

LEC 2015

Friday October 2, 2015 10:45 AM – 12:00 Noon

Sustainability and Terms for Commercial Use for Data Access & Data Use – Session I

Brad Taylor & Amy Sokol

- **Who: Patient Engagement Officers, Patients, Cohorts**
- **What: Brad will describe some of the ideas and directions the GPC may take with the data that has accumulated.**

Attendees:

Berniak, Huang, Gravlin (Cerner), Liu, Prittie, Nathan, Fothergill, Albright, Gyore, Montgomery, McClay, Dominique, Bhargav

Sustainability and Commercialization are very integral topics. How do we engage with commercial entities. Support for our Junior investigators. Where do we find the resources to sustain.

4 buckets – GPC, PCORI, the PI and the Institution. Commercialization fits into all of these.

Commercialization – what is it in relation to the GPC?

Interest from stakeholder groups.

- Montgomery - Cardinal interested in Outcomes comparisons. Interest in the improvement of care and access. Ultimately interested in the complete picture. Publication ultimately.
- Dom - Market research – physician preferences. How dynamic the environment is. Perception of value and choice.
- Continuum of data needs.
- Can't sell our data as an Academic Medical Center!
- External entities use of the data? Separate data use agreement
- Cardinal may have data for the GPC to use.
- Payers are the most difficult stakeholder to work with.
- KUMC/GPC has the ability to lock the data to prevent sharing if need be. Can choose to opt out of any agreement.
- Interacting with industry – they might provide the expertise that we need to process huge requests. Not having the talent in house.

Amy - Barriers from the Medical Center's POV. Data concerns from the pts. Data different from "biospecimens".

- Must have restrictions on further use.
- Legal structure restrictions, controls
- Competition
- NY POV – charge to an unaffiliated academic medical center
- Important to write this into grants – needs a checklist – similar to what we do for the use of the CTSU
- Pay for use – dollar requested covers cost to use the servers, the o and m costs, FTE cost – this is what Brad does at Medical College of Wisconsin.

Commercial Engagement

- Standard bill rate
- Fee structure – a blended rate across the GPC network
- One model might not work for all
- Intellectual property considerations – what if we discover a cure to a specific form of cancer?
- Publication Rights – specify in advance
- Markets
- Need to consider these when coming up with an agreement, or writing the playbook.

Will the individual Medical Centers use this data to improve their “level of care”?

GME would like to use the data.

Use of data inter-institutionally – central line management

Flip board notes

a. Valuation – completion of data set

- Health economics
- Market share
- PT. recruitment – identification, management, protection
- Perceptions – pt, provider, c-suite
- Time changes
- Preferences – PT, provider, c-suite
- Non-profit vs for profit entities
- Talent sharing

b. Industry sponsored research

- Trust over time
- Focus on the asset – “Data”
- Does the GPC become a separate organization? – enter into business agreement, has a valuable asset

c. Sustainability \$\$ where does it come from

- Pay to play – fees – sliding scale
- Micro grants – determine value
- Taxes – Deans
- Where does the money go? DTROC, IRB, contracting, surveys, infrastructure, study coordinators, honest brokers
- “Cover costs” (plus small margin)
- Who collects the money?

- What “business” are we in?
- New Grants – How to use GPC to get the Grant

d. Commercialization

- What is it?
 - Risk Tolerance
 - Ethics
 - Privacy rights
 - What does de-identification mean? Really?
 - Valuation
 - Who can contribute data?
 - Intellectual Property Considerations
 - Publication Rights
 - Markets?
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Friday October 2, 2015 1:00 PM – 2:30 PM

Sustainability and Terms for Commercial Use for Data Access & Data Use – Session II

Quick refresh

Attendees:

Intros; Ann Lucas, Tim Green, Sue Rodgers, Warren, Dan, Russ, Bhargav, David Gwynne, Pollock etc.

- Pt POV – How does a non for profit contract with a for profit organization? What about any profit?
- Is a license agreement an option for the use of our data?
- What is PCORI’s long term view of this?
- Have to support our junior investigators to do research
- Should be value based pricing not cost based pricing! Cost based for institute, value based for industry.
- PT POV – are there some uses that are more valuable to PT than others?
- Comparison of trials based data vs real world data. Industry – Cardinal are very interested in the real world data!
- Outcomes research data – pt. data has tremendous potential which is seen by industry
- IRB responsibility to protect the pt’s POV
- Good uses v bad uses. It’s a perspective thing. Pt can’t opt out of having their data in the GPC.
- Compare Drs. A to B to C and their pts response to care
- Pts could use the data to select a “best” health system
- How do the pts get to see what the benefit of the data usage is? There needs to be a continuum of information – the need for the PEO!!
- DROC has been set up. Tamara leads this – reviews any requests – participation of other GPC sites.
- Could offer this to a for profit entity.

At the moment there are 3 types of requests

- One type is Prep to research counts – a read only
- 2nd is a de-identified data set
- 3rd is a limited data set

Considerations/Comments

- ~\$1,000 for a network wide search
- Must have an agreement for the researcher to be an Ethical Steward.
- As an example, the receiving non for profit people make the holy grail, using the GPC data - the GPC is very happy?
- A research data question – result is a publication. All in the use language – on the website – for the non for profits.
- Within our network, all sites have signed the data sharing agreement. Any researcher at one of these sites would be bound by the agreement.
- Thoughts on sustainability included in GPC Phase II application.
- GPC has the ability to accept credit cards or checks.
- Need an a la carte menu for services.
- Might need to scope out an individual project on a case by case basis.
- Need to do better to generate an estimate on people's time to do the various jobs they have been requested to do. For e.g. for the 3 cohort surveys, 5% of a coordinator's time over 2 years. This was never budgeted for!
- Unfunded PIs in the network do not have the \$\$ to pay for a data request
- Level of review – Scientific review – would you want a pt on this sort of review?
- Foundation model – 12 partners pay \$10 K to keep the GPC running. Sites would expect to get revenue back from trials.
- This is in the GPC proposal
- Modified foundation model. Discounted rate for those who are willing to have their data shared.
- There should be enough activity through grants and trials to sustain a % of the GPC.
- The F&A associated with the grant could be used to fund/directed to the GPC.
- You are the indirect for their grant!
- Brad Pollock has a “charge menu” from something he was involved in. A bundled service charge that they add to their grants.

Follow-up/moving forward items?

- Ideas for a demonstration project to bring industry in with one or more of the GPC sites – apply for a PCORI grant.
- Amy is keen to have all of the site's legal counsel involved in the development of all of the sustainability and commercialization ideas.
- Brad to gather the site fees for all of the various services.
- For a large multicenter trial, need to figure the budget – at KUMC the RI would do this for us.