ACR Response to RFI on NIH Strategic Plan for Data Science

The appropriateness of the goals of the plan, the strategies and implementation tactics proposed to achieve them, including potential benefits, drawbacks, or challenges.

The American College of Radiology (ACR) - a professional association representing more than 41,000 diagnostic radiologists, interventional radiologists, radiation oncologists, nuclear medicine physicians and medical physicists, offers the below considerations regarding the NIH Strategic Plan for Data Science.

The ACR agrees with the concepts to promote trustworthy artificial intelligence (AI) that are described in NIH Strategic Plan for Data Science. It should be noted that generative AI mapping solutions could be used in challenging data normalization efforts.

The Strategic Plan for Data Science is unclear on the funding source for the development of new software technologies for extraction and use of data (Section 3.2). Although this is a worthy goal, funding for this software may ultimately come at the expense of the funding intended for resources of investigator-initiated research and clinical trials. NIH would be a consumer of such a software product and should not take on the financial responsibility to develop these tools. The plan is also ambiguous about how the NIH plans to harness Real World Evidence from patient data and Electronic Health Records to gain new knowledge on the benefits and risks of drugs and devices being used in traditional and non-traditional clinical settings. It is not clear that the data ecosystem being proposed fits within the purview of the NIH, or that its creation would not detract from NIH investment in basic and clinical research. Again, a clear source of funding is not identified to build out this infrastructure, which would be a multi-agency investment.

Opportunities for NIH to partner to achieve these goals.

The NIH continues to be a leader in developing innovative technologies, including those related to radiology and biomedical imaging, and the ACR serves as a valuable partner with the NIH on a variety of projects. As the Strategic Plan for Data Science illustrates, there is a need for NIH to partner with additional federal agencies in the handling of data tools and access. The ACR recommends that the NIH utilize modern data-handling tools to make data available in a way that protects study endpoints during studies, rather than after studies are completed and results are published. Within NIH, oversight should be conducted by the Central Institutional Review Board and the Data Safety and Monitoring Board, as well as by the research base leadership and study teams, with the goal of sharing data during studies for approved projects.

The ACR agrees that a federated biomedical research data infrastructure is a critical dimension to creating diverse, representative data sets. Because unlocking local site data includes challenges that transcend technical, logistical, and business issues, it is important that we have a comprehensive strategy that is deployable and creates synergies with complementary mechanisms used to interact with sites. For example, the ACR currently uses its Connect/TRIAD network to work with thousands of imaging facilities to exchange data and perform local processing, and it serves as the standard ingestion mechanism for the NCI National Clinical Trials Network. Edge strategies that complement existing systems and infrastructure provide important opportunities to extend the infrastructure in ways that are deployable across a broad array of clinical sites. By leveraging these connectors or nodes, we provide sites with a straightforward and tractable pathway to share data without it having to leave the site's firewall. The ACR could serve as a potential resource to the NIH in building support for a federated biomedical research data infrastructure.

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Emerging research needs and opportunities that should be added to the plan.

The ACR recommends that the Strategic Plan for Data Science recognize the additional “research need” of resource funding for investigators to responsibly contribute to data sharing. Tasks such as the preparation of data to share after trial completion are insufficiently funded, even though the public display of this data is federally mandated. This funding is especially necessary to enable the data sharing of medical images, as these are tedious to share due to the needed anonymization of the data. Funding for these tasks, which could include the creation of a de-identified data registry, should be added to the plan.

The plan should identify the additional "research need” of clarification regarding how NIH handles data collected from medical images used in research projects and AI training. There is an opportunity to describe how NIH intends researchers to utilize a data registry cataloging medical images, where the images stay on prem and are used in a secure cloud.

Any other topic the respondent feels is relevant for NIH to consider in developing this strategic plan.

The ACR recommends that the Strategic Plan for Data Science should also address the topic of public distrust of data sharing, specifically in the context of AI and machine learning. It is essential NIH provides clear communication to explain patient confidentiality safeguards, as well as the significance of the development of new systems to advance and monitor novel treatments and diagnostics. Additionally, NIH should consider a security effort to use data for certain use cases, such a project or legitimated transaction. This could include the sharing of deidentified data or granting permission of limited access to data on site or in a private cloud enclave.

Thank you for your consideration of these suggestions. Please contact Katie Grady, Government Affairs Director at kgrady@acr.org, with any questions.