Patients at the Center of Clinical Trials Workshop

November 14, 2013

Guest List

Name	Bio / Role
Sarah Kucharski	Writer & magazine editor, ePatient, #hcsm consultant, public speaker, procedural gadfly, thinker, doer, founder @FMDChat, Stanford #MedX adviser. @AfternoonNapper
Tracy Zervakis	Lover of life, music and beauty where few choose to look. Chiari & POTS. International rare disorder advocate and Director of Member Services for Ben's Friends. @ChiariTracy
Cathy Collet	Passionate champion for ALS patients and research. @alsadvocacy
Jeri Burtchell	Clinical trial participant ("A hypochondriac in a clinical trial"). MS Activist, ePatient Speaker, MS Blogger, Freelance Writer, Seeker of a Cure. Guest blogger of Lilly COI "Meet Subject #0008: A Patient Perspective on Clinical Trials." Jeri served as a judge on the CT Visualization Redesign Challenge. @FingoHead
Regina Holliday	Regina Holliday is the founder of #TheWalkingGallery, mother, artist, author, blogger, speaker using paint & #hcsm to promote patients' rights within medicine. Regina served as a judge on the CT Visualization Redesign Challenge. @ReginaHolliday
Casey Quinlan	Chief Message Officer, speaker, content strategist, e-Patient, author "Cancer for Christmas,"rabble-rouser. @MightyCasey
Gilles Frydman	Smart Patients co-founder, ACOR founder, daily witness of the amazing power of networked patients. @gfry

Susan Poteat	Medical Physicist and member of ACOR, seeker of information to help others understand disease and clinical trial options; wife of Gary
Gary Poteat	Medical Physicist and member of ACOR. RCC survivor, with experience in multiple clinical trials; husband of Susan.
Sharon Terry	President and CEO of Genetic Alliance, a network of more than 10,000 organizations, of which 1,200 are disease advocacy organizations. Genetic Alliance enables individuals, families, and communities to reclaim their health and become full participants in translational research and services. Sharon served as a judge on the CT Visualization Redesign Challenge. @SharonFTerry
Shantal Feltham	Founder of Stiris Research, an entrepreneurial Clinical Trial Management Company, providing comprehensive study management solutions for Phase I through Phase IV clinical research. Proud mom of three, entrepreneur, hockey coach, and wine lover. Problem solver, connector, and innovator. @StirisPres
Rahlyn Gossen	Founder of RebarInteractive, a digital strategy and patient recruitment company. Former clinical research coordinator with a love of technology and digital marketing. Proud Louisianian. Rahlyn served as a judge on the CT Visualization Redesign Challenge. @RebarInter

Agenda

Time	Topic	Goal
08:30 – 9:00	Coffee and Social	
09:00 – 10:00	Kickoff and Introductions	
10:00 – 11:00	Patient Panel – Hearing the patient perspective on clinical trials	A combination of patient led commentary and Q&A from the Lilly participants (bring your questions or ideas to engage the panel)
11:00 – 11:15	Break	
11:15 – 12:00	CT Visualization Redesign Challenge Winners Announcement	Announcement, winning examples, next steps (see submissions at: http://ctdesign.challengepost.com/submissions)
12:00 – 12:15	Grab Lunch for Breakout Intro	
12:15 – 1:15	Breakout Introduction: Lilly's Patient Centric Engagement (PCE) Strategy overview and demos	Sharing the Lilly direction with the external guests, to set up targeted breakouts for deeper dialog
1:15 – 1:30	Self-Select Breakouts	Planned Breakout Themes: • Understanding clinical trials (pre-trial) • Joining a clinical trial (consent) • Support while in a CT • CT Integration into patient lifestyle

		• Option to create your own theme
1:30 – 2:30	Breakouts by themes	Breakout time. Listening for patient perspectives
2:30 – 2:45	Break	
2:45 – 3:45	Breakout team readouts	All
3:45 – 4:00	Closeout and final thoughts	

Patient Perspectives on Clinical Trials – Panel Discussion

Patients' Experiences in Attempting to Join a Trial:

Regina Holliday (@ReginaHolliday)

- Make the experience more friendly to people, especially the physical environment and the Informed Consent Document
- Why the obsession with de-identified information? It seems that if you have a rare disease, investigators are afraid you'll be identified. This can make it difficult to get enrolled.
- No one asks if you want to be de-identified. Most of the advocates could care less, they share their information publicly anyway and would be willing to give as much information as you like.

Casey Quinlan (@MightyCasey)

- Make clinical trial information available and easy enough to find for the average human. Provide better ways to communicate, as it's often hard to find and connect with investigators.
- Is information about clinical trials really up to date? This is particularly important when you look to try to enroll in a site. Patients need to know which slots are open, and where. Where can I get that?

Sarah Kucharski (@AfternoonNapper)

- I was informed that researchers are not legally allowed to tell a patient if researchers discover something to be medically wrong with the patient during the trial process. Is this true? How can it be ethical for researchers not to share what they learn about patients?
- It's frustrating to try to take a rare, and most likely fatal, diagnosis and make the most of it, but not have any help. Advocates do not receive enough support from the healthcare system.
- How can I find out if a trial's inclusion/exclusion criteria apply to me more quickly and easily
- When multiple sites are working on a trial or a patient has received a diagnosis from one doctor and is entering a trial based on that diagnosis, there must be some level of general acceptance of basic lab and screening data from site to site. Why can't existing electronic health record data be used? Why do patients have to go through redundant tests?
- Geographic location is a major barrier to research participation; anything that can be done to reduce these barriers would be tremendous such as accepting data and records from another site—i.e. patients' GP collecting samples and doing follow ups thus limiting time-consuming, expensive trips to trial sites.

- Interacting only with interns, nurses, or nurse practitioners and not principle researchers feels like a real blow off. If patients are not important enough to draw the researcher's attention, why should patients bother going to the effort to participate in research?
- The industry needs to work with insurance companies such that employers will not penalize people with pre-existing conditions—even healthy people can be hit by a bus and die.

Tracy Zervakis (@ChiariTracy)

- I think of clinical trials and there are not clinical trials for rare disorders. It took about five years to get diagnosed and 50 specialists, and there are thousands that have a similar story.

Sharon Terry (@SharonFTerry)

- The spectrum of all diseases, rare and common, need to be represented with any system built: granular and dynamic.

Cathy Collet (@ALSAdvocacy)

- The process of getting my mother enrolled into a CT for patients with ALS took a very long time, which was a huge delay. My mother died before she was enrolled. Her purpose in joining was not to find a miracle drug but to contribute to the study and science in hopes of furthering the fight.
- I get that there's risk in research and why it can take a while, but please know that risk is different for each disease. There's greater risk in taking a while to get someone enrolled when they have a disease like ALS then expediting the process.
- Peer Recruitment is big.
- Every patient should be a researching patient. Here's how you do that: The day mom goes in and gets diagnosed, the doctor needs to say "We need you to be a research patient. We need your information; we'll contact you about monitoring your measurements, etc." Every patient needs to be handed that. Then the data, the electronic data can let you know information from that point on (not just when they get enrolled in a trial) can be useful to you.
- She felt like we were always fighting the FDA and that the FDA was "protecting her" to death.

Patients' Experiences Who've Been In Trials

Susan & Gary Poteat

- Susan: We would be happy to have our faces on the web with the trials. Some people need that personal touch. Some people need the data. Why not provide both?
- Susan: Trials are unpleasant, but I get that it is about science as much as it is about the patient.

- Gary: I would prefer Phase 1 or 2 because I know I'm getting new, innovative treatments. I don't want to do a Phase 3 and get a placebo. I would never intentionally seek out to join a Phase 3 trial.

Jeri Burtchell (@FingoHead)

- Educate people on what it means to join a trial. Patients have the most to risk.

Break Out Sessions

Group 1 – Understanding Clinical Trial Information and Finding a Trial
ISSUE 1a: Ease of finding appropriate trials: Better tools for Online Patient Search

- Finding a trial should be more like a shopping experience.
    - Clear transparency of what trial is, reviews by others, ability to research other sources of information on the trial, ability to compare across studies
    - Enable "professional" reviews so that experts can "handicap" the studies. Example classifications could be:
        - Novelty of intervention (drug)
            - It is a me-too drug, or is this a novel drug/target
        - What does previous evidence show – both pre-clinical and clinical
        - Patients don't consider a trial in the abstract
    - Is the trial design "patient-friendly"
        - What is likelihood of getting placebo?
        - What is the level of burden and impact on the patient? Are other designs more appropriate
    - How useful to the patient are the study outcomes? Is it (just) a scientific scale or something that patients will be able to experience a personal outcome improvement (eg. mobility for ALS or RA patients)?
- Enabling patients to find matching studies is huge and needs to be much easier.
- Review of eligibility criteria is manual and difficult-text entry of eligibility criteria is not database search enabled. For any given disease there are usually only a few criteria that exclude the majority of ineligible patients
    - Historical treatment and disease progression and comorbidities are usually key criteria (very disease specific). Example of matching questions are given below
        - Are you treatment naive?
        - Do you have any of the following comorbidities? Need for oxygen or breathing device, heart problems, abnormal liver test values–etc.
        - Have you had disease symptoms longer than a specific duration (e.g. ALS symptoms greater than 24 months are often excluded – yet diagnosis is often well into the 24 months of symptoms)
        - IDEA: patients know why they are excluded for their specific disease. Ask them (crowdsource) to define the exclusion characteristics common in their specific disease. Listen and learn from patients. The goal is to allow patients to answer only a few questions, but with those questions to eliminate a majority of trials for which they fail to meet eligibility criteria.

ISSUE 1b: Ease of finding appropriate trials: Better tools for Call Center to help patients in their trial search

Currently, the call center representative typically has no more information than is posted on the internet. The Call Center needs to provide a Navigator (or Concierge) style interaction with potential trial participants.

- Call Center needs access to more real time info and needs to be enabled with more tools
- For Phase 1 and 2 trials, if you call the 1-800 phone number, you can't find out if there are slots available. They refer the patient back to the individual site. Put more information into the hands of the 1-800 folks who answer the phone and help the patients. Give them the ability beyond being able to read what is on the internet.
- Call center needs access to the data (live time) on where there are slots.
- "Live chat" for the call center would be useful
- Call center needs to be able to do initial eligibility screening
- Call center needs to be able to provide consent documents and refer to Trial Buddy Advisor
- Call center needs to be able to stay with the patient until "hand off" to the clinical site. Help patients understand available "spots" at the open sites. Let us reserve a site that is conditional on arrival (it would reopen after a period of time – a week or so).
- If there is travel required Call Center should be able to refer the patient to a travel agent who can provide Lilly discounts and arrange special needs travel.
- Don't forget the doctor!
    - The call center needs to be equipped to help the patient's oncologist
    - Often the HCP providing the primary care/oversight doesn't have deep knowledge on clinical trials or a specific trial. They need information too.
    - IDEA: provide a hotline call center number for physicians to talk to scientific leaders of clinical trials. Enable them to better understand the study, its merits and how to consider if a patient should participate in the study.
    - Is there an email that allows for a dialogue between the investigator and the potential patient to answer questions quickly

ISSUE 2: Patient Education about the Trial Participation Process

- We like the direction of the Trial Buddy Adviser to help patients deeply understand the study. But it is more than the patients. The main suggestion was to also provide information that might be needed by the caregiver.
- For example, in a serious disease like cancer, it is common that the patient will need to stop working and might lose their insurance. Their spouse often is the only income generator in the home and has the insurance. If the study puts a heavy burden on the caregiver to be away from their work, it jeopardizes the whole family in terms of income and potential risk of losing a job/insurance.

    - IDEA: In Trial Buddy Adviser, have both logistic/impact information for the patient AND the caregiver. Example: Patient will need to be hospitalized and monitored for 48 hours. Caregiver will need to stay with patient during this time and have a hotel. Or, the patient may be able to go home, but will need to be monitored 24/7 for a week for potential adverse events or complications.
    - One step further past the scheduling and timeline, scheduling and appointments for the caregiver. Things like on the second trial visit, you'll need someone who can drive you and be with you for the next 24 hours.

ISSUE 3: More Access to Promising Early Phase Drugs

For serious diseases the number of slots for promising early phase treatments is limited-both in number and scope. If we want patients to think of clinical trial participation as part of the continuum of care, increasing access to trial slots is important. ALL IDEAS WERE BIG CRAZY BLUE SKY IDEAS. But we did try to keep in mind what could be done without slowing down the approval process, without causing the drug developer unreasonable cost or liability, and what might be possible under the FDA.

- BIG IDEA: Design studies that meet the core study (approval) goals, but have an optional arm for patients with more advanced (less exclusion criteria) disease. Consider creative options of partnership with patient advocacy/non-profits/individuals for funding and support of additional arm. Decouple the timing of the additional arm from core arm (possibly second study?) so that they product can still move forward as quickly as possible for the initial indication approval.
- INCREASE REGISTRY OR DATA COLLECTION FOR OFF LABEL USE OF SERIOUS AND RARE DISEASE: Examples-a registry for metformin use as a cancer chemo-preventative. Registry for off label use of cabozantinib for RCC. The goal is to reduce "lost" information that might speed drug development and change clinical use patterns helping to identify trends that might be promising enough to pursue in more formal trials.
- CRAZY BIG IDEA: Most Phase 1 drugs are shelved after phase 1 safety testing. One way to increase the number of Phase 1 clinical trial slots would be to offer a "sharing agreement" for early phase drugs. The agreement would allow a small company or research entity to take over the liability and clinical development of the drug. If Phase 1b and II testing showed a drug with potential for market development, then Lilly would retain rights and profit sharing if a drug moved into late phase development. The goal is to keep more Phase 1 drugs in development.
- Patient Cost Sharing for trial participation. Patients presented this as a possibility for expansion of early Phase access. While this might be criticized as "not fair", the fact is that it could be used to increase early phase development and it's a model widely used in other areas of medicine. Examples include: Stem Cell Clinics, Infertility Clinics, Plastic Surgery centers. Once again the goal is to keep more Phase 1 drugs in development.

    - Note: These alternative, patient-centric clinics in other areas of medicine tend to take a “customer” point of view with high-touch service. Examples include assistance in pre-screening/fit and even financial assistance models-these techniques could be adapted to standard or self-pay trial models.
- Crowd source or go to disease specific groups and ask what kind of eligibility criteria would be helpful.
- SmartPatients ‘notebook’ feature where expert patients could presort and annotate trials.
    - IDEA: use the tagging system (by trial, disease, etc…) to better understand the key issues from a patient point of view for studies.

Group 2 – Joining a Clinical Trial

- Informed consent process may be iterative.
- Consider example like Pinterest’s terms of service, where the full text is on the left and the simple 1 sentence distilled version is on the right. Makes it easy to read for those reading it and covers the legal side as well.
- Fair Information Practice Principles:
    - Notice/Awareness
    - Choice/Consent
    - Access/Participation
    - Integrity/Security
    - Enforcement/Redress
- Reorder the content – put important information information for the patient up front, legalize at the end.
- Give the patient control over the information – dynamic and granular. Enable choice around what is shared and how.
- It’s a matrix: severe disease to mild disease; so it’s granular choice by nature (people in a disease such as cancer and ALS may care more about getting involved and getting results more so than how their information is shared.)
- Informed consent may be progressive.
- Consent form is a “cover your butt” perspective. In other cultures it works well not to have a ton of consent documents, in the United States not so much. Requires a shift away from a primarily legal construct to an “informing the patient” construct.

Group 3 – Social Media For Pharma

- Net net: the challenge put to the pharmaceutical industry, more specifically the individuals who work at Lilly. Start investigating and looking at what groups exist out

there, what communities exist, and then take a step and start interacting with them and find out what would be of value to them. You're not representing Lilly, you're representing yourself. Share why it would be of interest/value to join that group and then, be yourself in that group.
    - Example: People were here because of Jerry, not because of Lilly.
- Educate. Recognize that the employees get the brand. Share your passions and your limitations.
- Lots of different channels, platforms, etc. It's like ice cream – it's all ice cream, just different flavors. Try not to be afraid of the platform but rather embrace it.
    - Example, patients helped the pharma expedite the process. They did and saved over 2.5 billion dollars, and pharma never gave them a thank you.
    - Examples of who does it well and poster child on who to emulate?
- The advocates can tell whether someone is authentic, real and in it for the right reasons – and who is not. You could get so many participants by going through that "one right" person.

Group 4 – Patient Initiated Trials

- Step "A" before Step 1: A way for a patient to help them identify a hypothesis. Coming up with an observational research model that would lead to that hypothesis (quantified self, etc.). That hypothesis would then become the study engine and would lead to or trigger investigator-initiated trials.
- An example, pricing for tests and operations, etc.
- "I've got a thing I want to study. You're gonna help me." Sort like "GitHub."
- Pharma can help by helping patients understand.
- Walgreens using the pricing structure that someone could walk in and use. Saying "We have this….can you help us with this?"
- Having help creating their own clinical trials.

Group 5 – Getting Support While In Clinical Trials

- The more ability to live your normal life while in a clinical trial, the better.
- Liked the idea of the trial app
    - Tell us about the type of test you're going to be having (i.e. you're getting your blood drawn tomorrow, so drink a lot of water today; or your eyes will be dilated so bring someone to drive you home.)
    - App and the video to help.
    - Reminders to take medicine (text, pop ups, alerts, etc.)

- More patient-friendly medicine. Ex: a trial ends and the drug gets put into a package that's hard to use.
- Training put on YouTube, particularly once it's public
- Be very conscious when you're getting your meds what that entails: example, a patient receives a 3 month supply and takes up half their refrigerator
- Could it be Walgreens or does it have to be your primary care physician that you can go to and get your blood drawn?
- A process of getting un-blinded once the trial process was over and how can you get more additional information about the trial after it's over.
- Concept of "rating" the trial
- Surveys during the trial. Similar to Traitwise, a live service feedback platform.
- Way to access 1-800- number or the clinical trial site.

Group 6 – Integrating Into Everyday Lives

- Clinical trials don't integrate into patient's lives right now.
- Patients often aren't consulted on how CTs can be better integrated into their lives.
- Thinking about the multiple patient journey being visible during that patient journey, having the CT being visible to their pharmacist, doctor, etc.
- Taking the trial to the patient. Example: quantified self or people sending out study nurses to their home. Technology solutions are good but it may just be a solution that changes your thinking and how a trial should be run.
- We tend to only talk to patients when we want them in our trial, we usually don't talk to them before. On social media, you don't just go and make the ask of someone. It's really about having the conversation and talking with them and building the relationship. So talking with patients before they enter a clinical trial and being honest/transparent with them.
- Protocols being better at integrating into their lives.

#PACCR Reports from Symplur

Analytics

Transcript

PACCR Presentations

Tom Krohn's presentation on Lilly's Patient Engagement Initiative:

https://www.slideshare.net/slideshow/embed_code/28888735

Kevin Hudziak's presentation on electronic informed consent:

https://www.slideshare.net/slideshow/embed_code/28889038