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?

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

- Opened Survey: 231
- Total Sample: 201
- Conducted only 1 study: 158
- One and Done: 109

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

- Hypothesized reasons for only doing one study before investigator survey

- Investigator & staff involvement & investment
  - Lack of investigator input on protocol
  - Excessive training for investigators/staff
  - Limited opportunities to learn about new studies
  - Inadequate training for investigators/staff

- Time
  - Time required by investigator to support trial and staff
  - Amount of time required by staff to support trial
  - Amount of time required to prepare for trial set up

- Finance

- Data and safety reporting

- Balancing trial with other activities
  - Long work hours
  - Unpredictable work hours
  - Finding time to devote to:
    - Clinical and non-clinical activities
    - Activities fostering academic promotion
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

Investigator & staff involvement & investment
- Lack of investigator input on protocol
- Excessive training for investigators/staff
- Limited opportunities to learn about new studies
- Inadequate training for investigators/staff

Time
- Amount of time to implement trial in general
- Time required by investigator to support trial and staff
- Amount of time required by staff to support trial
- Amount of time required to prepare for trial set up

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

Corneli et al, Contemp Clin Trials Commun 2017
One & Done Survey

2. Time & Balance

1. Too much time

3. Data Burden

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

- Time to lead trial takes away from other necessary activities
  - Long work hours
  - Unpredictable work hours
- Trial time makes it difficult to devote time to:
  - Clinical and non-clinical activities
  - Activities fostering academic promotion
- Too much time required to lead trial
  - Amount of time to implement trial in general
  - Time required by investigator to support trial and staff
  - Amount of time required by staff to support trial
  - Amount of time required to prepare for trial setup
- 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
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

Fordyce et al, from BMIS 1572 database (manuscript in preparation)

Number of investigators:

- Stop and Go, Non-US
- Stop and Go, US
- Stayer, Non-US
- Stayer, US
- One and Done, Non-US
- One and Done, US

Years: 1999 to 2015

The graph shows the number of investigators over time, categorized by their activity status (Stop and Go, Stayer, One and Done) and their location (US, Non-US). The y-axis represents the number of investigators, and the x-axis represents the years from 1999 to 2015.
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.

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