Contemporary Clinical Research in Adult Cardiovascular Medicine: A Perspective from ClinicalTrials.gov

Society for Clinical Trials
33rd Annual Meeting

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CLINICAL TRIALS TRANSFORMATION INITIATIVE

SCT
SOCIETY FOR CLINICAL TRIALS

Disclosures

- Financial support for this work was provided by grant U19FD003800 from the U.S. Food and Drug Administration awarded to Duke University for the Clinical Trials Transformation Initiative

- Within the past 12 months, the presenter or their spouse/partner have had a financial interest/arrangement or affiliation with the organizations listed below:

  Abbott Vascular, Allmed Healthcare, American College of Cardiology Foundation, Eli Lilly, FDA, IBM, Irvine Scientific, Medtronic, Sanofi-Aventis, Terumo Corp.

CLINICAL TRIALS TRANSFORMATION INITIATIVE

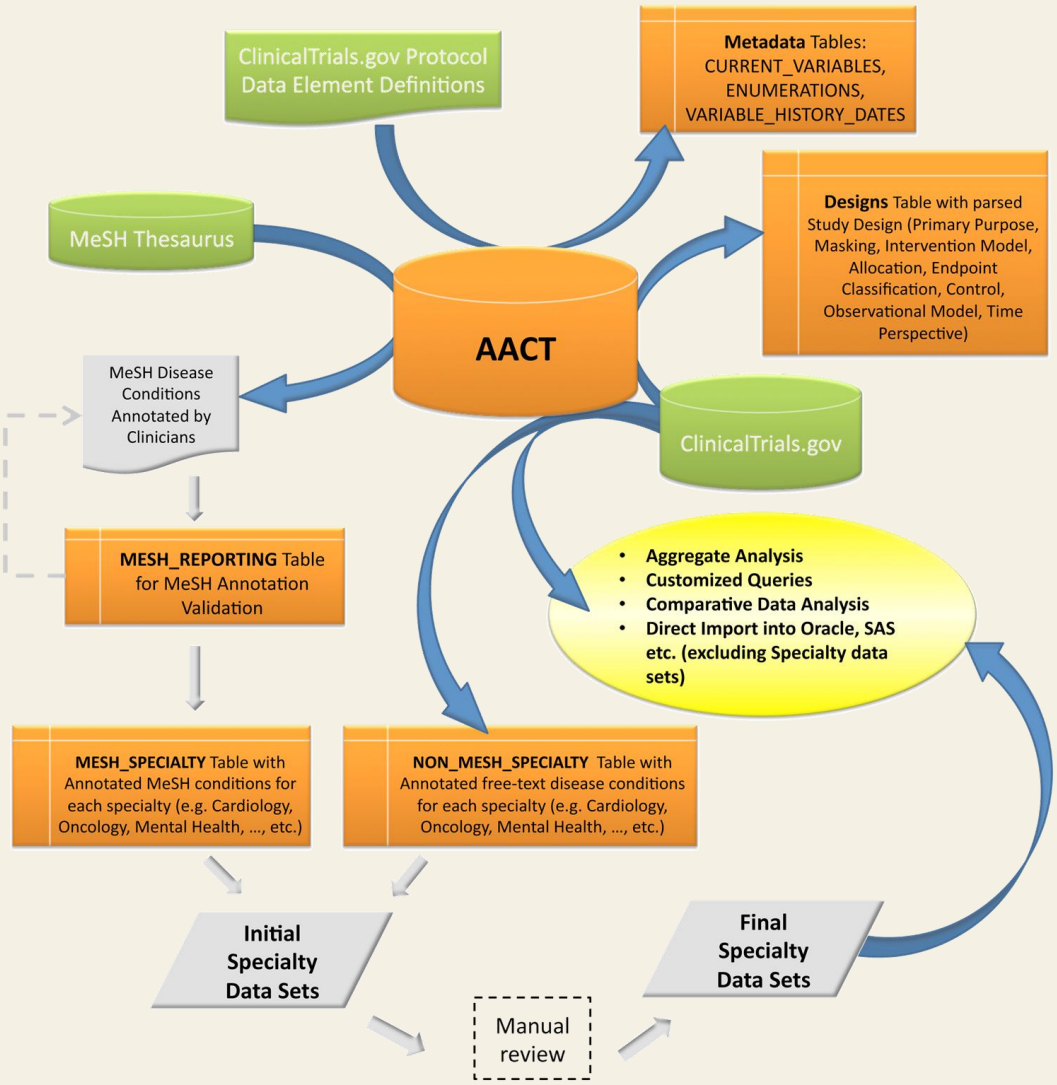
- A public private partnership co-founded by FDA and Duke in late 2007
- All stakeholders involved
- Through a memorandum of understanding with FDA, Duke "hosts" the initiative
- Website: www.ctti-clinicaltrials.org

Mission: To identify practices that through broad adoption will increase the quality and efficiency of clinical trials

ClinicalTrials.gov History

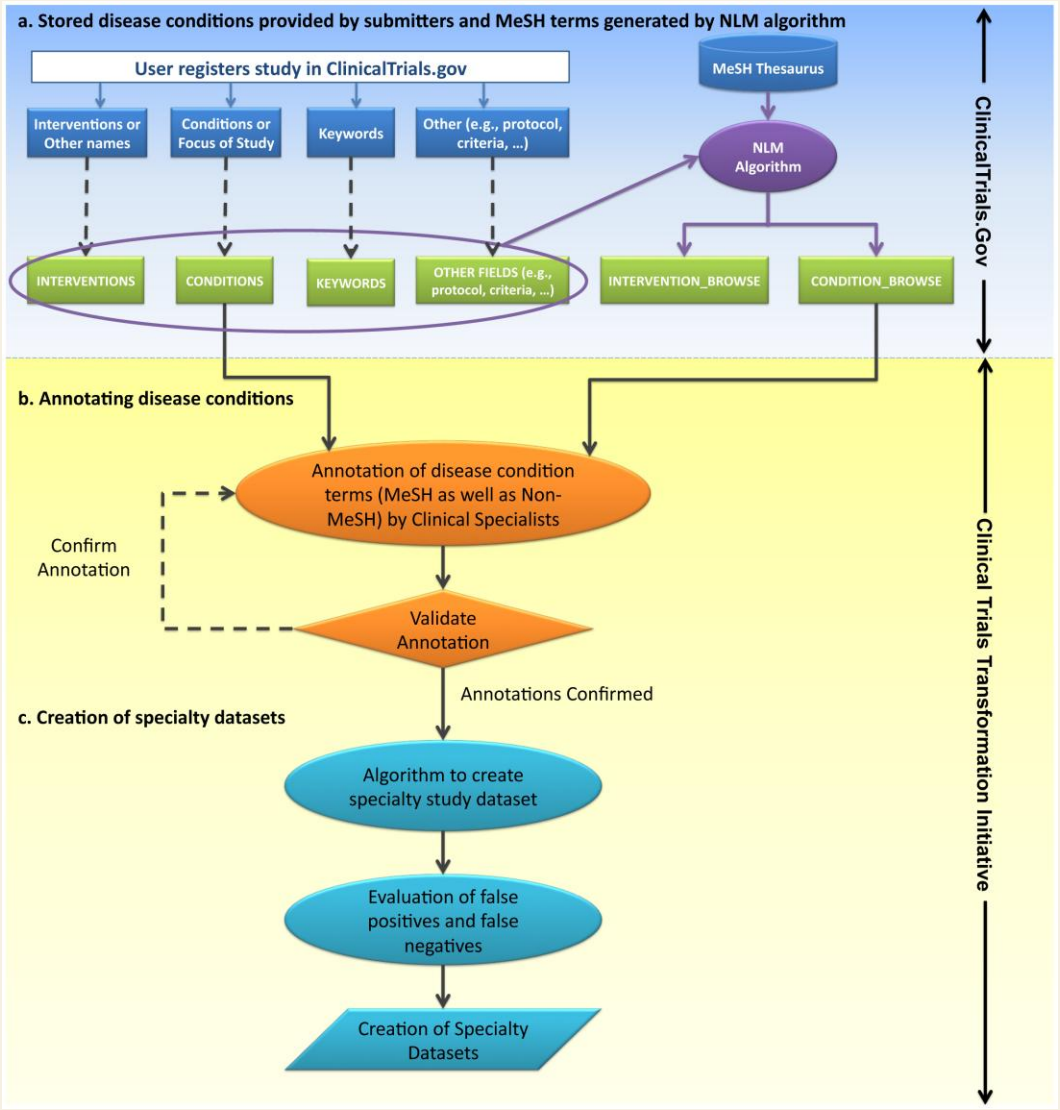
Date	Event	Description
Nov 21, 1997	Food and Drug Modernization Act of 1997 (FDAMA) section 113 enacted	Mandated the creation of the clinicaltrials.gov registry for efficacy trials in serious and life-threatening conditions and interventions regulated by the FDA
Feb 29, 2000		First version ClinicalTrials.gov publicly available
September 2004	International Committee of Medical Journal Editors' (ICMJE) policy established	Required studies published in their journals be registered in Clinicaltrials.gov or other equivalent publicly available registries.
September 27, 2007	US Public Law 110-85 FDA Amendments Act (FDAAA) section 801 enacted	Created a legal requirement for the registration of trials of drugs, biologics, and devices,
September 23, 2008		Results reporting launched
September 28, 2009		Adverse Event reporting launched

Aggregate Analysis of ClinicalTrials.gov (AACT)



Tasneem A, Aberle L, Ananth H, Chakraborty S, Chiswell K, et al. (2012) The Database for Aggregate Analysis of ClinicalTrials.gov (AACT) and Subsequent Regrouping by Clinical Specialty. PLoS ONE 7(3): e33677. doi:10.1371/journal.pone.0033677

Developing Clinical Specialty Datasets



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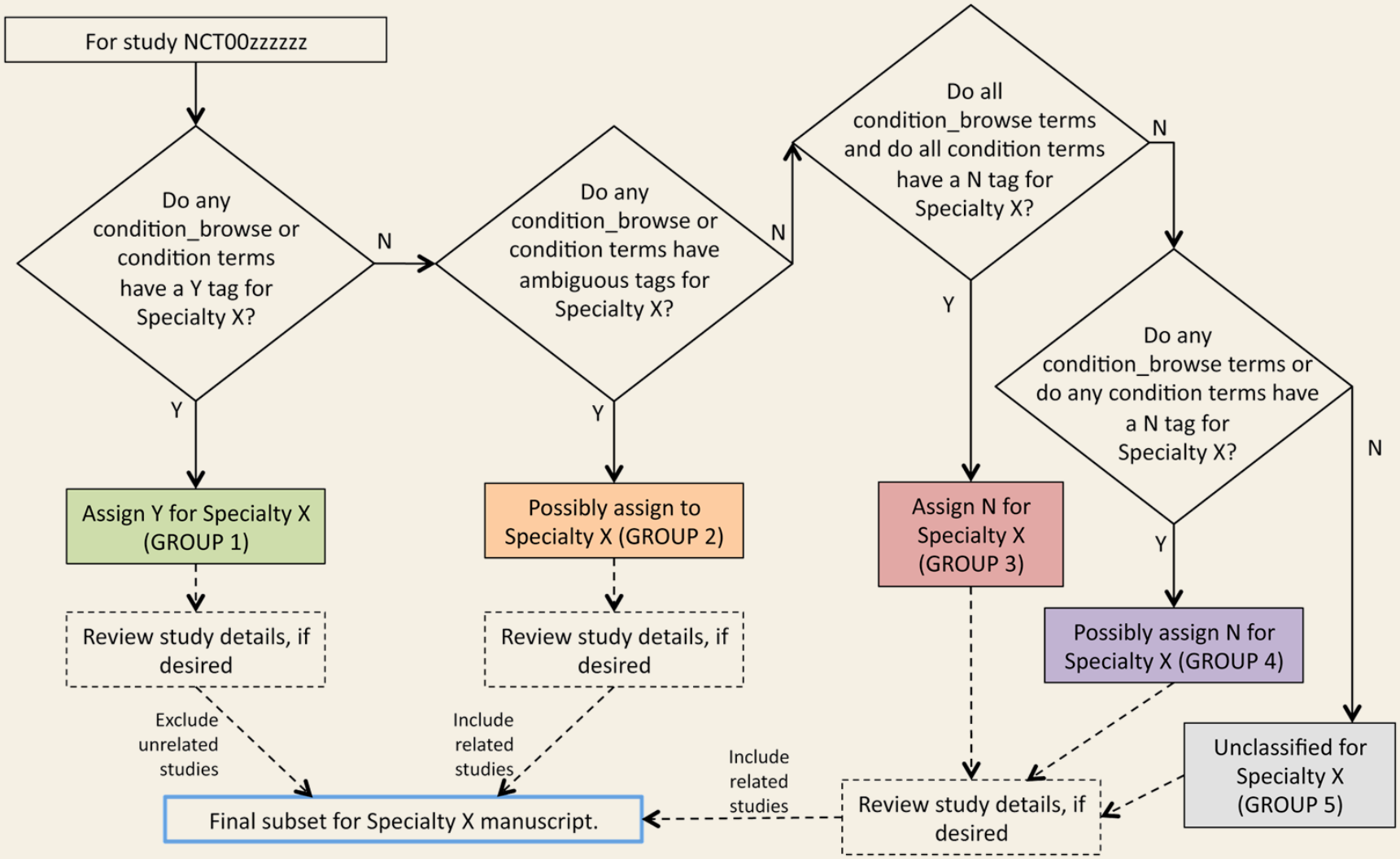
Assigning Studies to a Specialty



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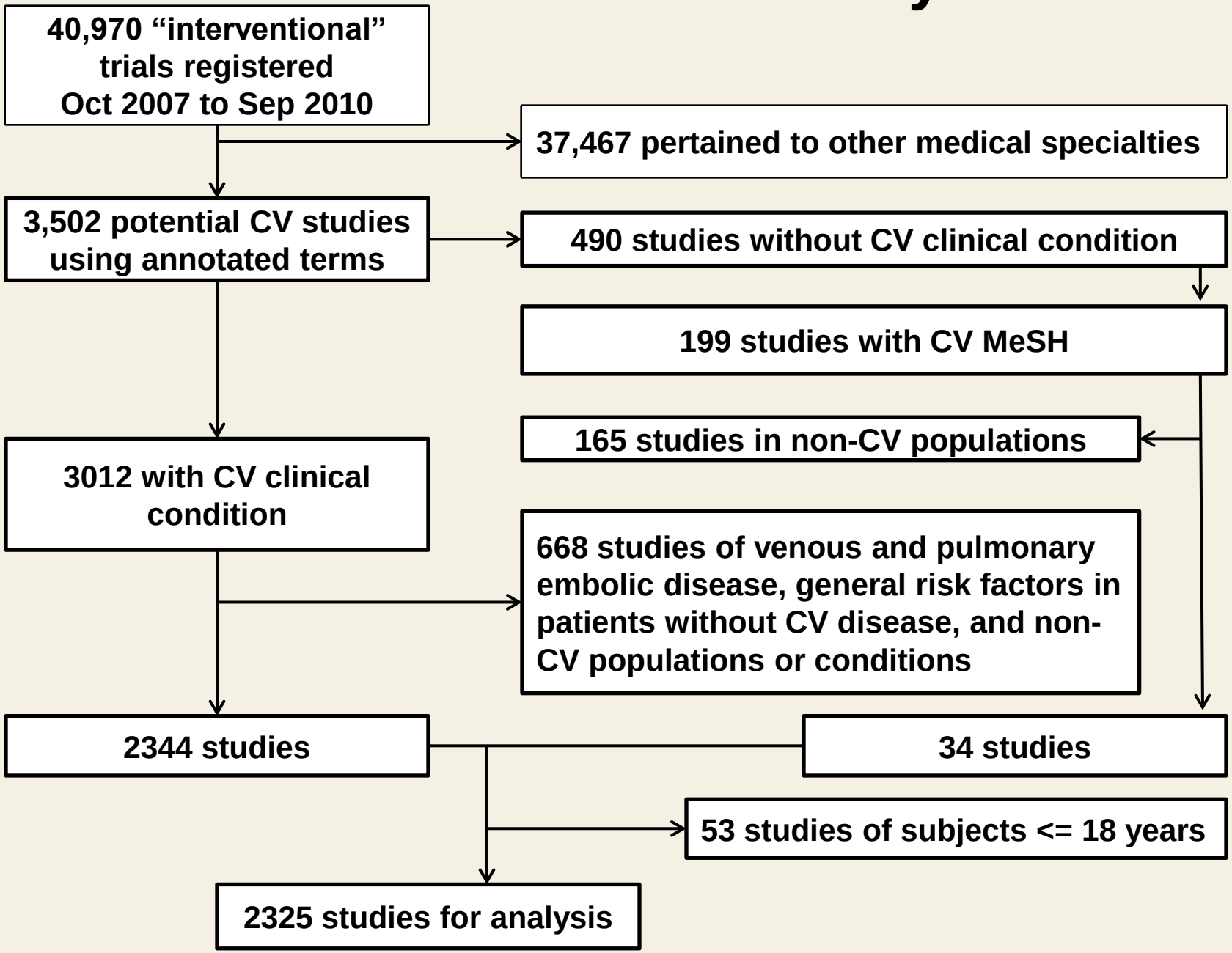
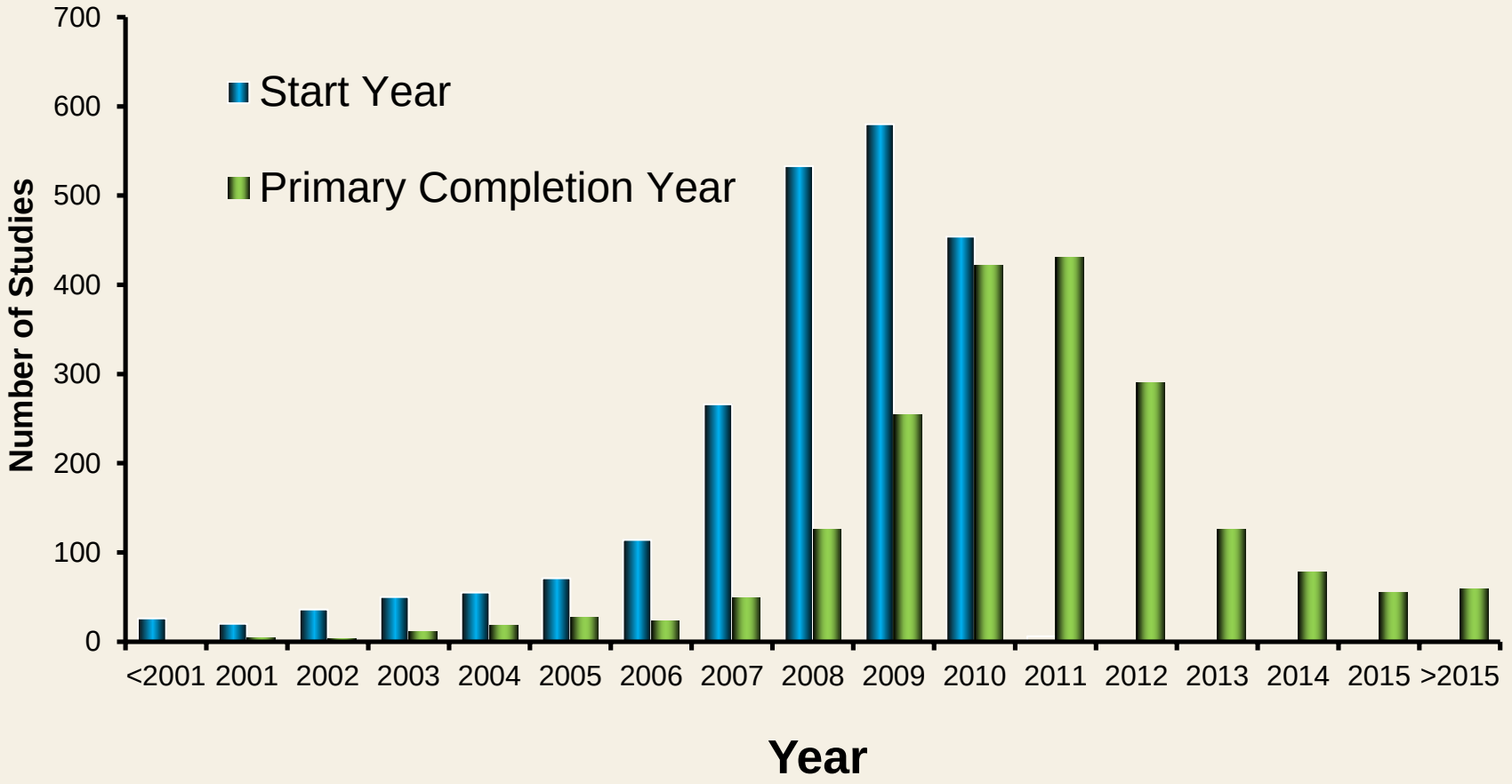
Study selection

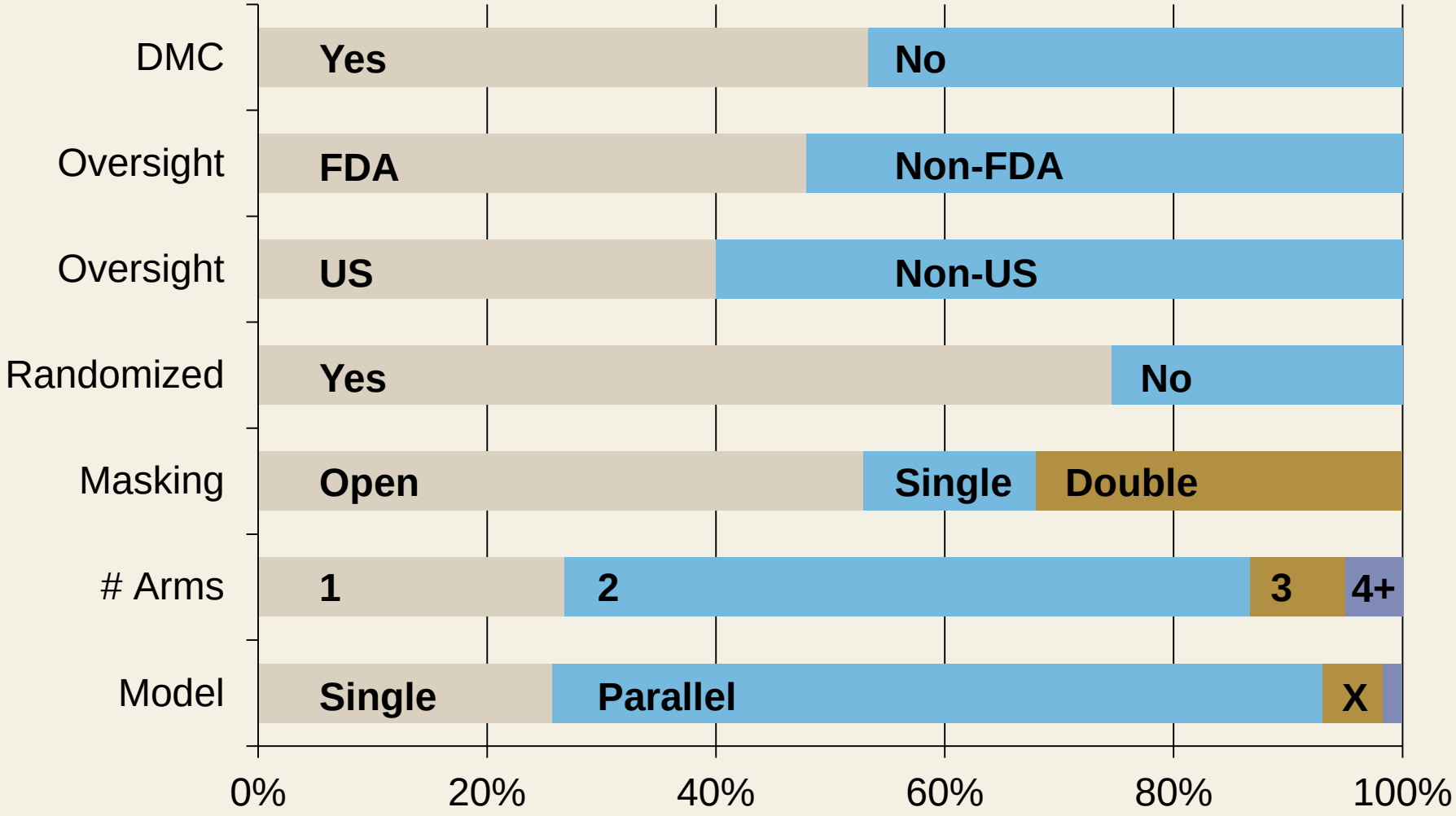


Study Start Year, Primary Completion Year

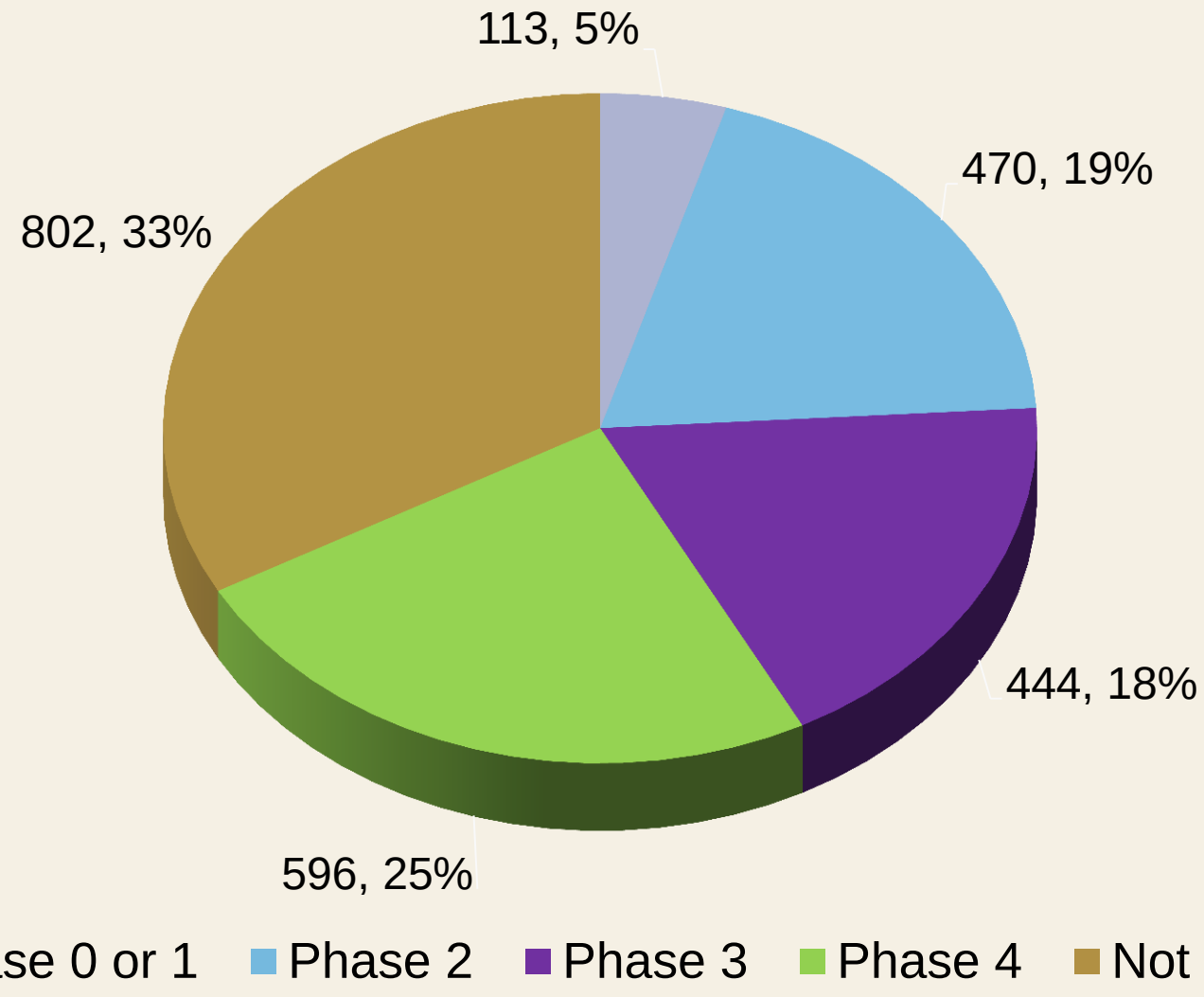
Ongoing and Completed Studies (N=2,233)



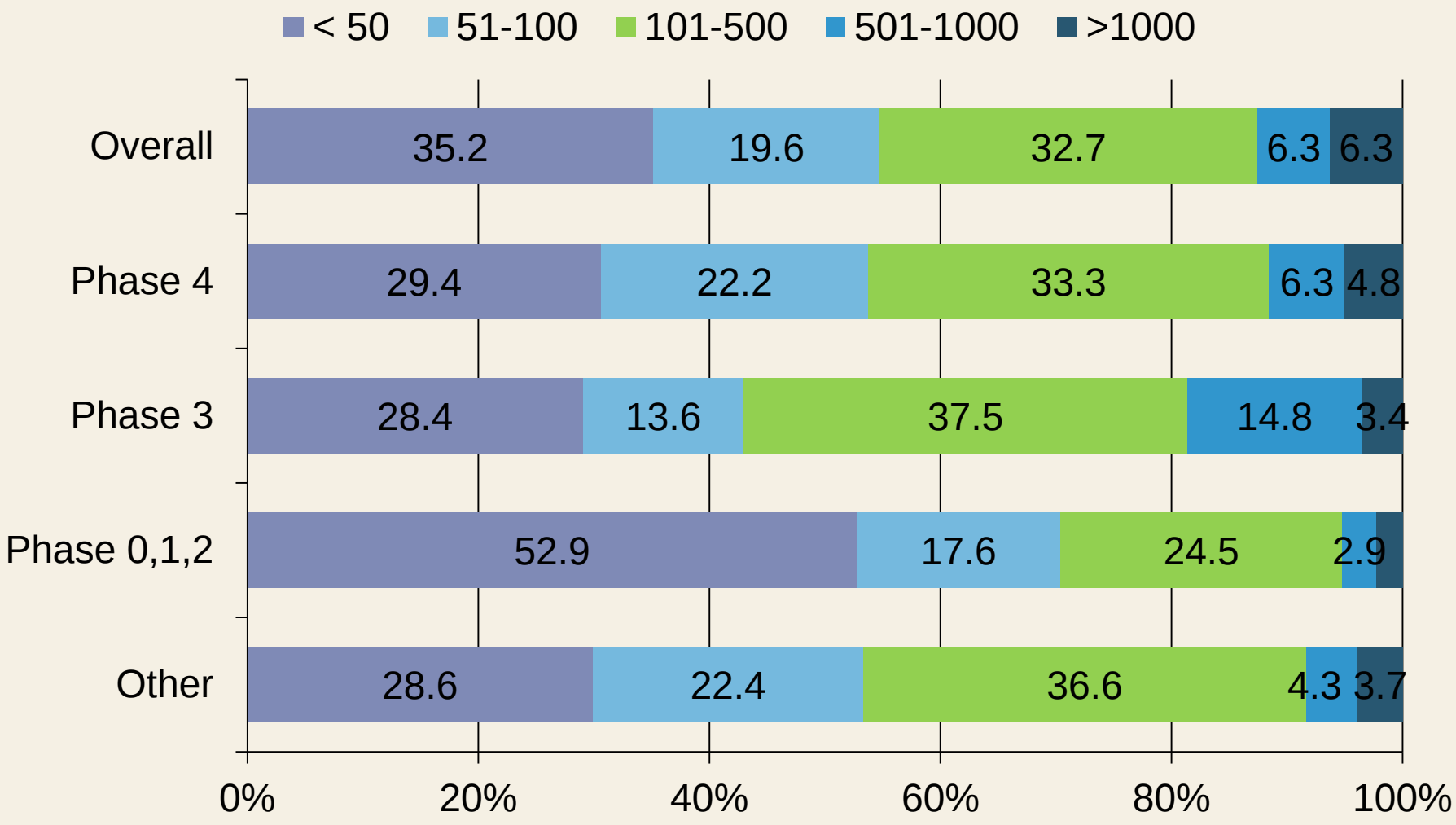
Study Design Characteristics



Clinical Phase (n=2325)



Actual Enrollment



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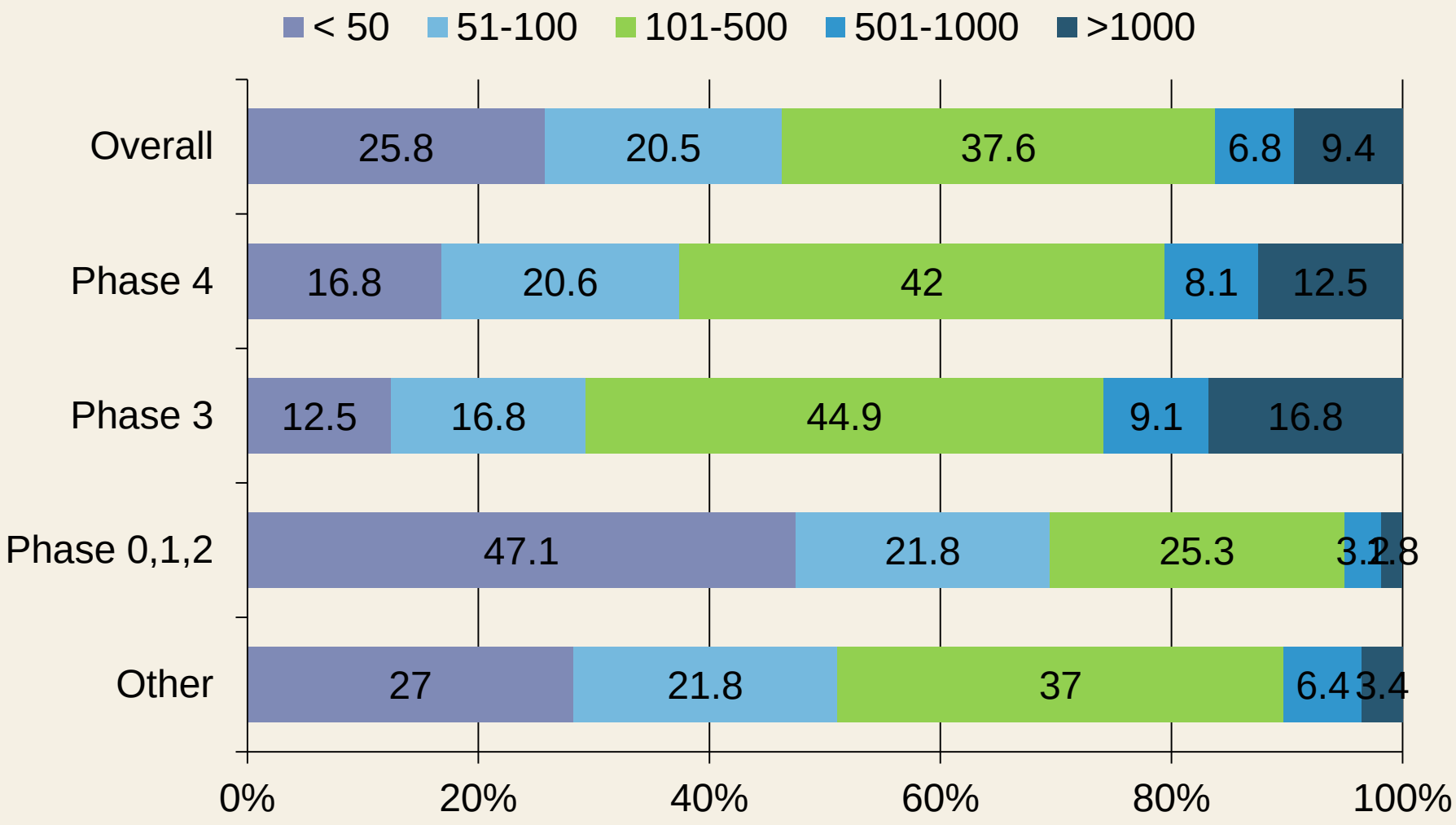
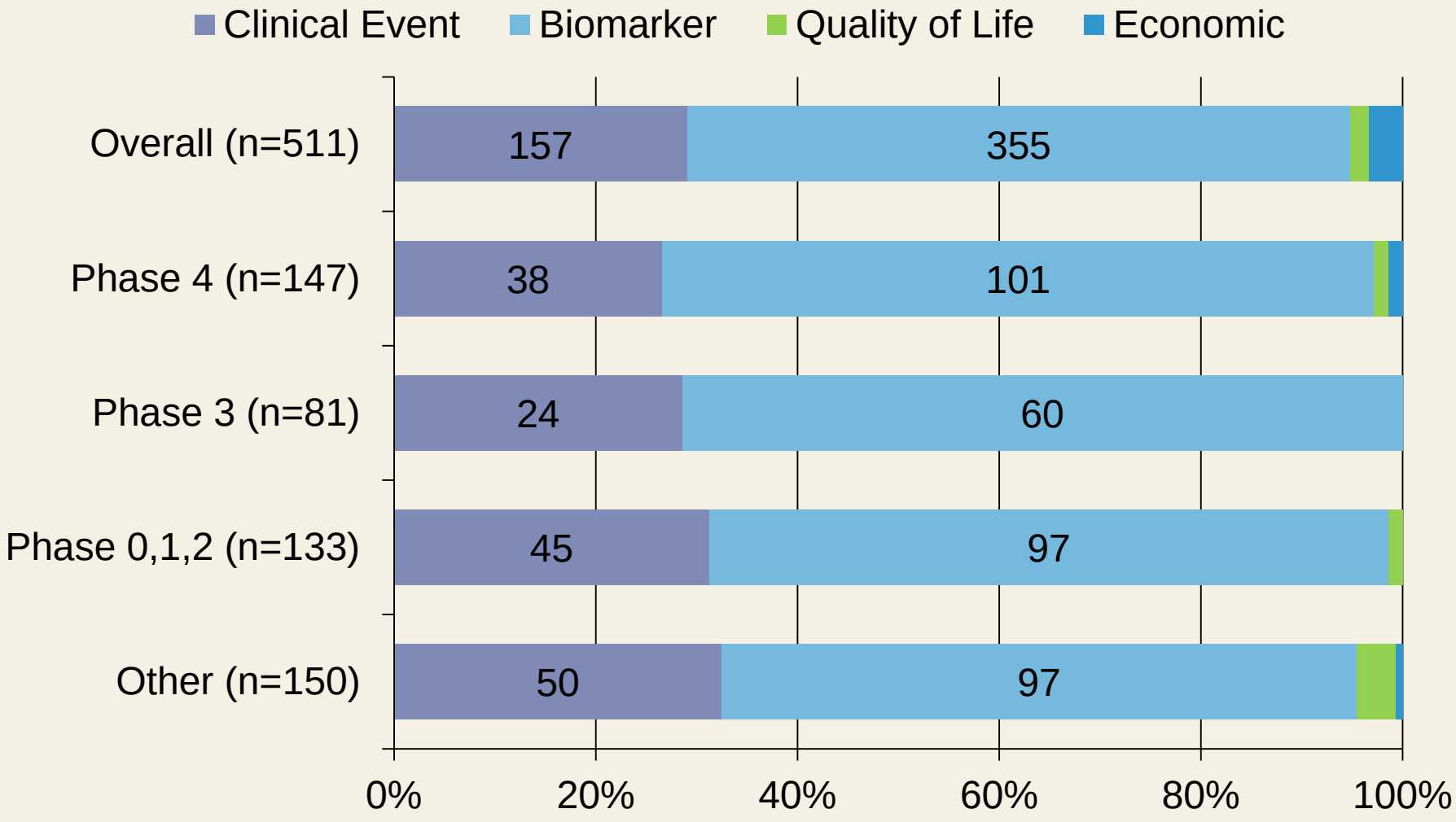
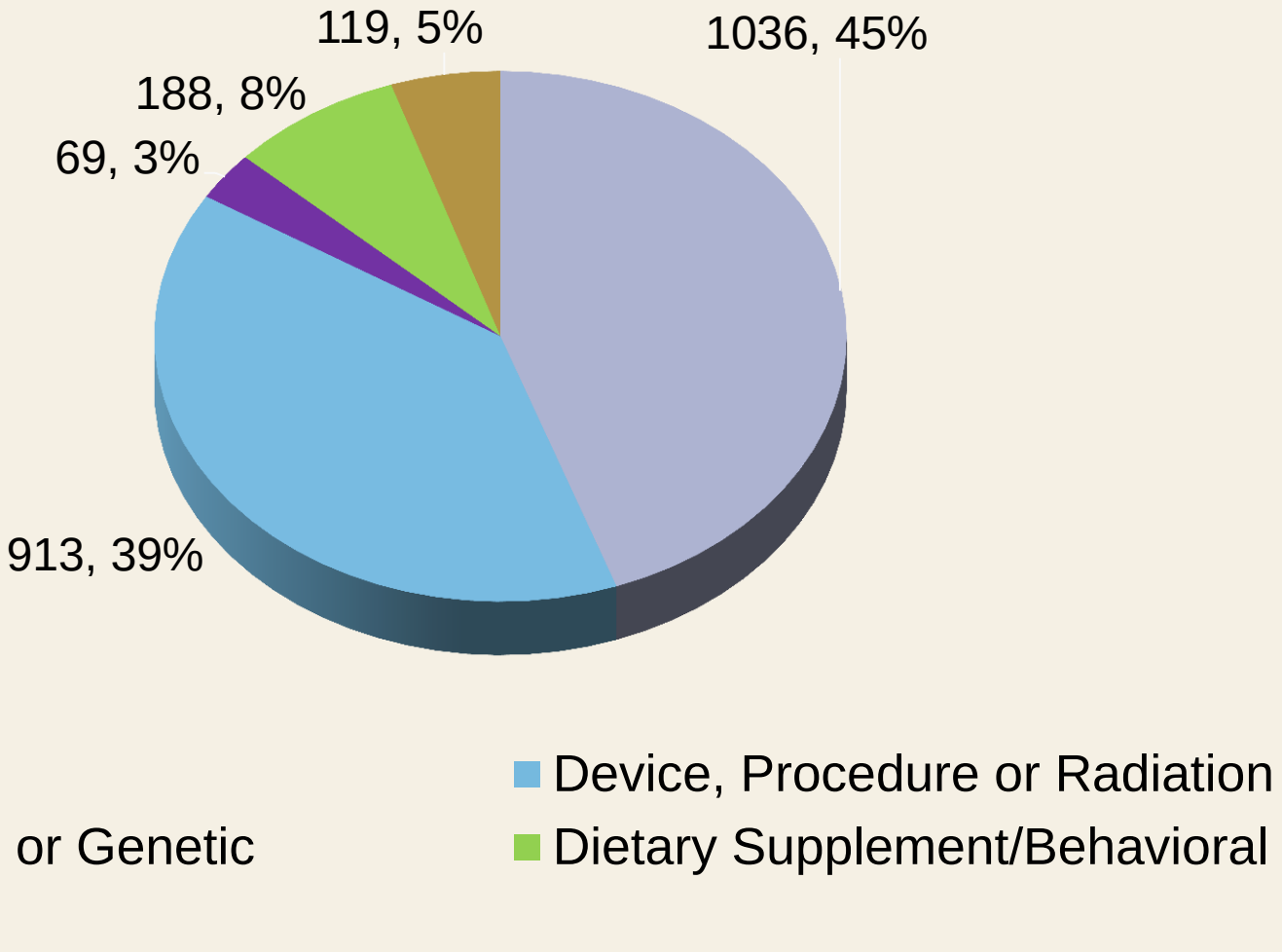
Anticipated Enrollment



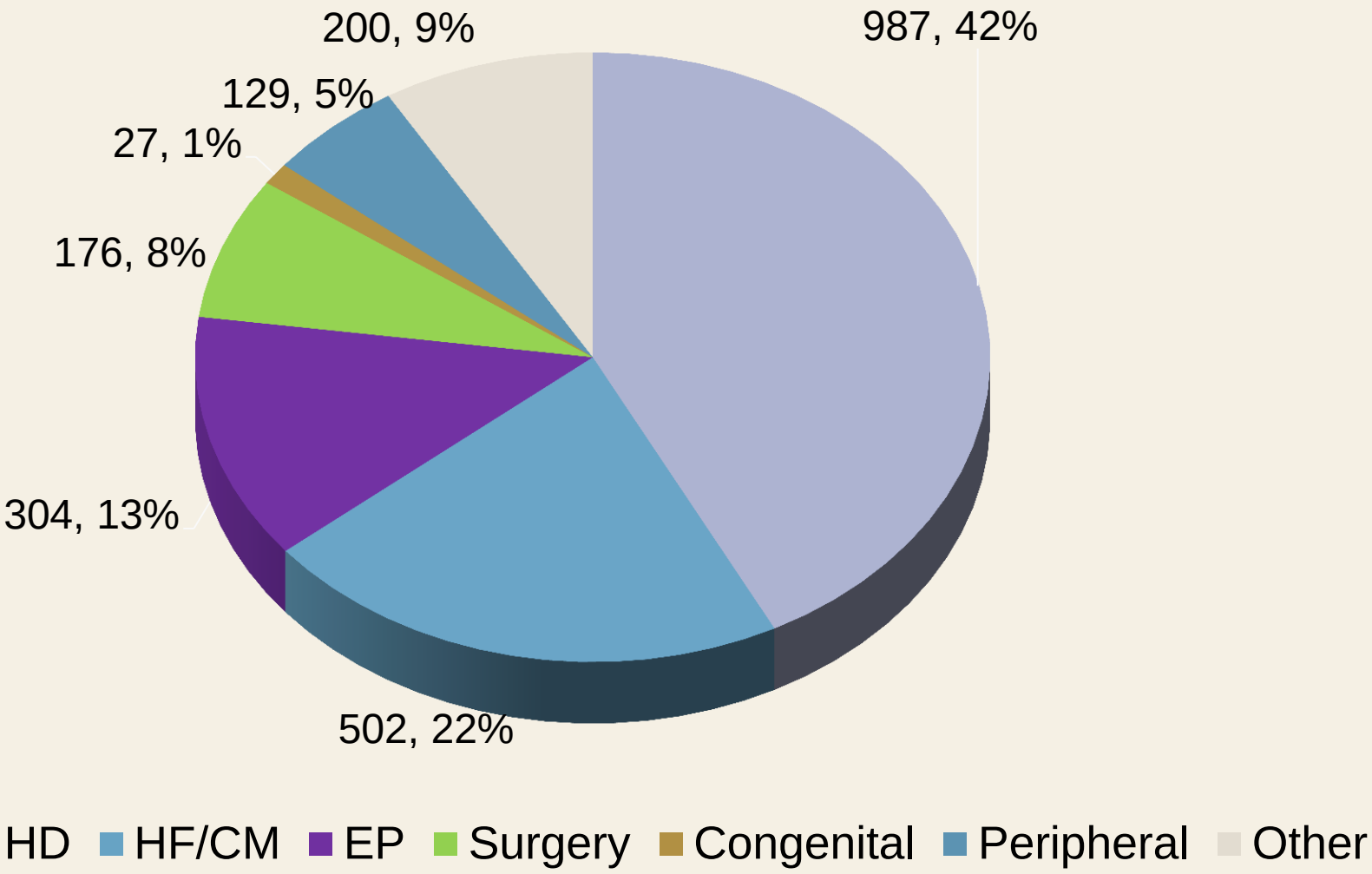
Primary Outcomes for Completed Studies (n=511)



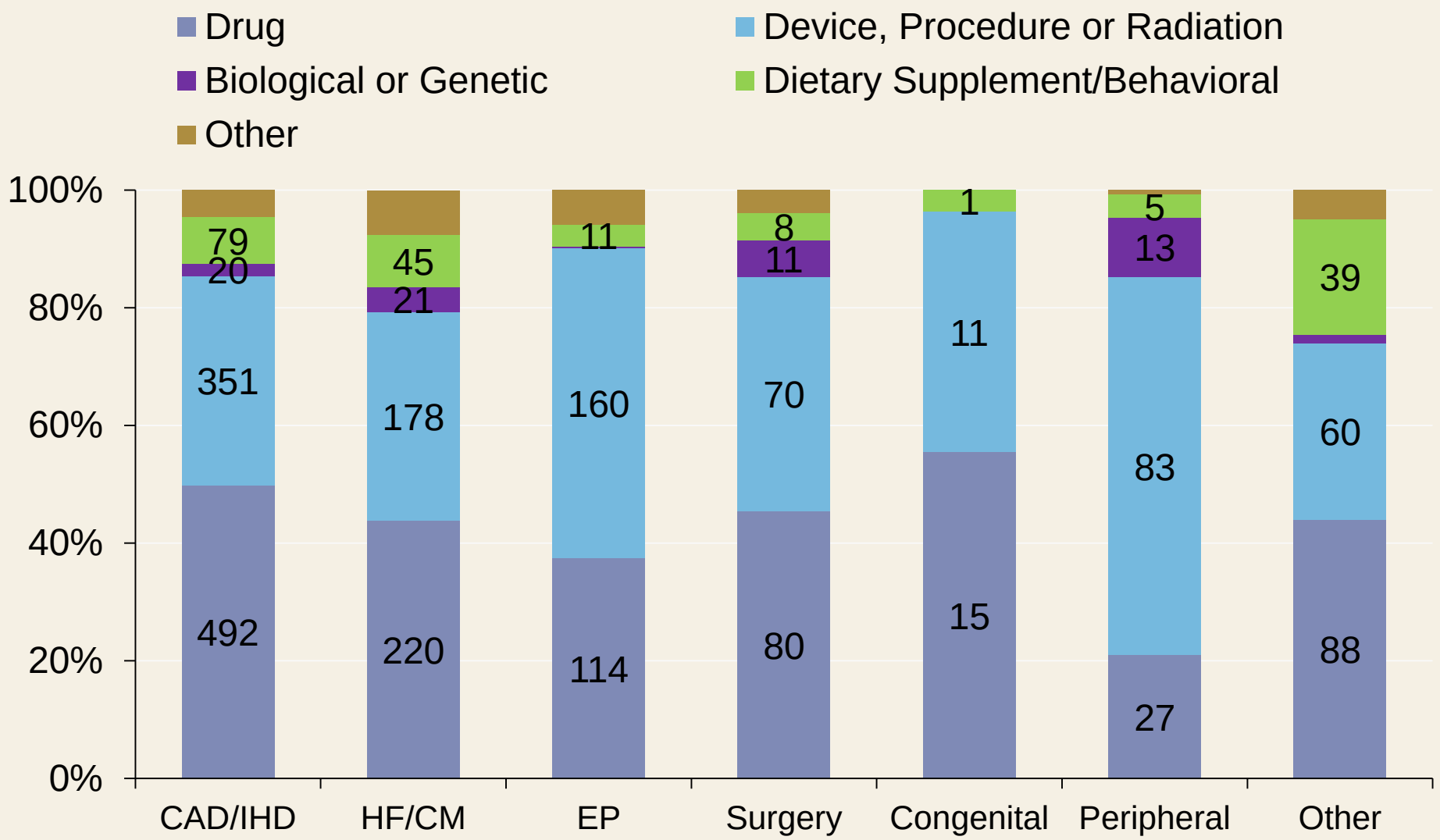
Intervention Type (n=2325 studies)



Specialty Subtype
(n=2325 studies)



Intervention Type by Subspecialty



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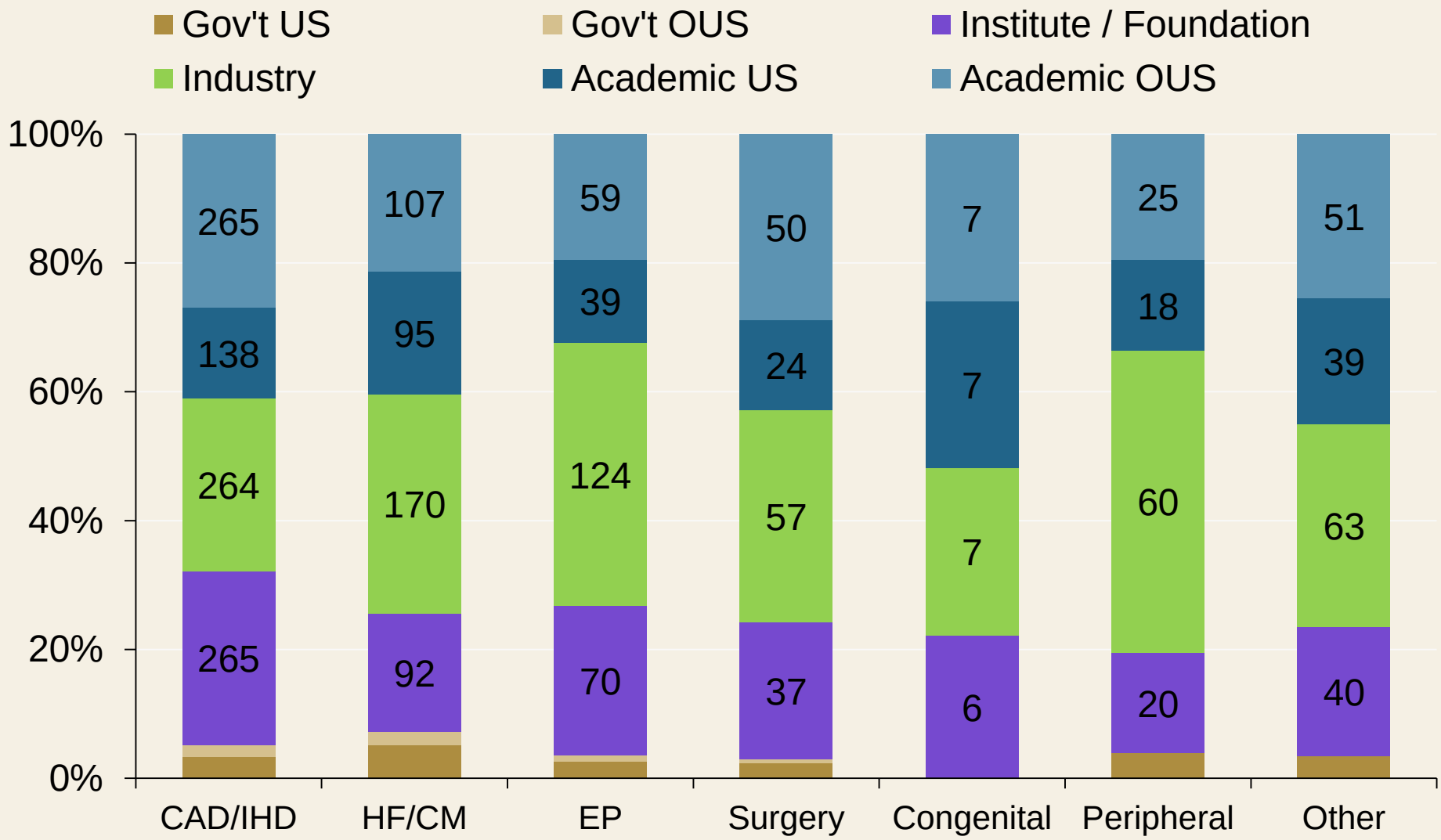
Lead Collaborator/Sponsor by Subspecialty



Summary

- Cardiovascular medicine is widely regarded as a vanguard for evidence-based drug and technology development.
- Prevalent diseases do not automatically translate into large, controlled trials of clinical endpoints.
- There exists substantial heterogeneity in study design and sponsorship.
- Registration in clinicaltrials.gov, while an important step forward, provides little assurance of study quality or scientific validity.
- A preponderance of small trials represents an opportunity to encourage collaboration and foster research networks.