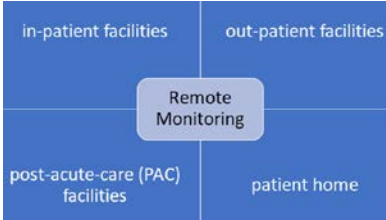


<p>Title of the project: Accelerating Safe, Effective and Secure (SES) Remote Monitoring and Mobile Health Interoperable Solutions</p> <ul style="list-style-type: none"> Addressing the immediate and future needs and gaps exposed by the Pandemic focusing on: in-patient, outpatient, post-acute-care & patient home care scenarios. <p>Research area addressed: Standards development</p> <ul style="list-style-type: none"> Length of the performance period: 1-2 years, 2020-2021 Initial SMEs in the project <ul style="list-style-type: none"> KM: Kosta Makrodimitris TC: Todd Cooper SS: Stephan Schlichting GD: Gora Datta KF: Ken Fuchs JR: John Rhoads Initial collaborative SDO partners/groups <ul style="list-style-type: none"> ISO TC215: WG2 & JWG7 IHE-DEV IEEE 11073 HL7 - Mobile Health, FHIR, DEV Government partners <ul style="list-style-type: none"> FDA CDC CMS ONC EU, Asia health departments Healthcare providers partners <ul style="list-style-type: none"> Hospital PCP PAC 	<p>Specific Aims</p> <p>A. Publish White Paper: Evaluate current interoperability standards (HL7 FHIR/IEEE/ISO/IHE/HIMSS) applicability + maturity for Remote Monitoring and Mobile Health Interoperability of specific parameters (heart, respiration, temperature, mental health, imaging, compliance, sleep apnea, orthodontics, maternal-fetal etc.) for high risk patients affected in pandemic</p> <ul style="list-style-type: none"> Home use devices/patients Patients in bedside in hospital env "clinic" / primary care post-acute-care <p>B. Define a possible Minimum Set of Safe, Effective & Secure Medical Device and Mobile Health Interoperability for rapid implementation in virtual settings. What SES principles and risks should be used to evaluate readiness for interoperable virtual settings, for Emergency Use Authorizations (EUA) by regulatory bodies and healthcare providers in pandemic.</p> <p>4 KIPs: Connectivity, reporting, alerting & controlling Leverage IHE SDPi + FHIR efforts, profiles to monitoring devices, Home setting to use protocols for 4 KIPs (Key Interoperability Processes)</p> <p>C. Measure/Monitor conformance, adoption and implementation to generate interoperable harmonized data from devices, reduce data delays, and ambiguity, improve the quality of care by making the right data available at the right time, at the right place to the right doctor and the right patient, and making interoperable Real World Data (RWD) available for analysis supporting Real-World Evidence (RWE) for clinical decision-making and innovation</p> <p>D. Initiate a Governance Body & Public Private Partnership to oversee the implementation, adoption, cases, value for ROI of standards</p>
<p>Objective Evaluate the needs/gaps and accelerate and simplify the implementation of interoperability standards in pandemic era to enhance remote monitoring</p> <p>Expected Outcomes A new project on MS-SES-MDI to ballot and create</p> <ol style="list-style-type: none"> White paper (IHE/HL7/others) TR: technical report (ISO TC215) TS: technical specification (ISO TC215) Governance: Monitor conformity/adoption/value <p>Joint proposal: ISO TC215 JWG7/WG2</p> <p>Goals/Vision</p> <ul style="list-style-type: none"> How the project advances the ISO TC 215 standardization goals in pandemic era now and in the future. <p>To Present PWI: May 18 (WG2/JWG7 virtual meeting 9-11am US ET)</p>	<p>GRAPH</p>  <p>Courtesy GD</p> <p>Literature:</p> <ul style="list-style-type: none"> https://confluence.hl7.org/pages/viewpage.action?pageId=66926431 https://github.com/AudaciousInquiry/fhir-saner/wiki/About-The-SANER-Project https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-non-invasive-remote-monitoring-devices-used-support-patient-monitoring-during https://www.fda.gov/regulatory-information/search-fda-guidancedocuments/enforcement-policy-digital-health-devices-treating-psychiatric-disorders-during-coronavirus-disease https://www.himss.org/what-interoperability https://www.hl7.org/fhir/overview.html https://en.wikipedia.org/wiki/ISO/IEEE_11073 https://en.wikipedia.org/wiki/IEEE_11073_service-oriented_device_connectivity https://sequoiaproject.org/ https://www.cdc.gov/coronavirus/2019-ncov/ https://www.healthcareitnews.com/news/guide-telehealth-vendors-age-covid-19 https://www.hhs.gov/hipaa/for-professionals/special-topics/emergency-preparedness/notification-enforcement-discretion-telehealth/index.html https://www.smfm.org/covid-19-white-paper