Smartsheet Free Clinical Research Project Manager Checklists

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Study Startup Phase Checklist

- [ ] Protocol finalization and review
- [ ] Budget development and approval
- [ ] Site identification and selection
- [ ] Regulatory document preparation
- [ ] Contract and budget negotiations
- [ ] Ethics committee submissions
- [ ] Study team identification
- [ ] Kick-off meeting planning
- [ ] Timeline: _____
- [ ] Status: _____
- [ ] Owner: _____
- [ ] % Complete: _____

Site Initiation Tracking

- [ ] Site assessment completed
- [ ] Confidentiality agreement signed
- [ ] Feasibility questionnaire returned
- [ ] Site contract executed
- [ ] Budget finalized
- [ ] Regulatory package submitted
- [ ] IRB/EC approval received
- [ ] Site initiation visit scheduled
- [ ] Due Date: _____
- [ ] Actual Date: _____
- [ ] RAG Status: _____
- [ ] Notes: _____

Enrollment Tracking Dashboard

- [ ] First participant enrolled date
- [ ] Weekly enrollment targets set
- [ ] Actual vs planned enrollment
- [ ] Screen failure tracking
- [ ] Site-specific enrollment rates
- [ ] Recruitment material distribution

- [ ] Enrollment projections updated
- [ ] Rescue plan activated if needed
- [ ] Target: _____
- [ ] Actual: _____
- [ ] Variance: _____
- [ ] Action Items: _____

Milestone Management Grid

- [ ] Protocol approval
- [ ] First site activated
- [ ] First participant in (FPI)
- [ ] 25% enrollment
- [ ] 50% enrollment
- [ ] 75% enrollment
- [ ] Last participant in (LPI)
- [ ] Last participant last visit (LPLV)
- [ ] Planned Date: _____
- [ ] Actual Date: _____
- [ ] Days Variance: _____
- [ ] Impact Assessment: _____

Budget Tracking Worksheet

- [ ] Initial budget approved
- [ ] Site payments processed
- [ ] Vendor invoices tracked
- [ ] Monthly burn rate calculated
- [ ] Variance reports generated
- [ ] Forecast updates completed
- [ ] Change orders documented
- [ ] Financial reconciliation done
- [ ] Budget: $_____
- [ ] Spent: $_____
- [ ] Remaining: $_____
- [ ] % Used: _____

Risk Register Template

- [ ] Risk identification completed
- [ ] Risk assessment conducted
- [ ] Risk owner assigned
- [ ] Mitigation plan developed
- [ ] Risk monitoring schedule set
- [ ] Trigger points defined
- [ ] Contingency plan ready
- [ ] Risk review meetings held
- [ ] Risk Level: _____

- ☐ Probability: _____
- ☐ Impact: _____
- ☐ Response: _____

Vendor Performance Tracker

- ☐ Vendor contracts executed
- ☐ Deliverables timeline set
- ☐ KPIs established
- ☐ Performance reviews scheduled
- ☐ Invoice approval process
- ☐ Issue escalation path defined
- ☐ Quality metrics tracked
- ☐ Relationship meetings held
- ☐ Vendor: _____
- ☐ Score: _____
- ☐ Issues: _____
- ☐ Action: _____

Regulatory Compliance Matrix

- ☐ Protocol version control
- ☐ Amendment tracking
- ☐ Consent form versions
- ☐ Site regulatory files
- ☐ Safety report distribution
- ☐ TMF completeness
- ☐ Inspection readiness
- ☐ CAPA tracking
- ☐ Item: _____
- ☐ Status: _____
- ☐ Due: _____
- ☐ Complete: _____

Meeting Management Tool

- ☐ Meeting purpose defined
- ☐ Agenda distributed
- ☐ Attendees confirmed
- ☐ Materials prepared
- ☐ Minutes template ready
- ☐ Action items tracked
- ☐ Follow-up scheduled
- ☐ Decisions documented
- ☐ Meeting: _____
- ☐ Date: _____
- ☐ Attendees: _____
- ☐ Actions: _____

Data Management Checklist

- ☐ CRF design completed
- ☐ EDC system built
- ☐ User acceptance testing
- ☐ Training completed
- ☐ Data entry timelines set
- ☐ Query management process
- ☐ Data cleaning milestones
- ☐ Database lock criteria
- ☐ Metric: _____
- ☐ Target: _____
- ☐ Current: _____
- ☐ Gap: _____

Communication Plan Matrix

- ☐ Stakeholder identified
- ☐ Communication frequency set
- ☐ Channel determined
- ☐ Message templates created
- ☐ Distribution list maintained
- ☐ Feedback mechanism established
- ☐ Escalation path defined
- ☐ Archive system in place
- ☐ Stakeholder: _____
- ☐ Frequency: _____
- ☐ Method: _____
- ☐ Owner: _____

Quality Metrics Dashboard

- ☐ Protocol deviations tracked
- ☐ Monitoring findings logged
- ☐ CAPA implementation
- ☐ Training compliance
- ☐ Document quality scores
- ☐ Audit findings tracked
- ☐ Process improvements identified
- ☐ Lessons learned captured
- ☐ Metric: _____
- ☐ Goal: _____
- ☐ Actual: _____
- ☐ Trend: _____