1 Phase 1 trial registration increased after 2007, but results disclosure remains low

2 What did we learn from this investigation?

3 What are the recommendations for the future?

# Background

## Objective

To assess whether changing a policy has affected results reporting and publication of industry-sponsored and non-industry-sponsored phase 1 trials, we surveyed the trend for registration of phase 1 trials with the National Library of Medicine (NLM) via PubMed and the periodical ICMJE (International Committee of Medical Journal Editors) policy was seen to result in an immediate increase in the number of industry-sponsored and non-industry-sponsored phase 1 trials.6

## Results

From 2000–2012, 8063 trials were registered at ClinicalTrials.gov after December 31, 1999, and 795 in 2012. The percentage of industry-sponsored trials with results reported on ClinicalTrials.gov was generally similar to that reported on Trialtrove, except for a decrease between 2002 and 2004 and a sharp increase in 2005 (when registration of phase 1 trials was required).

Number of phase 1 trials recorded year-wise on ClinicalTrials.gov versus Trialtrove

Figure 5: Year-wise breakdown of industry-sponsored and non-industry-sponsored phase 1 trials on ClinicalTrials.gov and Trialtrove

Disclosure of phase 1 trial results on ClinicalTrials.gov

Figure 6: Ratio of phase 1 trials recorded on ClinicalTrials.gov versus Trialtrove

## Summary and Conclusions

- The total number of phase 1 trials lies indicated by the number of publications retrieved from PubMed or trials recorded on the Trialtrove database has steadily increased over the past decade.
- Industry and academia should voluntarily endeavor for timely disclosure of clinical trial results on publicly available registries. Additionally, extending the logic for results disclosure of phase 1 trials to that of phase 2 trials would ensure results disclosure.

## References