

Innovative Approaches to Recruitment and Retention

Sharing Best Practices to Support Trial Teams and Study Sites

September 30, 2013

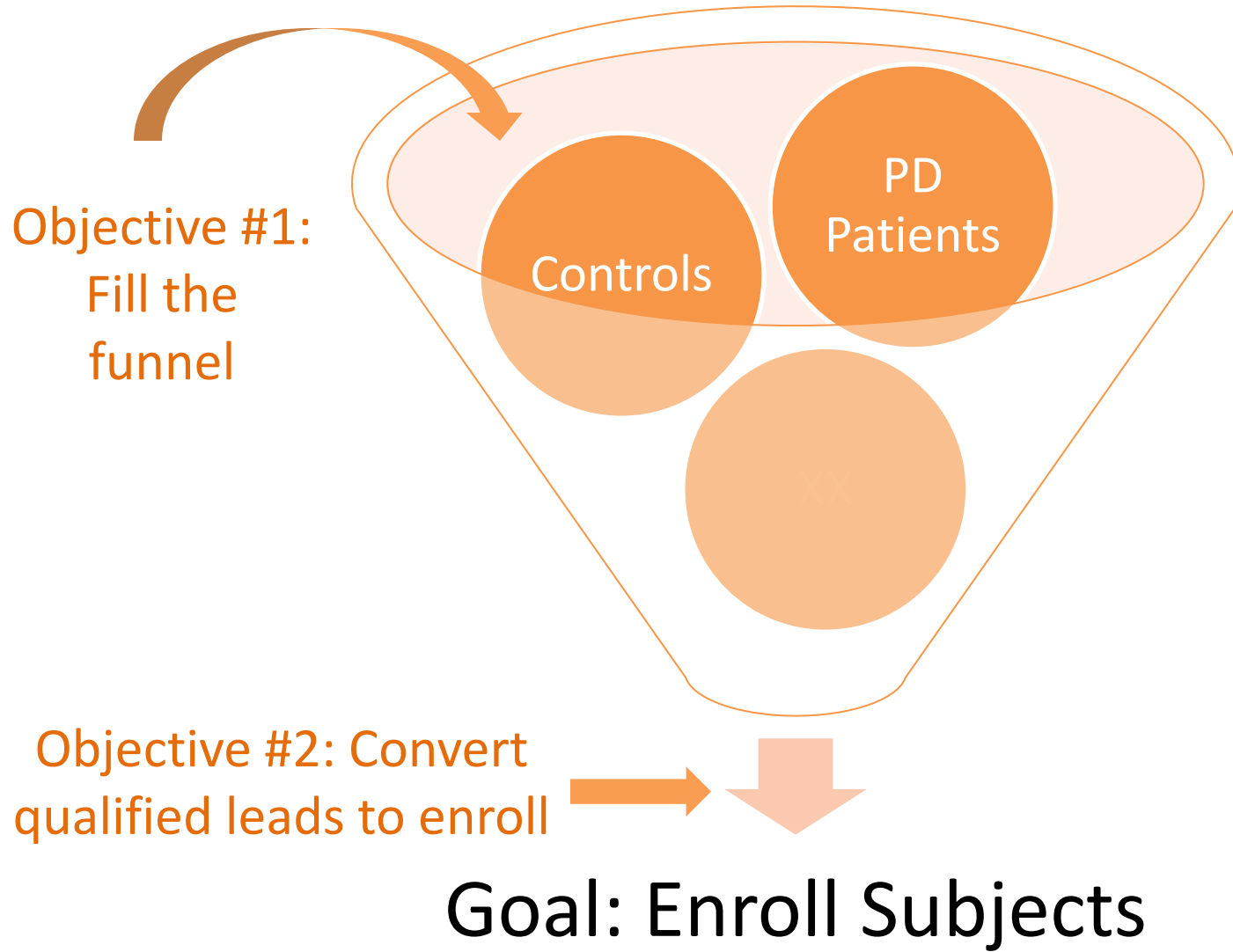
Claire Meunier, Director, Research Partnerships

The Michael J. Fox Foundation for Parkinson's Research

MJFF's focus on clinical trial recruitment

- Support recruitment and retention as sponsor of the Parkinson's Progression Marker's Initiative (PPMI)
- Serve as consultants for all MJFF funded clinical trials and studies
 - Develop a tailored recruitment plan at the outset to guide recruitment strategy
 - Conduct recruitment check-ins at key milestones in every grant; partner with awardees to develop recruitment rescue strategies as needed
 - Incorporate subject travel and accommodation funding into clinical grants
- Manage Fox Trial Finder, a clinical trial matching tool that enables multi-site trials to recruit volunteers with de-identified profiles through a two way messaging system
 - Over 22,000 PD and control participants are registered to date
 - Preliminary analyses suggest that 11% of registered volunteers have participated in a trial as a result of being on FTF

Our Approach to Recruitment



What we have achieved: Resources at your disposal

- Centralized bank of expertise on historical trial recruitment experiences and clearing house for recruitment materials
 - Guide to Recruitment Planning
 - Recruitment Best Practices Manual
 - FAQ Patient Handouts: LPs, Biomarkers, Value of Controls, Imaging
(Available at <https://www.michaeljfox.org/research/trial.html>)
- Specific experience in funnel filling and conversion activities:
 - Communicating with potential subjects about daunting procedures (i.e. Lumbar Punctures, risk of side effects, etc)
 - Equipping sites with talking points and training to recruit
 - Developing a centralized suite of materials to support funnel filling and conversion
 - Establishing study infrastructure to support trial recruitment
- Massive outreach campaign to patient community to raise awareness about need for trial participants, to educate about what it means to enroll in a trial and to share Fox Trial Finder
 - Presentations and tables at local PD events
 - Clinical Trials Fairs in cities with multiple trial sites
 - MJFF communications– emails, blog, newsletter, etc

Opportunities for Sites

- Spearhead making sure your practice is integrating your research mission
 - How are patients welcomed?
 - New patient packet– mention research mission
 - In your clinic wait room– prime opportunity to educate about trials broadly and specific opportunities underway at your site
 - How is everyone in your clinic updated on all trials that are underway?
 - Identify the best time and place to share this info with everyone regularly
 - Develop aids to keep this top of mind– grid of trials in every patient room
 - Central email address for people to refer their qualified patients to
 - How is everyone sharing all of the trials that are underway?
 - Slide that goes at the end of every patient presentation that has an updated list of studies
- Recruitment plan for every study individually
 - Determine efficient opportunities to go beyond a ‘one-size-fits-all’ approach to develop a custom recruitment plan– PD ambassadors, media, etc.
- Join a study Recruitment and Retention committee
 - Expertise of PIs and Coordinators is critical to ensure a thorough plan and that sites get the support they need

Opportunities for sites (continued)

- Develop a MD referral network
 - This is an activity that takes significant time, resources and buy-in
 - Make sure that everyone is coordinated about how this is going to work– one mishap can ruin a relationship
 - Waiting until a study that needs referrals starts is already too late
 - Tips:
 - Start with a kickoff event– opportunity to introduce what you are trying to do and answer questions
 - Develop systems and processes for communication about what studies are recruiting and who you need for them
 - Leverage affiliated clinics– already loyal to your system and no fear of poaching; likely to reap rewards sooner
 - Feed information back to physicians about their patient’s participation and how the research is going
 - Quality over quantity-- It only takes a few referring physicians to make this worth the investment
- As a PI of an entire study, be proactive about recruitment planning
 - Integrate funding for recruitment materials and activities into your planning (include subject travel and accommodation)
 - Appoint a Recruitment and Retention committee earlier than you think

Study Retention

- The primary thing that subjects want is to know that their data is being put to good use and what you are learning from their participation
 - You know a lot about the science of PD and the focus of a specific trial -- study subjects are very interested in learning more from you
 - Even if there isn't breaking news to report, give them an update on where things stand
- Opportunities to share this information with study volunteers
 - Study newsletter
 - Retention events
 - Final outcome report in writing and/or call format

MJFF Coordinators Community focused on trial recruitment

- Observations from experiences to date
 - Coordinators are the lynchpin that holds the site together– site success is dictated by you!
 - Successes/failures at one site in a study aren't systematically shared across a study; Successes/failures in one study aren't recorded and mined for future studies
 - Key central support (i.e. recruitment planning, materials development, outreach/partnerships, etc) enables coordinators to be more effective on the ground
- Plan for 2014– create something
 - There is a prime opportunity to develop a community – opportunity to share lessons learned, pool resources, discuss strategic recruitment planning, and build cutting edge model here
 - Key questions:
 - What is the best format? Online, calls, in person
 - What resources, collaborations and conversation are needed?
 - » Materials toolkits
 - » Bringing new coordinators into the fold on PD recruitment
 - » Sharing of best practices and lessons learned
 - » Others?

Appendix

- Recruitment Planning Guide
- FTF Overview

Recruitment planning guide

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

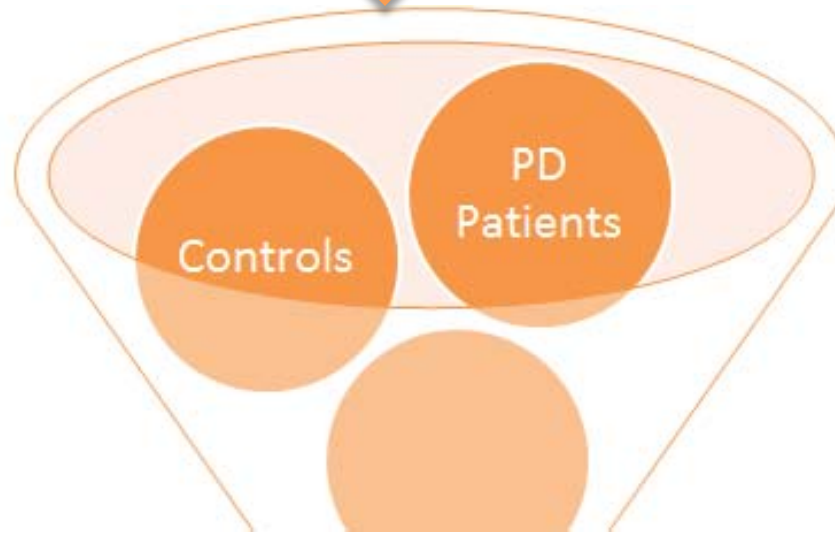
Objective #1: Fill the Funnel

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

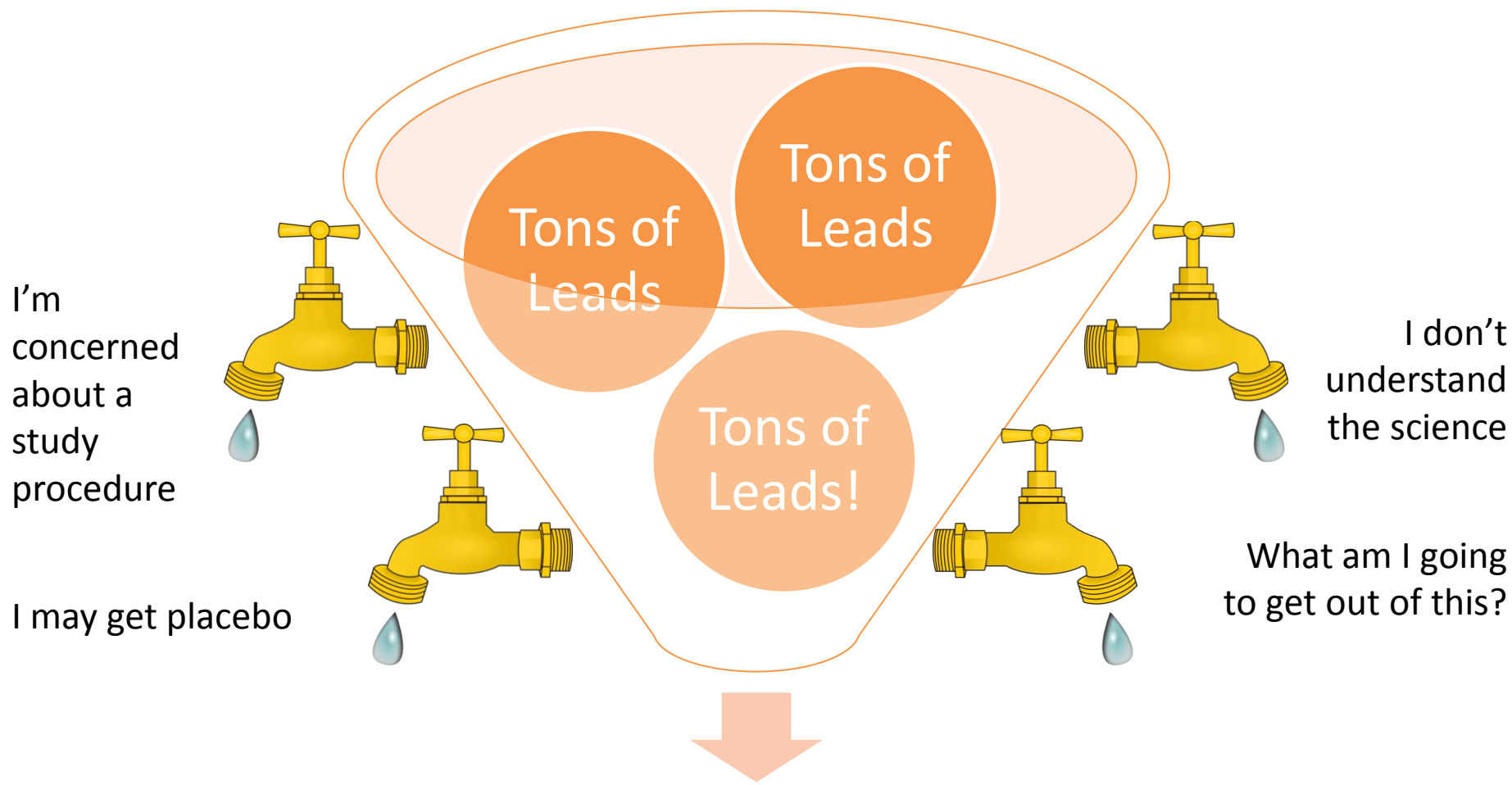
- **Figure out how to get buy in and equip agents to help recruit**
 - Make a plan to provide patients with information about the study
 - Develop more than just a study flyer– slides, education article, newsletter blurbs are also useful.
 - Make a plan for cultivating key agents to support the study
 - 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!



Goal: Enroll Subjects

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

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



Accelerating Clinical Trial Recruitment

Lily Cappelletti, Associate Director, Research Partnerships
Michael J. Fox Foundation



Our focus on clinical trial recruitment

- Under-enrollment slows the progress toward breakthroughs and deters investment in Parkinson's research; this delays new and promising treatments in reaching pharmacy shelves.
- 85 % of all clinical trials face delays and 30% never get off the ground due to a lack of volunteers
- 80% of PD patients surveyed by MJFF are at least somewhat likely to participate in research, yet less than 10% have participated in a clinical trial

Our Objective: Mitigate barriers to recruitment

- Provide trial coordinators with an efficient way to connect with potential subjects
- Provide PD patients and control volunteers with a mechanism for identifying clinical trial opportunities on an ongoing basis

Fox Trial Finder: A Clinical Trial Matching Tool

INFO FOR VOLUNTEERS

INFO FOR TRIAL TEAMS

ABOUT FOX TRIAL FINDER

FIND TRIALS

MY FOX TRIAL FINDER



FIND A TRIAL

- I have Parkinson's or am registering for someone who does
- I do not have Parkinson's but would like to volunteer for a trial

I am located in

United States

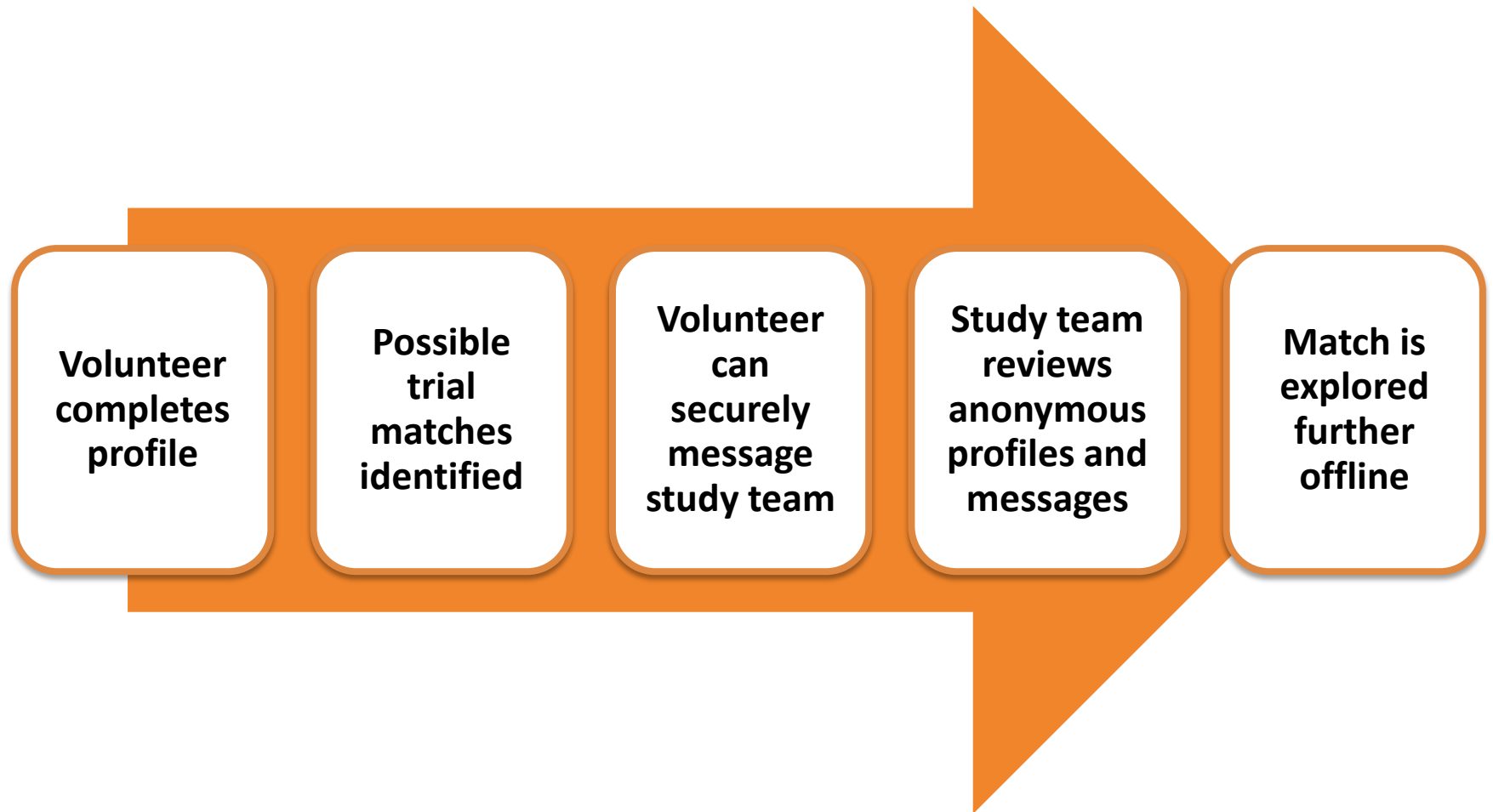
My birthday is

Month

[GET STARTED](#) or see [Quick Search](#) results



Clinical Trial Matching: How it works



Exploring the Match Process: Suggested matches

The screenshot shows the FOX TRIAL FINDER website interface. At the top, the logo reads "FOX TRIAL FINDER" with the tagline "THE MICHAEL J. FOX FOUNDATION FOR PARKINSON'S RESEARCH". A navigation bar includes links for "INFO FOR VOLUNTEERS", "INFO FOR TRIAL TEAMS", "ABOUT FOX TRIAL FINDER", "FIND TRIALS", and "MY FOX TRIAL FINDER". The user is logged in as "Laura" and has 41 suggested matches. A sidebar on the left contains navigation options like "My Matches", "Interested", "Not Interested", "My Messages", and "My Profile". The main content area displays three suggested matches, each with details such as study type, focus, sponsor, and location, along with an "Are You Interested?" section with buttons for "Interested", "Not Interested", and "Contact Trial Team".

FOX TRIAL FINDER
THE MICHAEL J. FOX FOUNDATION FOR PARKINSON'S RESEARCH

HELLO, LAURA. (LOG OUT)
SHARE: [Email] [Facebook] [Twitter]

INFO FOR VOLUNTEERS | INFO FOR TRIAL TEAMS | ABOUT FOX TRIAL FINDER | **FIND TRIALS** | MY FOX TRIAL FINDER

HOME > MY FOX TRIAL FINDER > MY MATCHES

MY FOX TRIAL FINDER

Laura's Dashboard

MY FOX TRIAL FINDER

- My Matches
- Interested
- Not Interested
- My Messages (0)
- My Profile

MY MATCHES

You have 41 Suggested Matches

Hello, Laura. Take a look at the matches Fox Trial Finder identified for you.

SUGGESTED MATCHES

Fox Trial Finder has suggested these matches for you based on your [volunteer profile](#).

PD/Ashkenazi Jews and LRRK2 Consortium

Study: Observational
Type:
Study: Anxiety, Biomarkers, Bradykinesia (slowness of movement),....
Focus:
Sponsor: The Michael J. Fox Foundation
Closest: New York, NY US (RECRUITING)
Location:

Are You Interested?

- Interested
- Not Interested
- Contact Trial Team

Share this trial:
[Email] [Facebook] [Twitter]

Psychiatric and Cognitive Manifestations of Parkinson's Disease

Study: Observational
Type:
Study: Anxiety, Cognitive Deficits, Depression, Fatigue, Impulse....
Focus:
Sponsor: NYU School of Medicine
Closest: New York, NY US (RECRUITING)
Location:

Are You Interested?

- Interested
- Not Interested
- Contact Trial Team

Share this trial:
[Email] [Facebook] [Twitter]

Recruitment for skin sample donations for stem cell research

Study: Observational
Type:
Study: Biomarkers, Genetics

Are You Interested?

- Interested
- Not Interested

Volunteers can review their suggested matches and can review trials in more detail by clicking on the name of the trial

Exploring the Match Process: Trial Details

The screenshot shows the FOX TRIAL FINDER website interface. At the top, there is a navigation bar with links for 'INFO FOR VOLUNTEERS', 'INFO FOR TRIAL TEAMS', 'ABOUT FOX TRIAL FINDER', 'FIND TRIALS', and 'MY FOX TRIAL FINDER'. Below this is a search bar and a 'FIND TRIALS' button. The main content area displays the title 'Magnetic Resonance Imaging (MRI) of Neuropsychiatric Patients and Healthy Volunteers' and a brief description. A 'Purpose' section explains the study's goal to compare brain imaging technology. A 'Detailed Description' section provides more context on the protocol. A 'Key Information' table lists the study type as 'Observational' and provides the study focus and website URL. On the right side, there is a 'Are You Interested?' section with radio buttons for 'Interested', 'Not Interested', and 'Contact Trial Team'. Below that is an 'ATTENTION TRIAL TEAMS' section with a 'Contact us' link. Further down, there is a box with trial details: Trial ID: 000627, Status: Recruiting, Phase: Observational, and Lead Sponsor: Michael J. Fox Foundation for Parkinson's Research.

TRIAL DETAILS

If you are interested in this trial or have questions, connect with the trial team! If the trial team is registered on Fox Trial Finder, click "Contact Trial Team" to send them a message. Otherwise, scroll down the page and click on any trial location below to see available contact information for that trial site.

Magnetic Resonance Imaging (MRI) of Neuropsychiatric Patients and Healthy Volunteers

Structural and Functional Imaging of Neuropsychiatric Patients and Normal Volunteers With 3.0 Tesla MRI and Magnetoencephalography

Purpose:

The purpose of this study is to use brain imaging technology to compare differences in brain structure, chemistry, and functioning in individuals with brain and mental disorders compared to healthy volunteers. Schizophrenia is a brain disorder that results from subtle changes and abnormalities in neurons. These deficits likely occur in localized regions of the brain and may result in widespread, devastating consequences. The neuronal abnormalities are believed to result from a complex combination of genetic and environmental factors. Brain imaging technologies can be used to better characterize brain changes in individuals with schizophrenia. This study will use magnetic resonance imaging (MRI) scans to identify predictable, quantifiable abnormalities in neurophysiology, neurochemistry, and neuroanatomy that characterize schizophrenia and other neurological and neuropsychiatric disorders.

Detailed Description

This protocol is meant to provide a matrix for multiple, simultaneous brain imaging investigations using magnetic resonance imaging (MRI) at 3.0 Tesla (3T). We intend to study regional brain structure, physiology, and biochemistry in living human subjects, both healthy and ill. Based on multiple clinical, neuropathological, and functional neuroimaging studies, it is clear that schizophrenia is a brain disorder arising from subtle neuronal deficits (for lack of more specific terminology). These deficits likely arise

Key Information

Study Type:	Observational
Study Focus:	
Study Website:	clinicalstudies.info.nih.gov/cgi/detail.cgi?A_2006-01-0085.html

Are You Interested?

Interested

Not Interested

Contact Trial Team

ATTENTION TRIAL TEAMS
Is this your trial? [Contact us.](#)

Trial ID: 000627
Status: Recruiting
Phase: Observational

Lead Sponsor:
Michael J. Fox Foundation for Parkinson's Research
Sponsor Type:
Other
Collaborators:
Institute for Neurodegenerative Disorders

- Trial details provide in depth information about the trial including:
 - Purpose,
 - Description
 - Locations
 - Recruitment Information
 - Inclusion and Exclusion Criteria

Taking Action: Mark interested or send a message

- Indicate interest
- Send a message to trial teams
- Name, email and all identifying information will be provided by

Are You Interested?

- Interested
- Not Interested
- Contact Trial Team

TEERS INFO FOR TRIAL TEAMS ABOUT FOX TRIAL FINDER FIND TRIALS MY FOX

TRIALS TRIAL DETAILS

MESSAGE TO TRIAL COORDINATOR

- Select a Location -

Subject:

Message:

Are You Interested?

- Interested
- Not Interested
- Contact Trial T

ATTENTION TRI
Is this your trial? (

carefully to see if this

gation of


on's Disease (COMBEN-17)

omised, Double-blind, Placebo-controlled Study to Investigate the Efficacy, Safety and

PYM50028 in Subjects With Early-stage Parkinson's Disease Administered Once Daily for

Trial Team View of De-identified Profile

Volunteer 01109

 Send a Message

Age: 38
Gender: Female
Location: New York, NY
ZIP Code: 10019
Travel Distance: 300 Miles
Second Address: N/A
Second ZIP: N/A
Race / Ethnicity: White or Caucasian

SYMPTOMS

Motor Symptoms: Resting Tremor
Non-Motor Symptoms: Depression
Time Since Diagnosis: 8 Months
Time Since Symptoms Began: 19 Months
Describes Disease Progression as: Experiencing PD symptoms on one side of the body.


TREATMENT & MEDICATION

PD Medications Currently Taken: N/A
PD Medications Taken in Past: N/A
Side Effects: N/A
Surgical Treatments: N/A
Supplements Currently Taken: Vitamin C
Supplements Taken in Past: N/A
Time Since Started Medication: N/A
Experiences Symptom Fluctuations: N/A

HEALTH

Family Members with PD: Father
Known Genetic Mutations for PD: PARK8/LRRK2 or dardarin
Has Participated in Trials: N/A

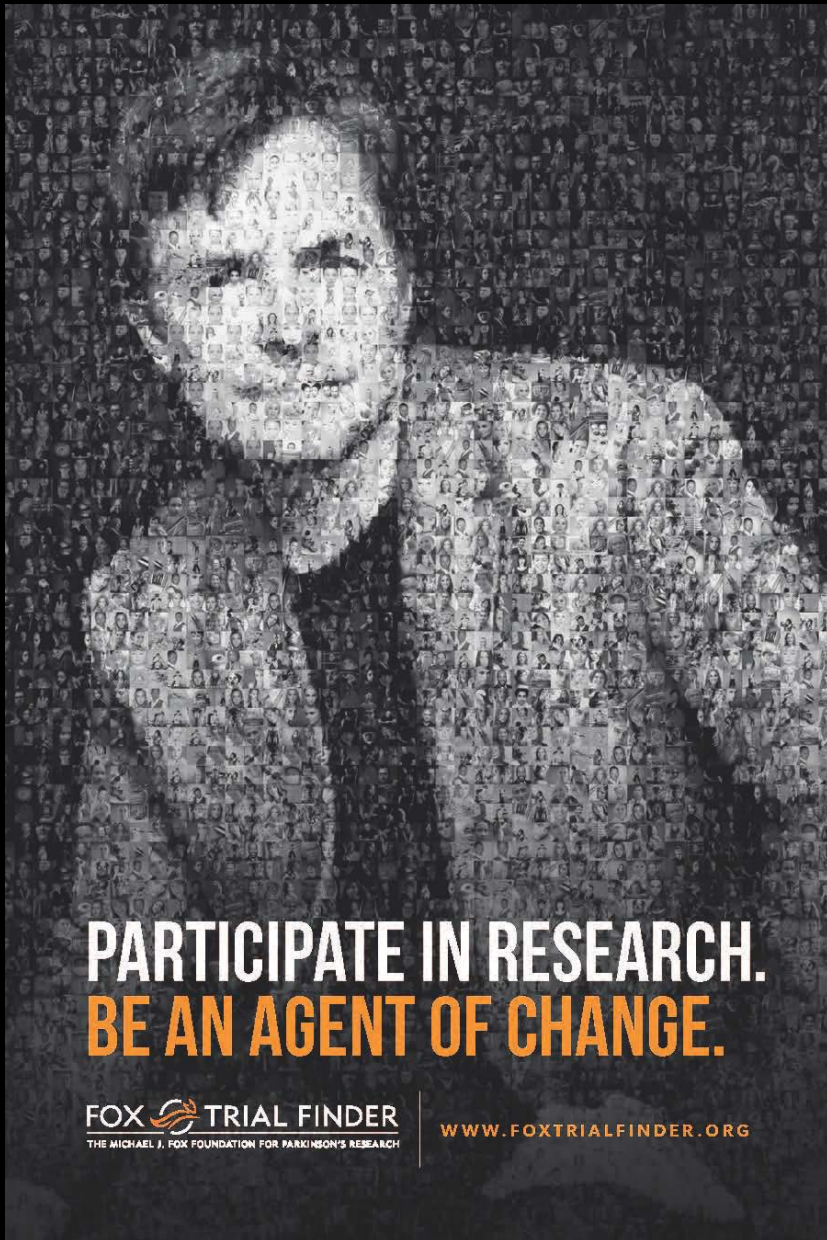
Profile Last Updated: 8/17/2011

 Send a Message

- Trial teams view volunteer profiles
- A trial team member will never see your personal information unless you provide it

Impact to date

- 22,000+ registered clinical trial volunteers currently matching to 300+ PD trials across the US, Canada, UK, Ireland and Australia
- 300+ PD researchers using the tool for recruitment
- Of those volunteers who have reported their actions:
 - 12% have enrolled in a clinical trial
 - 16% have visited a trial site in-person
 - 33% have inquired about a trial either via phone or FTF messaging



**PARTICIPATE IN RESEARCH.
BE AN AGENT OF CHANGE.**

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WWW.FOXTRIALFINDER.ORG