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Sustainability Through Technology Licensing and Commercialization: Lessons Learned from the TRIAD Project

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Abstract
Ongoing transformation relative to the funding climate for healthcare research programs housed in academic and non-profit research organizations has led to a new (or renewed) emphasis on the pursuit of non-traditional sustainability models. This need is often particularly acute in the context of data management and sharing infrastructure that is developed under the auspices of such research initiatives. One option for achieving sustainability of such data management and sharing infrastructure is the pursuit of technology licensing and commercialization, in an effort to establish public-private or equivalent partnerships that sustain and even expand upon the development and dissemination of research-oriented data management and sharing technologies. However, the critical success factors for technology licensing and commercialization efforts are often unknown to individuals outside of the private sector, thus making this type of endeavor challenging to investigators in academic and non-profit settings. In response to such a gap in knowledge, this article will review a number of generalizable lessons learned from an effort undertaken at The Ohio State University to commercialize a prototypical research-oriented data management and sharing infrastructure, known as the Translational Research Informatics and Data Management (TRIAD) Grid. It is important to note that the specific emphasis of these lessons learned is on the early stages of moving a technology from the research setting into a private-sector entity and as such are particularly relevant to academic investigators interested in pursuing such activities.

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Sustainability, Data Management, Infrastructure, Commercialization

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ABSTRACT

Ongoing transformation relative to the funding climate for healthcare research programs housed in academic and non-profit research organizations has led to a new (or renewed) emphasis on the pursuit of non-traditional sustainability models. This need is often particularly acute in the context of data management and sharing infrastructure that is developed under the auspices of such research initiatives. One option for achieving sustainability of such data management and sharing infrastructure is the pursuit of technology licensing and commercialization, in an effort to establish public-private or equivalent partnerships that sustain and even expand upon the development and dissemination of research-oriented data management and sharing technologies. However, the critical success factors for technology licensing and commercialization efforts are often unknown to individuals outside of the private sector, thus making this type of endeavor challenging to investigators in academic and non-profit settings. In response to such a gap in knowledge, this article will review a number of generalizable lessons learned from an effort undertaken at The Ohio State University to commercialize a prototypical research-oriented data management and sharing infrastructure, known as the Translational Research Informatics and Data Management (TRIAD) Grid. It is important to note that the specific emphasis of these lessons learned is on the early stages of moving a technology from the research setting into a private-sector entity and as such are particularly relevant to academic investigators interested in pursuing such activities.

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Introduction

As has been noted in a variety of reports and publications, the funding climate at the local, regional and national levels for healthcare research continues to undergo significant and systems-level change[1-3]. As a whole, the climate for individuals or teams of investigators wishing to pursue and successfully secure extramural funding to support healthcare research projects is one of the most competitive in several decades[4]. Given this competitiveness, increased emphasis has been placed on ensuring that projects being funded have both: 1) direct clinical actionability (e.g., the ability to positively impact the health and wellbeing of individuals and/or populations); and 2) that the commitments being made to those projects are not open-ended (e.g., that projects have a sustainability plan such that durable research products or activities can continue beyond the scope of an initial funding period without the need for a subsequent or follow-up research contract or award). This later objective concerning sustainability is particularly acute in the context of data management and sharing infrastructure that is developed as part of such funded research programs, given the frequent need for ongoing support and development of those technologies beyond the scope of an initial and funded performance period. This challenge is exacerbated by a number of issues, including:

- Situations in which such data management and sharing infrastructure has an indirect return on investment relative to clinical actionability. That is, the infrastructure enables clinically actionable knowledge and evidence generation that is in turn clinically actionable but, in and of itself, the infrastructure does not directly correlate with such translation into the clinic or populations.
- Obtaining institutional or other forms of sustainability funds for the continued operation of research-oriented data management infrastructure beyond the specific extramural contract or award time frame remains a "hard sell" to organizations struggling to address the new budgetary norms of the non-profit, academic and healthcare delivery sectors. This is largely because research is often perceived as a "luxury" in those types of settings, rather than a necessity, by both financially-empowered decision makers and over-extended clinicians at the point-of-care[5].

Given these challenges, the computational and biomedical informatics communities that develop and deploy research-oriented data management and sharing infrastructure have increasingly looked to alternative sources of funds for platform sustainability. These sources include, but are not limited to, technology licensing and commercialization (referred to as "commercialization" in the remainder of this article). Such commercialization efforts often involve the formation public-private partnerships that can manage and expand upon research data management platforms while simultaneously generating revenue from productization and sales[6-8]. Unfortunately, many important dimensions that may impact the success of such technology commercialization ventures are unfamiliar to individuals involved in non-profit and academic research programs, thus limiting access to this important sustainability model[8-10].

Given this gap in knowledge, the remainder of this article will provide a series of lessons learned from an effort undertaken at The Ohio State University to commercialize a prototypical research-oriented data management and sharing infrastructure known as the Translational Research Informatics and Data Management (TRIAD) Grid[11]. It is important to note that the specific emphasis of these lessons learned is on the early stages of moving a technology from the research setting into a private-sector entity and thus is particularly relevant to academic investigators

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interested in pursuing such activities. As such, a fuller discussion of the factors that may influence the ultimate success of the private sector entity created to commercialize TRIAD over a time frame extending beyond this initial technology licensing and transfer phase is beyond the scope of this particular report. However, given that such early stage commercialization activities present immediate opportunities for licensing, royalty, and equity-based revenue to originating institutions, even such early stage activities have a likelihood of immediate and measurable impact on technology sustainability.

Project Context: The TRIAD Grid

As noted previously, and for the purposes of providing a concrete example of how research data management and sharing infrastructure can be commercialized as a means of pursuing near- and long-term sustainability, an example project from The Department of Biomedical Informatics at The Ohio State University (OSU-BMI) will be utilized, namely the aforementioned TRIAD Grid. The TRIAD project represents a multi-year, NIH-funded program to develop, deploy and evaluate a service-oriented architecture (SOA)[12] for research data federation that spans traditional organizational boundaries[11]. It is a derivative version of the caGrid SOA that was initially created under the auspices of National Cancer Institute's caBIG initiative[13] in order to enable data sharing between and among NCI-funded cancer centers. The core caGrid technologies were designed to enable the sharing of syntactically and semantically annotated data, as well as corresponding analytical resources, via a Globus-based grid-services framework[14] that also includes shared capabilities such as (but not limited to) user management, common data element publication, service directories, computational workflow orchestration, and a variety of security services[15]. Building upon this technological foundation, TRIAD was created as a domain-agnostic variant caGrid, supported by funding from the National Center for Research Resources (now the National Center for Advancing Translational Science) Clinical and Translational Science Award (CTSA) program.

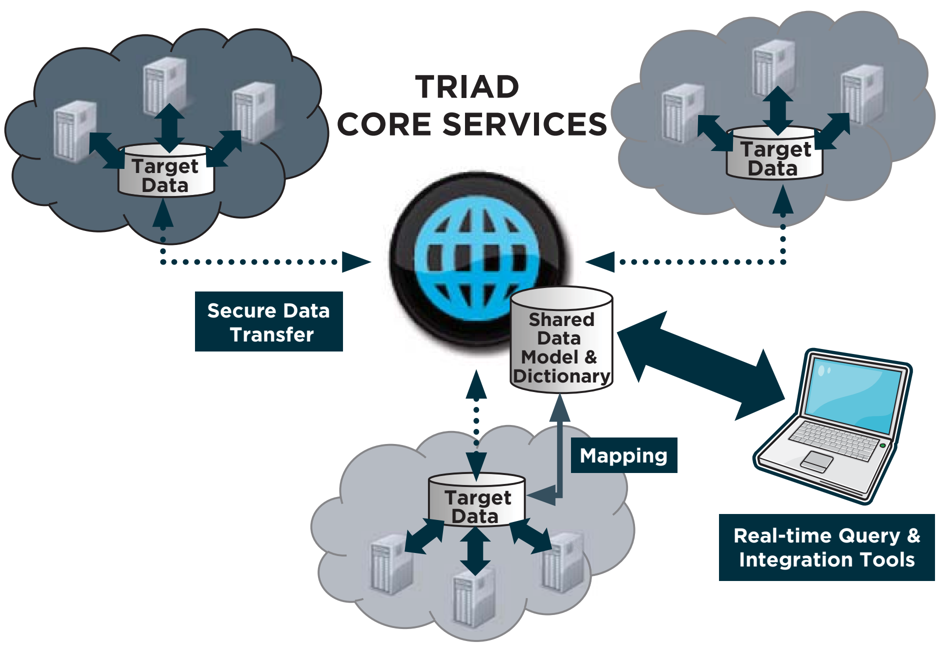
As part of these scaling and scope-expansion efforts, TRIAD was designed to differ in many ways from the original caGrid project, including: 1) its emphasis on peer-to-peer negotiation of "working interoperability" approaches to knowledge management and semantic interoperability of distribute data, as opposed to more costly and top-down "computable interoperability" paradigms; 2) the provision of easy-to-deploy data service "appliances" that utilize common data models and ETL tooling to enable rapid technology deployment; and 3) the incorporation of highly flexible data discovery and query applications the enable knowledge-worker driven access to grid data services in an extremely user friendly manner. While outside of the scope of this report, a complete enumeration of the differentiation of TRIAD from the foundational caGrid infrastructure can be found in several of our prior published manuscripts[11, 16-19]. Furthermore, a functional overview of the way in which TRIAD enables multi-site data discovery and integration is provided in Figure 1.

As the TRIAD technology stack has matured, it has been adopted and adapted by a variety of stakeholder groups and organizations, such as academic health centers, multi-site research consortia, professional medical associations, and private-sector entities. Further descriptions of the use cases and types of entities who have or are currently adopting and adapting TRIAD can be found in[20] and at the TRIAD community web portal (http://www.triadcommunity.org). Concurrent with wider use of TRIAD, the focus of development efforts has shifted from a historical emphasis on novel software architectures and components associated with a scientifically focused informatics research and development agenda towards functionality and extensions driven by end-user information needs. This shift has led to challenges in securing ongoing federal or equivalent research funding to support/enable the ongoing use of the platform.

In light of this funding gap, the TRIAD development team at OSU-BMI began to pursue commercialization efforts as a means of long-term sustainability. This effort has resulted in the creation of a partnership with a large private equity firm that has significant business development expertise. This relationship has in turn yielded the creation of a university spin-off company known as Signet Accel LLC (http://www.signetaccel.com) that will: 1) productize and market the TRIAD infrastructure for a variety of healthcare use cases; 2) use private sector monies to continue developing the platform; 3) provide access to downstream variants of TRIAD to members of the academic and non-profit research communities actively involved in scientific collaborations with OSU-BMI; 4) generate licensing, royalty and equity related revenue that will "flow back" to OSU-BMI over the period of multiple years[21].

At the same time, and in keeping with federal requirements, the agreement resulting in the licensing and transfer of TRIAD retains the ability of academic and non-profit collaborators to adopt/adapt the software outside of this commercial venture. In this way, the commercialization and sustainability of TRIAD can achieve a dual and synergistic benefit to both the academic/non-profit and private sector communities. When taken as a whole, this can be considered an important first step towards providing sustainability for the TRIAD platform. However, achieving this outcome was a major challenge for the TRIAD research and development team within OSU-BMI due to the numerous unknowns associated with the processes

Figure 1. Overview of the Functional Architecture for the Translational Research Informatics and Data Management (TRIAD) Grid Platform



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required to arrive at a successful commercialization initiative. The remainder of this article will discuss lessons learned based upon those experiences.

Lessons Learned "From the Trenches"

Building upon the preceding use case, we believe there are a number of valuable "lessons learned" that relate to the process of achieving technology sustainability via commercialization, particularly at the critical juncture during which technologies are licensed and transferred from academic laboratory settings to commercial or otherwise private-sector entities. At a high-level, these lessons can be organized around a linear model of commercialization consisting of four major phases, as illustrated in Figure 1 and described below:

Phase 1 – Proof-of-Concept

During the initial phase of research and development for a given technology platform, the ability to tightly couple driving problems with novel technical solutions is of paramount importance. While this may seem self-evident in the research setting, it can be argued that such a need is amplified when considering commercialization as a downstream sustainability mechanism. Specifically, and in order to successfully commercialize such a platform, it is imperative that:

1. The resulting technology have a unique or competitive advantage as compared to prevailing solutions in the same space, such that there is a perceived first-mover advantage when taking the product to market;
2. It is possible to articulate compelling and tangible user stories surrounding the use of the technology that will resonate with entrepreneurs and funders who may not be familiar with the targeted application area, such that an emotional appeal to engage in the commercialization of the product is created; and
3. Similarly, it is then possible articulate those same user stories in a manner that enables commercial adopters/adapters to recognize the target problem and how the technology may benefit them (even if they are not necessarily aware they have the same problem at the outset of such discussions).

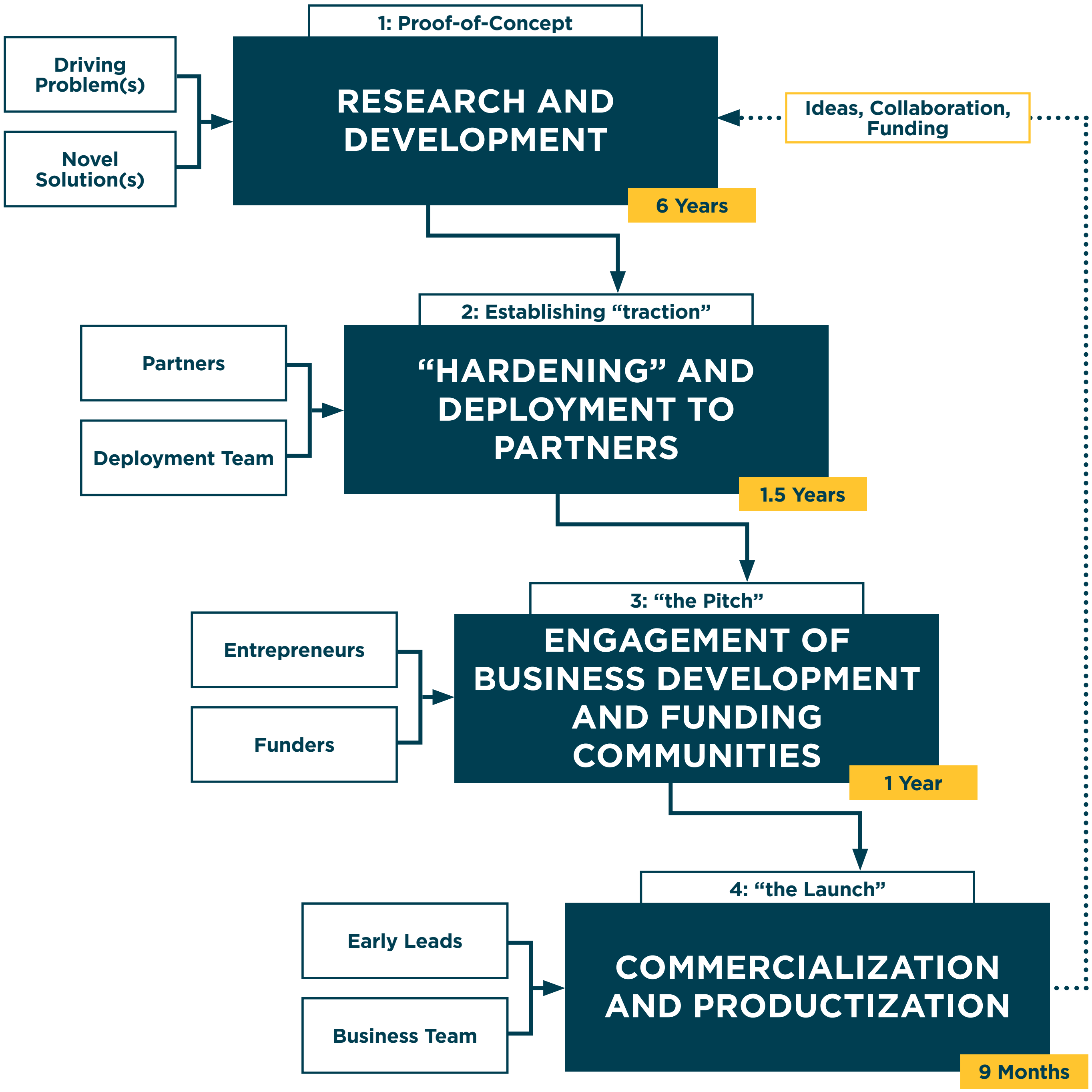
In short, *if commercialization is a goal for sustainability, it is never too soon to think about the stories you need to deliver to entrepreneurs, funders and potential customers*. If this facet of the work is left until later in the project lifecycle, it may be too late to build a reasonable evidence base to support such narratives.

Phase 2 – Establishing "Traction"

The literature discusses in great detail the commercialization of new compounds for pharmaceutical purposes and the importance of "de-risking" these compounds so that they are appealing to pharmaceutical and bio-technology companies[22]. While the stakes and acuity levels may differ significantly, we believe that there remain a number of similar principals that can be applied to software products. Individuals and organizations interested in licensing and commercializing software products generated in the research setting can and will ask critical questions during the initial evaluation and subsequent due diligence processes, such as:

1. Who are the "customers" using the software now?
2. What are their experiences with the software?
3. How much would they pay for this software or what is the equivalent value proposition?
4. How do we know the software performs "as advertised"?

Being able to answer these questions in an empirically defensible manner requires *research-oriented software developers to engage in*



This workflow shows important stages, relationships, and contributing resources or expertise. For each phase in this workflow, the key lessons learned, as described in this manuscript, are indicated. In addition, the approximate duration and timing of each such phase is indicated relative to the TRIAD case study to provide a frame of reference relative to the TRIAD use case being used in this particular report.

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informatics "translation" as their platforms mature, behave like a start-up company, and solicit potential adopters/adapters to contract equivalent types of relationships that generate revenue, and data that can in turn answer the preceding questions. In effect, this process creates evidence of market-based "traction" relative to the software in question so as to address concerns that may be raised by potential business development partners and investors (thus serving as an analog to the preceding "de-risking" concept).

Phase 3 – "The Pitch"

If you have successfully navigated through phases 1 and 2, it is then necessary to engage in "the pitch," a process that requires leveraging professional networks, technology transfer mechanisms associated with your institution, local incubators or business development entities, and/or local/regional/national influencers (e.g., faculty with prior industry experience). This networking is needed in order to get into the room (either virtually or in person) to present your technology and the business opportunity its commercialization makes possible.

Being able to do this also requires the formulation of a clear, concise and "business savvy" presentation that not only explains the technology but also articulates the targeted markets for commercialization, types of potential revenue, and resources necessary to build a company that can take advantage of this opportunity. In almost all cases, this requires the technology developer to partner with individuals who have expertise in the above areas as this type of presentation has almost no similarity to a prototypical scientific lecture or talk. It is highly likely that this pitch will be made dozens of times before a good partner is found. The term "partner" is used purposely here, because this process is as much about finding a willing entrepreneur or investor who wishes to build a business around your product as it is about making sure the personalities and goals of those individuals are compatible with the initial developers of the technology and their own goals.

If this type of match is made and discussions regarding licensing and commercialization move forward, there are additional important dimensions to consider and address, including the deal structure (e.g., the nature and type of licensing fees, royalties and equity sharing associated with the deal) and the licensing terms. Of note, licensing terms are of the utmost importance when considering whether academic or research endeavors surrounding a given technology can or should continue to occur in an integrated or parallel fashion with the commercialization effort. The specific details of such deal structures are beyond the scope of this article but can be found in a number of excellent manuscripts[6-10, 23].

Overall, the preceding factors demonstrate that it is critical for technology inventors to devote time, effort and cognitive capital to synthesize, communicate and actively participate in business development activities, in which they may not be otherwise engaged and/or familiar as members of a traditional research enterprise. *These types of efforts will not be successful if inventors approach commercialization efforts at arm's length; inventors must be an integral part of the business development team.*

Phase 4 – "The Launch"

Phase 4 of this process may appear to be the "final stretch" and in many ways it is. However, there remain a number of critical issues to be considered at this phase, including:

1. How do the academic or non-profit developers of the technology interact with the spin-off company or licensee in a way that is appropriate

and respectful of ethical, conflict of interest or commitment, and operational needs for both types of organizations?

2. In what ways do the funds from licensing, royalty and/or equity and potential new ideas for research and/or public-private collaboration come back to the units responsible for the technology such that all parties benefit from commercialization efforts and can leverage those benefits for the sustainability of the core technologies in question as well as derivative works?
3. How do the technology originator and the spin-off company and/or licensee collaborate to ensure that the staffing and resourcing needs of both organizations are met in a timely manner without negatively impacting either (e.g., managing potential attrition or transfer of staff between and among such entities as they work to operationalize their respective goals)?

Overall, as was the case in the preceding phase of this linear model, *technology inventors and key stakeholders representing all parties must engage in, and sustain, constructive dialogue intended to strike a mutually beneficial balance in all of the preceding (and many other important) dimensions of the commercialization effort "launch."* .

Discussion

The challenges facing the academic and non-profit sectors and their partners relative to the establishment and sustainability of research data management infrastructure are significant and wide ranging. One of those major challenges is how and in what capacity funds can be generated outside of traditional grants and contracts in order to sustain the long-term adoption and adaptation of such technologies. The pursuit of technology licensing and commercialization efforts represents a potential path forward. However, engaging in this type of sustainability mechanism requires that technology developers take measures and a well-informed approach to moving software from research to the market.

Despite what we believe are the extensible aspects of these "lessons learned," there are a number of important limitations to this report that should be noted, including: 1) our assertions are based on a single technology licensing and transfer experience; 2) specific data regarding the performance of the ensuing start-up company created as part of our case study cannot be shared for instructional purposes due to a variety of constraints (including non disclosure agreements and the protection of trade secrets); and 3) the long-term impact of this specific licensing and transfer arrangement (e.g., in terms of the operation of the planned public-private partnership over a multi-year time period) remains to be determined. However, we still believe that there is value in this preliminary report in terms of creating transparency and visibility surrounding important issues that all individuals pursuing such commercialization-based sustainability plans should consider during the early stages of such endeavors.

Conclusion

In the this report, a number of "lessons learned" from the initial licensing and ongoing development of a business intended to market and sustain a research data management technology developed by OSU-BMI have been presented. This discussion is intended to inform the types of questions that can and should be asked and answered when pursuing similar commercialization efforts, and to help fill gaps in knowledge concerning such technology licensing and transfer processes that may otherwise prevent academic or non-profit investigators from pursuing such initiatives.

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