Background: Clinical research provides information about infection prevention, diagnosis, prognosis, and treatment. However, many common questions related to ID specialties are not addressed by evidence-based medicine.

Methods: The mission of the Clinical Trials Transformation Initiative (CTTI), a 10-year initiative (2007-2017) to improve the conduct of clinical research, is to identify practices that through broad adoption can improve the efficiency, effectiveness, and ethical conduct of clinical research. This work is the first to characterize the ID clinical trials portfolio.

Results: Among the 36,970 interventional trials registered with ClinicalTrials.gov, 4,890 (13.1%) were ID studies. Most ID studies were infectious disease (IQR 44-400) subjects vs. 60 subjects (52.3% vs. 77.0% for non-ID trials) followed by Prevention (n=908, 25.0%) for non-ID studies. Most ID studies are randomized (73.2%) but unblinded (55.8%). Industry is the probable funding source algorithm:6

• NIH-funded: NIH either lead sponsor or NIH involvement
• Industry-funded: Collaborator and industry not the lead sponsor
• Collaborator-funded: Collaborator from industry without NIH involvement
• Probability-funded: Method: In the 3-years following the FDAAA, there were 96,346 interventional trials registered with ClinicalTrials.gov. The current spectrum of ID clinical trials has largely gone without systematic scrutiny regarding patterns of special focus, geographical distribution, and levels of industry involvement. ClinicalTrials.gov, a registry of over 100,000 trials from 174 countries, provides a unique opportunity to take a "snapshot" of ID trials.

Abstract (Modified)

Aims of this Study: To take a "snapshot" of ID trials.

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Conclusion: Further Subcategorization and other Definitions: ID trials were subcategorized based on study aim and description. World Health Organization (WHO) cause-of-death categories were used when possible.1 WHO Global Burden of Disease work used to calculate the % of ID-related mortality and disability-adjusted life years (DALYs) coordinate future ID clinical research priorities.

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Disclosures: None of the authors has any conflicts of interest to declare.

References:
5. ClinicalTrials.gov. A Systematic Analysis of ClinicalTrials.gov. ID clinical trials are well represented in the overall clinical trials enterprise, but would be much less than non-ID trials if one limited the analysis to those outside the U.S. et al. Original studies.

Conclusions:
• ID trials are well represented in the overall clinical trials enterprise, but would be much less than non-ID trials if one limited the analysis to those outside the U.S. et al. Original studies.

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

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