LEC 2015

Thursday October 1, 2015 10:00 AM – 12:00 Noon

Discussion of Trials/Studies – Paseo Room

Gary Rosenthal

- Who: Site PIs
- What: There are already a number of research studies being conducted across the GPC, and to make sure that all of the sites understand their responsibilities and have the opportunity to discuss institutional problems, the lead person from each site (called the Principal Investigator) will meet.

Barohn, Parker, Brad Taylor, Bill Barnett Indiana, McClay, Umberto, Statland, Alfredo, Michelle Coady, Brad Pollock, Greenlee

On the phone; -

Time to discuss issues on implementation of trials. Time to look back – brainstorm.

2 main goals – Update on studies on-going and look at opportunities down the line. Use discussion to take a global look – going well, not going well, challenges, what could we do better – engagement, understanding, align with PCORnet with Institutional agendas.

Brief introductions;

Coady - Constantine will be PI for Phase II. PCORI funding and get the name out there.

Statland

Parker

McClay – PCORnet problem – what they are all about – not well defined – needs to be the organizer of the thought process!

Barohn – Haven't really used PCORnet for patient recruitment – issue with the PAINS trial – may be shut down. IRB issues at most of the sites. Reliance agreement did not work. Not what they agreed on. They agreed on GPC simple surveys not high risk!

Alfredo – IRB issue. Inter - CDRN studies.

Brad Taylor – CTSA just got refunded. Helped greatly in network infrastructure. Member of many networks. Need model to sustain infrastructure post CTSA – GPC world.

Bob – Site PI side and Engagement side. Defined populations – challenges in terms of data completeness.

Pollock – Davis. Works with pSCANNER folks in CA. Leads Network Collaboration on their CTSA. On the Design Team that drew up the ADAPTIVE trial.

Gary – one of the big challenges is the very broad mandate that PCORnet took on. Engagement – each stakeholder has their own set of criteria. Today – reality testing on how we go about this. What are the tactical things we can do.

Umberto – Phase II proving to be a game changer for them. Seeing every day or another – data exchange – how do we go beyond that? Sustainability and/or scalability. External and internal demands on our resources. Prioritizing is becoming a new business for us. I2b2 is proving insufficient to cope with the volume of requests. Need to use much more than that on a regular basis. Funding an issue then. Marketing and synergy with CTSA and CC proving to be very powerful! –ve comments on using multi funding sorces to fund the infrastructure. Involvement of Clinical leaders is critical. New branch of technology with EHR functionality. Planning on the fly so to speak.

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Clinical trials on-going – that most of the sites are involved in. Financial perspective – only way to maintain central infrastructure – robust pipeline of studies that can help/support the infrastructure.

Phase I – we made a lot of progress. Requirement to maintain the validity and reliability of the data being collected.

Discussion of issues regarding ADAPTABLE.

- Research regulations. Informed consent process. Is it a minimal risk study?
- Implementation of the Common Data Model.
- Clinician integration

Overview of the trial.

Goal is 20,000 pts enrolled & follow for 3 years. PRO.

$10 mill vs $75 - $150 mill for similar patient cohorts in other disease states.

Sites will be reimbursed on a per pt basis.

~ $210 per patient

Budget constraints by PCORI

Was a “middle dose” discussed. Yes. No evidence out there on the best dose.

Minimize disruption of clinical workflow. But must have clinician engagement.

Patients eligibility based on the computable phenotype from the CDM. Could not rely on detailed investigation of the EHR. The hope was that 95% of the pts will be able to be recruited on-line. Still relies on providers recommending the trial to their pts.

Who is the ideal PI for this study? GPs, although the cardiologists have to be interested in the trial.

Not a rolling accrual. Enroll immediately by using the EHR.

So where are we? Vanderbilt will review it for IRB. Then use IRB Share – 45 sites within the 7 CDRNs. Not all of our sites have signed the IRB Share agreement. We are going to use our IRB Reliance and go thru Iowa as lead site. Currently waiting on the Vandy IRB review.

Addendum: On the Steering Committee call on October 6th, it was announced that Vanderbilt will not conduct an initial review and that the reviews would begin with the CDRN reviews after the protocol is finalized

One sticking point is the Informed Consent on the Trial site. PCORI wanted a common document – with local specifics included. If it is defined as a minimal risk study, some of the HIPPA and Indemnification language would not be needed.

There will be some flexibility to work on the eligibility criteria at the individual CDRNs. Coordinating center willing to make some compromises to get the trial up and running.

Implementation of the CDM. Now on version 3! Still working on Version 1.

Bob described the CDM. CDM equates to a data dictionary. Jim had the PCORnet CDM Version 3 on the screen.

We all render the data in i2b2. Have to put it into SAS. Then each site would need a SAS licence. SAS is free to Academic Institutions. There are some data elements missing because our i2b2 is not keeping up with the CDM.

CDM variability across Institutions – there will be!

- What are different sites doing for Clinician Engagement?

  Iowa - Cardiologists & 2 main Primary Care groups. Meetings are on-going. Concern over clinical workflow disruption.

Study coordinator funding? Someone needs to go in and do the "dump". GPC ADAPT Committee – will have to focus on the implementation of the details.

Budget for PT reimbursement.

GPC FTE – shared between KUMC & Iowa?? Central resources are not great.

It is clear that these PCORnet trials are not going to be money makers! Need to make sure we don't go bankrupt!

PCORI wants to show how well they have done to impress Congress with their impact – 2019!!

How do the participant institutions integrate the GPC to show their worth? What is the worth to them?

Strategies for clinician engagement? 2 pager for ADAPTABLE. Anything else?

Connecting across the campuses.