As the national coordinator for the U.S. private-sector system of voluntary standardization, the American National Standards Institute (ANSI) has convened this meeting to explore opportunities for progress through collaboration and standardization, identify challenges, barriers and gaps, and discuss steps to optimize regulatory frameworks.

The goal of this virtual workshop is to set the stage and momentum for an in person workshop in 2021, where recommendations for coordination of standardization and governance to meet expectations of safety, quality, responsibility, and risk can be developed.

<table>
<thead>
<tr>
<th>Time</th>
<th>Discussion Topic and Speakers</th>
</tr>
</thead>
</table>
| 1:00 – 1:10 pm | Welcome and Opening Remarks –  
Jamie Ferguson, VP, Health IT Strategy & Policy, Kaiser Permanente  
Lisa Carnahan, Assoc. Dir. for IT Standardization, Information Technology Laboratory, NIST |
| 1:10 – 1:25 pm | Overview of Artificial Intelligence Standards landscape -  
Pat Baird, Sr. Regulatory Specialist - Head of Global Software Standards, Philips  
Mr. Baird will provide an overview of the current standards landscape as well as projects under development. |
| 1:25 – 2:10 pm | PANEL: Data (and all its demons)  
Moderator: Joe Lewelling, Senior Advisor on Content & Strategy, AAMI  
The requirements and issues for operational data and training data are very much intertwined with respect to AI because of the ML-aspect. When and where they differentiate will be explored along with issues of measuring data quality, bias in inputs and outputs, data classification, and semantic standardization.  
Panelists:  
- Ittal Dayan, Executive Director of Strategy and Operations, MGH & BWH Center for Clinical Data Science, Partners Healthcare  
- James M Dzierzanowski, Executive Director, Innovation and Strategic Advisory Services, Kaiser Permanente  
- Dr. Tanuj Gupta, VP of Cerner Intelligence, Cerner Corp.  
- Wayne Kubick, CTO, HL7 (Invited) |
<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Moderator/Chair</th>
<th>Panelists</th>
</tr>
</thead>
</table>
| 2:10 – 2:55 pm | PANEL - Transparency AND Explainability | **Moderator:** Heike Sichtig, Ph.D., SME & Team Lead, Digital Health, FDA | What is the “Intent” (goals/performance) compared to “Output” (accuracy/validation) and the Regulatory Impact?  
Panelists:  
- Dr. Andrea M. Matwyshyn, Professor, FDA  
- Dr. Jesse M. Ehrenfeld, Chair, American Medical Association  
- Suzanna Hoppszallern, Senior Editor Data and Research, American Hospital Association |
| 2:55 – 3:10 pm | Virtual Break                     |                                                            |                                                                                                |
| 3:10 – 3:55 pm | PANEL - Governance and Risk Management | **Moderator:** Dr. John Halamka, President, Mayo Clinic Platform | There is a need for governance of AI (organizational level) in healthcare with regard to:  
- Privacy  
- Risk management  
- Efficacy  
How to govern the systems for managing processes? Is a risk management framework needed?  
Panelists:  
- Marilyn Zigmund-Luke, VP, AHIP  
- Amy Mahn, International Policy Specialist, NIST  
- Pat Baird, Sr. Regulatory Specialist - Head of Global Software Standards, Philips  
- John Dickerson, Assistant Professor in the Department of Computer Science, University of Maryland |
| 3:55 – 4:15 pm | Next Steps and Plans for 2021 Workshop | Jamie Ferguson, VP, Health IT Strategy & Policy, Kaiser Permanente  
Lisa Carnahan, Assoc. Dir. for IT Standardization, Information Technology Laboratory, NIST |                                                                                                |
| 4:15 pm     | Adjourn                           |                                                            |                                                                                                |