Advancing Patient Safety: Role of FDA

U.S. FOOD & DRUG ADMINISTRATION

Robert M. Califf M.D., MACC

November 14, 2022

FDA Mission

FDA is responsible for <u>protecting the public health by assuring the safety, efficacy and security</u> of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation.

FDA is also responsible for <u>advancing the public health by helping to speed innovations that make medical products more effective, safer, and more affordable</u> and by <u>helping the public get the accurate, science-based information they need to use medical products and foods to maintain and improve their health</u>.

https://www.fda.gov/about-fda/what-we-do

Leveraging Technology to Improve Safety

FDA

The FDA is modernizing measures to improve the safety of medical drugs and devices while continuing to create more efficient pathways to bring lifesaving drugs and devices to patients.
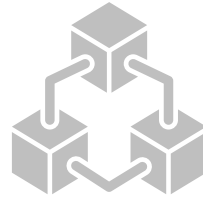
The COVID-19 pandemic underscored the importance of aligning technology, operations and data strategies to drive positive outcomes in our critical work addressing public health challenges.
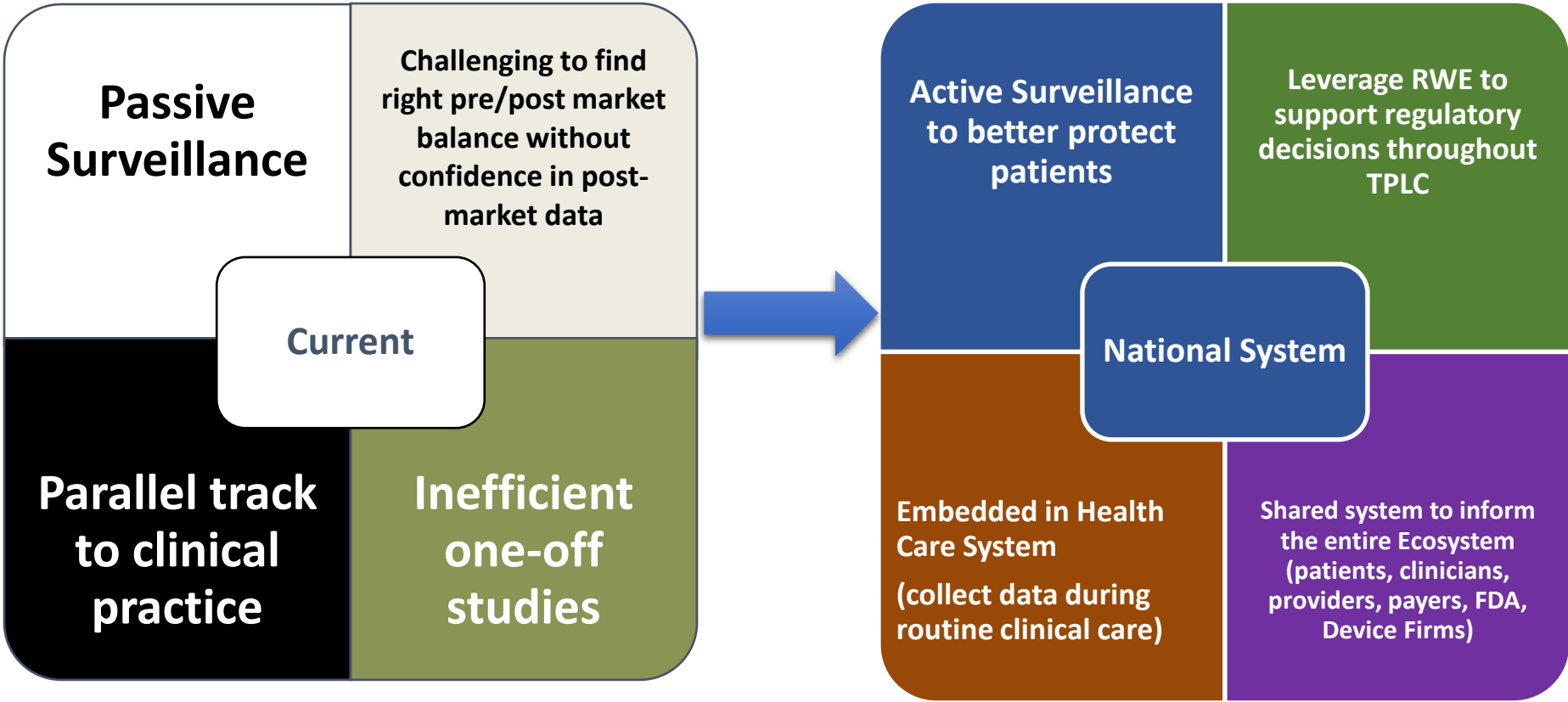
From how we integrate new technology into medical product applications reviews and food safety, to using data insights to help treat disease, **technology and data are ubiquitous to the FDA's work.**

Technology Modernization

Ongoing modernization of FDA's core technology infrastructure complements cutting-edge FDA policies and actions.

- As one example, FDA is building the scientific and policy infrastructure to support increasing use of real-world evidence to support regulatory decisions.

- Real world evidence is only one area in which new technologies will shape future medical product development. Sophisticated data collection and analysis are also reshaping traditional clinical trials, offering the ability to make clinical trial data more efficient to collect and more representative of diverse patient populations.

- Novel and rapidly evolving technologies also promise to enhance the generation of evidence where the size of a clinical trial is limited—for instance, in the context of a rare disease. These technologies will also give FDA sensitive new tools for detecting safety issues, allowing rapid and targeted response.

However, without modernized technical capabilities, FDA will not be able to help close the gap between the promise of these new technologies and policies, and the patients who stand to benefit from them.

National System Paradigm Shift

Current

- **Passive Surveillance**
- Challenging to find right pre/post market balance without confidence in post-market data
- **Parallel track to clinical practice**
- **Inefficient one-off studies**

National System

- **Active Surveillance to better protect patients**
- Leverage RWE to support regulatory decisions throughout TPLC
- **Embedded in Health Care System** (collect data during routine clinical care)
- Shared system to inform the entire Ecosystem (patients, clinicians, providers, payers, FDA, Device Firms)
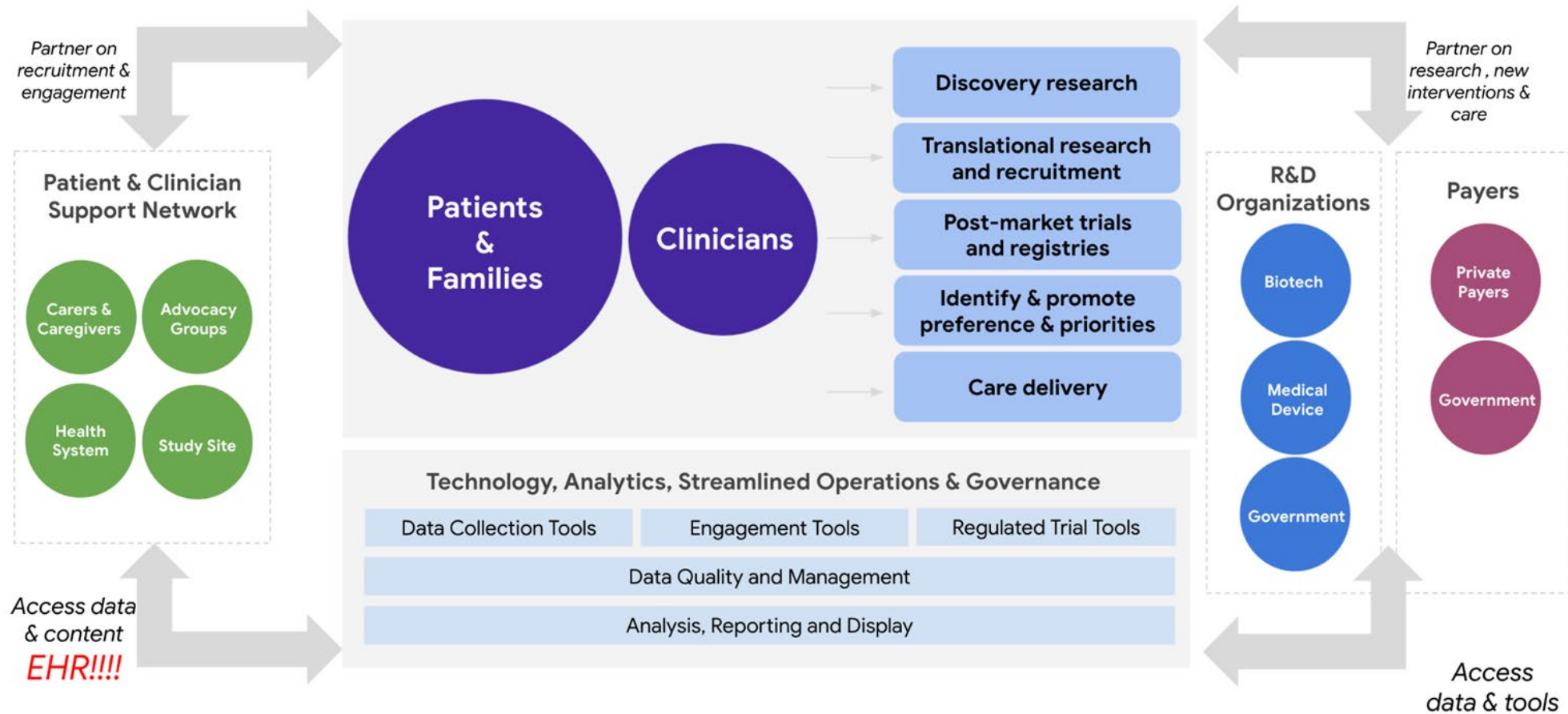
The reality is we have is a disaggregated, fragmented system with lack of organization around common, transparent high-quality information
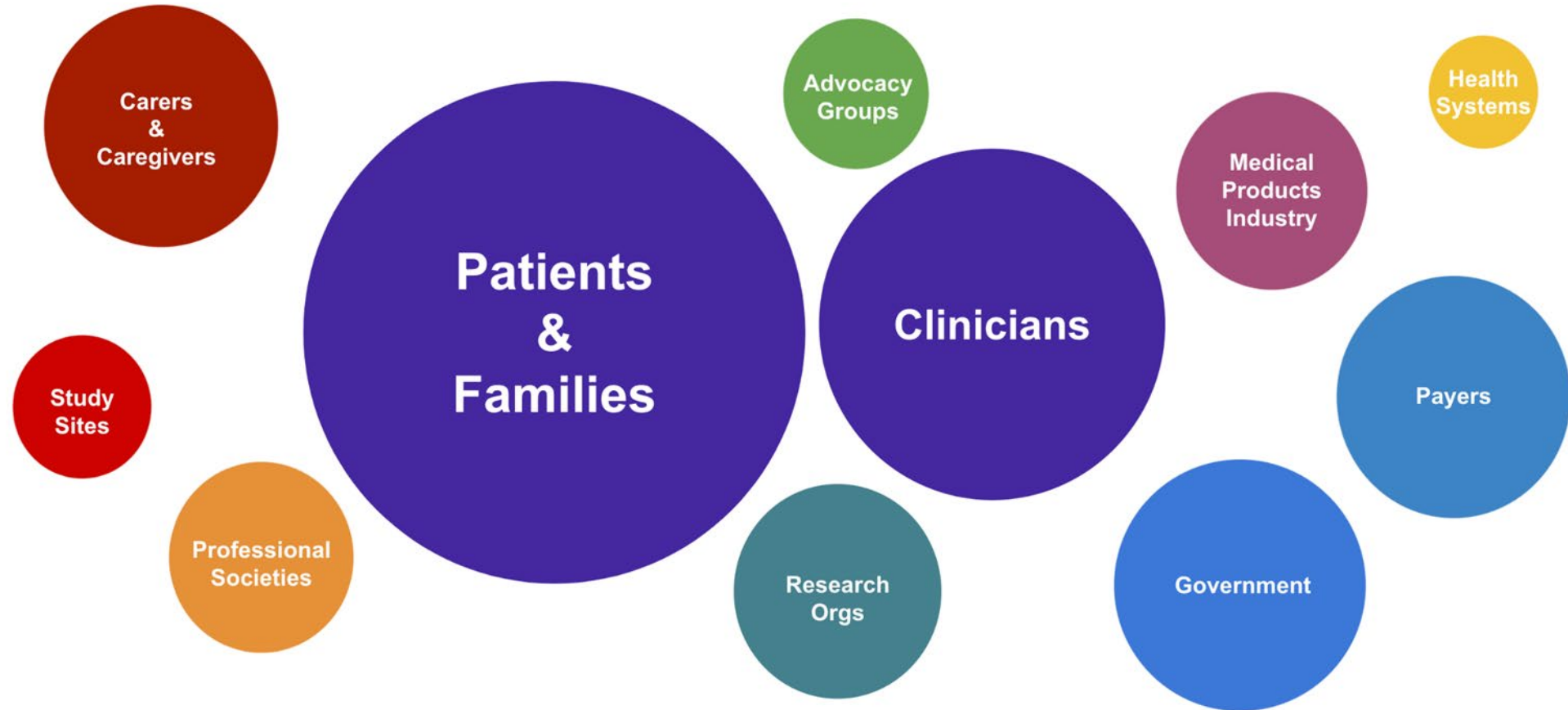
Given common goals, current technology could support a common information base that could support the primary mission: better outcomes for patients

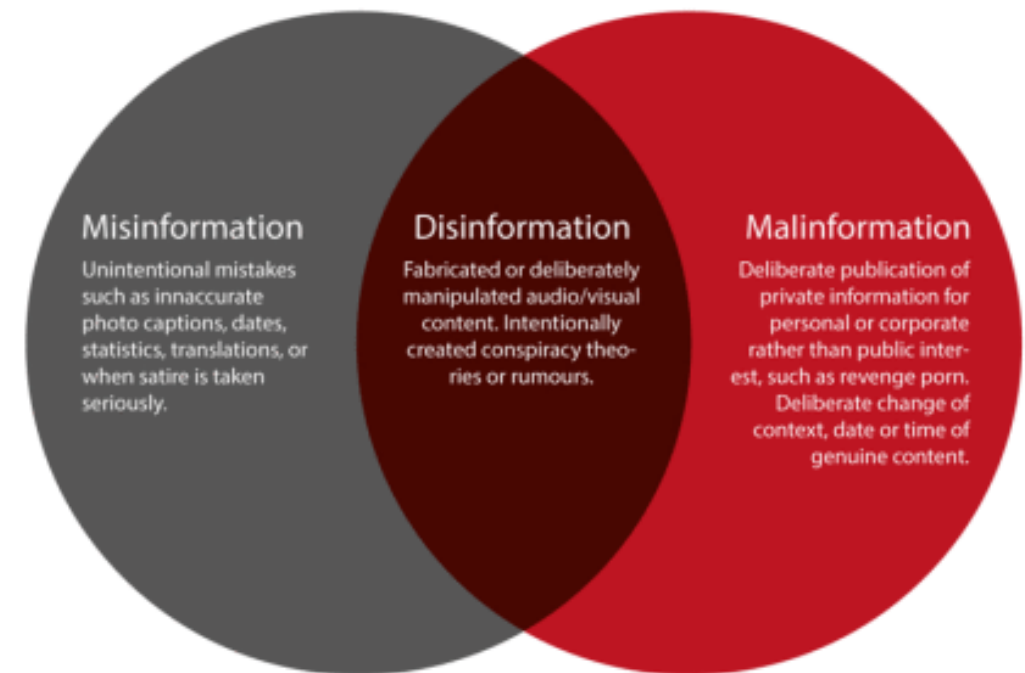# Varying forms of misinformation carry different levels of threat

"Disinformation," is intended to mislead and is disseminated with knowledge that those who succumb to it could be harmed

"Malinformation" is which represents a purposeful effort to harm others directly by spreading incorrect information.

TYPES OF INFORMATION DISORDER

FALSENESS   INTENT TO HARM

Misinformation
Unintentional mistakes such as innaccurate photo captions, dates, statistics, translations, or when satire is taken seriously.

Disinformation
Fabricated or deliberately manipulated audio/visual content. Intentionally created conspiracy theories or rumours.

Malinformation
Deliberate publication of private information for personal or corporate rather than public interest, such as revenge porn. Deliberate change of context, date or time of genuine content.

https://flowersforsocrates.com/2018/08/12/disinformation-misinformation-malinformation-involves-framing/

The FDA is actively trying to find ways to improve coordination internally (within HHS) and externally (with stakeholders) to improve patient safety.