SENSOR DATA
INTEGRATIONS

Quick Start Guide to Sensor Data Integration: **Data Collection**

Sensor generated data must inform a clinical or behavioral measure that matters and offers value to the decision maker and patient.

- Learn how to select high value sensor generated measures that matter using DiMe's 'measures that matter' framework

The connected sensor technology must collect data of sufficient quality to support optimized decisions on behalf of patients

- Learn how to evaluate the performance of a sensor generated technology using the verification, analytical validation, and clinical validation steps of DiMe's V3 framework

Data Collection

Beginning with data acquisition – the process of measuring physical world conditions and phenomena such as electricity, sound, temperature and pressure – data collection is the ongoing process of accumulating sensor data and metadata at each step of the data lifecycle. Data collection is critical to ensuring that the necessary contextual information about the data and its management over time is available to use the sensor data for clinical decision making.

To optimize the completeness of data capture and support health equity the choice of connected sensor technology must be fit for purpose for all of the patient users who can benefit from these data in a given context of use

- Walk through all the considerations that go into optimizing the selection of a connected sensor technology in *The Playbook*: Digital Clinical Measures
- Deploy DiMe's EVIDENCE checklist

The operational deployment of the connected sensor technology for data capture must be effective and equitable to collect data suitable for use in healthcare decision making

- Access operational best practices for collecting sensor generated data in *The Playbook*: Digital Clinical Measures
- Access the DATAcc by DiMe toolkit developed specifically to support inclusive deployment of digital clinical measures in healthcare and research

Collect necessary metadata to contextualize the sensor generated data for use and reuse in powering high quality decisions in healthcare and research

→ Apply FAIR data principles

Apply applicable standards

→ Review current standards pertinent to data collection here

See quick-start guides on other ART criteria


Data Transmission


Data Processing


Data Privacy


Data Security


Data Quality

SENSOR DATA
INTEGRATIONS

Quick Start Guide to Sensor Data Integration: **Data Transmission**

Sensor generated technologies should leverage transmission protocols that optimize:

1. The diversity and inclusion of the patients who can benefit from sensor generated data
2. Access for all patients and decision makers with appropriate permissions
    - → Access best practices and nine action oriented resources from DATAcc by DiMe's inclusion toolkit

Data Transmission

For sensor data and its accompanying metadata to contribute to a data ecosystem driving clinical decision-making, the processes by which these data are transmitted must be considered.

Data should be transmitted using open data transmission protocols and standards

- → Review current standards pertinent to data transmission here
- → Learn about emerging API-based standards from HealthIT.gov
- → Reference aligned FAIR principle

Beyond connectivity, data transmission optimization includes protocols that contemplate bandwidth, software updates, and firewall related issues

- → Learn more about best practices pertinent to these issues in *The Playbook*: Digital Clinical Measures

Where appropriate, transmission protocols allow for authentication and authorisation procedures

- → Access appropriate best practices, examples, and resources from FAIR

See quick-start guides on other ART criteria

Data Collection | Data Processing | Data Privacy | Data Security | Data Quality

SENSOR DATA
INTEGRATIONS

Quick Start Guide to Sensor Data Integration: **Data Processing**

Sensor generated technologies should leverage transmission protocols that optimize:

1. The diversity and inclusion of the patients who can benefit from sensor generated data
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Ensure that all data processing steps are known and documented

- → Learn about different types of sensor data at varying levels of processing here
- → Use the DiMe Sensor Data Integrations Data Flow Design tool to record where data processing is happening and documentation of these operations are necessary

Data Processing

Sensor-generated data is not clinically interpretable at the point of collection. For example, the electric currents on the skin captured by an ECG must be processed into heart rate before a person can understand the clinical relevance of the data. Substantial data processing is required to transform the signals captured by sensors and the high velocity flows of data they generate into information suitable for clinical decision-making.

Algorithmic transformation of pre-processed data to clinically interpretable data and information must be correct and perform equally well across all members of the population of intended patient users

- → Learn how to evaluate the performance of an algorithm processing sensor generated technology using the analytical validation steps of DiMe's V3 framework
- → Review specific considerations pertinent to equity of algorithms used to generate digital clinical measures in DATAcc by DiMe's inclusion toolkit

Appropriate standards should be applied to data processing

- → Review current standards pertinent to data processing here

See quick-start guides on other ART criteria

Data Collection | Data Transmission | Data Privacy | Data Security | Data Quality

SENSOR DATA
INTEGRATIONS

Quick Start Guide to Sensor Data Integration: **Data Privacy**

Ensure compliance local laws and regulations, recognizing that there is no one single standard, nor single agency or regulation governing data security in healthcare

- Review the very limited U.S. legal protections for data rights in *The Playbook*: Digital Clinical Measures
- Learn more about the EU's General Data Protection Regulation (GDPR), the legal framework that provides the core of Europe's digital privacy legislation
- Access standards pertaining to security and sensor generated data here

Implement privacy by design to protect patients and build trust in connected sensor technologies and healthcare data ecosystem ecosystems

- Review privacy by design principles in *The Playbook*: Digital Clinical Measures

Data Privacy

The protection of personal, sensor-generated data from those who should not have access to it and the ability of individuals to determine who can access their personal information is not only required by laws and regulations in some instances, but also fundamental to establishing trust in a health data ecosystem that relies on sensor-generated data for clinical decision-making.

Ensure that the end-user license agreements (EULAs) and terms of service (ToS) of connected sensor technologies and data platforms are congruent with local laws, regulations, and informed consent

- Learn more about EULAs and ToS in *The Playbook*: Digital Clinical Measures and DiMe's Primer on Digital Medicine: Measurement

Manage security and privacy through reusable processes

- Access resources and checklist in the US Digital Services Playbook

Conduct a data protection impact assessment when sensor data is likely to involve "a high risk" to other people's personal information

→ Access the EU's GDPR data protection impact assessment template

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SENSOR DATA
INTEGRATIONS

Quick Start Guide to Sensor Data Integration: **Data Security**

Ensure compliance local laws and regulations, recognizing that there is no one single standard, nor single agency or regulation governing data privacy in healthcare

- Review cybersecurity regulators and regulations in the U.S. and Europe in *The Playbook*: Digital Clinical Measures
- Access standards pertaining to security and sensor generated data here

Expect security best practices to be built into each tier of a data architectures – the web tier, application tier, and data tier.

- Review DiMe Sensor Data Integrations cybersecurity reference data architecture

Data Security

The practice of protecting sensor-generated data, and the systems that store and process these data, from unauthorized access, corruption, or theft throughout its entire lifecycle is an essential component of establishing sensor-generated data as a viable source of information to support clinical decision-making.

Apply security best practices at each step of the sensor data flow

- Apply security best practices at each step of the sensor data flow from *The Playbook*: Digital Clinical Measures

Manage security and privacy through reusable processes

- Access resources and checklist in the US Digital Services Playbook

Use a software bill of materials (SBOM) to reduce the security risk of including third-party connected sensor technologies in the healthcare data ecosystem

- Learn how SBOMs provide transparency into a medical technology's components, which can eventually reduce the feasibility of attacks here

Deploy no-cost tools from the US Federal Cybersecurity and Infrastructure Security Agency (CISA) to support your security approaches

- Access CISA's ransomware guide, healthcare resources, bad practices, tabletop exercise package, cybersecurity evaluation tool, and cyber hygiene services.
- Sign up for CISA alerts and bulletins

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The connected sensor technology must collect data of sufficient quality to support optimized decisions on behalf of patients

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To optimize data quality and support health equity the choice of connected sensor technology must be fit for purpose for all of the patient users who can benefit from these data in a given context of use

- Walk through all the considerations that go into optimizing the selection of a connected sensor technology in *The Playbook*: Digital Clinical Measures
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Data Quality

The Institute of Medicine defines high quality data as data strong enough to support conclusions and interpretations equivalent to those derived from error-free data (IOM). Sensor-generated data must be high quality to be useful for clinical decision-making, noting that this bar will vary with the nature of the decision. Sensor data quality is determined by the completeness, validity, uniqueness, consistency, timeliness, and accuracy of the data.

The operational deployment of the connected sensor technology for data capture must be effective and equitable to collect data of sufficient quality for use in healthcare decision making

- Access operational best practices for collecting sensor generated data in *The Playbook*: Digital Cinical Measures
- Access the DATAcc by DiMe toolkit developed specifically to support inclusive deployment of digital clinical measures in healthcare and research

Ensure there is access to the necessary metadata to contextualize the sensor generated data for use and reuse in powering high quality decisions in healthcare and research

→ Apply FAIR data principles

In order to create a high quality, comprehensive dataset, data must be aggregated to combine disparate pieces of information

→ Learn how to clean and harmonize data in order to integrate heterogeneous sources here

Apply applicable standards

→ Review current standards pertinent to data quality here

See quick-start guides on other ART criteria


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