Executive Summary

Realizing the Promise of a Digital Ecosystem for Science and Scholarship

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- The National Library of Medicine (NLM) joined the National Institutes of Health (NIH) in 1968. NLM conducts and supports research and training in information science, informatics, and data science. It is also the world's largest biomedical and medical library. In addition to its vast collection of book, journal, manuscripts and other items, the NLM is home to hundreds of digital data and information resources. It receives and delivers a vast amount of digital content for user including researchers, healthcare providers, and the general public.

- Medicine and biomedicine are a substantive scope of the NLM. As biomedical research becomes increasingly digital, the NLM will likely pay attention to digital research objects (DROs), which might include software used to generate or analyze research data, as well as models and workflows used in research. After the NLM applies information science, informatics and data science to the digital research objects, they are findable, accessible, interoperable, and re-usable (FAIR). The processes of NLM applied to DROs make those objects compliant with FAIR principles.

- When DROs are findable, accessible, interoperable, re-usable, and attributable, they make possible a more data-centric and open paradigm of science and scholarship. To bring DROs into an open ecosystem, first the data must be shared. The benefits and objections to data sharing are discussed. Most biomedical research does not use a data-centric and open approach, but rather a concept-centric approach. This is about to change with both society expectations to data from funded research to be available and directives from federal government to encourage data sharing. The author discusses what the NIH is doing to make digital research objects findable, accessible, interoperable and re-usable.

- Key issues have been identified for NLM to assume the leadership role for data science and open science at NIH. One is to engage with others across the NIH as economies of scale and experience can be realized with a strategic enterprise approach. Another is the use of evidence based value assessment of data to provide guidance about future investments in data, infrastructure and policy. Other priorities include strategic engagement beyond NIH; development of a data-savvy workforce; promotion of open science; and research and innovation in data science and open science.

- The cumulative biomedical knowledgebase and breathtaking powerful scientific technologies available today present significant opportunities to understand health and mitigate illness. A digital ecosystem wrought of data science and open science promises to multiply these opportunities many-fold.

From Hospital Informatics Laboratories to National Data Networks: Positioning Academic Medical Centers to Advance Clinical Research

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- Pioneering academic medical centers (AMC) have been leaders in developing medical informatics systems to improve patient care and aggregate biomedical data to advance research. The potential to aggregate biomedical data now extends to all healthsystems. Led by the National Institutes of Health and the Patient Centered Outcomes Research Institute's creation of PCORnet, federal, nonprofit, and industry sponsors along with clinicians, patients, and investigators are seeking to capitalize on these new clinical data. Institutions are creating local, regional and national data networks that can support research and realize the vision of a learning heath system.

- The 2010 proposal for the University of Kansas Medical Center's Clinical and Translational Science Awards (CTSA) program, Frontiers, provides an example of a regional vision for biomedical informatics. The program's central aim was creating HERON Clinical integrated data repository. The open source i2b2 for data integration and warehousing was implemented. In addition to i2b2, Frontiers biomedical informatics adopted and promoted REDCap as a common tool for research data capture across the enterprise and partner institutions.

- Frontiers biomedical informatics' choice of i2b2 and REDCap was fortuitous for supporting broader collaboration nationally. Frontiers biomedical informatics saw high alignment with its work for integrating data in support of the CTSA program and the PCORI funding opportunity to create a Clinical Data Research Network (CDRN). Frontiers worked with other institutions in the Midwest to organize a response and create the Greater Plains Collaborative (GPC) and successfully compete for an initial Phase 1, and subsequent Phase 2 CDRN contract.

- In addition to becoming a viable Clinical Data Research Network, network partners' efforts were shifted to support a new data infrastructure, the PCORnet Common Data Model (CDM). As they worked to develop the network, the difference in perspectives between epidemiology focused coordinating center data modeling team and those embedded in health systems with rich clinical research goals was apparent.

- While much of PCORnet's activity was establishing governance and data infrastructure, the network also collaboratively prioritized and devised three national demonstration projects: the prospective ADAPTABLE pragmatic trial and two observational studies regarding obesity.

- As the University of Kansas Medical Center and peers in the Greater Plains Collaborative complete four years of building PCORnet, they reflect that this participation has impacted the campuses. The majority of the campuses are involved in all three demonstration projects. Their network leads the national collaborate research group for advancing PCORnet's cancer research; and Dr. Russ Waitman has served as the national chair for the PCORnet data committee. PCORI announced in 2017 that it will transition infrastructure support to a newly created nonprofit which will in turn contract with

Clinical Data Research Networks instead of networks contracting with PCORI. Though this will provide flexibility, questions arise as to how structure informs network design and collaboration.

Cross-disciplinary Activities in Big Data for Agricultural Innovation

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- Agriculture is broad, involving not only crops and animals, but also the ecosystems that support their growth and development. Pressures on agricultural systems are increasing and there are pressures for improvements in agriculture, which tell us that we need to discover, design, and invent news ways to improve agricultural products.

- Solving agricultural problems involves a multidisciplinary approach. A way to engage a broader group is to make data that describes ecosystems, crops and animals more accessible to researchers. This extreme data sharing is in keeping with long-standing traditions in science. Limiting access to data stands in the way of agricultural innovation, and that position cannot be supported.

- Data standardization seeks to improve both human and machine access to and analysis of data. Phenotype is the primary datatype selected for crop improvement and it includes many different types of data imaginable, making standardization difficult. The development of standards is in it's infancy, with the first standard for data was released only two years ago. In opposition, is the view against the development and use of standards for this emerging field of research. The concerns against standardization make the debate a topic at scientific meetings where phenotyping is a focus.

- There is a need for scientist with broad expertise to work together to address agricultural issues. Through the Iowa State University Plant Sciences Institutes (PSI) Faculty Scholar initiative, researchers working in the areas of plant sciences, data sciences, and engineering are funded to focus on plant phenomics problems. Another Iowa State initiative on this front is a grant from the National Science Foundation in Predictive Plant Phenomics (P3) that supports graduate education and research.

- The general approach to agricultural improvement must evolve to meet anticipated future needs. Researchers are developing the infrastructure and human resources to support the development of a new paradigm for research that results in agriculture innovation.

Developing Data Science at UNL: Progress, Challenges, and Opportunities for Research

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- Over the past several years we have seen a groundswell of interest and investment in data science, as the author has come to appreciate data science as more encompassing endeavor that encourages interdisciplinary research. The author was hired by the University of Nebraska-Lincoln in 2013 in the primary role as Director of the Quantitative Life Sciences Initiative (QLSI), whose mission is to develop expertise and resources in data science and 'Big Data' to meet the growing needs for the disciplines in the Life Sciences. Advances in computing has brought us the era of "Big Data", which can be defined as more data than one is accustomed to or more than one can manage. The four common attributes of Big Data are volume, velocity, variety, and veracity.

- One of the challenges of the 21st century science is how to get from data to information to knowledge when data are large, noisy and complex. This process requires a diverse skill set drawn from many disciplines. To meet the national workforce needs in data science, we need to rethink undergraduate, graduate and continuing education. Through a process of identifying opportunities to benefit the campus and stakeholders, UNL decided to develop an interdisciplinary doctoral program in Complex Biosystems. QLSI has active research and partnerships with local, regional, national, and international organization. These partnerships are critical to the success of the initiative because the field is evolving. Partnerships are an effective way to stay informed of developments, and they provide opportunities for graduate training.

- A recent area of emphasis for QLSI is reproducible research and Big Data management and analysis. The collaborate activities help support faculty associated with federally supported research centers comply with standards and expectations. How to finance the maintenance and sharing of data remains a challenge that must be overcome.

Enhancing and Automating University Reporting
Of R&D Expenditure Data Using Machine Learning Techniques

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- Most of what we know about research and development performed at the nation's colleges and universities is derived from data collected by National Science Foundation's (NSF) National Center for Science and Engineering Statistics (NCSES) as part of its Higher Education R&D (HERD) survey. The data collected in the HERD Survey are derived from institutional responses to an annual survey sent by NCSES.

- Responsibility for responding to the HERD survey at research universities is likely delegated to one or more specialist and this method of collecting data results in three distinct problems: responding is costly, there is a lag time in the availability of data, and there are inconsistencies of data collection across institutions, and even variation within an institution. To address these problems, the authors engaged in an experiment to apply techniques of machine learning to automated project classification. They determined these are potentially feasible but require further efforts.

- The goal of their project is to develop a classification algorithm that can be used to either supplement or replace human judgement in classifying sponsored research projects. Working with the University of Kansas Office of Research, they obtained complete data from approximately 1500 historical projects. The process and results of the experiment of applying machine learning to predict project classification are discussed in the paper. Among the different machine learning models, the authors found that the Logistic Regression classifier provides the best overall performance.

- The authors have not yet succeeded in developing a set of classifiers that precisely reproduce the human judgements underlying the University of Kansas' response to the HERD Survey, though it is not clear this should be a measure of the project's success. The project has been successful in showing that developing reasonably accurate machine-learning classifiers is possible. Future goals for the project include assessing the ability of the classifiers to successfully classify projects at other institutions. Classifiers can further be refined through adding additional projects from other institutions to the training data set.

Clinical Research and Data: HIPAA, the Common Rule, the General Data Protection Regulation, and Data Repositories

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- The way we do clinical research has changed. This article touches on different legal aspects arising at the intersection of technology, data, and clinical research—specifically HIPAA (the Health Insurance Portability and Accountability Act), human subjects research, the European data law (the General Data Protection Regulation), and data repositories. It explains how two different law-making bodies, the US and EU, have tried to balance the needs of the use of data with the privacy and risk issues.

- There is not one overarching law that protects all data. Instead, the US has a patchwork of federal and state laws that protect different types of data. HIPAA applies a different standard than that of the Common Rule and FDA Regulations, which require there are provisions in place to protect privacy of subjects and confidentiality of data. HIPAA applies to "covered entities", and may or may not apply to researchers, depending on the situation.

- Some researchers incorrectly believe removing certain information de-identifies data under HIPAA. To be considered de-identified, it must meet the requirements of safe harbor or expert determination. The safe harbor requires removal of specific identifiers of the patient and the patient's relatives, employers or household members. Under the expert determination method, it must be determined that the risk is very small that the information could be used alone or combined with other available information to reidentify an individual. HIPAA and its regulations do not apply to de-identified data under either method.

- Researchers often need information that is not available in properly de-identified data sets. A limited data set (LDS) is protected health information where some information is permissible to remain, and some information has been removed. HIPAA Privacy Regulation require covered entities must enter a data use agreement with recipients of LDS.

- There are two separate legal analyses that must occur when creating a data repository; does HIPAA apply and is it considered human subject research under the Common Rule. Each time protected health information is accessed for research, then the requirements for access must be met. There is the HIPAA analysis and the Common Rule analysis for accessing data. If a limited data set or fully identifiable protected health information is requested, then certain circumstances and conditions must by met under HIPAA. The Common Rule analysis is equally as complicated.

- Issues arise when US researchers want to use data from other countries for their research. Researchers who use data from multiple countries must navigate not only their own country's laws, but also the international legal waters.

Hitting the Mark– Facilitating Research Administration to Support the Institutional Strategic Plan

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- Kansas State University has a bold vision to be recognized as one of the nation's Top 50 Public Research Universities by 2025. This vision presents a challenge for research leadership on how to monitor the progress and facilitate growth. K-State will need to roughly double its research expenditure to achieve Top 50 public university status.

- Due to the scope of the bold vision, K-State needs the ability to understand how each award impacts the progress toward the overall goal. To accurately assess the progress towards the institutional goals, information needs to be harvested from each of K-State's three disparate systems; human resource information system, financial information system, and research administration system. K-State has undertaken a reporting initiative to provide a cohesive and timely view of the research activities. K-State Consolidated Award Tracking System (K-CATS) is the branded research administration intelligence solution that gives leadership and stakeholders insight into the research activities.

- The HERD Project is a collaborative effort between Kansas State University and Microsoft. This reporting solution will allow for greater insight into K-State's research activities compared to other institutions. K-State is utilizing the wealth of information regarding its research activities to help align research with funding opportunities, highlight interdisciplinary partners, and to move its research efforts forward.

Influencing the Culture of Scholarly and Professional Communities to Advance Clinical Research and Accelerate Knowledge Translation

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- Professional and scientific associations for health care disciplines have an opportunity to help shape how evidence-based practice becomes integrated into the fabric of the professions that they support. The efforts of these associations to "bridge the research-to-practice gap" are numerous, with the most promising are efforts that make use of big data, especially when coupled with text and data mining, semantic computing, and artificial intelligence. Three areas have been evolving over the past 75 years that have shaped the priorities of the American Speech-Language Hearing Association: evidence-based practice and implementation science movements; rapid changes in healthcare; and big data and data science, which is redefining scientific publishing.

- In this paper, the authors discuss the historical roots of evidence-based practice and data driven outcomes improvement. Physician Archibald Cochrane's work yielded the terms effective, efficient and equitable. Coupled with three additional domains, safe, patient-centered, and timely, these became the cornerstone for assessing ROI for health care expenditures in the U.S. The Commonwealth Fund supports research that compares health care quality and expenditures across high-income countries. Despite the authoritative data from this report, it is a puzzling, yet predictable phenomenon that it has not had a more influential effect. It has been observed that despite compelling scientific evidence, behavior and attitudes do not necessarily change, and if so, change will be slow. Everett Roger's *diffusion of innovations theory* and Prochaska and DiClemente's subsequent *transtheoretical model of change* are presented. Other theories of change also contribute to our understanding of how behaviors and attitudes might be influenced to promote the adoption of evidence-based practices.

- Dissemination and implementation science is a growing focus of research that seeks to lessen the gap of new knowledge and its application by identifying the factors that influence change. Estimates of the time it takes for research to become translated into evidence-based policies, programs, and practices is about 15 and 20 years. Though it is a challenging process, there is a consensus that evidence-based practices need to be integrated into clinical care at a more rapid pace. Understanding the strategies and factors that can help or hinder new knowledge has become a central focus in health care. Using a combination of dissemination approaches, perhaps the most important of which include social learning opportunities, could help achieve the goal of improved health through better evidence-based decisions.

- Clinical data registries hold much promise to fill in gaps in the investigator-initiated research. Because clinical data registries and electronic health records accumulate large samples of patient populations, there are questions that are best addressed through big data and data science. The vision of a learning health care system is that analyses of large clinical data repositories will provide information about what works best for whom under which circumstances. Decisions can then be made about improving services and outcomes. After these adjustments, new data will provide information on the success and failure of the adjustments. Learning health care systems are expected to accelerate the rate at which evidence-base practices and innovations in health care are adopted; thereby, reducing the research-to-practice gap.

- There are many ways that professional and scientific associations can leverage their innate strengths to increase the implementation strategies. Publishers, such as the American Speech-Language-Hearing Association, have increasingly adopted continuous publishing models so important research can be timely released. The standardization of the data behind the full range of publication steps has also shaved from the time it takes to disseminate knowledge. In this publishing era, granular tagging is applied to articles, extending a user's discovery. All these advances are emblematic of the tide of big data flooding all publishers. The next two decades should lead to measurable improvements in reducing the gap from research to practice.

Towards a Research Profiling Ecosystem
Weaving Scholarly, Linked Open and Big Data

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- Research profiling systems provide programmatic support for discover and use of research and scholarly information. Many systems have been developed including open source, commercial, and local institutional systems, such as Loki, the University of Iowa's research profiling system. The work on extending Loki into the Semantic Web serves as a substantial case study in modular architectures extending into Linked Open Data (LOD). Loki is an investigator-rather than institutionally-focused, supporting many phases of the research life cycle.

- Several approaches in the design of Loki proved to be valuable. Work involved definition of a Loki ontology and the mapping of relational database entities into the resulting ontological concepts, including synthesizing the tag library layer of the architecture from an entity-relationship diagram. Furthermore, the clean partitioning of the logical components allowed them to represent those components as discrete triple stores, supporting an overall LOD environment of interlinked triple stores that reflected the modularity of the initial tag library design. Several conscious design decisions were made in the development of Loki. Initially, they opted to develop a Loki ontology that directly represents the semantics of their local environment. Subsequently, they mapped the Loki ontology to the VIVO ontology, demonstrating the value in maintaining separation between the representational and conceptual levels in the overall information architecture.

- CTSAsearch is a federated search engine using VIV-compliant Linked Open Data published by 87 institutions. User feedback on CTSAsearch showed a desire for more sophisticated search than what was provided by a simple 'bag-of-words' relevance list. The default search mode currently used has been successful in pruning low level relevance hits from results. For "reasonable" result scales, approximately 200 queries, useful force graph visualizations are possible. Challenges arise when queries return thousands of results, leading to a network hairball. Two approaches have been taken to address this challenge: one is aggregating results at the institution; and a second is inter-institutional community visualization.

Aligning Data Collection with Multi-Dimensional Construct Definitions: The Example of Behavioral Tasks for Measuring Risk–taking Behavior

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- Data plays an important role in the understanding of real world risk taking behavior. Ensuring the quality of that data requires an understanding of the rational for the tasks developed and used. It also requires a clear sense of what useful existing data or new behavioral tasks can provide and where they fall short.

- The Iowa Gambling Task (IGT) and the Balloon Analogue Risk Task (BART) assess risk taking in different ways, and together they may provide a strong comprehensive picture. IGT was the original standard for measuring risk taking. Slovic's Devil Task was the first behavioral task designed and used to assess Risk Taking Propensity (RTP), a commonly used behavioral measure currently used. The simplicity of the Devil's Task led to the development of the BART, a computerized measure of RTP, that allows for complex ways to study complex risk behavior seen in the real world.

- In the BART task, the participant is presented with a balloon and asked to pump the balloon by clicking a button on the screen. As the balloon inflates, winnings are added; however, if pumped beyond the explosion point, the balloon explodes, and the participant loses the money earned on the balloon. Existing data shows a correlation between risk taking on the task and current levels of real world risk behavior. However, there appears to be no evidence of risk taking on the BART at one time point that predicts future risk-taking behavior. Several studies have been done to understand how risk taking is impacted by external factors in the real world by manipulating those factors in a controlled laboratory. The studies presented include one that examined the effects of varying cash reward magnitudes on RTP; another that examined the effect of peer influence on BART RTP; and one that examined the impact of anxiety on risk taking.

- Isolating risk taking in a controlled laboratory setting and providing the opportunity to manipulate key variables thought to impact risk behavior in the real world should be the focus of experimental studies. This work has begun with the BART, but work including studies that bring in genetic factors, neural assessment, as well as environmental factors is crucial to further progress.

Aligning Researcher Practice to Support Public Access to Data
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- There is a national move towards open science and open enquiry. The resources and systems for openly sharing publications are well developed, though the policies for data sharing are less defined. Open access to data will be effective if there are common standards for communicating data and a cohesive strategy used.

- AAU-APLU Public Access Working Group is working on common goals for data sharing, federal agency recommendations and guidance for research institutions. At Iowa State University, the implementation is being coordinated across the Library, IT services and the Office of the Vice President for Research. A faculty committee is providing perspective for the rigorous process of data sharing. Key questions for consideration to develop polices are: what is the purpose of sharing, what data should be shared, what is the standard for documenting data, what are options for data storage, and how to train researchers to adopt the new mindset.

If a Tree Fell in a 300 Million-year Old Forest, Did it Leave a Data Trail?
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- Researchers in many fields at universities are creating masses of data at a record rate. This paper explores the sources of this increase in data, describes the challenges created by the ever-increasing pace of data creation, and looks at the strategies universities are considering in managing the expansion of data creation.

- Because of technological advances, compute capacity per dollar increases, and a decrease in the price of data storage capacity, investigators are analyzing more comprehensive and realistic data sets. These big data applications are being used in the analyses of varying fields. Universities are addressing this challenge of supporting research with big data by investing in high-quality high-performance research computing (HPC). The University of Kansas (KU) has only had a centralized HPC strategy for five years.

- The increase in the size of data sets has offset the cost savings of declining cost of computing, network and storage capacity. Though there are desires to off-load HPC computing and storage capacity to the cloud, unfortunately, most present analyses of cloud computing services do not support moving university enterprise HPC to a cloud platform. Accessing data that is stored in the cloud adds to the cost of the service, yet, glacial cloud storage which is used for long-term archiving is more cost-effective.

- There are several key challenges facing universities and researchers. Investigators have flocked to low-cost and sometimes low-quality technologies for data storage. In response, funding agencies have begun to intervene out of concern for data integrity and accountability. The mandate for Office of Science and Technology (OSTP) to make data collected through federal funding available to the public has created a dilemma for research universities as few have the server capacity for public access and security concerns are an issue. Another challenge is the leakage of academic research and development activities.

- To promote a healthy data culture in higher education, the following is recommended; provide economical access to professionally maintained computing capacity and archival storage; give ownership of computational and storage hardware to commercial vendors; facilitate the transition of research records to electronic records; standardize meta-data to identify data sources and ownership; create internal training and policies to minimize the volume and extended time of retained data; engage disciplinary experts to incorporate data management best practices; develop shared application interfaces to bring computing tasks to large data sets, create institutional capacity to ensure compliance; and continue dialog with funding agencies about sustainable support for research data archives.

Data, Consent, Privacy, and Insight

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- The changes brought about by technology are deep and profound. Some of the changes include the creation of megacities, concentration of wealth in a small fraction of the population, direct consumer engagement resulting in elimination of some existing companies and creation of new ones, and polarization of social perspectives and political opinions.

- Technological change continues against this backdrop of social issues. Digitization of our world ranks at the top of technological change with examples including big data, deep learning, automation, biomedicine advances, and environmental change and global warming.

- Data is important in both enabling technical changes and remediating the damaging effects. Within this context, the paper discusses the scale and scope of big data, the privacy and legal challenges created by digital data flows, and the emerging issues surrounding sensors and passive data. Thoughts are shared on a new model of digital privacy. Combining three principles creates a more nuanced model for data sharing: one principle that attaches a lifetime to data at the time of its release, a second principle limits sharing of data, and a third principle is claims-based access that would specify the purpose for which the data can be used.

- Within the broader context of social and technological change, we must ask wise and thoughtful questions about how this data is used and by whom. Only by concurrently considering social implications and technological capabilities can we create sustainable approaches.

Research Planning at Nebraska
Research and Economic Development Growth Initiative (REDGI): 2012-2017

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- The University of Nebraska-Lincoln's launching of the Research and Economic Development Growth Initiative (REDGI) is an example of the use of data and analytics in research planning. In 2011, the University of Nebraska Lincoln was ranked as one of the top US universities in research growth over the previous 10 years. In his 2011 State of University Address, Chancellor Harvey Perlman emphasized the need to increase the academic stature and gave these specific goals: increase total research expenditures to $300 million, increase academic stature through increased faculty awards and memberships, increase the number of faculty working with scientists in the private sector, and increase student enrollment by 20%.

- The Office of Research & Economic Development (ORED) was charged with carrying out the research growth goals, a mission that would require buy-in from research-active administrators, faculty and staff. From the fall of 2011 through spring 2012, targeted forums with key audiences were held to discuss issues to accomplish the goals and solicit input on the strategies. Following these forums, the Research and Economic Development Growth Initiative (REDGI) was created with two broad goals: to enhance the quality of research, scholarship, and creative activity at UNL, and to increase the quality and quantity of industry partnerships.

- Metrics would be a driving force for REDGI. The approach was to use a variety of analytical tools to better understand UNL's scholarly strengths and market position. REDGI defined specific metrics and actions to meet each of its two goals. The REDGI roll-out to campus included promotions and education campaign to engage the campus in the effort of the new platform for disseminating data and analytics to track their progress toward the REDGI goals. REDGI dashboards were developed and made available specific to the university, college and department levels.

- Metrics are provided on the success of the project. Total research expenditures for the Fiscal year 2017 nearly meet the fiscal year 2018 goal of $300 million. The growth goals for industry funding were not met, but UNL exceeded the goals for faculty engagement in sponsored programs and exceed by almost double the number of faculty awards and memberships.

- Several lessons were learned from the REDGI experience. Engaging leaders at all levels is critical to success. Incorporating goals into the story of the research institution is critically important. New staffing is necessary with any new, large undertaking. Most important, strong and clear data measurements and analytics is critical.