FasterCures

The Center for Accelerating Medical Solutions

Clinical Trials Recruitment and Retention: Best Practices and Promising Approaches

Meeting Report *September 2006*

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Within each patient is a Rosetta Stone of information that could unlock the potential to cure disease.

Helping Patients Help Doctors

Introduction by Greg Simon, President, FasterCures / The Center for Accelerating Medical Solutions

Clinical trials play a central role in scientific advances. Yet recruiting patients into clinical trials, and keeping them in trials once they've signed on, is a huge challenge that many in the industry view as daunting—and perhaps even insurmountable. We all hear about a litany of problems that add up to a shrinking pool of available patients:

- *increasingly complicated lives that leave little extra time for all but the most essential treatment;*
- *low awareness of the opportunity to participate in clinical trials;*
- *an aging population that takes drugs for multiple chronic conditions, which makes them ineligible for most trial protocols;*
- *a public concerned about the safety of new medications in the wake of major drug recalls; and*
- *skepticism about trials designed only to expand the market for a drug to include an additional condition.*

These challenges are compounded by additional problems from within the infrastructure of the medical research enterprise:

- *an industry that focuses attention on the trial protocol, without a strategy for how to fill the trial;*
- *concentration of trials at academic medical centers that are out of geographic reach of many Americans;*
- *the lack of economic incentive for physicians to refer patients to trials or to conduct trials themselves; and*
- *widespread fatigue and resignation among professionals that the difficult recruiting situation cannot be resolved without major overhaul of the healthcare financing system, which few believe is realistic.*

And one additional obstacle seems to compound all other challenges: professionals from all corners of the clinical research enterprise express frustration with the complex web of problems and the long-term gridlock they perceive. They are weary of devoting time and energy to any effort—whether a one-time conference, an ongoing process, a consortium or alliance—that will revisit the "same old issues" surrounding clinical trials. They are skeptical that any organization or forum can identify practical solutions and resources to implement them.

The Best Practices and Promising Approaches Conference

On September 15, 2006, FasterCures hosted a conference, "Clinical Trials Recruitment and Retention: Best Practices and Promising Approaches," as part of our Patients Helping Doctors (PHD) initiative, which highlights the critical role patients can play in the search for cures and to give them the information they need to get involved.

The conference focused not on the many challenges, but on solutions that already show potential to break down the barriers to filling clinical trials. When we conducted research among leading professionals in the field and community physicians around the country, we heard many people say that they're tired of hearing about the same problems, and that they believe that there are great examples of problems solved. They urged us to identify those approaches, and share them with others. And they said that one reason improvements in rates of clinical trial participation are slow is because successes and experiences are seldom shared.

That's what this conference set out to do. We brought together an unusual mixture of people from various viewpoints—nonprofits that sponsor research, government agencies, clinical research centers, consulting firms that specialize in clinical trials recruiting, and patient advocacy organizations. We also brought together representatives from different disease groups, since usually we work on this problem one disease at a time. Once they had heard examples of best practices and promising approaches, we asked them to join together to explore how these ideas could work in other settings. What would need to change? How realistic—how "doable"—is this approach? Who would need to participate to make it happen? Is this change a big step, a small step, or something in between?

At FasterCures our mission is to save lives by saving time in the research and development of new cures for deadly and debilitating diseases. We try to ask "what if" and "why not?" when we see obstacles and challenges that impede progress. We think of ourselves as an "action tank," and we bring together leading thinkers and "do-ers" who can forge workable solutions. We support and facilitate ideas that will break down long-established barriers that slow down the progress of medical research.

While many problems seem intractable, we also hear about determined problem solvers who have focused on a few key aspects of the issues that can yield results. In other words, they focus on what they can fix.

The conference was designed to highlight the work of such innovators, and look at the components of their successful strategies that go beyond the traditional approaches. Our intent was to spread the word about innovative methods that produce results.

Focusing on the Fixable

The PHD program began with qualitative background research to help us plan our course of action. That research included:

- An ***environmental scan*** to assess activity in the field, ranging from the work of other organizations, to articles, papers and studies, and survey data related to our PHD program goals and objectives. The scan identified needs in the field, opportunities for collaboration, related activity to build upon or leverage, and gaps that *FasterCures* might fill. It was also intended to help avoid duplication of effort.
- ***In-depth interviews with 20 experts in the field of clinical trials recruiting and management*** to gain insights and ideas on the most appropriate and productive role for the *FasterCures* PHD initiative; and to identify opportunities, needs, pitfalls to avoid, and issues in the field that may not have been apparent in the literature review and environmental scan.
- ***In-depth interviews with community physicians*** — researchers and non-researchers, specialists and primary care — to gain understanding about the assumptions, experiences, concerns, and ideas of community physicians about clinical research and their ability to conduct or participate in it.
- ***Focus groups with community physicians*** — researchers and non-researchers, primary care physicians, oncologists, and non-oncology specialists — in large and mid-size metropolitan areas where participation in research is easily available. The groups helped identify and frame issues, challenges and opportunities; elicited proposed solutions to infrastructure challenges; and tested optional program approaches.

The "system" that influences clinical trials can be grouped into three broad domains:

1] patients;
2] physicians — both those who do research and those who don't; and
3] the industry players and institutions that make up the "system" and its economic drivers.

That system includes:

- *the academic medical centers and research centers where most research is conducted;*
- *clinical research organizations (CROs) and other types of consulting groups that support the industry;*
- *public and private payers of healthcare that influence the provision of healthcare services; and*
- *the many sponsors of research including pharmaceutical, medical device, and biotech companies, nonprofit organizations, government agencies, and foundations.*

The consensus of the many experts we talked with, as well as our analysis of the literature, pointed us toward focusing on the patient and physician rather than on the industry players. We concluded that we would be more likely to effect behavior change among individual patients and physicians rather than institutions, where challenges are far more interdependent and complex.

Structure of the Conference

Several months in advance we invited research sites around the country to submit their recruiting and retention success stories for presentation at the conference. We planned the agenda as a workshop format to engage participants in small-group discussion to analyze, expand upon, and extrapolate from the strategies presented. Our hope was that by catalyzing creative and constructive energy among professionals determined to be a part of progress, the exchange of ideas, collective brainstorming, and refinement of approaches would forge new hybrids that could break through long-established logjams.

The conference was held on September 15, 2006 in Washington, DC. The morning began with a discussion between Greg Simon, President of *FasterCures*, and Ken Getz, Co-Founder of the Center for Information and Study on Clinical Research Participation (CISCRP), to provide an overview of the issues and suggest a variety of visionary goals.

The rest of the day included two panels, each followed by facilitated small break-out groups. The first panel focused on the needs of patients and the patient point of view in the recruiting and retention process. This panel included:

- *Peggy Devine, Founder and President, Cancer Information and Support Network;*
- *Andy Miller, Director of Survivorship Programs, Lance Armstrong Foundation;*
- *Suzanne Pattee, Vice President of Public Policy and Patient Affairs, Cystic Fibrosis Foundation;*
- *John Walsh, President and CEO, Alpha-1 Foundation; and*
- *Charles Marshall, CEO, Peeramyd.*

The second panel focused on the physician's role in the recruitment process. Panelists included:

- *Tarit Banarjee, Marshfield Clinic; and*
- *William Hicks, Ohio State University Medical School.*

Break-out groups after each panel were charged with identifying the approaches they heard in panel discussion that seemed most promising. In addition, break-out groups categorized the approaches according to the level of challenge they estimated would be required to implement them on a broader scale, used a consensus process to select the ideas with most potential, and proposed refinements to the selected approaches.

Thoughts from an Early Innovator

Greg Simon's interview with Ken Getz, Co-Founder of CISCRP

Ken Getz, Co-Founder of the Center for Information and Study on Clinical Research Participation

Greg Simon interviewed Ken Getz, who has pioneered new approaches to solve old problems. As founder of Center Watch, he developed one of the early searchable, Web-based databases of clinical trials to give patients the ability to locate research for their medical conditions. Later he founded the nonprofit organization CISCRP, which has been a leader in educating the public about the importance of clinical trials.

Ken's remarks highlighted a few system-wide issues that must be resolved:

- ***Lack of a comprehensive, holistic view of the way we approach clinical trials.*** We tend to think of the challenges in fragmented ways, without seeing the connections between them. Ken envisions that implementing and integrating many incremental solutions will produce results far greater than isolated solutions. Examples of discrete activities that can be integrated to produce success include registries, better communication between clinicians and patients, electronic records, and greater engagement of community physicians.

"We have to get out of the mindset that there is a silver bullet somewhere." **KEN GETZ**

- ***Recruiting goals are not realistic because they are created in a vacuum.*** Recruiting is approached as a separate process from the research protocol. Ken observed that lack of collaboration between the Principal Investigators (PIs) and the research coordinators, with each working in their own "silos," perpetuates the problem, because the criteria for entry into a trial are often so exclusionary that it makes recruitment even more challenging.
- ***Retention is poor.*** A lack of follow-up systems contributes to losing patients before they have completed a trial. For example, many trial sites do not follow up with participants to let them know when the trial has ended, or the results of the research and the contribution it made to medical knowledge.

Realistic Timelines: Integrating Protocol and Recruiting Goals

GREG "Clinical trials are always delayed, on average, several months because of a difficulty in recruiting patients. So why don't they just start recruiting a few months earlier? If we know there is going to be a delay, why do we not build something in on the front end, and why are we always surprised by this problem?"

MR. GETZ "The statistic alone does not fully explain it. For one thing, the timelines we set are often very unrealistic, so whatever time we start it is taking much longer than we anticipated based on our plans and our projections to find an adequate number of volunteers."

GREG "So researchers are too optimistic in their timelines?"

MR. GETZ "Possibly, or they are perhaps unrealistic in the projections."

GREG "They are unrealistic in their expectations even though this is a well-documented problem?"

MR. GETZ "It is. Part of the challenge with planning is that it is often done in a very compartmentalized way. The people who design the protocols and the people who developed the initial plan for the project are not really on the front line; they are not the study coordinator or the physician investigator. They do not really know what it is like in the trenches to find the patients and bring them into the study.

"And as a result, you have lots of people in different silos, not really communicating with each other, racing against a clock that was set unrealistically. So you could start 10 months earlier. Whatever time you start, there is a good chance you are going to have a hard time hitting your target."

Patient Retention: Communication and Feedback

GREG "So we don't treat patients in clinical trials really well? Do we not send them thank you letters and commendations for volunteering their time and going through pain and trouble?"

MR. GETZ "We certainly do not. When it comes to retention and the acknowledgement of the valuable contribution that every volunteer makes, that is probably one of the areas that we do the worst."

GREG "So is there good news?"

MR. GETZ "There is a lot of data showing that once the patient has participated in the trial and they are familiar with the professionalism and the integrity of the research system, they become ambassadors and can play a valuable part as members of the lay public helping to shape an understanding of this enterprise and its value. And we do that with a number of different kinds of programs. You have many studies today that will offer thank-you cards or that will have a special gathering at the end of the study, but it is still not enough. A large percentage of patients, roughly 80 percent of patients in clinical trials, will say that they would like to know the value of the contribution that they gave. They want to know whether it made any contribution to knowledge in medical science. And yet 79 percent of all volunteers who have completed enrollment never hear from the site again."

GREG "Wow. Seventy-nine percent?"

MR. GETZ "Seventy-nine percent."

GREG "So you go and you do this, and you give blood, and you get tested, and you try things that might hurt you, and you never hear back?"

MR. GETZ "You never hear back. And often the patient directs their concern to the PI or the study coordinator. These individuals have their hands tied as well, especially when it is an industry-funded study; the investigator has no additional knowledge either, so there is a gap in time when the volunteer wants to know that their contribution had some value, yet the research staff cannot inform them."

"There is no public pride and appreciation in the valuable role that clinical research plays in public health, and that is a huge problem today. We have neglected the most important part of the enterprise, and that is engaging the lay public." **KEN GETZ**

The Role of New Technologies

GREG "Now, lots of technologies are emerging. We have genomics, proteomics, pharmacogenomics. We have data and computing power and all kinds of computing networks. Will any of these technologies overcome the barriers to making clinical trials more efficient, more timely, more productive?"

MR. GETZ "Every one of these pieces could play an important part. It might be the use of a new technology, it might be a new approach to targeting the patient community, or identifying the investigators, a new type of study design that requires far fewer numbers of patients. All of these things have got to be managed in a more comprehensive and holistic way.

"The technologies hold tremendous potential. There is no question that the electronic medical record could play a huge part. There are new types of design approaches, adaptive clinical trial design. Personalized medicine is really changing the way we design our studies. We are re-targeting much smaller populations although we now need to recruit much larger numbers of sites who can offer one or two patients that meet that phenotype or that profile. Every one of these things can play a role, but fundamentally, until we really address the issue of engaging the public and engaging the healthcare community, we are really only addressing part of the problem."

> ***"There is no question that the electronic medical record could play a huge part."*** **KEN GETZ**

The Booming Industry and the Big Disconnect

GREG "A lot of very big clinical research organizations make a living doing this. When you meet with them everything seems to be going well; they have been involved in trials of all the major drugs and they are working in 75 countries, they have populations engaged, and yet that does not seem to move the needle, overall. How is it that these large CROs have not done more to solve this problem when it is their livelihood? It seems to be a big disconnect."

MR. GETZ "Let's put it in perspective. There are over 1,600 companies around the world conducting at least one clinical trial. There are over 300 CROs involved in clinical research. Granted, there are 10 that essentially control about 60 percent of the market for CRO services. There are in total as many as 13,000 research centers conducting at least one clinical trial around the world. So even when you have a number of organizations that may be good at this because they are throwing a lot of money at it, they are not going to affect the enterprise as a whole. It is just far too large. Over $60 billion is spent in research and development, and of that,

close to $40 billion just on clinical research activities alone. Until we find solutions that essentially help all of the organizations involved, or unless the market consolidates at such a rapid rate that you only have the top performers involved, you are going to continue to see what you are describing.

"One reason I view this as such a challenge is that we typically take on a return-on-investment mentality—a very short-term mentality when we look at any clinical study. Our top performers know that their next project depends on their ability to meet the goals of that individual project.

"We have to look far beyond that, and that is a very hard thing to do in today's research culture, in today's corporate environment, or almost any environment where we are watching every dollar. At the same time if you look overall you will see that while spending is rising by 12 percent annually on clinical research activity, enrollment rates are declining and retention rates are dropping, so somehow we are getting a diminishing return, overall, on every dollar we are spending."

When asked by Greg Simon to name three key things that need to change, Ken summarized them as follows:

1] ***The need to create a higher level of engagement among volunteers and community doctors, especially minority physicians.***

2] ***The need to refine site selection for clinical trials.*** *Keep adequate data to select and support those sites that are consistently effective and efficient, while discontinuing use of sites (at least 50% of sites) that do not produce results.*

3] ***The need to focus on retention.*** *About 30% of enrollees drop out for various reasons. Better communication and protocols that are more realistic for patients would increase retention.*

Planning for a Patient Focus

Many conference participants agreed that focusing on the patient and on engaging community physicians will catalyze a new way of looking at trials, causing a ripple effect that can transform the industry. They advocated that it is time to re-think the process of recruiting and retention from the patient point of view, as an integral part of developing the research protocol.

The Patient Point of View

Panelists and participants called for nothing less than a complete overhaul of the recruiting process to focus squarely on the patient. Examples include:

Redefine the way we look at clinical trials, as if we were the patient

This would lead to:

- *a greater focus on communicating with volunteers about the larger contribution they make to medical advances by participating, and sharing the results of research accordingly;*
- *promoting the opportunity to receive state-of-the-art care and then providing it consistently;*
- *offering the convenience of staying in the community practice while participating in research;*
- *providing patients access to their own records as well as overall trial data online so they feel part of the progress; and*
- *creating online support networks for participants.*

Andy Miller of the Lance Armstrong Foundation challenged us to "think in terms of rewarding patients. Say thank you." Andy discussed the Foundation's activities, including their recent partnership with EmergingMed to provide an updated clinical trials matching service, as ways to empower patients to take their care into their own hands. He urged us to consider this view as another window into the motivation of our potential pool of recruits. (*FasterCures* also provides a clinical trials matching service powered by EmergingMed on the *FasterCures* Web site.)

> ***"Until we put the patient at the center of things, and look at the [clinical trials] enterprise through their eyes, I think we will always be trying to fit a square peg into a round hole."*** ANDY MILLER

CASE STUDY / Lance Armstrong Foundation and EmergingMed

Providing a patient-centered clinical trials matching service

*The Lance Armstrong Foundation's mission is to support cancer patients and survivors in every way, through education, advocacy, public health and research programs. Its well-known "*LIVE**STRONG**™*" tag line bespeaks its single-minded focus on the needs of the people living with cancer.*

In order to make it faster and easier for patients and their families to find and understand available treatment options, the Foundation offers a Clinical Trial Matching Service in partnership with EmergingMed. As EmergingMed's CEO writes on the company's Web site, "access to new treatment options, including clinical trials, should not be serendipitous. This is a time when pharmaceutical companies, biotech companies and the government have enlisted the support of nearly 50,000 doctors to conduct more than 10,000 clinical trials each year—almost one-third are designed to test new drugs and therapies for cancer patients. Patients and families should have a way to find these new drugs and therapies without having to depend on luck."

Existing information resources about clinical trials are frequently out-of-date, incomplete, difficult to use or understand. In addition, even if patients are able to find out about a trial for which they seem to be appropriate or eligible, they frequently do not end up enrolling for a variety of reasons. The Lance Armstrong Foundation and EmergingMed seek to bridge the gaps in the system into which patients too often fall.

Patients complete a disease-specific questionnaire about their diagnosis and treatment history, over the phone or online. EmergingMed's matching technology allows them to compare this short personal profile to the enrollment criteria of thousands of Institutional Review Board (IRB)-approved clinical trials—both privately sponsored and public—in a matter of minutes.

Clinical trial specialists review each patient's questionnaire with them over the phone—even if they have initiated the process via the Web—and provide a general education about clinical trials, then offer to send trial summaries and contact information for trial matches. The clinical trial specialists stay in touch with each caller to ensure that the patient is able to contact the trial site, to assist the patient when possible with any barriers to clinical trial access, and to keep the patient up to date on new clinical trials for which they might be eligible.

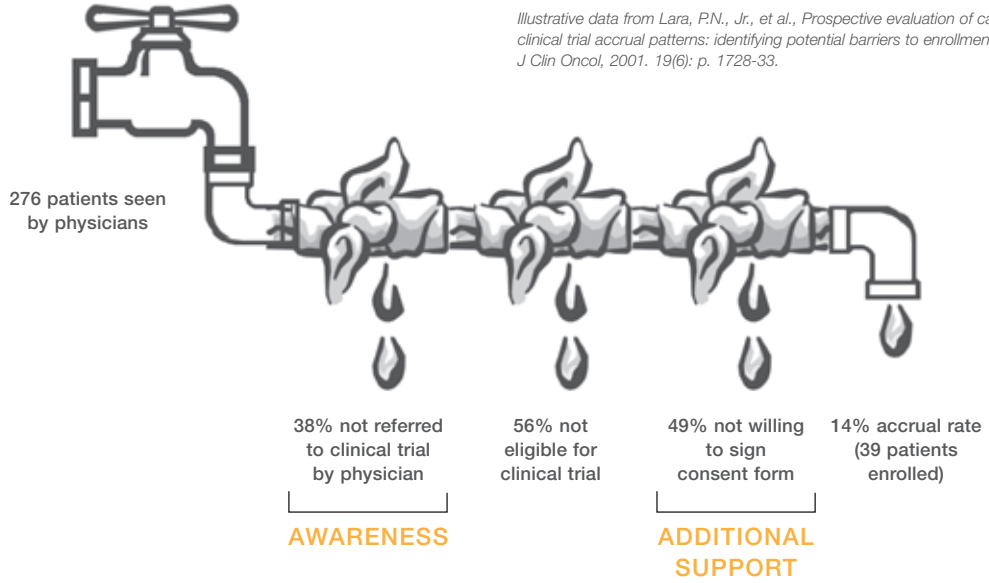
The Lance Armstrong Foundation and EmergingMed are taking a new approach to remove the barriers that prevent many patients from enrolling in trials appropriate for them.

Reinvent the "informed consent" process and convert it to an "informed choice" process

This would require using "clear health communication" principles as well as a complete overhaul of the training that site coordinators and recruiters receive, to include psychosocial training.

Peggy Devine of the Cancer Information and Support Network shared her extensive work in simplifying the informed consent process for patients, while also ensuring that it meets IRB standards. Her organization developed a one-page graphic schema that helps research volunteers understand an entire research protocol and their role in it. She stressed that most likely candidates for clinical trials have multiple concerns, and are completely unfamiliar with the vocabulary used by the industry. Peggy described her work with IRBs and legal teams to gain their approval for a simplified informed consent process that builds trust. She urged us to realize that patient trust in the sponsor is critical; without trust high attrition is a predictable problem.

The Data: The Leaky Pipe of Clinical Trial Participation



Peggy Devine of The Cancer Information and Support Network shared this one-page graphic to illustrate the points in the recruitment process at which increased awareness of clinical trials and specific support can increase accrual. Slide courtesy of Jeff Belkora, UCSF.

"Trust in research is such a huge issue. Industry and government both need to understand that it's almost a sacred concept." **PEGGY DEVINE**

CASE STUDY / Cancer Information and Support Network

Moving from "informed consent" to "informed choice"

Peggy Devine, Founder and President of the Cancer Information and Support Network (CISN), knows all too well the flagrant flaws in the clinical trials recruiting process. As a breast cancer survivor who was frustrated as she actively pursued an appropriate trial for herself, she felt compelled to start an organization that would change the system. "I think the informed consent process is broken," says Peggy. She began by designing an overhaul of the process, so that it becomes more about educating and supporting a patient, and less about simply collecting data from the patient.

CISN developed a variety of education materials for patients, among them a graphic schema that illustrates to patients the entire process of participating in a clinical trial in one-page. The schema addresses topics such as decision-making models, randomization, and steps in the implementation of a trial.

In addition to educating patients, CISN focuses on educating clinical trials staff as well. The organization has developed a process and a training course to provide Clinical Research Coordinators with psycho-social training. CISN has worked with clinical trial sites around the country, helping them improve their recruitment process by engaging Clinical Research Coordinators in supportive education that takes the patient point of view.

Identify satisfied research participants and utilize them as ambassadors

Conference participants heartily agreed that identifying and recruiting research participants who were satisfied with their clinical trials experience could build a strong base for "viral" marketing and important word-of-mouth endorsements. People at the conference suggested a variety of ways to identify and recruit such ambassadors, including placing ads in Google and health Web sites, through the more than 20 groups that are part of *FasterCures'* TRAIN (The Research Acceleration and Innovation Network) organization, and through Web sites, newsletters and email listservs of the National Health Council's 50 voluntary health agency members.

Focus on communication with patients so that it is direct and two-way

Conference attendees suggested that clinical trials sites could set up patient-to-patient mentor programs, as well as email communication between participants and site coordinators. Another approach is to involve patient advocacy organizations, which already have infrastructure and communications venues in place, to guide people through the process so they are not lost in information overload on their own.

Suzanne Pattee of the Cystic Fibrosis Foundation (CFF) stressed that in the case of rare diseases such as CF (affecting 30,000 people in the U.S.) it is essential for the regular physician practice to ask every single patient to consider volunteering for clinical research. CFF's marketing research revealed that while participation among

"Thanking the patients is really important, but also providing them with information about the outcomes, either positive or negative, is critical." **SUZANNE PATTEE**

CF patients is high, the primary reason people cite for not participating is that they have never been asked. Conversely, the recommendation of the physician's practice team is cited as the most important influence for those who do decide to volunteer.

Because CF affects a small population, the Foundation has established and funded its own network of clinical trials, and it has had strong success by encouraging research coordinators to be direct with patients in helping them see how they are making a difference.

CASE STUDY / Cystic Fibrosis Foundation

Creating the infrastructure to bring patients and researchers together

The Cystic Fibrosis (CF) Foundation is one of the "grand-daddies" of disease research organizations, in business for more than 50 years and widely cited (and copied) as one of the most innovative. The Foundation's research mission is to get therapies—and ultimately a cure—to patients as quickly as possible, and it has built a robust research network to achieve that goal.

It begins with more than 117 accredited CF care centers nationwide, where more than 24,000 patients have received care and which contribute data about patients' condition and treatment to a centralized patient registry. CF research centers at leading universities and medical schools throughout the United States pursue promising research, and 18 of these centers form the Therapeutics Development Center Network, which have received specialized training in how to design and conduct clinical trials. (The number of centers in the network has more than doubled in the last few years, to accommodate the growing number of clinical trials and the research interest in CF.) And finally, Cystic Fibrosis Foundation Therapeutics, Inc.—the nonprofit drug discovery and development affiliate of the Foundation—offers matching awards to scientists, as well as access to its specialized network of research centers and its clinical trials expertise.

The efficiency of this infrastructure has attracted biotech companies to make the sizeable investment required to develop a new CF therapy. The network saves them both time and money. Further, data from these studies are centralized and shared to achieve maximum mileage for the researchers (and ultimately the patient).

The CF Foundation brings together access to and knowledge of the patient community, relationships with academic and corporate researchers, and its clinical trials capabilities, and is achieving remarkable success at moving potential therapies through the development pipeline.

Use the most up-to-date technology, where appropriate, to enhance communications

Some conference attendees suggested creating a social networking Web site for people who have participated in trials so that people can share personal stories and feel part of something larger. The Web site can be organized by health condition and funded by an alliance of research sponsors.

Charles Marshall explained how his company, Peeramyd, supports the professional recruiting industry with Web-based networking.

> ***"One part of the system we developed [for recruiting for a nursing association] is a sophisticated networking system, where every person on the Board, everyone can have their own accounts for referral and manage those referrals. This could also be adapted for clinical trials."*** CHARLES MARSHALL

Clinical trials sites should work with and through other trusted organizations and venues to reach potential participants

Examples include working with the American Medical Association to produce a video in their video series on public health issues, and to work with Medline Plus to create a more consumer-friendly version of this government-sponsored database. Several people called for the consolidation of online clinical trials databases into one, user-friendly online resource.

John Walsh described how he and his brother founded the Alpha-1 Foundation in 1995, when NIH ran out of funds to conduct further research after a seven-year trial. Since then, Alpha-1 has set up a network of clinical trial sites devoted to Alpha-1 research. Within that structure, the Foundation also runs a registry of patients who would be willing to participate in research as well as a DNA and tissue bank that are tremendous resources to researchers. Because the organization is a trusted source of general patient education, it is easy for them to talk about research as part of the overall treatment picture.

"One of the most important documents we have is 'Taking Part in Alpha-1 Research,' and we build that into the culture of our patient community. At every support group and in every communication, research is a topic." **JOHN WALSH**

CASE STUDY / The Alpha-1 Foundation

Treating patients as the key to the search for a cure

The Alpha-1 Foundation knows its patient community better than almost any other disease research organization around. Many have received care by experts in clinical practice and/or Alpha-1 research at one of over 50 ***Clinical Resource Centers*** *(pulmonary and liver centers) overseen by the Foundation's Medical and Scientific Advisory Committee. Many have also received free, confidential testing for Alpha-1 through the* ***Alpha-1 Coded Testing (ACT) Study****, which also facilitates research on the perceived risks and benefits of genetic testing.*

The Foundation maintains the largest ***Alpha-1 registry*** *in the world, a confidential database of individuals diagnosed with Alpha-1 Antitrypsin (AAT) Deficiency and persons identified as Alpha-1 carriers. Members of the Registry receive updates on recent developments in Alpha-1 research and are notified of studies in which they may be eligible to participate. It is an invaluable resource for investigators seeking individuals to participate in clinical trials, surveys, and other scientific and medical data collection activities. The Registry's Family Linkage Program facilitates genetic research and other studies requiring family member participation while protecting the privacy and autonomy of each family member. The Registry is also a vital component to other Alpha-1 research endeavors such as the ACT Study and Genetic Modifiers Study.*

Alpha-1 patients have also helped the Foundation establish a ***DNA and tissue bank****, now the world's largest researcher-accessible repository of Alpha-1-specific tissue, biological fluid or genetic material. The Bank is a resource for DNA and tissue samples that are studied by researchers investigating Alpha-1 and other diseases.*

All of these resources help attract researchers and biopharmaceutical companies to study Alpha-1, speeding the development of new treatments and giving hope to the patients who participate in the Foundation's work.

Connect communications to "life path points."

A communications opportunity may be explored by approaching people about the clinical trials opportunity and decision process at key "life path points" (e.g., entering the work force, buying a first home, marriage, having a child, caring for a parent). This concept includes reaching people at each of these life path points in ways that are already part of their everyday life, by developing corporate partnerships with

Alpha-1 Foundation
Clinical Trial Recruitment: Core of Organizational Structure

The Alpha-1 Foundation structure stresses the importance of research in the process for all patients who join the organization.

corporations such as Johnson & Johnson, Citibank, or General Foods. Another aspect of this concept would lead us to reach patients through health clubs, chiropractors, pharmacies, vitamin stores, Home Depot, Starbuck's, Target, and other retailers.

Focus on the relationship

Discussion emphasized that clinical trials participation is a small part of a patient's life, but it is a long-term relationship. All participants agreed that if clinical site coordinators and recruiters viewed it and presented it that way to prospective patients, they would be more likely to succeed.

The Role of the Community Physician

Doctors Tarit Banerjee of Marshfield Clinic in Wisconsin and William Hicks of Ohio State University Medical School have widely divergent types of practices and approaches, yet both agree that the established relationship between a patient and community physician is the best foundation for clinical trials participation. Both researchers believe that a clinical trials recruiting approach must be integrated into every aspect of practice to be consistently successful.

Building Trust with and through Community Physicians

Dr. Hicks, as a recipient of a National Cancer Institute (NCI) Barriers grant, focuses on recruiting African-American patients into oncology trials, working against a legacy of mistrust of the clinical research community. He rebuilds trust by his regular presence in the community, talking with community physicians on their own turf, and with community organizations and individuals in places where they work, worship and socialize.

With his NCI grant, Dr. Hicks has produced down-to-earth materials such as a Powerpoint presentation to use in church settings and a video that features five research volunteers to humanize the clinical trials process. He also hosts a regular radio show in which he answers callers' questions about cancer and other health issues.

Implementing a Research Culture in the Medical Practice

Working from a community clinic base, Dr. Banerjee stressed the importance of the entire research team working together, with strong institutional support including dedicated staff and electronic medical records. He emphasized that his organization is successful at filling clinical trials because it is part of the overall organizational

culture and is expected. Marshfield Clinic has a centralized data and information hub, which regional and community clinics can gain access to.

Dr. Banerjee also addressed the issue of an imbalance in status between community doctors and those in research institutions. He suggested that research centers need to find ways to put community doctors on more equal footing to engage them, whether to conduct research or to refer patients.

In breakout groups, the following topics were discussed as key elements of engaging community physicians.

Completely realign financial incentives to make it more attractive to community physicians to conduct research or to refer patients to trials

While some conference attendees found this prospect discouraging, others focused on the fact that some practices make it work, and their tactics can be replicated.

CASE STUDY / Making research work in the community practice

Dale Halter, a rheumatologist in the Houston area, has run a solo practice for more than 20 years. He sees a wide range of patients with rheumatoid conditions including arthritis, psoriasis, and lupus. He participates heavily in research because as he says, "Doing research is a breath of fresh air. It's win, win, win—for patients, and for me."

How does he make it work, without disrupting his busy practice and draining it financially? He identifies patients and suggests a study to them, then refers them to a nearby, outside clinical center site for processing. The clinical research site is actually an administrative management group, Houston Institute for Clinical Research, that employs research nurses and technicians to do the informed consent process, screening, data collection, reporting, and all related paperwork. Dr. Halter then sees his own patients at the center one afternoon a week, so that he maintains his relationship with them for the near and long term future.

As Dr. Halter sees it, participating in research provides him with frontline education that would be very hard to come by through continuing medical education (CME). The design of the research shows him what leading thinkers and innovators are discovering before it is common knowledge, and his patients receive new treatments long before they are widely available to the public. Also, his patients with no insurance or with poor coverage get the most advanced treatment, often at no cost to them. They usually get any medications free, and he receives compensation, although minimal, as well.

Dr. Halter acknowledges that the administrative burden of clinical research is huge. The key to making it work, he cautions, is "to find a good RN or LPN who is already well-trained in clinical research. You can't just work it into your practice, you must have an extremely good person to run it."

Develop a full package of incentives to engage community physicians

Dr. Hicks suggested that research institutions could offer CME credits or tuition reimbursement for CME courses in exchange for patient referrals.

Create a support network for community physicians to encourage their involvement

This could include creating local and regional "mini-CROs" to provide support services to doctors' offices to decrease administrative burden. One way to implement this approach is to identify existing successful support services and promote them or replicate them.

Encourage physicians to not discourage clinical trials participation among their patients

This would beneficial even if they do not actively support it or make direct referrals.

Cross-Cutting Approaches

Two approaches generated widespread enthusiasm for their ability to apply pressure to various weak points in the system. They cut across various challenges, and although they may prove to be resource-intensive, they appeared both realistic and likely to provide a tremendous return on investment.

1. Create a national registry of patients willing to participate in trials, with its own self-generating funding stream

Patients could "opt in," much as they do to become organ donors or bone marrow donors. In anonymous records they can offer information on their medical histories and conditions, to amass a large pool for recruiting. Clinical trials sites can then contact specific patients to invite them to participate in selected trials.

Research sponsors could pay for referrals that meet their criteria, providing a funding source. In addition, the registry would be Web-based, yet password-protected for registered users only, and thus could carry highly targeted advertising as an additional funding source.

2. Fund a major, ongoing public education campaign by convening a coalition of groups interested in promoting clinical trials participation

Several nonprofit organizations have undertaken public education efforts from time to time, but none has been large-scale, frequent, and using state-of-the-art communications. Groups such as CISCRP, *FasterCures*, National Health Council, and Research!America may want to form the core group to attract others, and explore corporate funding from research sponsors and other health-related corporations.

CASE STUDY / The national organ donor program

A model for a national clinical trials registry?

In 1973, the Uniform Anatomical Gift Act recognized the right of individuals to indicate their wish to donate organs by means of an organ donor card, and also gave the immediate family of a deceased person the ability to decide to donate.

In 1986, a nonprofit organization, the United Network for Organ Sharing (UNOS), was contracted by the federal government to run the Organ Procurement and Transplantation Network (OPTN). UNOS oversees a system of 59 organ procurement organizations (OPOs) which recover organs in their regions. In 1999 UNOS launched UNet, a secure, Internet-based transplant information database system, which matches donated organs with recipients throughout the country.

Participation in the program is encouraged in a number of ways. On the donor side, 21 states have made it easy for individuals to register as a donor by offering the option at the Department of Motor Vehicles or driver's license bureau. In 1992 UNOS helped start a campaign to build public support for organ donation called "Donate Life America" (www.shareyourlife.org).

On the provider side, a number of "required request" laws mandate that hospitals give the families of all eligible patients the option to donate; the Health Care Financing Administration (HCFA) has made Medicare reimbursement contingent on the practice, and the Joint Commission on Accreditation of Health Care Organizations has made it a requirement for hospital accreditation. HCFA also requires that all hospitals notify their local OPOs about recent and imminent deaths ("required referral" or "routine notification").

While there remains a considerable shortage of organs available for transplantation, and advocates fervently wish to increase the uptake rate, the fact remains that 99% of Americans are aware that organ donation is an option, and a little less than half actually consent. If the same success rate could be achieved in clinical trials recruitment, a significant acceleration of progress in medical research would surely result.

Consensus of the Breakout Groups

In moderated discussion, small groups brainstormed, refined, and selected the approaches they thought would have the most potential to reorient clinical trials recruiting and retention to embrace the patient point of view.

Top Approaches to Support Patient-Focused Recruiting and Retention and Greater Engagement of Community Physicians

APPROACH	*DISCUSSION*
Establish a centralized, national registry *(like Alpha-1 Foundation's) of patients willing to participate in research. Researchers can search the database for patients who fit their protocols*	■ *High impact* ■ *Organ donor and bone marrow donor registry were cited as examples* ■ *Could be offered as part of driver's license registration, incorporated into HIPAA form, through doctor's offices, health insurance sign up process, when people join voluntary health agencies, or other means* ■ *HIPAA regulations and security and privacy were a concern, but most thought an "opt in" system could overcome these issues* ■ *If done through health insurance plans, insurance codes could help capture ongoing medical history* ■ *Requires electronic records* ■ *How to fund it? Who will regulate?* ■ *Could research sponsors pay for access to support funding?*
Greater community education *(general campaign on what clinical trials are, what people should expect, making clinical research more relevant, creating a sense of service about participating). Support ongoing campaigns within organizations like CISCRP, and in tandem with patient advocacy organizations. Consider creating a large coalition to pool resources*	■ *The industry may feel that education has been plentiful, but in fact it has never been high visibility or ongoing* ■ *General lack of education makes recruiter's job difficult* ■ *Start education young. Middle school and high school health class curriculum, Boy Scout and Girl Scout merit badges offer opportunities* ■ *Corporate sponsors may be attracted to this approach*

Work with national physician organizations *to improve physician education about the need to support clinical trial recruitment and how to communicate with patients on the topic*	■ *Physicians and their staffs need to receive better information on how trials can work for them, why they should support them, and how to encourage patients to volunteer* ■ *Even if we expect some doctors not to participate, we should educate them to not discourage patients from research* ■ *We need to segment; identify characteristics that predispose doctors to research (e.g. location, age, type of practice, etc.)* ■ *Educate payers and sponsors of clinical trials to develop new financial models to incentivize physicians*
Build improved recruitment and retention practices into protocols by making them a requirement for funding	■ *Tying recruitment to funding will force a more sophisticated level of thinking about recruitment and retention*
Create local clinical trials support and processing centers *("outsource" selected parts of the recruiting and intake process and data collection to centralized, specialized facilities)*	■ *Huge undertaking, but high return on investment* ■ *Supports community physicians; answers their most common concerns* ■ *Could be funded by research sponsors diverting their resources from unsuccessful recruiting practices*
Develop a new system of incentives for community physicians	■ *Huge, long-term effort, but can begin incrementally* ■ *High impact* ■ *Incentives would include more cost-based reimbursement, recruitment assistance, supplying data collection personnel, recognition in the community and among peers, CME credits; an integrated package of benefits to make it more attractive for physicians to participate*

Agenda for Action

Human clinical trials are the only way of evaluating whether new diagnostics, drugs, experimental medical devices, and surgical techniques actually work, and therefore well-functioning trials are absolutely critical to medical progress. Recruiting volunteers to participate remains one of the costliest aspects of the drug development process. Reducing the length of a clinical trial by just one month by improving patient recruitment could not only save lives, but also generate additional revenue to reinvest in the research and discovery of new therapies.

Staying on the path we are on is simply not an option if we want to accelerate the search for cures to deadly and debilitating diseases.

This one-day agenda-setting session showed that if we focus on what's fixable, on promising approaches already in use, and on patients and their doctors as central players in making the system work, we can make positive progress against seemingly intractable problems. Some of the ways in which we can collectively do that include:

- ✓ ***Creating a national Web-based registry of individuals willing to participate in clinical trials;***
- ✓ ***Orchestrating a major public relations effort to highlight the critical role patients play in the search for cures and to give them the information they need to get involved;***
- ✓ ***Partnering with community physicians to educate them about clinical trials, develop new incentives for their participation, and create "mini-CROs" to ease their administrative burden;***
- ✓ ***Institutionalizing methods for making research protocols more patient-centered, such as revamping the informed consent process.***

In the months ahead *FasterCures* will be looking for ways to work together with other organizations toward real solutions. We each have our unique missions and distinct roles, and it is important that we work together to avoid wasting resources or duplication of effort. We will focus on identifying resources needed, potential partners, and timelines for action.

FasterCures also pledges to make our Patients Helping Doctors Web site (www.patientshelpingdoctors.org) a resource for patients and professionals committed to the reinvention of clinical trials.

Closing Thoughts

In 1799 explorers unearthed in Egypt a stone slab—the Rosetta Stone—bearing parallel inscriptions in Greek, Egyptian hieroglyphic, and demotic characters, which made it possible to decipher the written language of the ancient Egyptians and the stories that it told about the people and their culture. Each of us is, in a sense, a Rosetta Stone, for within us is the information necessary to unlock the relationship of genetics, proteomics, behavior, nutrition, and environment to the emergence and, ultimately, the management of disease.

The three "languages" of our Rosetta Stone are medical records; biological material such as tissue, blood, and DNA; and our biology as observed in clinical trials.

By enrolling in clinical trials to test potential new therapies—as well as by providing tissue samples, blood, or medical histories—patients can provide critical information and resources, without which the search for cures could slow to a halt. *FasterCures* has focused on all three of these tools for discovery under our Patients Helping Doctors (PHD) program.

Looking back on the lively discussion of the day, the following definition of a "system" emerged for me, based on five "Ps": ***people, place, purpose, process and product:***

- ***People:*** Whether they are insured or not insured, young or old, healthy or sick, people must be at the center. We must develop a system that works for people.
- ***Place:*** We need to be more creative about the places where we reach people. It can't be all about the doctor's office or the hospital or the clinic. Where is the best place to educate a factory worker or an office worker or a single mother of teenagers? Where are the places where people spend most of their time?
- ***Purpose:*** The purpose of a clinical trial has to involve the patient's purpose. Patients want some control in their health. We have to think of the purpose on the personal level for the patient, not just at the institutional level for the sponsor.
- ***Process:*** The process must work better for and be respectful of the people in it. Respect comes from what we do and how we communicate it. Finding out about a specific clinical trial should not be a hit-or-miss process, dependent on a patient's doctor, location, and access to informational resources rather than on appropriateness and eligibility.
- ***Product:*** People deserve to know the results of their contribution. What happened and why? You can live and die in a clinical trial, giving your time and your blood and your energy even when you're sick, and no one ever says "thank you." Sounds simple enough, but it doesn't happen. This is totally within our power to change, now.

Special thanks go to Melane Hoffmann for writing this report and for conducting the initial agenda-setting research for *FasterCures*.

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