Analytical Overview of the CDER Risk-based GCP Clinical Investigator Inspections Site Selection Tool

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INTRODUCTION

The Food and Drug Administration (FDA) protects the rights, safety, and welfare of research participants through oversight of the conduct of clinical studies and verification of the integrity of efficacy and safety data submitted to the FDA in support of New Drug Applications (NDA), Biological License Applications (BLA), and supplemental applications. FDA accomplishes this by ensuring compliance with current FDA regulations and statutory requirements through on-site inspection of the clinical trial sites. The traditional application and inspection site selection decision process has proved challenging due to finite inspectional resources, the complexity of the clinical trial enterprise, expansion of clinical trials in emerging markets, high level efficiency requirements in the review timelines, and variation in the decision making framework. To address these challenges, FDA has developed a series of models using a multi-criteria decision analysis (MCDA) framework. This poster is a descriptive analysis of the first 30 applications that were processed for use in the CDER Good clinical practice (GCP) Inspection Site Selection tool.

PURPOSE

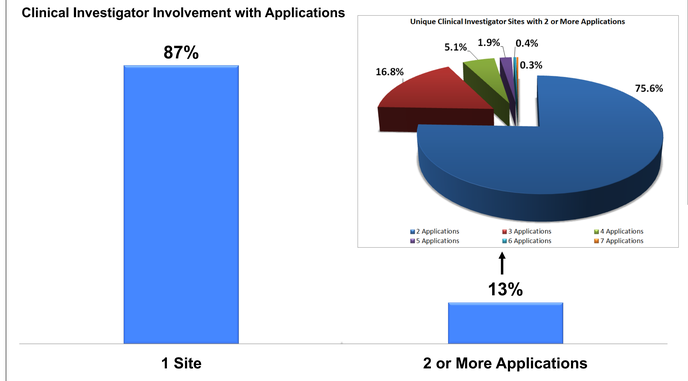
Examine and explore the data from the first 30 applications processed for used in the GCP Inspection Site Selection tool.

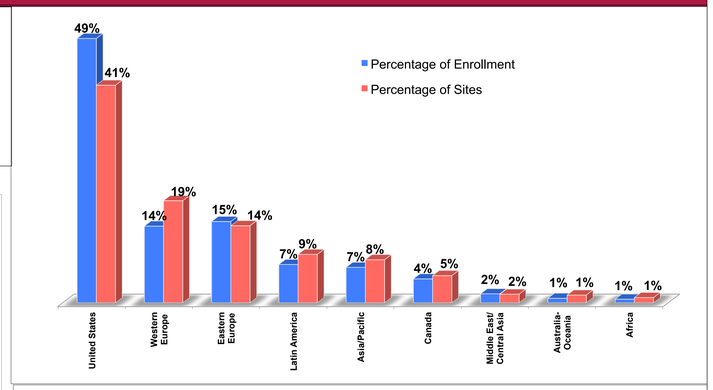
METHOD

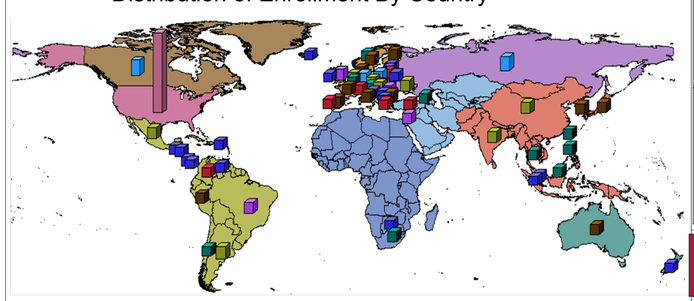
The source data for the analysis were extracted from the CDER GCP Inspection Site Selection tool database. This database is a central data repository for the sponsor-submitted datasets, matched internal FDA data criteria for the tool, site selection rational from the reviewers, and the sites selected for inspection.
The data from the 30 applications were analyzed and displayed as histograms, pie charts, and Chernoff face plots. A Chernoff face plot is a graphical representation of multivariate data in the shape of a human face. Key variables in the tool are represented by facial features in the Chernoff face plots across the 9 different regions, allowing for the identification of regional differences and similarities depending on the shape, size, placement, and orientation of the individual features (hair, eyes, mouth, nose, etc.). The Regional Classifications were derived from CIA World Factbook Regional classifications, United Nations sub-regional classifications, and CDER/OC/OSI regional classifications.

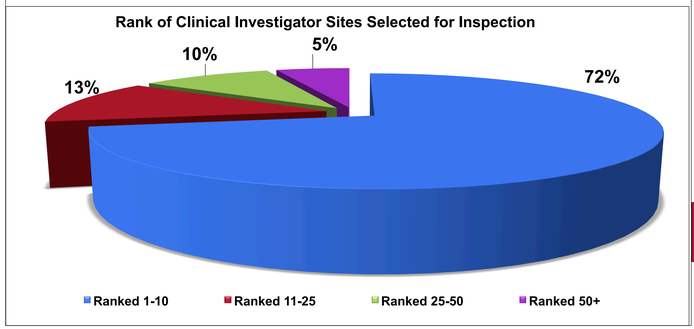
RESULTS

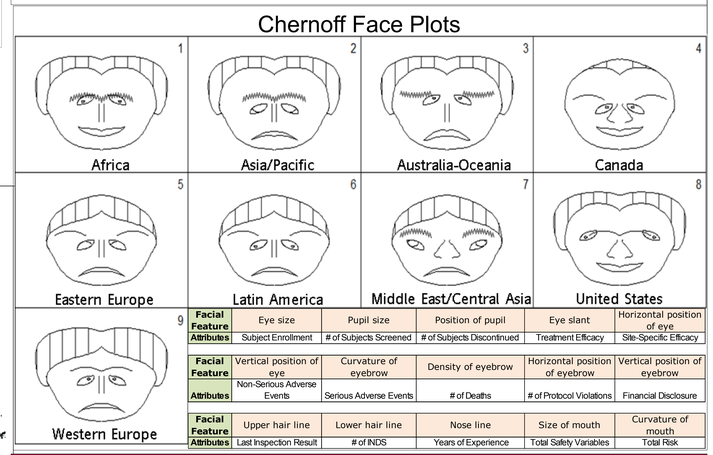
- Number of Applications: 30
- Number of Enrollment: 369,650
- Number of Pivotal Studies: 81
- Number of Sites: 11568
  - CIs associated with 1 unique site: 87%
  - CIs associated with 2 or more unique site: 13%











SUMMARY

Collecting of information in the GCP tool database presents a unique opportunity permitting risk attributes and weights to evolve over time based on inspectional findings and associated risks to data integrity. It will also permit analyses across regions, multiple trials and applications.
No conclusions were drawn from this analysis since the data represents a subset of the applications submitted for use in the tool and an even smaller subset of all New Drug Applications (NDA) submitted to FDA.

REFERENCE

Bioresearch Monitoring website; http://www.fda.gov/ICECI/EnforcementActions/BioresearchMonitoring/default.htm