AACT-Results: The Results dataset extensions for the AACT database

{AACT: Aggregate Analysis database of ClinicalTrials.gov}

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CLINICAL TRIALS **TRANSFORMATION** INITIATIVE

Disclosures and Learning Objectives

- **No Disclosures**
- **After participating in this talk the learner should be better able to:**
  - Describe the rationale for clinical trials registration and results reporting
  - Describe the informatics approach to the construction of an analyzable data set from Clinicaltrials.gov
  - Describe strengths and weaknesses of ClinicalTrials.Gov dataset for aggregate analysis

Background

- **ClinicalTrials.gov**
  - National registry hosted by the NLM/NIH
  - Studies conducted in the United States and around the world; sponsored by the NIH, other federal agencies, and private industry
  - Currently stores >164,000 studies
  - Web interface for patients and patient advocates

- **The Clinical Trials Transformation Initiative (CTTI):**
  - a public-private partnership between FDA and Duke
  - CTTI was established by the FDA and Duke University in 2007, and now comprises more than 60 member organizations.
  - Mission: to identify and promote practices that will increase the quality and efficiency of clinical trials
  - Project: To improve the public interface for use of aggregate data in ClinicalTrials.gov

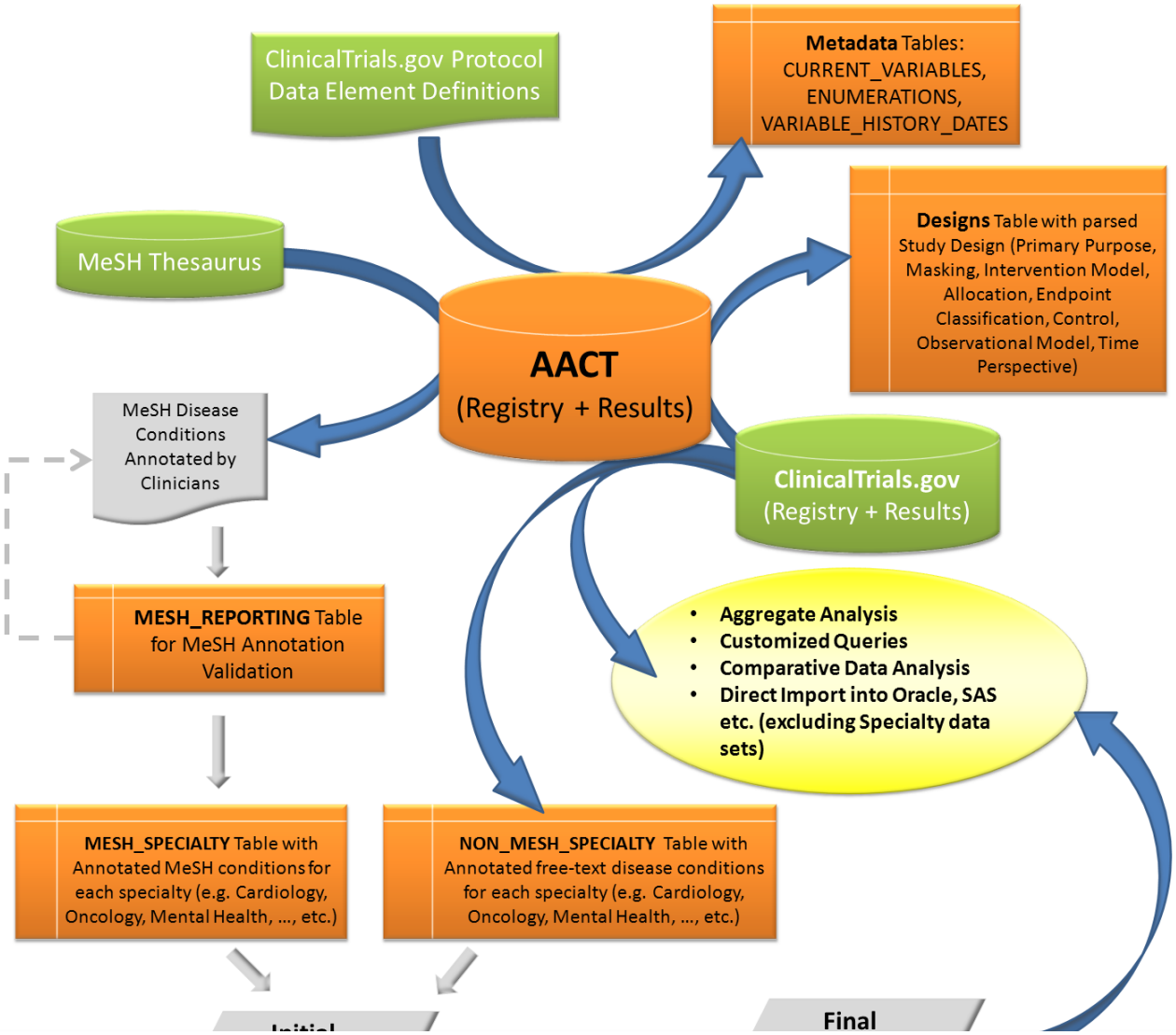
Phase I: AACT-Registry and AACT-Specialty

- **Available Data**
  - Data Element Definitions document of study data elements
  - Study dataset XMLs
  - MeSH Thesaurus
  - Public XSD
- **Created AACT-Registry**
  - Aggregate Analysis database of ClinicalTrials.gov (AACT) – Oracle dataset
  - Oracle extracts in three formats (Dmp, Text, SAS)
  - Integrated metadata along with Comprehensive and High-level data Dictionaries
  - Change History document for data element definitions
  - Integrated MeSH thesaurus
  - Parsed study design
  - Date converted to Date datatype
- **Created AACT-Specialty**
  - Grouped dataset into specialty groups
  - Annotated disease condition terms
  - 13 clinical specialties and 5 subspecialties

Phase II: AACT Results and ETL Updates

- **Available Data**
  - Public XSD
  - Results and Registry XMLs (results publicly available since 2012)
  - Data Element definitions documents – study and results data elements
- **Created AACT- Results**
  - Integrated results dataset into AACT database
  - Oracle extracts available in three formats (DMP, Text, SAS)
  - Integrated metadata along with Comprehensive and High-level data Dictionaries
  - Built semi-automated update process
  - Automated system to update data
  - Currently this process runs semi-annually

AACT database overview with its key enhancements



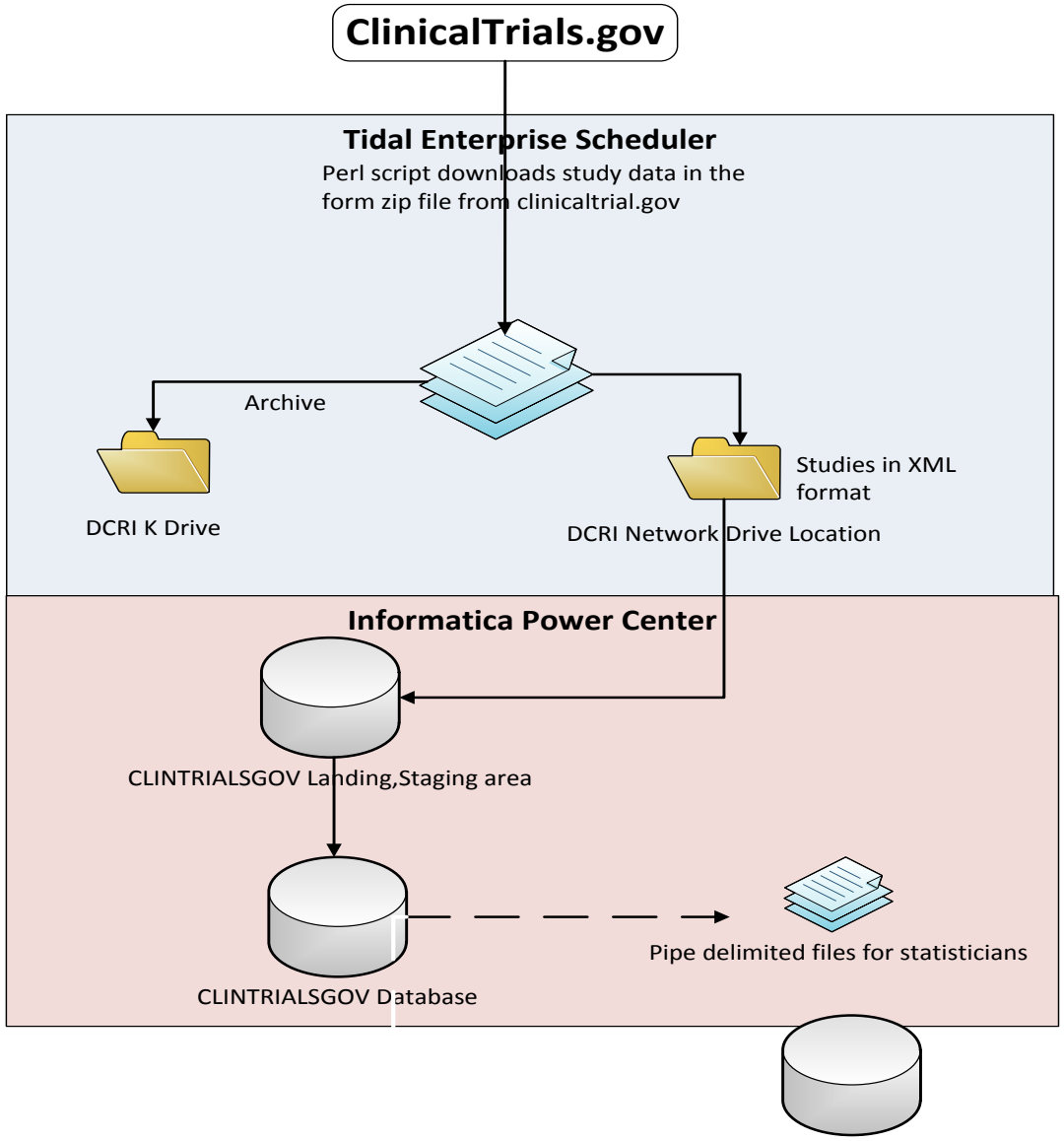
AACT Schema : Bird's eye view

AACT Metadata Summary

- **Number of Tables: 42**
  - Registry dataset: 24
  - Results dataset: 16
  - Registry and Results: 1
  - MeSH Thesaurus:1
- **Number of Data Elements: 270**
  - Registry dataset: 153
  - Results dataset: 108
  - Registry and Results: 6
  - MeSH Thesaurus: 3
- **Number of Enumerated Fields: 50**
- **Requirements**
  - NLM required fields: 85
  - FDAAA required fields: 36

ClinicalTrials.gov process flow diagram

Use of Informatica



Methods (PLoS ONE, March 2012)

OPEN ACCESS Freely available online

PLoS one

The Database for Aggregate Analysis of ClinicalTrials.gov (AACT) and Subsequent Regrouping by Clinical Specialty

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Abstract

Background: The ClinicalTrials.gov registry provides information regarding characteristics of past, current, and planned clinical studies to patients, clinicians, and researchers; in addition, registry data are available for bulk download. However, issues related to data structure, nomenclature, and changes in data collection over time present challenges to the aggregate analysis and interpretation of these data in general and to the analysis of trials according to clinical specialty in particular. Improving usability of these data could enhance the utility of ClinicalTrials.gov as a research resource.

Methods/Principal Results: The purpose of our project was twofold. First, we sought to extend the usability of ClinicalTrials.gov for research purposes by developing a database for aggregate analysis of ClinicalTrials.gov (AACT) that contains data from the 96,346 clinical trials registered as of September 27, 2010. Second, we developed and validated a methodology for annotating studies by clinical specialty, using a custom taxonomy employing Medical Subject Heading (MeSH) terms applied by an NLM algorithm, as well as MeSH terms and other disease condition terms provided by study sponsors. Clinical specialists reviewed and annotated MeSH and non-MeSH disease condition terms, and an algorithm was created to classify studies into clinical specialties based on both MeSH and non-MeSH annotations. False positives and false negatives were evaluated by comparing algorithmic classification with manual classification for three specialties.

Conclusions/Significance: The resulting AACT database features study design attributes parsed into discrete fields, integrated metadata, and an integrated MeSH thesaurus, and is available for download as Oracle extracts (.dmp file and text format). This publicly-accessible dataset will facilitate analysis of studies and permit detailed characterization and analysis of the U.S. clinical trials enterprise as a whole. In addition, the methodology we present for creating specialty datasets may facilitate other efforts to analyze studies by specialty groups.

Aggregate Analysis (JAMA, May 2012)

Characteristics of Clinical Trials Registered in ClinicalTrials.gov, 2007-2010

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Deborah A. Zarin, MD
Judith M. Kramer, MD, MS
Rachel E. Sherman, MD, MPH
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Context Recent reports highlight gaps between guidelines-based treatment recommendations and evidence from clinical trials that supports those recommendations. Strengthened reporting requirements for studies registered with ClinicalTrials.gov enable a comprehensive evaluation of the national trials portfolio.

Objective To examine fundamental characteristics of interventional clinical trials registered in the ClinicalTrials.gov database.

Methods A data set comprising 96 346 clinical studies from ClinicalTrials.gov was downloaded on September 27, 2010, and entered into a relational database to analyze aggregate data. Interventional trials were identified and analyses were focused on 3 clinical specialties—cardiovascular, mental health, and oncology—that together encompass the largest number of disability-adjusted life-years lost in the United States.

Main Outcome Measures Characteristics of registered clinical trials as reported data elements in the trial registry; how those characteristics have changed over time; differences in characteristics as a function of clinical specialty; and factors associated with use of randomization, blinding, and data monitoring committees (DMCs).

Results The number of registered interventional clinical trials increased from 28 881 (October 2004–September 2007) to 40 970 (October 2007–September 2010), and the number of missing data elements has generally declined. Most interventional trials registered between 2007 and 2010 were small, with 62% enrolling 100 or fewer participants. Many clinical trials were single-center (66%; 24 788/37 520) and funded by organizations other than industry or the National Institutes of Health (NIH) (47%; 17 592/37 520). Heterogeneity in the reported methods by clinical specialty; sponsor type; and the reported use of DMCs, randomization, and blinding was evident. For example, reported use of DMCs was less common in industry-sponsored vs NIH-sponsored trials (adjusted odds ratio [OR], 0.11; 95% CI, 0.09-0.14), earlier-phase vs phase 3 trials (adjusted OR, 0.83; 95% CI, 0.76-0.91), and mental health trials vs those in the other 2 specialties. In similar comparisons, randomization and blinding were less frequently reported in earlier-phase, oncology, and device trials.

Conclusion Clinical trials registered in ClinicalTrials.gov are dominated by small trials and contain significant heterogeneity in methodological approaches, including reported use of randomization, blinding, and DMCs.

JAMA. 2012;307(17):1838-1847 www.jama.com

CLINICAL TRIALS ARE THE CENtral means by which preventive, diagnostic, and therapeutic strategies are evaluated,[1] but the US clinical trials enterprise has been marked by debate regarding funding priorities for clinical research, the design and interpretation of studies, and protections for research participants.[2-4] Until recently, however, we have lacked tools for comprehensively assessing trials across the broader US clinical trial enterprise.

In 1997, Congress mandated the creation of the ClinicalTrials.gov registry to assist people with serious illnesses in gaining access to trials.[5] In September 2004, the International Committee of Medical Journal Editors (ICMJE) announced a policy, which took effect in 2005, of requiring registration of clinical trials as a prerequisite for publication.[6,7] The Food and Drug Administration Amendment Act (FDAAA)[8] expanded the mandate of ClinicalTrials.gov to include most non–

Therapeutic Area Publications

Pediatrics dataset analysis (Pediatrics, Oct 2012)

Status of the Pediatric Clinical Trials Enterprise: An Analysis of the US ClinicalTrials.gov Registry

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KEY WORDS
clinical trials, health policy

ABBREVIATIONS
FDA—Food and Drug Administration
NIH—National Institutes of Health

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PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

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FUNDING: Financial support for this work was provided by cooperative agreement U19 FD003800 awarded by the US Food and Drug Administration to Duke University in support of the Clinical Trials Transformation Initiative.

WHAT'S KNOWN ON THIS SUBJECT: There are limited data regarding the current status of the pediatric clinical trial enterprise.

WHAT THIS STUDY ADDS: Evaluation of the ClinicalTrials.gov data set allows description of the overall portfolio of clinical trials relevant to US children, which was previously not possible.

abstract

BACKGROUND AND OBJECTIVES: Clinical trials are the gold standard for generating evidence-based knowledge in medicine. Recent legislation requiring trials to be registered at ClinicalTrials.gov has enabled evaluation of the clinical trial enterprise as a whole, which was previously not possible. The purpose of this study was to create a snapshot of the pediatric clinical trial portfolio.

METHODS: All interventional trials registered at ClinicalTrials.gov from July 2005 to September 2010 were included. Pediatric (ie, enrolling patients aged 0–18 years) trial characteristics, therapeutic area, location, and funding were described. Secondary objectives included describing pediatric trials over time and comparison with nonpediatric trials.

RESULTS: During this time, 5035 pediatric trials were registered compared with >10 times as many nonpediatric trials. Neonates/infants were eligible for enrollment in 46.6% of trials versus children (77.9%) and adolescents (45.2%). Nearly one-half of pediatric trials enrolled <100 subjects, and more pediatric trials versus nonpediatric trials evaluated preventive therapies. The proportion of pediatric trials evaluating a drug intervention declined over time, and there were fewer Phase 0 to II versus Phase III to IV trials. Infectious disease/vaccine studies (23%) were the most common, followed by psychiatric/mental health (13%) studies. Many trials enrolled patients outside the United States, and <15% of trials were sponsored by the National Institutes of Health or other US federal agencies.

CTTI

Diabetes dataset analysis (Diabetologia, Deb 2013)

Diabetologia
DOI 10.1007/s00125-013-2890-4

ARTICLE

Are current clinical trials in diabetes addressing important issues in diabetes care?

W. C. Lakey · K. Barnard · B. C. Batch · K. Chiswell · A. Tasneem · J. B. Green

Received: 19 November 2012 / Accepted: 26 February 2013

Abstract
Aims/hypothesis Clinical trials assessing interventions for treating and preventing diabetes mellitus and its complications are needed to inform evidence-based practice. To examine whether current studies adequately address these needs, we conducted a descriptive analysis of diabetes-related trials registered with ClinicalTrials.gov from 2007 to 2010.
Methods From a dataset including 96,346 studies registered in ClinicalTrials.gov downloaded on 27 September, 2010, a subset of 2,484 interventional trials was created by selecting trials with disease condition terms relevant to diabetes.
Results Of the diabetes-related trials, 74.8% had a primarily therapeutic purpose while 10% were preventive. Listed interventions included drugs (63.1%) and behavioural (11.7%). Most trials were designed to enrol ≤500 (91.1%) or ≤100 (58.6%) participants, with mean/median times to completion of 1.8/1.4 years. Small percentages of trials targeted persons aged ≤18 years (3.7%) or ≥65 years (0.6%), while 30.8% excluded patients >65 years and the majority excluded those >75 years. Funding sources included industry (50.9%), NIH (7.5%) or other, with most being single-centre trials of other sponsorship (37.7%) or industry-funded multicentre studies (27.4%). A small number of trials (1.4%) listed primary outcomes including mortality or clinically significant cardiovascular complications. The distribution of trials by global region and US state does not correlate with prevalence of diabetes.
Conclusions/interpretation The majority of diabetes-related trials include small numbers of participants, exclude those at the extremes of age, are of short duration, involve drug therapy rather than preventive or non-drug interventions and do not focus upon significant cardiovascular outcomes. Recently registered diabetes trials may not sufficiently address important diabetes care issues or involve affected populations.

Keywords Clinical trials · Diabetes mellitus · Evidence-based medicine · Registry

CTTI

Oncology dataset analysis
(JAMA Internal Medicine, Apr 2013)

ORIGINAL INVESTIGATION

HEALTH CARE REFORM

Characteristics of Oncology Clinical Trials

Insights From a Systematic Analysis of ClinicalTrials.gov

Bradford R. Hirsch, MD, MBA; Robert M. Califf, MD; Steven K. Cheng, PhD; Asba Tasneem, PhD; John Horton, MS; Karen Chiswell, PhD; Kevin A. Schulman, MD, MBA; David M. Dilts, PhD; Amy P. Abernethy, MD

Importance: Clinical trials are essential to cancer care, and data about the current state of research in oncology are needed to develop benchmarks and set the stage for improvement.

Objective: To perform a comprehensive analysis of the national oncology clinical research portfolio.

Design: All interventional clinical studies registered on ClinicalTrials.gov between October 2007 and September 2010 were identified using Medical Subject Heading terms and submitted conditions. They were reviewed to validate classification, subcategorized by cancer type, and stratified by design characteristics to facilitate comparison across cancer types and with other specialties.

Results: Of 40 970 interventional studies registered between October 2007 and September 2010, a total of 8942 (21.8%) focused on oncology. Compared with other specialties, oncology trials were more likely to be single arm (62.3% vs 23.8%; $P<.001$), open label (87.8% vs 47.3%; $P<.001$), and nonrandomized (63.9% vs 22.7%; $P<.001$). There was moderate but significant correlation between number of trials conducted by cancer type and associated incidence and mortality (Spearman rank correlation coefficient, 0.56 [$P=.04$] and 0.77 [$P=.001$], respectively). More than one-third of all oncology trials were conducted solely outside North America.

Conclusions and Relevance: There are significant variations between clinical trials in oncology and other diseases, as well as among trials within oncology. The differences must be better understood to improve both the impact of cancer research on clinical practice and the use of constrained resources.

JAMA Intern Med. 2013;173(11):972-979.
Published online April 29, 2013.
doi:10.1001/jamainternmed.2013.627

CTTI

Cardiovascular Diseases dataset analysis
(JAHA, Sep 2013)

ORIGINAL RESEARCH

American Heart Association | American Stroke Association

Portfolio of Clinical Research in Adult Cardiovascular Disease as Reflected in ClinicalTrials.gov

Karen P. Alexander, MD; David F. Kong, MD; Aijing Z. Starr, MS; Judith Kramer, MD; Karen Chiswell, PhD; Asba Tasneem, PhD; Robert M. Califf, MD

Background—Cardiovascular medicine is widely regarded as a vanguard for evidence-based drug and technology development. Our goal was to describe the cardiovascular clinical research portfolio from ClinicalTrials.gov.

Methods and Results—We identified 40 970 clinical research studies registered between 2007 and 2010 in which patients received diagnostic, therapeutic, or other interventions per protocol. By annotating 18 491 descriptors from the National Library of Medicine's Medical Subject Heading thesaurus and 1220 free-text terms to select those relevant to cardiovascular disease, we identified studies that related to the diagnosis, treatment, or prevention of diseases of the heart and peripheral arteries in adults (n=2325 [66%] included from review of 3503 potential studies). The study intervention involved a drug in 44.6%, a device or procedure in 39.3%, behavioral intervention in 8.1%, and biological or genetic interventions in 3.0% of the trials. More than half of the trials were postmarket approval (phase 4, 25.6%) or not part of drug development (no phase, 34.5%). Nearly half of all studies (46.3%) anticipated enrolling 100 patients or fewer. The majority of studies assessed biomarkers or surrogate outcomes, with just 31.8% reporting a clinical event as a primary outcome.

Conclusions—Cardiovascular studies registered on ClinicalTrials.gov span a range of study designs. Data have limited verification or standardization and require manual processes to describe and categorize studies. The preponderance of small and late-phase studies raises questions regarding the strength of evidence likely to be generated by the current portfolio and the potential efficiency to be gained by more research consolidation. (*J Am Heart Assoc.* 2013;2:e000009 doi: 10.1161/JAHA.113.000009)

Otolaryngology dataset analysis

(Otolaryngology -- Head and Neck Surgery, Oct 2013)

Original Research

AMERICAN ACADEMY OF OTOLARYNGOLOGY–HEAD AND NECK SURGERY FOUNDATION

Otolaryngology–Head and Neck Surgery
XX(X) 1–8

DOI: 10.1177/0194599813506545
http://otojournal.org
SAGE

An Analysis of Registered Clinical Trials in Otolaryngology from 2007 to 2010: ClinicalTrials.gov

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Sponsorships or competing interests that may be relevant to content are disclosed at the end of this article.

Abstract

Objective. To describe the conditions studied, interventions used, study characteristics, and funding sources of otolaryngology clinical trials from the ClinicalTrials.gov database; compare this otolaryngology cohort of interventional studies to clinical visits in a health care system; and assess agreement between clinical trials and clinical activity.

Study Design. Database analysis.

Setting. Trial registration data downloaded from ClinicalTrials.gov and administrative data from the Duke University Medical Center from October 1, 2007 to September 27, 2010.

Methods. Data extraction from ClinicalTrials.gov was done using MeSH and non-MeSH disease condition terms. Studies were subcategorized to create the following groupings for descriptive analysis: *ear, nose, allergy, voice, sleep, head and neck cancer, thyroid,* and *throat.* Duke Health System visits were queried by using selected ICD-9 codes for otolaryngol

Keywords

otolaryngology, clinical trials, evidence-based medicine, database

Received April 1, 2013; revised August 23, 2013; accepted September 4, 2013.

Background

Practice guidelines that inform clinical decision making depend on the quality of the research supporting them[1]; however, previous investigations suggest that many rely on inadequate evidence.[2] An analysis of data from the ClinicalTrials.gov registry showed that approximately 50% of interventional trials registered from 2007 to 2010 enrolled <70 participants and found substantial variation in use of randomization and blinding.[3] Other studies examining this data set by clinical specialty have found misalignment between funding and disease prevalence.[4,5]

Similar issues affect otolaryngology–head and neck surgery (OHNS). Despite expanding research activity, concerns linger about research quality and evidence supporting therapeutic

CTTI

Infectious Diseases dataset analysis
(PLoS ONE, Oct 2013)

OPEN ACCESS Freely available online

PLOS | ONE

The State of Infectious Diseases Clinical Trials: A Systematic Review of ClinicalTrials.gov

Neela D. Goswami[1☯], Christopher D. Pfeiffer[2,3☯], John R. Horton[4], Karen Chiswell[4], Asba Tasneem[4], Ephraim L. Tsalik[1,5*]

1 Division of Infectious Diseases and International Health, Department of Medicine, Duke University School of Medicine, Durham, North Carolina, United States of America, **2** Department of Hospital and Specialty Medicine, Portland VA Medical Center, Portland, Oregon, United States of America, **3** Division of Infectious Diseases, Oregon Health and Science University, Portland, Oregon, United States of America, **4** Duke Clinical Research Institute, Durham, North Carolina, United States of America, **5** Emergency Medicine Service, Durham VA Medical Center, Durham, North Carolina, United States of America

Abstract

Background: There is a paucity of clinical trials informing specific questions faced by infectious diseases (ID) specialists. The ClinicalTrials.gov registry offers an opportunity to evaluate the ID clinical trials portfolio.

Methods: We examined 40,970 interventional trials registered with ClinicalTrials.gov from 2007–2010, focusing on study conditions and interventions to identify ID-related trials. Relevance to ID was manually confirmed for each programmatically identified trial, yielding 3570 ID trials and 37,400 non-ID trials for analysis.

Results: The number of ID trials was similar to the number of trials identified as belonging to cardiovascular medicine (n = 3437) or mental health (n = 3695) specialties. Slightly over half of ID trials were treatment-oriented trials (53%, vs. 77% for non-ID trials) followed by prevention (38%, vs. 8% in non-ID trials). ID trials tended to be larger than those of other specialties, with a median enrollment of 125 subjects (interquartile range [IQR], 45–400) vs. 60 (IQR, 30–160) for non-ID trials. Most ID studies are randomized (73%) but nonblinded (56%). Industry was the funding source in 51% of ID trials vs. 10% that were primarily NIH-funded. HIV-AIDS trials constitute the largest subset of ID trials (n = 815 [23%]), followed by influenza vaccine (n = 375 [11%]), and hepatitis C (n = 339 [9%]) trials. Relative to U.S. and global mortality rates, HIV-AIDS and hepatitis C virus trials are over-represented, whereas lower respiratory tract infection trials are under-represented in this large sample of ID clinical trials.

Conclusions: This work is the first to characterize ID clinical trials registered in ClinicalTrials.gov, providing a framework to discuss prioritization, methodology, and policy.

Citation: Goswami ND, Pfeiffer CD, Horton JR, Chiswell K, Tasneem A, et al. (2013) The State of Infectious Diseases Clinical Trials: A Systematic Review of ClinicalTrials.gov. PLoS ONE 8(10): e77086. doi:10.1371/journal.pone.0077086

Editor: Tim Friede, University Medical Center Göttingen, Germany

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Competing Interests: The authors have declared that no competing interests exist.

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☯ These authors contributed equally to this work.

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Pulmonary dataset analysis (Annals ATS, Oct 2013)

Published in final edited form as:
Ann Am Thorac Soc. 2013 October ; 10(5): . doi:10.1513/AnnalsATS.201305-111OC.

Using ClinicalTrials.gov to Understand the State of Clinical Research in Pulmonary, Critical Care, and Sleep Medicine

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Abstract

Rationale—ClinicalTrials.gov is the largest trial registry in the world. Strengthened registration requirements, including federal mandates in 2007, have increased study representation. A systematic evaluation of all registered studies has been limited by the absence of an aggregate dataset and specialty-specific search terms.

Objective—We leveraged a newly transformed database containing annotated data from ClinicalTrials.gov to define the portfolio of interventional clinical research in pulmonary, critical care, and sleep medicine.

Methods—Analysis was restricted to studies registered after September 2007 through September 2010 and defined as "interventional" (n=40,970). A specialty-specific study dataset (n= 2,226) was created using disease condition terms provided by data submitters and medical subject heading terms generated by a National Library of Medicine algorithm. Trial characteristics were extracted and summarized using descriptive statistics.

Measurements and Main Results—Pulmonary, critical care, and sleep medicine trials composed 5.4% of all interventional studies registered over the 3-year period. In contrast, oncology and cardiovascular disease comprised 21.9% and 8.4% of trials respectively. Within pulmonary trials, asthma and chronic obstructive pulmonary disease were the most studied conditions (27.4% and 21.8% of studies), and measures of lung function or safety were the most frequent primary outcomes. Nearly two-thirds of trials indicated enrollment of 100 patients or fewer, and a majority of studies were phase II or III trials. The single largest funding source (43.5%) was industry and study characteristics varied by funding source.

Conclusions—We applied a novel approach to describe the portfolio of interventional clinical research in pulmonary medicine. Our results indicate a disparity between trial representation and

Nephrology dataset analysis (American Journal of Kidney Diseases, Dec 2013)

AJKD

Original Investigation

The Landscape of Clinical Trials in Nephrology: A Systematic Review of ClinicalTrials.gov

Jula K. Inrig, MD,[1,2] Robert M. Califf, MD,[1] Asba Tasneem, PhD,[1] Radha K. Vegunta, MD,[3] Christopher Molina, BS,[4] John W. Stanifer, MD,[1] Karen Chiswell, PhD,[1] and Uptal D. Patel, MD[1]

Background: Well-designed trials are of paramount importance in improving the delivery of care to patients with kidney disease. However, it remains unknown whether contemporary clinical trials within nephrology are of sufficient quality and quantity to meet this need.

Study Design: Systematic review.

Setting & Population: Studies registered with ClinicalTrials.gov.

Selection Criteria for Studies: Interventional (ie, nonobservational) studies (both randomized and nonrandomized) registered between October 2007 and September 2010 were included for analysis. Studies were reviewed independently by physicians and classified by clinical specialty.

Predictor: Nephrology versus cardiology versus other trials.

Outcomes: Select clinical trial characteristics.

Results: Of 40,970 trials overall, 1,054 (2.6%) were classified as nephrology. Most nephrology trials were for treatment (75.4%) or prevention (15.7%), with very few diagnostic, screening, or health services research studies. Most nephrology trials were randomized (72.3%). Study designs included 24.9% with a single study group, 64.0% that included parallel groups, and 9.4% that were crossover trials. Nephrology trials, compared with 2,264 cardiology trials (5.5% overall), were more likely to be smaller (64.5% vs 48.0% enrolling ≤ 100 patients), phases 1-2 (29.0% vs 19.7%), and unblinded (66.2% vs 53.3%; $P < 0.05$ for all). Nephrology trials also were more likely than cardiology trials to include a drug intervention (72.4% vs 41.9%) and less likely to report having a data monitoring committee (40.3% vs 48.5%; $P < 0.05$ for all). Finally, there were few trials funded by the National Institutes of Health (NIH; 3.3%, nephrology; 4.2%, cardiology).

Limitations: Does not include all trials performed worldwide, and frequent categorization of funding source as university may underestimate NIH support.

Conclusions: Critical differences remain between clinical trials in nephrology and other specialties. Improving care for patients with kidney disease will require a concerted effort to increase the scope, quality, and quantity of clinical trials within nephrology.

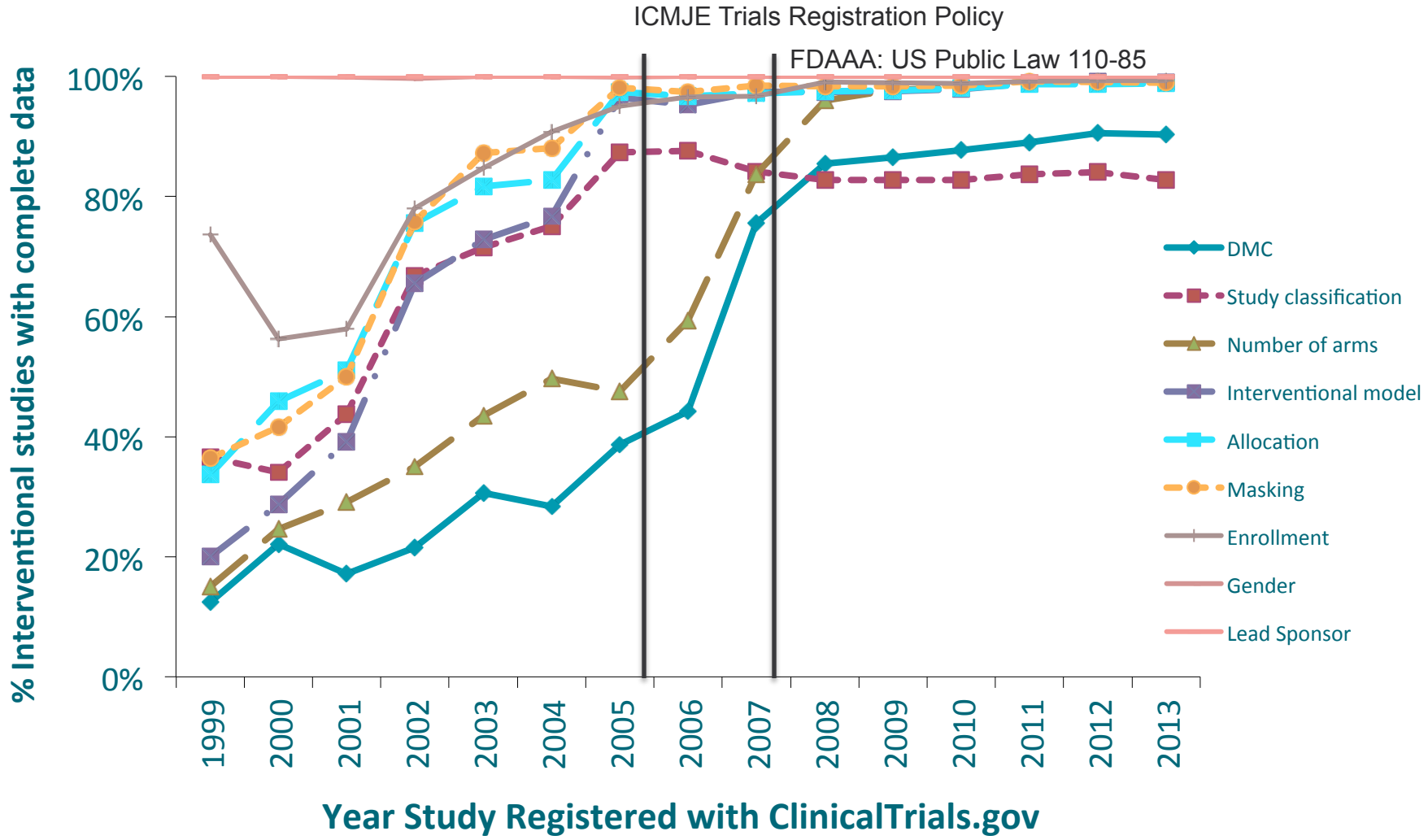
Am J Kidney Dis. 63(5):771-780.

INDEX WORDS: Chronic kidney disease; end-stage renal disease; kidney transplantation; randomized controlled trial; systematic review.

CTTI

Aggregate Analysis: Trends and Outliers

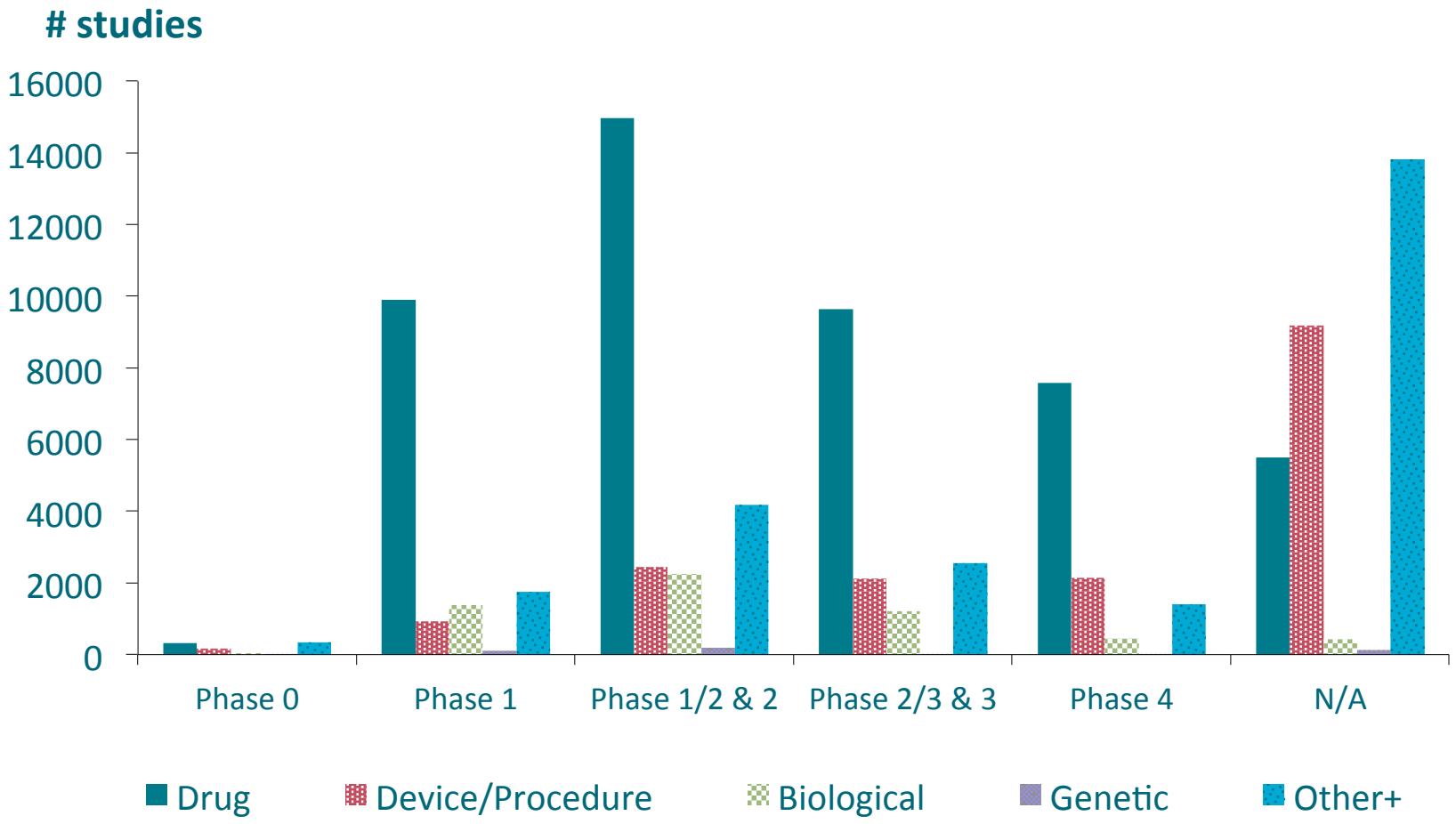
Completeness for Selected Study Data Elements
For Interventional Trials



Gender and Lead Sponsor required by FDAAA and ClinicalTrials.gov. Enrollment required by FDAAA. At least one of interventional model, allocation, and masking required by FDAAA. Number of arms may be required by FDAAA. DMC and number of arms introduced in 4/2007.

CTTI

Study registration by intervention type and phase



Studies of drugs, biologics and devices in phases 2-4 are required to be registered by FDAAA.
+ Includes behavioral, radiation, dietary supplement, in addition to other interventions

N=1 study did not report intervention type information

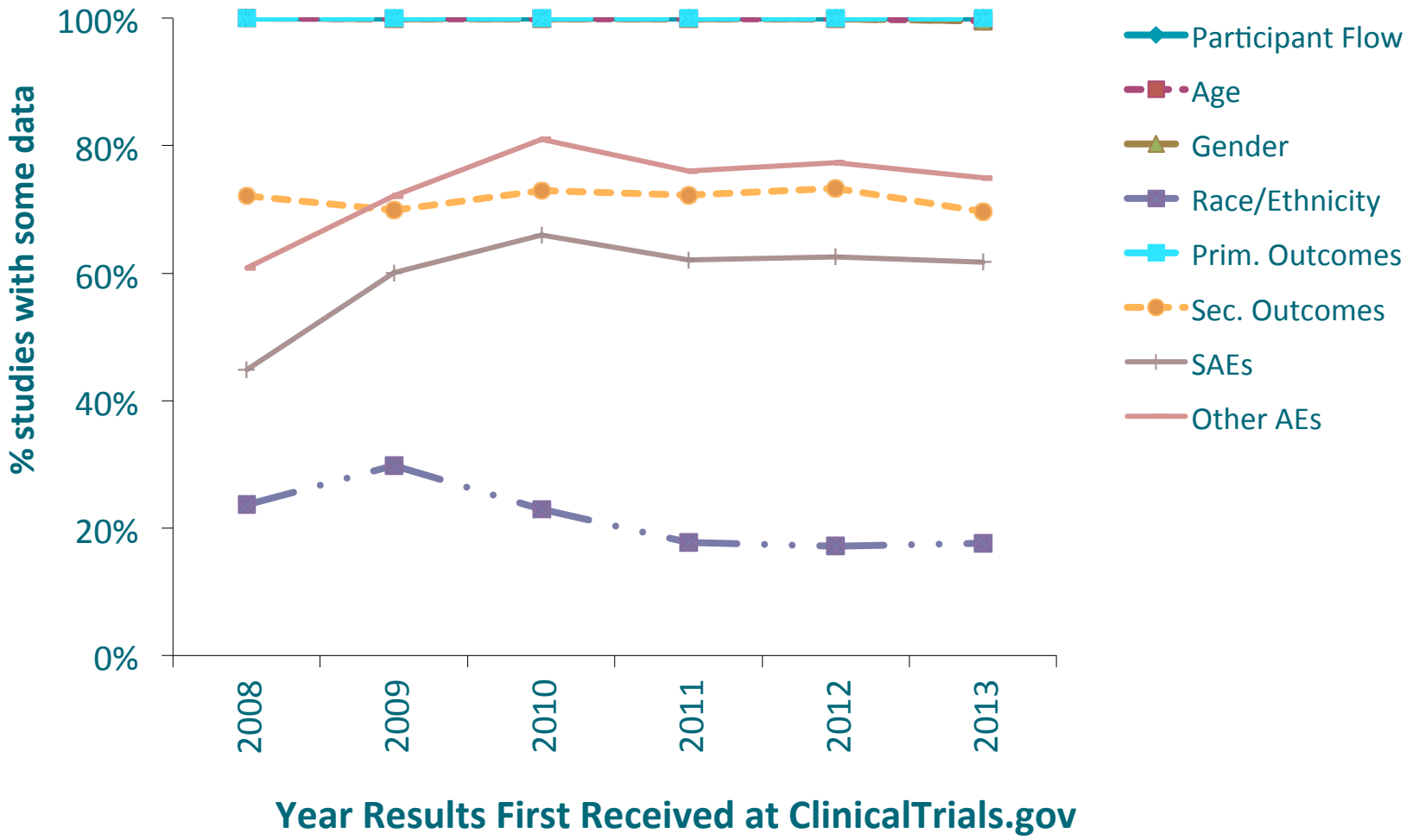
CTTI

Studies Reported Results by Study Type

* The ClinicalTrials.gov “basic results” database was launched on September 23, 2008
** Includes studies with results released through 27 September 2013

CTTI

Completeness for Selected Results Data Elements
For Interventional Trials with Results



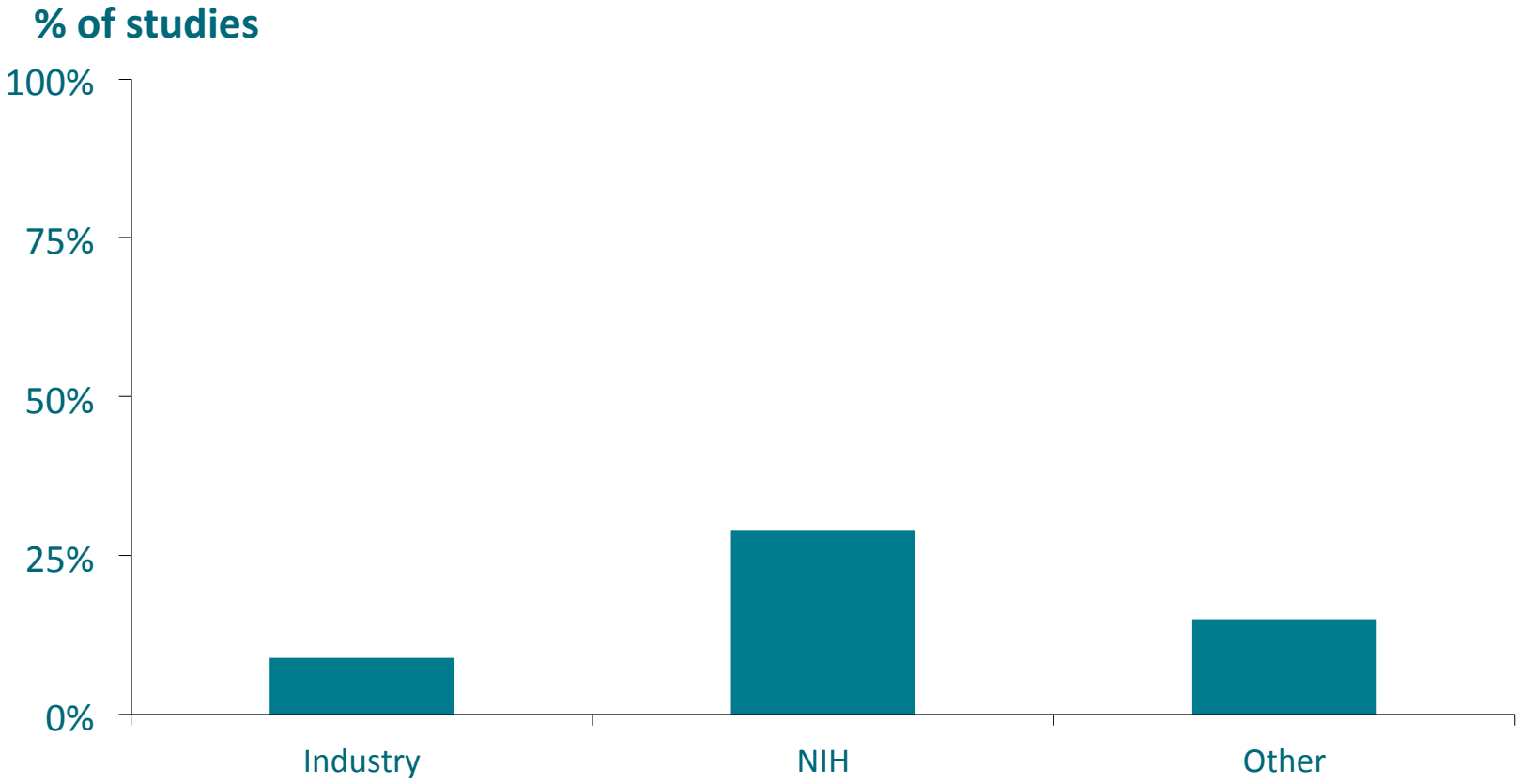
Participant, Age, Gender, at least one primary outcome, all SAEs, and other non-serious AEs with ≥5% incidence required for studies reporting results.

SAE and AE reporting optional prior to September 28, 2009.

CTTI

Trials Providing a Citation to Published Results by Funding

Among interventional trials with results posted at ClinicalTrials.gov

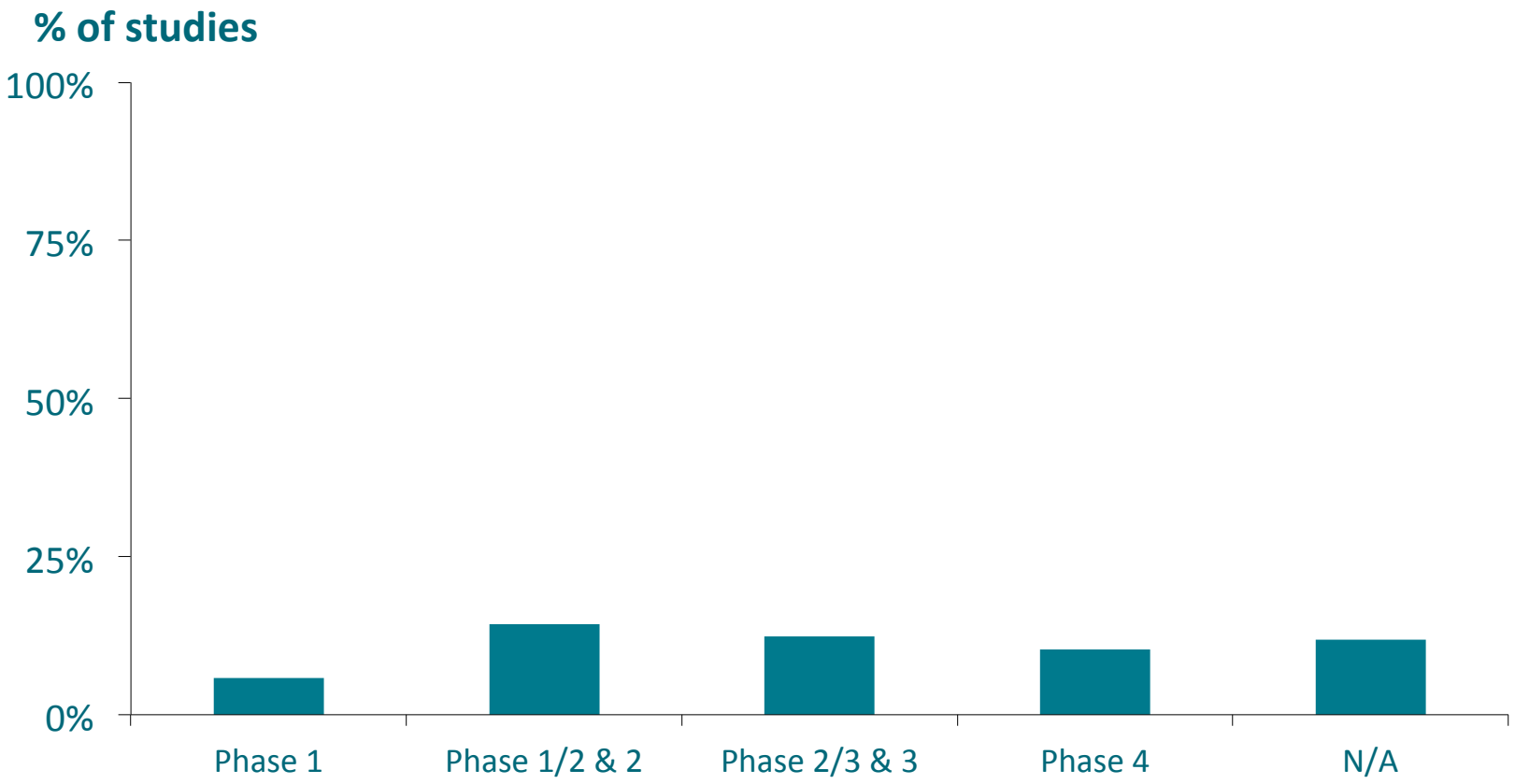


Funding source derived from information provided in lead sponsor and collaborator fields. Trials with NIH involvement, (e.g., as a collaborator) but no industry lead sponsor are classified as funded by NIH. Providing reference citations, including references withy published results, is optional in ClinicalTrials.gov

CTTI

Trials Providing a Citation to Published Results by Phase

Among interventional trials with results posted at ClinicalTrials.gov



Providing reference citations, including references withy published results, is optional in ClinicalTrials.gov

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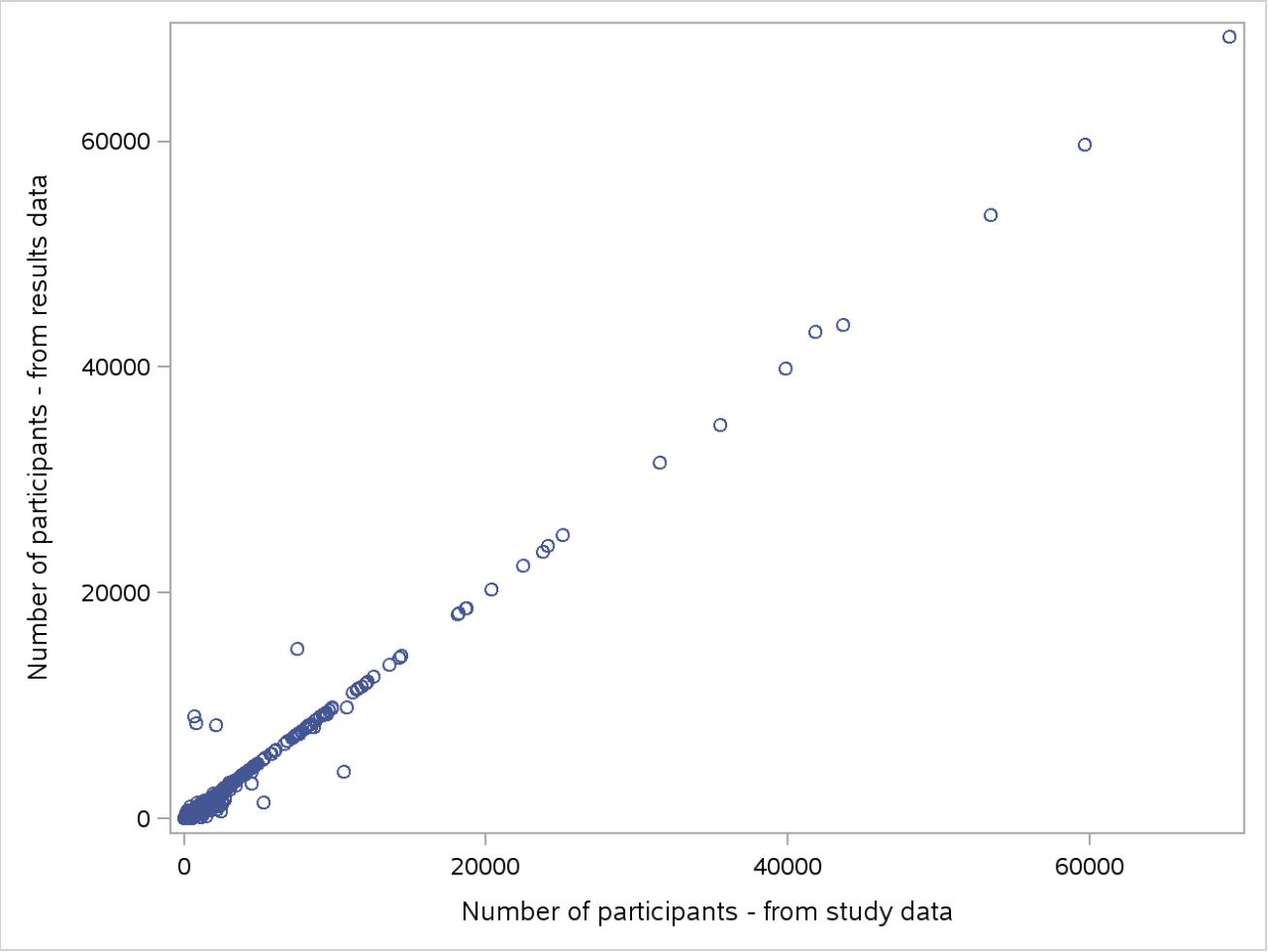
Number of Participants Enrolled

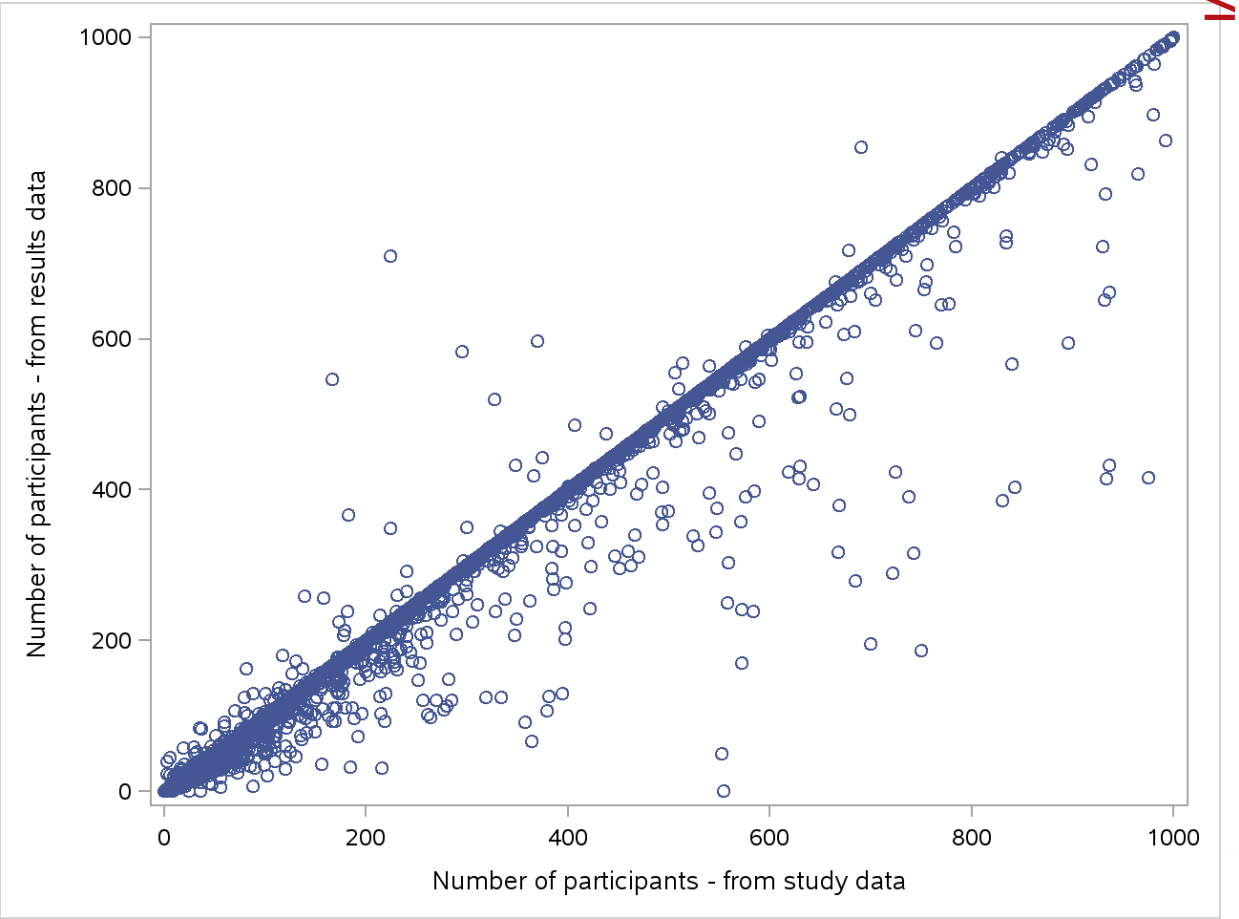
Comparison of results vs. study data for interventional trials reporting results



Number of Participants Enrolled

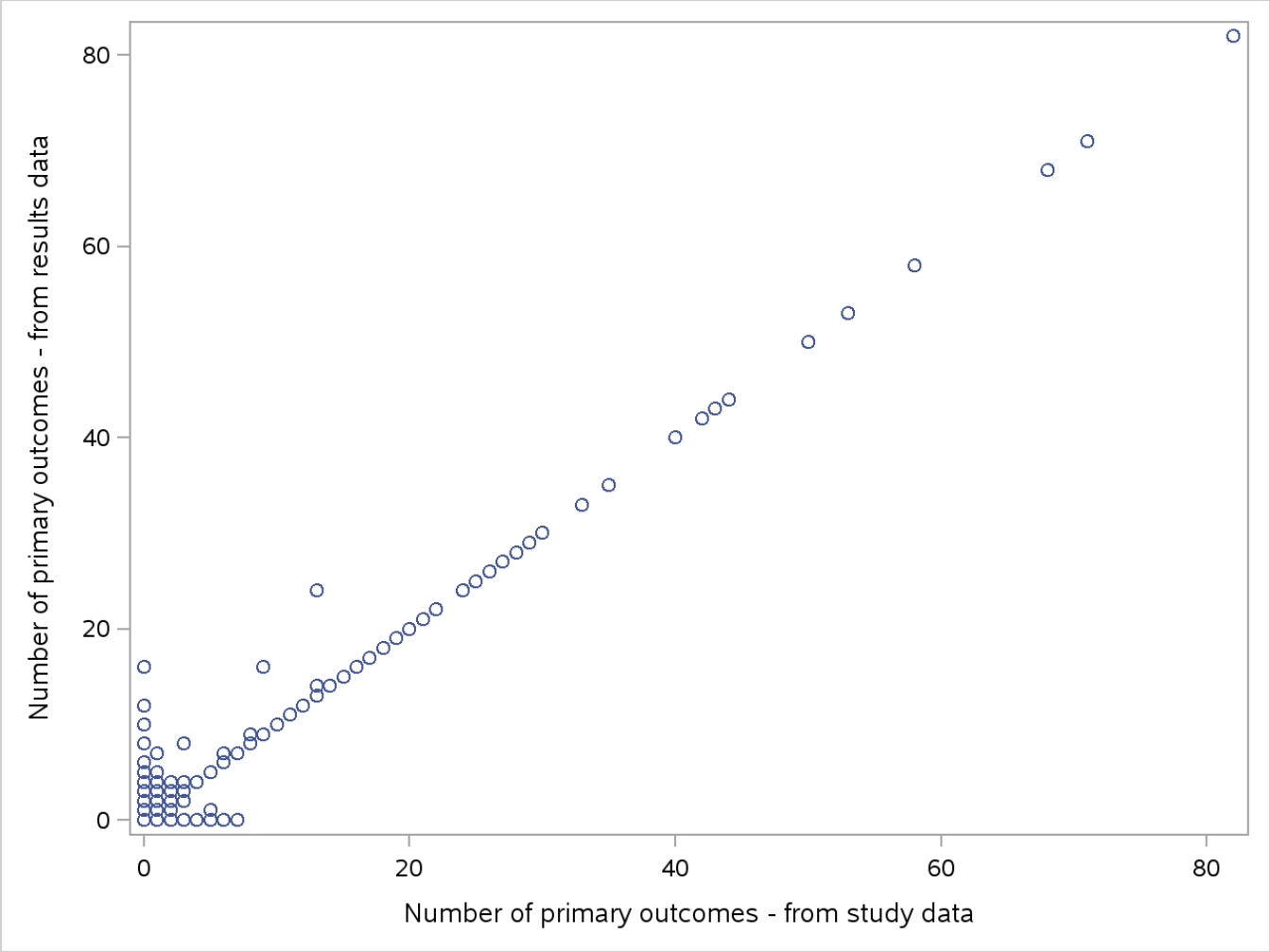
Comparison of results vs. study data for interventional trials reporting results

Axes limited to ≤1000 participants



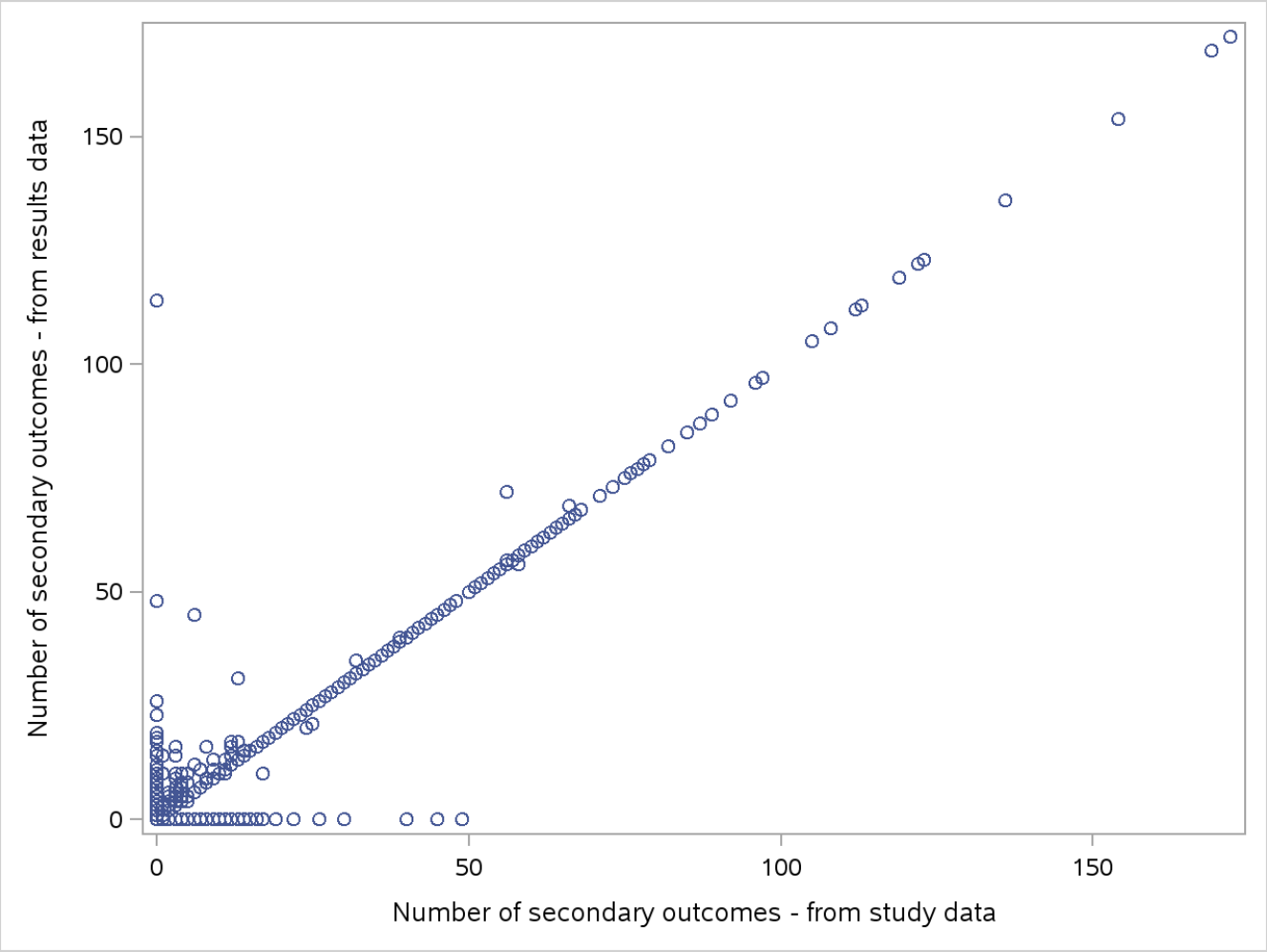
Number of Primary Outcomes

Comparison of results vs. study data for interventional trials reporting results



Number of Secondary Outcomes

Comparison of results vs. study data for interventional trials reporting results



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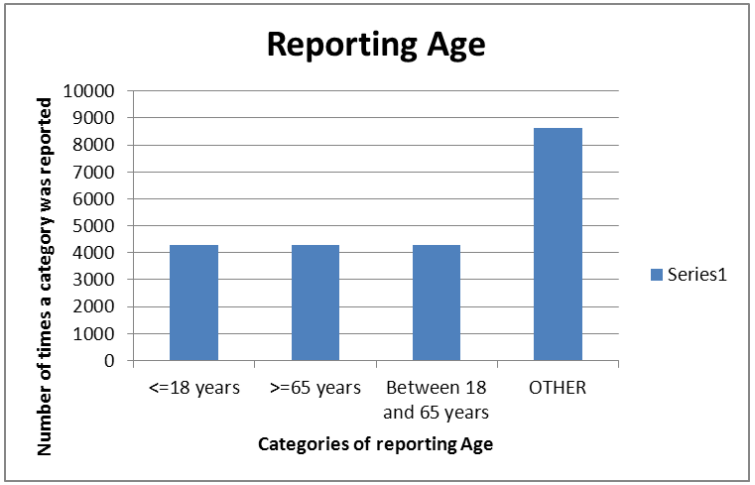
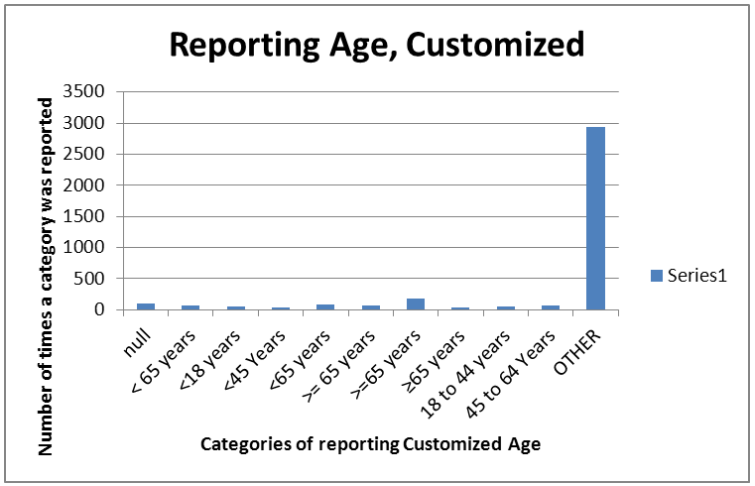
Results Data Reporting in ClinicalTrials.gov: Baseline Measures – variations in reporting

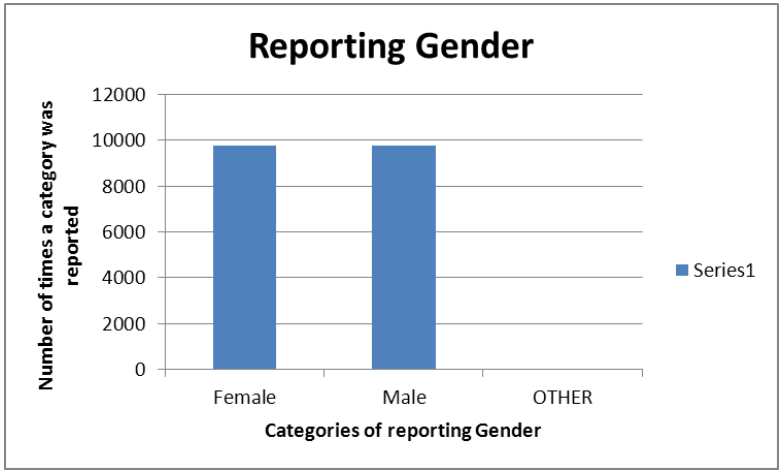
- Age
- BMI
- Body Weight
- Race
- Ethnicity
- Gender
- Region of Enrollment
- Smoking Status

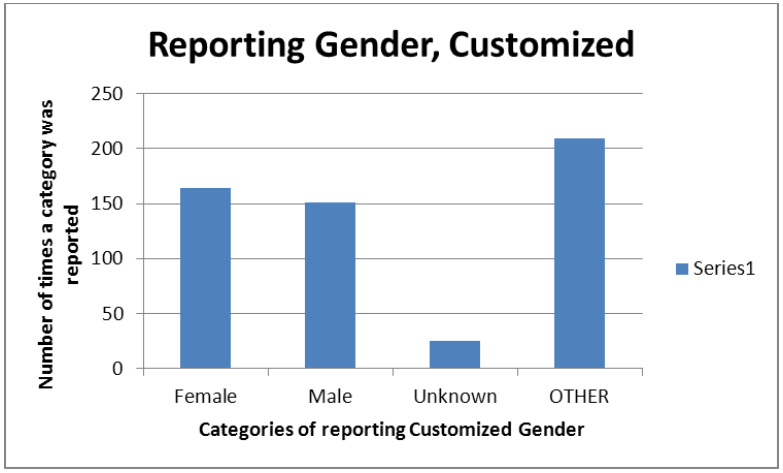
Baseline Measure: Age



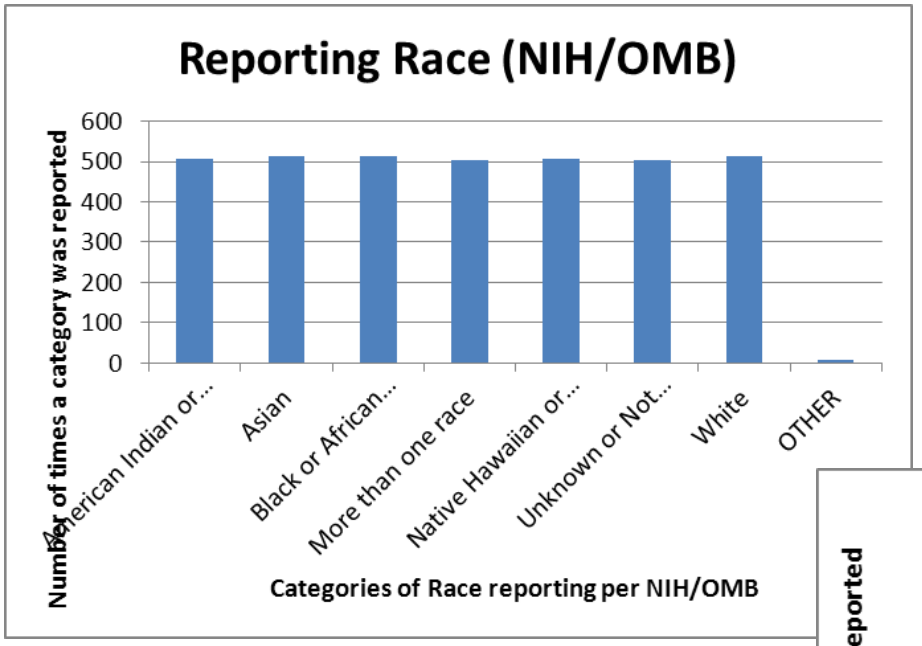


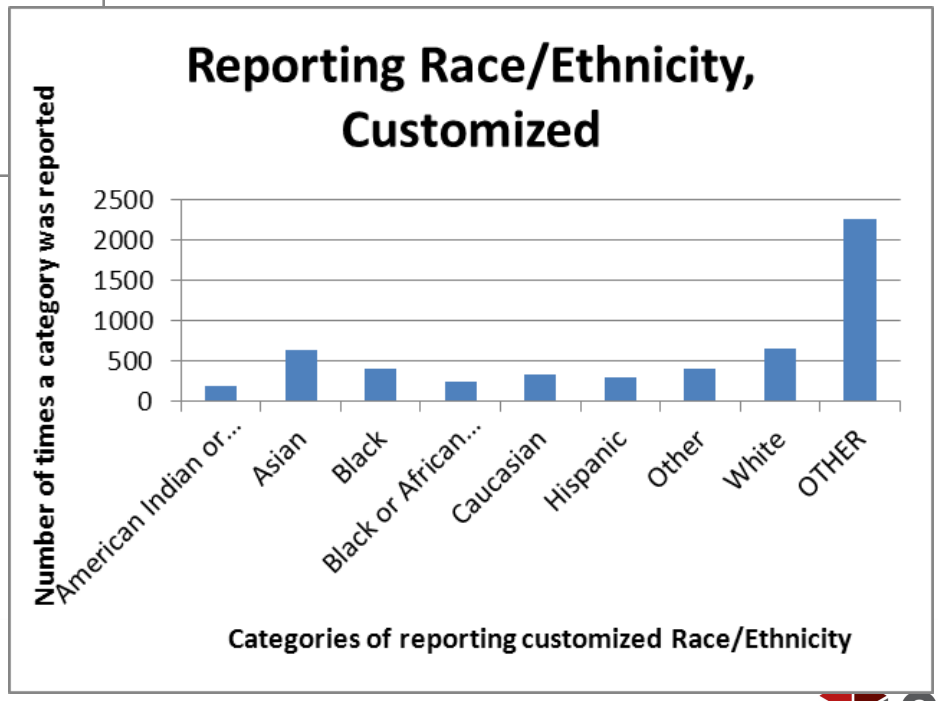
Baseline Measure: Gender





Baseline Measure: Race/Ethnicity





How can I download AACT?

- **Oracle Extracts (Registry + Results)**
  - Oracle dmp
  - Pipe delimited text output
  - SAS CPORT transport
- **Supporting Documents**
  - Comprehensive Data Dictionary
  - High Level Data Dictionary
  - Readmes
- **Points to Consider When Using AACT**

Download Database: CTTI website

http://www.ctti-clinicaltrials.org/what-we-do/analysis-dissemination/state-clinical-trials/aact-database

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ClinicalTrials.gov & AACT: key milestones

ClinicalTrials.gov

- 2000 – Study database launched
- 2005 – ICMJE requirement policy
- 2007 – FDA Amendment Act (FDAAA) enacted
- 2008 – Results reporting included in Protocol Registration System (PRS)
- 2012 – Results database made publicly available

AACT: Aggregate Analysis database of ClinicalTrials.gov

- 2011 – AACT database launched (dataset download: Sep 27, 2010)
- 2012 – AACT Specialty Classification (dataset download: Sep 27, 2010)
- 2013 – AACT-Results launched (dataset download: Sep 27, 2012)
- 2014 – Semi annual updates (dataset download: Mar 27, 2014)

CTTI Website Analytics Jan 1-Apr 1, 2014

- **The top 3 most visited pages on the CTTI website are (in descending order):**
  - The Homepage
  - The AACT Database
  - The State of Clinical Trials Project (Project that includes AACT)
- **The average site visitor spends 6 min and 43 sec on the AACT page, which is nearly 5 times more than the other top 10 pages on the CTTI website**
- **During this timeframe, there were 1,811 page views (1496 unique) on the AACT page**
- **Number of clicks through to the AACT database zip files – 887**
- **49% of AACT page visitors go the extra step and download the files.**

Acknowledgments

Duke University

- Robert Califf (PI)
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- Sara Calvert, Project Manager

NLM (ClinicalTrials.gov)

- Deborah Zarin (Director, ClinicalTrials.gov)
- Nick Ide

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