

**CONCEPT CLEARANCE RECORD
FY 2016 RESEARCH INITIATIVE – NCATS**

TITLE: Sensors and Devices to Detect Clinical Outcomes

OBJECTIVE(S): To advance the integration of real-time data from multiple devices and sensors to meaningfully inform clinical outcome assessment.

DESCRIPTION: Many sensors and devices are available; however, the clinical utility of these is limited. This proposal will focus on solving technical, computational, engineering, social and cultural barriers to collecting, integrating and analyzing data from multiple devices and sensors and patients' health care data in the context of addressing a pilot study of a compelling clinical question that could not be answered without such data integration. To ensure clinical relevance of the clinical question and feasibility, patients must be an integral part of the project team.

IMPORTANCE: A diverse collaborative team (technology leaders, patients, data scientists, etc.) is required to uniformly collect and analyze sensor and device data for assessing clinical outcomes. The resolution of engineering, technical, computational, social and cultural barriers to adoption and use of sensor and device data also is required.

HISTORY: Many sensors and devices are available to measure physiologic, environmental and patient-reported information; however, the clinical utility of these is limited by lack of integration of the data from multiple sources. This problem includes the collection, transfer and management of the data, as well as informatics and computational methods to integrate data within a meaningful clinical context. The types of data could include environmental measurements, periodic static analyte measurements, vital sign measurements, videos or photographs, text data, coded data, and dynamic, complex waveform data. Data collection and transmission may be impeded by proprietary interfaces and formats; harmonization to align with openly available and accepted standards will be required. The analysis of the collected data should inform a clinical outcome assessment or biomarker. Additionally, information about patient and physician attitudes, beliefs, values, knowledge about devices, privacy and security concerns, and clinical validity and utility could inform future approaches.

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