

Improving patient participation in Parkinson's clinical trials: the experience of the Michael J Fox Foundation

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Timely and efficient clinical trial recruitment is a chronic problem across diseases. The Michael J Fox Foundation for Parkinson's Research (MJFF) is a leading funder and sponsor of Parkinson's disease research. Solving recruitment challenges in Parkinson's disease is a priority for the MJFF and led to the development of an online tool – Fox Trial Finder – that connects participants to trials. As the sponsor of the Parkinson's Progression Markers Initiative, an observational biomarkers study, the MJFF developed first-hand expertise in recruitment planning and tactical implementation. Solving poor enrollment relies on all stakeholders involved – sponsors, funders, site personnel and patients – to work together to raise awareness of the problem and implement strategies to increase the number of people who participate in research.

Keywords: clinical trials • enrollment • Fox Trial Finder • Parkinson's disease
• Parkinson's Progression Markers Initiative • recruitment

Parkinson's disease (PD), the second most common neurodegenerative disease in the world, is characterized by progressive motor symptoms marked by slowness of movement, gait problems, rigidity and tremors. Significant non-motor symptoms such as cognitive problems, depression, sleep disorders, digestive problems among others are also important aspects of the disease. The disease etiology, believed to result from a combination of genetic and environmental factors, is probably as complex as the diverse symptomology. In fact, PD occurs with a broad spectrum – early onset versus late onset, slow versus fast progression, motor predominant versus more widespread symptoms. No two people with Parkinson's seem to have exactly the same disease.

Despite this complexity, the understanding of the underlying biology of the disease is increasing dramatically. New genetic findings have uncovered completely novel therapeutic targets and opened the opportunity to develop treatments that could address the specific cause of the disease, slowing progression and even preventing onset [1]. Therapies against these new targets are rapidly moving through the drug development pipeline and beginning to enter clinical testing.

It is in this context that the role of the PD patient becomes even more critical. It is only people with PD and their loved ones who can help us decipher the complexity of the disease phenotype and determine what aspects have the greatest impact on quality of life and the ability to function with the disease. Only through the involvement of people with Parkinson's will we be able to execute optimal clinical trial designs and ascertain conclusive trial end points to efficiently and accurately test the novel treatments that are in development. However, as numerous researchers point out, poor recruitment is a chronic problem faced in clinical research leading to scientific challenges of underpowered studies and economic consequences of increased trial costs as the duration of a study is prolonged to meet enrollment targets [2,3].

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In this review, we will discuss the challenge of participant recruitment in PD clinical studies, the important role both physicians, clinical site staff as well as patients and their families play and, through a case study, discuss existing initiatives that attempt to accelerate recruitment in PD clinical studies. Our suggestions and recommendations are informed by the first-hand experience the Foundation had in supporting recruitment efforts for one specific clinical study as well as outreach and engagement efforts that the The Michael J. Fox Foundation for Parkinson's Research (MJFF) pursued to raise broad awareness of the role patients and supporters can play in PD clinical research.

Dissecting the problem: why is there poor participation in clinical trials?

The reasons for poor participation in trials vary, but a critical factor in improving trial participation is initiating patient awareness and maintaining their interest in clinical trials. Encouraging and building sustained interest results from ongoing activity in three areas: awareness building, education and creating easily actionable next steps.

Much has been written about the phenomenon known as 'Lasagna's Law', namely the overestimation by clinical researchers of available participants in the early phase of trial planning [2]. However, this assumption can also be applied to trial volunteers who may assume they are not needed for research unless specifically asked. The possibility of being a trial participant will only suggest itself to an individual if that individual is aware that trials are occurring and are seeking volunteers [4]. Widespread awareness about the critical need for research volunteers is a necessary first step toward addressing poor trial participation.

Lack of awareness of the need for trial volunteers may stem from the fact that clinical trials are not part of the standard dialogue between a patient and treating physician. If the treating physician is not also conducting clinical research, the likelihood that they will even bring up the option of trial participation with a patient is much less [5]. Ensuring that this topic is integrated into standard patient care is critical in communicating the need for trial volunteers. Moreover, the option of trial participation needs to be part of the dialogue a patient has with all groups connected to their disease, such as disease advocacy organizations, health associations, physical therapists, and so forth. Trial participation also involves discussions the patient must have with his/her family. Often family will play a crucial role in supporting and enabling a patient to participate in a trial. The education and awareness that is described below is also as applicable to a patient's family as it is to a patient.

While raising trial participation awareness is an important first step, the patient community also needs access to information about what it means to participate in research, including explanations on the trial process, different types of trials, the informed consent process and regulatory and patient protections that govern research [6]. This education must also include demystifying key myths that are long held beliefs, often deeply ingrained in the lay community. An informal survey conducted in 2012 by MJFF of 832 PD patients highlighted some of the misperceptions that exist among the population. In total, 46% stated they believed it was true that 'Patients in clinical trials are guinea pigs'; 32% believed that participating in a trial meant exposure to experiments they did not agree to and 33% believed that participation in a trial would interfere with their usual care. These misconceptions must be addressed to diminish some of the perceived barriers to participation.

As the targeted patient population understands the role it can play in advancing research through trial participation and gains increased understating of how trials operate and the rules governing patient safety and privacy, it is critical to be able to easily communicate information about recruiting trials that seek volunteers. One can 'prime' a patient fully, but unless that patient is able to identify what trials are underway, determine if a participating site is located nearby and know how to contact a trial site, awareness and education will have a limited impact on trial recruitment rates. Moreover, it is critical that information about a trial be provided in a clear and concise manner; it is unlikely a patient will consider trial participation if they cannot understand its goal and the participation parameters [7]. Therefore, awareness building and education outreach/campaigns need to include a clear and easy 'next step' a patient can take once a decision has been made to participate in research.

While much needs to occur on the patient-facing side of trial recruitment, there are challenges that need to be addressed on the trial site side that can positively impact trial recruitment. At a basic level, sites need to be proactive in addressing patient concerns in an appropriate manner. Minimizing the effort involved in participating in research, creating a welcoming environment and establishing a rapport with patients are critical factors in 'converting' trial inquiries into trial participants [8]. And while the topic of retention is not the topic of this paper, it is important to note that retention techniques need to be built into recruitment strategies. Often the relationships established between trial personnel and trial participants in the recruitment phase can directly affect eventual trial attrition [7].

The use of the leaky pipe metaphor is a common one in describing the potential participant pipeline [4].

However, the metaphor has its use in highlighting the role a site can play in supporting increased trial participation as well. If one assumes that awareness and education has primed a pipeline of interested trial volunteers, sites need to identify the 'leaks', that is, why and where a potential participant will opt out of the enrollment process. Creating a welcoming environment for potential trial participants is a step a site can take in plugging the first leak. However, attention must also focus on addressing those issues related to the logistics and activities of a trial that could be valid reasons a prospective participant may decline participation. Factors such as transportation, time required for participation and reimbursement are valid and real concerns for potential trial volunteers. Ensuring that trials have adequate budget support to provide parking or transportation service, have flexible operating hours and can provide some reimbursement for patient time are simple fixes to these types of 'leaks'. Everyone recognizes the financial and scientific cost of a trial delayed by poor recruitment – if we wish to find ways to encourage patient participation in trials, mandating that trial budgets should always include funds to support travel and patient participation may be an upfront investment that can help avoid down-the-road costs of adding more sites or prolonging the enrollment period when a trial does not meet its targets.

Clearly informing, and when necessary, correcting assumptions about trial parameters – receiving a placebo, trial safety, perception of painful tests or treatments – need to be proactively addressed. Sites must recognize that differences in the target population and trial parameters may require new ways to recruit for and inform potential participants about a trial. Adopting a standard approach to all trials and not identifying the specific (and often different) potential leaks in each trial participant pipeline means that sites will be ill-prepared to plug leaks when they occur.

Patient- or participant-centric research initiatives is becoming a more frequently used term. It is critical that trial sites recognize that the research participant is an equal partner in the research process and that trial protocol and logistic parameters take into account the needs of the patient population [9]. Specifically during the consent process, thought ought to be given to how to best explain the goals of the research project, the unique role the qualified volunteer can play as well as a fair presentation of the risks/benefits of participation. Many of the suggestions above touch on aspects covered and discussed during the consent process. Providing support and guidance to site personnel on how to share this information in a noncoercive, easily understandable way can really help transform a 'participant' into a 'partner' in research. Codifying basic best practices, such as routinely informing trial participants of trial results and

findings, can help promote a positive experience for a trial participant and increase the likelihood that she/he will share that positive experience with other patients and participate in future trials [7].

Tackling poor trial participation

■ Addressing the patient side: awareness, education & next steps

MJFF, founded in 2000, is a public charity that funds medical research to develop new and improved therapies for Parkinson's patients. As a funder and sometime sponsor of clinical trials, MJFF has experienced firsthand the effects of poor trial recruitment, including increased research costs and methodological challenges related to a smaller than expected sample size [8]. Most significantly, slow and incomplete recruitment delays our ability to develop the novel therapies that patients and their loved ones desire.

Beginning in 2010, MJFF decided to prioritize outreach and education about the role a patient can play in research. While the Foundation has multiple mechanisms to promote the message of trial participation through media, its online presence and its events, a clear action step for those receptive to the message of trial participation was missing. To fill this need, MJFF created Fox Trial Finder, an online clinical trial matching tool. Fox Trial Finder connects interested trial volunteers with the trial teams that urgently need them and is the most comprehensive database of recruiting PD clinical research. Volunteers are notified of new matches as new trials are added. Trial teams can access a growing list of individuals interested in participating in trials. The site allows volunteers and study personnel to exchange messages and learn more about each other to further pursue enrollment offline. Fox Trial Finder is currently available in English, French, German, Italian and Spanish with trials posted in the USA, Canada, the UK, Australia, Ireland, Austria, France, Germany, Italy and Spain.

Interested volunteers and trials are matched to one another through the site's proprietary algorithm, purpose-built to generate quality leads. The match algorithm takes into account an individual's location and characteristics of their health and demographic profile and runs these against a trial's inclusion and exclusion criteria. The data points included in the matching algorithm were informed by a comprehensive review of the inclusion and exclusion criteria most common across industry and academic protocols. Volunteer information is self-reported through a registration form and includes data points on age, gender, location, date of diagnosis and disease progression, symptoms, treatment history, and genetics. Trial data are imported from www.clinicaltrials.gov and can also be submitted

directly to Fox Trial Finder by a trial team member. MJFF staff conducts an administrative review of all and require documentation of ethical approval by an ethical review board before a trial is published.

Launched in beta in July 2011 and officially in April 2012, Fox Trial Finder has amassed a database of more than 20,000 interested volunteers (76% PD) and between 400 and 500 actively recruiting trials at any one time. As of June 6 2013, 466,979 matches have been generated between potential participants and recruiting trials and 16,694 messages have been sent between interested potential participants and trial teams. A survey of the database indicated that 38% of respondents have inquired about a specific trial and 11% have enrolled in a clinical trial using Fox Trial Finder. Trial teams using Fox Trial Finder as a recruitment tool report accelerated recruitment timelines. **Tables 1 & 2** provide some demographic information captured on US participants (10,096) who were registered as of 31 July 2013.

From the patient perspective, Fox Trial Finder is an easy ‘one stop shop’ to learn about ongoing Parkinson trials, identify local sites recruiting participants and connect with trial sites. MJFF awareness building and education about the need for trial volunteers includes information on Fox Trial Finder and Fox Trial Finder is suggested as an action item by many stakeholders in the field, whether another PD organization, a physician at a PD research center or a patient group leader.

■ **Addressing the role trial sites play in recruitment**

MJFF defines clinical trial recruitment as a two stage process: funnel filling and conversion. Our experience in supporting recruitment efforts in a large-scale biomarker study – described further in this article – has shown that executing on both fronts can be effective in achieving timely and efficient recruitment. Leveraging the learnings from our experience with supporting recruitment efforts of numerous funded trials, MJFF has developed a clinical trial recruitment strategies team tasked with partnering with sponsored and funded trials to advise and consult on best practices in both areas.

In supporting recruitment efforts, we advise our awardees that discussions on recruitment should occur early – often in the trial design stage – to enable identification of key infrastructure and staffing to support planning and implementation of recruitment strategies

over the course of the recruitment period. Just as a study needs to identify key personnel or departments that are required to run the trial, so must a study identify (and potentially build) the necessary factors required for recruitment. In MJFF’s experience, organizing a recruitment committee comprised of coordinators and Principal Investigators and patients in multicenter studies has been crucial to inform and monitor the recruitment strategy from the outset, brainstorm new tactics and, if necessary, devise a rescue strategy if recruitment is not progressing well. This group can also be tasked to determine recruitment materials that need to be centrally created as well as other outreach mechanisms that may be required to support sites in recruitment. Finally, by monitoring recruitment, this committee can provide a centralized infrastructure – monthly calls – through which identified ‘successes’ can be called out and shared across participating sites.

Incorporating a recruitment committee at the trial design stage is critical; to effectively perform its function, a study will need funds to support recruitment committee teleconferences, the creation of collateral and other tasks associated with outreach plans. Investing upfront and allocating funds specifically earmarked for recruitment, MJFF has found, will result in cost savings down the road if these early investments enable a trial to meet its enrollment target on time.

Once recruitment infrastructure has been established, a site can focus on filling its recruitment funnel and converting ‘leads’ to enrolled trial participants. Funnel filling describes activities related to identifying individuals who are appropriate for screening for a study [4]. Defining who should be referred for screening is an important starting point. MJFF found that distilling a few critical characteristics of the target population in a concise way is critical to helping trial teams remember who they should be targeting. Rather than citing a full list of inclusion/exclusion criteria, keeping things simple and concise better enables investigators and physicians not directly involved in the trial, but who have potential as ‘referral sources’, identify individuals within their respective patient populations who may qualify for the trial.

Once characteristics of the target population are identified, MJFF suggests that the next step should be to focus on mechanisms to connect with the target population. Funnel filling activities may happen within the clinic, through referring physicians, in communities

Table 1. Age, gender and volunteer breakdown of US Fox Trial Finder registrants as of 31 July 2013.

Demographics of US volunteers	Proportion of total registered population (%)	Gender ratio (male/female)	Median age (years)	Median age at diagnosis (years)	Time since diagnosis (years)
Parkinson’s disease	77	61/39	64	59	3.6
Control	23	29/71	48	–	–

related to the disease or through outreach to the entire local population around a site. Given that a large percentage of individuals in the 'funnel' will eventually never enroll in the study, we recommend a multipronged widespread approach to identifying potential participants for a study [2]. Depending on how funnel filling takes place, recruitment materials can be produced centrally and distributed to sites for local recruitment efforts, which we have found to be more cost- and time- efficient rather than having each site tasked with producing its own set of materials.

While funnel filling is often the primary focus of recruitment when a trial commences, we have found that for many trials a focus on conversion can be even more fruitful in delivering enrollments for a study. Conversion describes the process leading to the enrollment of a qualified person who has inquired about a specific trial. Successful conversion is dependent on addressing the concerns and needs of a patient who comes in with limited information about the study. It requires thorough thought about how to convey the goals of the trial and appropriately pacing the distribution of information (including the consent form) so that a potential participant is not overwhelmed. While it may be appropriate in some trials to mail a consent form after a first call from an interested individual, for other trials a cultivation strategy needs to be mapped out to help patients identify with and understand the relevance of the trial in question before they are presented with a lengthy and technical consent form. Educating potential participants on trial goals, for instance, is a step that is often not addressed fully by trial teams; however, in our experience, PD patients want to know new information about the disease and understand cutting-edge research relevant to therapeutic development and/or improved disease understanding. Moreover, clearly explaining why an individual fits the trial parameters conveys a sense that they have been chosen for something; it is human nature to want to feel needed. Finally, clearly communicating what trial participation entails is also a critical step in the conversion process. At each step, whether it is study goals, why an individual fits trial parameters or activities comprising trial participation, materials (including talking points for trial teams) should be developed to provide more details and guide site teams in talking about invasive or daunting procedures. We have found that it can be useful to create a 'straw man' that outlines the pacing and steps to convert a lead, which could be used as a guide by sites.

The greatest source of qualified leads are in the local area surrounding a site; funnel filling and conversion materials should be part of a wider menu of recruitment strategies a site can utilize. Sites have a wealth of knowledge about their patient population and market,

Table 2. Ethnicity of US Fox Trial Finder registrants¹.

Ethnicity of US Volunteers	Proportion of registrants (%)
American Indian or Alaska Native	2
Asian	3
Black or African American	1
Hispanic or Latino	3
Native Hawaiian or other Pacific islander	0
White or Caucasian	91

¹Parkinson's disease & Control – as of 31 July 2013.

and often have unique relationships, experience and resources that can be leveraged for success in thinking of how to fill its funnel and convert leads to enrolled participants. In our experience, value from these assets is best realized when a toolkit exists to support sites in their work and items can be taken 'off-the-shelf' as needed to make their work easier.

■ Case study: the Parkinson's Progression Markers Initiative

MJFF's experience working on the Parkinson's Progression Markers Initiative (PPMI), a trial it funds and sponsors, provides an example of successful funnel filling and lead conversion. PPMI is a 5-year observational study of 400 early-stage *de novo* (unmedicated) PD patients and 200 age- and gender-matched controls to verify and identify progression biomarkers of PD. Enrolled participants – both PD and controls – undergo frequent and extensive study visits, which include extensive clinical assessments, imaging and collection of biosamples. In-person study visits occur over 5 years, with five visits in the first year and two visits ever year thereafter [10].

Early in the design phase of the study, key recruitment challenges were recognized: identifying and enrolling PD patients – just diagnosed and not yet on medication – who would be willing to participate in an observational study; identifying control individuals who would be willing to undergo extensive follow up; convincing participants to perform all assessments at every visit, including lumbar punctures (LP), which would take place three times the first year and once annually thereafter, and enrolling 600 participants at 24 sites over a 2-year period. To address and mitigate these challenges, PPMI leadership set up a recruitment committee comprised of 14 site investigators and coordinators that met on a monthly basis. Information on *de novo* PD and control recruitment best practices and how to discuss LPs with prospective volunteers was collected from participating sites and outside experts to inform the development of recruitment materials, talking points, toolkits and referring physician materials. These efforts were geared toward funnel filling and

helping sites convert leads to enrolled participants. A patient committee was also established to brainstorm and help evaluate recruitment ideas. As Parkinson patients, the Committee's insights on messaging and how to 'pitch' PPMI to their peers was invaluable. They also became informal ambassadors for PPMI; their voices helped raise awareness of the role biomarkers – and PPMI – could play in drug development through critical peer-to-peer education.

While conversion strategies and materials were being finalized, a phased recruitment plan was developed to fill the funnel at sites. Phase I focused on activities that supported the study launch once a site was activated to enroll individuals. This phase included 'salons' at each site whereby the local Parkinson community was invited to learn about the role of biomarkers in PD drug development, hear about the launch of PPMI and understand the impact of the study on Parkinson's research. Although the majority of salon attendees were not eligible for PPMI – most were not newly diagnosed PD patients – it was recognized early on that the PD community could be an extremely effective recruitment resource as 'peer-to-peer' discussion and communication of the study helped spread information. In addition to salons and press announcements about the study launch, sites also focused on identifying leads within their research center through tagging of charts, presentations to colleagues treating PD patients and support group outreach.

Phase II was initiated as lead flow in phase I diminished. Phase II focused on building relationships with local physicians not affiliated with PPMI. Physician salons were organized by MJFF to inform local neurologists about the study and encourage referrals to the participating site. To assist physicians in communicating the study to patients and referring patients to sites, pocket cards with key messages about PPMI, a fax referral template and patient materials were provided to physicians. As individuals were enrolled, media stories were built around those participants who consented to do media and were willing to share their story and explain why they chose to participate in PPMI. These 'PPMI participant ambassador' media stories created new and sustained interest in local communities resulting in additional queries to the site by interested individuals.

Phase III focused on targeting specific populations needed to complete enrollment. For example, male controls aged 56 years or older were needed to match the enrolled PD population. A mailing to veterans was initiated to focus recruitment efforts on older male controls. Out of this mailing, 76 male controls meeting the inclusion/exclusion criteria were identified and seven enrolled in PPMI.

PPMI met its goal and closed recruitment in April 2013. On average, once a site was activated, it fulfilled

its enrollment objectives in 26 months. The average recruitment rate across sites was 1.1 participants enrolled per site per month, with the enrollment range spread between 0.5 and 2.3 participants per site per month. Strong emphasis was placed during initial site training on recognizing the efforts required of an enrolled individual and prioritizing their treatment within the study. While it is difficult to quantify how that approach supported enrollment amidst all the other strategies employed, retention of participants to date has been very strong. With 683 individuals enrolled, as of 23 October 2013 only 21 subjects have withdrawn participation from the study to date, and of the 21, five were due to deaths unrelated to the study.

Although successful in recruiting and retaining subjects, PPMI recruitment was hampered by one issue that is an ongoing challenge when considering participant recruitment: enrollment of minorities. Over 90% of enrolled PPMI subjects are Caucasian. Numerous papers have focused on the challenge of enrolling minorities in clinical research, so we will not delve into the potential reasons behind poor research participation rates, but it is a problem faced in PD as well as in other diseases [6]. Our experience with PPMI recruitment and minority enrollment is that broad tactics cannot be assumed to work for all groups and that a strong emphasis on how recruitment approaches ought to be tailored to be able to effectively communicate and conduct outreach to different communities should be part of every recruitment plan.

Conclusion

MJFF's experience in supporting development and execution of recruitment strategies for PPMI has highlighted lessons that we now apply to and share with other Parkinson's trials and across other diseases. The focus on providing support for conversion helped overcome two challenges often cited as concerns by participating sites at the start of the study: enrolling controls and consenting subjects for a series of LPs. Unsurprisingly, friends and family members of Parkinson patients were key control targets. PPMI messaging to control populations was simple and straightforward; outreach and materials stressed that everyone – whether they had PD or not – could play a role in research and PPMI was an opportunity for people to support their friend/family member with PD by engaging in research. This message seemed to resonate and control enrollment surpassed expectations; mid-way through the recruitment phase, control enrollment was placed on hold for several months as higher rates of control enrollment over PD enrollment created discrepancies in age- and gender-matching across the two groups.

Preventing LPs from becoming the reason why prospective participants decline enrollment was an immediate focus of the study recruitment committee. All materials and outreach efforts highlighted the study goal – identify biomarkers – and connected biomarkers to drug development. Follow-on efforts and discussions with prospective participants first explained why the protocol focused on collecting as much information as possible (including CSF) to find biomarkers. Participants, whether controls or PD patients, were educated about why CSF is so critical for a neurodegenerative disease and clinicians were given support in ‘demystifying’ LPs. Simultaneously, site investigators were given extensive support in communicating with individuals about LPs; talking points and videos were provided to the sites. Perhaps most important though was the monthly teleconference where site teams shared best practices and experiences with one another on the topic of LPs and other issues. These calls served multiple goals: they broke the siloed approach often found in multicenter clinical research whereby a site operates on its own when recruiting participants. The teleconferences made sites realize the shared challenges they were all facing. By the end of the study, these calls became moments of encouragement and inspired a ‘can do’ attitude amongst the sites as increasing reports of successes in converting participants and answering LP questions poured in. As the sponsor, MJFF encouraged the sense that enrollment was ‘doable’ and issued monthly challenges to sites where they were acknowledged publicly for continued success. PPMI closed enrollment in spring 2013 and of the fully enrolled cohort, 98% of all enrolled participants underwent the baseline LP. To date, 93% of all scheduled LPs at study visits have been completed [11].

As other researchers have pointed out, taking a multi-pronged approach over the course of the enrollment phase has the greatest impact and we have seen that approach confirmed in PPMI [3]. At any given time, sites were holding events to inform local physicians of the study to seek referrals from these clinics. Sites also utilized community events and support group meetings to talk about the study, had media highlighting the study either locally or nationally, and went through site databases to identify possible candidates, among other strategies. Through a combination of approaches, general outreach about the study permeated the community in parallel with targeted outreach to specific groups seen as more likely candidates for PPMI. Utilizing multiple approaches also acknowledged that each site had its own approach to recruitment; tailoring recruitment plans to play to a site’s strength seemed to result in steady recruitment over the 2-year enrollment phase.

MJFF’s experience with Fox Trial Finder has also impacted our thinking about recruitment. After just

2 years in existence, over 20,000 people have registered on Fox Trial Finder. The positive reaction of the PD community has reinforced assumptions that patients want to be engaged in research and see themselves as active and equal stakeholders in the clinical research arena. The development of the Clinical Trial Recruitment Community Partners, a community of 18 global, national and regional organizations that serve the PD patient communities, helps support this assertion. The Community Partners are committed to raising awareness of the importance of trial participation and have used Fox Trial Finder as an action step for their outreach efforts.

Being part of the solution is the crux of how MJFF is addressing the challenge of poor trial recruitment in PD. Lessons learned from PPMI and Fox Trial Finder illustrate that every constituent involved in clinical research, from study sponsors, to clinical sites, to disease research/patient advocacy groups to the participants that are being sought for trials have a role to play in the recruitment process. We recognize that our experience with PPMI and Fox Trial Finder will not be wholly applicable to other diseases; rather our experiences provide one approach and set of recommendations for the research community to consider when thinking of clinical trial recruitment strategies. We believe that ongoing research on recruitment approaches and sharing of best practices and lessons learned through the field of Parkinson’s and across diseases will better equip the entire research community in addressing the challenge of efficient and timely research recruitment.

Future perspective

Fox Trial Finder was initially received skeptically by the research community, who felt that its value would be limited because the online nature of the tool would not appeal to an older population. The successful adoption of Fox Trial Finder by the Parkinson’s community refutes that assumption and is a harbinger of the changes that will come to Parkinson trial recruitment over the next decade. A recent survey by the Pew Research Center found that over half of American adults aged 65 or older are using the internet or email. As social media and internet smart phone usage become even further integrated into individuals’ lives, the opportunity to target this population for trial enrollment in greater numbers and with greater cost-savings rises. ‘Tried and true’ recruitment approaches – media stories, advertisements in newspapers and on the radio, and sourcing participants through a clinic’s database – will still be used, but there will be increased opportunity to ‘cast a wider net’ through the use of social media and other online tools yet to be developed. Moreover, novel technologies may enable a greater number of trials to use a virtual model of visits rather than requiring in-person site visits. Telemedicine,

still in its early days, presents a real opportunity to connect with patients who have not traditionally been able to participate in research due to their geography – not being located close to a university research center, where most PD trials take place. Conducting trial visits via the internet and enabling Parkinson’s patients to participate from their home radically changes the pool of participants a trial can draw from and the costs associated with recruitment. No longer is travel a time or cost a burden to trial participation.

Of course, as new technologies are leveraged and applied to trial recruitment, the research and patient community will inevitably need to grapple with new privacy and security issues. However, it will be important to ensure that the dialogue on privacy and security boundaries is a dialogue between and among researchers and patients. Patients rightfully view themselves as partners in the clinical trial process – this has been clearly demonstrated in patients’

interactions with the US FDA – and problem-solving around recruitment issues – whatever they may be in 10 years’ time – will still require participation of all relevant stakeholders.

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Executive summary

- Patients are not aware of the need for trial participants – outreach and education on trials must occur and better mechanisms for them to connect to trials must be developed.
- Clinical trial sites do not have optimized systems and processes in place to effectively recruit; sites should be supported in planning for recruitment for specific studies and should prioritize developing the necessary structure to successfully recruit within the clinic.
- Clinical trials require dedicated time, attention, planning, budgeting and monitoring to support successful recruitment.
- Patients are equal partners in the clinical trial process; integrating their viewpoint in recruitment strategies is necessary and beneficial.

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