TRCC Clinical Trials Network

Investigator and Patient Pools

1) Generate and maintain a pool of investigators
2) Patient and PI databases to support preparatory to research queries
3) Standardization of trial metrics

Harmonization of institutional procedures

1) Standardize the collection of data (forms) that characterizes the study requirements per protocol/event schedule and correlates the resources that will be required at each campus involved, e.g.:
    a. Institutional Resources: Recruitment, Enrollment, Study Conduct, Follow-up
    b. Services: Laboratory, Pharmacy, Radiology, Respiratory Therapy, Nursing Services, Medical Records
2) Standardize the key financial data collected to ensure resourcing and management/compliance:
    a. Funding Source(s)
    b. Budget Development
        i. Medicare Coverage Analysis for Services (billing grid)
        ii. Full Cost Estimate
    c. Billing Plan & Communication to Service Providers
3) Standardize the planning for the regulatory requirements
    a. Determination of FDA regulated and IND/IDE requirements
    b. Determination of ClinicalTrials.gov responsibilities
    c. Developing Data Safety Monitoring Plan & identifying visit frequency, where visits will occur (affiliate sites), and access to electronic records.

Data Coordinating Center

The SDCC has a number of functions, responsibilities, and systems. The items below represent the necessary operations for a centralized SDCC. Several of the items below may be managed in a virtual operation.

Information Systems

1. Efficient electronic data collection
    - Need low marginal site costs to participate and take advantage of centralized services
        - FISMA, APIs, existing software licenses, etc.,
    - Multiple remote users with different browsers and OSs
2. Centralized Computer Operations
    - Capitalize on UTRC efforts from a single location, Centralized Disaster Recovery, Version Control
3. Informatics integration
    - Biospecimen repository data
    - Imaging data

Data Management Operations

1. Data Collection
    a. Information validation
        i. Enforce collection standards with flexible upload capacity
            1. Laboratories, clinical facilities, study participants' homes
    b. Heterogeneous data types
        i. Clinical research data from protocol, imaging, biological, EHR
    c. Transaction audits
    d. Honest Broker operations
2. Data Curation
    a. Management activity required to maintain research data long-term such that it is available for reuse and preservation
3. Future-proofing database designs for repurposing
    a. Data dictionary, ontologies

Biostatistics Services

1. Hypothesis development
2. Study design
3. Endpoint definition
4. Statistical analysis plans
5. Monitoring
    a. Efficacy/futility, accrual, safety, DSMC
6. Data Analysis
7. Reporting/publishing

Trial Operations

1. Eligibility, Enrollment, and Randomization operations
2. Trial protocol coordination and Operations
    a. Data collection (CRFs or eCRFs)
    b. Data Entry
    c. SOPs and operational procedure manuals
    d. Quality control/monitoring procedures
    e. Communications
        i. Between clinical site PIs, research coordinators, and other network staff.
3. Specimen tracking
    a. Specimen inventory, release, links

Quality Assurance

1. Quality and Clinical Monitor
    a. Electronic Sign-offs (Editor → Monitor → PI)
2. Central Audit
3. Data Safety and Monitoring
4. Patient Advocates

<u>IRB and Institutional Agreements, Contracting, etc.</u>

1) Centralized versus other systems for IRB review
2) Evaluate utility of best practices from CTNeT single IRB implementation (including IRB and contract agreements and use of for-profit IRB provider
3) Confidentiality disclosure agreements, contract negotiations, etc
4) Legal and regulatory tools that will advance the initiative (cover memo of CTNeT related IRB procedures, UT system master clinical trial agreement from Beth Lynn Maxwell)

<u>Biobanking</u>

1) Best practices for sample collection/processing/storage
2) Good laboratory practice (GLP) for freezer monitoring and temperature history logs
3) Centralized or federated model for biobanking
4) Biorepository software for inventory and sample progeny
5) Identify common freezer inventory currently across sites
6) Integrating biorepository and clinical information
7) Regulatory considerations: historical and moving forward (PHI linked/de-identified etc.)