| Item | Notes | Cost (1,000 subjects, 18 months) |
|---|---|---|
| **Project Management and Communication** | | |
| **ACP Project Management** | Project management activities by ACP staff | **$93,750** |
| **Clinical Project Management** | General management activities by non-ACP entities | **$240,954** |
| **Project Management for DM** | Project management associated with data | **$90,675** |
| **Study Newsletter** | Quarterly newsletter to opt-in study participants and investigators | **$20,315** |
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| **Study Start-up** | | |
| | | |
| **CRO Staff Training + Project Kick Off and Plan** | Training of CRA and RA regarding study protocol, disease state, study processes, etc. | **$3,948** |
| **Central lab startup and project prep** | Start-up fee, develop sample distribution database, prep data transfer to new vendor | **$2,300** |
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| **Study Design** | | |
| | | |
| **Protocol Design** | Write/review protocol | **$10,028** |
| **ICF Design** | Write/review ICF | **$2,636** |
| **CRF Design** | Write/review CRF | **$2,775** |
| **EDC requirements document** | Documentation | **$2,092** |
| | | |
| **Site Management** | | |
| | | |
| **Contract Development** | Creation of standard contract | **$2,625** |
| **Site Identification** | Generate list of potential sites to approach | **$6,686** |
| **Site Recruitment & Qualification** | Recruiting and qualifying sites from identified site list | **$5,507** |
| **Contract Execution** | Negotiation of contract with site | **$13,125** |
| **IRB Submission** | Site IRB fees | **$56,000** |
| **IRB Renewal** | Annual renewal (accrue this monthly) | **$31,500** |
| **Misc. Site** | Bucket for other per site charges (admin fees, laptops, etc) | **$15,000** |
| **Clinical Site Training** | Conduct training and provide materials to site (includes start up packet costs) | **$2,596** |
| **DM Site Training** | Conduct training on eCRF (includes user manuals) | **$19,650** |
| **Administer Site Payments** | Quarterly Payments to sites based on successful enrollments | **$9,686** |
| **Maintain Regulatory Documents** | Required documents for human study | **$16,947** |
| **Clinical Site Management** | Periodic check in with site to answer questions, deal with problems, help with CRF tracking/queries | **$45,927** |
| **Site Management for DM** | Interaction with sites related to data (includes help desk) | **$10,429** |
| **Site Visits (ACP)** | Site visit by ACP personnel to each site (assumed once) | **$22,500** |
| **Site Visit (CRO)** | Some sites may require visits for training or cultivation | **$29,841** |
| **Site Closeout** | Cost of shutting down a site when done with project | **$3,397** |
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| **Sample and Data Collection at Sites** | | |
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| **Study Coordinator Reimbursement** | Incentive payment to site for participation in study - currently for study coordinator | **$600,000** |
| **Consent Subject** | Time to Consent Subject | **$242,000** |
| **CRF Administration, Disease Ascertainment and Blood Draw** | CRF portion done by study coordinator and PI. Collection of samples. | **$235,000** |
| **Subject Stipend** | Reimbursement to subject | **$35,000** |
| | | |
| **Central Laboratory** | | |
| | | |
| **Sample Processing and Storage** | Lab processing, QC and annual storage | **$292,000** |
| **Kit Creation and Shipping** | Build and ship sample kits (both directions) | **$80,500** |
| | | |
| **Electronic Data Capture** | | |
| | | |
| **Study DB Design** | Database creation | **$31,500** |
| **Data from repository to DM SETUP** | Get link between central lab and DSG working | **$5,000** |
| **Study Data Processing** | Data entry, validation, follow-up and QC | **$70,350** |
| **MEDDRA License** | Required for medDRA coding | **$6,000** |
| **Data transfer from central lab to ACP or 3rd party** | Assuming 1 transfer to 3rd party per month (not sure if this cost is for clinical data or for researcher data) | **$3,600** |
| **Data to reseacher/ACP** | Transfer data to researcher/ACP | **$2,250** |
| **SW maintenance** | Licensing/maintenance fees | **$15,750** |
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| | TOTAL | **$2,379,838** |
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