



Mission Critical: Conquering the Clinical Trial Activation

Strategic Approaches to Reducing Clinical Trial Startup Delays

Monica Polk, DNP, MBA, RN

Director Research Operations and Clinical Trials Office

Office of Research Operations Dartmouth Hitchcock Medical Center

About Me:

Monica Polk, DNP, MBA, RN

Director of Research Operations and Clinical Trials Office

Dartmouth Hitchcock Medical Center

15 Years Research Administration and Clinical Trials



Presentation Roadmap



The Problem

- Current state of trial activation timelines
- Economic and human cost of delays



The Bottlenecks

- Contract sticking points and process challenges



Four Proven Solutions

- Master agreements and standardized templates
- Process optimization and technology enablement



Implementation Strategy

- Case study, roadmap and keys to success



Contract Negotiation Timelines



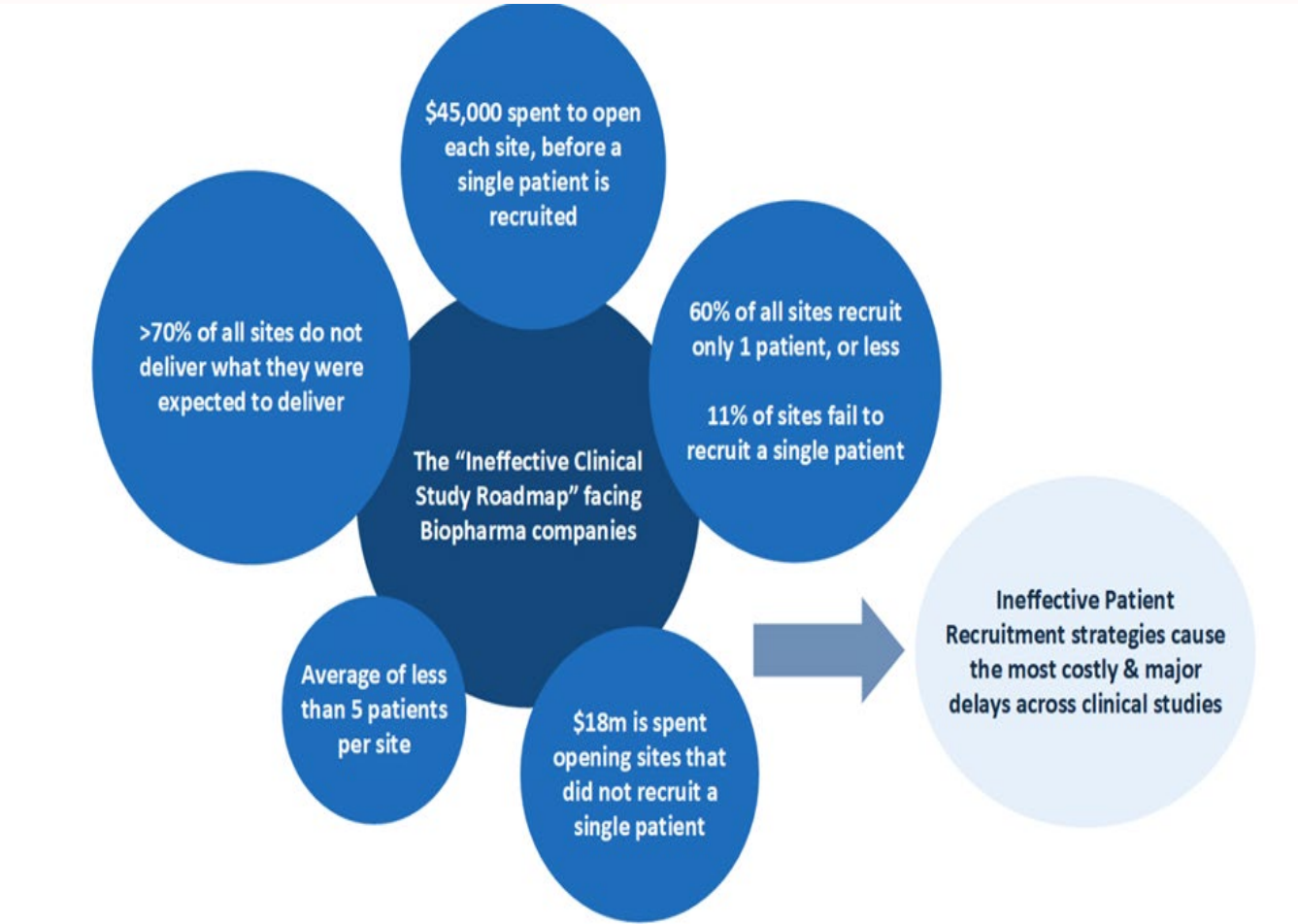
How many days does your institution average from contract receipt to execution?



Raise your hand if your institution's contract negotiation typically takes:

- Less than 30 days
- 30-60 days
- 60-90 days
- More than 90 days

The Contract Bottleneck: By the Numbers



100

Days Average

Contract negotiations

145

Days Average

Local IRB sites to execute CTA

45

Days Average

Central IRB sites to execute CTA

80%

Sponsor Consideration

Consider previous negotiation experience in site selection

Every day of delay costs \$600,000-\$8 million in potential lost revenue

The True Cost of Delays

Economic Impact

- Lost revenue opportunities
- Decreased site competitiveness
- Reduced future trial opportunities



Human Impact

- Patients waiting for treatments
- Frustrated investigators
- Strained sponsor relationships



Common Bottlenecks in Activation

1. Document Collection & Coverage Analysis

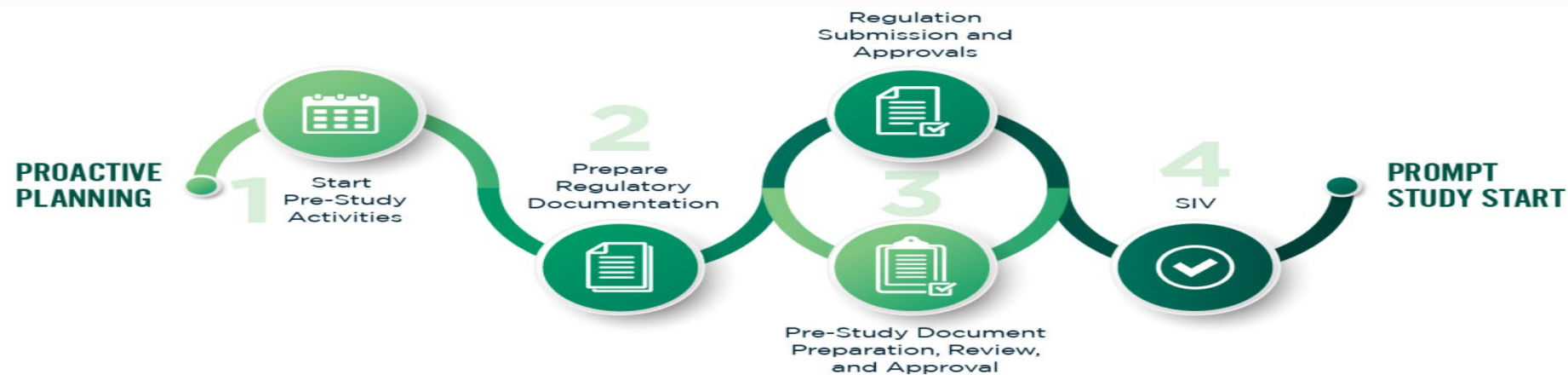
- Incomplete documentation
- Complex protocol designs
- Research vs. standard of care determinations

2. Coordination & IRB Synchronization

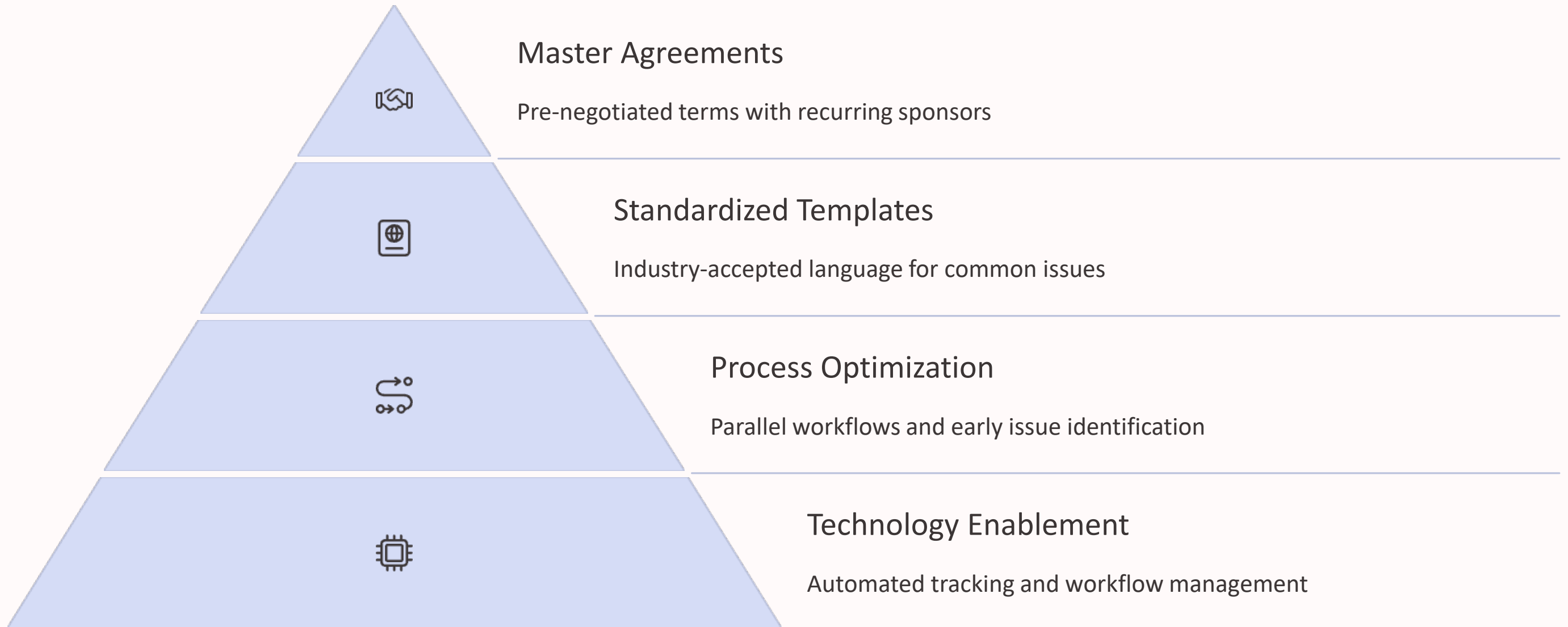
- Scheduling conflicts and insufficient preparation
- Misalignment between IRB review and contract execution
- Protocol amendments during review

3. Financial & Harmonization Issues

- Complex billing designations
- Inconsistencies between final documents
- Late-stage compliance concerns



Strategy Overview



Which approach seems most promising for your institution?

Strategy #1: Master Agreements

The Approach

- Pre-negotiated terms for recurring sponsors
- Standardized legal language for common provisions
- Focus negotiations only on protocol-specific items

The Results

- Reduces negotiation time from 55 to 22 days (60% reduction)
- Decreases administrative burden
- Builds institutional knowledge



Master Agreement Implementation

Start with your top 5 sponsors by volume

Identify the sponsors you work with most frequently to maximize impact

Develop internal approval processes for deviations

Create clear guidelines for when exceptions can be made

Create a digital repository for approved language

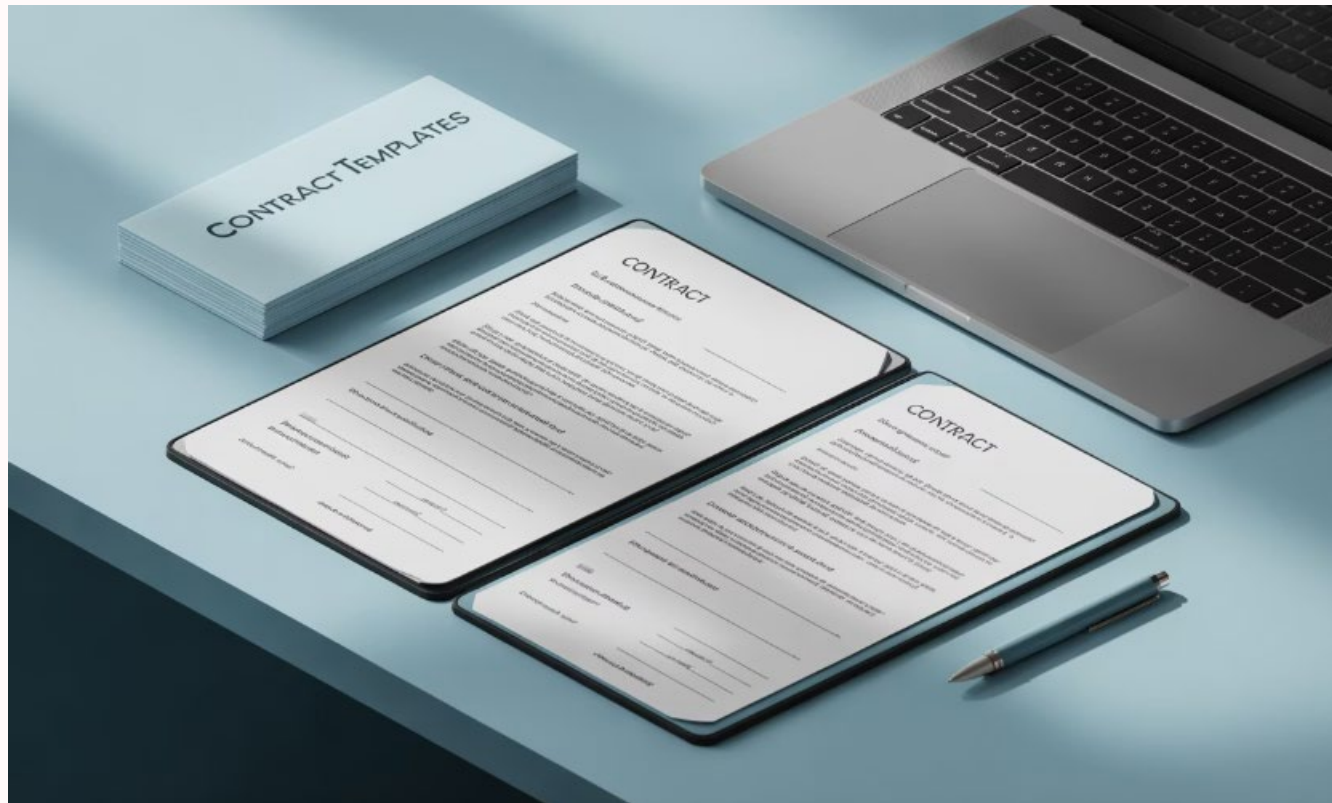
Build a searchable database of pre-approved contract terms

Reflection Question: What sponsor would you target first at your institution?

Strategy #2: Standardized Templates

The Approach

- Adopt widely-accepted standard agreements (e.g., ACTA)
- Develop tiered fallback positions for common issues
- Create decision trees for negotiators



The Results

- ACTA implementation saves 48 days in negotiation
- Reduces negotiation rounds by 50-70%

Example: "Sponsor shall reimburse subjects for the costs of medical care for research-related injuries" vs. lengthy provisions with insurance billing requirements

Strategy #3: Process Optimization Best Practices



Begin coverage analysis immediately

Don't wait for complete documentation

Use standardized templates with common procedures



Early Identification of Complex Elements

Flag "red flag" procedures requiring expert review

Establish non-negotiable minimum thresholds in advance



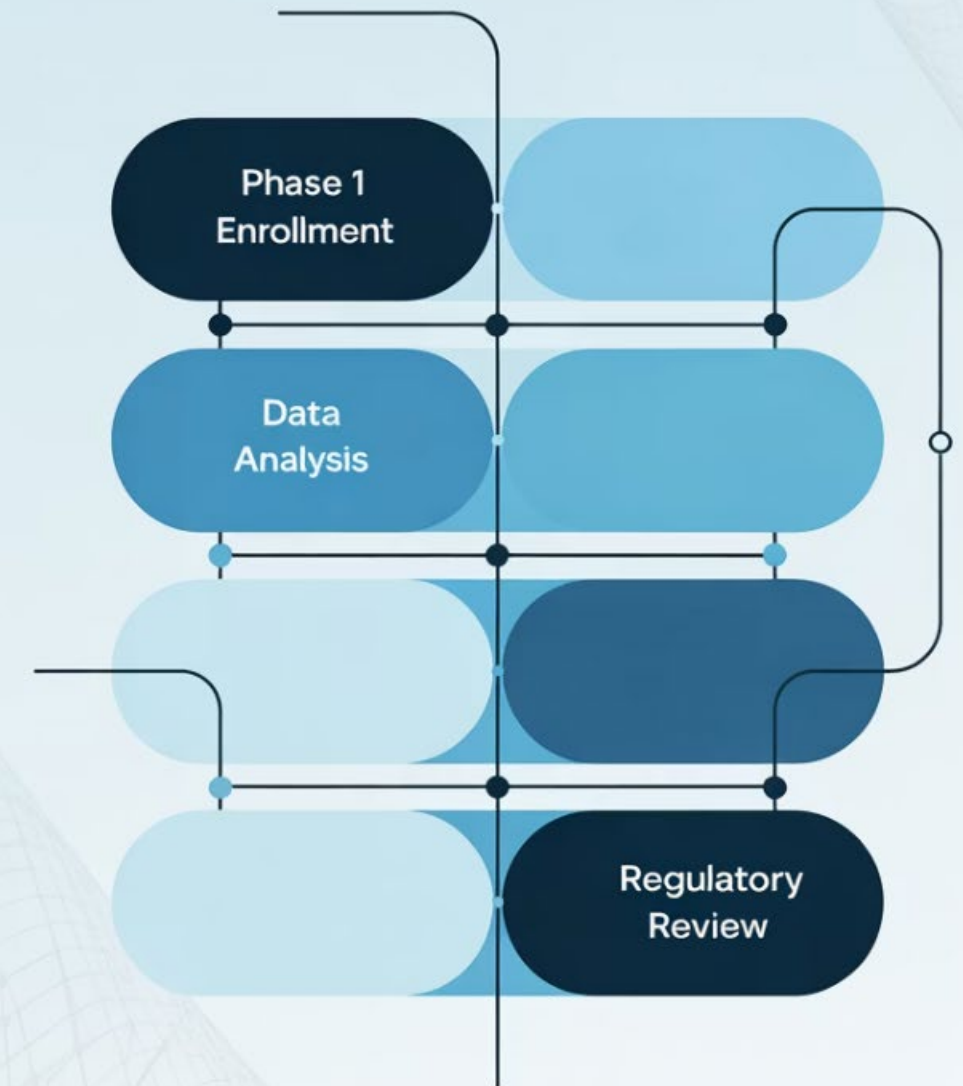
Parallel Processing & Proactive Communication

Conduct budget and contract negotiations simultaneously

Implement 48-hour response time standards

Establish clear escalation process for delayed responses

Optimized Workflow Process for Clinical Trials



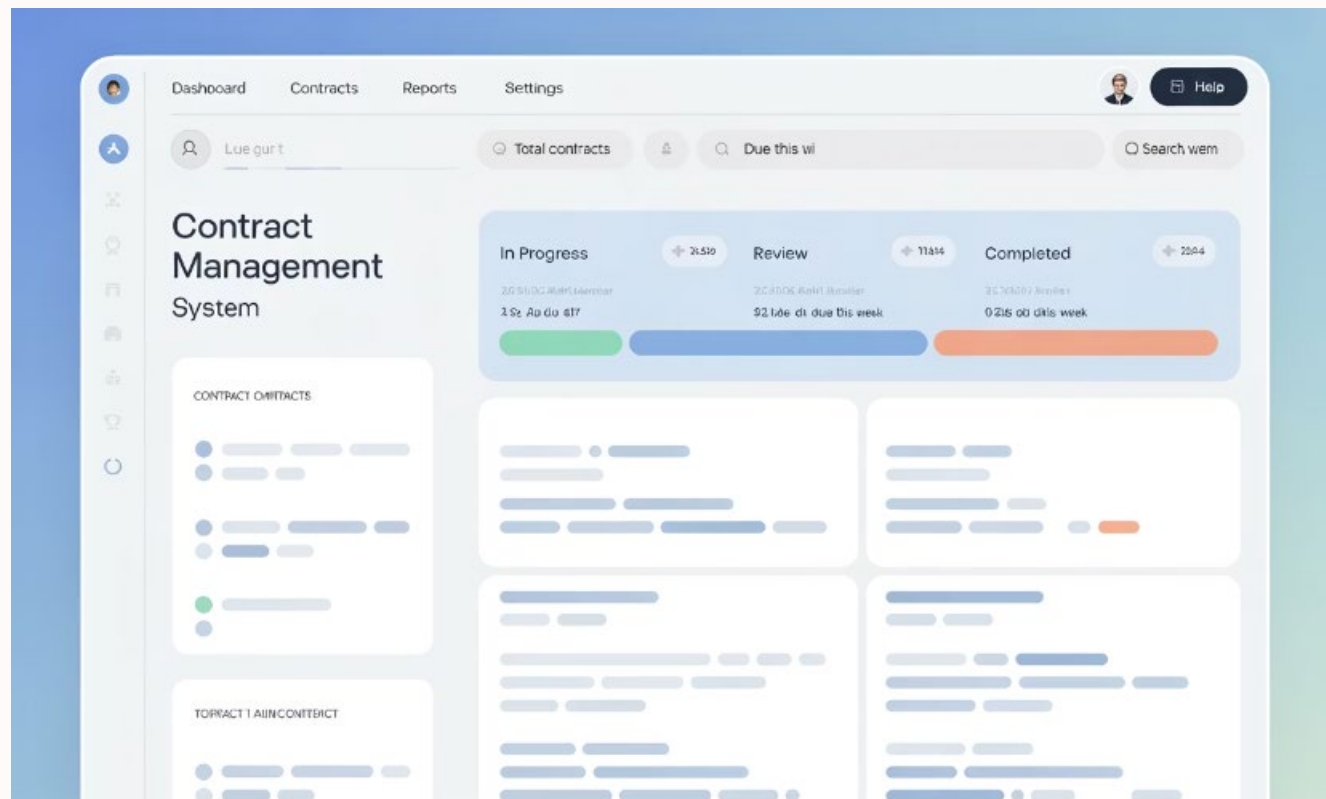
Strategy #4: Technology Enablement

The Approach

- Contract lifecycle management (CLM) systems
- Electronic signature platforms
- Automated tracking and visual dashboards

Key Features to Look For

- Real-time status visibility
- Automated reminders for pending actions
- Performance metrics and accountability tracking
- Integration with email/calendar
- Document version control



Institutional Best Practices



Centralized Study Activation Team

- Dedicated specialists focused solely on activation process
- Specialized expertise in complex protocols
- Clear accountability for timeline milestones



Risk-Based Approach

- Implement tiered review process based on study complexity
- Allocate resources according to risk profile
- Fast-track minimal risk or standard protocol designs



Automated Tracking Systems

- Track all timeline milestones electronically
- Set up automated alerts for approaching deadlines
- Generate performance metrics against timeline targets

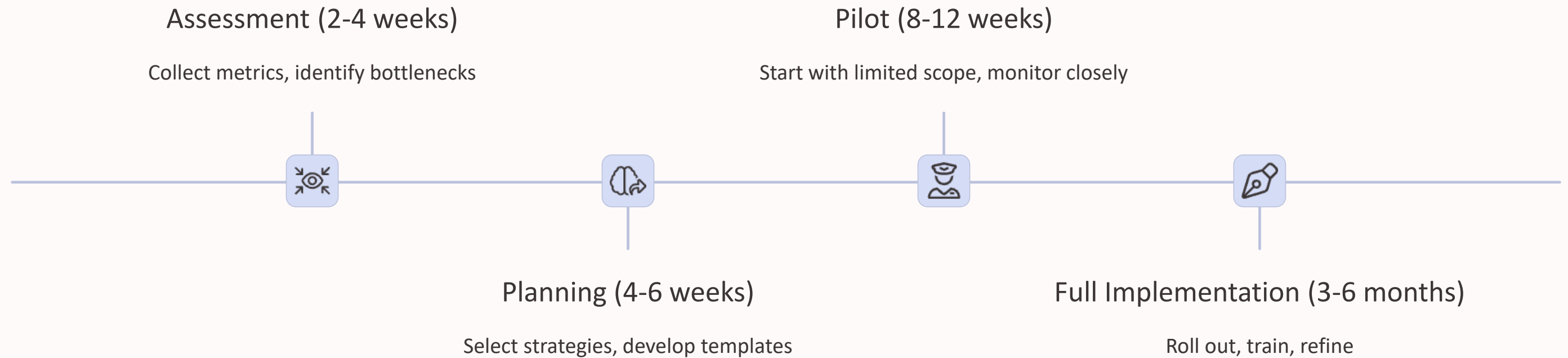


Sponsor Engagement Program

- Education on institutional requirements
- Preferred sponsor program with standardized agreements
- Sponsor scorecard for negotiation responsiveness



Implementation Roadmap & Keys to Success



Keys to Success:

- Early identification of complex elements
- Structured process with clear accountability
- Parallel processing whenever possible
- Strategic negotiation with defined thresholds
- Continuous performance monitoring

One Action to Take



One specific action you will take in the next 30 days



When you'll do it

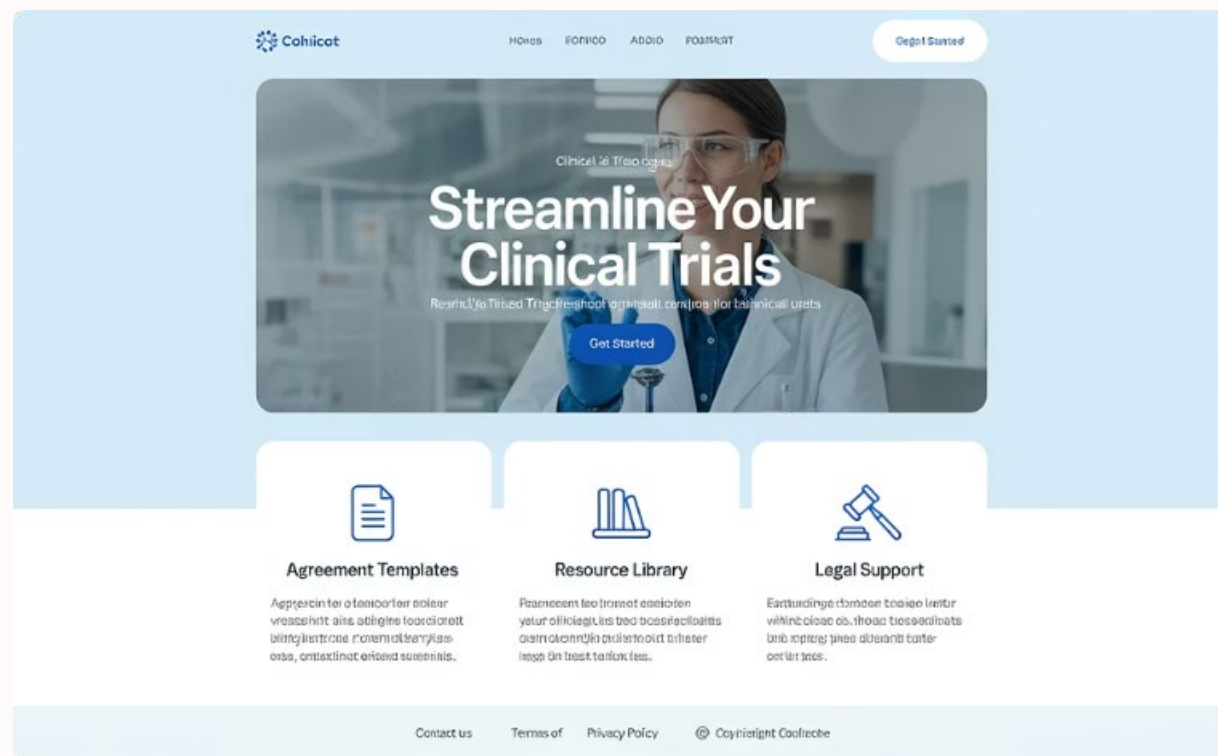


How you'll measure success

Questions to Consider:

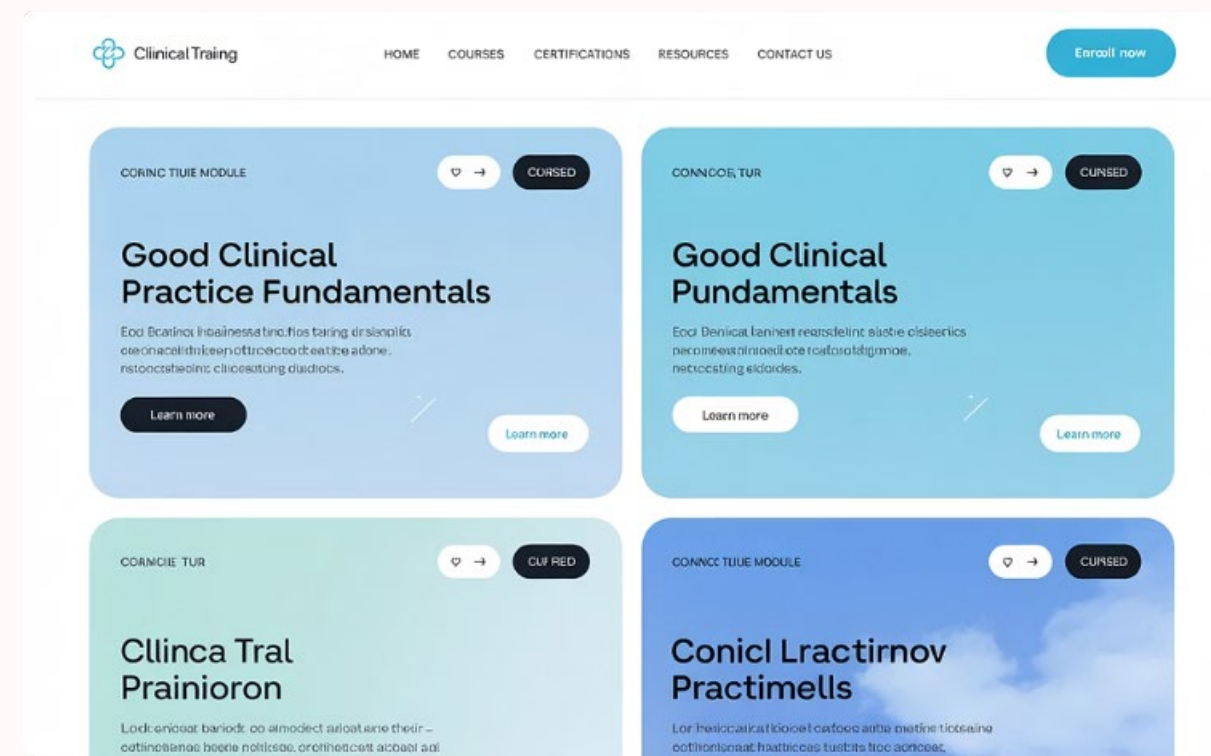
- What if your institution set a 30-day activation guarantee?
- How might financial incentives improve timeline performance?
- What if you created a pre-approved investigator pool?

Resources for Implementation



Templates and Standards

- ACTA: <https://www.uidp.org/publication/accelerated-clinical-trial-agreement/>
- FDP-CTSA: <https://thefdp.org/default/committees/research-administration/clinical-trials/>



Organizations and Training

- SRAI: <https://www.srainternational.org/>
- MAGI: <https://www.magiworld.org/>

Q&A and Final Thoughts

What questions do you have?

What's one idea from today that you plan to implement?



What strategies have worked at your institution?

What challenges are you still facing?

Open Discussion

Thank You!

