Clinical Trial Financial Activation Readiness Checklist

Activating a clinical trial requires more than finalizing a budget. Financial success depends on a range of regulatory, operational, staffing, technology, and compliance considerations that can influence study costs, reimbursement, revenue capture, resource utilization, and overall financial performance. The PYA Clinical Trial Financial Activation Readiness Checklist helps academic medical centers, hospitals, physician practices, and other organizations address these dependencies before study activation to help avoid delays, unanticipated costs, budget shortfalls, risk, and lost revenue.

This checklist is intended as a general, non-exclusive resource and does not address every legal, regulatory, financial, operational, or organizational consideration. Organizations should evaluate their specific facts and circumstances and consult with legal counsel and other advisors to ensure compliance with applicable laws, regulations, and business requirements.

Protocol Alignment and Feasibility	
☐	Review protocol and schedule of assessments (SoA) to determine if the site is capable of conducting the trial.
☐	Validate site feasibility by evaluating staffing, infrastructure, and patient population, including • Availability of appropriate personnel to conduct the trial • Availability of necessary space for the trial • Ability to perform all protocol-required testing, procedures, assessments, and ancillary services within the required timelines • Availability of needed equipment
☐	Confirm enrollment assumptions, including inclusion/exclusion criteria and projections for participant screening activities that do not result in enrollment.
☐	Identify protocol complexity drivers that may impact cost and resources: • Deviations from standard of care • Provision of potential sponsor-required electronic medical record access (onsite or remote) • Ability to fulfill potential drug storage requirements • Procurement or geographical constraints • Drug administration in a clinic or inpatient setting

Protocol Activity Mapping	
☐	Deconstruct the study protocol into all required activities: • Visit-based and non-visit-based activities (e.g., number, duration, and location) • Fiscal, regulatory, and operational workflows • Monitoring and sponsor interaction activities (i.e., monitoring that is remote, in person, or both; sponsor-required electronic regulatory system)
☐	Confirm all lifecycle phases are addressed before activating the trial: • Start-up • Study conduct • Maintenance • Close-out

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Personnel Effort and Time Assumptions	
☐	Define and document effort across all roles, including principal investigator (PI), sub-investigator, coordinators, and fiscal and administrative staff.
☐	Validate inclusion of effort: • PI oversight and procedure-level involvement • Coordinator effort beyond clinic visits (e.g., data entry, documentation, query resolution, scheduling, monitoring support, patient communication and coordination) • Administrative, fiscal, and regulatory activities [e.g., billing and invoicing, institutional review board (IRB), Clinical Trial Management System (CTMS), coverage analysis]

Coverage Analysis and Billing Compliance	
☐	Complete and document coverage analysis.
☐	Confirm appropriate allocation between sponsor and third-party payers.
☐	Validate compliance with Centers for Medicare & Medicaid Services Clinical Trial Policy and payer requirements.
☐	Ensure no duplicate billing across funding sources.

Comprehensive Cost Review	
☐	Evaluate cost categories: • Direct (e.g., personnel, procedures, investigational product handling, patient-related costs) • Indirect (e.g., overhead, administrative, facility) • Study-related services provided by central laboratories, imaging providers, vendors, or other third parties
☐	Confirm inclusion of facility (i.e., hospital) and clinic space utilization.

Trial Cost Coverage	
☐	Ensure costs are captured across the full study lifecycle: • Start-up (e.g., budget and contract review and development, regulatory preparation, training, site initiation) • Active study conduct (e.g., per-patient activities, monitoring activities) • Ongoing maintenance (e.g., amendments; unscheduled visits; administrative effort such as billing compliance review, invoicing, collections) • Close-out (e.g., final monitoring, reconciliation, archiving)
☐	Assess costs and operational impacts associated with protocol amendments, enrollment variability, and study delays.

Per-Patient Budget Structure	
☐	Align budget to visit and procedure-level requirements.
☐	Confirm all protocol-required activities, procedures, assessments, and associated site efforts are captured in the budget.
☐	Clearly distinguish standard of care vs. research-only services (i.e., is the study a qualifying clinical trial? what costs will be covered by insurance or the trial sponsor?).
☐	Validate staff time-based assumptions supporting per-visit costs.
☐	Account for inflation in multi-year studies.

Payment Terms and Financial Viability	
☐	Confirm payment structure (e.g., per-patient, milestone, or invoice-based).
☐	Align payment triggers with study activities and deliverables.
☐	Evaluate holdbacks and payment timelines.
☐	Address screen failures, early terminations, and withdrawals.
☐	Ensure payment structure supports operational cash flow.

Fair Market Value and Commercial Reasonableness	
☐	Validate that compensation to/for the following clinical trial budget items is consistent with fair market value and is commercially reasonable: • PIs, sub-investigators, and study coordinators • Ancillary services such as laboratory testing, imaging, and data management • Patient recruitment activities • Patients (i.e., expenses and stipends) • Facilities and equipment
☐	Ensure that arrangements with outside third parties for ancillary services, facilities, and equipment, if applicable, are consistent with fair market value and are commercially reasonable.

Benchmarking and Negotiation Preparedness	
☐	Compare proposed budget to internal benchmarks and prior studies.
☐	Identify key cost drivers and high-risk areas for underfunding.
☐	Develop support for negotiation positions and assumptions.
☐	Distinguish negotiable vs. non-negotiable elements.

Documentation and Finalization	
☐	Maintain version control and supporting documentation.
☐	Obtain internal approvals (i.e., PI, finance, research administration).
☐	Ensure alignment with final budget, informed consent, and Clinical Trial Agreement (CTA).
☐	Retain documentation to support audit and compliance requirements.