TITLE: Evolving Practices of Results Reporting in ClinicalTrials.gov

BACKGROUND: It is ethical and professional to disclose results of clinical trials to the public. In 2007, US Congress passed the Food and Drug Administration Amendments Act (FDAAA) that requires Applicable Clinical Trials (ACTs) to submit basic results to ClinicalTrials.gov (CT.gov) database independent of journal publication or conference presentation in timely fashion (normally within 1 year after primary completion date). However, the compliance was poor (Anderson et al. 2015). The final rule for FDAAA 801 was issued in 2016 to further clarify the results reporting requirements with the effective date on January 18, 2017. The goal of this project is to examine the results reporting in CT.gov over the past decade.

METHODS: We analyzed trials registered in CT.gov that completed or terminated in or after 2008 and defined likely applicable clinical trial (LACT) status for individual trial based on public available information in CT.gov. We plotted the cumulative percentages of trials that reported results after the primary completion date group by LACT status. We calculated the proportion of trials that reported results within 12 months interval group by LACT status and year of completion. Among the trials with results reported, the key result elements, including outcome measures, adverse events and baseline characteristics, were examined for completeness and interpretability.

RESULTS: Of 130,407 trials completed or terminated between 2008 and 2017, 26% of trials were flagged as LACT. Overall, 59% of LACTs and 15% of non-LACTs had reported results to date. For LACTs, the percentages of trials submitted results to CT.gov within one year after completion increased from 10% among trials completed in 2008 to 30% among trials completed in 2017. On the contrary, for non-LACTs, the percentages increased from 5% to 6% during the same period. The result elements reported on CT.gov became more informative regardless of the LACT status over the past decade, including specifying methods for adverse events collection, reporting all-cause mortality, summarizing the ethnicity / race background etc. More details and visualization of results will be presented at the meeting.

DISCUSSION: Since CT.gov released its results database in 2008 and the final rule was issued in 2016, reporting results at CT.gov has been gradually becoming a more popular practice, which is an important next step after the prospective trial registration and a prior step to the effort of sharing individual participant data (IPD). We hope the continuing improvement in universal results reporting practice brings more values to clinical trials for the societal advancement.