

ACR Response to Request for Information (RFI) on the FY 2021-2025 National Institutes of Health (NIH) -
Wide Strategic Plan Framework

Cross-Cutting Themes articulated in the framework, and/or additional cross-cutting themes that may be considered.

- **Increasing, Enhancing, and Supporting Diversity**
- **Improving Women's Health and Minority Health, and Reducing Health Disparities**
- **Optimizing Data Science and the Development of Technologies and Tools**
- **Promoting Collaborative Science**
- **Addressing Public Health Challenges Across the Lifespan**

ACR supports these cross cutting themes as presented in the NIH strategic plan framework and agrees with the emphasis on embracing diversity and addressing disparities. The ACR Patient and Family Centered Care Commission was formed to bring increased attention to the needs of all members of our society and to recognize the unique needs of the various segments of the population. Our Commission on Women and Diversity is now 7 years old and actively works on increasing diversity and inclusion in the radiology specialties to better reflect the patient population. The work of ACR's Research Commission has also underscored the challenges associated with engaging those members of society who represent minorities, diversity, and the need for targeted outreach efforts to truly appreciate the benefits of personalized medicine. Additional incentives are required to promote increased diversity in research initiatives and to provide researchers with the resources necessary to properly engage these populations.

The ACR formed the Data Science Institute in 2018 to respond to the rapidly accelerating role of advanced imaging informatics and artificial intelligence in both research and clinical practice. Through the combined efforts of ACR's Center for Research and Innovation and the Data Science Institute, the ACR has endeavored to respond to the needs for data repositories which include curated data and images and which facilitate longitudinal studies of populations. There remain significant challenges associated with the creation of such databases stemming from anonymization methods and institutional firewalls, along with variability in data structure and nomenclature due to the lack of any standards at the patient medical record level. Current efforts to create databases have resulted in fragmented and redundant approaches rather than a coordinated approach that will yield maximum value. Support for the advancement of tools such as validated artificial intelligence methods and federated models will help address these concerns, but addressing these critical systemic issues are necessary steps to truly optimize the power of data science tools and methods.

Previously, the ACR filed comments with the White House Office of Science and Technology Policy and the HHS Office of the National Coordinator for Health IT suggesting that there is an urgent need for trusted third party validation and real world performance monitoring of artificial intelligence/machine learning (AI/ML)-enabled tools to help mitigate or manage risk for these developing technologies. Challenges associated with the basic premise of image exchange also needs to be addressed. Federal agencies can enable the radiology community's work in this area in several ways, such as through the development of a national image-sharing strategy covering provider-to-provider exchange and enabling patient access to medical images via open APIs, incorporation of medical images into the U.S. Core Data for Interoperability (USCDI), requiring image exchange facilitation of health information networks

participating in the Trusted Exchange Framework and Common Agreement (TEFCA). We recommended that federal agencies require that AI algorithms deployed in a clinical setting be validated and continually monitored. We also recommended a collaboration with third party organizations who are able to provide validation and monitoring services, such as ACR DSI, to help ensure the clinical utility, safety, trustworthiness, and performance of AI/ML-enabled software. We believe that NIH could play a role in the aforementioned areas by supporting third party AI validation organizations and supporting image exchange and related standards development efforts in the radiology community.

NIH's priorities across the three Objectives articulated in the framework, including potential benefits, drawbacks or challenges, and other priority areas for consideration.

Objective 1: Advancing Biomedical and Behavioral Sciences

- **Driving Foundational Science**
- **Preventing Disease and Promoting Health**
- **Developing Treatments, Interventions, and Cures**

The ACR has an extensive history of developing clinical practice guidelines for the diagnostic radiology and radiation oncology community and the ACR also provides the community with numerous evidence-driven platforms for quality improvement initiatives which promote healthy communities through detection, monitoring, and where warranted, intervention. Changes in clinical practice standards are driven by research initiatives undertaken by the ACR and other researchers, and such research has been predicated upon the traditional clinical trials structure.

Future advancements may be accelerated through the inclusion of novel approaches that include the use of data registries and virtual clinical trials. These research models alleviate the burdens encountered by clinical researchers and accruing institutions and represent opportunities for more rapid collection of clinical data at lower cost, with some compromise in the quality of the data. The ACR has experience with the development and operation of clinical data registries and was one of the first adopters of the CMS Coverage with Evidence Development program, leading to the development of the National Oncologic PET Registry (NOPR) and more recently the Imaging Dementia – Evidence for Amyloid Scanning (IDEAS) study. Both of these registry projects have led to definitive results to change patterns of clinical care, while also creating a tremendous wealth of data that can be used for secondary analysis projects for years to come when paired with systems such as ACR's Data Archive and Retrieval Toolkit (DART) or other data lakes.

The ACR would also advocate for the significance of new biomarker discovery and development as a fundamental element in the strategic framework. ACR's collaboration with other medical disciplines (such as the IDEAS study or the Detection of Early lung Cancer Among Military Personnel (DECAMP) study has led to the formation of consortia which are dedicated to the exploration of blood and tissue based biomarkers. Such biomarkers promise to radically transform ACR's ability to predict those at higher risk of disease and also provide invaluable information to optimize therapy for those that have become ill.

Objective 2: Developing, Maintaining, and Renewing Scientific Research Capacity

- Cultivating the Biomedical Research Workforce
- Supporting Research Resources and Infrastructure

The ACR fully supports this objective. The Center for Research and Innovation has collaborated with academic researchers, federal sponsors, and industry sponsors to conduct over 500 clinical trials over the past 51 years and has generated significant scientific results which have translated into changes in clinical practice in both diagnostic imaging and radiation oncology. Adequate funding to support the costs associated with conducting clinical research, which complies with regulatory requirements and ensures the integrity of the data and the research outcomes is critical to sustaining the organizations conducting the research. The value of the time and dedicated effort associated with physicians conducting federally funded research has been shown to be a small percentage of the actual cost of their time. In addition, the burdens associated with leading a multicenter trial performed under NIH funding has often led investigators to not pursue additional such research projects, depriving the research community of the leadership and expertise of these leading minds.

Objective 3: Exemplifying and Promoting the Highest Level of Scientific Integrity, Public Accountability, and Social Responsibility in the Conduct of Science

- Fostering a Culture of Good Scientific Stewardship
- Leveraging Partnerships
- Ensuring Accountability and Confidence in Biomedical and Behavioral Sciences
- Optimizing Operations

ACR agrees with the NIH strategic plan framework Objective 3. The need for integrity in research and ACR's approaches to managing and analyzing data is critical to ensuring we have a system, which will generate credible results. The ACR represents nearly 40,000 diagnostic radiologists, interventional radiologists, nuclear medicine physicians, radiation oncologists, and medical physicists. In addition to collaborating with members, the ACR has leveraged numerous partnerships and consortia, which combine the specialized knowledge needed to answer complex medical questions.

Future opportunities or emerging trans-NIH needs:

- Nationwide registries for generating real world evidence at a fraction of the cost of randomized controlled trials;
- Inclusion of AI models in the research framework which enable new efficiencies and new analytic models and ;
- Promoting research environments, which recognize emerging integrated diagnostic centers of excellence.