ODQ Educational Session December 13, 2016: Questions and Answers

GCP Training Requirement – NIH Policy Update

- **How will ODQ track GCP training compliance for personnel whose role is not in OnCore as protocol staff (e.g. Research Pharmacists, Biostatisticians)?**
  - *Staff profiles in OnCore will be used to capture training dates and track compliance. Even research staff members that are not added to a protocol in OnCore will have an active staff profile in OnCore.*
  - *Reminder: new research personnel (or their managers on their behalf) should submit a ticket to Partners IS to request a new OnCore profile prior to sending training certificates to ODQ. Please use the following template for profile requests:*

    ATTN: OnCore Oncology Team – New user profile request

    - ***First Name:***
    - ***Middle Name/Initial:***
    - ***Last Name:***
    - ***Earned Degrees:***
    - ***Partners User Name (for Partners users only):***
    - ***Office Location:***
    - ***Disease Program:***
    - ***Work Phone:***
    - ***Pager (if applicable):***
    - ***Work Email:***

- **How far does the GCP training requirement extend? For example, do lab technicians responsible for processing samples need to complete GCP (or HSP) training?**
  - *The NIH expects research personnel involved in the design, conduct, management and oversight of human research protocols to complete GCP training every 3 years. Typically, this would not include staff such as lab or pharmacy techs.*

- **Are DF/HCC Sponsor-Investigators of multi-center trials required to track GCP training compliance of staff at external sites?**
  - *DF/HCC policies do not require the Sponsor-Investigator to track or collect HSP or GCP training documentation from external institutions. External institutions are responsible for ensuring compliance with the NIH GCP policy and other regulatory requirements, where applicable.*

CT.gov and CTRP

- **Is posting results on CT.gov considered prior publication for the medical journals?**
  - *(Per ICMJE): While the ICMJE recognizes the potential problems associated with posting preliminary research results that have not yet undergone an independent peer-review*

process, it acknowledges that the Food and Drug Administration Amendments Act of 2007 (FDAAA; U.S. Public Law 110-85, Title VIII), mandates the posting of summary results data for certain trials in ClinicalTrials.gov. Thus, the ICMJE will not consider results data posted in the tabular format required by ClinicalTrials.gov to be prior publication. http://icmje.org/about-icmje/faqs/clinical-trials-registration/

- **Who should I contact regarding updating a CTEP-managed CT.gov record where DFCI is a participating site?**
    - *Contact whoever is listed as the "responsible party" for that record in CT.gov.*

Data Management

- **Questions regarding the breakdown of data management responsibilities between ODQ and CTRIO (e.g. who is responsible for building or updating eCRFs?)**
    - *ODQ responsibilities include:*
        - *Providing missing forms reports (MFRs) to PIs and study teams.*
        - *Receipt and triage of data requests.*
        - *Verifying data is clean and complete prior to fulfillment of data requests.*
        - *Coordination of DSMC and DSMB, including distribution of notifications and DSMC/DSMB data reports.*
    - *CTRIO responsibilities include:*
        - *Design and development of Inform CRFs (eDC) and related rules*
        - *Post-production changes to CRFs (e.g., due to protocol amendment)*
        - *Programming missing forms reports for ODQ (eventually for study team use)*
        - *InForm training and access requests*

- **How do you submit a data request?**
    - *Please submit a Data Request Form to ODQDataManagement@dfci.harvard.edu.*

- **When should a data request be submitted?**
    - *Please submit requests at least 2 weeks in advance for trials in Inform EDC, and at least 4 weeks in advance for trials using paper CRFs. Whenever possible, it is helpful for study teams to ensure data entry is up to date, and all queries answered, for the data being requested prior to submitting a request.*

- **What does the data cleaning process look like?**
    - *During data cleaning, ODQ will verify that data entry is complete and up-to-date and ensure all required visits and forms were triggered and completed appropriately. ODQ will also perform a series of manual edit checks on the data to identify potential errors or inconsistencies in the data. Finally, ODQ also reviews study team responses to both automatic queries and queries issued by ODQ.*

- **Does ODQ only manage Inform data (versus RedCap, etc.)?**
    - *ODQ manages data for trials that use electronic case report forms in InForm and some paper CRF trials. We do not have access to data collected in other systems or managed by a non-DF/HCC party (e.g., industry sponsor, CRO).*

- **Can we use an excel sheet to document data and send that to ODQ for cleaning and management?**
    - *The protocol document will state how data collection occurs for a given trial. If data is captured in electronic CRFs (e.g., InForm), that is considered the database of record. ODQ is only concerned with the database of record, which must be used for data analysis (e.g., for publication or abstracts).*

Subject Registration

- **On external site registrations, what is the minimal amount of subject information needed to enroll in OnCore?**
    - *The external site must provide:*
        - *Subject name or initials*
        - *D/O/B*
        - *Gender*
        - *Diagnosis*
        - *Treating MD*
        - *Date treatment begins*
        - *Treating Institution*
        - *Name of Consenting Investigator (to compare to consent)*
        - *Name of registering person (site and DF/HCC coordinator)*
        - *Contact information of registering person*
    - **** The following information may be redacted from the checklist:*
        - *Address*
        - *Race/Ethnicity – preferred, but can be entered as Unknown*
        - *Hospital #*
    - *The subject must be identified on all pages of the signed ICF, in order to tie the consent to the individual being registered.*

- **What are some of the common pitfalls seen on external site registrations?**
    - *The external site is using an expired checklist.*
    - *Required subject information missing from first page of the checklist.*
    - *Numerical values do not include the correct units or exponents to match eligibility criteria (e.g., lab results).*
    - *Note indicates "requirement waived by PI" but there is no evidence an eligibility exception was submitted to OHRS.*
    - *Subject identifiers missing from the signed ICF.*

- **Can ODQ put randomization sheets in Excel format or take the information directly from biostats and formulate their own sheets?**
    - *ODQ will provide a randomization sheet template in Word format, and this can be easily transferred to an Excel sheet where necessary. However, in order to eliminate the potential for errors, ODQ will not alter spreadsheets or transfer data between files or formats.*
    - *At minimum, ODQ requires the following information on randomization sheets:*
        - *Columns for patient name, sequence #, and date randomized (blank; to be filled in by ODQ at randomization)*
        - *A column of pre-filled treatment assignments in the order they should be used.*
        - *A separate table is required for each combination of stratification factors (where applicable).*