~9-12 months	~2-3 months
Contract/Budget Cycle	~8-10 months	~ 1-2 months
Active Trials	~ 2	~65
PI Engagement	Limited	Expanded

Where to start?

Define your biggest challenge:

- Slow decisions = define ownership
- Long timelines = pilot parallel workflow with 1 or 2 studies
- Staff overloaded = add capacity to feasibility
- Budget Gaps = stress test your budget model
- No visibility = track key metrics

Key Takeaways

1. Redesign the System — Not Just the Steps
Startup delays are structural. Fix ownership, decision authority, and workflow design.

2. Run Startup in Parallel — Not Sequence
The biggest gains come from changing how work is organized, not how fast people work.

3. Make Feasibility a Capacity-Based Decision
Use tools like OPAL and workload estimates to decide what your team can realistically support.

4. Budget for Reality — Not the Ideal Study
Account for screen failures, amendments, and long-term follow-up to avoid downstream gaps.

5. Define, Measure, and Act on Performance
Set target timelines, track key metrics, and address bottlenecks in real time.

6. Communicate Early, Clearly, and Often
Align expectations across investigators, finance, legal, and sponsors — before delays occur.