American Society of Hematology

Helping hematologists conquer blood diseases worldwide

2026

President
Robert Negrin, MD
Stanford University
269 W. Campus Drive
Stanford, CA 94305
Phone: 650-868-8065

President-Elect
Cynthia Dunbar, MD
2127 California Street, NW
Washington, DC 20008
Phone: 202-819-6806

Vice President
Alison Loren, MD, MSCE
University of Pennsylvania
3400 Civic Center Boulevard
Philadelphia, PA 19104
Phone: 215-662-4859

Secretary
Jennifer Brown, MD, PhD
Dana-Farber Cancer Institute
450 Brookline Avenue
Boston, MA 02215
Phone: 617-632-5847

Treasurer
Joseph Mikhael, MD, FRCPC, MEd
Translational Genomics Research Institute
City of Hope Cancer Center
445 N. Fifth Street
Phoenix, AZ 85004
Phone: 602-343-8445

Councillors
Jennifer Holter-Chakrabarty, MD
Adam Cuker, MD, MS
Chancellor Donald, MD
Christopher Flowers, MD, MS
H. Leighton Grimes, PhD
Mary Horowitz, MD
Charlotte Niemeyer, MD
Mikkael Sekeres, MD, MS

Executive Director
Martha Liggett, Esq.

February 17, 2026

Robert F. Kennedy Jr.
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Ave., SW Washington, DC 20001

Submitted electronically via http://www.regulations.gov

Re: Request for Information: Accelerating the Adoption and Use of Artificial Intelligence as Part of Clinical Care (RIN 0955-AA13)

Dear Secretary Kennedy:

On behalf of the American Society of Hematology (ASH), thank you for the opportunity to comment on the Health and Human Services (HHS) Request for Information (RFI): Accelerating the Adoption and Use of Artificial Intelligence (AI) as Part of Clinical Care. The Society appreciates HHS' commitment to improve efficiencies within the health care system through new technologies and innovation and commends the Agency for seeking input to responsibly accelerate the adoption and use of AI in clinical care.

ASH represents more than 18,000 clinicians and scientists committed to studying and treating blood and blood-related diseases. These disorders encompass malignant hematologic disorders such as leukemia, lymphoma, and multiple myeloma, as well as classical (or non-malignant) conditions such as sickle cell disease (SCD), thalassemia, bone marrow failure, venous thromboembolism (VTE), and hemophilia. Hematologists have been pioneers in advancing the understanding and treatment of various hematologic diseases. Hematologists continue to be innovators in the fields of stem cell biology, regenerative medicine, transfusion medicine, and gene therapy. ASH membership is comprised of basic, translational, and clinical scientists, as well as physicians providing care to patients. Our mission is to foster high-quality care, transformative research, and innovative education to improve the lives of patients with blood and bone marrow disorders.

With these goals in mind, ASH recognizes the potential of AI tools to improve efficiencies, streamline administrative processes, and provide additional clinical support to physicians. Simultaneously, ASH members have emphasized the importance of responsible implementation of these technologies; ensuring the patient-physician relationship remains central in care delivery, emphasizing transparency in the underlying data and logic of AI tools to support their reliability and validity in clinical care, and upholding the highest standards for data privacy and protection of health information.

Specifically, ASH's comments focus on the following themes: governance and transparency; implementation and workflow; interoperability; clinician responsibility and patient trust.

Governance and Transparency

Regulations and guidance that support governance standards and transparency of AI models are critical for their safe and effective use in clinical practice. ASH members consistently raise questions about how various AI tools are regulated, especially as expectations grow for clinicians to use these tools in clinical care. Members have specifically expressed concerns that the lack of standardized governance or transparency for the types of data used in AI models, the frequency of data updates, and the underlying logic of predictive models and AI tools may lead to a "one-size-fits-all" approach in AI tools. This approach may not be appropriate when these tools are used for complex or rare conditions commonly found in hematology.

Several studies[1,1,1,1] show significant and persistent inconsistencies in medical care and health outcomes among patients across a range of blood disorders, underscoring the need for governance or standards for the reliability, validity, and sensitivity of these tools to be applicable for the patient population for whom our members care. In prior ASH comments, the Society has emphasized the importance of transparency as to the types of data used in AI models, the frequency of data updates, and the underlying logic of predictive models and AI tools.

Meanwhile, individual health systems are developing and adopting their own internal best practices for governance around the use of AI tools, leading to a patchwork of varying standards. This institution-by-institution approach creates uncertainty about how AI should be evaluated for applicability and adopted across health systems.

ASH encourages HHS to establish clear definitions of the various classes of AI tools used in clinical practice and develop a framework that specifies where and how different types of AI tools are appropriate for clinical use. ASH also encourages the Agency to set clear regulatory expectations for the datasets and underlying logic used to build and continuously validate AI models and tools. These standards will support clinicians and patients in understanding the basis of these tools and support trust for broad implementation.

Implementation and Workflow

ASH members have shared that the greatest immediate potential of AI tools to improve efficiencies is through their application in administrative tasks. For example, ASH members have shared that AI- enabled notetaking and ambient listening tools may support provider efficiency in some instances within the electronic health record (EHR), allowing physicians to focus on the interpretation and analyses of the patient's health information.

However, while AI may reduce the burden of administrative tasks in some instances, it is important to recognize that physicians have a finite capacity to incorporate and continuously monitor these tools alongside their many other responsibilities. ASH members have described several experiences in which AI tools have "hallucinations" or provide inaccurate information; hallucinations underscore the need for continuous monitoring or a human-in-the-loop to ensure that clinical information in these tools remain accurate and clinically appropriate. Human oversight of these tools is essential for their implementation, but the Society encourages HHS to carefully consider the workload implications before placing this additional responsibility on physicians. Continuous monitoring of these tools should not become an additional burden for physicians.

Interoperability

Many of these tools are already being incorporated as additions or extensions in EHR systems, often with new or separate interfaces that require a different workflow with additional or parallel documentation. Duplicative work is an additional burden on physicians, but importantly, this also raises questions about the interoperability of AI tools across health IT systems. AI tools that cannot be cleanly embedded into existing EHR workflows or that rely on proprietary integrations create barriers and disincentivize adoption and scalability. This can be especially challenging for smaller or under-resourced community practices and institutions, such as those in rural areas, that may not have the resources to support the integration of these tools.

ASH encourages HHS to develop a framework of interoperable standards for AI tools used across all types of clinical practice and health systems, which will be key to support the integration and use of these tools across health care systems.

Clinician Responsibility and Patient Trust

Lastly, successful implementation of AI tools in clinical practice must also be supported by patients. Maintaining patient trust is foundational to preserving the patient-physician relationship, which is in turn central to ASH members' ability to deliver high-quality and clinically appropriate care to patients with hematologic diseases and disorders. ASH members have reported barriers to implementing AI tools in their clinic because patients have shown hesitancy with AI being used for care delivery. Members noted that their patients cited privacy concerns, specifically about how their protected health data is being stored and used.

ASH recommends that the Agency consider educational resources for both clinicians and patients to foster a shared understanding of the purpose and use of AI tools in clinical care. Resources that help clinicians clearly communicate how data are used and protected may help with patient trust and support more effective implementation.

ASH thanks HHS for the opportunity to provide these comments on AI in clinical practice. Should you have any questions or require further information, please contact ASH Manager for Health Care Access Policy, Carina Smith at casmith@hematology.org.

Sincerely,

Robert Negrin, MD
American Society of Hematology, President

---

[1] Ioannis Farmakis, Mary Cushman, Luca Valerio, Nikolaos Giannakoulas, Lukas Hobohm, Gregory Piazza, Stavros Konstantinides, Stefano Barco; Social Determinants of Health and Pulmonary Embolism Treatment and Mortality: The Nationwide Inpatient Sample. *Blood* 2022; 140 (Supplement 1): 343–344. doi: https://doi.org/10.1182/blood-2022-166550

[2] Arushi Khurana, Raphael Mwangi, Loretta J. Nastoupil, Patrick M. Reagan, Umar Farooq, Jason T. Romancik, Timothy J. McDonnell, Shaun M Riska, Izidore S. Lossos, Brad S. Kahl, Peter Martin, Thomas E. Witzig, James R. Cerhan, Christopher R. Flowers, Matthew J. Maurer, Grzegorz S. Nowakowski; Evaluating the Impact of Lab-Based Eligibility Criteria By Race/Ethnicity in Frontline Clinical Trials for Diffuse Large B-Cell Lymphoma (DLBCL): A LEO Cohort Analysis. *Blood* 2022; 140 (Supplement 1): 2056–2058. doi: https://doi.org/10.1182/blood-2022-169433

[3] Warren Fingrut, Stephanie Chinapen, Angela Katrichis, Caroline Carino, Eric Davis, Brian C. Shaffer, Christina Cho, Gunjan L. Shah, Juliet N. Barker; Analysis of 372 Adult Allograft Recipients Reveals Associations between Non-European Ancestry, Low Socioeconomic Status, and Receipt of HLA-Disparate Grafts. *Blood* 2022; 140 (Supplement 1): 313–314. doi: https://doi.org/10.1182/blood-2022-168486

[4] Molly Tokaz, Helen Baldomero, Andrew J Cowan, Wael Saber, Hildegard T. Greinix, Mickey Koh, Nicolaus Kröger, Mohamad Mohty, Sebastian Galeano, Shinichiro Okamoto, Naeem A. Chaudhri, Amado J Karduss, Fabio Ciceri, Vergilio Rensi Colturato, Selim Corbacioglu, Alaa M. Elhaddad, Lisa Force, Cristobal Augusto Frutos Ortiz, Andres Gomez-De Leon, Nada Hamad, Nelson Hamerschlak, Naya He, Aloysius YL Ho, Xiao-Jun Huang, Benjamin Jacobs, Heeje Kim, Minako Iida, Leslie E. Lehmann, Régis Peffault de Latour, Mary-Elizabeth M. Percival, Walid Rasheed, Kirk R. Schultz, Adriana Seber, Bor-Sheng Ko, Anderson Simione, Alok Srivastava, Jeff Szer, William A. Wood, Yoshihisa Kodera, Arnon Nagler, John A Snowden, Daniel J. Weisdorf, Jakob R. Passweg, Marcelo C Pasquini, Anna Sureda, Yoshiko Atsuta, Mahmoud Aljurf, Dietger Niederwieser, Martina Perdomo; An Analysis of the Worldwide Utilization of Hematopoietic Stem Cell Transplantation for Acute Myeloid Leukemia. *Blood* 2022; 140 (Supplement 1): 8146–8149. doi: https://doi.org/10.1182/blood-2022-158338