Integrating Clinical Research into Clinical Care

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Outline

- Protocol Start-Up (Before the Visit)
- At the Visit
- After the Visit

Protocol Start-Up - Feasibility

- Feasibility Review:
  - Patients targeted - do you have the patients?
    - Tumor type and sub-types
  - Competing studies? Prioritization?
  - Resources needed? Do you have the resources?
    - Regulatory, CRCs, Nursing, Pharmacy, Lab services, Pathology, Imaging, XRT, etc.
  - Interested co-investigators? (assistance with recruiting, coverage, etc)

Protocol Start-Up – Finance, Pre-Award

- QCT and Coverage Analysis Review
  - Is it a Qualifying Clinical Trial?
  - Designating items as research vs routine care
    - Important for billing compliance once the trial starts.
- Budget & Contract
  - Research items (including personnel time) need to be covered.
  - If no external funding, who pays?
    - Labs pharmacy fees, drug procurement, staff time, etc.

Protocol Start-Up – Finance, Pre-Award

- Industry trials:
  - Budget negotiations- cover your time and effort!
    - Not just on-study time, but pre-study start-up activities (*Portals! Oh the portals!*)
  - Don't underwrite for-profit companies.

Q: Fees for PI time/effort: % salary, or line item?

Protocol Start-Up

- Regulatory
  - IRB
  - Protocol Review Committee (for NCI Cancer Centers)
  - Sponsor documents (1572, FDFs, etc.) and required trainings
  - IIT: ClinicalTrials.gov and CTRP

Q: Budget before regulatory? Parallel with regulatory?

- Study Initiation Meeting (internal logistics)
  - Walk through study with plan for who does what

At the Visit – Preparation is important

- Pre-screen for potential subjects
  - Coordinators & investigators review upcoming clinic appointments, and discuss potential subjects
  - Consent forms prepared prior to clinic
- Consenting
  - Physician explains the study
  - Coordinator does the “nitty-gritty” (full consent review, obtaining signature & copy, documenting the consent process).
  - Subjects usually take consent form to review, and sign at next visit.

At the Visit – Preparation is important

- Enrolled subjects
  - Coordinators prepare for visit.
  - "Research order" is prepared so investigator knows exactly what to do in clinic
    - Required tests/procedures (labs, radiology, etc.)
    - Required documentation (PS, AE review, con meds, etc.)
    - AE attributions: try to capture in clinic, with physician)
  - Schedule research subjects early in the day to avoid glitches, back ups, and Murphy's Law issues.
  - Reconsents and Notifications prepared in advance.

After the Visit – Much to do!

- Newly consented subjects
  - Eligibility review
  - Registration to study
  - Entry into CTMS
  - Set up appointments for treatment, exams, imaging, etc.
- Data submission (*Death by Portals*)
  - CRFs
  - Imaging
  - Specimen tracking
  - XRT data

After the Visit – Post-Award Finance

- Research patients and visits flagged in EMR
- Work queues reviewed by study coordinator, to assign items to Research or Routine Care
  - Coverage Analysis guides assignment of these items & helps with billing compliance.
  - Finance team & CRCs must be informed and communicate regularly. Have a process!
  - Billing compliance is critical for staying legal, and getting paid!

Monitors and Sponsors

- Define monitoring visits when negotiating budgets
- Monitor visits away from clinic
- Limit CRC and investigator time with the monitor
- Coordinate with your internal QA/QC for help with audit preparation, investigator training, remediation plans, & ongoing training
- Push back on IND Safety Reports

Questions & Discussion

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