

# Advancing Health Equity in Medical Devices

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# What is Health Equity vs Health Disparities?

- **Health equity** is the state in which everyone has a fair and just opportunity to attain their highest level of health.
- **Health disparities** are preventable differences in the burden of disease or opportunities to achieve optimal health. It is the metric often used to measure progress toward achieving health equity.
- Often impacted by race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, preferred language, or other factors that affect access to care and health outcomes.



# Examples of Health Disparities

- **Life expectancies** vary by race, ethnicity, and sex.
- **High blood pressure**, a major risk factor for heart disease, is more common and not as well controlled in African-American and Hispanic adults as in White adults.
- In the United States, rural populations have higher rates of death due to **heart disease, chronic lower respiratory disease, and stroke** than urban populations.
- The rate of **diabetes** is as high as 14.5% for Native Americans/Alaskan Natives compared to 7.4% for non-Hispanic whites.
- The 5-year survival of non-Hispanic Black and rural patients was consistently lower than urban patients for each **cancer** type, independent of sociodemographic or health care variables.
- Non-Hispanic Black, Native Hawaiian and other Pacific Islander **babies** are twice as likely to die as White babies.

[Sources: Health Disparities and Inequities | NHLBI, NIH](#) ; 5:e2212246.

[Statistics About Diabetes | ADA](#);

[Infant Mortality | Maternal and Infant Health | Reproductive Health | CDC](#)

MW Lewis-Thames et al, *JAMA Netw Open* 2022.

# Social Determinants of Health

- Social determinants of health (SDOH) are the conditions in the environments where people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks
- Examples
  - Safe housing, transportation, and neighborhoods
  - Racism, discrimination, and violence
  - Education, job opportunities, and income
  - Access to nutritious foods and physical activity opportunities
  - Polluted air and water
  - Language and literacy skills



Source: [Social Determinants of Health - Healthy People 2030 | health.gov](https://www.health.gov/ourpriorities/social-determinants-of-health)

# Differences Among Race, Ethnicity and Ancestry

- **Race** represents a sociocultural definition recognized in this country and not an attempt to define race biologically, anthropologically, or genetically.
- **Ethnicity** refers to the shared social, cultural, and historical experiences stemming from common heritage, nationality, lineage, country or region of birth.
- **Ancestry** refers to a person's ethnic origin or descent, "roots," or heritage or the place of birth of the person on the person's parent or ancestors before their arrival in the United States.

Adapted from <https://www.census.gov/topics/population/race/about.html>

# Draft FDA Guidance to Advance Health Equity



- Improve Enrollment of Underrepresented Participants
- Foster Innovation that Addresses Disparities

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## **Diversity Plans to Improve Enrollment of Participants from Underrepresented Racial and Ethnic Populations in Clinical Trials**

### **Guidance for Industry**

[Click for Link to Guidance](#)

**DRAFT GUIDANCE**

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to <https://www.regulations.gov>. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document, contact (OCE/CDER) Lola Fashoyin-Aje, 240-402-0205, (CBER) Office of Communication, Outreach, and Development, 800-835-4709, or 240-402-8010, or [CDRHClinicalEvidence@fda.hhs.gov](mailto:CDRHClinicalEvidence@fda.hhs.gov).

U.S. Department of Health and Human Services  
Food and Drug Administration  
Oncology Center of Excellence (OCE)  
Center for Drug Evaluation and Research (CDER)  
Center for Biologics Evaluation and Research (CBER)  
Center for Devices and Radiological Health (CDRH)  
Office of Minority Health and Health Equity (OMHHE)

April 2022  
Clinical/Medical

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*Contains Nonbinding Recommendations*

*Draft – Not for Implementation*

## **Select Updates for the Breakthrough Devices Program Guidance: Reducing Disparities in Health and Health Care**

### **Draft Guidance for Industry and Food and Drug Administration Staff**

**DRAFT GUIDANCE**

This draft guidance document is being distributed for comment purposes only.


Document issued October 21, 2022.

You should submit comments and suggestions regarding this draft document within 60 days (standard), days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to <https://www.regulations.gov>. Submit written comments to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions about this document, contact CDRH Office of Clinical Evidence and Analysis (OCEA) at 301-796-5550 or [BreakthroughDevicesProgram@fda.hhs.gov](mailto:BreakthroughDevicesProgram@fda.hhs.gov). For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010.

When final, this guidance will update the Introduction and Section III of “Breakthrough Devices Program,” issued on December 18, 2018.

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 **U.S. FOOD & DRUG ADMINISTRATION**  
CENTER FOR DEVICES & RADIOLOGICAL HEALTH

U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Devices and Radiological Health  
Center for Biologics Evaluation and Research



# FDA Guidance Documents

- Informed by Office of Management and Budget (OMB) Directive 15
- FDASIA Section 907 Action Plan
- FDARA Section 601(a)(3) mandate
- Goal to improve demographic subgroup gaps in data

*Contains Nonbinding Recommendations*

## Collection of Race and Ethnicity Data in Clinical Trials

### Guidance for Industry and Food and Drug Administration Staff

Document issued on October 26, 2016

For questions about this document, contact the FDA Office of Minority Health at 240-402-5084 or [omh@fda.hhs.gov](mailto:omh@fda.hhs.gov).

U.S. Department of Health and Human Services (HHS)  
Food and Drug Administration (FDA)  
Office of the Commissioner (OC)  
Office of Minority Health (OMH)  
Office of Women's Health (OWH)  
Center for Drug Evaluation and Research (CDER)  
Center for Biologics Evaluation and Research (CBER)  
Center for Devices and Radiologic Health (CDRH)

October 2016  
Clinical Medical

## Evaluation of Sex-Specific Data in Medical Device Clinical Studies

### Guidance for Industry and Food and Drug Administration Staff

Document issued on August 22, 2014.

The draft of this document was issued on December 19, 2011

For questions regarding this document, contact CDRH at 301-796-5900 or Kathryn O'Callaghan ([kathryn.ocallaghan@fda.hhs.gov](mailto:kathryn.ocallaghan@fda.hhs.gov)); for Office of Device Evaluation specific questions, Jisun Johnson ([jisun.johnson@fda.hhs.gov](mailto:jisun.johnson@fda.hhs.gov)); for Statistics specific questions, Lily Yue ([lily.yue@fda.hhs.gov](mailto:lily.yue@fda.hhs.gov)); for Office of In Vitro Diagnostics and Radiological Health specific questions, Robert Becker ([robert.becker@fda.hhs.gov](mailto:robert.becker@fda.hhs.gov)); or for Epidemiology specific questions, Nilsa Loyo-Berrios ([nilsa.loyo-berrios@fda.hhs.gov](mailto:nilsa.loyo-berrios@fda.hhs.gov)).

For questions about this document regarding CBER regulated devices, contact the Office of Communication, Outreach and Development (OCOD) by calling 1-800-835-4709 or 240-402-7800.



U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Devices and Radiological Health  
Center for Biologics Evaluation and Research

*Contains Nonbinding Recommendations*

## Evaluation and Reporting of Age-, Race-, and Ethnicity-Specific Data in Medical Device Clinical Studies

### Guidance for Industry and Food and Drug Administration Staff

Document issued on September 12, 2017.

The draft of this document was issued on June 20, 2016.

For questions about this document regarding CDRH-regulated devices, contact CDRH at 301-796-5900 or [CDRHPatientDiversity@fda.hhs.gov](mailto:CDRHPatientDiversity@fda.hhs.gov) or [CDRHClinicalEvidence@fda.hhs.gov](mailto:CDRHClinicalEvidence@fda.hhs.gov).

For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010.



U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Devices and Radiological Health  
Center for Biologics Evaluation and Research

# Food and Drug Omnibus Reform Act (FDORA) of 2022

One Hundred Seventeenth Congress  
of the  
United States of America

AT THE SECOND SESSION

*Began and held at the City of Washington on Monday,  
the third day of January, two thousand and twenty-two*

An Act

Making consolidated appropriations for the fiscal year ending September 30, 2023,  
and for providing emergency assistance for the situation in Ukraine, and for  
other purposes.

## Provisions and Deliverables of FDORA



§3601 Diversity Action Plans  
for Clinical Studies

§3602 Guidance on Diversity  
Action Plans for Clinical Studies

§3603 Public Workshop

§3604 Annual Summary Report



# CDRH Strategic Priority: Advancing Health Equity

- CDRH can advance the development of knowledge for safe and effective technologies to meet the needs of all patients and consumers
- Technology can help bridge the divide while advancing better healthcare, quality of life, and wellness for all
- No person should be left behind in health care

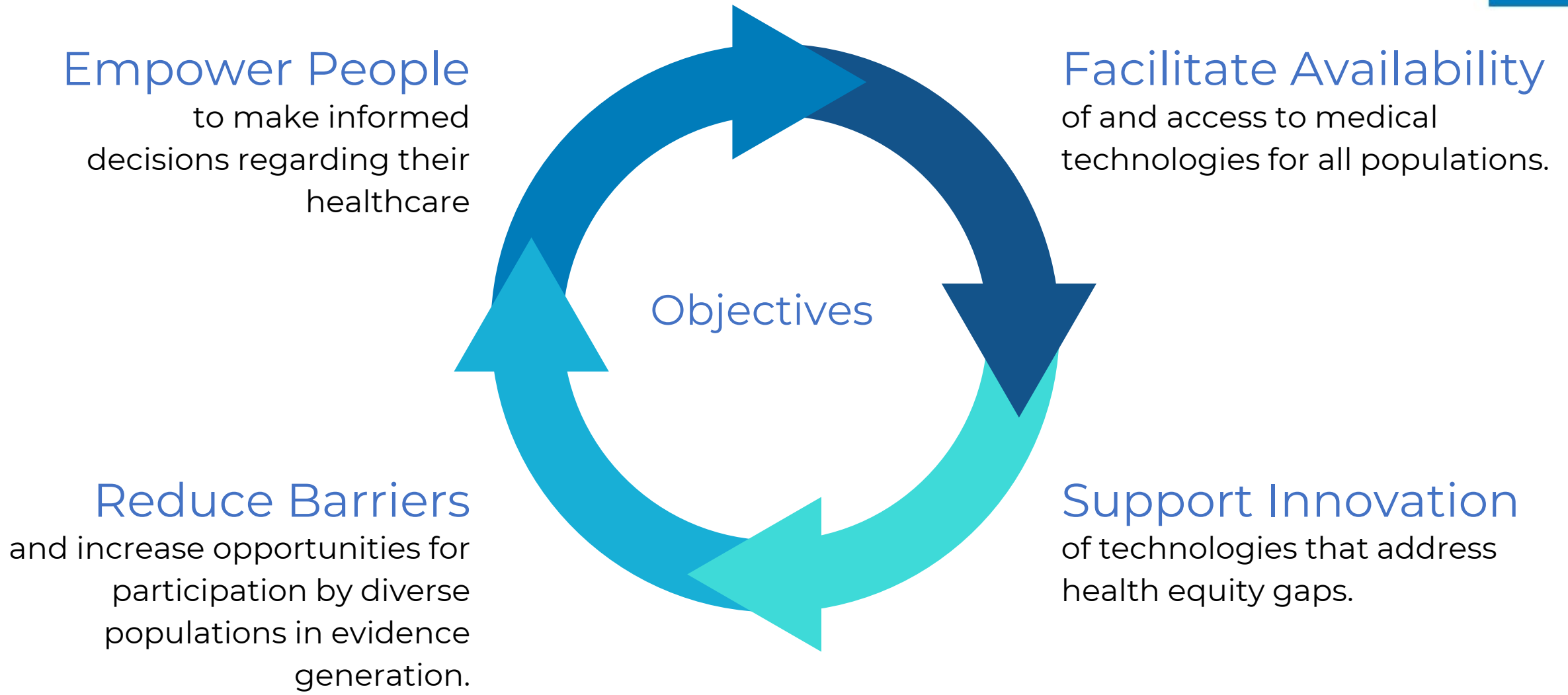
FDA

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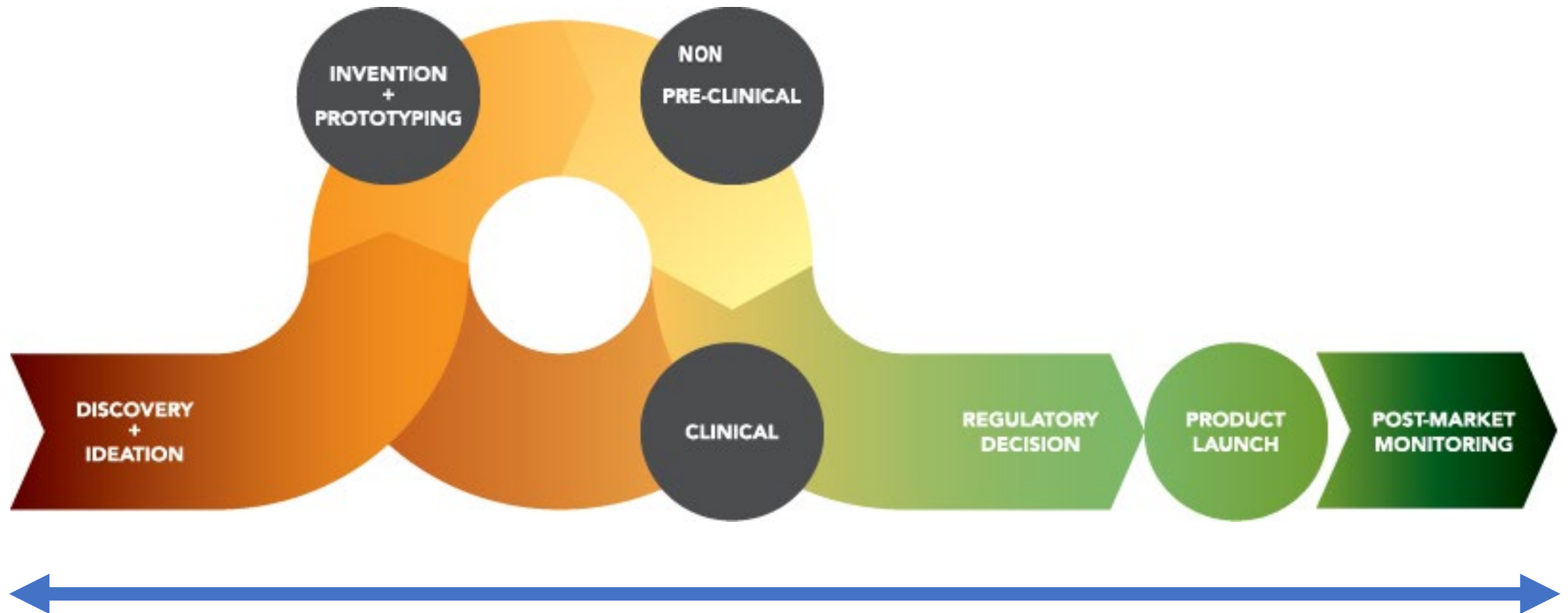
Center for Devices and Radiological Health

2022 - 2025  
STRATEGIC PRIORITIES





# Consider Equity Across the Total Product Lifecycle of Medical Devices





# What are “Home Use” Medical Devices?

- A home use device is a medical device labeled for use in any environment outside of a professional healthcare facility.
  - Home, outdoor environment, office environment, schools, vehicles, independent living retirement homes, etc.
- A user is a patient, caregiver, or family member that directly uses the device or provides assistance in using the device.
- Growth of home healthcare ⇒ More frequent use of devices in home settings
  - Home use devices are becoming more common and more complex
  - FDA wants to ensure safe and effective use of home use devices

# Considerations for Home Use

- A home environment is generally less controlled than a healthcare setting without access to the same support infrastructure
  - Repair, maintenance, cleaning
  - Electromagnetic interference, noise, emergencies, temperature, humidity, location, transportability
  - Non-sterile or unclean environments
  - Delays in steps, reading results, and/or taking actions
- Matching usability of the device to the user
  - Simple to use by those with various physical and cognitive abilities
  - Results and outputs easily interpretable with clear next steps
  - May require user-friendly training or customer support
  - Choices may be limited

# Treatment Example: Home Hemodialysis

- Different frequency (i.e., days/week) and duration of treatment than conventional HD
  - Conventional: every other day, 3-4 hours/treatment
  - Home Hemodialysis: 5-7X/week, 5-8 hours/treatment
- Considerations/features for home hemodialysis devices
  - Portability of home device
  - Streamlined preparation of dialysis
  - Package of tubing sets and hemodialyzers (cassette) instead of individual components

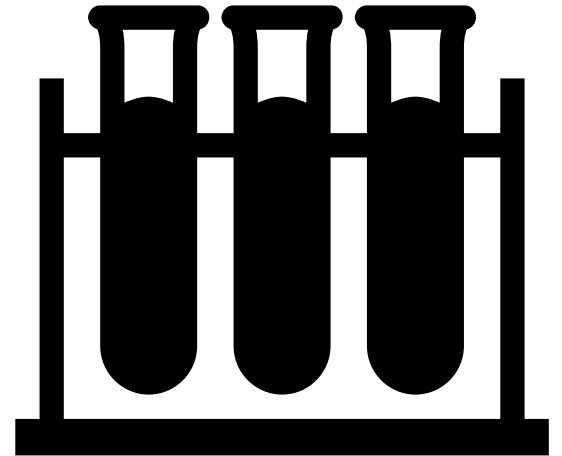




# Diagnostic Example – At-home COVID-19 Tests

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- Commonly referred to as rapid tests
- Patient collects sample, perform the test, and reads the result
- Antigen (detecting proteins from the virus)
  - Tend to be simpler to perform
  - Tend to be less likely to detect virus
  - May require serial repeating
  - Most commonly available home use COVID-19 tests, authorized for emergency use under an Emergency Use Authorization (EUA)
- Molecular Tests (detecting the genetic material of the virus)
  - As of today, one at-home OTC COVID-19 test has received marketing authorization through traditional marketing pathways ([DEN220028.pdf](#) [\(fda.gov\)](#) ) and it is a molecular diagnostic test





Digital Health Technologies (DHTs) can transform how we study medical products and care for patients



Enable remote data collection in decentralized clinical investigations and for clinical care



Improve access to clinical investigations and clinical care



Facilitate collection of innovative clinical endpoints

# Public Consumption of CDRH Digital Content

Jan. 1-June 30, 2023:

- Approx. 7 million unique visitors to CDRH webpages
- Mobile 59.3%, desktop 40.69% (FDA.gov)\*

Top drivers to web content:

- External search engines (Google, Bing)
- CDRH's 1.3 million email subscribers

Social Media:

- 2.1 million impressions across "X" (formerly Twitter), LinkedIn, Facebook



**FDA Medical Devices**  
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Official FDA - device recalls, safety, approvals, radiation-emitting products.  
Contact us DICE@fda.hhs.gov or 800-638-2041 [fda.gov/privacy](https://www.fda.gov/privacy)

Education Silver Spring, Maryland, USA [fda.gov/medical-device...](https://www.fda.gov/medical-device...)  
Joined May 2010

433 Following 99.5K Followers



\*Data is for the entire FDA.gov website, analytics for CDRH pages are not available



# Putting patients first means **ALL** patients

**CDRH Vision:** Patients in the U.S. have access to high-quality, safe, and effective medical devices of public health importance first in the world.

