



CLINICAL
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INITIATIVE

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Talking to Active Investigators: Interview Findings

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Active Investigator Interviews

Active Investigator: principal investigator in a minimum of four distinct FDA-regulated drug trials in the two years prior to June 1, 2016

- Identify reasons active investigators have been successful at participating in multiple FDA-regulated drug trials
- Identify challenges experienced or avoided by active investigators in the conduct of FDA-regulated drug trials and describe the strategies used to manage and/or prevent these challenges

Approach

Did you experience challenge?

Yes:

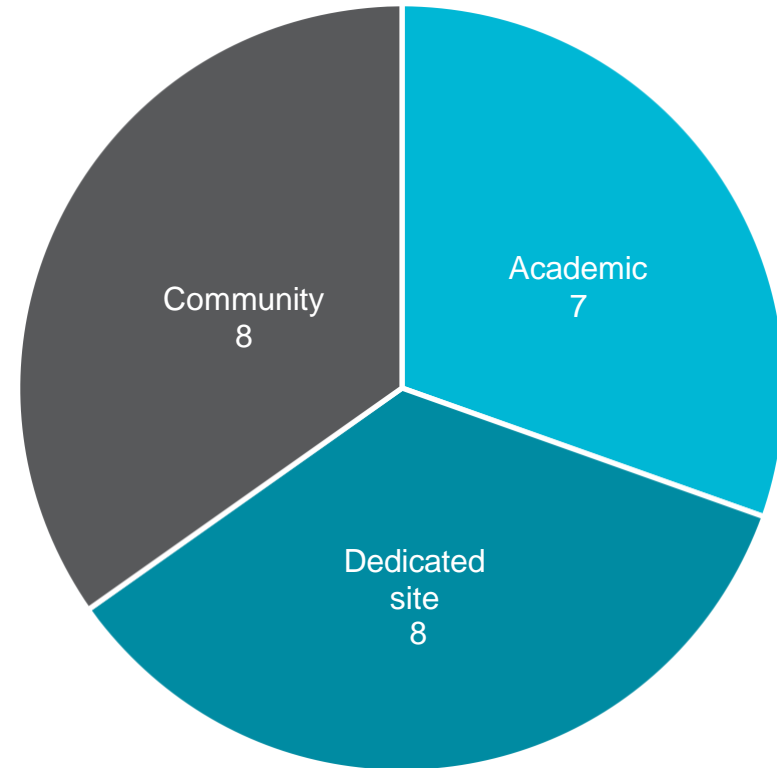
- How did you cope with /overcome the challenge

No:

- What buffered you from this challenge that others identified

Research careers

- ▀ First exposure to FDA trials
 - As a fellow, with the PI
 - Served as a sub-I/co-PI
 - Immediately as PI (few)
- ▀ First served as PI:
 - 1 to 3 years after residency
 - After practicing medicine for 10 or more years



Accessing opportunities to conduct FDA-regulated drug trials

- Nearly all: sponsors contacted them directly about new trial opportunities
- Reputation matters in order to participate in additional studies

- Clinical trial networks
- Reached out directly to pharmaceutical companies
- Networking

Reasons active investigators have been successful at participating in multiple FDA-regulated drug trials



Key Findings

- Sufficient and well-trained staff
- Strong commitment and work ethic
- Institutional support Ability to recruit patients
- Business knowledge and experience
- Strong reputation Ability to network
- Ability to be realistic when selecting protocols/ recruitment

Sufficient and well-trained staff

- Staff support was a critical component of their success
- Study coordinator was mentioned most often
- Other key staff mentioned:
 - Administrative, regulatory, research nurses, data, IT, budget and contract, research pharmacist

A well-organized clinical research team that can deal with all aspects of the research, from the regulatory, the contract side of it, and then the clinical team including the sub-investigators, the research nurses, other patient recruiters, etc. who have a clear screening and recruitment plan and can implement that plan. —A

Personal commitment to clinical research and good work ethic

- ▶ Investigators enjoy the work, even though long hours and meager compensation

You must really enjoy doing what you're doing. And you must believe that what you're doing is important. Because there is a lot of work. And even though there is some compensation, it doesn't even come close to compensate for the amount of time invested in it. So you have to enjoy it. You have to enjoy the interaction with other PIs. You have to be eager or inclined to publish the data that you are working on. So you have to enjoy it and you have to believe that it is going to be important. —A

Institutional support

▸ Included:

- Budget and contracting expertise
- Protected time to devote to research
- Physical space to conduct the research and store files

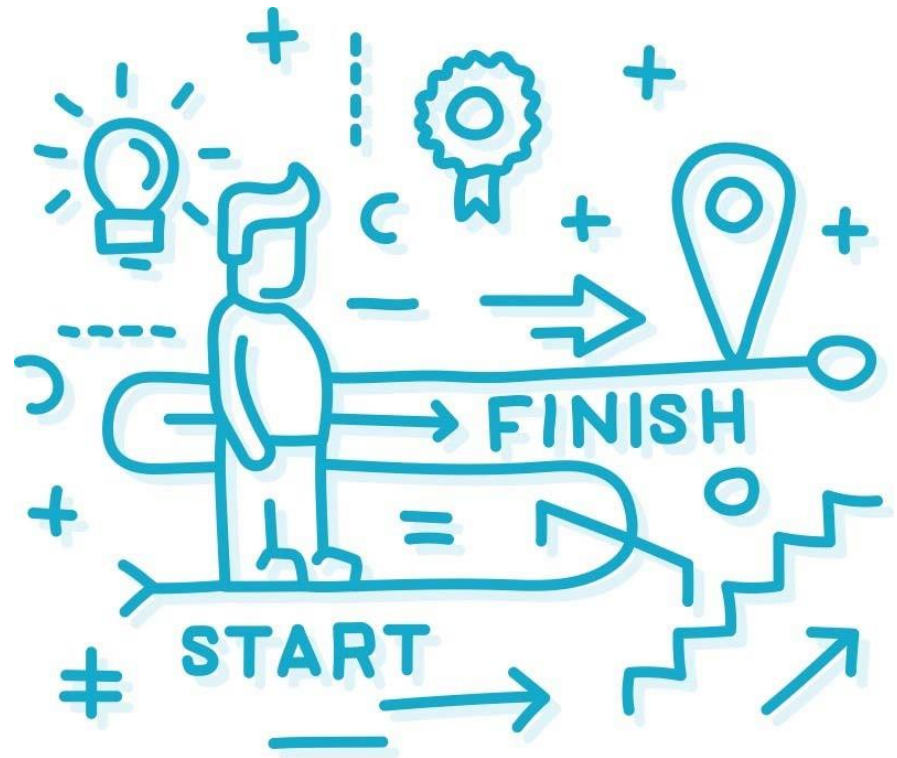
I think the support of the institution is critical. The dedicated time for the PI. Because it is not something that can be done with a full load of clinical work. —A

Ability to recruit

➤ Two dimensions of recruitment:

- Assessed ability to recruit from own patient population when considering whether or not to do the trial
 - Declined if reaching the target sample size seemed difficult
- Ensured had good recruitment plan with appropriate staffing

Identify challenges experienced or avoided by active investigators in the conduct of FDA-regulated drug trials and describe the strategies used to manage and/or prevent these challenges



Key Findings

- Two of the four major challenges identified by the one-and-done investigators were identified by nearly all active investigators as challenges they had also experienced: trial finances and time required to implement trial
- Data and safety reporting also challenging
- Other challenges experienced:
 - Recruitment
 - Regulatory agencies, sponsors, and CROs
 - Quality protocols

Trial finances

- **Tight budgets** mentioned far more often than any other finance-related issue
- Leads to the inability to sufficiently cover the work, particularly their ability to conduct a quality trial
- Trend: less funding for more work and responsibilities

- Other challenges:
 - Budget negotiations
 - Payment delays
 - Inaccurate budgeting by study team
 - CROs are
 - competition for limited funds

Time required to implement trial

- ▶ Actual time needed to conduct the trial was more than originally anticipated
- ▶ Additional staff—or more effort by existing staff members—was required to conduct the trial than originally planned and budgeted
 - Negotiating for coverage nearly impossible
- ▶ Delays in starting trial

Even after start-up, a lot of times, there's delays in getting supplies, getting drug, getting IRB approval, so I think that tends to be the next level of frustration that can vary. —D

Data and safety reporting

- ▶ Almost two-thirds said they had found the burden of data and safety reporting challenging
- ▶ Just too much...
 - Quantity of AE and SAE reporting
 - Time required to meet reporting needs
 - Number of AEs to sign off on
 - Requested information from sponsors and/or CROs/monitors

Workload balance

- ▶ One-third said they have found the time that trial implementation takes away from other activities to be challenging.
- ▶ Primary concerns focused on **salary coverage**

Other Challenges



Recruitment and eligibility criteria

- ▶ Challenges related to recruitment and eligibility criteria were described by three-fourths of investigators

Recruitment is the big thing. Sometimes the protocols are so complicated and have so many different assessments that are required, and the inclusion/exclusion is so difficult, they become very difficult to recruit for. So, I would say those would be sort of the lengthy delays, the extensive correspondence and programming and all this stuff, and then recruitment becomes the next biggest challenge in difficult studies. —D

Recruitment and eligibility criteria

- ▶ Stringent or unrealistic eligibility criteria
 - Even more so now than in the past
 - Makes investigators question the appropriateness and usefulness of the criteria
 - Affects the ability to conduct the study, the study timeline, and can unexpectedly alter study finances
- ▶ Reflects changing environment
 - Moving away from seeking clinician involvement during protocol development
 - Landscape is now less flexible and more complex
 - Does not appear to place value or trust in their clinical skills
 - Counter-productive to its overall scientific aim when presented with unrealistic criteria

CROs and sponsors

CROs

- Increase challenges
- Hinder trial progress (CRO monitors)
- Have poor quality staff
- Have high turnover
 - Increases site's workload and financial stresses
 - Perpetuates challenges, since there is no learning from experience

CROs and sponsors

- CROs act as a wall between the site and sponsors
 - Leads to a disconnect between researchers and sponsors, specifically when it comes to understanding and listening to the challenges that sites face
- Incentive model used by sponsors and CROs endangers the quality of work
 - Model is profit- and market-driven instead of patient-focused or science-based
 - Lacking in academic or investigator input
 - Lacking in investment in trials or commitment to quality work

Quality and clarity of protocols

▸ Protocols are often:

- Poorly written, inappropriate, not feasible
- Written by those who lack experience and who don't seek the input of experienced clinicians

Recommendations for becoming an active investigator



Getting started

- ▶ Engage in education and training programs
 - Conferences put on by professional organizations
 - Institutional resources (e.g., lecture series)
 - Degree programs (e.g., masters in clinical investigations)
- ▶ Network with experienced investigators/find a mentor Serve as a sub-Investigator
- ▶ Find out about available trials

Advice on overcoming challenges

- Have realistic expectations
- Engage in proper planning before committing
 - Assess the feasibility of conducting the trial
 - Have a good source of patients
 - Have full understanding of the PI's roles and responsibilities
- Have a recruitment plan

My advice would be to take the time to conduct the feasibility aspect of a clinical trial so you make sure that what you're committing to is what you're really able to do, and that it is a study of interest etc., so that you're very selective in the trials that you participate in. —A

I think making sure you have an established database of good patients. Having a source of patients that other sources, other doctors, are aware of what you're doing.

So, you really have to have a wide source of patients...the fact is that in regular practice you may think you have all these people, but you really don't. —D

You need to be prepared that it will be a slow start. It just is. You can't expect, I'm going to open my doors and sponsors are going to flood to my site because I'm so great. It just doesn't happen that way. So, realistic expectations. —D

The other key thing is absolutely to have – wherever you are, to have commitment from your institution that this is important to them, and they will support this through an organizational structure with regulatory affairs, with a clinical trials office, with running trials, and really have a team behind you to do this. Without that, it's virtually impossible to do this. As physicians, we are way too busy to try to do all of that without the support. That's key. —A

Discussion

Now:

- What findings did you expect to see that aren't present?
- What findings were surprising to you?

Next Session:

- Identifying essential themes and proposing solutions
 - Additional data presented by project team members
 - Investigator perspective
 - Continued attendee participation

THANK YOU.



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