Tim Fenton
Vice President, Global Government Relations
& Public Affairs

Thermo Fisher Scientific
168 Third Avenue
Waltham, MA 02451
www.thermofisher.com

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Suzanne H. Plimpton
Reports Clearance Officer
National Science Foundation
2415 Eisenhower Avenue
Alexandria, VA 22314

Re: Docket Number NSF-2025-OGC-0001: Request for Information on the Development of a 2025 National Artificial Intelligence (AI) Research and Development (R&D) Strategic Plan

Dear Ms. Plimpton:

Thermo Fisher Scientific welcomes the opportunity to provide comments to the National Science Foundation in support of the development of a 2025 National Artificial Intelligence (AI) Research and Development (R&D) Strategic Plan, focusing on the goal of reducing clinical trial costs and efficiency while increasing Phase 3 clinical trial volume and improving approval rates for life-saving therapies.

At Thermo Fisher, our Mission is to enable our customers to make the world healthier, cleaner and safer. Our colleagues manufacture products and provide services that help our customers accelerate innovation and enhance productivity.

Thermo Fisher supports the goal of reducing clinical trial costs and inefficiency while simultaneously increasing Phase 3 clinical trial volume and improving approval rates for life-saving therapies. Given our extensive experience supporting end-to-end clinical development from early-stage discovery to clinical trial execution across all development phases, through to post marketing approval, we are uniquely positioned to share insights on how AI-powered tools and processes can drive improvements to the current system.

Recommendations for consideration include:

1. Foundational programs and actions to amplify AI/machine learning adoption and integration:

    a. Establish AI regulatory standards balancing innovation with patient protections expanding U.S. Food and Drug Administration (FDA) draft guidance from January 2025. Possible standards include: (1) binding framework for AI use in drug discovery, trials and manufacturing; (2) clarity on validation protocols and

model explainability; (3) defining acceptable endpoints, evidence standards and AI-specific safety thresholds; and (4) enhanced interagency AI standards (FDA, National Institutes of Health (NIH) and National Institute of Standards and Technology (NIST)).

b. Public-private partnerships that build on current private sector real world databases, disease registries, electronic medical records/electrical health records and lab data. The goal would be to create a national connected network of harmonized, scientific and clinical research ready, longitudinal, anonymized patient data for AI capability acceleration and trial activation.

c. U.S. Department of Health and Human Services-approved registry of AI tools, models and capabilities (across companies), certified for drug discovery and clinical development built with public-private partnership.

d. AI safe harbor sandbox that allows companies to test AI tools for drug discovery, trials and manufacturing in partnership with regulators.

e. Encourage AI adoption to reduce FDA review cycle times (data analysis, submission reviews, responses).

f. Bioethics code of conduct for use of AI in clinical research and enhancing control mechanisms to detect potential fraud (data, documentation, patients), including:

    i. Digital Forensics: develop AI-powered tools and enhanced training and regulatory expertise to verify inspection documentation and detect AI-generated fraud;

    ii. Increase security of data and transactions using blockchain and other novel technologies; and

    iii. Enhanced training for investigators, sponsors, providers and organizations to detect AI generated fraud.

2. Introducing operational and cost efficiencies across clinical development

    a. Greater adoption of more robust precision medicine approaches across indications: current industry clinical development processes underutilize advanced bioinformatics (Bayesian dynamic borrowing) and AI-powered tools (digital twins, disease modelling, AI-informed precision medicine, risk management and outcomes prediction), which can support the advancement of novel therapies and optimize protocol design, model patient sample size and trial scenarios, forecast trial enrolment and predict possible trial operational challenges and outcomes.

    Increase regulatory partnership and provide updated guidance to:

    i. Encourage drug development innovation and selection of novel therapies for trial advancement;

ii. Drive smarter trial design and increase targeted patient selection to optimize trial sample size;

iii. Improve targeted data volume collection strategies; and

iv. Reduce source data verification and data reviews.

b. Encourage the use of advanced trial design methodologies while maintaining evidence integrity. For example, and when appropriate, encourage the adoption of AI-powered analytics with seamless Phase 2/3 designs or intermediate endpoints, combined with post-marketing safety monitoring and clinical effectiveness commitments. This will help accelerate data analysis and decision making while reducing overall trial duration, supporting efficient resource allocation and maintaining patient safety.

c. Decentralized and community-based clinical trials: increasing adoption of decentralized and community-based trials can narrow the current gap between clinical development versus clinical practice. Also, using AI wearables to power automated real time monitoring, data collection and analysis of remote trial participants can accelerate patient enrolment, increase trial retention and expand patient cohorts while contributing data to the connected data network (see 1(c) above). Also, AI can support the training of clinical trial naïve community-based sites and assist with protocol and research specific questions.

d. Integrated manufacturing/supply chain: support engagement of supply chain and AI integration during protocol development. This will better unify remote supply chains, optimize stock inventory, reduce waste of comparator and investigational products and improve anticipation of possible drug supply disruptions.

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Sincerely,

Tim Fenton