

The State of Clinical Trials in Rheumatology: A review of the clinicaltrials.gov dataset

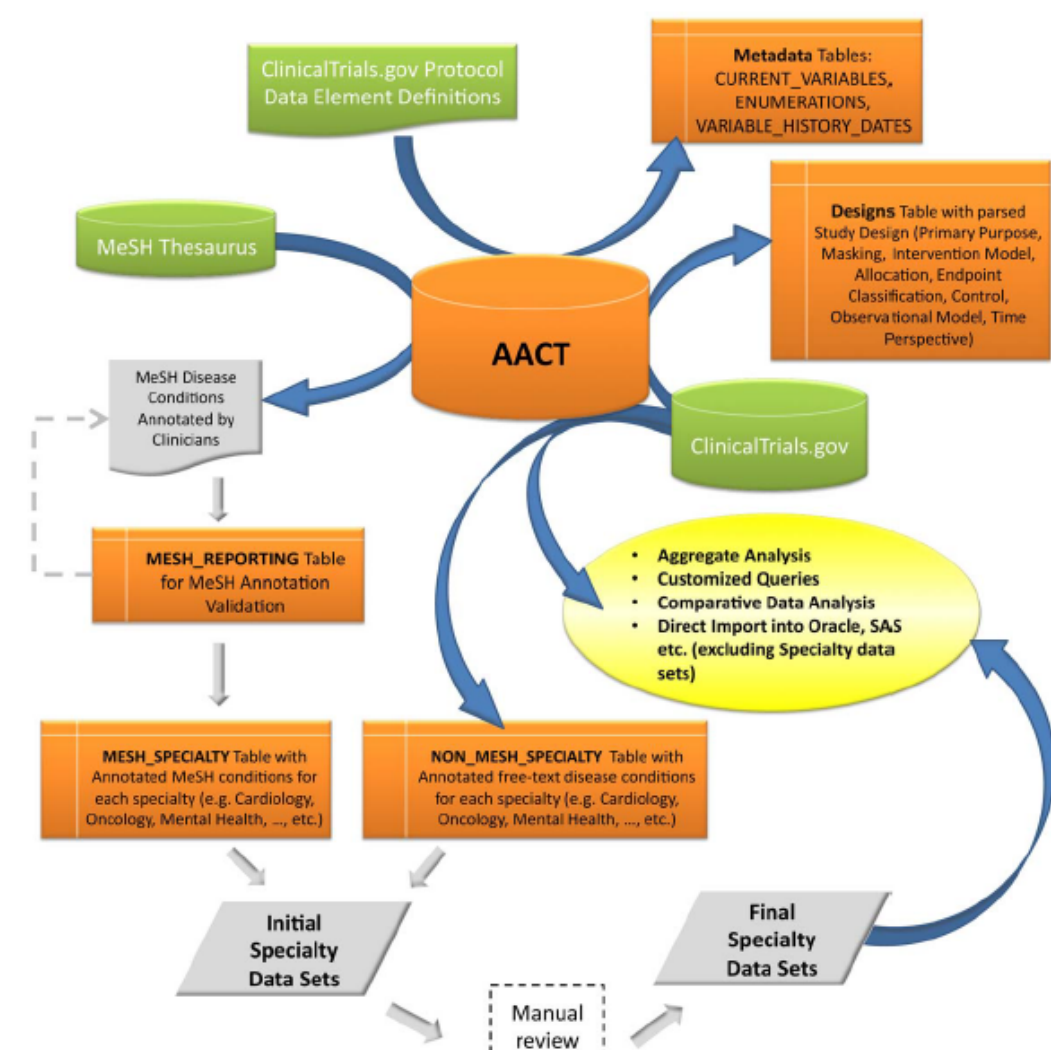
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Background

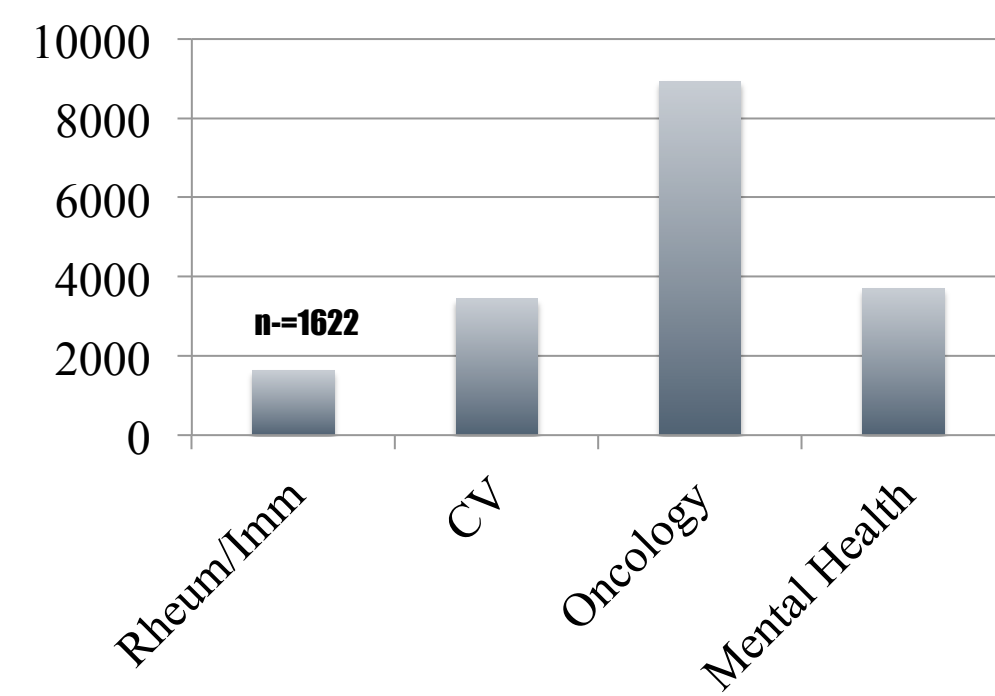
In an effort to provide a comprehensive listing of clinical trials Congress initiated the creation of the ClinicalTrials.gov (CTG) registry in 1997. In 2007 the FDA Amendment Act mandated registration of most non-phase I interventional drug, biologic, and device trials. Until recently, there has been no systematic analysis of the clinical trial enterprise, either broadly or for rheumatologic diseases. As part of the Clinical Trials Transformation Initiative, we analyzed the CTG database to describe the current state of clinical trials in rheumatology and compare these findings to other specialties.

Methods

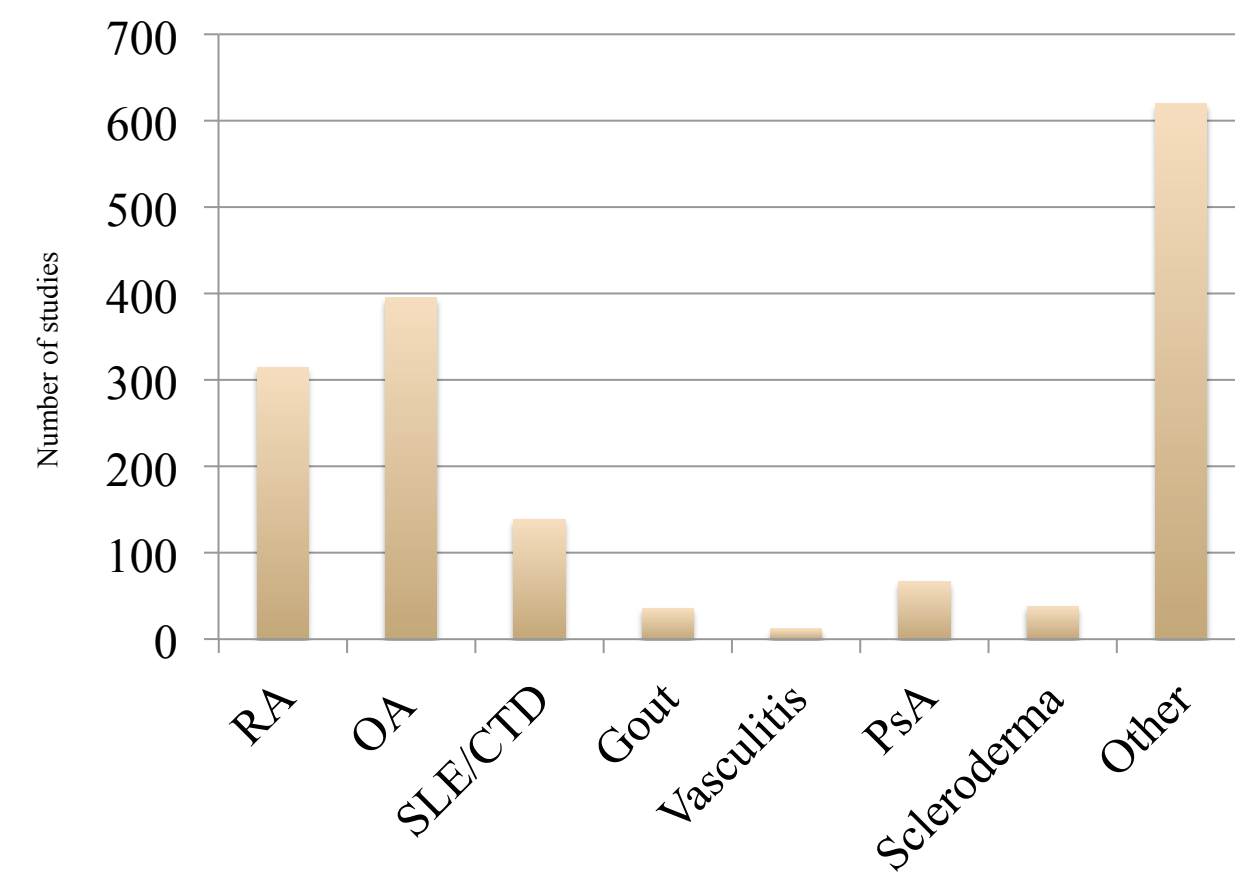
A dataset of 96,346 studies was downloaded from CTG on 9/27/2010 and a database for Aggregate Analysis of ClinicalTrials.gov (AACT) was created to facilitate analysis. The dataset was restricted to 40,970 interventional studies registered between 10/2007 and 9/2010. The Clinical specialists annotated medical subject heading terms and common disease terms for relevance to rheumatology. An initial dataset identified studies with ≥ 1 disease relevant term. Manual review of individual studies, and additional keyword searching yielded the final rheumatology study dataset (R). Studies were further divided into disease and sponsorship subcategories and comparisons were made between these subcategories, and with non-rheumatology (NR) studies.



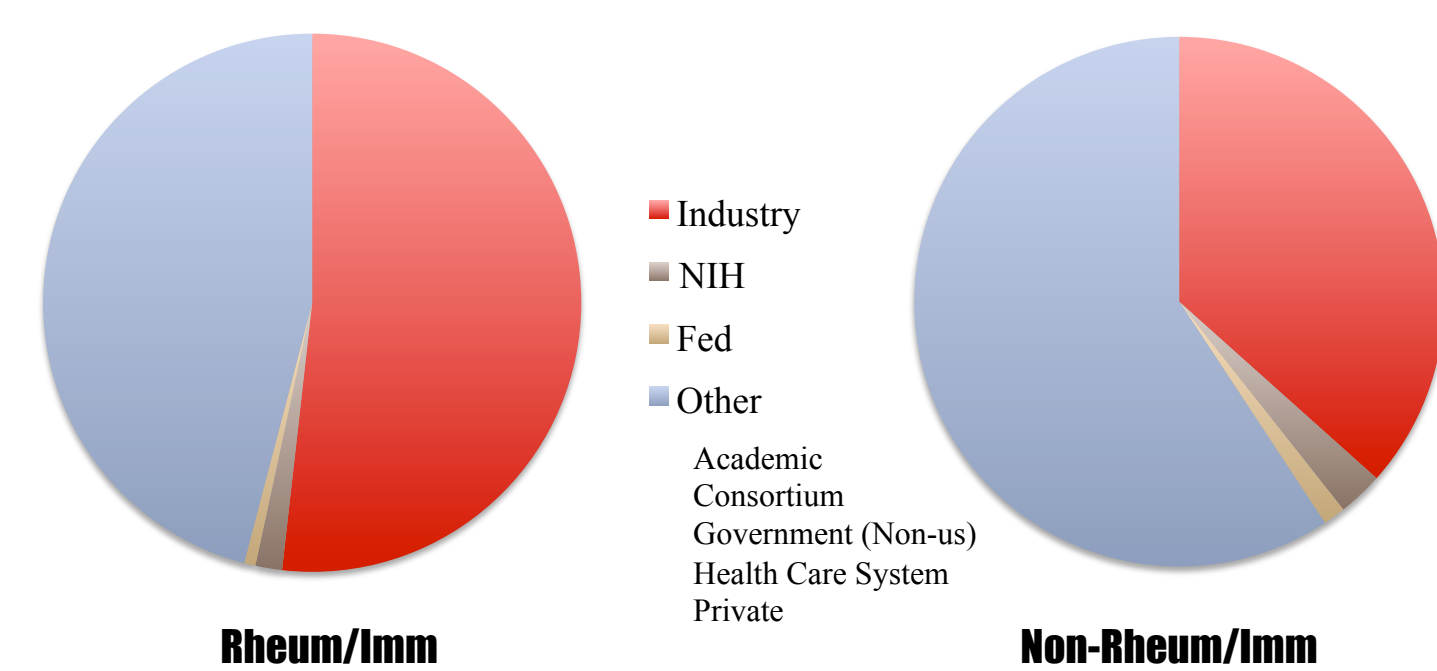
Number of studies (Total studies = 40,970)



Diseases

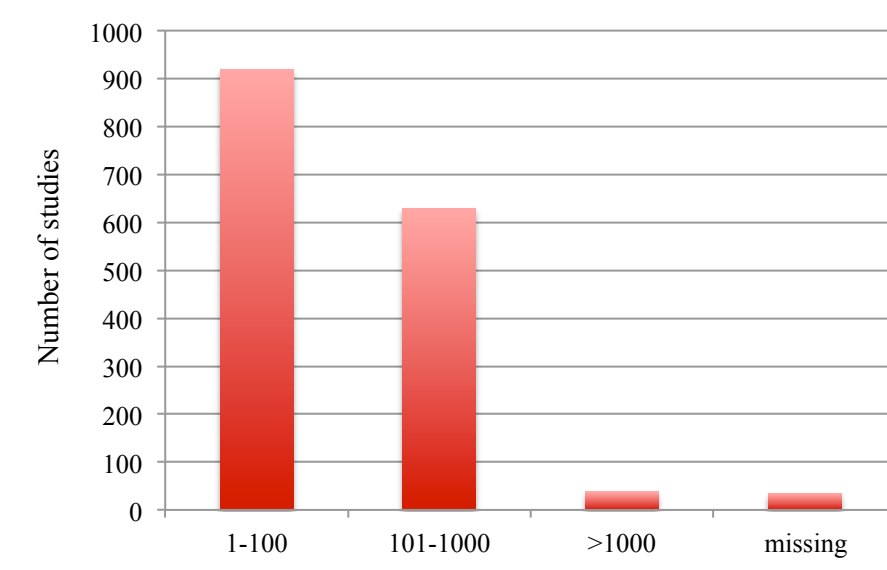


Lead Sponsor

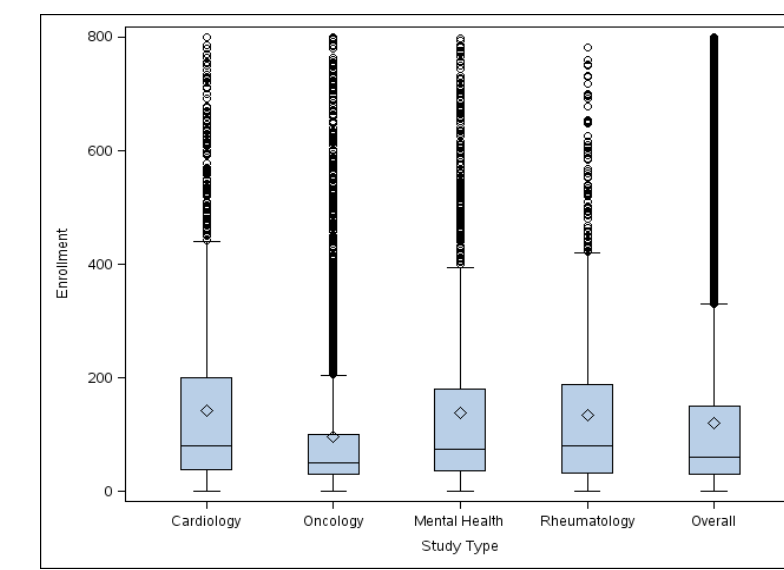


Results

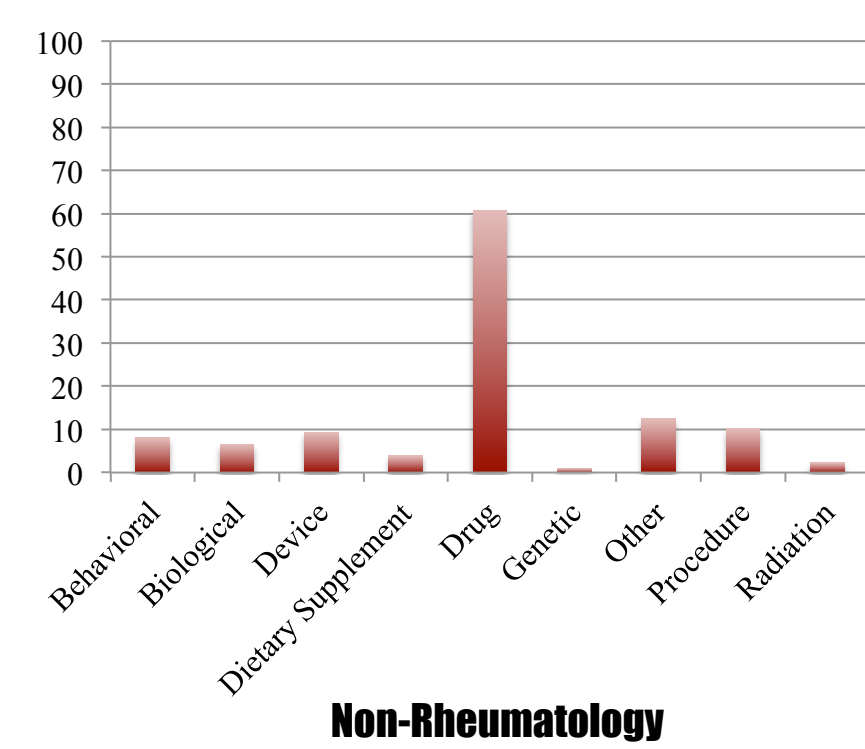
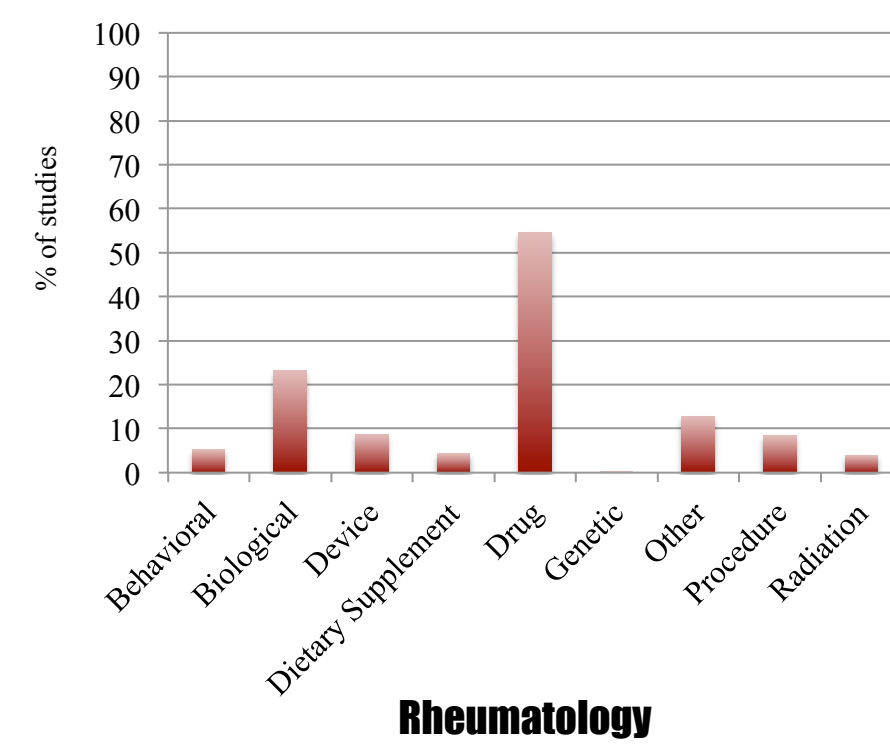
Enrollment



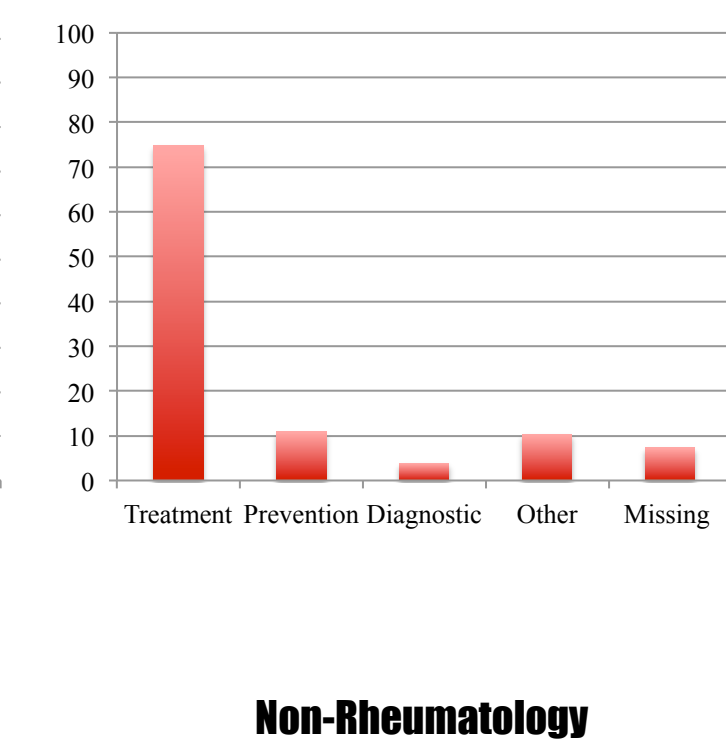
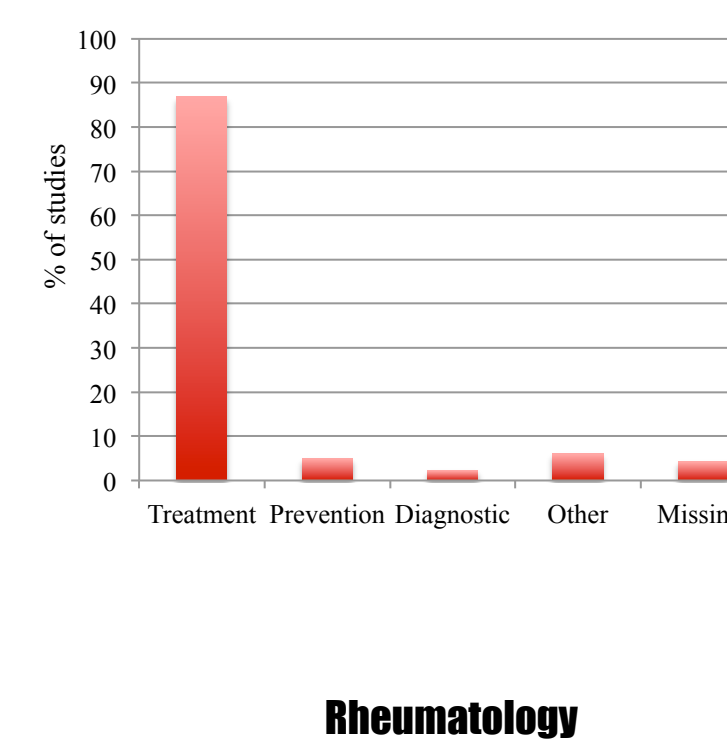
Enrollment Comparison



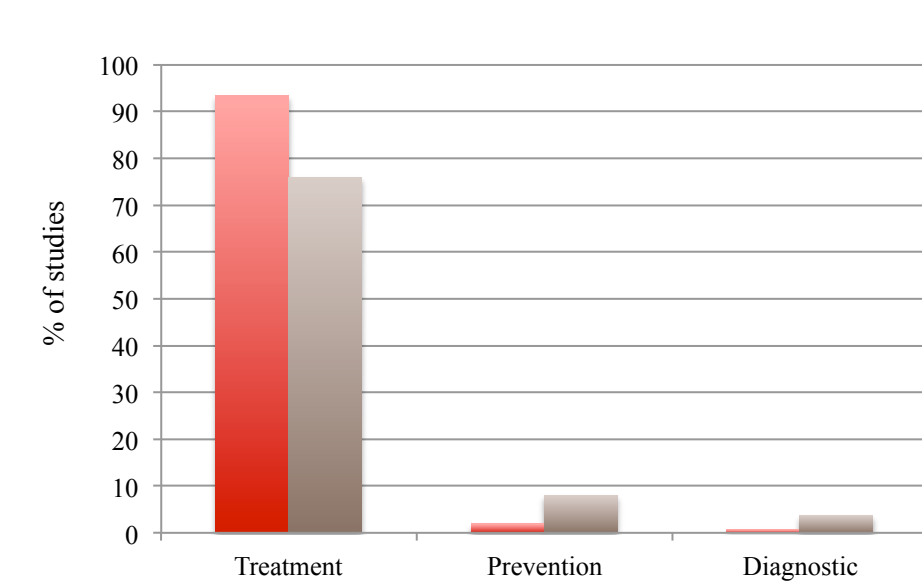
Interventions



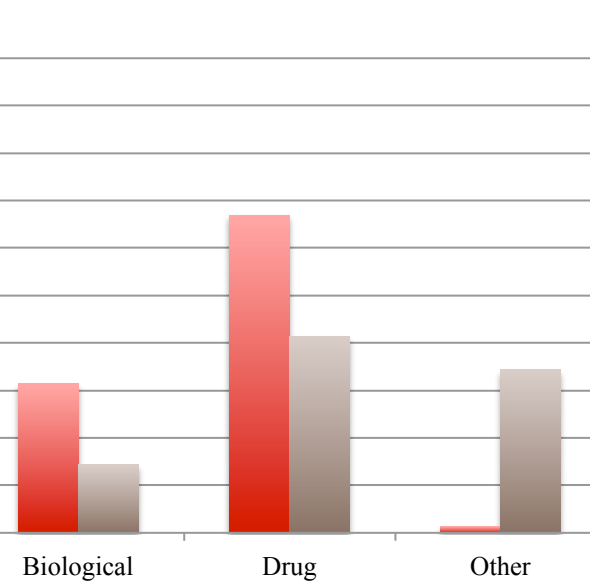
Primary Purpose



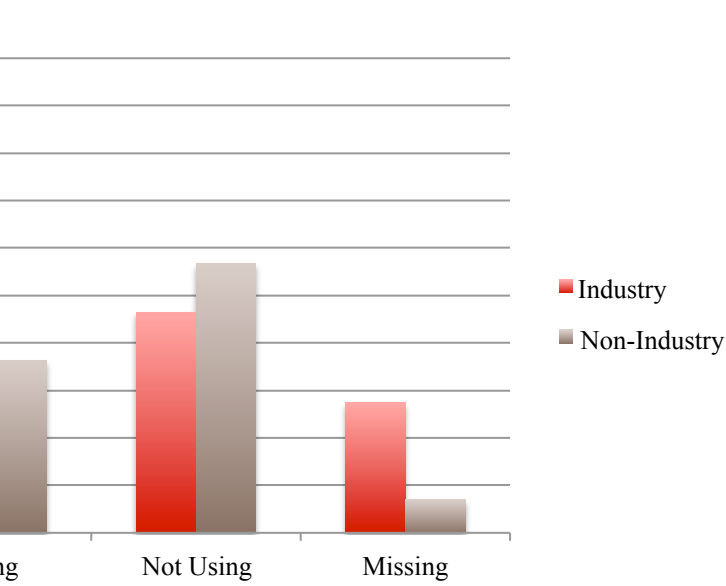
Primary Purpose



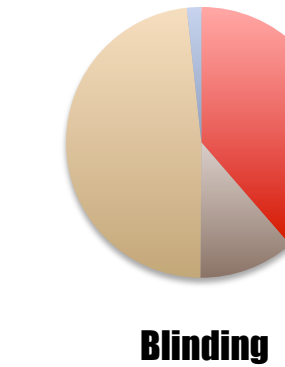
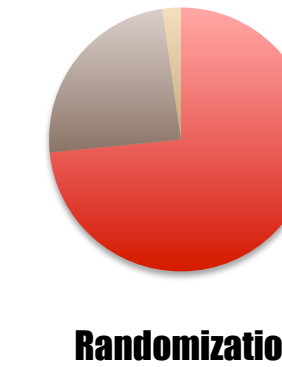
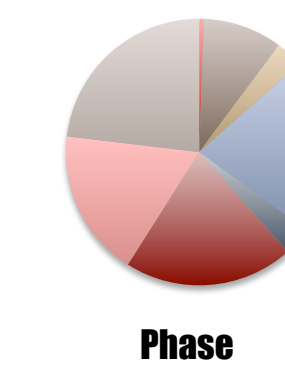
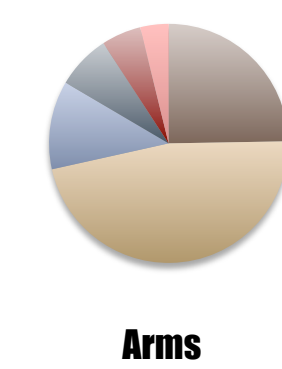
Intervention



Use of DMC



Design



Conclusions

- The rheumatology clinical trial enterprise represents a small number of trials in the CT.gov database between 10/2007 and 9/2010.
- Rheumatologic diseases with high prevalence and substantial unmet need are under represented relative to less common rheumatologic diseases.
- Half of the studies had enrollment of 80 participants or less, although this is comparable to studies in other disciplines.
- Most studies were randomized between two arms however double-blind masking was employed in less than half of studies
- More studies in rheumatology were sponsored by industry than non-rheumatology studies. Industry studies were more likely to focus on treatment and utilize drugs/biologics than non-industry sponsored studies. They were also less likely to employ a DMC; although often failing to supply this information.
- There is an opportunity to improve the quality of clinical trials in rheumatology and initiate a policy discussion on whether resources are optimally focused on the highest priorities.

Acknowledgments

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