

## Sponsor Reimbursement Tips

**Examples of line items to include in your grant/sponsor contract to recover the cost of the Complion eRegulatory study management solution:**

- **Include as a separate line item:**
  - Non-negotiable (similar to accessing an electronic medical record)
  - Example Locations
    - Study Start-up Fees
    - Administrative Fees
    - Regulatory Document Management Fees
    - Coordinator Administrative Fees
    - FDA Submissions
    - Multi-Center/Coordinating Center Regulatory Administration
    - Archiving Fee (Average Paper Cost is 4 boxes for 15 years)
  
- **Distribute the cost of the system across several line items:**
  - Overhead costs
  - Coordinator time per Patient Visit
  - Patient Visit Fees
  - Remote Monitoring Fees
  - General Monitoring Activities
  - Long Term Archiving of Study Materials
  - Investigator Regulatory Documentation and Maintenance

### **Justification for consideration of inclusion for line items:**

- **Essential Document Remote Monitoring / Access Fee:** This fee reimburses the time for staff remote monitoring preparation as well as remote monitoring access for external sponsor and/or CRO users.
- **Essential Document Maintenance / Startup Fee:** In addition to our normal startup fees, this fee reimburses the cost of performing specific activities in the eRegulatory system:
  - Support, hosting, updates/patches, training, and related compliance services
  - Software license of a new study
  - The time for staff to startup a new study
- **Archiving Fee:** This fee reimburses the cost of secure and high-quality long-term digital storage in our Regulatory e-System. We can also provide a certified export of our electronic regulatory binder into an interactive PDF format for long term archiving in paper and/or electronic form by the sponsor and/or CRO.