

Clinical Trials Results Analyst, ICF International

Technology & Management Solutions
Health Informatics & Technology Solutions
Bethesda, MD

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Job Description:

The Health Informatics & Technology Solutions (HITS) Division seeks a ClinicalTrials.gov Results Analyst to support our National Institutes of Health/National Library of Medicine (NIH/NLM) client.

ClinicalTrials.gov database Background:

ClinicalTrials.gov is a registry of federally and privately supported clinical research conducted in the United States and around the world. The registry was established in 2000 and expanded in 2007 after the passage of the Food and Drug Administration Amendments Act of 2007 (FDAAA). Section 801 of this law mandates that a "responsible party" of certain "applicable clinical trials" register the trial protocol, and report the results to a database "made publicly available through the internet". Both registration and results reporting are accomplished through the Web-based Protocol Registration System (PRS) [<http://prsinfo.clinicaltrials.gov/>]. The "basic results" section of the ClinicalTrials.gov database was launched in September 2008. Submitted results data are displayed on ClinicalTrials.gov with the corresponding registered summary protocol information.

Responsible parties commonly report results prior to a journal publication. Unlike journal articles that are reviewed by both scientific colleagues and editors, results submitted to ClinicalTrials.gov are not peer reviewed prior to posting, although minimal quality criteria must be met. For example, the public display of results in stand-alone tables needs to be self-explanatory and meaningful to a range of users; and, results entries should not contain discussions or textual conclusions about the data. The successful candidate for this position will be responsible for reviewing results data submissions to ascertain whether they meet minimal quality criteria for posting on ClinicalTrials.gov.

*Information regarding the ClinicalTrials.gov database and reporting requirements can be found at <http://prsinfo.clinicaltrials.gov/fdaaa.html>

**Some information in this job posting announcement is adapted from: [Tse T](#), [Williams RJ](#), [Zarin DA](#) (July 2009) Reporting "Basic Results" in *ClinicalTrials.gov*. *CHEST* 136(1):295-303.

Key Responsibilities:

- Gain and use a working knowledge of the ClinicalTrials.gov Basic Results Data Element Definitions (http://prsinfo.clinicaltrials.gov/results_definitions.html)
- Gain and use a working understanding of ClinicalTrials.gov review criteria (<http://prsinfo.clinicaltrials.gov/ResultsDetailedReviewItems.pdf>)
- Perform reviews of clinical trial results submissions for consistency with review criteria

- Clearly communicate with “responsible parties” (i.e., clinical trial sponsors, designated principal investigators, and/or statisticians) regarding consistency of clinical trial results with review criteria
- Perform general proofreading
- Create new documentation to help responsible parties submit their clinical trial records

Basic Qualifications:

- PhD (or equivalent degree) from an accredited college in a public health and/or mathematic related discipline (epidemiology, biostatistics, statistics, etc.)
- A Master’s degree plus 3 years experience in a comparable field
- 3 years experience with standard mathematical concepts and statistics (correlations, trends, significance, etc.)
- 3 years experience with standard quantitative measures for health studies

Preferred Skills/Experience:

- Experience with analysis and reporting of clinical trial data
- Background knowledge relevant to understanding and interpreting clinical trial data and statistics
- Ability to identify internal inconsistencies in clinical trial data reporting
- Strong critical thinking and analysis skills
- Ability to critically appraise clinical trial design, methodology and analysis information
- Experience (via coursework and/or job duties) working with and interpreting the following concepts:
- Mean, median, least square mean, standard deviation, range, inter-quartile range, confidence intervals, etc.
- Frequency, incidence, proportion, percentage, rate, etc.
- Time-to-event measures,
- Parametric and non-parametric statistical tests, interpreting p-values

Professional Skills

- Ability to work within a team environment and contribute to consensus-based decision making
- Ability to identify, analyze, and solve problems creatively and independently
- Ability to handle multiple tasks simultaneously and shift priorities as directed
- Able to efficiently work in fast paced environment with team members
- Excellent oral and written communication skills
- Excellent interpersonal skills and ability to work with people at every level
- General computer and email skills

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