University Industry
Demonstration Partnership

Session 7:

Managing Confidentiality, data sharing

Marla Gorges

Associate Director, Health IT Extension Services

I3L General Operations lead

Enterprise Innovation Institute

Georgia Institute of Technology

October, 4-5, 2016

Background

- Consortia is a membership-based Health IT sandbox: The Interoperability & Integration Innovation Lab (I3L)
- Located in Atlanta – virtual and physical presence
- Start-ups, established electronic health records (EHR) vendors, public health and policy orgs
- A “first of a kind” in terms of organizational structure within a University setting
- Role of the I3L “Objective Convener”
- My Role: “Helping to Make it Work in a University” – Contracting, IP, Faculty Resources, Cross-Campus Accounting Systems / Finance
- EDA grant and internal investment funded – 4th full year in progress and on the way to sustainability

Confidentiality

- University's need to publish:
  - Pre-publication review and comment period: Extended and flexible for "first to market" industry players
  - Projects contract for first multi-year mover was structured to align milestone deliverables with pre-publication completions / reviews

- Industry's need to protect all IP and the confidentiality of some components of the research project
  - Confidentiality terms have been negotiated from standard for regulation-heavy industries; mark-up and NDAs (individual and institutional) are of prime importance – has student participation and client market and trade secret implications
  - Patent, trademarks, know-how and copyright protection: Start declaring early and ongoing: These things are not always obvious for "first of a kind" proofs of concept
  - Extra pre-publishing member / client review is accommodated for IP protection (and what we think will need to be protected)

Publication

- Industry needs to be thoughtful about sharing its proprietary information, yet it must “reveal substantially *all*” for the research to translate to product / process innovation

- University should and does allow Industry partners extended review: In the case of our biopharma partner, the publication review process is coordinated by their Communications team to ensure IP and trade secrets protections – requires flexible Principle investigators and contracting team

- Industry must be able to designate its information as priority and confidential to the Industry – this is of critical importance!

Process for establishing the confidentiality protocols

- Data Use Agreements are driven by ownership of the data, cost / pricing, degree of necessity for deliverables and member preferences; in general, University would like expanded data sharing privileges that industry may not be able to grant
- In our world, data is ultra-sensitive: It's healthcare data. We are normally a third party, bound by a TPA on behalf of the member / client
- Confidentiality is relatively harder to control in an educational environment; the Institution has to be flexible. Upside: Excellent 'real world" training for students on business case confidentiality
- I3L Agreements are never fully standard (except for a few start-ups)
- Data management, storage and access protocols took time to develop for layered reasons: Nature of the business (healthcare), nature of the steward location (Good hackers want to hack GT), nature of the data (PHI, limited, de-identified, synthetic) and nature of the projects: Bifurcation between repositories for multi-party research and project-purpose only data

Process for establishing the confidentiality protocols continued…

- Data is shared and access is allowed to the extent possible for researchers; a trust and benefit relationship precedes wider sharing for faculty research beyond sponsored projects
- We “Walk our Talk:” Healthcare Data comes in multiple categories (HIPAA): synthetic, anonymized / de-identified, Limited and PHI. De-identified data for sponsored research projects is mapped in accordance with emerging federal standards changing healthcare interoperability, as we advise members / clients to do.
- Informatics infrastructure development - an ongoing process. Donor level members helped with synthetic datasets. We worked with early partners such as CMS and Childrens to obtain valuable research datasets and design “overprotections” for them such as a HIPAA entity would have to comply with
- The University environment checks and balances ensured multi-disciplinary approvals and the IRB protocols required for faculty and industry-sponsored research reinforce “overprotection” of data

Process for establishing the confidentiality protocols continued…

- There are data stewards, administrators and PI's; the inability to be the data manager or steward if you are the investigator is a check and balance healthcare data security is a hot topic!

- The client culture and the institutional culture align through experience and time and TRUST is paramount (in healthcare we are all figuring it out together)

- Absolute key to progress milestones is managing the natural, desired tension between faculty / P.I. academic researcher work patterns and deliverables attached to effort levels, i.e. project dedicated time and institutional shared resources, human and otherwise

Lessons Learned

- Data operational protocols will always take longer than you think they should (weigh in organization risk propensity)
- IP is possibly the greatest industry “stickler” – ownership, asset booking, defining: It’s way more choppy under the water’s surface
- Every time will be the first time, at least for a while – patience is not only a virtue, it’s a necessity
- Both industry and faculty will have to compromise: Neither culture can “win” on contractual Ts & Cs and Language of Agreements
- Approach it as a partnership and be a dedicated financial fiduciary

Thank you!

Marla Gorges
Associate Director
Health Information Technology Extension Services
Enterprise Innovation Institute
Georgia Institute of Technology
706 338 5023
margaret.wagnerdahl@innovate.gatech.edu