

Supplemental Online Content

Perakslis E, Ginsburg GS. Digital health: the need to assess benefits, risks, and value. *JAMA*. Published online December 28, 2020. doi:10.1001/jama.2020.22919

eFigure. Benefit-Risk and Value Assessment in Digital Health

This supplemental material has been provided by the authors to give readers additional information about their work.

eFigure. Benefit-Risk and Value Assessment in Digital Health

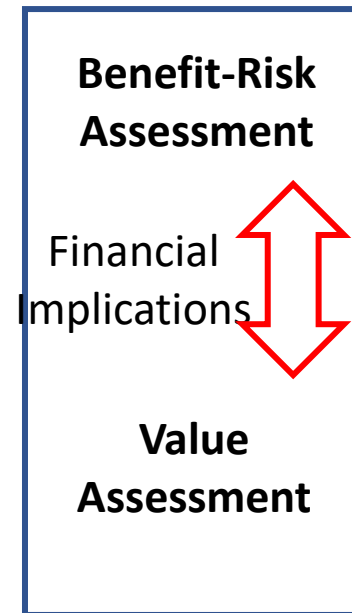
Standard of Care Exists:

Benefits/Clinical Utility?

- Less invasive?
- Real-time vs episodic?
- Enables clinical-grade measurement at home?
- Replaces clinical encounters?
- Easier to use? Reduces error?
- Replaces labs/imaging?
- Educational?
- Improves adherence?

No Standard of Care – novel solution

- Analytical validity?
- Clinical validity?
- Regulatory rigor? (approved vs cleared)
- Level of unmet need?
- Ability to manage?



Effects on Known & Quantified Risks:

Risks of the digital tool?

- Improper use
- Inappropriate alarms
- Misinterpretation
- Privacy and security
- Technical implementation risks
- Tool malfunction
- Confounding data

Suspected but unquantified Risks

- Cyber attacks
- Privacy and security
- System failure
- Over diagnosis/treatment
- Financial burden
- Risks of user error