Statement for the Record
Hearing on "ARPA-H: The Next Frontier of Biomedical Research"
House Committee on Energy and Commerce
February 8, 2022

On behalf of Siemens Healthineers, thank you for holding this important hearing on ARPA-H. As you consider approaches to authorizating this important new program, our company would like to share with the subcommittee some of our recent experiences partnering with the federal government and its network of dedicated grantees to accelerate research concepts into products – not only to maintain our nation's global healthcare innovation leadership, but more important to help every American get access to the right care at the right time. We hope you find them illustrative, and we thank you for your vision and for the drive to bring this program to reality.

Siemens Healthineers is one of the largest healthcare companies and the largest diagnostics company in the world. Our solutions, ranging from laboratory diagnostics (including rapid point of care testing), medical imaging and interventional imaging solutions to radiation therapy, touch 240,000 patients every single hour. In addition to our tests' very high-volume clinical utilization, we are very focused on research to accelerate developments from bench to bedside. For this reason, we are collaborating on over 1,500 active research projects with hundreds of academic medical centers and hospitals across the USA. Additionally, because of our numerous collaborations and the breakthroughs made by our researchers, we can proudly say that as a company, we currently hold over 17,500 patents connected to successful research outcomes.

Historically, the research highlighted above was funded solely by Siemens Healthineers, focusing on product-specific developments; however, we have recently made the decision to bring more focus to government supported research. In conjunction with our academic collaboration partners, we applied for several NIH - National Institute of Biomedical Imaging and Bioengineering (NIBIB) grants, some of which were awarded and are currently active. These grants do not focus on the Siemens-specific development roadmap but do focus on areas that are of broader significance, ones we might not have explored otherwise. Unfortunately, all these projects are in the early stages, targeting basic research. This changed with our joint application for a RADx grant. RADx utilized not only our research strength but placed a heavy focus on our experience of bringing safe and reliable solutions to the market. Bringing a product to the market requires many process steps and most academic institutions, hospitals and/or small organizations do not have the experience in-house.

The following comments will hopefully help in achieving the goal to "drive transformational innovation in health research and speed application and implementation of health breakthroughs:"

- ARPA-H should implement the positive aspects of RADx, such as frequent stakeholder meetings including the FDA, while removing or limiting some constraints such as ultra-quick turnaround timelines that were necessary to combat COVID-19. We believe RADx would have led to additional sustainable solutions if time intervals between milestones would have been slightly longer. The longer intervals should hopefully be acceptable and sufficient to many future projects.

- In the current NIH structure, the majority of Academic Industrial Partnership Grants have an academic prime awardee and an industry sub awardee. Additionally, funding levels are often capped at $500,000 before indirect costs. While this setup will also work for many ARPA-H grants, one recommendation

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would be to have grants that allow companies to focus on topics such as safety, efficacy, regulatory and production. The goal is not to fund industries product roadmap, but to make it intriguing for industry to take a risk. Unfortunately, such projects would require funds north of $500,000 and in many cases would require industry as prime.

- Based on the outlined "examples of potential projects that ARPA-H could drive," we could see ARPA-H as a great home for visionary projects such as the scenarios that follow:

- **Health care access, equity, and quality**
    - Every 40 seconds a United State citizen suffers a stroke. Every 4 minutes, someone dies of stroke. Unfortunately, survival rates and outcomes do not only depend on the patient, but it very much depends on where the stroke occurs. In stroke there is the saying, "Time is Brain," and every minute makes a difference in the long-term effect. Living in close proximity to a comprehensive stroke center might allow a patient to be treated within minutes, where some areas of the country have hours of transportation time - even by helicopter. We are proposing a revolutionary way to treat stroke throughout the country, using endovascular robots at remote hospitals that usually could not treat stroke. The aforementioned robots would allow an expert, highly trained user (e.g neurosurgeon), to perform the procedure from hundreds or even thousands of miles away from the patient. While we will begin working with the FDA rather soon for this remote application, this will be a first in healthcare to bring a highly complex, life-saving procedure closer to the patient. ARPA-H funding would allow Siemens Healthineers to accelerate the work with practitioners, FDA, States Officials, CMS and other payors. ARPA-H would have the potential to bring such lifesaving solutions faster to patients independent of their geographic location.
    - The increased prevalence and acceptance of smart devices and self-testing has created opportunities to significantly impact the management of chronic diseases, from onset to the course of the disease. These devices, such as AI based vitals monitoring, home or self-tests for chronic kidney diseases, women's health conditions, infectious diseases etc., coupled with population health data have given us the ability to envisage a healthcare system where individuals can be monitored far more precisely for their risk in developing chronic conditions. And consequently, delay onset of more severe conditions such as End Stage Renal Disease, significantly improving quality of life. In our more connected world this enables bringing prevention and management of disease anywhere in the community irrespective of distance from a clinician. A similar approach on episodic events is also highly impactful, for example a diagnosis of AMI at the point of occurrence dramatically reduces time to diagnosis and intervention and therefore, potential for recovery and reduces ER crowding. Siemens Healthineers is at the forefront of developing an infrastructure and integrated solutions to enable seamless integration of information across these settings – from the home, to an outpatient setting through to a hospital. ARPA-H funding would greatly accelerate this development, which we strongly believe will have a tremendous benefit in keeping people

healthy independent of access to healthcare and reduce the overall burden on the healthcare systems.

- **Cancer and other chronic diseases**
  - The knowledge gap between Comprehensive Cancer Centers and a non-specialized hospital where cancer treatment is limited to chemo- and radiation therapy is significant. We have been working on a pathway companion approach that pulls all the relevant information about the patient from the electronic medical record and integrates this data using smart logic. This logic will provide information about potential treatment options that go beyond chemo- and radiation therapy. Tools such as this have the potential to inform local physicians about advanced treatment options such as CAR T Cell Therapy or Proton Therapy. ARPA-H could support further standardization of such integrated diagnostics tools to ensure that all patients and practitioners are aware of all applicable treatment options.
  - Currently, Radiation or Proton Therapy are lifesaving treatments that require multiple patient visits over weeks or months and have significant side effects. A potential new technology called FLASH might have the ability to bundle this lengthy treatment in a sub-second long one-time treatment. Aside from the convenience, the approach holds the promise to significantly reduce side effects of the treatment. One of the reasons is that blood will have very, very little exposure to radiation, unlike in the current method. ARPA-H could significantly accelerate the introduction of this revolutionary treatment, when compared to normal industry product development process.

- **Infectious disease**
  - Our recent experiences with SARS-COV-2 have demonstrated the critical need for a comprehensive response strategy for infectious disease screening to monitor and control spread of infection – allowing treatments and vaccines to be effectively developed. This involves testing at all levels – from self-test, to decentralized settings to central laboratories – as well as an intelligent monitoring system using AI to identify areas of concern, increase testing by rapid deployment of tests and provide reporting to monitor the infection. Through internal development, access to partners, informatics tools and use of our AI companion pathway, Healthineers is uniquely poised to realize such a solution. Through our global reach, we are able to deliver a robust supply chain strategy, as well as adapt to evolving variants or testing requirements in a timely manner, and with rigor.

As an organization, we are highly motivated by opportunities that allow us to engage in innovative research. We excel at providing tailored solutions to support routine cases to complex treatments. Our portfolio boasts both expertise and experience that can bridge the clinical and technical divide. Given these capabilities and the qualifications mentioned above, we would like to express our interest in assisting with the development of this program, specifically as it relates to contract structure. We recognize the value and importance of having an industry representative serve in this capacity to ensure all perspectives are included and taken into consideration.

On behalf of Siemens Healthineers, we would like to thank you again for the opportunity to comment on this very important initiative. ARPA-H has the potential to change the pace of developments and distribution of healthcare and this initiative has our strong support. Please let us know if we can assist in the development of ARPA-H.

Best regards,

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