

Welcome To Today's Event

Thanks for joining us!

Today's Topic:

READI-Home Innovation Challenge

June 24, 2026

READI-Home Innovation Challenge

Lisa Simone, PhD

Senior Health Scientist

Office of Readiness and Response

Office of Strategic Partnerships and Technology
Innovation

Kimberly Kontson, PhD

Biomedical Engineer

Division of Biomedical Physics

Office of Science and Engineering Laboratories

**Center for Devices and Radiological Health
U.S. Food and Drug Administration**



U.S. FOOD & DRUG ADMINISTRATION

U.S. FOOD & DRUG ADMINISTRATION

U.S. FOOD & DRUG ADMINISTRATION



Lisa Simone, PhD
Senior Health Scientist
Office of Readiness and Response
Office of Strategic Partnerships and Technology
Innovation





Home as a Health Care Hub

helping innovators, providers, and patients reimagine
the home as an integral part of the health care system

READI-Home Innovation Challenge

Reducing Readmissions through Device Innovation for the Home



Learning Objectives

- Understand the scope of the Home as a Health Care Hub Initiative and activities supporting the initiative
- Describe the goals and background of the READI-Home Innovation Challenge
- Understand who should consider participating in the Challenge
- Understand details of the Challenge, including the prioritization elements, information for evaluation, and the timeline
- Describe how to prepare and submit your information

Home as a Healthcare Hub (HHH)

Reimagining device use in the home environment as an integral part of the healthcare system, with the goal of promoting health and wellness, and potentially leading to higher quality of life for all



READI-Home Innovation Challenge

Accelerate patient access to
medical device technologies
aimed at reducing
hospital readmissions.



IdeaLab & LilyPad
Innovation Environments



Sensor-Based DHT
Public List (Updated)



Draft Guidance on
Cuffless Blood Pressure



The TEMPO Pilot



Experiential Learning
Program Areas of Interest



Broad stakeholder
engagement

READI-Home Innovation Challenge



READI-Home

FDA

READI-Home Innovation Challenge

Reducing Readmissions through Device Innovation for Home



Innovation Challenge Goal:
*Accelerate patient access to
medical device technologies
aimed at reducing hospital
readmissions*

FDA invites innovators to pursue potential participation in the Innovation Challenge by providing proposed solutions for medical device technologies to be used in the home setting.

Background



- 30-day readmission rate for people with chronic conditions reported to range from 2.8%-18.4%; for people without chronic conditions, reported to be 13.9% (2016-2020)
- Broad acceptability of hospital-at-home care
- Innovation in medical device technology used in the home to reduce hospital readmissions may:
 - reduce morbidity and mortality
 - reduce a financial and logistical burden on the healthcare system and patients
 - empower patients to play a more active role in their healthcare



Why an Innovation Challenge?



Through an innovation challenge, the FDA may:

- Stimulate innovation to address unmet clinical needs
- Accelerate development of emerging medical device technologies
- Encourage and facilitate FDA-industry interactions
- Gain an understanding of emerging home-use technologies and development opportunities/challenges

Participation Incentives



Opportunity for early and more frequent engagement with the FDA to discuss challenges in designing, developing, and testing device technology



Opportunity for in-person demonstration of proposed solutions in OSEL labs



Gain an increased understanding of regulatory pathways

Public recognition through FDA communications

Who Should Consider Participation?

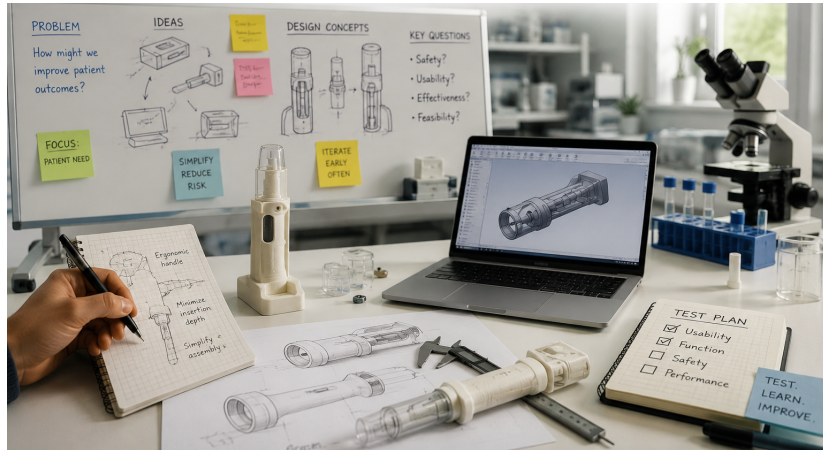


Who should consider participation in the READI-Home Innovation Challenge?



The READI-Home Innovation Challenge is designed to accelerate patient access to medical device technologies aimed at reducing hospital readmissions. We encourage medical device innovations in both the...

Early stage *and* Late stage



Who should consider participation in the READI-Home Innovation Challenge?

FDA



Software medical devices may be in scope.



Medical device technologies intended for adult and/or pediatric populations may be in scope.



Medical devices with existing marketing authorization proposed to be changed/modified to address the challenge goals may be in scope.

Kimberly Kontson, PhD
Biomedical Engineer
Division of Biomedical Physics
Office of Science and Engineering Laboratories



Challenge Details



Prioritization Elements

- 1) The device is intended to **address an unmet or emerging health care need in the home**, where expanded availability would be in the best interest of patients.
- 2) At least one intended user is a **patient and/or caregiver**, as opposed to the device only being used by a trained medical professional.
- 3) At least one of the intended use environments for the device is in a patient's **home and/or community environment**. For the purposes of this Challenge, the home environment includes, but is not limited to, an individual's residence without the continuous presence of trained medical professionals.
- 4) Sufficient evidence (e.g., literature, data) exists to support that the device may be associated with **reduction in or prevention of readmission(s)** for the target population(s).
- 5) Sufficient evidence exists to **support the feasibility** of the device under consideration.

Information for Evaluation

The FDA will consider the following information:

a Description of the device and the clinical challenge it is intended to address

b Novelty of the device/concept

c Current development status of the device

d Data Development Plan (DDP) for the device

Preclinical → Clinical Testing → Planned Studies





e Overview of key expertise within the team

f Anticipated impact

Timeline



Public launch April 7, 2026

| 2026 | Apr | May | Jun | Jul | Aug | Sept | Oct | Nov | Dec |
|---|---|--|---|-----|-----|------|-----|-----|-----|
|  <p>1 Submission Period Participants submit information (anytime within 6-month period)</p> | <p>April 7, 2026 (public launch) — Sept 30, 2026 (6 months)</p> | | | | | | | | |
|  <p>2 FDA review of information Rolling review with final notifications NLT 12/4/26</p> | | <p>Rolling review Final notifications NLT December 4, 2026</p> | | | | | | | |
|  <p>3 Announce participants advancing to Interaction phase</p> | | | <p>On or before December 4, 2026</p> | | | | | | |
|  <p>4 Interaction phase FDA interactions to help refine device design and/or testing for home use (variable time depending on company and goals)</p> | | | <p>Variable time depending on participant (Interaction phase begins immediately following a given selection notification) →</p> | | | | | | |

Preparing and Submitting Your Information



Preparing and Submitting Information



- Provide an executive summary (NTE 1 page) summarizing how your device meets prioritization elements (1) - (5)
- Provide additional information identified in (a) - (f) on the website
- Limit this information to 16 total pages (excluding references)
- Submit your eCopy PDF as an Informational Meeting Q-Submission through the CDRH portal with the following information in the relevant sections:
 - Company Name: Prefix with “READI-Home Innovation Challenge” (e.g., READI-Home Innovation Challenge – DeviceCompanyName)
 - Submission purpose (see [How to Submit](#))



Informational Meeting Q-Sub Steps

Generate your information for submission

HYPOTHETICAL MOCK DEVICE:
FOR EXAMPLE PURPOSES ONLY

- Generate PDF document with the following content:

HomePulse™

Continuous Remote Hemodynamic Monitoring System

| | | | |
|---|--|--|---|
| Submitter Kontson Tech | Date of Submission May 16, 2026 | Submission Type Informational Meeting Q-Submission | Challenge READI-Home Innovation Challenge |
| Device Name HomePulse™ Remote Monitoring System | Contact Kimberly Kontson EMAIL: PHONE | | |

This informational meeting Q-submission provides information related to a medical device innovation intended to reduce or eliminate hospital readmission following post-acute hospital stays, consistent with the goal of the READI-Home Innovation Challenge. I understand this Q-submission will be reviewed by relevant CDRH staff for potential Breakthrough Devices (BTD) designation or Safer Technologies Program (STeP) designation as described for the Innovation Challenge, and may or may not result in a face-to-face meeting with the FDA. Regardless of the outcome of this review, I understand that I may still submit subsequent Q-submissions related to this medical device innovation. If my device is selected for the interaction phase of the READI-Home Innovation Challenge, I understand and agree that FDA will publicly disclose this participation in the Innovation Challenge, including the name and a description of my device and the name of the submitting company/organization, and I am duly authorized to agree to such disclosure.

Informational Meeting Q-Sub Steps



Generate your information for submission

- Generate PDF document with the following content:
 - Submission purpose statement on page 1
 - Executive summary (limited to 1 page) that summarizes how your device meets prioritization elements 1-5
 - Information described in (a)-(f)

FOR EXAMPLE PURPOSES ONLY

- ❖ Submission Purpose statement (1 page)
- ❖ Executive Summary (1 page)
- ❖ Detailed discussion of the following information (14 pages or fewer)
 - a) Description of the device and the clinical challenge it is intended to address
 - b) Novelty of the device/concept
 - c) Current development status of the device
 - d) Data Development Plan (DDP) for the device
 - e) Overview of key expertise within the team
 - f) Anticipated impact
- ❖ References (no page limit)

Informational Meeting Q-Sub Steps

Generate your information for submission

- Generate PDF document with the following content:
 - Submission purpose statement on page 1
 - Executive summary (limited to 1 page) that summarizes how your device meets prioritization elements 1-5
 - Information described in (a)-(f)
- Limit submitted information to 16 total pages (excluding references)
- All content should be written in English and converted to PDF format with Times New Roman font no smaller than 11-point.

FOR EXAMPLE PURPOSES ONLY

- ❖ Submission Purpose statement (1 page)
- ❖ Executive Summary (1 page)
- ❖ Detailed discussion of the following information (14 pages or fewer)
 - a) Description of the device and the clinical challenge it is intended to address
 - b) Novelty of the device/concept
 - c) Current development status of the device
 - d) Data Development Plan (DDP) for the device
 - e) Overview of key expertise within the team
 - f) Anticipated impact
- ❖ References (no page limit)

Informational Meeting Q-Sub Steps

Complete Form 3514

- Fill out the following sections in [Form 3514](#)
 - **Check ‘Informational Meeting’ under Q-submission in Section A**

| Q-Submission | |
|-------------------------------------|--------------------------------|
| <input type="checkbox"/> | Pre-Submission |
| <input checked="" type="checkbox"/> | Informational Meeting |
| <input type="checkbox"/> | Submission Issue Meeting |
| <input type="checkbox"/> | Day 100 Meeting |
| <input type="checkbox"/> | Agreement Meeting |
| <input type="checkbox"/> | Determination Meeting |
| <input type="checkbox"/> | Study Risk Determination |
| <input type="checkbox"/> | Other (<i>Specify below</i>) |



Informational Meeting Q-Sub Steps

Complete Form 3514

- Fill out the following sections in [Form 3514](#)
 - Check ‘Informational Meeting’ under Q-submission in Section A
 - Include READI-Home Innovation Challenge before company name in Section B. Fill out remainder of this section.

FOR EXAMPLE PURPOSES ONLY

Company/Institution Name

READI-Home Innovation Challenge - Kontson Tech

Informational Meeting Q-Sub Steps

Complete Form 3514

- Fill out the following sections in [Form 3514](#)
 - Check ‘Informational Meeting’ under Q-submission in Section A
 - Include READI-Home Innovation Challenge before company name in Section B. Fill out remainder of this section.
 - **Fill out sections C – G to the best of your ability.**
 - **For Section H, only fill out H3. Check ‘Informational Meeting’ and ‘Request Face-to-Face Meeting’**

| | |
|-------------------------------------|---|
| <input checked="" type="checkbox"/> | Informational Meeting: |
| <input checked="" type="checkbox"/> | Request Face-to-Face Meeting |
| <input type="checkbox"/> | Request Teleconference |
| <input type="checkbox"/> | Submit Meeting Minutes |
| <input type="checkbox"/> | Request Meeting Minutes Disagreement T-Con |



Informational Meeting Q-Sub Steps

Complete Form 3514

- Fill out the following sections in [Form 3514](#)
 - Check ‘Informational Meeting’ under Q-submission in Section A
 - Include READI-Home Innovation Challenge before company name in Section B. Fill out remainder of this section.
 - Fill out sections C – G to the best of your ability.
 - For Section H, only fill out H3. Check ‘Informational Meeting’ and ‘Request Face-to-Face Meeting’
 - Sections I, J and K are not required for the Informational Meeting Q-Submission for this Challenge
- **Register for an account with the [CDRH portal](#)**



Informational Meeting Q-Sub Steps

Submit through CDRH Portal

- Create ZIP folder containing Form 3514 and PDF
- Click 'Send a Submission'

Tip: Append '001_' and '002_' to the filenames for Form 3514 Cover Sheet and information PDF to avoid eCopy hold

The screenshot shows the FDA CDRH Portal interface. At the top, it says "Welcome, Kimberly Kontson". Below this, there are three main sections: "Your reviews", "Your sent eCopy/eSTAR submissions", and "Your draft requests".

Your reviews
0 Records Active reviews only (default) Fields Original view

| ID | Received date | Progress | Type | Track | Goal date | Days | More info |
|----|---------------|----------|------|-------|-----------|------|-----------|
|----|---------------|----------|------|-------|-----------|------|-----------|

You don't have any active reviews or reviews closed in the last 30 days.

Your sent eCopy/eSTAR submissions
0 Records Recent submissions only (default)

You haven't sent anything yet. [Send a submission](#), or select "+ send a submission" in the main navigation. Send it before 16:00 ET on a business day for us to process it the same day.

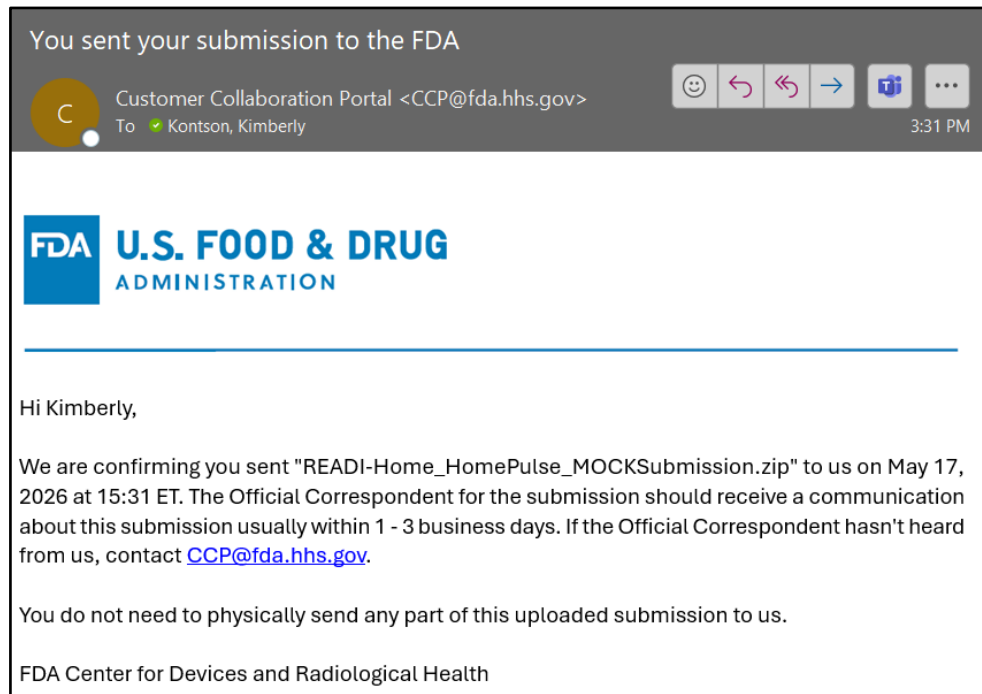
Your draft requests
0 Drafts



Informational Meeting Q-Sub Steps

Submit through CDRH Portal

- Create ZIP folder containing Form 3514 and PDF
- Click 'Send a Submission'
- Select 'eCopy' as the format
- Upload ZIP file
- Press send
- Confirmation email sent from Customer Collaboration Portal



Resources

| Slide Number | Cited Resource | URL |
|--------------|---|--|
| 5, 7 | Home as a Health Care Hub | www.fda.gov/medical-devices/home-health-and-consumer-devices/home-health-care-hub |
| 7 | READI-Home Innovation Challenge | www.fda.gov/medical-devices/home-health-care-hub/fda-readi-home-innovation-challenge-reducing-readmissions-through-device-innovation-home |
| 7 | READI-Home Innovation Challenge FAQ | www.fda.gov/medical-devices/home-health-care-hub/readi-home-innovation-challenge-frequently-asked-questions |
| 7 | IdeaLab and Lilypad | www.fda.gov/medical-devices/home-health-care-hub/idea-lab |
| 7 | Sensor-based Digital Health Technology List | www.fda.gov/medical-devices/digital-health-center-excellence/medical-devices-incorporate-sensor-based-digital-health-technology |
| 7 | Draft Guidance Cuffless Non-invasive Blood Pressure Measuring Devices | www.fda.gov/regulatory-information/search-fda-guidance-documents/cuffless-non-invasive-blood-pressure-measuring-devices-clinical-performance-testing-and-evaluation |
| 7 | TEMPO Pilot | www.fda.gov/medical-devices/digital-health-center-excellence/tempo-digital-health-devices-pilot-frequently-asked-questions |
| 7 | Experiential Learning Program Areas of Interest | www.fda.gov/science-research/fda-stem-outreach-education-and-engagement/experiential-learning-program-elp-areas-interest |



Resources

| Slide Number | Cited Resource | URL |
|-------------------|----------------|--|
| 22, 23 | How to Submit | www.fda.gov/medical-devices/home-health-care-hub/fda-readi-home-innovation-challenge-reducing-readmissions-through-device-innovation-home#submit |
| 26, 27, 28, 29 | Form 3514 | www.fda.gov/media/72421/download |
| 30, 31 | CDRH Portal | ccp.fda.gov/prweb/PRAuth/app/registration |
| 34 | Email Us | Email HealthHomeHub@fda.hhs.gov with the subject line “READI-Home Innovation Challenge Inquiry” |



Summary

We described:

- Scope of the Home as a Health Care Hub Initiative
- Goal and background of the READI-Home Innovation Challenge
- Who should consider participating in the Innovation Challenge
- Details of the Innovation Challenge
- Information preparation and submission

If you have questions about this Innovation Challenge, please email HealthHomeHub@fda.hhs.gov with the subject line “READI-Home Innovation Challenge Inquiry”



Additional Panelists

Christopher Scully

Assistant Director
Division of Biomedical Physics
Office of Science and Engineering
Laboratories

Susannah Gilbert, MS

Assistant Director
Office of Regulatory Programs
Office of Product Evaluation and
Quality








Let's Take Your Questions

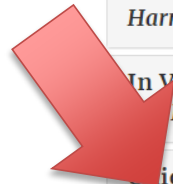
- **To Ask a Question:**
 1. Raise your hand
 2. Moderator will announce your name and invite you to ask your question
 3. Once your mic is enabled, unmute yourself to ask your question
- **When Asking a Question:**
 - Ask one question only
 - Keep question short
 - No questions about specific submissions
- **After Question is Answered:**
 - Mute yourself and lower your hand
 - If you have more questions - raise your hand again

Thanks for Joining Today!



- **Presentation, Slides and Transcript will be available at CDRH Learn**
 - www.fda.gov/Training/CDRHLearn
- **Additional questions about the Innovation Challenge**
 - Email: HealthHomeHub@fda.hhs.gov
- **Additional questions about today's event**
 - Email: DICE@fda.hhs.gov
- **Upcoming CDRH Events**
 - www.fda.gov/CDRHEvents

- Start Here/The Basics! (Updated 10/3/2024) 
[MDUFA Small Business Program, Registration and Listing](#)
- How to Study and Market Your Device - (Updated module 9/11/24) 
510k, De Novo, IDE, PMA, HUD/HDE, Q-Submissions, Standards, Classification
- Postmarket Activities (New module 10/7/24) 
Quality System, QMSR, Exporting, Device Recalls, MDR, Inspection - Global Harmonization
- In Vitro Diagnostics - (Updated 9/27/24) 
Development, CLIA, and Virtual Town Hall Series
- Unique Device Identification (UDI) System 
- Specialty Technical Topics - (Updated 10/8/24) **
- Radiation-Emitting Products 
- 510(k) Third Party Review Program (for Third Party Review Organizations) 
- Industry Basics Workshop Series 





U.S. FOOD & DRUG
ADMINISTRATION