



Glossary for the Digital Health Trials Recommendations

The following terms and definitions are designed to support the CTTI recommendations addressing scientific and technological issues surrounding the use of digital technologies in clinical trials. In some cases, the terms are taken from existing resources such as the BEST (Biomarkers, EndpointS, and other Tools) [Glossary](#). In other cases, the definition was agreed upon by a diverse set of stakeholders across the clinical trials enterprise to create a baseline and common understanding to support future collaborative efforts. All definitions are consistent with applicable U.S. regulations and pertinent FDA guidance.

Accuracy – The agreement between the measurement made by a single digital technology and a known standard.

Adaptive Design – Describes a clinical trial that includes a prospectively planned opportunity for modification based on analysis of interim data from study participants in the study.

Application Programming Interface (API) – The means by which one piece of software is able to communicate with a second piece of software, typically used for passing data between these two software components.

Atypical Data – Unusual or abnormal readings.

Audit Trail – A process that captures details of information—such as additions, deletions, or alterations—in an electronic record without obscuring the original record; an audit trail facilitates the reconstruction of the course of such details relating to the electronic record.

Calibration – The process of evaluating and adjusting the digital technology to ensure the accuracy and precision of the raw data it generates.

Centralized Monitoring – Remote evaluation carried out by sponsor personnel or representatives at a location other than the clinical investigation sites.

Concept – In a regulatory context, the concept is the aspect of an individual's clinical, biological, physical, or functional state or experience that the assessment is intended to capture (or reflect).

Confidentiality – The principle that ensures data from study participants will not be shared with people or organizations beyond those whom the subjects have agreed to in the process of providing consent.

Consistency – The agreement between multiple measurements made by a single digital technology over a long period of time (tests performed over days, weeks, or months).

Consumer Products – Consumer grade digital technologies are generally considered Class I devices and are not FDA-cleared. As consumer products, these digital technologies tend to be appealing in style, functionality and price point to consumers. Many have a consumer-facing app paired with the digital technology.

Context of use (COU) – A statement that fully and clearly describes the way the medical product development tool is to be used and the regulated product development and review-related purpose of the use.

Data Attribution – The process of establishing a particular individual/participant as the creator of a data point.



Data Authenticity – A term describing a property of data saying that it is what the originator claims it to be, or what it is claimed to be by the data originator/processor.

Data Element – A recorded assessment of a single observation associated with a subject in a clinical study.

Data Epoch – A measurement of duration, the brief time interval during which data is collected and summarized.

Data Integrity – Data that is not modified or corrupted in an undetectable and/or unauthorized way during its generation and flow.

Durable Medium – Media that can be stored, accessed easily, and reproduced at convenience.

End-to-End Data Security – End-to-end security relies on protocols and mechanisms that are implemented on the endpoints of a data connection.

Firmware – Permanent software programmed into the digital technology that serves as its operating system.

High-Quality Data – Data strong enough to support conclusions and interpretations equivalent to those derived from error-free data.

Measurement – The obtained value using a test, tool, or instrument.

Medical Device – Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease. Medical devices are regulated and subject to FDA's laws and regulations.

Metadata – A set of data that describes and gives information about other data. Metadata is structured information that describes, explains, or otherwise makes it easier to retrieve, use, or manage data.

Digital Technologies – Digital applications and other wearables, ingestibles, implantables, and portable technologies containing sensors for the capture of outcomes data.

Outcome Assessment – An assessment (interpretation or evaluation of the measurement) of an outcome (measurable characteristic that is influenced or affected by an individuals' baseline state, or an intervention as in a clinical trial or other exposure) that results in recorded data point(s).

Precision – The agreement among multiple measurements made by a single digital technology over a period of time that is short enough so that the quantity being measured can be assumed constant and the variability of the measurements is due solely to the variability in the measuring technology.

Principle of Least Privilege – The practice of limiting access rights for users to the bare minimum permissions they need to perform their work.

Principle of Need to Know – A principle that, when applied, grants access to covered data only when strictly necessary for specific processes associated with the clinical study.



Private Information – Information about a behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual, and which the individual can reasonably expect will not be made public.

Processed Data – Output from digital technology firmware; raw data that has been mathematically processed.

Raw Data – Output from physical sensor. If the sensor data is not accessible because it is processed by the firmware before being recorded, then the output of the firmware is often considered “raw” data.

Real-Time Data – Information that is intended to be delivered immediately after collection; while real-time data will always be subject to some latency, it is distinct from data that is intended to be archived for future use of viewing.

Risk-Based Approach – With respect to data security, the process of identifying potential high risks and focusing security solutions toward these high risk areas.

Source Document – Original documents, data, and records are source documents. The earliest practically retainable record should be considered as the location of the source data and therefore the source document.

Source Data – All information in original records and certified copies of original records detailing clinical findings, observations, or other activities in a clinical investigation used for reconstructing and evaluating the investigation.

Structured Data – Data that can be easily stored, queried, recalled, analyzed, and manipulated by machines.

Uniformity – The agreement between measurements made by multiple digital technologies, either simultaneously or over a short period of time (tests performed back-to-back).

Validation – The process of ensuring that the digital technology is meeting its intended use by generating data that accurately represents the outcome assessment it purports to be measuring. This may include analytical validation (the validation of the tool's technical performance) and clinical validation (the validation of the tool's usefulness to acceptably identify, measure, or predict the concept of interest).

Verification – The assessment of accuracy (which may include routine calibration), precision, consistency across time, uniformity across digital technologies, and possibly also across different environment conditions. Verification also provides assurance that the relevant firmware /software that generates processed data is accurate, precise, consistent, and uniform.