

MJFF Guide to Recruitment Planning



Preparing to Launch a Study

- Establishing infrastructure around recruitment
 - Form a Recruitment and Retention working group of PIs and coordinators
 - Institute monthly calls of all site PI's and coordinators to discuss study operational issues and recruitment progress

- Centralize key activities to support sites
 - Develop a recruitment plan
 - Create and produce materials for a site toolkit
 - Patient materials
 - Information for practitioners
 - Media documents
 - Guidelines and talking points for difficult to discuss or invasive procedures
 - Study Website
 - Allocate other necessary resources and support



Objective #1: Fill the Funnel

Define the target of who the study wants to screen



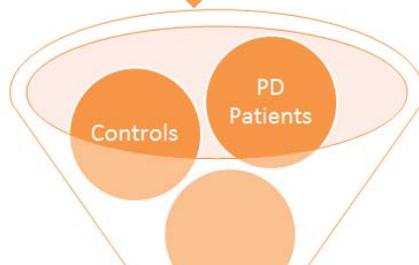
Identify key channels to reach the target



Determine who the “agents” are



Develop plan to equip agents and reach targets



Filling the funnel: Define a target

- **Define the target of who the study wants to screen**
 - In 1-2 sentences, who is the study hoping to identify to then screen for this study?
 - NOT the entire list of inclusion exclusion criteria
 - Focus on the big categories that help pre-screen people, but don't limit who might get referred before they even get referred
 - Examples:
 - Study looking at pre-motor PD– seeks people who are over 60 who have a smell loss
 - TARGET = people over 60 to take a screening survey (not people who have trouble smelling since people often don't even realize that they can't smell)
 - Study of patients on Azilect from 8 weeks to 8 months
 - TARGET = at study start, patients on Azilect less than 8 months; ongoing, any patient who is being prescribed Azilect as they get the prescription

Filling the funnel: Identify Channels

- **Identify key channels to reach the target**
 - Where are these people? How do I reach them?
 - Prioritize key channels with a high concentration of these targets; multi-pronged does not mean doing a little bit of everything
 - Key channels to consider:
 - Site clinical practice
 - Community physician's office
 - Support groups and reoccurring meetings
 - Events and symposia
 - Other opportunities in the broader community (i.e. health fairs)
 - Examples:
 - Newly diagnosed, unmedicated patients
 - CHANNEL = community physicians offices where they are diagnosed; likely not coming into tertiary care centers that are the study's clinical sites
 - PD patients with hypotension
 - CHANNEL = can come from MD referrals, but patients can also be educated to recognize the signs and symptoms and self refer
 - Controls who are 1st degree blood relatives of people with PD (siblings, parents and kids)
 - CHANNEL = Media story on the need for these people; likely not going to PD support groups since spouses don't qualify



Filling the funnel: Identify agents

- **Determine who the "agents" are**
 - Who will I need to build relationships with to get to these people?
 - What relationships exist? What new relationships need to be built?
 - Key agents:
 - Clinic colleagues
 - Colleagues in another clinic at the same site
 - Community physician colleagues
 - Internal media team
 - Support group leaders
 - Local and national disease advocacy organizations



Filling the funnel: Develop plan to equip agents and reach targets

- **Figure out how to get buy in and equip agents to help recruit**
 - Make a plan to provide patients with information about the study
 - Develop more than just a study flyer– slides, education article, newsletter blurbs are also useful.
 - Make a plan for cultivating key agents to support the study
 - Develop a toolkit of materials for key agents-- tee things up for them to share information about the study
 - If well planned, agents can do much of the funnel filling for a study
 - Examples:
 - Patient's self identifying for hypotension study
 - Created "education to action step" handout that explains the condition, talks about signs and symptoms and provides information about the study
 - Media story for 1st degree relative's to be controls
 - Deployed a media agency to work with each site's media team; Created Press release template, study fact sheet



Other strategies to optimize sites for recruitment for all trials

- **At the Site**
 - Leverage colleagues in the same clinic
 - Share digestible information across a practice (this is your target definition) + develop systems within a site clinic to get referrals from all physicians in the clinic
 - Share study information and materials with other clinics who are seeing these patients
 - Partner with satellite and affiliated clinics– gets around issue of poaching
- **In the Community**
 - Patient/community champions are great ambassadors– encourage sites to partner with them on trial recruitment
 - Physician referral networks
 - This is an activity that takes significant time and resources– the start of a study is not the time to start this.
 - Sites that have these networks should be funded to cultivate them further
 - Study dinner to discuss study, continued outreach out to post them on progress, thanks for referrals, share patient progress and data back to maintain rapport



I'm done now that I have identified good leads ...FALSE!

I'm concerned about a study procedure

I may get placebo

Tons of Leads

Tons of Leads

Tons of Leads!

I don't understand the science

What am I going to get out of this?

Goal: Enroll Subjects

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Objective #2: Converting Qualified Leads

Overview of why the research is important

Rationale for seeking someone like them

**(only after you have completed the first two)
Explain the study and answer Q's**

Goal: Enroll Subjects

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Converting Leads: Scientific background and rationale

- Overview of the science and why the study they are about to hear about is important
 - DO NOT SKIP THIS STEP! This macro view of why you are initiating the conversation is typically the single more important motivation for someone being interested.
 - Explain the science behind the study
 - We often assume that patients aren't sophisticated enough to understand, but they are increasingly advanced in their knowledge of their disease
 - Patients also *want* to understand.
 - Take the time to convey the rationale for the study, what the results could mean and how the scientific enterprise goes about finding those results
- Educational materials to support this should be included in the site toolkit. Examples include:
 - Handout on the connection between cognition and PD
 - White paper on Biomarkers and progress to date in PD



Converting Leads: Why we need you specifically

- Rationale for seeking someone like them
 - DO NOT SKIP THIS STEP! Everyone wants to feel important and needed
 - Tell a potential subject why the study needs someone at their stage of disease or on their meds is needed
 - Explain how I/E criteria work and the rationale for the specific criteria for this study
- Additional materials to support this may be valuable in the site toolkit. Examples include:
 - Article on Controls volunteers and why studying 1st degree relatives of patients is valuable and important



Converting Leads: What is involved in participating

- Explain the study and answer questions
 - Only after you have completed the overview of the research and why you need them, introduce the study
 - Explain each test and assessment and identify why it is included in the study and what it could tell us
 - Ex. LP discussion should be introduced by the PI (or another MD) or should be followed up immediately by a call from the doctor to discuss it further – make the time for this; Can follow up LP discussion by sending them home with more info
 - In addition to core study recruitment materials, develop additional toolkit materials if there are going to be patient concerns about a drug with significant side effects or a procedure that is quite invasive
 - Talking points for sites to address these head on
 - Handouts for a potential subject to take home, share with their doctor, etc. as they decide if they want to participate
 - Examples include:
 - Article detailing the risks for gout as a side effect from Pioglitazone
 - Lumbar puncture talking points and a patient handout that outline FAQ's



Role the sponsor/CRO can play in recruitment during a study

- Measures what matters (consents and enrollments) and be transparent that you are measuring it
 - Motivate sites to consent more by issuing monthly recruitment challenges to get a stretch number of subjects consented at each site
 - Share mid-month how sites are performing on the challenge
 - Celebrate sites (individually and among all sites) that are top performers; copy the entire steering committee for effect
- Hold one-on-one site check in calls with sites that are lagging early and on an ongoing basis
 - Set an expectation up front that all sites will be required to have these calls– meant to bolster recruitment, not be a punishment
 - Use recruitment committee members as “good cops” to check in and help peer sites brainstorm on new ideas– best recommendation is to go back and revisit the study recruitment plan
- Require PI's to be involved in recruitment discussions as much as possible– patients want to hear from the doctor and the best sites have PI's who view recruitment as their role



Resources

- MJFF Clinical Trial Recruitment Toolkit
 - Best Practices Manual: michaeljfox.org/recruitmentbestpractices
 - Handouts: <https://www.michaeljfox.org/research/trial.html#worksheets>
 - Biomarkers white paper, FAQ's about tricky procedures, value of controls in trials
- Fox Trial Finder www.foxtrialfinder.org

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INFO FOR VOLUNTEERS | INFO FOR TRIAL TEAMS | ABOUT FOX TRIAL FINDER | FAQ | GO TO FOX TRIAL FINDER

TODAY 15,000. TOMORROW A CURE.

WHY ARE CLINICAL TRIALS IMPORTANT?

- Clinical trial recruitment is a challenge across all diseases, and Parkinson's disease is no exception. This special set of documents has been created to help you and your team of busy health care staff to recruit-participants. Despite a willingness to participate, less than 10 percent of PD patients have opted to take. Find out why the obstacles exist for recruitment in clinical research, and it means longer time to access to treatment and diagnosis.
- With an estimated 1 million people living with Parkinson's in the U.S. alone, the PD community is generally more likely to volunteer than other chronic conditions. Fox Trial Finder is one solution to help identify and reach these great volunteers to research by creating a space to help them that are right for them.

FIND A TRIAL

I have Parkinson's
 I am not Parkinson's
 I am interested in research for a group

I am located in:

United States | Postal Code:

My birthday is:

or

FROM MICHAEL J. FOX

TRIAL TEAMS

Do you need volunteers for your trial or study? Find them with Fox Trial Finder!

JOIN THE 15,136 CLINICAL TRIAL VOLUNTEERS WHO HAVE ALREADY STEPPED UP.

