

In a recent meeting, the CHAI Predictive AI work group convened to discuss various aspects of integrating predictive AI into clinical trials, particularly focusing on under-resourced rural and reservation-based communities. The session covered ongoing projects, AI governance structures within health systems, and the development of assurance standards for AI solutions.

### **Predictive AI Integration with Clinical Trials**

The meeting began with a presentation on integrating predictive AI with clinical trial safety. The project, funded by the Genentech Innovation Fund, aims to predict the safe alignment of research phases with resource availability. The initiative employs community-based participatory design and EHR change management frameworks to ensure stakeholder involvement and iterative processes, essential in diverse rural settings. The focus on principles such as usefulness, safety, and transparency was highlighted, along with efforts to support children with cancer by enabling communities to utilize collected data for informed decision-making.

### **AI Governance in Health Systems**

The discussion then shifted to the AI governance structure within a health system encompassing 51 hospitals across seven states. The presentation outlined the creation of two new committees: the AI Governance Committee (AIGC) and the AI Technical Committee (AITC). The AIGC is responsible for establishing protocols, while the AITC administers these protocols, mainly focusing on technical aspects such as data science and engineering.

The governance process includes risk tracks for evaluating new vendors and technologies, categorized into Tier 1 Trusted Vendors, Tier 2 Niche Vendors, and Tier 3 Internal Build. Legal collaborations ensure that contracts with third-party vendors protect against risks associated with fourth-party vendors. Compliance with the NIST framework and regular risk assessments every six months and annually were emphasized, alongside integration and ongoing monitoring of AI products.

### **Challenges and Principles for AI Solutions**

The next segment addressed the challenges in adopting AI solutions and the principles necessary for ensuring positive impacts without harming patients. The principles discussed included usefulness, transparency, fairness, safety, explainability, and privacy enhancement. The process for assessing AI solutions involves a comprehensive review covering security, compliance, technical performance, marketing, and clinical qualification. A risk classification system based on clinical and algorithmic risk was developed to aid in this assessment. An established monitoring system ensures that AI solutions meet expected standards over time.

### **Assurance Standards Guide and AI Solutions Lifecycle**

The meeting concluded with a discussion on the Assurance Standards guide and AI solutions lifecycle. The guide and its accompanying checklists are designed to evaluate AI solutions throughout their lifecycle. This development followed a thorough literature review and stakeholder engagement process, which included input from patients, clinicians, and nurses. The effort aligns with the NIST Risk Management framework and the White House's AI Bill of Rights to create a trustworthy AI blueprint. Emphasis was placed on information sharing to inform future work.

### **Follow-Up Tasks**

The meeting outlined follow-up tasks, including reviewing the Assurance Standards guide and checklists for applicability to current projects. Additionally, a snippet from the Generative AI kick-off meeting, detailing the Assurance Standards guide, is to be shared with the work group.

Overall, the meeting highlighted the need for robust frameworks and governance structures to ensure the safe and effective integration of predictive AI into clinical trials and health systems, with a particular focus on underserved communities.



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[www.chai.org](http://www.chai.org)



[admin@chai.org](mailto:admin@chai.org)



[LinkedIn](#)