One and Done Survey Findings

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Purpose of Survey

- Among “one-and-done” investigators:
  - Identify the barriers to conducting FDA-regulated drug trials
  - Identify the barriers that affected their decisions to no longer conduct FDA-regulated drug trials
  - Identify possible solutions for enhancing their experiences in conducting FDA-regulated clinical trials
  - Identify the benefits of conducting FDA-regulated clinical trials

Why do PIs conduct only one trial?

Contemporary Clinical Trials Communications 6 (2017) 31–38

Contents lists available at ScienceDirect

Contemporary Clinical Trials Communications

journal homepage: www.elsevier.com/locate/conctc

One and done: Reasons principal investigators conduct only one FDA-regulated drug trial

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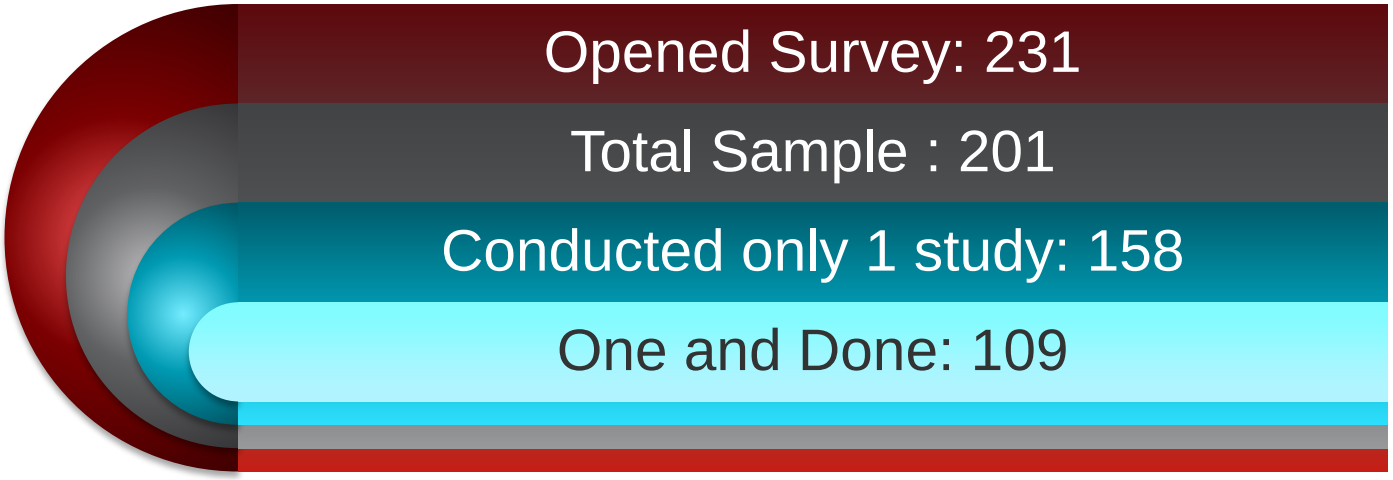
One and Done Survey

- Identify the barriers to conducting FDA-regulated drug trials
- Identify the barriers that affected investigators' decisions to no longer conduct FDA-regulated drug trial

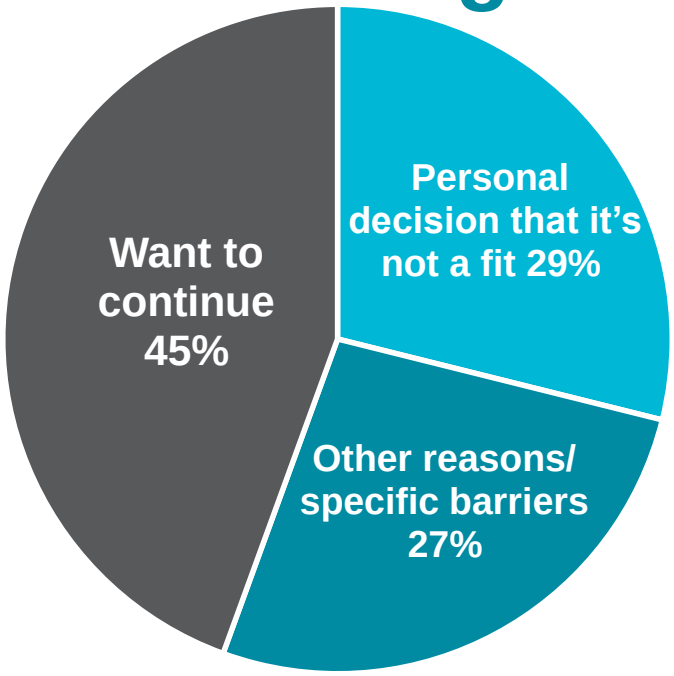
2933 surveys sent to active emails



More than half of respondents were truly "one-and-done"

Overall reasons for discontinuing

- Many investigators want to continue
  - A large proportion of respondents wanted to conduct more FDA-regulated trials but lacked opportunities to do so
  - Mechanisms that match interested investigators with research sponsors are needed
- Identified barriers that affected investigators' decisions to no longer conduct FDA-regulated trials



Future efforts to reduce investigator turnover can target issues that matter the most to investigators

Hypothesized reasons for only doing one study before investigator survey

Finance

- Sponsor/site contract negotiations
- Sponsor/site budget negotiations
- Final contract
- Final site budget
- Schedule of site payments

Data and safety reporting

- Amount
- Method
- Frequency

Question sequence

- The six categories of barriers were presented, one by one
- After naming the barrier category, a question followed asking if the barrier in general has been problematic in some way
  - If yes, investigators were asked their perceptions about several sub-factors in the overall barrier category
    - Investigators who indicated that they had made a personal decision to no longer conduct FDA-regulated drug trials or said “other” reason for decision, then asked about effect of sub-factor on decision
  - If no, skipped to next barrier category

What the survey showed

Finance

- Sponsor/site contract negotiations
- Sponsor/site budget negotiations
- Final contract
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Data and safety reporting

- Amount
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Corneli et al, Contemp Clin Trials Commun 2017

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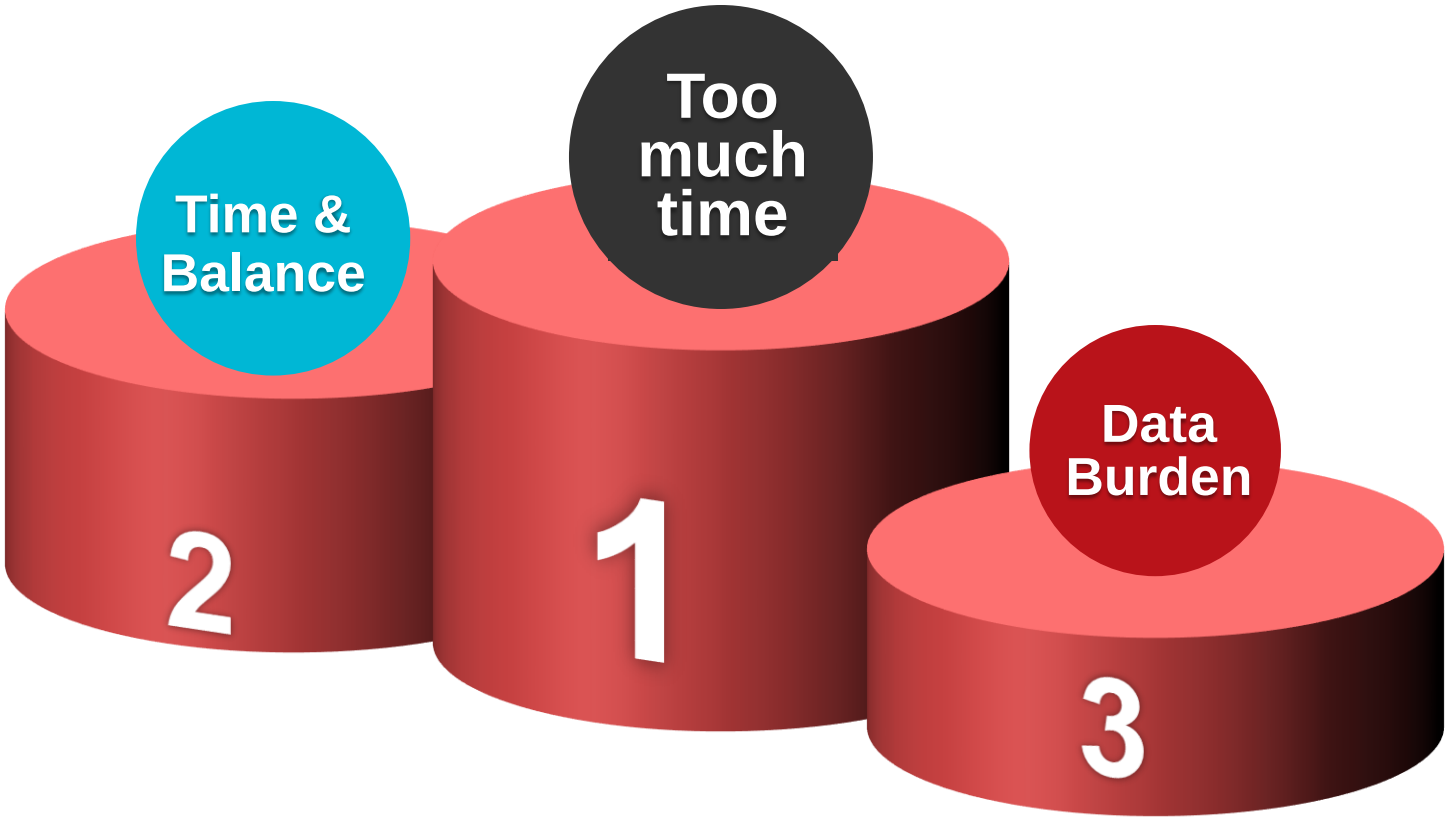
One & Done Survey



4. Finance

Reasons “one-and-done” investigators no longer conduct FDA-regulated drug trials

Burden of data and safety reporting

- Amount
- Method
- Frequency

Dissatisfaction with trial finance

- Sponsor/site contract negotiations
- Sponsor/site budget negotiations
- Final contract
- Final site budget
- Schedule of site payments

Corneli et al, Contemp Clin Trials Commun 2017

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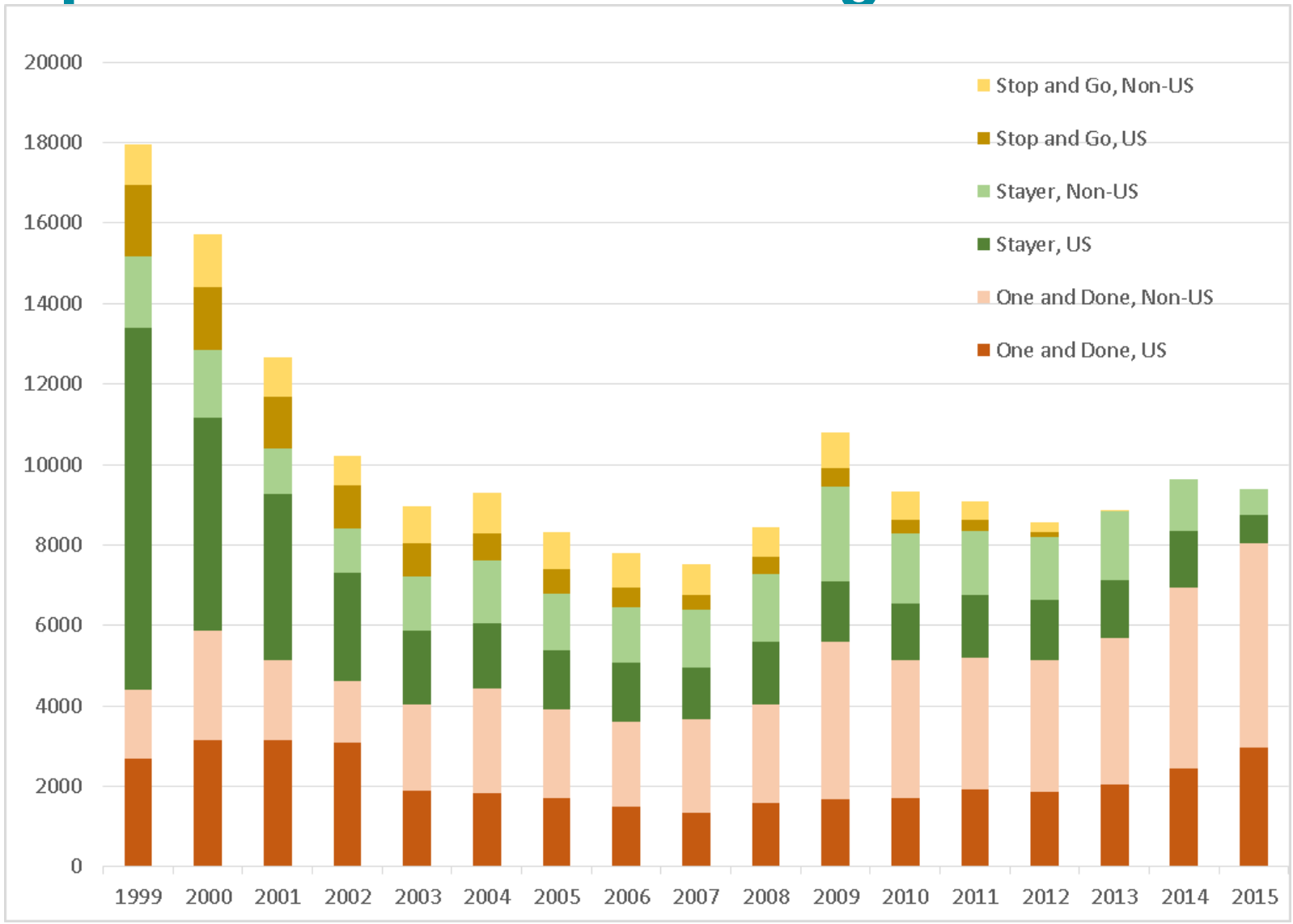
What Investigators Had to Say About Other Barriers

"Too much effort, without enough help, with too much bureaucracy, for no recognition (no authorship of paper, no kudos or appreciation from my section chief, etc.)"

"Conducting research costs me money, the time and effort is not paid and takes me away from the financially rewarding parts of my job. There is constant paperwork, site visits, protocol amendments, and need to reconsent. All time sucking."

Temporal Trends in Investigator Turnover



Discussion

- After Active Investigator Presentation:
  - What findings did you expect to see that aren't present?
  - What findings were surprising to you?
- Later today:
  - What findings are important for informing next steps and recommendations?

THANK YOU.

CLINICAL TRIALS **TRANSFORMATION** INITIATIVE

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