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"Emerging bioethical trends in safe and responsible applications of Big Data (BD) and Artificial Intelligence (AI) in clinical and translational research (CTR) involving priority populations"

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Background. The dramatic proliferation of BD and AI technologies in health care delivery and clinical translational research (CTR) gives rise to multiple pressing ethical issues explored by the Georgetown-Howard Universities Center for Clinical and Translational Science (GHUCCTS).

Translational science objective. Given the opacity of current BD/AI algorithm biases, development of an ethical and regulatory framework is essential for further large-scale BD/AI use in health care and health research.

GHUCCTS approach. Research, training and educational activities conducted at the GHUCCTS aims to address key ethical challenges generated by current and near-future applications of BD/AI approaches in CTR, and their negative impact on minority and other vulnerable populations under-represented or engaged in the evaluation or development of specific guidance for practical applications, distribution, and/or security of BD/AI approaches.

Findings: capacity building for priority populations. (1) to design, implement and disseminate CTR that will have a high impact on populations with health disparities; (2) to develop and apply innovative analytical and computational methods to speed and enhance CTR; (3) further deploying scalable, secure, and standardized IT tools to enable regional and national CTR collaboration, while developing resources for integrating molecular and phenotypic data, and (4) providing education and training in informatics to new generations of CTR investigators, including minority investigators, in partnership between GHUCCTS and local, as well as the national NIH AIM-AHEAD program.

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GHUCCTS

Georgetown-Howard Universities Center for Clinical and Translational Science

Partnership of five institutions with the mission of improving the infrastructure that supports high quality multidisciplinary clinical and translational research.
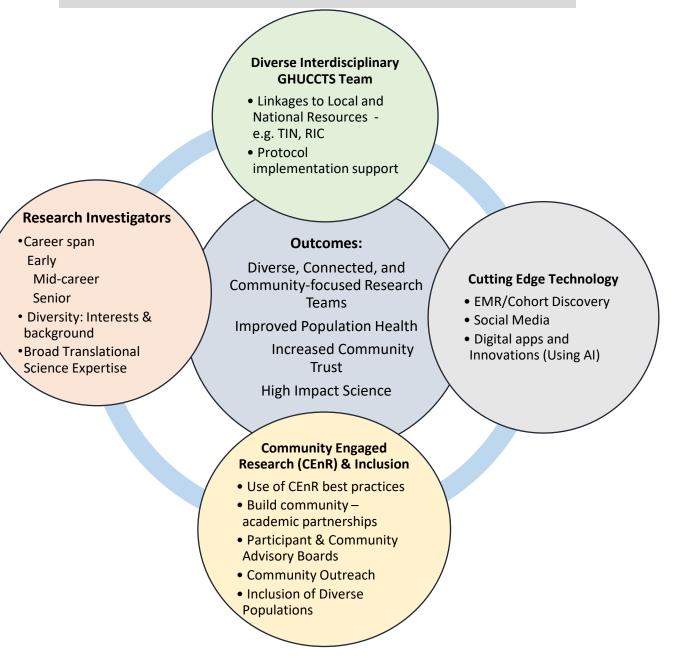
Georgetown University

HOWARD UNIVERSITY
1867

MedStar Health Research Institute

WASHINGTON DC
VETERANS AFFAIRS MEDICAL CENTER
CAPITOL * EXCELLENCE

OAK RIDGE
National Laboratory

Abstract

The proliferation of BD and AI in health care and CTR gives rise to pressing ethical issues, e.g., susceptibility of BD/AI to human biases and errors from institutional processes rooted in racial, ethnic, gender, disability and economically based inequalities. Studies demonstrate discrimination in facial recognition, speech detection, and gender identification, leading to exacerbated racial, social, and economic disparities. Although awareness of such issues exists, healthcare systems increasingly rely on BD/AI applying algorithms to identify those who require additional resources for optimal care. Given the opacity of algorithm biases, developing an ethical and regulatory framework is essential for further large-scale BD/AI use. Yet there is a dearth of ethical and regulatory guidance and oversight of BD/AI in medicine and CTR. Ongoing biases in health care impact disproportionately minority and other marginalized populations, result in diminished access to, and inadequate quality of health care, and barriers to participation in CTR. Research conducted at the Georgetown-Howard Universities Center for Clinical and Translational Science {GHUCCTS) aims to address key ethical challenges generated by the applications of BD/AI in CTR, and their negative impact on minority and other under-represented populations in the development of specific guidance for practical applications, distribution, and security of BD/AI. GHUCCTS aims to design, implement and disseminate CTR with high impact on health disparities including among people from diverse racial, ethnic, and cultural backgrounds, people with disabilities, older adults and veterans; and develop and apply innovative analytical and computational methods to translation by expanding the use of institutional Electronic Health Records for cohort discovery and recruitment to clinical trials; continuing to make cutting-edge analytical methods, including AI and machine learning, available to investigators and trainees; deploying scalable, secure IT tools for collaboration, integrating molecular and phenotypic data, and providing informatics education to CTR investigators, including minority investigators.
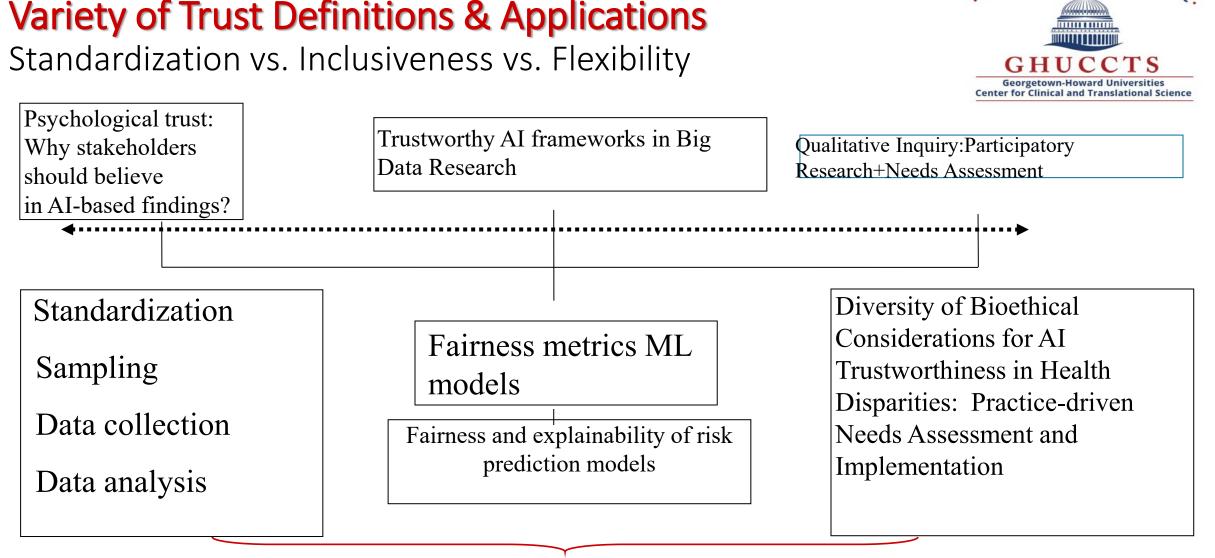
GHUCCTS MULTIDICIPLINARY CONSULTATION MODEL:
CATALYST FOR RESEARCH EXCELLENCE

Diverse Interdisciplinary GHUCCTS Team

- Linkages to Local and National Resources - e.g. TIN, RIC
- Protocol implementation support

Research Investigators

- Career span
  Early
  Mid-career
  Senior
- Diversity: Interests & background
- Broad Translational Science Expertise

Outcomes:

Diverse, Connected, and Community-focused Research Teams

Improved Population Health

Increased Community Trust

High Impact Science

Cutting Edge Technology

- EMR/Cohort Discovery
- Social Media
- Digital apps and Innovations (Using AI)

Community Engaged Research (CEnR) & Inclusion

- Use of CEnR best practices
- Build community – academic partnerships
- Participant & Community Advisory Boards
- Community Outreach
- Inclusion of Diverse Populations

GHUCCTS *Diversity* (DEI Survey)

Race/Ethnicity	GHUCCTS Personnel	K & T Scholars	DMV Composition
White	45%	26%	45%
Black /AA	31%	26%	25%
Hispanic, Latino or Spanish	8%	26%	16%
Asian	14%	20%	10%
Some other race	4%	0%	4%
Prefer not to say	0%	6%	
Gender Identity			
Female	69%	67%	51%
Male	27%	27%	49%
Prefer not to say	4%	7%	

The Trustworthy AI Principles

The ChatGPT generated image captures the essence of collaboration among the NSF AI Institute for Research on Trustworthy AI, the European Union, IEEE, the OECD, and the NIH, all working together to promote trustworthy AI.
(Dr.Libin vs. AI: A CyberAnthropology Experiment, 2024)
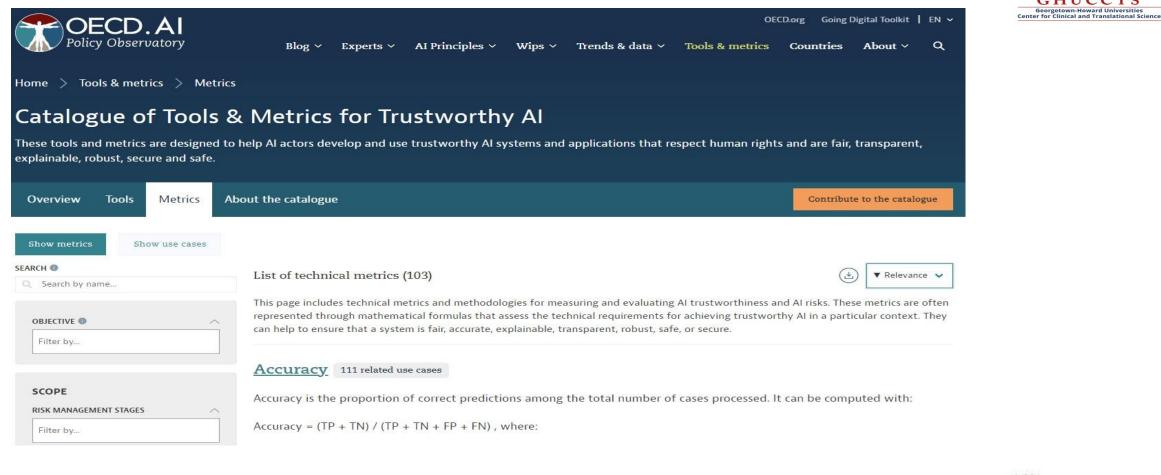
Yes, trust between humans and AI can be established, but it involves unique considerations compared to trust between humans. Building trust in AI systems requires addressing several key factors:

1. **Transparency**: People are more likely to trust AI systems when they understand how decisions are made. Transparency in AI processes and decision-making criteria can help users feel more comfortable and confident in using these systems.
2. **Reliability and Consistency**: For AI to be trusted, it needs to perform reliably and consistently over time. Users need to see that the AI system can consistently deliver accurate, dependable results or actions.
3. **Explainability**: AI systems should be able to explain their decisions in a way that is understandable to humans. Explainability is closely related to transparency but focuses more on the ability of AI to articulate its decision-making process.
4. **Fairness and Bias Mitigation**: Trust can be severely undermined if an AI system is biased or unfair. Ensuring AI systems are designed and regularly audited for biases and that steps are taken to mitigate any identified biases is crucial.
5. **Accountability and Responsibility**: Establishing clear lines of accountability and responsibility for AI decisions is essential for trust. Users need to know who is responsible for the AI's actions, especially in cases where decisions have significant consequences.
6. **Security and Privacy**: Trust in AI also involves confidence that the system is secure from attacks and that personal data used by the AI is handled respectfully and protected.
7. **Alignment with Human Values and Ethics**: AI systems should be designed and operated in a manner that aligns with ethical principles and human values, reinforcing their acceptability and trustworthiness.
8. **User Experience**: A positive, user-friendly experience can enhance trust. If users find the AI system easy to interact with and feel that it enhances their decision-making or workload, trust is more likely to develop.

Building trust in AI is an ongoing process that requires careful attention to these and other factors throughout the design, development, and deployment stages. As AI technologies become more integrated into everyday life, ensuring these systems are trustworthy will be crucial for their acceptance and effective use.

The Trustworthy AI Metrics

Can There be Trust Between Humans and AI: Success to Date, Challenges and Future Steps

Computational Success:

Early prototypes of ML, NLP and LLM algorithms with embedded Trustworthy AI Principles have been developed.
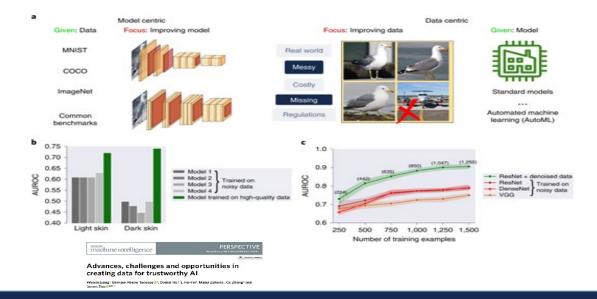
Trustworthy AI tools are tested through experimental clinical and big data research

AI-tailored Data Challenge:

More attention needs to be placed on developing methods and standards to improve the data-for-AI pipeline.

Trust Metrics Challenge:

Developing standardization guidelines

on Trustworthy AI implementation

in real-world setting

Conceptualizing AI Trustworthiness through Stakeholders Needs Assessment – AI-LEARN Initiative: AIM AHEAD Case Study

Author Names: Alexander Libin, Sara Stienecker, Omar Aljawfi, Rose Yesha, Singh Prabhjeet, Nawar Shara
Presenter Names: Alexander Libin

26 Frontline Healthcare Workers (FHW) from 14 states were engaged with a survey and focus groups to assess the needs for an AI curriculum. Results: A curriculum aimed at developing AI competencies could be useful for the daily work and careers of FHW.

Methods and Analysis: For the purposes of our AI-LEARN initiative, a mixed-methods approach was employed with qualitative and quantitative methodologies focused on FHW. We developed a working definition of who can be defined as FHW: *individuals who are employed at any worksite with direct patient contact. They provide care at hospitals, community-based clinics, mental health facilities, and drug rehabilitation centers.* The assessments were approved by the IRB via educational exempt status. There were 26 FHW from 25 organizations recruited across 6 AIM AHEAD HUBS from 14 states and territories, ranging from community healthcare centers to medical. 90% of surveyed participants were representatives of minority serving institutions (MSIs).

Results: Study findings clustered across 3 dimensions spanning 34 presented items. 58% of respondents consider _focus on health disparities_ as a critical part of their mission in the areas of AI development; the most identified _collaborative experiences_ were the public health (50%), medical school (41%), health education (30%) and nursing (30%). The experiences with the _data science and clinical informatics departments_ were the least established collaboration accounting for only 1% each. FHW stakeholders would like to expand their _experiences with the training_ in AI (69%), Society, Ethics and Technology (65%), Data Analytics (62%), and Data Science (50%). Preferred educational formats were workshops and conferences (48%); research programs (44%); curriculum and coursework (28%).
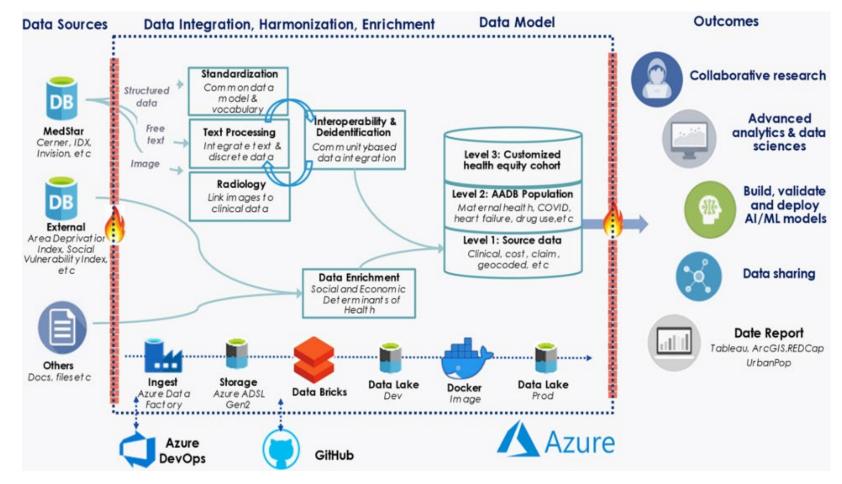

A ChatGPT visual representation of the distribution and recruitment effort for the 7 AIM AHEAD HUBS and 26 MSI's organizations across the United States, highlighting 14
states and territories.
(Dr.Libin vs. AI: A CyberAnthropology Experiment, 2024)

Biostatistics, Epidemiology & Research Design (BERD)

Established sophisticated data environment/infrastructure to facilitate access to complex, diverse, curated EHR datasets aimed at development and training of AI/ML models for CTR and training.
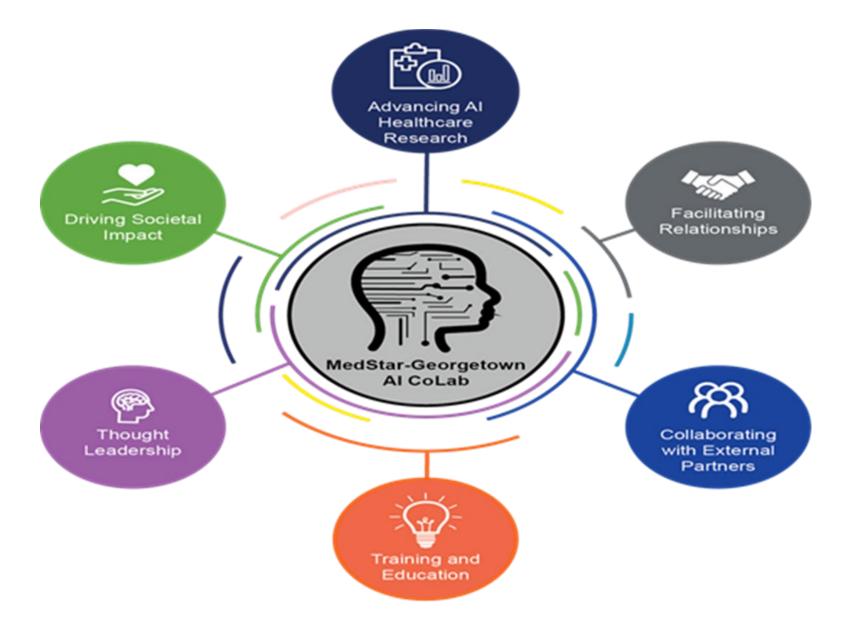
BERD/GHUCCTS practical applications

Provided design, statistical and data science support to ~500 projects, developed numerous collaborative, multidisciplinary, multi-institutional AI/ML proposals.

- NIH: Data Bridge: data repository in support of AI/ML innovative training and research.
- NIH/NIMHD R01: REmote symptom COllection to improVE postopeRative care (RECOVER).
- FDA P50: Alliance for Pediatric Device Innovation.
- FDA+AIM-AHEAD infrastructure: AI/ML in Medical Imaging, Detection, Classification and Diagnosis of the Breast and the Lung Cancers.
- GHUCCTS: NLP/DL to uncover parameters with high potential in preventing onset of Diabetes and to promote Healthcare equity.
- GHUCCTS: Healthcare Utilization During the COVID-19 Pandemic and the Supplementary Role of Telemedicine: Retrospective Study of Chronic Disease Cohorts.
- Industry: Applying ML-diagnosis support systems in EHR to identify wild-type ATTR.

AI CoLab, a joint MedStar-GU center, founded to facilitate research and educational efforts for ethical and equitable AI/ML in healthcare.

CHUCCTS capacity building for priority populations

(1) to design, implement and disseminate CTR that will have a high impact on populations with health disparities;

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Q & A

Thank You!