Investigator Qualification Evidence Gathering: Our Approach to Data Collection

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Overview

Brief review of:
- Study objectives
- How we collected our evidence
- How we conducted our analysis
- Characteristics of our investigator and sponsor populations
Study Objectives

- Describe the impact GCP training has on the quality conduct of clinical trials
- Identify gaps and redundancies in the current training of investigators in preparation for the conduct of clinical trials
- Identify key learning objectives for training to qualify investigators for the quality conduct of clinical trials
How We Collected Our Evidence (1)

- CTTI uses both qualitative and quantitative descriptive study designs; however qualitative designs using methods such as in-depth, semi-structured interviews are used most often when little information is known about an issue.

- Qualitative methods provide rich, in-depth information that describes the range of expert experiences and possible technical approaches about a particular phenomenon that isn’t possible to capture in survey data.

- Goal is to provide a strong foundation for developing recommendations based on the evidence gathered.
How We Collected Our Evidence (2)

**Approach**: One-on-one semi-structured phone interviews

**Data Collection**: May 12\textsuperscript{th} to August 4\textsuperscript{th}, 2017

**Interviewers**: RTI Consultants

**Study population**:
- Investigators, n = 13
- Sponsors, n = 10
Additional Comments

Structured demographic survey administered prior to collecting qualitative interview data

Interviews focused on the following topics:

- definition of the quality conduct of sponsored clinical trials
- concerns about the quality conduct of clinical trials
- critical tasks that lead to the quality conduct of sponsored clinical trials
- knowledge and skills required for performing those critical tasks with quality
- training, including investigator training on the critical tasks identified and on good clinical practice (GCP) in general
How We Conducted Our Analysis (1)

- Applied Thematic Analysis: two-stage analysis approach
  - 1st stage: multiple analysts apply deductive codes based on specific interview topics and organized by research objectives
  - 2nd stage: Analysts divide deductive coding reports and code for inductive (emergent) sub-themes
    - Inductive coding reports reviewed to identify themes and sub-themes related to the study’s objectives
- Descriptions of themes and sub-themes, along with illustrative quotes are provided in summary reports, which form the basis for the final report
- Data are not quantified or lend themselves to summary in graphs or tables
How We Conducted Our Analysis (2)

Demographic survey data summarized in the following slides were analyzed using descriptive statistics and open text fields were thematically analyzed.
Characteristics of Study Population: Investigators (1)

- 13 investigators:
  - Clinical specialties:
    - Ranged from highly specialized clinical practice (e.g., oncology and hematology) to more general practice (e.g., general internal medicine, and family medicine)
  - Years of experience in medicine: 10-35 years
Characteristics of Study Population: Investigators (2)

- **Institutional affiliation:**
  - Dedicated research sites with no affiliated clinical practice responsibilities (n=5)
  - Academic institutions or academic health systems with research and education opportunities (n=4)
  - Community-based outpatient clinics or private practice with primary clinical responsibilities (n=2)
  - Hospital systems or community-based hospitals with no affiliated academic institution (n=2)
Characteristics of Study Population: Investigators (3)

- **Wide variation in experience leading Phase III clinical trials** of drugs, biologics, and/or medical devices for registrational purposes:
  - PI, co-PI, and sub-PI: 1-31 years
  - Number of trials led: 3-300

- **Types of Phase III trials led:**
  - 62% (n=8): Phase III trials of biologics
  - 54% (n=6): Vaccines trials
  - 54% (n=6): Medical devices
Characteristics of Study Population: Sponsors (1)

10 sponsors

- **Size of company:**
  - Small: market cap at $300 million to < $2 billion (n = 2)
  - Mid-size: market cap between $2 billion and $10 billion (n = 4)
  - Large: market cap > $10 billion (n = 3)

- **Variation in types of products developed:**
  - combination products (60%; e.g., drug-devices)
  - therapeutic or preventative drugs (50%)
  - biologics (40%) and/or devices (40%)
Characteristics of Study Population: Sponsors (2)

- **Variation in sponsor representatives’ roles and years of experience in these roles:**
  - vice presidents, senior or executive-level directors, departmental directors or heads, and managers
  - 1-23 years of experience

- **Sponsors’ partnership with research organizations:**
  - all sponsors: had partnered with academic institutions to conduct their registrational trials
  - most sponsors: had partnered with community-based outpatient clinics and hospitals (90% and 70%, respectively)
  - half of sponsors: had partnered with dedicated research sites
THANK YOU.

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