**Nick Bryan Interview for ITCR SIP WG**

**10/15/19**

CD: There needs to be a need on the clinical side. What tools are most needed in the clinic?

NB: New computational techniques are developing very powerful image analysis tools. Tasks range from measuring volumes to differential diagnosis. There will be continuing growth in the number of algorithms that are developed and validated on the research side. Challenge is how to effectively bring them into the clinic.

At Penn, we felt we had developed tools that could be useful in the clinical setting. But now, they don’t use any tool that is not commercial (a very small number of exceptions). Financial, regulatory, operational – these are the drivers. This is why he started a company (not to make money). Since then, this has become easier to do. But the reality is that commercialization is required for it to be used in the hospital. As a rule, this software is classified as a device and the FDA is putting out new guidelines for dealing with this software. This is not a trivial or inexpensive task to go through the FDA.

CD: Would like to sustain in the academic community as well. Strong OS atmosphere. How do you see this synergistically working? Can you have a commercial and a research arm to a software project?

NB: Need to have a feel for what it takes to go through the commercialization route. If not, how do you support, distribute, and maintain a piece of software to be used in the clinical environment?

AS: Examples include Slicer, XNAT. Grant mechanisms have supported these project. Context is important. Software that has a strong research bias can be maintained this way. But agree, there’s not a consistent mechanism.

NB: Yes, completely agree. But, what do you mean by “use clinically”? Yes, this software is well maintained and widely available. But the results of the use of this software is not used in the clinic. The output is not put in a clinical report.

GS: Right, software has to undergo FDA approval to be fully vetted for clinical use.

AS: No, this is too broad of a statement. The nature of usage is important. Ex, XNAT can sustain work at the university without FDA clearance.

LC: There are LDT’s.

JS: Yes, agree. FDA put out specific guidance on this in the last couple of weeks. Very readable, easy to use guide on this. Analysis that is post-contact with the patient, for example, is not in their purview.

NB: Within an institution, if you have developed a lab test, software, algorithm, you may use it. if you take this through an IRB and use clinically in your institution. But, you cannot disseminate to another institution.

JS: Yes, this is the guidance I am referring to. This is guidance was issued in the past few weeks. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-decision-support-software>

NB: Very important. The FDA is continuously updating their guidance in this area because it is changing so fast. Dealing with the FDA right now. Moving target. When you move the device beyond your site, people start asking questions. There is a form where you document that your software is not covered by the FDA.

AS: We just did something similar. We submitted an application that has the quality of a good manuscript. A lot of work but we found the FDA staff to be very approachable.

NB: Agency is doing its best. Submission is not trivial. The amount of work is well beyond what most people have done. To broadly disseminate this software is not trivial.

CD: If we assume there is a commercialization arm and an OS arm, can they co-exist? You want to encourage researchers to contribute so that the technology improves. Is this feasible?

NB: It is straightforward to incorporate OS software into commercial products. The company using the OS software needs to make sure it is maintained at the commercial requirements. To make a change in the FDA-approved product, the change process is very explicit. But puts a burden on the contributor. There are OS products that do this. But it costs money to maintain this software.

CD: Could you see the industrial partner picking up this work. Example: ITK

NB: Where the large vendor provides the basic software, small companies can develop a “widget” (specific task). Vendor provides guidelines for app to join their platform. Most are still trying to figure out what the rules are. But backing off and saying they must document that it does not have to be FDA-approved. This is an area undergoing a rapid evolution. It’s going to take time to sort this out. But, could the NCI play a role here? If there is a multi-site clinical trial and we have a software tool that measures something. Research project, under IRB, could the NCI support that software as part of the research project and allow it to be extended?

MB: Idea is sustainability, not who pays for it. Don’t agree that you have to commercialize to put in the clinic. NCI can only carry tools for a finite time – 10 yrs at the most. What do you do next? Example: Our de-ID tool was funded for about 10 yrs through NLM funding. Very popular. Copyrighted it and de-ID Data Corp licensed it. Most ITCR tools are for use in the research community. Not a completely binary question.

GH: We initially formed a 501c3. Did find that some companies contributed source code but none contributed funding. Ended up folding the non-profit and kept the working group.

NB: These are all very good examples of working around the usual commercial model. The realities of the not-for-profit is not trivial. Sympathetic about what you are trying to do. On the clinical side, not many alternatives. Research side is clearly different. How far do you go on the research side before you want it to be used clinically. You’re going to have to deal with this. Only 25% of the code is what you’re going to be using many years later.

CD: Right, this is the challenge. If we assume a partnership between academia and industry, how do you see this working best? Earlier or later involvement?

<JK called dropped for a couple of minutes>

GS: Talk about IP rights?

NB: Good question because it involves the home institution – they are often a major player in this process. University owns the IP for commercial purposes. PI can publish. Once PI has published, commercial value has disappeared. But if the investigator might want to commercialize their IP, they are obligated to disclose to the university. Now things become murky. Different universities TTOs handle this differently. University may spend $ to patent the rights. IP is a major factor. When you publish, commercial rights disappear but dissemination increases. Getting companies to partner is difficult.

JS: Key success factor: If it looks like vendor software (support services), people are willing to take it on. Traverse from research software to hardened support software, it’s about becoming “vendor-like” including security reviews, answer questions from the FDA, etc.

NB: Agree with this – software has to be vendor-like and that’s not easy.

GH: We built the platform for ourselves, then others wanted it. So we re-wrote from scratch to have a commercial-grade product. We collect fees for usage. Challenging to do licensing with other institutions. Ex, spent a year licensing to a Texas institute and just couldn’t get past the Terms and Conditions. University not willing to take on the risk. But we have been able to generate revenue that we put back into to our own development. Multiplier effect. What does NCI think about commercialization?

JK: There is not a one-size-fits-all model of sustainability. This workgroup is about exploring many paths, documenting successful paths, and providing options.

NB: Not trying to push the commercialization approach. In some ways, doesn’t work very well. Not necessarily the best approach. But want to find ways to distribute valuable academically-developed software.