



## **Accelerating** Open Science

3rd Annual Summit White Paper  
May 13-15, 2014 | Arlington, VA

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## Publication Information

### Source Material

This document was developed using conference notes of the 3<sup>rd</sup> Annual One Mind Summit, Accelerating Open Science, held May 13-15, 2014 in Arlington, Virginia.

### Writing and Graphic Design

The writing and graphic design of this White Paper was completed, at no cost, by the Proposal Collaboration Center (PC2) of Cisco Systems, Inc.



### Fostering Fundamental Changes

*“We believe that the key to these fundamental changes is an adherence to open science principles, where high quality data is made available and shared among researchers.”*

## Accelerating Open Science: An Introduction

### The Need for a Common Direction in Brain Disease Research

At One Mind, we are dedicated to fostering fundamental changes that will radically accelerate the development and implementation of improved diagnostics, treatments, and cures for diseases and injuries of the brain – all while eliminating the stigma and discrimination that those affected may experience. We believe that the key to these fundamental changes is an adherence to open science principles, where high quality data is made available and shared among researchers. As part of this effort, One Mind is continually working to create an environment for researchers involved in brain disease research where data sharing, cooperation, and creation of high-quality data are rewarded. This includes promoting global partnerships within the governmental, corporate, scientific, and philanthropic communities; supporting groundbreaking research that adheres to open science principles; and advocating policy change when necessary.

Major programs of One Mind already in progress include:

- Apollo, an open science interactive knowledge and data exchange portal for brain disease and brain injury.
- Gemini, a pilot program established to demonstrate that the support of large research studies for diseases and injuries of the brain, in concert with open science principles, will greatly accelerate the discovery of better diagnostics, treatments, and someday, cures. The researchers supported by One Mind under Gemini will enroll more than 8,000 patients internationally with Post-Traumatic Stress (PTS) and Traumatic Brain Injury (TBI) in multi-year longitudinal studies. Research indicates that many brain diseases are related, so as this pilot program proves successful, and as the data is shared, One Mind will branch out to other diseases and injuries of the brain.

### Mapping the Path to Progress

In 2014, One Mind’s 3rd Annual Summit had a single focus. We addressed



### Focusing on the Future

*"We at One Mind are grateful to the speakers and participants for their time, their thought, and the intensity with which everyone at the Summit participated."*

barriers and incentives to sharing data in medical research, which we had encountered in our work on PTS and TBI. Our goal was to examine how current systems for recording, storing, and sharing data could be reengineered to be more useful for sharing and for integration into meta-analyses and other "big data" projects that will advance knowledge. For such a goal to be effective, we also addressed the interests of all involved: patients, clinicians, researchers, regulators, publishers, industry innovators, and others. Based on the Summit discussions, a consensus concerning the next steps needed has begun to form, one with the needs of the patient as the guiding principle.

Some of these proposals can be taken forward by One Mind in the field of PTS and TBI. There was a striking consensus at the Summit that the correct approach to many of the complex issues discussed was to address them first in a smaller disease community. However, many proposals must be carried forward by others with the required combination of determination, community support, skills, and resources.

### Moving Forward in 2015

Going into the Summit, we believed factors that deserved attention included informed consents, patient and Institutional Review Board (IRB) concerns over privacy and security of their personal data, national and international data regulations, intellectual property policies, academic incentives for advancement, publishing models, the goals of grant-making bodies, and the pressing issue of the reproducibility of research. We believed that grant makers, publishers, and scientific communities should consider technical and scientific requirements that will maximize use of data most likely to be shared. In addition, that strategy, most notably from grant makers, could include requirements for enforceable data sharing plans in applications and a focus on data usefulness. This could include use of common data elements and formats that are acceptable to the broader scientific community, regulators, and industry. Our speakers addressed these issues and proposed next steps. While our initial beliefs were in many cases confirmed, other issues and proposed solutions arose during the conference. In particular, concerns over training of researchers, the quality of research, the reproducibility of the results of that research, and proposed solutions, were a major theme of the Summit.

We at One Mind are grateful to the speakers and participants for their time, their thought, and the intensity with which everyone at the Summit participated. We are particularly grateful to our sponsors and speakers who made the event possible (please see the Appendices for a list of sponsors and speakers). We look forward to working with partners and collaborators in 2015 and beyond to develop these ideas into a workable reality.

**Stephen Johnson**

*Chief IP and Policy Officer, One Mind*

*Organizer and Moderator of the 2014 One Mind Summit*



### We Must Move Forward

*"The timely sharing of accurate and verifiable data will allow researchers around the world to access reliable data that can be used for years to come. And its creation via a transparent, high-quality, and collaborative approach will maximize benefits for those who suffer from diseases of the brain."*

## Building a Foundation of Open Science and High Quality Data

### Key Drivers to Moving Forward

One Mind believes there are two key drivers to building a strong foundation for brain disease research – data sharing and reproducible science. Their realization is critical in breaking down the barriers which currently hinder advancements in the field. The timely sharing of accurate and verifiable data will allow researchers around the world to access reliable data that can be used for years to come. And its creation via a transparent, high-quality, and collaborative approach will maximize benefits for those who suffer from diseases of the brain.

### Data Sharing Is Harder Than You Think

The sharing of data related to brain disease research is critical to the advancement of the field. Unfortunately, sharing is hard even for those researchers who wish to share and multiple barriers exist which discourage or prevent sharing from happening. The barriers debated at the Summit are discussed below with issues surrounding privacy regulation and intellectual property addressed in detail in separate sections.

### Most Current Incentives Encourage Hoarding of Low-Quality Data

Perhaps the primary barrier to sharing of high-quality data is the academic environment of the scientists themselves. At most research universities, scientists are forced to compete for tenure and promotions - and usually rely upon research grants for funding. They work in an underfunded environment with little common infrastructure and few agreed standards for data creation and sharing. They must meet tenure, promotion and grant criteria that fail to incent or reward sharing, but rather encourage data retention as a basis for multiple publications. This academic incentive system must be re-engineered.

### Quantity and Position in Authorship

In most areas of neuroscience, first and last authorship positions on high impact papers, and the number of those papers, are the predominant metric used for tenure, promotion, and funding decisions. Some scientists who are data creators are concerned that other scientists may publish and claim authorship on the basis



of that data, thus free-riding on the work of the data creators. In addition, there is a concern that scientists who are simply data users may also draw erroneous conclusions from unfamiliar data sets which could, in turn, reflect badly on the data creators.



### We Must Remove Barriers

*“Perhaps the primary barrier to sharing of high-quality data is the academic environment of the scientists themselves... This academic incentive system must be re-engineered.”*

### Lack of Funding and Recognition

Even for scientists who support the concept of data sharing and believe that the benefits outweigh any risks, there are considerable barriers that may prevent them from doing so. These can include current grant criteria that generally do not reward a prior history of data sharing and grant awards that provide no funding for creation of re-usable high-quality data, or sharing of that data. Grants usually do not include funding or recognition of the time-consuming and arduous tasks of data curation and annotation - or any funding for data repositories or other technology needed for data sharing. If data sharing is required by a grant, it is usually treated as an “unfunded mandate.” And in an age of shrinking budgets, it is very difficult to find the extra funding necessary to support these activities.

### Misuse of Data

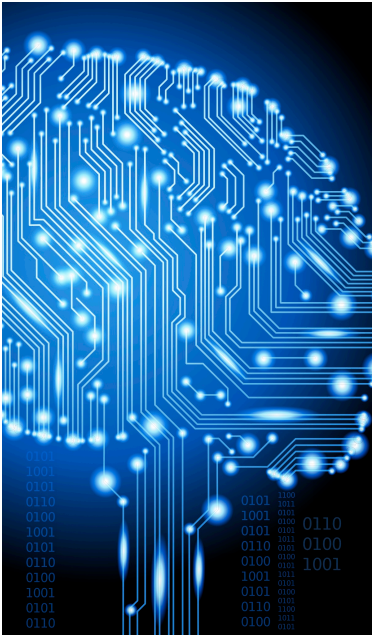
Data privacy and data misuse are major concerns. Privacy laws such as the Health Insurance Privacy and Portability Act (HIPAA) are complex and penalties for non-compliance severe. Access may be limited or, in some cases, it may be easier for some institutions simply to refuse to share data rather than undertake the legal analysis necessary to determine how to comply with applicable regulations. These issues are discussed further below.

### Patient Privacy and Consents

Patients have legitimate rights and concerns with respect to their personal medical data. Consents to data use and sharing need to be obtained and ethical standards strictly observed. But depending on the terms of those consents, further data sharing may be prohibited without re-contacting the patients in question, and as discussed below, the regulatory system is so onerous and poorly understood that it too may act as a barrier.

### Technology and Training

At its heart, data sharing is not a technology problem. There is no need to develop new and expensive technology to address it. In fact, the needed technology



### The Lack of Quality Data

*“Currently, there is a lack of quality data in neuroscience . . . Unfortunately the data that does qualify is often difficult and costly to curate. Only a small amount of it is coherent and of high enough quality for further use.”*

already exists. What is lacking is the will or consensus to use that technology in a manner that promotes, and does not impede, data sharing. However, to enable the high-quality collection of large volumes of research data, a huge need exists for researchers with data science training. There are simply too few data scientists working in neuroscience and existing training activities are uncoordinated.

### Lack of Standardization

The lack of common data elements and other forms of standardization limit the usefulness of data that is shared for aggregation, greatly increasing costs and wasting effort.

### Concerns over Loss of Intellectual Property or Revenues

Some institutions have taken positions that data owned by them should not be shared, or only be shared if a fee is charged for the data, or in some cases, on condition that if a revenue making discovery is made through use of the data, the institution shares in that revenue. These types of demands may inhibit data sharing desired by a researcher.

### Publication Policies

Some editorial policies of scientific publishers, even when requiring data to be published, may require delays in releasing data until publication of the paper based on that data. The schedule of data release is often based on peer review and the overall schedule of publication, the pace of which is generally slow.

### Lack of Common Approaches and Standards

Finally, there still remains a lack of understanding on just how data should be configured, accessed, and archived for sharing. In the end, these issues, combined with the lack of common data elements and standardization, have generally resulted in a splintered and limited universe of data. As a result, there is a lack of quality data in neuroscience. Unfortunately the data that is available is often difficult and costly to curate. Only a small amount of it is coherent and of high enough quality for further use.

### New Incentives and Solutions to Enable Data Sharing

New incentives need to be devised to overcome current barriers to sharing data and solutions developed to enable data sharing in neuroscience. These are



discussed below.

### Establishment of Metrics

To encourage data sharing, publishers and institutions should start to reward team science. This could include a new system of metrics and a unique “handle” (or hashtag) to identify each author or creator of data, even when working as part of a larger team. This handle could be attached to code, data, articles, and such to permanently identify its creator. See [www.orcid.org](http://www.orcid.org) for an example. This would allow promotion committees to track the impact of an author by his or her collective contributions to multiple projects, even if he or she is not the first or last author. The hashtags could also be used in a system of “citation chains,” in which all an author’s or data creator’s citations, and citations of citations, are tracked so that credit is properly assigned. The current “H index” measuring the productivity and impact of a scientist could also be modified to an “HD” index where recognition of the impact of a paper is not permitted without availability of the underlying data. This could be phased in over a number of years. In addition to providing access to data, data repositories and journals should work to provide more information to readers/users (e.g., on methods) and provide the software used to analyze the shared data. In conjunction with this, depositories and the community should find ways to create incentives for the data creators who make available all this material (e.g., based on use of frequency of access to their data sets and associated materials).

### Use of New Technology

The brain disease research community would benefit from a registry or portal that allows the identification of available data, access to that data, easily accessible tools for data analysis, and social aspects that allow open communication and collaboration. This would aid community members in better understanding the benefits of data sharing. Metrics to reward data creators could also be created and promoted within the portal. This could include data citations and measurements of frequency of data use, all tied back to the originating author.

### Publication Policies

Data sharing also requires that techniques to speed the dissemination of knowledge be better understood by the field. This includes a closer look at data



### Open Science Needs Open Communication

*“The brain disease research community would benefit from a registry or portal that allows the identification of available data, access to that data, easily accessible tools for data analysis, and social aspects that allow open communication and collaboration.”*

release dates imposed by funders, which are an incentive to early publication, because data creators wish to publish first on the basis of the data they create. In addition, there is also a need for more effective post-publication peer review to speed up publication and distribution of knowledge currently delayed through the process of peer review.

### Education

The community should be educated on the true benefits of data sharing versus the perceived risks of doing so, such as the concern that shared data could be misunderstood. Education should also be provided on the potential for new insights (and new papers) that curated data provides when analyzed using available analytical tools. Where current incentives still stand in the way of open data sharing within the entire community, researchers should understand that teaming data creators and users in collaborations can resolve current time, resource, and incentive problems and lead to productive data sharing.

### Funding and Funding Criteria

Costs of data curation, sharing, and long-term storage need to be allocated between funders and institutions and properly funded. Criteria for awarding funds must go beyond scientific merit and novelty. They should reward institutional behavior such as team science and data sharing. In addition, metrics such as the “innovation score” should not be used to penalize work that will enable data aggregation and sharing.



### The First Step: Data Standards

*“There is no need to develop new and expensive technology to address it (data sharing). In fact, the needed technology already exists. What is lacking is the will or consensus to use that technology.”*

## Moving Towards Standardization

### Solving the Data Sharing Dilemma

For the field of brain disease research to maximize the scientific and economic benefit of the research undertaken and funded, the community must begin the process of standardization. In reality, there is no lack of data standards. The problem has been the failure to adopt common data standards across the field when, generally, neither researchers nor data repositories have had any incentive to pursue a common approach. As noted, currently there is a lack of “quality data” in neuroscience. Quality data can be defined as data created using widely accepted common data elements with rigorous standards for collection, coupled with proper annotation to put the data in context. To overcome these issues, data sharing must be built upon standardized elements including:

- Collection
- Data Elements
- Data Annotation
- Data Storage.

A key contributor to lack of standards in the past has been the lack of a global appreciation that individual studies may have a purpose beyond the initial publication. And unless funding sources, publishers, and the researchers themselves begin to appreciate – and more importantly plan for – such future use, progress will not be made.

### The Need for Community-Wide Action

The first step towards standardization is for the applicable research community to agree on data standards. Publishers alone cannot require them – it must be a communal effort. At One Mind, we believe the following opportunities should be explored to help in the establishment of standards fully acceptable to the community at large.

### Funders Should Push for Standards

Currently, most funders fail to mandate common data elements and other forms of standardization and could do more to teach and instruct researchers how to create and format data. The absence of mandates has an impact. This is most visible in the lack of high-quality collections of large volumes of research data that are generally available. Those who fund brain disease research need to step forward and push for



### Do Mandates Matter?

*“The absence of mandates has an impact. This is most visible in the lack of high quality collection of large volumes of research data. It is also reflected in the general shortage of training of scientists in the area of data science.”*

common standards and fund the promotion and creation of standard data elements within communities of researchers. Funders should be a convening body for data standards and the FDA and healthcare payers need to be brought to the table in these discussions. Although there remains some perceived tension between standardization and individual efforts, individual breakthroughs do need to be reproducible and sustainable and there is no real conflict in most cases. Ideally, mandates should require the use of common data elements, while also allowing flexibility for innovation. If an innovative study requires unique data elements, they should be fully defined and included in a dynamic data dictionary for others to use in the future.

### Institutional Training

Institutions should train scientists to understand the benefits of disciplined and standardized data collection. Everyone, even the data producers, can get more out of each dataset when standards are used.

### Common Data Input Tools

Common platforms for data input would facilitate data standardization. For example, common data capture platforms are being developed in the TBI field. The medical and research industry could develop solutions for data capture that would reduce costs across the system.

### Funder Mandates on Data Sharing

In the case of the National Institutes of Health (NIH), every research grant over \$500,000 requires a data-sharing plan. However, the NIH has not been aggressive about making sure data sharing happens under individual grants. Requiring and funding the infrastructure of data sharing for all NIH-funded research would be expensive. And big data should not be looked at as a panacea although cross-disciplinary research may hold much promise. Hence, a full policy analysis and strategic plan is required.

Currently, hard information concerning the amount of data being developed, shared, and used is not available, nor is much needed information regarding how data is being stored. Sustainability of data systems is also a concern. New business models are required to drive true sustainability to a point where costs

would be funded long term from sources other than government.

Work is now underway by the Associate Director for Data Science at the NIH to understand and address data sharing issues and to try to create a “digital enterprise” (for example, machine-readable data sharing plans). Efficiencies are needed within the current government-funded system to better use resources that are available and to focus on areas of need. In the end, NIH activities are an investment - not an entitlement - so a culture of return on investment needs to be widely promoted and accepted.

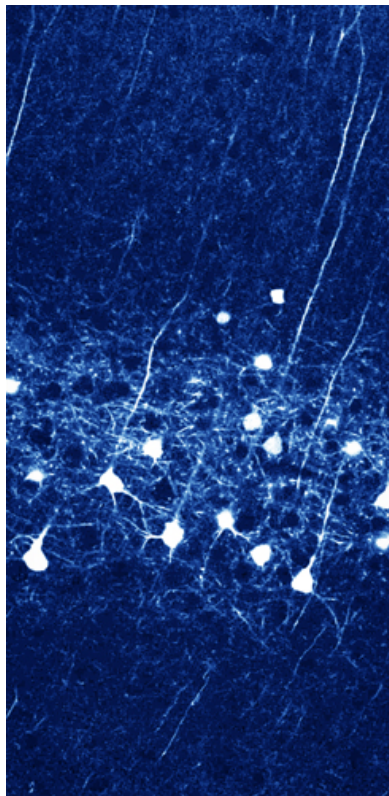
Efficiencies can also be driven within current approaches by, for example, funding several projects at the same research center or using the same data infrastructure. This would allow economies of scale for curation and infrastructure.

### Use of Existing Data

There is much value in existing data. Funders should support reconciliation and curation of existing data sets. The medical and research industry should continue to make data from failed clinical trials available, consistent with avoiding loss of patent rights, that could encourage efforts to repurpose “failed” drugs for new indications (See, e.g., [Arti K. Rai and Grant Rice, “Use Patents Can be Useful; The Case of Rescued Drugs” Sci Transl Med 6 August 2014](#)). The potential of Electronic Health Records (EHRs) should also be unleashed from ill-understood concerns over HIPAA compliance (see below).

### Shift in Community Attitudes

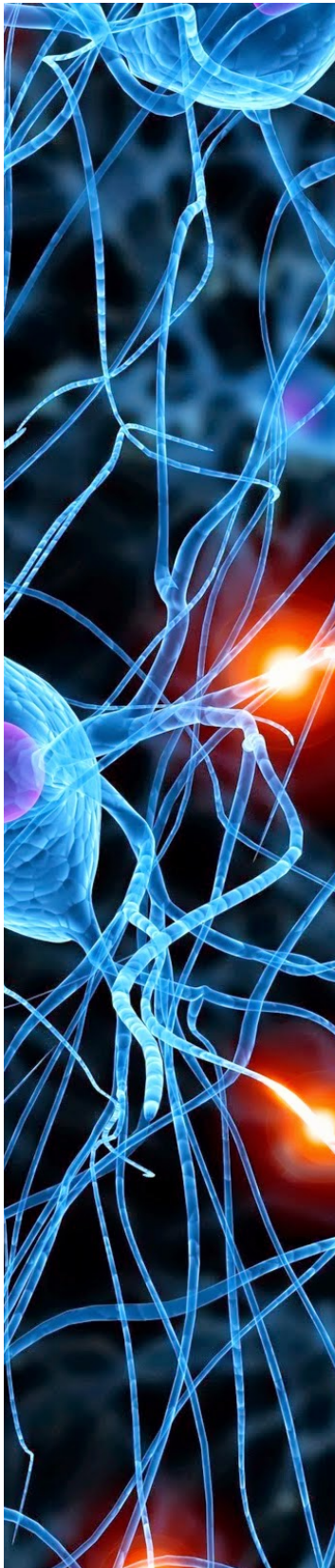
Given the number of constituencies involved, creation of high-quality data and sharing of that data requires community buy-in at all levels (research, funder, institution, and patient). In other areas of science, a shift to a sharing of data and collaboration has occurred among a community of researchers. Examples include the consensus that has formed around groups or manifestos such as the Bermuda Principles and the Fort Lauderdale Statement. The norms and etiquette of publishing in the field have adapted to preserve incentives and rewards. However, community change requires a trusted leader or intermediary and modular tasks that the community agrees are important. Among the Summit



### The Need for Community Buy-In

*“... Given the number of constituencies involved, creation of high-quality data and sharing of that data requires community buy-in at all levels (research, funder, institution, and patient).”*





attendees, there appeared to be a strong consensus that progress can be made in a smaller disease community, with One Mind serving as a leader of change in PTS and TBI.

### Learning from the Past Initiatives of Others

While there are many paths to data sharing and standardization that can be followed, One Mind believes the following initiatives by others, and learning from both their challenges and successes, can provide a strong roadmap for future efforts.

#### Innovative Medicines Initiative

The Innovative Medicines Initiative (IMI) has successfully organized multi-stakeholder collaborative projects involving industry, government, and academia. Its success requires pharmaceutical companies to work together in an area of non-competitive research, with regulators and patient advocates being closely involved. See: [M. Goldman, “New Frontiers for Collaborative Research”. Sci. Transl. Med. 5, 216ed22 \(2013\).](#)

#### Human Connectome Project and the National Database for Autism Research

While in the past, the sharing of data from grants has been slow and inconsistent, Federal law now requires that summary data be submitted for clinical trials. Access to individual-level data remains a challenge, but the NIH has been successful in instituting timely, individual-level data sharing in select initiatives. This includes the Human Connectome Project, the National Database for Autism Research (NDAR) and the Federal Interagency Traumatic Brain Injury (FITBIR) Informatics System.

In the Human Connectome Project, individual-level data sets are released every few months and can be accessed along with analytic tools online at <http://www.humanconnectome.org>. In the NDAR project, clinical autism research data from NIH-funded grants are deposited and shared broadly. Some raw data are available in real time (4 months after submission), but data supporting a publishable finding are released at the time of publication. But it should be noted that any data infrastructure takes time to accumulate enough information for data mining. And for longitudinal samples, data are especially





### We Must Reward Quality

*“They should reward authors based on the quality of their published work rather than quantity. And as a community, scientists need better training in experimental design, statistics, and interpretation so they can produce higher quality data.”*

slow to accumulate and be made available to the research community. The NIH’s policy for the National Database for Autism Research may serve as an example and can be reviewed at:

[http://ndar.nih.gov/ndarpublicweb/Documents/NDAR\\_Policy.pdf](http://ndar.nih.gov/ndarpublicweb/Documents/NDAR_Policy.pdf)

### Sharing of Clinical Trial Data by Industry

Responsible sharing of clinical data by industry usually comes about due to a common goal. Industry sharing must also ensure patient privacy, maintenance of the integrity of regulatory systems, and maintenance of incentives to innovate and invest. The results should also be shared with patients to maintain transparency.

To learn more, we suggest reviewing the “[PhRMA Principles for Responsible Clinical Trial Data Sharing](#).”

### Data Sharing in Other Scientific Areas

In other areas of science, data sharing and collaborative science have become the norm. Universities and publishers adapt to benefit team approaches and there is self-regulation within the community so that data producers are acknowledged and allowed to publish first based on the data they create.

### Actions by Publishers

Several scientific journals have recently instituted new initiatives related to data sharing. These include:

- The Public Library of Science (PLOS) has initiated a new data deposit policy, where a data deposit and sharing plan is required at the time of submission of an article. More information can be found at [PLOS Sharing Policies](#) and [PLOS New Data Policy](#).
- Nature Publishing has initiatives on data reproducibility and a new scientific publication for data sets called “Scientific Data.” These are available for review at [Reducing Our Irreproducibility](#) and [Sharing Data](#). See also “[A Call for Transparent Reporting to Optimize the Predictive Value of Preclinical Research](#).”

### Resolving Reproducibility Problems

Data collection practices are affected by incentives: Industry researchers scrupulously record their experiments in lab notebooks because that is what is required. Academic laboratories are not subject to such requirements. To ensure results can be better reproduced, incentives should be encouraged that require



higher standards in academic research. This could include removing the institutional pressure to frequently publish and mandating stricter experiment recording. Institutions should also develop the infrastructure and internal incentives that support reproducibility. They should reward authors based on the quality of their published work rather than quantity. Young scientists should not be under such extreme pressures to compete and publish. And as a community, scientists need better training in experimental design, statistics, and interpretation so they can produce stronger analyses.

At One Mind, we believe that an accreditation standard for research laboratories should be developed. It might be modeled on the [Joint Commission on Accreditation of Healthcare](#) (JCAHO), where grants are only awarded to accredited laboratories. A solution to the data quality issues could also include an institutional rank. By implementing a ranking system based on a Capability Maturity Model (CMM), institutions would have to demonstrate their excellence in experimental and data collection techniques. Standard processes to do this could easily be developed along with industry. Publishers should also require greater transparency by publishing a dataset's collection process, methods, and associated software. They should also accept negative results as worthy of publication as much as they do positive results. In addition, while standardization should be the adopted norm whenever a patient impact is involved, solid experimental methods that still provide flexibility should be instituted in more basic research.

### The Need for More Transparency on Bayh-Dole

Within the field of brain disease research, there continues to be a lack of understanding over the legal framework surrounding sharing of federally-funded research. This is particularly so with the Patent and Trademark Law Amendments Act, also known as the Bayh-Dole Act, passed by congress in 1980. The passing of time has only muddled the waters concerning the legal authority under which the NIH approaches data sharing. This lack of legal clarity has hindered a policy-level discussion between funders and universities about the costs and benefits of mandating sharing of publicly funded data. Separately, the increased focus by



institutions on ownership and monetization that the bill promoted has created unrealistic expectations within the university community about revenue that may be obtained from technology transfer. This has in some instances served to slow the process of collaboration.

### What is Bayh-Dole?

The Bayh-Dole Act covers ownership to (potentially patentable) “inventions” arising from federally-funded research. More importantly, this also includes patents arising from them and licenses granted to these patents. But Bayh-Dole makes no mention of data or ownership to data. It does not require patents to be filed on every invention and filing is completely at an institution’s discretion. However, if no patent is filed, the invention does then default to the federal agency responsible for the original funding support. That agency may then file for a patent if they so desire. While data might be sequestered for a limited period of time in order to file a patent on an invention which is described using the data, the Bayh-Dole Act has no direct legal impact on questions such as whether an institution like the NIH can mandate data sharing or what rights universities have to data developed under Federal grants.



### Bayh-Dole and the Rise of Technology Transfer Offices

The most noticeable impact of the Bayh-Dole Act is the resulting formation of Technology Transfer Offices (TTO) around the country. Unfortunately, some of these offices seem overly concerned with revenue from intellectual property (not just patents, but also software, data, biomaterials, and other assets). Much of this emphasis on revenue is due to institutional administrations feeling that they are losing ground financially due to declining federal funding.

Far too many Boards of Trustees, research institution Presidents, and Deans believe technology licensing is the solution to their financial quandary. Despite this belief, the reality of the situation is much different. Statistics consistently show that technology licensing does not generate revenues across the university system in meaningful proportion to research costs. In fact, overall, technology transfer only accounts for around 4 percent of research budgets at U.S. institutions.

Some small proportion of this income has come from charging industry for access to data sets. Industry charging is usually based on a one-time fee; some TTOs, however, do require a reach-through agreement “just in case” the shared data leads to a discovery of value. Utilizing pay walls does help sustain research in some ways. But in the end, industry charging can inhibit the timely sharing of important data and ultimately prevents it from reaching the maximum audience. A further review can be found at “[Intellectual Property Rights and Innovation: Evidence from the Human Genome](#)” 2013, *Journal of Political Economy* 121 (1): 1-27.

### Bayh-Dole and Data Sharing

Even as the 35<sup>th</sup> anniversary of the passage of Bayh-Dole approaches, there continue to be misperceptions about the power of funders such as the NIH to mandate data sharing under investigator-initiated grants. Many continue to argue that grants cannot be conditioned on data sharing, while others argue the opposite. However, grants are subject to many types of obligations and the applicable Federal regulations indicate that the federal government has the right to obtain, reproduce, publish, or otherwise use the data first produced under an award.



### The Intellectual Property Non-Issue

In reality, Intellectual Property (IP) laws and Bayh Dole in particular do not seem to be a roadblock to data sharing. However, to dispel misunderstandings and encourage clear debate, more light needs to be shed on exactly what Bayh-Dole says about the patenting process surrounding government-funded research and intellectual property ownership. Clarity is needed regarding what applicable laws and regulations say about ownership and sharing of government-funded data. This clarity is also needed regarding an entity’s power to mandate data sharing. In this way, a true policy debate may occur rather than debate being avoided through concerns that further legislation or regulation may be required.

University presidents and research directors must also understand that the income potential from monetizing intellectual property at universities is not material and should not conflict with the primary mission of research universities to disseminate knowledge to benefit society.

**Respect of Patient Data**

*“At One Mind, we feel that patient privacy and consent are at the core of successful data sharing.”*

**The Still Undetermined Impact of HIPAA**

The privacy provisions of the Health Insurance Portability and Accountability Act (HIPAA) are often cited as a barrier to data sharing, even by those who fully support robust protection of privacy for patients. As HIPAA enforcement increases, it is becoming easier for regulated entities to refuse data sharing rather than work through the compliance issues. So far, HIPAA has created a huge regulatory burden, yet only impacts certain holders of medical information. Concerns have been raised that its definition of de-identified data and its permitted uses may not protect patients from re-identification. And patients are not in control of their own data and not generally brought into the research process. So if they have given broad consent for its use, it is unlikely they will have any understanding of its current and future use. Along with other issues, it seems current privacy practice is built on an unstable foundation and the medical profession as a whole may risk losing the trust of patients in the long term.

Leadership must accept that transparency is important for patients. Transparency can best be achieved by deeper involvement on the part of patients themselves in project design. This will do much to resolve patient privacy concerns. Patients are generally impatient with barriers that they perceive as holding back better treatments and cures, so their involvement will help remove those barriers.

**Suggested Approaches to Privacy**

At One Mind, we feel that patient privacy and consent are at the core of successful data sharing. The One Mind Summit panelists have proposed the following steps:

- Development of standardized approaches to patient consents, including across diseases.
- Patients should be involved in experimental design and review and understand privacy risks.
- Researchers should acknowledge that patients have rights related directly to the data they provide, such as the right to receive results.
- Consented patient data should be shared and used not discarded.





### The Strategy for One Mind in Brain Disease Research

*“One Mind has chosen a strategic approach based on thinking big, starting small – and scaling rapidly. With this approach, One Mind hopes to prove that an open science model can work in a focused disease area (PTS/TBI).”*

- When patients give consent, that consent should override prior consents and be portable.
- Patients deserve that results using patient-derived data should be fully reproducible.
- Users of de-identified data should pledge its ethical use
- Users of de-identified data should not attempt to re-identify patients.
- The handling of patient data must be by trusted recipients.
- HIPAA must be further examined in context of overall regulation.
- Clearer guidance on HIPAA compliance must be sought, so as to enable full data sharing.
- Government guidance on re-identification risks, and experts certified related to their competence to assess risks, should be pursued.
- Consideration of criminal prohibition on wrongful re-identification.
- General review of anti-discrimination laws.

## The Road Ahead

### A Strategic Approach for Data Sharing in Brain Disease Research

The issues discussed in this paper, as well as the proposed solutions, impact almost every member of the brain disease research community. This includes government, universities, and academic journals. So developing a culture that is supportive of collaboration and data sharing is critical to resolving these issues. One Mind has chosen a strategic approach based on thinking big, starting small – and scaling rapidly. With this approach, One Mind hopes to prove that an open science model can work in a focused disease area (PTS/TBI) and once successful, expand this approach to other related disease research. One Mind will also continue to work with data quality and data sharing initiatives in other areas of neuroscience for the purpose of avoiding duplications of effort.

### Thinking Big

Our current focus is on a new approach to diagnose, treat, and cure PTS and TBI. However, we have always believed that the data sharing principles, collaborative structures, and technology solutions that we are developing in our PTS and TBI programs will have broad application across the brain. From the initial “use case”



in PTS and TBI, the One Mind approach will ultimately advance diagnostics, treatments, and cures for many mental health and brain conditions.



### Starting Small

One Mind is planting seeds of innovation in several areas. This includes leading the development of the Apollo knowledge data portal where specially coded de-identified information gleaned from the PTS and TBI online communities, TRACK-TBI and CENTER-TBI (see below), and other programs will be available to research partners. By accessing the portal, researchers can come together and collaborate; share and analyze the data using data integration and analysis tools; and begin to understand not only PTS and TBI, but all diseases and injuries of the brain.

### The Big Test for Shared Data

*“Both TRACK-TBI and CENTER-TBI will use similar protocols and share data throughout the duration of their studies. It is our belief that the data generated, when supplemented with data from the online communities, will lead to better diagnostics, treatments, and cures for those living with PTS and TBI. These results will also be useful to researchers studying related illnesses.”*

We are also facilitating and supporting two innovative, large-scale research collaborations: TRACK-TBI and CENTER-TBI. TRACK-TBI is a partnership among 11 research universities whose trauma centers will enroll 3,000 patients in a longitudinal brain injury study. The first patient enrolled in February. With an \$18 million grant from the National Institutes of Health (NIH), TRACK-TBI represents one of the largest, cutting-edge studies of PTS and TBI. CENTER-TBI, similar in scope but focused on Europe and funded by the European Union, is expected to launch in October 2014 and follow another 6,000 patients over several years. Both TRACK-TBI and CENTER-TBI will use similar protocols and share data throughout the duration of their studies. It is our belief that the data generated, when supplemented with data from the online communities, will lead to better diagnostics, treatments, and cures for those living with PTS and TBI. These results will also be useful to researchers studying related illnesses such as depression, Parkinson’s, ALS, dementia, Alzheimer’s, and addiction.

One Mind is also a supporter of the recently funded Department of Defense (DoD) TBI Endpoints Development (TED) grant which represents a collaborative effort among TRACK-TBI, the Chronic Effects of Neurotrauma Consortium (CENC), and the Concussion Research Consortium (CRC), along with recruited experts in military, civilian, and sports TBI. The expertise of the team, coupled with the robust FDA regulatory experience of our public-private partners, will



### Moving Towards Incentives

*"One Mind's efforts in addressing these ongoing issues in brain disease research related to PTS and TBI are having an effect. Yet it is often inefficient. Work-arounds are in reality just carefully crafted temporary solutions that would be unnecessary if a truly functional incentives program existed."*

work towards validating endpoints and improving clinical trial design to inform and accelerate FDA approval of diagnostic tools and therapeutic agents for TBI. TBI investigators supported by One Mind generally adhere to the One Mind Open Science Principles. However, complete acceptance depends on showing that adherence does not impact career progression and funding and leads to faster transition "from the bench to the bedside" (patient focus).

Other initiatives One Mind is supporting that will help advance the cause of data sharing in PTS and TBI include:

- TRACK-TBI investigator and site research standardization training and use of a common Electronic Data Capture Platform (EDCP) such as QuesGen in Track-TBI, Center TBI, and hopefully other studies.
- General acceptance of the NINDS-generated Common Data Elements (CDEs) by all of the ongoing TBI studies and integration of those CDEs into QuesGen which guarantees substantial clinical standardization in those studies where QuesGen is the EDCP.
- Funding of Thompson Reuters (TR) to conduct Track-TBI data curation. TR also did data curation for the TRACK-TBI Pilot that was also funded by OM.
- Upload of all U.S. TBI data to the Federal Interagency Traumatic Brain Injury Research (FITBIR) informatics system database. FITBIR is a NIH/DoD joint venture that was designed to be an international repository.
- Working with TRACK-TBI investigators to ensure that de-identified patient data is made available to all investigators during the course of the study and to all researchers 6 months after the conclusion of the study – all while ensuring patient privacy.
- Partnering with patientslikeme.com (PLM) to create sophisticated online communities for those suffering from PTS and TBI, and their caregivers. Here, patients will share as much, or as little, of their data as they choose.

One Mind's efforts in addressing these ongoing issues in brain disease research related to PTS and TBI are having an effect, albeit an inefficient one. Workarounds are required to enable sharing of high-quality data that in reality are just carefully crafted temporary solutions that would be unnecessary if a truly functional incentives program existed. A good example of this is paying for the curation of data when investment in common data elements, computers, and software could

greatly reduce that task. Another example is paying to convert NIH-developed CDEs into a format that will allow generated data to be accepted by the FDA. Better coordination between agencies during development of CDEs would eliminate both the additional cost and the delay in the publication of FDA-approved CDEs. True efficiency and its many benefits to research will only come when researchers, universities, and government agencies make the cultural and policy changes that result in a re-engineered incentive system.

### Scaling Rapidly

Once we have shown that marginal changes to the incentive system and general adherence to open science principles speeds the discovery of better diagnostics and treatments for PTS and TBI, One Mind will identify lessons learned and expand our support to research designed to do the same in related diseases. A first look at this potential can already be seen in our emerging partnership with the American Migraine Association. In addition, PLM data is already helping to identify comorbid conditions that will help us understand where we should scale. And as the extent and quality of data increases, industry participation through public-private partnerships should shorten the timeframe “from bench to bedside.”



## About Us

### Who We Are

One Mind is an independent 501(c) (3) non-profit organization dedicated to helping those with brain illness and injury. By fostering fundamental changes in how neuroscience research is conducted, we can radically accelerate the development and implementation of improved diagnostics, treatments, and cures. One Mind believes in Open Science Principles and creates global public-private

### A Long Term Vision for Brain Disease Research

*“At One Mind, our vision is of a world free of the personal, social, and economic ravages of brain disease. Through Open Science Principles, we believe we can transcend existing barriers to scientific advancement in brain disease research. And by creating global public-private partnerships between governmental, corporate, scientific, and philanthropic communities, this vision can become a reality.”*

partnerships between health care providers, researchers, academics, and the health care industry - on a global scale - to cure all brain disorders. At One Mind, our initial focus is on two areas of brain injury and illness:

- Post-Traumatic Stress (PTS)
- Traumatic Brain Injury (TBI).

These two areas have historically been underfunded. However, they are areas in great need of better diagnostics, treatments, and cures. The staff, volunteers, and supporters of One Mind feel our continued efforts in the areas of PTS and TBI will also serve as proof of concept for our open science approach and establish a much needed framework that can be used in the study of other brain diseases as well.

### Our Vision

At One Mind, our vision is of a world free of the personal, social, and economic ravages of brain disease and injury. Through Open Science Principles, we believe we can transcend existing barriers to scientific advancement in brain disease research. And by creating global public-private partnerships between governmental, corporate, scientific, and philanthropic communities, this vision can become reality.

### Our Model

To achieve this vision, One Mind has adopted a model based on the development of a broad international coalition to deliver accelerated new treatments and cures for all brain illness and injury. This coalition consists of scientists, advocates, philanthropists, pharmaceutical groups, health-care interests, and government entities from around the globe. Together we are moving forward to:

- Create paradigm-changing Public-Private Partnerships that leverage government, industry, and other global efforts
- Secure new sources of major funding and use this funding to change incentives and promote collaboration
- Transform policy by uniting the advocacy community toward common goals.
- Reduce stigma and discrimination
- Establish standards for fair treatment of those suffering from brain disease.



**General Pete Chiarelli (Ret.)**

*Chief Executive Officer  
One Mind*

*Former Vice Chief of Staff  
U.S. Army*

### Our Leadership

General Pete Chiarelli, U.S. Army (Retired), is former Vice Chief of Staff of the Army and currently serves as the Chief Executive Officer at One Mind. As the 32nd Vice Chief of Staff, he led the Department of Defense efforts on Post-Traumatic Stress (PTS), Traumatic Brain Injury (TBI), and suicide prevention. Chiarelli was also responsible for the day-to-day operations of the Army and its 1.1 million active and reserve soldiers. This included the oversight of many of the Army's R&D programs, and the implementation of recommendations related to its behavioral health programs, specifically its Health Promotion, Risk Reduction, and Suicide Prevention Program.

General Chiarelli served as commander of the Multi-National Corps in Iraq under General George W. Casey, Jr. and was the Senior Military Assistant to the Secretary of Defense from March 2007 to August 2008. Chiarelli pioneered efforts to restore government, economic stability, and essential services during two tours in Iraq; exercised command and control of combat operations; and trained, prepared, and mobilized reserve forces for critical response operations. He retired from the Army in 2012 after almost 40 years of service. In 2013, General Chiarelli received the Patriot Award, the Congressional Medal of Honor Society's highest honor, for his work to help soldiers and families suffering from the invisible wounds of war.

General Chiarelli holds a Bachelor of Science degree in political science from Seattle University, a Master of Public Administration degree from the Daniel J. Evans School of Public Affairs at the University of Washington, and a Master of Arts degree in national security strategy from Salve Regina University.



## Action List for the Brain Disease and Injury Research Community from the One Mind Summit

### 1. Make Sure Research Is Reproducible

**Improve Researcher Training:** Strong endorsement of the need to improve researcher training in experimental science (e.g., from the keeping of lab notes and books to experimental design) and statistics (e.g., ability to do research study power calculations).

- This was identified as a “process problem.” There were recommendations to create a Joint Commission on Accreditation of Healthcare Organizations (JACHO)-like certification authority for labs receiving NIH grants and also to develop “Capability Maturity Model” scores for institutions.

**Address Cultural and Policy Issues:** Universities need to address the cultural and policy issues that negatively impact on the reproducibility of research (e.g., the intense competition for jobs; the pressure to publish fast and frequently).

**Focus:** Funders/journals should focus less on novelty as a basis for grants/publication.

**Develop:** Research journals and the research community should:

- Develop metrics for the quality and reproducibility of data.
- Link publication to the requirement to publish the associated data set and software.
- Work with data repositories (e.g., FITBIR) to allow data bases to be accessible to the entire research community.
- In conjunction with repositories, provide readers with more information about research methods and provide the software used to develop findings.



## 2. Eliminate Obstacles and Enable Open Science

**Adopt Community Principles:** There was a strong consensus that the changes required for open science can best be achieved by involvement of a research or disease community that could serve as a model for larger changes within neuroscience. The adoption of the Bermuda Principles occurred on a research community basis, as did the formation of the Structural Genomics Consortium. It was suggested that One Mind could take the role of leader in developing an open science approach in PTS and TBI.

**Establish Funding for Infrastructure:** There is no acknowledged funding source for data sharing infrastructure. That includes everything from common data elements, to data entry technology, to curation, to data base management, and to data storage. Surprisingly, researchers, government agencies, and universities all consider it an unfunded requirement. However:

- By contrast, data sharing and data infrastructure are at the core of Europe's Innovative Medicine Initiative (IMI) projects.
- The failure to provide a data infrastructure means that current processes are much more expensive than they should be; with standard data elements and entry, computers can quite easily accomplish many data set aggregation, curation, and integration tasks.

**Promote Benefits of Standardization:** There is little or no focus on the benefits of standardization. This results in unnecessary costs and inefficiencies and makes data sharing and collaboration more difficult than necessary. Standardization does not necessarily stand in the way of great science.

**Implement Incentives Program Community Wide:** There are few incentives for collaborative research that implements open science principles and many incentives against such cooperation.

**Reward Collaboration:** In addition to funding the infrastructure of data sharing, funders should reward a record of collaboration and data sharing and fund “non-innovative” work needed for data sharing and data analyses.

**Build A Community Portal:** There is an established need for a sustainable data repository or portal through which databases can be easily shared, identified, accessed, and analyzed. Through ease of use and availability of tools, this data repository would provide incentives for cooperation. The creation of, and the need for, a data registry was discussed at both the One Mind Summit and GE/Kavli Conference the week preceding the Summit.

**Involve Industry:** Industry should make available useful data sets (e.g., successful and unsuccessful clinical trials). Industry led pre-competitive partnerships are a confidence building measure.

**Reward Researchers who Share:** Research journals and the research community should:

- Create identifiers for researcher and research focus (e.g., ORCID.org) and develop metrics for data sharing and cooperation as well as for use of shared data.
- Develop metrics for the availability of data associated with journal articles (“HD index”).
- As noted with respect to replicability, link publication to the requirement to publish the associated data set and software and work with data repositories (e.g., FITBIR) to allow data bases to be accessible to the entire research community.

**Demystify Bayh-Dole:** Bayh-Dole should be demystified, thereby eliminating a perceived obstacle to data sharing and the adoption of open science principles. University leaders should be educated on the low returns from technology transfer and to refocus on the academic mission.

### 3. Engage Patients and Standardize Patient Privacy

**Engage Patients:** Increased patient focus, transparency, and involvement are required throughout the system.

**Standardize:** Disease-specific approaches to standardizing IRB and other approaches need to be standardized.

**Seek Clarification of Laws:** There is a need to provide clear guidance on the Health Insurance Portability and Accountability Act (HIPAA). Many argued that as written, interpreted by health care lawyers, and enforced by the government, it was time to re-write the 1996 statute; however, all agreed given the current atmosphere in DC, that would be impossible. The current law, and concern over re-identification, makes it hard to realize the potential of the data in EMRs. There was also concern that despite its complexity, the law does not necessarily protect patients.

**Prohibit Re-Identification of Data:** Legislation prohibiting the re-identification of data for unauthorized purposes would help with the concerns of patients. However, new norms for patient involvement and privacy and mechanisms for establishing trust

should be developed in conjunction with patient advocacy groups.

#### **4. Modernize the Dissemination of Research Findings**

##### **Increase Speed of Data Sharing:**

Early data publication should not preclude later publication of analyses.

Data, software publications, and other “non-traditional” publications should be given consideration in grant and advancement criteria. Journals should implement a system of post-publication peer review that rewards good science and enables more rapid dissemination of knowledge.

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### 3rd Annual Summit Speaker List

**Dr. Christopher Austin**, Dir., Nat. Center for Advancing Translational Sciences, NIH

**Robi Blumenstein**, President, CHDI Management

**Dr. Philip Bourne**, Associate Director for Data Science, NIH

**General Peter Chiarelli**, U.S. Army (Retired), Chief Executive Officer, One Mind

**Dr. William Chin**, Executive Vice President, Science and Regulatory Affairs, PhRMA

**Dr. Robert Cook-Deegan**, Senior Fellow, Faster Cures and Research Professor,  
Genome Ethics, Law and Policy, Duke Institute for Genome Sciences and Policy

**Honorable Chaka Fattah**, Congressman, U.S. House of Representatives

**Dr. Michel Goldman**, Executive Director, Innovative Medicines Initiative

**George Goldsmith**, Chairman and Founder, Tapestry Networks

**Hazel Grant**, Partner, Bristows

**Dr. Jeffrey Grethe**, Associate Dir., Center for Research in Biological Systems, UCal SD

**Dr. Magali Haas**, Founder and CEO, Orion Bionetworks

**James Heywood**, Chairman and Co-Founder, Patients Like Me

**Dr. Sean Hill**, Scientific Director, International Neuroinformatics Coordinating Facility

**Dr. Thomas Insel**, Director, NIMH, NIH

**Stephen Johnson**, Chief Intellectual Property and Policy Officer, One Mind

**Thomas Kalil**, Deputy Director for Technology and Innovation,  
The Whitehouse Office of Science and Technology Policy

**Honorable Patrick J. Kennedy**, Co-founder, One Mind

**Dr. Véronique Kiermer**, Dir. of Author and Reviewer Services, Nature Publishing

**Bron Kisler**, Vice President, Strategic Initiatives, CDISC

**Dr. Shiva Kumar**, Vice President, Strategy and Enterprise Initiatives, IBM

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**Dr. Geoffrey Manley**, Prof. and Vice Chairman of Neurological Surgery, UCal SF

**Elizabeth Marincola**, Chief Executive Officer, Public Library of Science

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**Dr. David Shern**, Senior Science Advisor, Mental Health America

**Dr. Shai Siberberg**, Program Director, Extramural Research Program,  
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**Garen Staglin**, Co-Founder and Co-Chairman, One Mind

**Dr. Don Stuss**, President and Scientific Director, Ontario Brain Institute

**John Wilbanks**, Chief Commons Officer, Sage Bionetworks

**Denis Wirtz**, Vice Provost for Research, Johns Hopkins University

**Note:** The views expressed in this document do not necessarily reflect those of speakers and participants at the One Mind Summit but rather represent individual opinions.