Compliance with Clinical Trials Reporting Requirements of the 
FDAAA Amendments Act 2007
Nicholas J. DeVito & Ben Goldacre

Introduction
The FDAAA Amendments Act of 2007 (FDAAA 2007) and its associated 2016 Final Rule require most interventional clinical trials in drugs, devices, and biologics regulated by the US Food and Drug Administration to report results directly to ClinicalTrials.gov within 1 year of primary completion. The Final Rule details which trials are required to report and how they should report. This poster details compliance with the reporting requirements of the FDAAA 2007, as outlined in the Final Rule, along with quantitative assessments of various related requirements that could be assessed quantitatively with data from ClinicalTrials.gov.

Methods
The FDAAA 2007 and its associated Final Rule were reviewed for requirements that could be assessed quantitatively with data directly from ClinicalTrials.gov. As part of the TrialsTracker project (fdaaa.trialstracker.net), a full version of ClinicalTrials.gov is archived every working day and processed to assess the results status of all covered trials under the FDAAA 2007. Adapting the methods developed for the FDAAA TrialsTracker, we identified applicable trials and extracted relevant study details from ClinicalTrials.gov for each analysis. All data handling and processing was performed in Python 3.7.

Results

Reporting Trends

- 62% of due trials reported as of 7 June 2019

- Sponsors must report results “no later than 1 year after the primary completion date of the applicable clinical trial.”

The proportion of all trials reported on time has decreased over time.

Reporting Secondary Outcomes – Pilot Data

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<thead>
<tr>
<th>Reported Fully</th>
<th>Reported With Potential Issues</th>
<th>Unreported</th>
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<tr>
<td>10</td>
<td>8</td>
<td>2</td>
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Table 1. Secondary Outcome Reporting Status

- Sponsors must update results to include full secondary outcome and safety data within a year of full study completion. Pilot data was collected to determine how compliance with this requirement could be systematically assessed.
- Of the 20 trials:
  - 10 had fully reported all outcomes;
  - 2 had confirmed unreported secondary outcomes;
  - 8 reported all outcomes but either have not updated their record post-full completion (3) or have outcome timeframes that do not match the dates provided (7)

Data issues may complicate the automated assessment of secondary outcome reporting and a more complex and resource-intensive methodology that manually considers the protocol, study design, and details of outcomes is likely required.

Conclusions & Discussion

Conclusions:
- As of 7 June 2019, 38% of applicable trials required to report have submitted no results; of due trials that did report, 35% reported late. Median time to report (422 days) is greater than the required reporting deadline (365 days).
- While the availability of documentation was high among reported trials, other areas raise concerns about the trial reporting process. The QC and Certificate of Delay procedures are both operating outside of the guidelines established in the Final Rule.
- Pilot data on secondary outcome reporting indicate future research on the extent of compliance with the requirement is warranted but would require additional resource and methods development to ensure accurate assessments.

Discussion:
Compliance with the reporting requirements of the FDAAA 2007 and its Final Rule is uneven and represents a failure to fully implement the law as described. Issues with the implementation and enforcement of the law continue to undermine the complete and prompt sharing of results more than 2 years after the Final Rule came into effect.

Ignoring these clearly established requirements delays the availability of results and reinforces lax reporting behavior by sponsors.

In our experience with the FDAAA TrialsTracker these unreported trials represent a combination of genuinely overdue trials and trials with incorrect or out-of-date information on the Tracker, both of which are violations of the FDAAA 2007. To date we know of no fines, nor other enforcement actions, that have been taken by the FDA pursuant to non-compliance with the reporting requirements of the FDAAA 2007.

Effective implementation and enforcement of the FDAAA 2007 is necessary to ensure the legislative goals of complete, accurate, and timely reporting of clinical trials are realized.

Contact
Nicholas J. DeVito
University of Oxford
nicholas.devito@phc.ox.ac.uk
@ndevito1

References