RPG Review

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Application #: NIH Draft NIH Strategic Plan for Data Science

Principal Investigator(s): NIH

Overall Impact

Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following five scored review criteria, and additional review criteria. An application does not need to be strong in all categories to be judged likely to have major scientific impact.

Overall Impact **9**

Write a paragraph summarizing the factors that informed your Overall Impact score.

This strategic plan has very low likelihood to exert any substantive influence on research fields – including Data Science. Data Science is a dynamic and heterogeneous field that goes far beyond simply assembling, storing, and managing data, and to exert influence on this (or any other) field, this Strategic Plan should have been based on a needs analysis of any of those fields. “NIH supports the generation and analysis of substantial quantities of biomedical research data”; but NIH also supports the generation of substantial quantities of data that are not actually supportive of research aims. The Draft Strategic Plan for Data Science conflates “all data” with “research data”, resulting in a Plan that, even if fully realized, cannot purposefully support the NIH mission of seeking or applying knowledge “to enhance health, lengthen life, and reduce illness and disability.” What this Plan mainly supports is data management; to “allow NIH to adopt more cost-effective ways to capture, access, sustain, and reuse high-value biomedical data resources in the future”. However, two previous 10-year programs to fund infrastructure (National Centers for Biomedical Computing, NCBC; Big Data to Knowledge, BD2K) have cost NIH and taxpayers millions, and yet while

they clearly should have laid the groundwork for at least some part of the vision laid out in this Strategic Plan, neither their failures nor their successes are featured or reflected on at all. Since neither of those two programs had any lasting influence at all on NIH's current thinking, it is unlikely that this Plan could be expected to have either sustained or powerful influence on the NIH, much less on research. Moreover, the foundational weaknesses in the evaluations contemplated throughout the Plan highlight an unwillingness – or inability - to formalize evaluation – which may be the reason why prior programs never had any substantive successes OR failures to report. It is obvious that, because the NIH awards grants to investigators, if this Plan were implemented, there would be *financial* influence on anyone who chose to compete for these funds. However, the "power" of that influence would be questionable – and only lasting as long as the funding does. There is literally no way for this Plan to have any effect or impact on Data Science; since it was developed with no apparent input from practicing data scientists, they will ignore this Plan and worse, most probably continue to develop the discipline with no reference to this Plan at all. Then at the end of this initiative, anyone who pursued "Data Science" following the NIH Plan will not be competent, or even proficient, in actual Data Science. There does not appear to have been any consideration of how any biomedical science could be affected in any way by the execution of this Plan; therefore weakening any likelihood of this Plan having any real influence on the biomedical research fields that should be of greatest interest to NIH.

Scored Review Criteria

Reviewers will consider each of the five review criteria below in the determination of scientific and technical merit, and give a separate score for each.

1. Significance **9**

Strengths

None noted.

Weaknesses

Does the project address an important problem or a critical barrier to progress in the field?

No barrier to progress in any field is meaningfully defined or characterized. This Plan appears to have been motivated by the survey results published by “CrowdFlower” reporting “How a Data Scientist Spends Their Day (p. 6) – but while this may in fact describe how * data scientists * spend their day, it does not describe how NIH funded scientists or biomedical scientists who are not employed as data scientists interact with data. People who are employed as data scientists may actually be specifically hired to do data wrangling to free up biomedical scientists for the rest of the scientific process. The more appropriate interpretation of this survey result (that 80% of time is spent managing/cleaning data) is that biomedical researchers may need to hire someone to do this, not that biomedical scientists need NIH to manage data or further fund data oriented initiatives.

The use of the expression “Plan for Data Science” suggests that executing this Plan may actually have some effects on Data Science as a discipline, but since there does not appear to have been any actual Data Scientists involved in crafting this Plan, that title is inappropriate. The first group to whom “workforce development” activities are directed are NIH employees (Objective 4-1). This is not a “critical barrier to progress in the field”, it is an NIH HR issue.

Is there a strong scientific premise for the project?

There is no scientific premise at all for the concept that NIH can contribute to Data Science by drafting a Plan with goals that are as weakly “evaluated” as the Plan describes. The idea that biomedical researchers need to harness the dynamic innovation that is always going on in Data Science makes sense, but this Plan does nothing to engage with actual data scientists, and it was clearly written without appeal to, or communication with, the work of Data Science or data scientists.

If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved?

It is *possible* that both the NCBC and BK2K programs resulted in incremental gains in scientific knowledge and technical capabilities – for a very specific few in the biomedical research field, but it is *certain* that no evidence is included in this Plan suggesting any such improvements as a result of its implementation. Moreover, the lack of reflection on these two previous programs suggests that, like them, no real advances or improvements are likely.

How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

By offering grant programs and RFPs that target data scientific investigators – irrespective of their actual, documented ability to have any effect whatever on biomedical research or the NIH mission of improving health – this Plan has some potential to drive Data Science as a field as far off course in the support of biomedical research as is conceivable. There is no reflection at all on prior NIH initiatives, and no consultation with the actual Data Science community, in the crafting of this Plan; so anywhere this Plan drives the field of Data Science will reflect the will of those who know very little, if anything, about the domain. Moreover, "successful completion of the goals" set forth in this Plan is **tautologically** determined: all of the goal evaluations involve counting events that NIH must already do: numbers of funded initiatives, numbers of initiatives that meet NIH-specified criteria, and other countable events with no consideration of whether incrementing the count by 1 or 1,000 is desirable. The impact that this Plan can have on the field of Data Science is negative, if it is non-zero. The impact the Plan can have on biomedical research is similarly limited.

Are the scientific rationale and need for <this proposal> well supported by preliminary data, clinical and/or preclinical studies, or information in the literature or knowledge of biological mechanisms?

Neither rationale (scientific or otherwise) nor need for this Plan is articulated. As noted, no reference is made to NCBC or BD2K, or to either failures or successes in those projects. So although NIH does have the ability to reflect on whether these initiatives had any effect at all, much less the desired effects, this Plan contains no rationale, no preliminary data, and no information or knowledge about the actual field that is emerging as Data Science. There is also no real representation of the role Data Science (in reality or as conceptualized in this Plan) can actually make for biomedical research.

For <trials> focusing on clinical or public health endpoints, is this <clinical trial> necessary for testing the safety, efficacy or effectiveness of an intervention that could lead to a change in clinical practice, community behaviors or health care policy?

There is no evidence or even suggestion that this Plan is warranted, needed, or necessary. No hypotheses about the effectiveness or efficacy of the execution of this Plan, which are all testable, have been put forward. There appears to be no interest at all in the NIH for justifying this plan rationally or with evidence. No one would ever propose to influence health care policy or clinical practice using “strategic plans” with the same total lack of awareness of what needs to be done, and how to do it, that this Strategic Plan for Data Science represents.

For <trials> focusing on mechanistic, behavioral, physiological, biochemical, or other biomedical endpoints, is this <trial> needed to advance scientific understanding?

The point of departure for this Plan is that data scientists should be spending less than 80% of their time wrangling data, without any consideration of the accuracy of that statement or its relevance for biomedical research. However, “do biomedical research” or indeed “do scientific research” is NOT one of the activities on the list of how data scientists spend their time, so spending less time wrangling data will not lead to “more time doing research”. Moreover, there is literally no need at all for this Plan to be executed in order to advance the understanding of Data Science; perhaps an RFP asking for informed, Data Science community-driven research into why data scientists spend so much time wrangling data (e.g., is that **because it is their job** OR is it **preventing them from doing their job**) would be informative -although reviews of applications responding to that RFP would require far more contextualization and articulated relationship to biomedical research than this Plan has. So far there appears to be no “advance of scientific understanding” that has accrued to the NCBC and BD2K initiatives. This Plan seems to strategize how to simplify the data scientist’s job – but has no real potential to affect the biomedical researcher’s job.

2. Investigator(s) **9**

Strengths

None noted.

Weaknesses

Are the PD/PIs, collaborators, and other researchers well suited to the project?

Given that this Plan is clearly lacking any input from actual, practicing data scientists, and the first group to whom “workforce development” activities are directed are NIH employees (Objective 4-1), there is clearly no one at NIH with the required qualifications for overseeing this Plan’s implementation, much less its drafting. The weaknesses in the alignment of the Plan goals and evaluations underscore the lack of qualifications of anyone drafting or reviewing this document at NIH to oversee its implementation or even its revision.

If Early Stage Investigators or those in the early stages of independent careers, do they have appropriate experience and training?

Data Science is a new domain. In spite of millions of dollars in funding, NIH has 20 years of experience (NCBC, BD2K) in this sort of infrastructure, but this proposal suggests it has still not moved any needle to promote or improve the discipline of Data Science. NIH has no evidence of the experience appropriate to undertake to guide or even influence Data Science. Meanwhile, statisticians, computer scientists, bioinformaticians, and business applications have all been actively defining Data Science and making tools and resources FAIR and accessible – mostly without interference or support from NIH.

If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)?

With no data whatsoever on, and no reflections on the successes or failures of, the NCBC and BD2K initiatives, anyone at NIH who has been working in or around Data Science sufficiently long to be considered “established” does not appear to have advanced their field in any way. Similarly, the NIH has not demonstrably improved biomedical research or the abilities of biomedical researchers to do anything more than contribute yet more data to existing resources where such data are stored.

If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

No. The team that authored this Draft Plan does not have the requisite expertise to lead a meaningful initiative that engages Data Science for biomedical research. The Plan represents a distinct lack of awareness of what Data Science as a field is and how it can be harnessed to support the NIH mission. This Plan could very well be used to find and fund investigators who similarly do not understand how Data Science can be used to strengthen biomedical research, simply by using this Plan to structure evaluations of the grant proposals that are submitted to whatever initiative this Plan may support. That would be a disappointing waste of money and resources. This Plan does not instill confidence that NIH has expertise or leadership sufficient to create and direct an initiative that meaningfully or effectively engages Data Science for biomedical research. Whomever commissioned or wrote this Plan needs to abandon it and start again. Ideally, a new Strategic Plan would focus on how Data Science can be leveraged for biomedical science, which would engage leaders and practitioners in the actual Data Science community who specifically support biomedical research. If the plan were drafted with independence, rather than with input from those who have had -and would rather maintain- NIH funding, it would be a promising start. The leadership that led to this Draft Plan needs to start over with a realistic and plausible Strategic Plan for engaging Data Science specifically in the support of biomedical research.

With regard to the proposed leadership for the project, do the PD/PI(s) and key personnel have the expertise, experience, and ability to organize, manage and implement the proposed clinical trial and meet milestones and timelines?

Unfortunately, NIH chose to draft this document themselves and ask for input later, rather than asking actual data scientists and actual biomedical researchers to draft something on which THEY, the NIH, could comment. The Draft Strategic Plan for Data Science, as a document, concretely supports a conclusion that the expertise, experience, and abilities required for success are absolutely *lacking* at NIH. No meaningful milestones are included and those that are reflect NIH priorities (counting up the number of things NIH does/values) rather than priorities in the scientific communities around data or biomedical research.

Do they have appropriate expertise in study coordination, data management and statistics?

Clearly not – see Objective 4-1. This Plan also underscores the lack of expertise in the NIH staff to coordinate, manage, or analyze the results of this Plan's implementation. The type of training in data intensive methods that the NIH appears to favour has been documented not to work (PNAS 2017, http://www.pnas.org/content/pnas/114/37/9854.full.pdf). Thus, not only is there

inadequate experience at NIH to coordinate or even propose strategies relating to Data Science, this Plan does nothing to support the formal and meaningful preparation of new **or experienced** biomedical researchers to work effectively with large data sets or with data scientists. As with the BD2K initiative, a focus on "training new researchers" when experienced researchers who use a new type of methodology/technology DO NOT YET EXIST is absurd. This Plan continues that absurdity - acknowledging that Data Science is a new and dynamic field (albeit one that the authors of the Plan know little about) but ignoring the fact that experienced researchers - the best prepared biomedical investigators to incorporate data-intensive methods into ongoing and productive research programs - should probably be the first who are specifically trained and supported to engage with the new and dynamic field that is Data Science. There is highly *inappropriate* "expertise" in anything that promotes the belief that new biomedical researchers - those who are not yet very experienced investigators - can simply attend a course on Data Science and suddenly have a totally new perspective on how to do the science they're really just learning to do *at all*. Data Scientists may be able to train workshop participants in data-intensive methods, but because they're not biomedical scientists, they won't be very capable of training participants in **biomedical research** that uses data. This may in fact be why there are no real results from BD2K showing positive impact on biomedical research (and, see http://www.pnas.org/content/pnas/114/37/9854.full.pdf).

For a multicenter trial, is the organizational structure appropriate and does the application identify a core of potential center investigators and staffing for a coordinating center?

In this case, if NIH did identify such a core, it would most likely represent individuals intent on obtaining and/or maintaining funding, and not on improving Data Science or supporting the evaluable integration of Data Science into biomedical research. There is literally no evidence in this Plan that NIH values the evaluable integration of Data Science into biomedical research; the goals are not aligned with this overall objective and the evaluation metrics that are proposed are orthogonal to that objective. Contributors who are independent of NIH should be solicited to start over, to draft a Strategic Plan for the evaluable integration of Data Science into biomedical research. This plan cannot be salvaged to accomplish this.

3. Innovation **9**

Strengths

None noted. This is NCBC 3.0 or BD2K 2.0 – not innovative in terms of prior NIH work. Similarly, the goals that are articulated are all achievable, if not already achieved, by the global biomedical research community leveraging data intensive methods, tools, and resources.

Weaknesses

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions?

The only paradigm this Plan will shift is to deflect real Data Science *away from novelty* to promote data wrangling and prioritize that ahead of science. No theoretical concepts, approaches, or methodologies relating to data or biomedical science are mentioned in this document (see Weaknesses in Investigators, above). Moreover, this Plan seems to encourage innovation in technology with no purpose except to make data wrangling and management easier for non-data scientists who then have no ability to use that data to improve health or their own research paradigms into biomedical problems.

Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense?

Nothing in this Plan is either innovative or actually reflective of the realities of Data Science as a discipline. Moreover, the Plan is also not sensitive to, or reflective of, the requirements of biomedical researchers who are **actually scientists now** to utilize the data that the NIH plans to wrangle for them.

Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

This Plan is a statement of vision, so no concrete refinements would be expected. What IS expected is that consideration of theoretical concepts, approaches, methodologies, instrumentations, or interventions from Data Science –and specifically, their

relevance to biomedical science – would have been proposed. Instead, there is only evidence that the drafters of the Plan do not understand either Data Science or its role in biomedical research.

Does the design/research plan include innovative elements, as appropriate, that enhance its sensitivity, potential for information or potential to advance scientific knowledge or clinical practice?

No. Even as a strategic vision, the Plan is irrelevant for Data Science as a field, for bioinformatics, and for biomedical research – mostly due to the lack of awareness so well captured in the document of what these three domains do and need relating to data, data intensive methods, and the harnessing of these to improve health and well being through biomedical research. Because NIH seems/seeks to reformulate how Data Science as a domain is perceived in the biomedical research community, the real potential is for a deviation of those funded by programs created based on this Plan from what the rest of the communities engaged with data/Data Science will be doing going forward. This Plan therefore has a worrying potential to wrongly direct scientists as it inappropriately diverts funding and attention from actual Data Scientists whose work would otherwise be fundable and useful in biomedical research.

4. Approach **9**

Strengths

None noted.

Weaknesses

Not only are no strengths noted in the Approach, and the Approach has inexplicable weaknesses that could actually result in negative momentum and ultimately, damage to Data Science and the reputation of biomedical researchers who actually need data intensive methods to do their work. The total lack of attention in the Plan to rigor and reproducibility as hallmarks of competent biomedical science is an unwelcome surprise. While data management and technology are engineered by those with training specific to practice in the domain to be rigorous and reproducible, these features of the data/data management/data wrangling systems do not translate simply to the science based on those systems.

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project?

This Strategic Plan is actually relevant to NIH, and not to Data Science as the title suggests. The overall strategy may be acceptable for NIH human resources and training, but not for the domain of Data Science. The methods of evaluation are totally inappropriate for such a wide ranging and probably-costly initiative, and also inconsistent with formal program evaluation approaches that have been articulated by other segments of the federal government. Instead, there is no plan whatever for any real evaluation of the proposal. Every "evaluation plan" for a goal is basically a description of the items they plan to count. By contrast, the NSF has a program evaluation handbook (https://www.purdue.edu/research/docs/pdf/2010NSFuser-friendlyhandbookforprojectevaluation.pdf)
and the OPM has a "beginner's guide" to program evaluation (https://www.opm.gov/wiki/uploads/docs/Wiki/OPM/training/Program%20Evaluation%20Beginners%20Guide.pdf) that highlights questions **any reader of this Strategic Plan** would like to know the answers to at least half-way through the initative, namely:

- Does the program work? And how can it be improved?
- Is the program worthwhile?
- Are there alternatives that would be better?
- Are there unintended consequences?
- Are the program goals appropriate and useful?

NONE of these will be addressed by the “evaluation” plans in this Strategic Plan. It is worth noting that counting up the number of grants that are funded, or the number of times keywords articulated in this Plan are used in proposals chosen for funding because they are aligned with this Plan, cannot possibly be informative about whether “the program is working”. Those counts will always be greater than zero - i.e., will always increment - simply because NIH is doing its usual work of funding proposals that are responsive to NIH RFAs. It is also imperative to point out that those counts cannot ever be used to determine how a program can be improved.

The CDC also has a systematic approach to evaluation (from 1999):

1. Engage stakeholders

2. Describe the program.
3. Focus the evaluation. *****
4. Gather credible evidence. *****
5. Justify conclusions. *****
6. Ensure use and share lessons learned. *****

https://www.cdc.gov/eval/framework/index.htm

***** emphasis added to highlight the fact these are ignored in the Strategic Plan and do not appear to have been considered.

NONE of the features of the CDC or OPM evaluation processes have been considered in the drafting of this Plan or its evaluation elements.

The Obama white house issued a memorandum in 2012 describing the importance of "credible evidence of the effectiveness of the program" – and "describe how the agency plans to demonstrate or validate impact, or otherwise learn from the initiative, and how the agency plans to act on the new information"
https://obamawhitehouse.archives.gov/sites/default/files/omb/memoranda/2010/m10-32.pdf
and they emphasized **the importance of impact evaluations**.
https://obamawhitehouse.archives.gov/sites/default/files/docs/erp_2014_chapter_7.pdf

By contrast, this NIH Strategic Plan demonstrates a total lack of "cultural competence" with respect to either Data Science as a discipline or to the role of data in biomedical research. Together with a total failure to consider formal (or even useful) evaluations of this initiative, it suggests that anyone involved in the drafting of this Plan is totally unqualified to do this particular job).

Have the investigators presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed?

The opposite is actually true. None of the evaluations are robust and nothing in the document is sufficiently contextualized in actual Data Science to qualify as "unbiased" or robust.

Are potential problems, alternative strategies, and benchmarks for success presented?

Not only are potential problems and alternatives not considered, the NIH's own history with NCBC and BD2K are also not considered for drawing useful lessons. The benchmarks for success that are included are to simply count up the number of times the NIH actually does its job, funding projects where the stated Plan outcomes are featured, but never determining if any benefit to science, society, or health ever accrue (like NIH has done with NCBC and BD2K). The "benchmarks" are actually counts, with no indication of how high a number would be considered "good" or even "satisfactory"; and similarly, "success" in any of the evaluations appears to be a nonzero count of whatever non-impactful yet countable event is indicated. The weaknesses in the approach stem profoundly from a failure to contemplate plausible indicators of positive impact, but also from the total failure to consider formal evaluations that are easily done if planned from the outset. The total lack of any evaluation or even reflection on prior NIH data intensive initiatives eliminates any enthusiasm for any reader with the sole exception of the reader who has no intention of proposing impactful work in their own submissions to this initiative.

If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?

Absolutely no consideration whatsoever has been given to feasibility or managing risk. This is the 3rd consecutive 10 (or so) year initiative in data intensive programming from NIH, making the lack of this consideration totally unacceptable.

Have the investigators presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects?

This is possibly the only NIH review criterion that isn't specifically relevant for the evaluation of this Strategic Plan.

If the project involves human subjects and/or NIH-defined clinical research, are the plans to address 1) the protection of human subjects from research risks, and 2) the inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (exclusion) of children, justified in terms of the scientific goals and research strategy proposed?

The project undoubtedly involves data from human subjects and absolutely no consideration whatsoever is given to them. Moreover, although the 2009 NOT-OD-10-019 states, "**NIH requires that all trainees, fellows, participants, and scholars receiving support through any NIH training, career development award (individual or institutional), research education**

grant, and dissertation research grant must receive instruction in responsible conduct of research", according to the 2013 FAQ, this is actually NOT true*, not everyone* has to have RCR - according to #219 specifically,

"**Does the education requirement apply to awards that do not involve human subjects?**

No, but it is important for all investigators, even those working with tissues or specimens derived from human sources to understand when proposed research triggers regulatory and policy requirements.

Human subject as defined in 45 CFR part 46 means a living individual about whom an investigator (whether professional or student) conducting research obtains: (1) data through intervention or interaction with the individual, or (2) identifiable private information.

Research using human specimens, tissues, or data that are unidentifiable may not be considered human subjects research. See: http://www.hhs.gov/ohrp/policy/cdebiol.pdf (PDF - 24 KB).

Investigators who conduct studies with human specimens, tissues, or data that are determined not to involve human subjects are not required to fulfill the education requirement."

(Emphasis added)

Study Design

Is the study design justified and appropriate to address primary and secondary outcome variable(s)/endpoints that will be clear, informative and relevant to the hypothesis being tested?

This vision statement may be justified for planning the “workforce development” of NIH staff, but it is wholly inappropriate for the domain of Data Science. It also does not promote real engagement by biomedical researchers with data or Data Science/scientists. It does not promote engagement with biomedical research by data scientists. The Plan does include clear “outcome variables”, but these count-based metrics do not support conclusions about relevance or impact of any activities that do - or do not - increment those counts.

Is the scientific rationale/premise of the study based on previously well-designed preclinical and/or clinical research?

The most important weakness here is that the previous two 10-year initiatives are not reflected on in any way in this Plan. Apparently, either nothing at all was learned from NCBC and BD2K or what was learned is being ignored in this current Plan.

Given <the methods used to assign participants and deliver interventions>, is the study design adequately powered to answer the research question(s), test the proposed hypothesis/hypotheses, and provide interpretable results?

This Strategic Plan is not devised in any way that can be considered “adequately powered”. The NIH-centric thinking behind the strategy, the absence of any formal outcomes that could be considered meaningful, and the lack of reflection by the authors of the strategy all point to tremendous weaknesses and a design that is completely inadequate. This Plan is not adequate to accomplish anything apart from supporting NIH Data Science workforce development, although given its own evaluation plans for such a goal, that will also not be accomplished in a meaningful way. Since no “results” of NCBC and BD2k have been interpreted or reported – ever, it is unreasonable to believe that this Strategic Plan would generate “interpretable results”. The example metrics given to evaluate achievement of stated goals are inherently uninterpretable: if the count is 1 (one event), that gives no information; if the count is 100 or 1000, the counts are equally uninterpretable. The circularity of these metrics is that if the NIH does fund any projects, then all of these counts will increment without actually providing any information about whether this Plan, its goals, or the NIH mission, are actually supported.

Is the trial appropriately designed to conduct the research efficiently?

No thought has been given to efficiency. Since the goals do not represent real issues – hard problems that are actually worth solving to improve biomedical research as well as health and well being – and there is no real plan for “evaluation” beyond counting up meaningless items, there is literally no sense in which any research done according to this Plan could be considered “efficient”.

Are potential ethical issues adequately addressed?

Absolutely not. See prior comment.

Is the process for obtaining informed consent or assent appropriate?

This Strategic Plan having been drafted – being actively considered by NIH for adoption apparently without ever having consulted with actual data scientists or biomedical researchers working with data/data intensive methods and resources, underlines that the process for obtaining assent from the communities that would arguably be most effective (and almost uniformly negatively) is NOT appropriate.

Is the eligible population available?

Oddly, all those who could have provided meaningful input to the process of drafting a real, useful, and evaluable Strategic Plan for Data Science in biomedical research were available – but for some reason, were not contacted by NIH.

Are the plans for recruitment outreach, enrollment, retention, handling dropouts, missed visits, and losses to follow-up appropriate to ensure robust data collection?

No. In fact, this Plan appears to have been designed specifically to ensure that data collection and storage are all supported while simultaneously ensuring that no biomedical researchers will ever really learn how to use those data. The Strategic Plan also includes nothing about encouraging NIH reviewers to prioritize, rather than penalize, grants that propose to analyze existing data.

Are the planned recruitment timelines feasible and is the plan to monitor accrual adequate?

Since no experienced or informed input was sought for this Strategic Plan, it is no surprise that whatever initiative this Plan ultimately seeds will not be feasible or adequate; moreover, the Plan specifies that whatever the result is, it will not be evaluated formally or meaningfully. Therefore, it is unlikely that anything resulting from this Plan will be feasible or adequate.

Are the plans to standardize, assure quality of, and monitor adherence to, the trial protocol and data collection or distribution guidelines appropriate?

There are no such plans, not because this Strategic Plan is a statement of NIH's vision, intended to be forward looking and describe the ideal state with respect to integrating Data Science with biomedical research (or even supporting this integration), but rather because there is insufficient expertise or experience to even conceptualize the field of Data Science in the future.

Does the application propose to use existing available resources, as applicable?

Not only are existing available resources not discussed – including evidence about the impact of prior initiatives, in terms of their strengths and weaknesses – but neither are prior experiences of NIH in data intensive initiatives mentioned or discussed. What *is* mentioned in Objective 4-1 is specifically that the NIH workforce *needs training in Data Science* - and is therefore NOT a resource that could be utilized. This Plan doesn't use the NIH's prior experience as a resource, and also doesn't mention institutional lack of experience as a limitation to be overcome. Neither is there any mention made of multiple initiatives and resources that are *already* freely available worldwide, and no mention is made of the lessons learned from any of those, either. This is a truly uninformed Plan, and that lack of informedness highlights the similar lack of plausibility of the NIH as an author of (or contributor to) a "Strategic Plan for Data Science", and undermines any enthusiasm for anything this particular Plan might eventually turn into.

Data Management and Statistical Analysis

Are planned analyses and statistical approach appropriate for the proposed study design and methods used to assign participants and deliver interventions?

The Plan is notable for the total lack of any mention of planned analyses; the specific disregard for appropriateness of statistics or statistical thinking/reasoning in how Data Science and biomedical research could interface removes all enthusiasm any reader might have.

Are the procedures for data management and quality control of data adequate at clinical site(s) or at center laboratories, as applicable?

The Strategic Plan, as noted earlier, is striking in its total lack of “quality control”. The evaluations that are proposed are stunningly inadequate, and the failure to use the NIH’s own prior experience -or apparently that of any informed participant in either Data Science or biomedical research requiring data scientific methodologies – suggests there *can be no quality control* in this Plan if it is executed.

Have the methods for standardization of procedures for data management to assess the effect of the intervention and quality control been addressed? Is there a plan to complete data analysis within the proposed period of the award?

Based on the total lack of reflection on prior efforts by the NIH, and the stark absence of input from informed data scientists or biomedical research requiring data scientific methodologies, the standardization of ANYTHING resulting from this Strategic Plan is truly worrisome. As noted earlier, among the worst features of the Plan is that if it is implemented, either those who are funded and follow this Strategic Plan will be/become the least knowledgeable Data Scientists – isolated from practicing communities by adhering to an absurd vision that is not grounded in reality; or they will gain absolutely nothing beyond having had a grant funded under this Plan. Neither of those is a desirable outcome; so this Plan should not be used or even “revised”. This Plan should be scrapped.

5. Environment **9**

Strengths

NIH has money to support data intensive initiatives, apparently.

Weaknesses

Overall, the NIH has demonstrated it has insufficient qualifications to strategize about Data Science. The document lacks any form of meaningful evaluation, and although counting up the number of times the NIH grants funding to applicants is apparently a key metric for NIH success, this has absolutely no relevance to the taxpayer or to the Data Science community.

In addition to excluding any meaningful evaluation of the impact of this Plan, this Plan also excludes any consideration of prior similarly data-intensive Plans and initiatives from the same environment (NIH). The failure to recognize what works and what does not work when NIH strategizes about data marks the NIH as a superlatively weak environment in which to propose any sort of strategy for Data Science.

This Strategic Plan is NIH centric and as such, essentially unrelated to the actual work required for effective and impactful integration of Data Science into biomedical research. The significant and profound weaknesses in this Plan underscore the marginality of the NIH environment for proposing, much less overseeing, a plan for that kind of integration.