Reducing Readmissions through Device Innovation for the Home (READI-Home) Innovation Challenge
June 24, 2026

Moderator: CAPT Kim Piermatteo
Presenters: Dr. Michelle Tarver, Dr. Lisa Simone and Dr. Kimberly Kontson
Panelists: Christopher Scully and Susannah Gilbert

Slide 1

[Slide not shown. No audio.]

Slide 2

CAPT Kim Piermatteo: Hello and welcome to today's CDRH webinar. Thank you for joining us. This is CAPT Kim Piermatteo of the United States Public Health Service, and I serve as the Education Program Administrator in the Division of Industry and Consumer Education in FDA's Center for Devices and Radiological Health. I'll be the moderator for this webinar.

Our topic today is the Reducing Readmissions through Device Innovation for the Home Innovation Challenge, or what is also referred to as the READI-Home Innovation Challenge. The goal of this Innovation Challenge, which is part of CDRH's Home as a Health Care Hub Initiative, is to accelerate patient access to medical device technologies aimed at reducing hospital readmission.

Today, you will first hear a few words from our Center Director, Dr. Michelle Tarver, regarding this topic. Then you will hear more details about this innovation challenge from Dr. Lisa Simone, Senior Health Scientist, in the Office of Readiness and Response in CDRH's Office of Strategic Partnerships and Technology Innovation; and Dr. Kimberly Kontson, Biomedical Engineer, in the Division of Biomedical Physics in CDRH's Office of Science and Engineering Laboratories.

After today's presentations, we will then invite you to ask your questions about this innovation challenge. We look forward to interacting with you during this segment of today's webinar and if you have a question, please wait and raise your hand at the end of the presentations to get into the queue.

Before I turn it over to Dr. Tarver, I'd like to remind everyone, the intended audience for this event is industry. National media and press members are encouraged to submit their questions through the FDA Newsroom at www.fda.gov/news-events/fda-newsroom.

Thank you all again for joining us. I'll now turn it over to Dr. Tarver for her remarks.

Slide 3

Dr. Michelle Tarver: More and more, the home is becoming a critical part of how Americans receive health care. At the FDA Center for Devices and Radiological Health, we believe medical device innovation has a powerful role to play in making that care safer, more effective, and accessible for everyone.

That's why we launched the Home as a Healthcare Hub Initiative. This initiative fosters the development of technologies designed to promote and protect the health and wellness of all people, where they live, where they work, and where they play. Our health care system is under real strain. Chronic disease is rising, health care workers are stretched thin, costs continue to grow, and too many hospitalized patients end up back in the hospital after they go home. At the same time, more patients want the option to

receive care where they're most comfortable, at home. This creates an opportunity. Innovative home use medical devices can help detect problems earlier, support faster treatment, and give patients a more active role in managing their health.

At CDRH, we're advancing clear regulatory pathways, strengthening our expertise to evaluate home use technologies, and advancing innovation through guidance, device review, and collaboration across the health care ecosystem. This work is about more than devices. It's about reimagining where and how care happens, making sure patients remain the focus.

One way we're looking to accelerate impact is through our READI-Home Innovation Challenge. We're inviting innovators to submit ideas for home use devices that could help reduce preventable hospital readmissions. We're glad you're here and we look forward to continuing the momentum.

Slide 4

Dr. Lisa Simone: Thank you, Dr. Tarver. Hi, my name is Lisa Simone, and I am leading the Home as a Health Care Hub Initiative for CDRH. Welcome to our webinar today. I'd like to share a bit about how the Innovation Challenge fits within our activities, so let's get started.

Slide 5

Dr. Lisa Simone: CDRH's mission is to protect and promote the public health by ensuring that patients and providers have safe, effective, and high-quality medical devices. We aim to meet that mission wherever medical devices are used, and increasingly, that use is happening outside of a health care facility.

Home-use medical devices can play a critical role in transitioning health care delivery to the home.

Our Home as a Health Care Hub Initiative is intended to help foster medical device innovation for use in the home while considering diverse perspectives, testing new ideas, and exploring the possibilities that come with making the home a critical component of health care.

As part of this overarching effort, we've launched an Innovation Challenge, which our team will tell you more about today.

Slide 6

Dr. Lisa Simone: We're excited to share more about the READI-Home Innovation Challenge, Reducing Readmissions through Device Innovation for the Home. Today's webinar will walk you through the background and goals of the challenge, who should consider participating, what we are looking for, and exactly how to submit your information. We'll also leave some time at the end for your questions.

Slide 7

Dr. Lisa Simone: Before we dive into the details of this challenge, I want to briefly frame the broader Home as a Healthcare Hub Initiative that this challenge supports. At FDA, we recognize that more care is moving into the home setting. At the same time, health care systems continue to face challenges related to chronic disease, workforce shortages, rising costs and avoidable hospitalization.

The Home as a Healthcare Hub Initiative is intended to help support innovation for medical device technologies designed for care where people live. This initiative includes activities related to real world home experiences, including the IdeaLab, LilyPad Innovation Environments, the TEMPO Pilot, and innovation challenges, like the one we will discuss today.

Other activities include updates to the sensor-based digital health technologies list and the issuance of a new draft guidance regarding cuffless blood pressure devices. We also intend to continue broad stakeholder engagement we started with our listening session in 2024 to help identify barriers and help collaborate on practical solutions.

Slide 8

Dr. Lisa Simone: With that broader context in mind, let's move to the READI-Home Innovation Challenge, which aims to encourage the development of technologies that bring high quality care into the home. And now I'd like to discuss what exactly is the goal of this challenge.

Slide 9

Dr. Lisa Simone: We are looking to accelerate patient access to medical device technologies aimed at reducing hospital readmissions. CDRH is encouraging innovators to submit information about medical device technologies intended to be used in the home, outside of the traditional clinical environment, by patients and or their caregivers. These technologies would support patients and caregivers after an acute hospital stay and may help prevent avoidable readmissions.

We want to be clear about what this means for the challenge. The device doesn't need to be a finished market-ready product. We are interested in innovations at various stages of development. What matters is that the device is intended for home use, that it may help prevent or reduce avoidable readmissions, and that there is sufficient evidence to support its potential for addressing the challenge goal.

And we'll talk about the specific prioritization elements for the challenge, as well as other considerations later in the webinar.

Slide 10

Dr. Lisa Simone: Let's talk about the scope of this challenge and why it matters.

Hospital readmissions are a significant and well-documented problem. The 30-day readmission rate for people with chronic conditions has been reported to range from 2.8% to as high as 18.4%, and even for those with chronic conditions, the rate was 13.9% between 2016 and 2020.

These are substantial numbers that represent real patient burden and cost to our health care system. At the same time, there is broad acceptability of hospital-to-home care. The pandemic accelerated this trend considerably, and it has continued to grow.

Medical device innovation in a home setting can make a meaningful difference on multiple fronts. It has the potential to reduce morbidity and mortality by enabling earlier detection of complications and more timely intervention.

It also has the potential to reduce the financial and logistical burden on the health care system and patients by keeping patients safely at home longer. And it enables patients to play a more active, informed role in their own health care. These are the outcomes that this challenge is designed to support.

Slide 11

Dr. Lisa Simone: You may be wondering, why an innovation challenge? Through an innovation challenge, FDA may act as a catalyst to address unmet clinical needs by focusing industry attention on a specific high-priority problem. It may accelerate the development of emerging medical device technologies by offering early engagement with FDA through sprint discussions, including more frequent interactions with FDA reviewers.

It also encourages and facilitates FDA industry interactions that might not otherwise occur early in the development process. And importantly, it helps FDA gain a deeper understanding of emerging home use technologies, including the development opportunities and challenges that innovators are encountering in this space. This is a learning opportunity for us as much as it is a development opportunity for you.

Slide 12

Dr. Lisa Simone: Let's talk about what participants can expect to gain from this challenge. There are several meaningful incentives for taking part. Participants whose devices are selected for the challenge will have the opportunity for early and more frequent engagement with FDA. Participants will also have the opportunity for in-person demonstrations of their proposed solutions in the Office of Science and Engineering Laboratories, or OSEL, which with CDRH researchers and reviewers in attendance. These sessions provide a forum to discuss challenges in designing, developing, and testing your technology facilitated through Informational Meeting Q-Submissions.

Participation may also deepen your understanding of regulatory pathways, and FDA may help direct participants to public-facing resources that may support their path to market. Finally, participants will also receive public recognition through FDA communications. Taken together, these incentives may provide significant value to innovators who engage with this challenge.

Slide 13

Dr. Lisa Simone: Let's talk about who should consider participation.

Slide 14

Dr. Lisa Simone: So, who exactly should consider participating in the READI-Home Innovation Challenge? The short answer is a broad range of innovators. This challenge is designed to accelerate patient access to medical device technologies aimed at reducing hospital readmissions, and it's intentionally open to different stages of product development.

We encourage submissions from innovators working on early stage concepts, as well as those with late stage technologies. If you're at an early stage, perhaps in the design or the feasibility phase, this challenge provides an opportunity to engage with FDA sooner and may help you shape your development and testing strategy with regulatory considerations in mind, early in the process.

If you're at a later stage, perhaps approaching or preparing for a regulatory submission, this challenge may help clarify your path and provide additional FDA feedback on your development program.

Think about the patient journey. A person leaves the hospital and returns home, and the goal is for them to stay there. If your technology may help support that transition, sustain recovery once a patient is home, detect early warning signs of patient deterioration, or otherwise help prevent another hospitalization. We encourage you to consider participation in the READI-Home Innovation Challenge.

The challenge is not limited to any particular technology or approach. What matters is the role your innovation may play in the patient's life after discharge. Regardless of your stage, your submission will be evaluated in consideration of five prioritization elements that will be discussed later in this presentation.

Slide 15

Dr. Lisa Simone: [Moving on to] who should consider participation, I want to highlight a few additional scope clarifications. Medical device innovators developing technology intended for adult populations may be in scope, and so may be those developing technologies for pediatric populations. We are interested in solutions that address readmission risk across the age spectrum.

Software medical devices may also be within scope for this innovation challenge. If your solution is software-based and meets the prioritization elements discussed on the next slides, we want to hear from you. Additionally, medical devices with existing marketing authorization that are proposed to be changed or modified to address the goal of this challenge may also be considered.

If you have a cleared or approved device that you are adapting for home use or a new indication related to readmission prevention, you may want to consider participation in the Challenge. When in doubt, we encourage you to submit. FDA will review all submissions in consideration of the five prioritization elements for the Challenge. The Innovation Challenge website has additional clarification on scope.

And now I'd like to turn it over to Dr. Kimberly Kontson.

Slide 16

Dr. Kimberly Kontson: Thanks, Lisa.

Slide 17

Dr. Kimberly Kontson: I'd now like to take some time to talk a little bit more about the challenge details.

Slide 18

Dr. Kimberly Kontson: When FDA evaluates submissions to the READI-Home Innovation Challenge, we will consider five prioritization elements. Let me walk you through each one.

The first element is that 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. We want technologies that are filling a real gap. Not duplicating what already exists.

The second element is that at least one intended user is a patient and or caregiver, as opposed to the device being used exclusively by trained medical professionals.

The third element is that at least one intended use environment is in a patient's home or community setting. For purposes of this challenge, home includes any individual residence without the continuous presence of trained medical professionals. So this covers a broad range of settings.

The fourth element is that there is sufficient evidence, such as literature or data, to support that the device may be associated with a reduction in or prevention of readmission for the target population. You don't need to have proven effectiveness, but there should be a credible evidentiary foundation.

The fifth element is that sufficient evidence exists to support the feasibility of the device. Again, this doesn't mean the device is fully developed, but we want to see that the underlying concept is technically achievable. All five of these elements will factor into how we evaluate and prioritize submissions.

Slide 19

Dr. Kimberly Kontson: When you prepare your submission, you will want to ensure that the information you provide gives FDA a clear picture of your technology and its potential. Submissions should address how your device meets the five prioritization elements we just discussed. In addition, submissions should provide certain information identified on the challenge website and shown on this slide.

A, asks you to describe the device and the clinical challenge it is intended to address. B, asks about the novelty of the device or concept. What makes it different from existing solutions? C, covers the current development status of the device. D, is your data development plan or DDP for the device. How do you

plan to generate evidence to support marketing authorization for the device? E, asks for an overview of the key expertise within your team, and F, addresses the anticipated impact. What difference will this technology make for patients, caregivers, and the healthcare system?

This information is designed to help us assess the overall strength and potential of your submission. I encourage you to visit the Innovation Challenge website for additional detail regarding what information to include. The website also includes a frequently asked questions section that may answer many of the questions you have today. We'll walk through the submission format in more detail in just a few slides.

Slide 20

Dr. Kimberly Kontson: Now, let's look at the timeline for the challenge. The challenge launched publicly on April 7th, 2026, and the submission period runs for approximately six months, closing on September 30th, 2026. During the submission window, FDA will conduct a rolling review of incoming submissions, meaning we will begin evaluating information as it arrives rather than waiting until the solicitation period closes. Following review, we will announce the participants whose devices are selected to advance to the interaction phase. Final notifications will be issued no later than December 4th, 2026.

The interaction phase, the interaction phase for each participant will begin immediately following with the participant's selection notification. The length of the interaction phase is variable and will depend on each participant's specific technology and development goals. I want to emphasize, because we use a rolling review process, that we encourage you to submit early. You do not need to wait until September 30th.

Slide 21

Dr. Kimberly Kontson: Now, let's talk about how preparing and submitting your information.

Slide 22

Dr. Kimberly Kontson: Please provide an executive summary of no more than one page that clearly summarizes how your device meets prioritization elements in one through five. Please then also provide the additional information identified in A through F on the challenge website and described earlier in this presentation.

There is no specific template to follow for providing this information, but we suggest structuring the body of your submission consistent with A through F. The total submission, excluding references, should be limited to 16 pages. This is an important constraint, so please plan accordingly. Your submission should be prepared as an e-Copy PDF and submitted through the CDRH portal as an Informational Q-Submission, Informational Meeting Q-Submission.

When naming your submission on the Q-Submission cover sheet, prefix your company name with READI-Home Innovation Challenge. For example, READI-Home Innovation Challenge dash your company name.

The next several slides will walk you through the specific steps to complete the submission.

Slide 23

Dr. Kimberly Kontson: The first step in submitting to the READI-Home Innovation Challenge is to generate your Informational Meeting Q-Submission as a PDF document. Put on the very first page a submission purpose statement that clearly identifies this as a READI-Home Innovation Challenge submission. The purpose statement to be included in your submission can be found in the How to Submit section of the READI-Home Innovation Challenge webpage. Please note that the device submitter, date

of submission, and contact information shown in the example on this slide are hypothetical and provided for illustrative purposes only.

Slide 24

Dr. Kimberly Kontson: Following that, include your executive summary, limited to one page, that summarizes how your device meets prioritization elements one through five. The remaining pages, up to 14, are for you to provide a detailed discussion on the additional information identified in A through F on the READI-Home Innovation Challenge website and described previously.

Finally, references can be appended without page limits. Please note the example shown is for illustrative purposes only.

Slide 25

Dr. Kimberly Kontson: Reviewers may be evaluating many submissions, and a well-organized document that directly addresses each prioritization element and all information described on the website may serve you well. You may include relevant references for supporting literature or data, and remember that references do not count toward the 16-page limit.

And again, please be mindful of the formatting requirements. English language, Times New Roman, minimum 11 point font, PDF format. If you have questions about what to include, we encourage you to visit the READI-Home Innovation Challenge page, which has additional detail and an FAQ section.

Slide 26

Dr. Kimberly Kontson: Once your PDF is prepared, the next step is to complete the FDA Form 3514, which is the standard form used for Q-Submissions through the CDRH portal. Let me walk you through the specific sections you need to complete for this Informational Meeting Q-Submission.

In Section A, check the box for Informational Meeting under the Q-Submission category. This is the appropriate submission type for the READI-Home Innovation Challenge.

Slide 27

Dr. Kimberly Kontson: In Section B, the company field is particularly important. Prefixing your company name with READI-Home Innovation Challenge allows our staff to correctly identify and route your submission. Without this prefix, your submission may not be recognized as related to the challenge.

Slide 28

Dr. Kimberly Kontson: Section C through G covers standard information about your submission and your company. Please fill out these to the best of your ability. For Section H, only H3 is required for this challenge. In H3, you will check Informational Meeting. We also recommend that you check Request Face-to-Face meeting. The face-to-face meeting request is generally how participants in the interaction phase will engage directly with FDA staff, including the potential for an in-person demonstration.

However, in the event a teleconference, rather than a face-to-face meeting is desired, check request teleconference.

Slide 29

Dr. Kimberly Kontson: Sections I, J, and K are not required and can be left blank. Before you finalize Form 3514, I encourage you to review your completed form carefully. Make sure the company name

prefix is correct, that Section A reflects Informational Meeting, and that H3 has both check boxes selected.

Also confirm that Sections I, J, and K have been left blank. Submitting unnecessary or incomplete information in those sections could create confusion during our review.

Also be sure to register for an account with the CDRH Portal. A direct link to the registration page is on this slide. You do not need to include the READI-Home Innovation Challenge prefix in your organization name when registering for a CDRH Portal account. That should only be included in Form 3514. Once you're satisfied that Form 3514 is complete and accurate, and your CDRH portal account is active, you are ready to move to the final submission step, which the next slide will walk you through.

Slide 30

Dr. Kimberly Kontson: The final step is to submit your materials through the CDRH Customer Collaboration Portal. The process is as follows. First, create a zip folder containing both your completed Form 3514 and your PDF submission document. Be sure that the file names for your Form 3514 and PDF files start with 001 underscore and 002 underscore respectively to avoid screening errors. Both files must be in the same zip folder. Next, log into the CDRH portal. Click Send a Submission in the Your Sent e-Copy/eSTAR submissions section or select the plus sign and send a submission in the main navigation panel on the left.

Slide 31

Dr. Kimberly Kontson: When prompted, select eCopy as the submission format. It's important that you send the submission as an eCopy to avoid any processing delays. Then upload your zip file and press send.

Once your submission is successfully transmitted, you will receive a confirmation email from the Customer Collaboration Portal. Please save this confirmation. It serves as your record that the submission was received. If you did not receive a confirmation email within a couple of hours, we recommend checking your spam folder first and then reaching out through the contact information provided on the Challenge website.

Slide 32

Dr. Kimberly Kontson: Here are the resources I mentioned earlier in the presentation, along with the full URLs that you can access after the presentation.

Slide 33

[No audio.]

Slide 34

Dr. Kimberly Kontson: Today we shared with you the scope of the Home as a Health Care Hub Initiative, the goal and background of the READI-Home Innovation Challenge, information regarding who may be interested in participating in the challenge, certain details regarding the challenge, and how to prepare and submit an Informational Meeting Q-Submission for the challenge.

If you have questions after today's webinar, please email us at the address listed here. Thank you so much for your time and attention today. We hope this webinar has given you a clear understanding of the READI-Home Innovation Challenge. We are genuinely excited about the potential of this challenge to

bring meaningful innovation to patients recovering at home, and we look forward to reviewing your submissions. Thank you.

I'll now turn it back to Kim to start our question and answer segment.

Slide 35

CAPT Kim Piermatteo: Thank you, Lisa and Kim K., for your presentations on the READI-Home Innovation Challenge, and thank you to Dr. Tarver for her introductory remarks.

Some of you noted audio issues. We do apologize for that. Note a full recording and transcript will be available a week or two after today's event. Or if you would like clarification on something you didn't hear, feel free to ask a question today as we move into this segment.

Slide 36

CAPT Kim Piermatteo: Joining our presenters today to assist with today's questions are Christopher Scully, Assistant Director in the Division of Biomedical Physics in CDRH's Office of Science and Engineering Laboratories, and Susanna Gilbert, Assistant Director in the Office of Regulatory Programs in CDRH's Office of Product Evaluation and Quality.

Thank you both for joining us.

Slide 37

CAPT Kim Piermatteo: I'd now like to go over how we will manage today's Q&A segment and provide a few reminders. To ask a question, please select the Raise Hand icon, which should appear at the top of your MS Teams screen if you're using a desktop, or under the three dots icon if you are viewing today's event on a mobile device.

I'll announce your name and allow you to unmute your mic. Once you see your mic has been enabled, please unmute your line and ask your question. When asking your question, please remember to limit yourself to asking one question only and try to keep it as short as possible. And we appreciate that you may have a very specific question involving your device or scenario, however, we may not be able to answer such specific questions during today's event. Therefore, we'll try to frame a broader response or ask that you follow up with us via email.

After your question has been addressed, I'll disable your mic again and I ask that you please lower your hand in Teams. If you have another question, please raise your hand again in Teams to get back into the queue and I'll call on you as time permits.

As you prepare your questions, I'd like to ask two questions, we've previously been asked about the READI-Home Innovation Challenge to our additional panelists who have joined us for this segment. So for the first question, I will direct that to Chris. And Chris, the question is, is there funding associated with selection to the interaction phase?

Christopher Scully: Thanks, Kim. So this challenge does not provide funding, grants, or monetary awards to participants. Just to reiterate, the goal of this challenge is really to help accelerate patient access to medical device technologies aimed at reducing hospital readmission as part of CDRH's Home as a Health Care Hub initiative.

While we can’t offer direct financial support, there may be other benefits participants receive that are selected for the interaction phase of the challenge, such as recognition or visibility within the medical device and health care community, early engagement with FDA staff, such as including more frequent

interactions and feedback to help refine device designs or relevant testing for home use indications and opportunities to demonstrate technologies at FDA's research facilities.

CAPT Kim Piermatteo: Thanks, Chris. Alright, Susannah, the next question I have is for you and the question is, do interested participants have to request a face-to-face meeting for their Informational Meeting, or can they request a teleconference instead?

Susannah Gilbert: Thanks so much for that question. Generally, a face-to-face meeting is preferred, but a teleconference may be held if a participant requests that instead.

CAPT Kim Piermatteo: Great, thanks Susannah. Alright, we're going to go ahead and take our first live question, which I believe is coming from Andrew. Andrew, I have enabled your mic. Please unmute your mic and ask your question.

There, oh, there you go.

Andrew Harrell: Apologies. Thank you.

CAPT Kim Piermatteo: You're good. Go ahead.

Andrew Harrell: My only specific question is if you could spend a little bit of time on the description of the evidence that might be considered, especially for my devices that might be premarket authorization.

CAPT Kim Piermatteo: Thank you, Andrew. I think I'm going to direct this question to Kim K. first. Kim, do you want to take a first take at this?

Dr. Kimberly Kontson: Absolutely. Thanks, Kim P. Yeah, thanks for that question, Andrew. I think when it comes to the evidence that's needed to support the submission to the Innovation Challenge, we really want to point you to the web page under the selection of challenge participants, challenge participants. We really want to see that whatever device you're putting forward for consideration to the challenge meets those five prioritization elements. And there's additional information in considerations A through F.

For things such as the data development plan for the device, you may find more information in Appendix 2 of the breakthrough devices guidance for content that's recommended to include in that DDP. But otherwise, I would certainly point to you there. And if you have specific questions about the type of evidence or the level of evidence that you might want to provide for your specific submission, you can send us an email to the Home Health Hub email address.

CAPT Kim Piermatteo: Great. Thanks, Kim K., and thank you, Andrew, for your question.

Alright, our next question is coming from Alexandra Kirby, I'm not sure, I apologize, which is your first name or last name, but Alexandra Kirby, okay.

Alexandra Kirby: Yes, yes. Hi, thank you so much. My question is, the READI-Home website notes that the device name and description will be publicly available. Can a submitter provide the desired name and description to be public in the submission or engage with the FDA on an appropriately public name prior to disclosure?

CAPT Kim Piermatteo: Thank you for that question. I'm going to turn to, I'm going to open it up to any of the panelists or presenters today. Would anyone like to provide a first response?

Dr. Kimberly Kontson: Yeah, I would say thanks. Thanks, Alexandra, for that question. Oh.

Dr. Lisa Simone: Hi, this is...Go ahead, Kim. You got it.

CAPT Kim Piermatteo: Yeah.

Dr. Kimberly Kontson: Okay, sorry about that. Yes, I think that could be a possibility. And as we said, one of the benefits of participating in this challenge is that interaction that you get with FDA. So that's something that can be discussed if you are selected to move on into the interaction phase.

Did anybody else from the panel want to add to that?

CAPT Kim Piermatteo: Great, thanks again. Alright, hearing none, thanks, Kim K., and thank you, Alexandra, for that question. Our next question is coming from Daniel. Daniel, I have unmuted your line. Please unmute yourself and ask your question.

Daniel Simpson: Okay, great. Thank you. So you mentioned briefly a little bit about going to the breakthrough guidance for maybe some of the evidence generation. And I saw on the website that there was a little bit of mention about breakthrough device. I was wondering if there was a specific connection to that program either that this could be maybe a stepping stone to that if you weren't accepted for the READI Challenge or if there was any benefits that kind of tie those two programs together.

Christopher Scully: Hi, thanks for your…

CAPT Kim Piermatteo: Thank you. Go ahead, Chris. Sorry, go ahead.

Christopher Scully: Yeah, thanks for your question. So for right now, we're focused on the challenge here and the information, you know, that would need to be submitted to support the entry for the challenge. If you have specific questions about how that might impact breakthrough designation requests or be leveraged for your particular device, we'd recommend that you reach out to the Home as a Healthcare Hub inbox with your specific questions to explain the scenario a little bit more and we can get back to you on that.

CAPT Kim Piermatteo: Great. Thanks, Chris. And thank you, Daniel, for that question. Alright, our next question is coming from Sanna, Sanna, I have unmuted your line. Please unmute yourself and ask your question.

Sanna Gaspard: Sure. Thank you. Yes. So I'm with a company called Rubetection. We're doing wound care. And I had a question about the pediatric and adult indications. If you have a device that can do both, how is that treated in the review process? Is there a different process or considerations for the pediatric versus the adult.

CAPT Kim Piermatteo: Thank you for that question. I'm going to look to Kim. Do you want to provide a first response?

Dr. Kimberly Kontson: Absolutely, yes. We, as we mentioned in that scope clarification, pediatric population is potentially within scope. We are not going to be treating those indications any differently. It's really those prioritization elements that you need to satisfy and the information that's provided in those considerations A through F is also going to help inform how we prioritize and advance submissions into the interaction phase.

CAPT Kim Piermatteo: Great. Thanks, Kim K. Alright, our next question is coming from Sam. Sam, I have unmuted your mic. Please unmute yourself and ask your question.

Sam Saladi: Hi, thank you for this webinar about the READI Challenge. Just a clarification question, maybe even related to one, two questions ago. So, I heard the submission phase is from April to September, and FDA will notify participants selected for interactions by December 4th.

And could you clarify, so devices that are submitted will also be considered for breakthrough device designation? Is that true? And if so, the breakthrough designation requests have the 60-day decision timeline. So does that mean that if you're submitting for the READI Challenge, you'll get your

breakthrough designation by December 4th? Or response on the breakthrough designation by December 4th, or does that mean that it'll be 60 days, 30 and 60 days after you submit?

I hope that was clear.

CAPT Kim Piermatteo: Thanks, Sam. I'm going to turn it over to Chris. Chris, do you want to provide a response?

Christopher Scully: Yeah, so yeah, thanks for the question. So the timeline for the challenge is being reviewed on a rolling basis with, as we note on the website, that all notifications are still expected to be made by December 4th. And the breakthrough designation request would be separate from that, a separate process. If your device is selected to participate, you know, in the interaction phase, CDRH will learn more about your technology and evaluation plans through the Q-Submission process and different relevant marketing pathways and programs may be discussed at that point. But the timeline on the challenge website is specific for the challenge itself.

Sam Saladi: Just a really quick follow up. Would there be an issue if submitter submitted to the READI challenge and for breakthrough designation at the same time?

Christopher Scully: So, I mean, I don't think there's an issue. If you have a question about your specific submission or scenario, you know, reach out to the Home as a Health Care Hub inbox.

Sam Saladi: Thank you so much. That was really clarifying.

CAPT Kim Piermatteo: Thank you, Sam, for the question, and thank you, Chris, for the response.

Okay, our next question is coming from Jordan. Jordan, I am unmuting your line. Please unmute yourself and ask your question.

Jordan: Hello, if selected, what is the frequency of interaction? …case of pre-subs.

CAPT Kim Piermatteo: Jordan, I don't know if it was just me, but you cut out after your first word. Can you repeat that?

Jordan: Sure, can you hear me now?

CAPT Kim Piermatteo: Yes, I can.

Jordan: If selected, what is the expected frequency of interaction and would this effectively take the place of pre-subs?

CAPT Kim Piermatteo: Great. Thank you, Jordan. Kim K., I'm going to turn it over to you.

Dr. Kimberly Kontson: Yeah, so for the interaction phase, if you are selected, one of the first things that will happen per the Informational Meeting Q-Submission is that we will have an initial meeting. And from there, we will discuss the frequency of interactions.

I think we're, we're aiming for at least every three months to check in with companies as they as they go through their development process. But as we had said before, these interactions are and the plan that we create is malleable.

Jordan: Great, thank you.

CAPT Kim Piermatteo: Thank you, Jordan, for your question, and thank you, Kim K., for your response.

The next question I have, coming back to Alexandra, I'm going to unmute your mic and if you have another question, please unmute.

Alexandra Kirby: Yes, thank you. My second question is, can FDA provide information on timeline expectations that sponsors should include, whether that be timeline expectations for testing to be conducted and or other development attributes?

CAPT Kim Piermatteo: Thank you, Alexandra. Kim, do you want to take another take of this question? Okay.

Dr. Kimberly Kontson: Sure. Yeah, thanks, Alexandra. Yeah, I think again, having some of that information that we list on the website about considerations A through F, your data development plan may point to some of that information. But there's no, I don't think we have set expectations in the review of when things are supposed to happen. I think we'll be able to have more discussions about that during the interaction phase if your medical device is selected to enter into that phase.

CAPT Kim Piermatteo: Great. Thanks, Kim K., and thank you, Alexandra, for that question.

The next question we have is coming from Maria. Maria, I have enabled your mic. Please unmute yourself and ask your question.

Maria: Sure, do you hear me?

CAPT Kim Piermatteo: Yes, we can.

Maria: Cool. So my understanding is that you're accepting nine companies this year. Are you planning on continuing the program to take more companies in 2027?

CAPT Kim Piermatteo: Thank you, Maria. I think the question is about taking on more companies. Oh, yes, okay.

Maria: Yes, I don't know if you heard me right. Yeah, it's just nine companies, 2027. Are you going to do it again? Are you more companies like the top program? Just, just wondering.

CAPT Kim Piermatteo: Great. Okay. Would any of our panelists, just open it up to anyone. Does anyone want to provide a response?

Christopher Scully: Yeah, so thanks. As you noted, yeah, we're expecting to accept nine this year for this innovation challenge. Right now, that's the current plans that have been announced. We'll continue to ideate on ways to encourage innovation and explore different avenues available to us to do so.

CAPT Kim Piermatteo: Great. Thanks, Maria, for that question, and thank you, Chris, for your response.

Okay, I don't see any more hands raised right now, but I want to encourage you to raise your hands, ask questions to our subject matter experts that are on our call today. But while you gather your questions, I'm going to go back to our panelists and ask some additional questions that we've received about this challenge.

The first question, I'm going to direct that one to Susannah. And Susannah, the question is, where can I find form 3514 for the Q-Submission?

Susannah Gilbert: Hi, thanks so much for that question. So Form 3514 is called the CDRH Premarket Review Submission Cover Sheet PDF. There is a link to this form in slide 33 of today's presentation, and you can also find it by doing a web search for FDA Form 3514, which should provide a direct link to that form.

CAPT Kim Piermatteo: Great. Thanks, Susannah. Alright, I am going to come back to another question. I believe that, Sanna, I'm going to come back to you. I'm going to enable your mic and please unmute yourself and ask your question.

Sanna Gaspard: So my question is around how the program will facilitate partnerships or pilots in the home. So do you guys already have a group of innovation partners who are running pilots in the home that you will connect us with? Are you going to connect us directly with patients? Are you going to connect us with advocate groups? What's the plan for connecting patients? Are people or companies accepted into the program to potential pilot sites to get the data for home use cases.

CAPT Kim Piermatteo: Thank you, Sanna. Would anyone on the panel like to provide a response?

Dr. Kimberly Kontson: Yeah, I can take a stab at this and see if my colleagues have any other follow-up. But I would say that we as FDA, CDRH, do have a lot of resources. And part of the interaction phase will be to better understand your device technology, the stage that you're in with development, and to see how the resources that we come across and we have can be used to help you with the that that development.

Sanna Gaspard: Okay, so is that going to be connection partner sites or directly patients or existing pilots?

Dr. Kimberly Kontson: I can't answer that broadly. I think it's all going to depend on your specific technology and what you bring to us. So that's part of what we'll uncover in some of these informational meetings.

Sanna Gaspard: Thank you.

Dr. Kimberly Kontson: Mhm.

CAPT Kim Piermatteo: Great. Thanks, Kim K., and thanks, Sanna, for your question. Alright, I see a few more raised hands. I'm going to come back to Sam. Sam, I've unmuted your mic. Please unmute yourself and ask your question.

Sam Saladi: Hi, thanks for this excellent webinar. Just one question about FDA recently announced with CMS the rapid coverage pathway, which, you know, to help increase access to devices. With part of the READI-Home program, has there been any thought given to coverage and, you know, if there's any way that FDA could help those conversations with coverage happen? So once a device is, if it makes it through the pre-market submission process they can make it out to patients.

CAPT Kim Piermatteo: Thanks, Sam. Again, I'm just, I'm going to make this more interactive. If anyone on the panel wants to provide a response or tag team it, that'd be great.

Dr. Lisa Simone: Hi, Sam, this is Lisa. Thank you for the question. So we are aware of the pathway. It's something that, as the Home is a Healthcare Hub initiative, we do want to be aware of those pathways, but it's not directly related to the READI-Home Challenge that we're talking about today. We could include that in later discussions when you reach an interactive phase and you're talking about the market pathway, but that would be specific to the device. I hope that answers your question.

Sam Saladi: It does. Thank you so much. Really appreciate it.

CAPT Kim Piermatteo: Thanks, Lisa, and thanks, Sam. Alright, our next question is coming from Carrie. Carrie, I have unmuted your mic. Please unmute yourself and ask your question.

Carrie Eddings: Hi, this is Carrie Eddings. Thank you so much for this webinar. The question I have is the READI-Home Challenge is focused on CDRH and devices. I'm wondering if this would be applicable to combination products, with a device and a drug or a device and a biologic.

CAPT Kim Piermatteo: Great. Thanks, Carrie, for that question regarding combination products. Kim, I'm going to turn it over to you.

Dr. Kimberly Kontson: Yeah, I would say if your device or your combination product is able to address those five prioritization elements and you can give us the information that we request on the website, then we should be able to evaluate that submission and determine if it will be selected in the interaction phase. So that was kind of a long-winded way of saying, yes, you could do that.

Carrie Eddings: Yes. Thank you so much.

CAPT Kim Piermatteo: Thanks, Carrie, and thanks. Oh, no, go ahead.

Dr. Kimberly Kontson: And we would hope that, oh, sorry, just one extra clarifier. I know with combination products, there can be a drug, it's drug-led or device-led. So it would be best if it was a device-led combination product.

Carrie Eddings: Yeah, understood. Thank you.

CAPT Kim Piermatteo: Alright, thanks, Carrie, and thanks, Kim. Our next question is coming from Mohamed. Mohamed, I've enabled your mic. Please unmute yourself and ask your question.

Mohamed Abou-Alam: Very much. This is Mohamed. Thank you for the webinar. Just a question on the boundaries of patients and caregivers and evidence endpoints. So for a clinician-directed implantable monitoring system, how does FDA define or think about the minimum patient caregiver intended user role that's needed for eligibility here and what home use feasibility endpoints would be most persuasive at submission?

CAPT Kim Piermatteo: Thank you, Mohamed, for your question. Does anyone on the panel want to address? I know that was a very specific question. Do we have anything generally we could provide a response?

Mohamed Abou-Alam: Sorry, I can maybe try and clarify a little bit to make it more general. So I know that it says prioritized devices should have at least one patient caregiver intended user, at least one intended use environment, et cetera. So we're just trying to understand because we're a little bit early in our program, how what sort of endpoints might be acceptable, thinking of early stage as an implantable, capture completeness, transmission reliability, things like that. You know, they're somewhat engineering driven, but still highly valuable for caregiver patient understanding. Would that be acceptable from the perspective of this eligibility and the challenge?

Dr. Kimberly Kontson: Hi, this is this is Kim K. I appreciate that question. I do want to just say that it might be best for you to email us and ask that question more specifically. But yeah, in terms of endpoints and everything, what we're asking for to determine prioritization for those selected in the interaction phase, it all goes back to those prioritization elements. And we're giving you the opportunity to address each one of those in an executive summary in the beginning of the submission.

And like we said, there are endless references that you can provide because that's limited to one page. So yeah, my response to you is maybe follow up with us via email and also utilize that executive summary to really make your point.

Mohamed Abou-Alam: Yes, thank you.

CAPT Kim Piermatteo: Thank you, Mohamed, for your question, and thank you, Kim K., for the response.

I think we are getting close to wrapping up. I don't see any more raised hands, but I do have one question that I would like to ask that we've previously received that I think will kind of wrap it up for us today. That question I'm going to direct to Chris. And Chris, that question is, who will be reviewing the information submitted and determining selections for the interaction phase. And how will this be done?

Christopher Scully: Thanks, Kim. So researchers and reviewers across CDRH with relevant expertise in the medical device area will be reviewing the information based on the prioritization elements that are on the website and we've been discussing here today, including other additional information for the READI-Home Innovation Challenge.

We expect some group discussions involving researchers, review staff, and leadership may be conducted to help evaluate these submissions and make the selections.

CAPT Kim Piermatteo: Great. Thanks, Chris. And that will wrap up our question and answer segment of today's webinar. We appreciate everyone's participation, so thank you very much.

Slide 38

CAPT Kim Piermatteo: Before we conclude today's event, I would like to turn it back over to Kim K. for some closing remarks regarding the READI-Home Innovation Challenge. Kim.

Dr. Kimberly Kontson: Yes, thanks, Kim P. We just wanted to thank everyone again for attending today's webinar and just wanted to also note that the submission period for the READI-Home Innovation Challenge is open through September 30th, 2026. And we are very, very excited to review the submissions that are coming in and encourage you to apply.

As was noted multiple times throughout this webinar, we encourage you to also reach out to us with any questions you might have related to the challenge using some of the information you can find on these slides. Back to you, Kim.

CAPT Kim Piermatteo: Thanks, Kim K. And again, thank you to all of our presenters and panelists for being a part of today's webinar. Before I close, I want to let everyone know a recording of today's event, a copy of the slides and a transcript will be posted as soon as possible to the event, to the event page, as well as to CDRH Learn under the section titled Specialty Technical Topics and the subsection Home Use.

Displayed on this slide is a screenshot of where you will be able to find these materials on CDRH Learn. If you have additional questions regarding today's topic, feel free to send those to the email that Kim K. has mentioned multiple times, but it is listed on this slide, the home health, healthhomehub@fda.hhs.gov.

And if you have additional questions regarding today's event, feel free to reach out to DICE at dice@fda.hhs.gov.

And lastly, I encourage you to monitor our CDRH events webpage at www.fda.gov/CDRHevents for a listing of all of our upcoming CDRH events.

Thank you all again for joining us. This concludes today's CDRH webinar.

Slide 39

[No audio.]