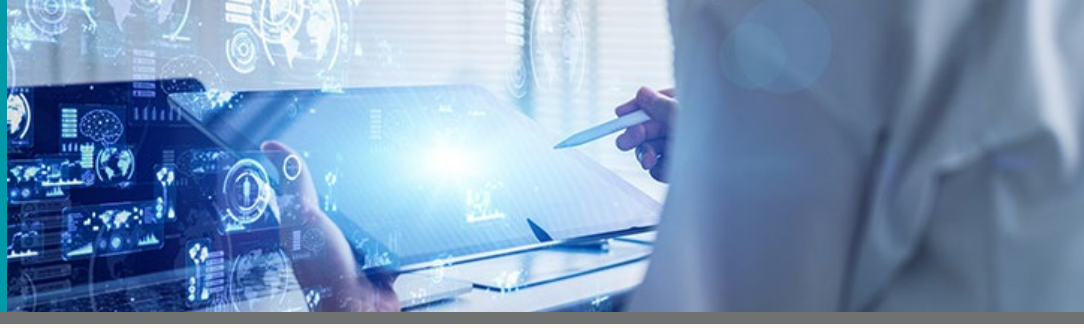
Pistoia Alliance



QDatE Code of Ethics for the Collection, Storage, Governance, Use, and Reuse of Sensor-Generated Data From Remote Monitoring Technologies

This Quality Data Generation and Ethical Use (QDatE) code of ethics is complementary to the Best Practice Guidelines and will ensure that the sensor-generated data from remote monitoring technologies (SDRM) is collected, stored, governed, used, and reused in a way that utilises the data to the best of its potential.

1. **PARTICIPANT PATIENT INVOLVEMENT (PPI)** – To ensure that the SDRM being collected is relevant to patients and that the burdens of the data collection and data upload are not too difficult or burdensome to the participants, PPI should be sought as early as practicable in the design stages of the clinical trial.
2. **FEEDBACK** – Provide feedback to the participants on how the SDRM that has been collected has and could be used in the future.
3. **SECURE** – As an addition to the current ethics surrounding security of participants, careful considerations need to be made for the secure transfer of SDRM from the remote device into storage. Current guidelines and legislation include and are not limited to the California Consumer Privacy Agreement (2018) and the EU's General Data Protection Regulation. Additional considerations for data security are required to protect the SDRM from potential hacks and being lost or going missing during transfer from the remote monitoring device to data storage.
4. **QUALITY AND REUSABILITY** – Ensure that the SDRM is collected as per the FAIR Principles to a quality that can be used and is reusable. This reduces the need for data to be collected again for subsequent studies and thereby results in a decrease in the duplication of time, effort, resources, and burden to the participants.
5. **PARTICIPANT EMPOWERING** – Allow the participants to access to their own data as the "data owners". Empowering the participant to understand their rights in making their own data available to others for reuse outside of the clinical trial it is being collected for or allowing their data to become an integral part of both their routine care and research by using interoperable standards that enable the patient and the healthcare providers to request the SDRM using the FHIR SMART Markers.
6. **STRIVING FOR EQUALITY** – Ensuring the correct training is provided and accessibility to use the remote monitoring technologies for the collection of SDRM is available to all who fulfil the clinical trial inclusion criteria. This enables all eligible participants equal access to the clinical trial, regardless of their ethnicity, gender, socio-economic status, religion, education, age, tech savviness, or any other potentially discriminating factor.
7. **PROPORTIONALITY** – Ensure that the data are collected, transferred, and made available as consented for by the participant and that it is used for the specific purpose as indicted to the participant. This is to be done in accordance with all applicable local regulations such as GDPR in Europe.

Quality Data Generation and Ethical Use

QDatE

This code of ethics is an addition to all current codes of ethics that are in place for medical research which include and are not limited to:

Nuremberg Code (1947)

Declaration of Helsinki (2000)

Council for International Organizations of Medical Science – CIOMS (2002)

The Department of Health and Human Services Title 45 CFR46 (public welfare) – "The Common Rule" (1991)

ICH Guidelines (1991)

American Association of Medicine Principles of Ethics (1979)

Ethics in Clinical Research Ethical Guidelines (1979)

Good Clinical Practice (1979)

The Belmont Report (1979)