



Health 360x Registry: Equitable Access To Point Of Care Decentralized Clinical Trials

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Disclosures

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- **Patent:** A System and Method for Chronic Illness Care (Ofili et al. Patent # US 8,234,131 B2) issued in 2012
- **AccuHealth Technologies** Small Business Innovation Research (SBIR) Award Number: 1R44TR003832-01 April 1, 2021-March 31, 2024
- **Founder and Chief Executive Officer:** AccuHealth Technologies Inc.

Background

- Addressing the lack of diversity in clinical trials is a top priority for the Pharmaceutical industry, the Food and Drug Administration and the National Institutes of Health (NIH)
- The Institute of Medicine(IOM) forum on drug discovery and workshop on *Public Engagement and Clinical Trials: New Models and Disruptive Technologies*, identified two major barriers :
 - I. Lack of involvement of community physicians and not addressing their infrastructure needs in the development and conduct of clinical trials
 - II. Increasing difficulty of recruiting and retaining an appropriate human subject population for specific clinical trials
- The 21st Century Cures Act enhances our ability to modernize clinical trial designs, including the use of real-world evidence which will speed the development and review of novel medical products

1. IOM (Institute of Medicine). 2012. Public Engagement and Clinical Trials: New Models and Disruptive Technologies: Workshop Summary. Washington, DC: The National Academies Press.
2. IOM (Institute of Medicine). 2015 Roundtable on the Promotion of Health Equity and the Elimination of Health Disparities: Strategies for Ensuring Diversity, Inclusion, and Meaningful Participation in Clinical Trials April 9, 2015 Keck 100 500 5th Street NW Washington, DC
3. H.R.34 One Hundred Fourteenth Congress of the United States of America, 21st Century Cures Act. January 4, 2016

21st Century Cures Act



- The 21st Century Cures Act (Cures Act), signed into law on December 13, 2016, is designed to **help accelerate medical product development** and bring new innovations and advances to patients who need them faster and more efficiently. Cures enhances our ability to modernize clinical trial designs, including the **use of real-world evidence** which will speed the development and review of novel medical products

Objectives

The goal of the SBIR Fast-Track award is to develop the knowledge, products and processes needed to implement Health 360x Clinical Research Platform Service in **real world practices** serving predominant African Americans, Latinx, and patients from rural communities.

Primary hypothesis: A point of care research registry platform will scale decentralized clinical trial (DCT) for efficient and sustainable access to clinical trials, by systematically addressing gaps in the practice infrastructure of community physicians

- Specific Aim 1-Phase I. Design the Health 360x Clinical Research Platform and SOP to support the Health 360x Registry and Clinical Trial Network
- Specific Aim 2-Phase II. Evaluate the adoption, implementation, effectiveness, and maintenance of Health 360x in practices serving under-represented patients

Primary outcome: The adoption and implementation progress of Health 360x Registry with recruitment and retention performance metrics for NIH and Industry sponsored Studies

Methods

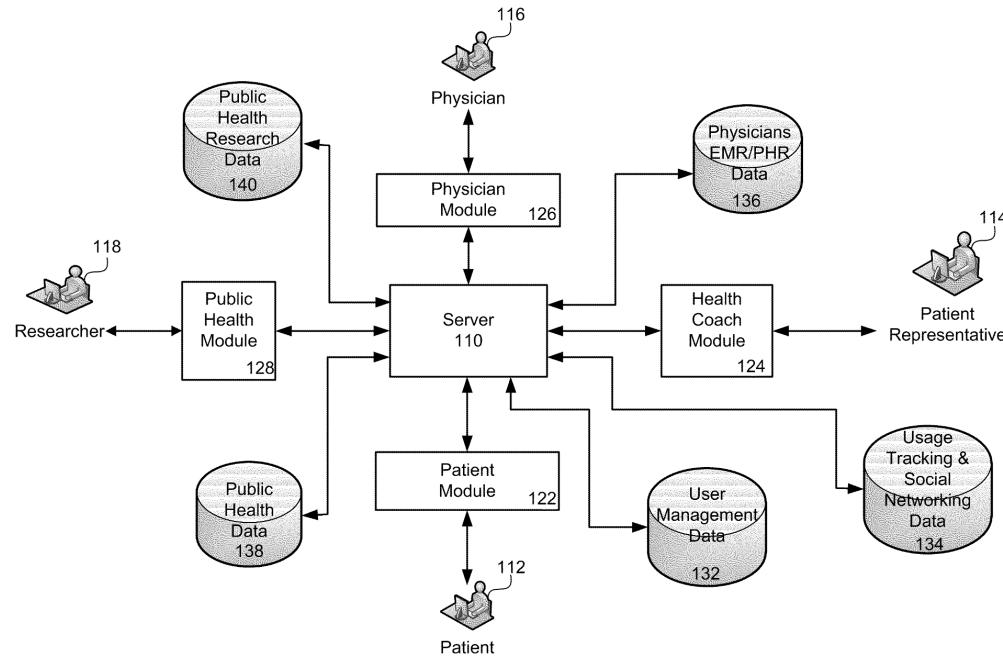
- Implement Health 360x™ Registry integrating **social determinants** in community facing **real world practices** serving predominant African Americans, Latinx, and patients from rural communities
- The conceptual model is **Practical, Robust Implementation and Sustainability (PRISM)** PRISM implementation targets **barriers at the patient, provider and practice levels**:
 - I. Recruitment and accrual
 - II. **Stakeholder engagement** through focus groups and key informant interviews
 - III. Integrate **novel informatics tool such as FHIR** (Fast Healthcare Interoperability Resources based standards)
 - IV. Opt-in informed consent for **pre-screening practice EMR** for eligible participants
- **RE-AIM evaluation** (Reach, Effectiveness, Adoption, Implementation, Maintenance) for rigor and sustainability

1. Ofili, E.O.; Pemu, P.E.; Quarshie, A.; Alema Mensah, E.; Rollins, L.; Ojutalayo, F.; McCaslin, A.; Saint Clair, B. Democratizing discovery health with N= me. *Trans. Am. Clin. Climatol. Assoc.* 2018, 129, 215–234. PMID: 30166716

2. Glasgow RE, Vogt TM, Boles SM. Evaluating the public health impact of health promotion interventions: The RE-AIM framework. *American Journal of Public Health.* 1999;89(9):1322-7.

3. Mandel JC, Kreda DA, Mandl KD, Kohane IS, Ramoni RB. SMART on FHIR: a standards-based, interoperable apps platform for electronic health records. *J Am Med Inform Assoc* 2016;0:1–10. doi:10.1093/jamia/ocv189, Research and Applications

Health 360x Clinical Research Platform: Patent Protection



Health 360x Registry

- Patient engagement and health coaching for Microlearning
- Standardizes Patient Reported Outcomes (PRO)
- Utilizes FHIR Resources to integrate Real World Data from EMR
- Implements a HIPAA compliant Repository and Data intelligence

Results: Health 360x Registry Participants and Coaches

N= 4,701 Participants

- 596 participants from 3 NIH sponsored research studies
- 12 community based practices
- 3741 patients enrolled from 15 practices for quality improvement and remote patient monitoring

2029 Coach Connections

- 6 research studies: 4 NIH; 1 AHA; 1 Industry
- 1 Quality Improvement

Health 360x Usability and Research Workflow

- Health 360x Overall System Usability Score: 95% (88-100)
- PhenX Survey integration and Micro-learning in Health 360x SOP and Research workflow: 85%

Results: Health 360x Registry Use Case-NCATS Innovation

- 170 participants in NCATS/NIH Innovation study from 12 community based practices
- Average age 62 years, 83% African American, 68% women, 51% have annual income less than \$25,000, and 15% are rural residents
- Focus groups and key informant interviews of study team members, identified themes of **recruitment resource** and **training of site team**
- Site investigators made 55% references to **knowledge of clinical trial budget process** ($p < 0.02$ compared to non network practices)
- Study participants made 75% references to **Health 360x™ patient engagement and micro-learning coaching**

Conclusion

- PRISM implementation framework of the Health 360x™ Registry demonstrates the readiness of trusted community practices in a Decentralized Clinical Trial Model.
- The Model has successfully integrated Social Determinants in SOP and Workflow of practices.
- Demonstrates readiness of the Health 360x™ Registry to support the African American Heart Study: A Real World Data Study of Atherosclerotic Cardiovascular Risk in 5,000 African American and Black Participants in the US: AMGEN Press Release-February 22, 2023
- Barriers Remain to FHIR implementation and the 21st Century Cares Act for real world data integration in research
- Future work will integrate data from text messaging and Micro-learning features of Health 360x™ to forecast study accrual

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Health 360x Network Sites (Active): One Third Toward Near Term Goal of Thirty Five Sites

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