There are *two types* of *outcomes* in clinical research: COAs and biomarkers

Outcome to be measured

The **measurable characteristic** influenced or affected by an individual's baseline state or an intervention

If you are conducting research, you will also define an **endpoint** to be measured.

Clinical outcome assessments (COA): an assessment of an outcome that describes or reflects how an individual feels functions or survives, made through a report by a clinician, a patient, a non-clinician observer or a performance-based assessment.

Biomarkers**:** defined **characteristics** that are **measured as indicators** of normal biological processes**,** pathogenic processes**,** or responses to an exposure or intervention, including therapeutic interventions.

Source: Karger - Digital Measures That Matter to Patients; BEST Glossary

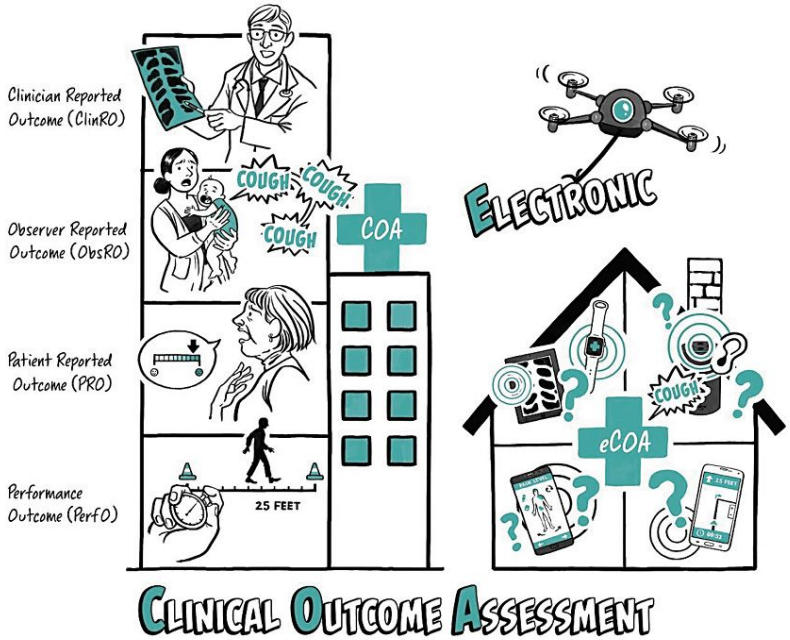
There are 4 types of *clinical outcome assessments* (COAs)

Clinician reported outcome (**ClinRO**)

Observer reported outcome (**ObsRO**)

Patient reported outcome (**PRO**)

Performance outcome (**PerfO**)



When a **COA** is collected using a digital technology, it is called an ***electronic outcome assessment*** or ***'eCOA'***. Note not all eCOAs are collected using a sensor. Ex: ePROs

Source: FDA Facts: Biomarkers and Surrogate Endpoints, Karger - Digital Medicine: A Primer on Measurement, Developing and adopting safe and effective digital biomarkers to improve patient outcomes - Coravos A. et al, Playbook team analysis

There are 7 types of *biomarkers*

Diagnostic Biomarker

Monitoring Biomarker

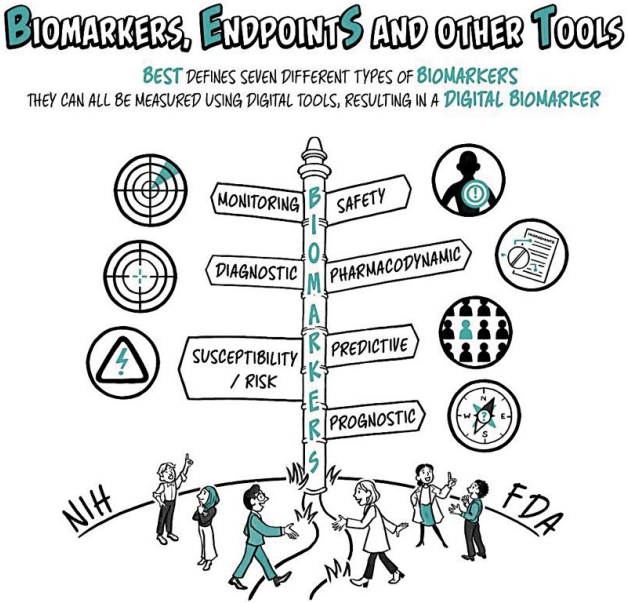
Pharmacodynamic / Response Biomarker

Predictive Biomarker

Safety Biomarker

Susceptibility / **Risk** Biomarker

Prognostic Biomarker



When a biomarker is collected using a digital sensing product, it is a ***digital biomarker***.

Source: FDA Facts: Biomarkers and Surrogate Endpoints, Karger - Digital Medicine: A Primer on Measurement, Developing and adopting safe and effective digital biomarkers to improve patient outcomes - Coravos A. et al, Playbook team analysis

What does the FDA say about *COAs*?

COAs and eCOAs "***directly measure*** **what matters most** to people—whether they **feel** or **function** better, or **live longer**. Therapies can be recommended with confidence when clinical trials show that **benefits**, as measured by clinical outcomes, **outweigh the adverse effects**."

Source: FDA Facts: Biomarkers and Surrogate Endpoints, Playbook team analysis

What does the FDA say about *biomarkers*?

"Biomarkers are defined ***characteristics*** that are ***measured as indicators*** of health, disease, or a response to an exposure or intervention, including therapeutic interventions.

Biomarkers can help **diagnose a disease**, or **predict future disease severity** or **outcomes**, like measurements of blood pressure as an indicator of cardiovascular risks or measurements of blood sugar in diabetes.

Biomarkers also are used to identify the best treatment for a patient, to monitor the safety of a therapy, or to find out if a treatment is having the desired effect on the body.

Source: FDA Facts: Biomarkers and Surrogate Endpoints, Playbook team analysis