September 29, 2016

The Honorable Francis Collins, M.D.
Director,
National Institutes of Health
Department of Health and Human Services
Attention: NOT-OD-16-133
Submitted electronically to: NIH_Repository_Metrics_RFI@mail.nih.gov

Re: Request for Information (RFI): Metrics to Assess Value of Biomedical Digital Repositories

Dear Director Collins:

The American Medical Informatics Association (AMIA) appreciates the opportunity to submit comments regarding this Request for Information (RFI) on Metrics to Assess Value of Biomedical Digital Repositories. This RFI was published by the National Institutes of Health (NIH) on August 12, 2016.

AMIA supports NIH efforts to articulate the value of deposition repositories and knowledgebases. We believe such repositories play a critical role in enabling research and promoting biomedical research rigor, transparency and reproducibility. AMIA is a strong proponent of FAIR data principles, and encourage NIH to leverage these principles wherever possible.

Regarding the question of measuring value, AMIA supports the identified domains of utilization, impact, quality of service and governance. However, we recommend NIH view these domains with varying degrees of importance. Further, we contend that no single set of measures will be sufficient for the vast array of different repositories in use today or in development for future research. There will be no "one-size fits all" scorecard given the wide range of data uses and repository models. Context will be important to reflect accurate value.

Additionally, we make the following recommendations and observations related to each domain:

- **Utilization:** Overall we do not believe utilization data, regardless of how it is captured, should be a strong indication of value for deposition repositories or knowledgebases. Counts of accesses or downloads may be easily measured, but they are at best proxies for desired outcomes. We encourage NIH to focus on measures that assess data stores in terms of meaningful scientific impact.
- **Impact:** We believe this category of metrics reveal more about a repository's value than other metrics, and we encourage NIH to look for both innovative and comparable measures. AMIA supports the listed examples to measure impact; however, we recommend that NIH be cognizant of the difficulty in capturing proximal and, more importantly, distal outcomes

measures – especially given that such measures are likely to be separated by indeterminate time periods.

- **Quality of service:** AMIA supports the listed measures, and would encourage RFI reviewers to view quality of service related to repositories similar to other consumer-facing web-based property, such as Amazon or GitHub.
- **Governance:** Experience to-date indicates that several best-practices are emerging from leading biomedical repositories around development of standard policies, processes and transparency. Data deposition policies, dataset descriptions and transparency around funders, advisors and operations are all important hallmarks of 21st century biomedical research. Insofar as repositories have specific kinds of policies in place and are transparent with regards to management and operations, AMIA would not encourage NIH to be overly prescriptive with expectations of legal requirements. NIH should articulate the kinds of information and policies that are expected to be made available, rather than articulate the contents of those policies.

One additional category we encourage NIH to consider is related to the dimension of data quality and data completeness. AMIA believes it is important to acknowledge that repositories are only useful if they are comprised of quality data, including meta-data. As NIH considers ways to measure value, we encourage NIH to focus additional attention on data veracity and completeness.

A group of AMIA members, listed in Appendix A, has provide detailed responses to this RFI in Table 1 of the enclosed document. These responses have been reviewed and duly approved by AMIA's Public Policy Committee and the AMIA Board of Directors. Should you have any questions or require additional information, please contact AMIA Vice President for Public Policy Jeffery Smith at jsmith@amia.org or (301) 657-1291 ext. 113. We, again, thank NIH for the opportunity to comment and look forward to continued dialogue.

Sincerely,

Douglas B. Fridsma, MD, PhD, FACP, FACMI
President and CEO
AMIA

Thomas H. Payne, MD, FACP
AMIA Board Chair
Medical Director, IT Services, UW Medicine
University of Washington

Enclosed: Detailed AMIA Comments on Measures to Assess the Value of Biomedical Digital Repositories

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Table 1

	The NIH is seeking information on qualitative and quantitative metrics such as those that describe:	
	Metric	AMIA Comment / Notes
1	Utilization at multiple levels (repository, dataset, data item). In addition to the frequency of access and number of downloads, this might include: • Size and measured demand of the community served, placed in the context of the overall field. • The ongoing rate of data deposition and data access or download	**AMIA Recommendation:** Overall we do not believe utilization data, regardless of how it is captured, should be a strong indication of value for deposition repositories or knowledgebases. While we recognize these data might be relatively easy to capture, utilization metrics measuring access rates do not necessarily assess desired outcomes in terms of scientific advancements. We recommend NIH focus less on transactional metrics and more on those metrics which indicate impact of use or productivity. We agree that frequency of access by unique individuals and number of downloads could prove useful data points for utilization in both kinds of repositories. Data access counts and frequency are helpful in making sure that repository infrastructure is adequate to the needs of the community, but do not specifically imply use or quality. However, we caution that not all repositories offer downloads or have user bases that download data / information. Furthermore, difficulties in determining appropriate measurement granularities – for example, what exactly defines a dataset as opposed to a data item – may make access metrics difficult to define and compare across resources. While we agree that capturing metadata on who is accessing / contributing data to repositories, we believe it would difficult to extrapolate demand of the community served, placed in the context of the overall field. This would prove especially difficult given the variance in kinds of repositories and data uses. Finally, we caution against overemphasizing usage at a granular level (such as individual data item) since some commercial users might consider their queries to be intellectual property, and such requirement – were it mandatory – might actually discourage the use of such repositories.

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		Deposition Repositories • Ongoing rate of data deposition • Number and nature of searches	Knowledgebases • Count of curated findings contributed to knowledgebase on a (monthly, quarterly, yearly) basis • Number and nature of searches
2	Indicators of data repository quality and impact. Examples include but are not limited to: • Publications from the data • Data citations • Altmetrics • Patents • Utilization of data sets in research studies • Outputs of those research studies, e.g. use in policies or guidelines • Enhanced data sharing and community collaboration around annotation/analysis of data sets • Economic measures such as investment and use value; efficiency impacts; return on investment	**AMIA Recommendation:** We believe this category of metrics reveal more about a repository's value than other metrics, and we encourage NIH to look for both innovative and comparable measures. We support the examples listed and indicate below additional examples, specific to one of the two kinds of repositories. Further, we encourage NIH to review published information on assessing the Dryad Data Repository[1] and the subject of impact measures.[2] For both deposition repositories and knowledgebases, we encourage NIH to consider: • Incorporation of data into larger data sets or data products • The number and nature of tools and methodologies derived from or used to manipulate the data as additional evidence of impact We reiterate that the dimension of time must be taken into account for this kind of metric, as a tool or methodology could take a number of months or years to build. In fact, many of the listed measures will need to be accompanied by a reasonable timeline of evaluation. As we are aware that the lack of fixed time	

[1] Whyte, A., (2011) "A Draft Framework for Assessing the Dryad Data Repository," Oxford University. Digital Curation Centre. Available online at http://wiki.datadryad.org/images/1/19/DryadUKAssessmentFrameworkRpt_1-0.pdf

[2] Ball, A., & Duke, M. (2015). 'How to Track the Impact of Research Data with Metrics'. DCC How-to Guides. Edinburgh: Digital Curation Centre. Available online: http://www.dcc.ac.uk/resources/how-guides

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<tr><th></th><th colspan="3">The NIH is seeking information on qualitative and quantitative metrics such as those that describe:</th></tr>
<tr><th></th><th>Metric</th><th colspan="2">AMIA Comment / Notes</th></tr>
<tr><td></td><td></td><td colspan="2">intervals may influence funding decisions, we suggest the use of intermediate assessments as to inform decisions regarding additional funding. For example, resources under initial development might propose preliminary metrics regarding the scope of data collected and curated, prior to the use of metrics assessing direct scientific impact.</td></tr>
<tr><td></td><td></td><td><u>Deposition Repositories</u>

• Amount of missing data could be measured; look for outcome information not in unstructured field; how populated are the fields;
• Measures that are specific to the data domain (e.g. how well diagnoses align in number with patients, how many diagnosis per encounter; per patients, e.g.)</td><td><u>Knowledgebases</u>

• Grants awarded based on resources
• Invention disclosures or patents
• Peer reviewed articles (especially reviews) generating citing knoweldgebase</td></tr>
<tr><td>3</td><td>Quality of service. Examples may include but are not limited to:
• Implementation of a rigorous quality assurance process
• Use of community-recognized standards
• User support and training</td><td colspan="2">AMIA Recommendation: AMIA supports the examples listed for both kinds of repositories. Additional measures could include:
• Third-party assessments of data or resources for annotation, accessibility, and (re)usability
o Usability metrics can be reported in terms of quantitative data (key clicks to data, time spent searching before data download,</td></tr>
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	The NIH is seeking information on qualitative and quantitative metrics such as those that describe:	
	Metric	AMIA Comment / Notes
	• Ease of data deposition and retrieval • Technical indicators, e.g., uptime, response time	etc.) and can be reported qualitatively (user experience testing, eye tracking, etc.). NIH should consider using third parties skilled in these sorts of metrics/testing. • Availability of assistance
4	Infrastructure and governance. Examples may include but are not limited to: • Existence of an independent advisory board • Legal structure, e.g., access, security, licensing • Long-term sustainability plan	**AMIA Recommendation:** We believe the existence of an independent advisory board is an appropriate metric for governance, but do not believe all repositories would need such a body. In terms of legal structure, we suggest NIH clarify whether this means "terms of service" and service level agreements or something more, such as a foundation. We do not believe many or most repositories would necessarily benefit from a large legal structure, as this would likely add tremendous overhead to operating budgets. • Does the repository clearly articulate data policies / terms of use?[3] • Are terms of use and reuse clearly stated and present in the form of community-accepted licenses such as Creative Commons or the Gnu Public License? • Does repository require contributors to provide standardized sets of information?[4]

[3] Scientific Data's Data Policies: http://www.nature.com/sdata/policies/data-policies
[4] NCBI's GEO and MIAME (Minimum Information About a Microarray Experiment) is an example: http://www.ncbi.nlm.nih.gov/geo/info/MIAME.html

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<tr><td></td><td></td><td>• Dataset descriptions describing latest version; editors and contributors; and other aspects of a given dataset[5]
• Does the repository issue requests for public input or otherwise provide for user feedback?[6]
• Does the repository clearly make available its funders and partners?[7]
• Are there policies in place to address “orphan data?” Good use can still be made of it, but what is the governance / access/ security structure around it?</td></tr>
<tr><td></td><td></td><td><table><tr><td><u>Deposition Repositories</u></td><td><u>Knowledgebases</u></td></tr></table></td></tr>
<tr><td>5</td><td>Qualitative metrics that may address many of the above categories, such as collection of use cases or case studies</td><td>AMIA Recommendation: We recommend that NIH consider the following metrics as a means to further articulate repository value:
• Does the repository include patient-generated data or link to patient-driven research networks; patient-reported metrics? Contributions from patients and patient groups could portent a level of sophistication and planning as to satisfy questions of value.
• Does the repository require users to register and is this information used to improve the service via survey or some other communications device?</td></tr>
<tr><td>6</td><td>Consideration of case studies demonstrating the value of the repository. For example, assessing the questions of:</td><td>AMIA Recommendation:
• Do geographical or geopolitical aspects impact repository value? Is it relevant if the repository is in Brasil, Russia, India or China vs. the more</td></tr>
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[5] Semantic Web in Health Care and Life Sciences Interest Group, WC3, https://www.w3.org/TR/hcls-dataset/
[6] bioCADDIE DataMed DDI Prototype – Call for Feedback, https://biocaddie.org/datamed-prototype-call-feedback
[7] BioSharing funders, https://biosharing.org/communities

	The NIH is seeking information on qualitative and quantitative metrics such as those that describe:	
	Metric	AMIA Comment / Notes
	• If the repository weren't available, how would that impact your work? • What are the data sharing alternatives to the repository? • What are the implications of using these alternatives?	usual US / EU / Japan? Are there well-known repositories that are not in English? • How does disappearance of an existing repository impact ongoing work? "Disappearance" can be due to termination of funds or change of policy from open-access to fee-for-access. • Did the repository facilitate your clinical work? If so, please tell us how. • How did you learn of the repository? • Have you recommended the repository to other colleagues or students?

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Appendix A
AMIA Response Team Members

Comment Opportunity: NIH RFI			
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