Technology-Enabled Meaningful Patient Outcomes (TEMPO) for Digital Health Devices Pilot

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CAPT Kim Piermatteo: Hello 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 within FDA's Center for Devices and Radiological Health.

The topic of this module is the Technology-Enabled Meaningful Patient Outcomes for Digital Health Devices Pilot or what is also referred to as the TEMPO pilot. This voluntary pilot is designed to promote access to certain digital health devices while safeguarding patient safety.

During this module you will hear from Eitan Bernstein, Acting Associate Director for Regulatory Documents and Special Projects in CDRH's Office of Policy and Dr. MiRa Jacobs, Director of the Division of Digital Health Policy in CDRH's Digital Health Center of Excellence.

I'll now turn it over to Eitan.

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Eitan Bernstein: Thanks Kim and thank you for taking the time to watch this module.

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Eitan Bernstein: This learning module is intended to provide an introduction to FDA's Technology-Enabled Meaningful Patient Outcomes for Digital Health Devices Pilot or the TEMPO pilot.

A federal register notice announcing this pilot was published on December 8th of 2025. The TEMPO pilot, in connection with the CMMI ACCESS model is intended to promote access to certain digital health devices while safeguarding patient safety.

As stated in the notice, FDA began to collect statements of interest for participation in the pilot as of January 2nd, 2026.

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Eitan Bernstein: In this learning module, we intend to cover, the goals of the TEMPO Pilot, key features of the pilot, including who may be eligible and interested in participating, the kind of information that should be included in a statement of interest, if you want to participate in the pilot, and the selection process for participation in the pilot.

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Eitan Bernstein: FDA launched the TEMPO pilot in connection with the new CMMI ACCESS model, which intends to test a new payment option that emphasizes patient outcomes, enabling clinicians to offer innovative technology-supported care to improve patients' health and prevent and manage chronic disease. The TEMPO pilot aims to promote access to digital health devices that may be used as part of this healthcare delivery model while safeguarding patient safety.

It also aims to evaluate a risk-based enforcement approach that supports digital health devices intended for use to improve patient outcomes in certain chronic conditions that align with the CMMI ACCESS model, specifically certain early cardio-kidney-metabolic, cardio-kidney-metabolic, musculoskeletal, and behavioral health conditions.

In addition, the TEMPO pilot will responsibly encourage innovation while real-world evidence is collected that may help FDA and CMS better understand how these devices perform for patients in their everyday lives.

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Eitan Bernstein: Next, we'll discuss some key features of the TEMPO pilot.

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Eitan Bernstein: As mentioned, the TEMPO pilot has been launched in connection with the new CMMI ACCESS model. This is important to note, because the TEMPO pilot is limited to when a device is offered to or by CMMI ACCESS participants for an intended use to improve patient outcomes, to be used in providing care expected to be covered by the CMMI ACCESS model.

Through the ACCESS model, CMMI intends to test a new payment option that emphasizes patient outcomes related to improving patients' health and preventing and managing chronic disease. What this means practically, is that the model introduces recurring payments for managing a patient's qualifying condition, where the payment will be tied to achieving specific, measurable health outcomes.

The model also includes several safeguards that support clinical quality and accountability. CMS will monitor performance in the model and may terminate payments to organizations that fail to meet quality, safety, or outcome standards. CMS also intends to publish risk-adjusted outcomes in a public directory.

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Eitan Bernstein: With this framing, we can now discuss the FDA's TEMPO pilot.

In general, if the manufacturer of a digital health device wishes to offer its device for an intended use to improve patient outcomes, for example, to cause measurable changes in chronic disease outcomes, the device must, among other things, be authorized by FDA for that use.

Therefore, if a manufacturer wishes to offer its device for such an intended use so that it may be used to provide care covered by the CMMI ACCESS model, FDA generally expects the device to be FDA-authorized for that use.

However, we understand that there may be manufacturers of certain digital health devices who have an interest in offering their devices for an intended use to improve patient outcomes such that they may be used to provide care under the ACCESS model, where the devices do not present a potential for serious risk to the health, safety, or welfare of patients, but they have not yet been authorized by FDA either for that specific use or at all.

Through FDA's TEMPO pilot, these manufacturers may request that FDA exercise enforcement discretion and not enforce certain applicable requirements when their device is offered to or by CMMI ACCESS participants for an intended use to improve patient outcomes, to be used in providing care expected to be covered by the CMMI ACCESS model.

For example, a manufacturer might request that FDA exercise enforcement discretion and not enforce premarket authorization requirements, investigational device exemption or IDE requirements, requirements under 21 CFR parts 50 and 56, or other applicable requirements.

As is often the case when FDA exercises enforcement discretion for certain applicable requirements, FDA will work with participants in the TEMPO pilot to identify the circumstances when enforcement discretion may be appropriate for that manufacturer's device, including, for example, when the labeling includes appropriate cautions, and when FDA requests that certain records be maintained. By identifying an appropriate scope of enforcement discretion for certain low risk digital health devices through the pilot, FDA will support the availability of devices that may help improve patient outcomes in connection with the ACCESS model, while also helping to ensure patient safety.

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Eitan Bernstein: FDA recognizes that real-world data, or RWD, may be collected in the course of clinical practice during the treatment and management of patients, particularly with the use of digital health devices. Under certain circumstances, RWD may be used to generate real-world evidence, or RWE, that can help inform or augment FDA's understanding of the benefit-risk profile of devices at various points in their life cycle. These data may also be supportive of FDA's review of devices, along with other information needed in a marketing submission.

FDA expects that manufacturers participating in the TEMPO pilot will collect RWD relating to the intended uses of their devices to improve patient outcomes while offering the devices for use in providing care covered by the CMMI ACCESS model. FDA also expects that participants will share the data with FDA during their participation in the TEMPO pilot; and, using the data collected during their participation in the TEMPO pilot, along with other information, will seek appropriate marketing authorization from FDA.

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Eitan Bernstein: For manufacturers participating in the TEMPO pilot, FDA will offer and encourage engagement in sprint discussions, with the goal of reaching mutual agreement on a specific topic that may relate to the planned marketing submission for the participant’s device, within a set timeframe, such as 45 days. The number, format, and duration of interactions within a sprint discussion may vary based on project needs.

As noted previously, FDA expects that manufacturers participating in the TEMPO pilot will use the data collected during their participation in the pilot to ultimately seek appropriate marketing authorization from FDA. However, please note that while data collected during participation in the pilot are intended to be supportive of a marketing submission, additional data may also be needed to support that submission. In addition, participation in the pilot is not an indication of whether FDA will issue a positive decision for a future marketing submission, such as 510(k) clearance or De Novo authorization.

I’ll now turn it over to my colleague, Dr. MiRa Jacobs.

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Dr. MiRa Jacobs: Thanks Eitan.

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Dr. MiRa Jacobs: Now that we’ve talking a little bit about what it means to participate in the pilot, we can talk about the statement of interest.

The first step toward participating in the TEMPO pilot is to send a Statement of Interest to the FDA.

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Dr. MiRa Jacobs: Statements of interest should be provided via email to the inbox, FDA-TEMPOPilot@fda.hhs.gov.

These statements of interest are meant to include some details about the device that you would like to be considered in the pilot, and the request for enforcement discretion by the FDA for the use of the device for an intended use to improve patient outcomes such that they may be used to provide care under the ACCESS model.

The statement of interest helps FDA understand, at a high level, your proposal for participating in the TEMPO pilot, and whether or not the proposal is likely eligible for participation in the pilot.

A complete statement of interest should include the following; first, the subject of your email should include that it is a "statement of interest for participation or for participation in the TEMPO pilot." Second, the statement of interest itself should clearly identify the device that you wish to be considered in the pilot as well as the manufacturer, which at a minimum should include the manufacturer's name, and could also include the manufacturer's address, identified point of contact, and/or additional contact information. As part of identifying the device and manufacturer, the statement of interest should also include any current authorization or prior interactions with the FDA related to the device, even if these interactions or authorizations were related to a different indications for use than the one you wish to be considered in the pilot. We ask that you include specific submission numbers whenever available.

Next, the statement of interest should also include a clear indications for use statement that identifies the particular intended use and related claims to improve patient outcomes in a clinical use area consistent with those in the CMMI ACCESS model that you are requesting for consideration within the TEMPO pilot.

Lastly, the statement of interest should include a request that FDA provide the manufacturer with a statement that FDA does not intend to enforce certain legal requirements when the device is marketed for use in care provided under the ACCESS model.

Manufacturers may choose to include additional information in their statements of interest, such as a brief description of the maturity of the manufacturer's quality management system, or a summary of information supporting the safety of the device. However, such information is not required to be included in the statement of interest space.

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Dr. MiRa Jacobs: Once FDA receives Statements of Interest in the pilot, FDA will begin evaluating those statements for potential selection in the TEMPO pilot.

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Dr. MiRa Jacobs: First and foremost it's important to note, that because TEMPO is a pilot, the FDA intends to initially limit participation.

At this time, FDA intends to select up to about ten, U.S.-based manufacturers in each of the four different clinical use areas described in CMMI's ACCESS model.

Among these approximately 40 participants, FDA hopes to select a broad representation of manufacturers of different sizes, types, and maturities.

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Dr. MiRa Jacobs: Further, the TEMPO pilot is intended for digital health devices. Therefore, as part of selection, FDA intends to evaluate whether the proposed devices are digital health devices that would not present potential serious risk to the health, safety, or welfare of patients but would generally be the focus of our regulatory oversight for their proposed use.

And, as mentioned briefly earlier, are products that not only meet the definition of a medical device but are also intended to be used in conjunction with clinician-supervised outpatient treatment for certain conditions in one of the four CMMI ACCESS model's clinical use areas. More specifically these areas are early cardio-kidney-metabolic, which means hypertension, dyslipidemia, obesity or being overweight with markers of central obesity, or prediabetes; cardio-kidney-metabolic, meaning in this case diabetes, chronic kidney disease, or atherosclerotic cardiovascular disease; musculoskeletal meaning chronic musculoskeletal pain; or behavioral health meaning depression or anxiety.

It's also important to note that FDA acknowledges that digital health devices may rely on off-the-shelf platforms, such as general-purpose computing platforms or wearables that may or may not themselves be regulated as devices. These digital health devices can still be considered within the TEMPO pilot.

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Dr. MiRa Jacobs: FDA began collecting statements of interest for the pilot on January 2nd. As described in the federal register notice, we intend to begin to send follow up requests to certain potential pilot participants that have provided statements of interest around March 2nd. Like I said previously, the statement of interest is not intended to be the complete information about your device that may be requested in the course of consideration for the pilot, so we expect follow up requests and the complete selection process to be interactive and tailored to each device under consideration.

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Dr. MiRa Jacobs: The specific information that may be helpful to share with FDA in response to a follow-up request may vary depending on the specific device, but, in general, we believe it will be helpful to provide a few different kinds of information to enable the FDA to understand your device and your proposal for its use as part of the pilot.

First, a device description including the information about the device that will be supplied in a statement of interest, like the proposed intended use, will be helpful to ensuring that it is clear how your device is meant to be marketed for use as part of the care provided under the ACCESS model. A clear device description is also important to help the FDA understand the kinds of risks that may be associated with your product and its use, as well as to ensure that the product does meet the definition of a medical device and would be one for which FDA would generally focus its oversight.

Additionally, data that demonstrates your device is adequately safe and can function as it is designed will be important to ensure that your device does not pose serious risks to patients, and also that it is both able to function as intended and FDA may have a reasonable expectation the device could provide the patient benefit you wish to claim.

It will also be helpful for FDA to understand the manufacturer's quality management system as, in part, this information will provide context for the FDA when reviewing your TEMPO-related plans.

Beyond ensuring that the FDA has an understanding of the scope and function of a device for consideration in the TEMPO pilot, it will also be important to share your plans for the device as part of the pilot. This means, one, sharing how a manufacturer will sufficiently mitigate risks to patients while the device is being used as part of the pilot and a plan for the collection, monitoring, analysis, and reporting of

real-world performance data. This kind of data collection will be a necessary part of use within the ACCESS model, and it will be necessary to demonstrate the device is remaining safe and data to support a future marking submission is being collected as part of the TEMPO pilot.

Two, proposing performance goals and a statistical analysis plan for patient outcomes. As just noted, it will be important to share how a manufacturer intends to evaluate the claims they are proposing as part of the TEMPO pilot and to have a plan to obtain data that will, at least in part, support a future marketing submission.

And three, proposing a reporting plan, including frequency, to share certain data and progress on data collection with the FDA as well as a general proposed timeline for collecting data as part of the pilot and submitting a marketing submission for the device.

In other words, the FDA will be looking to understand the device and claims for which you are seeking enforcement discretion when used within the limits of the pilot, to have reasonable support that the device may provide the intended benefit to patients, and that it can be used safely. FDA will also be looking to understand the manufacturer's plan for eventually bringing the device to market for the proposed claims through a typical marketing pathway, because the TEMPO pilot is intended only to provide limited enforcement discretion and is not intended to replace a marketing submission for participating medical devices long term. Eventual marketing authorization for devices that may provide patient benefit is a goal of the pilot.

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Dr. MiRa Jacobs: With that, here are the resources that were mentioned earlier in the presentation, along with the full URLs that you can access after the presentation.

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Dr. MiRa Jacobs: In summary, the TEMPO pilot aims to promote access to certain digital health devices while safeguarding patient safety. The pilot supports the CMMI ACCESS Model, which aims to increase beneficiary access to technology-enabled, integrated care.

Through the pilot, manufacturers may request that FDA exercise enforcement discretion for certain requirements when their device is offered to or by CMMI ACCESS participants for an intended use to improve patient outcomes, to be used in providing care expected to be covered by the CMMI ACCESS model.

TEMPO pilot participants are expected to collect real-world data demonstrating the digital health device's performance and share that data with FDA. And FDA expects to select up to about ten U.S.-based manufacturers in each of the four clinical use areas and to have broad representation of manufacturers of all sizes, types, and maturities.

So with that I will close and pass this back to Kim.

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CAPT Kim Piermatteo: Thank you Eitan and MiRa for presenting this information.

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CAPT Kim Piermatteo: For this module Eitan will present a few frequently asked questions about the TEMPO pilot.

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Eitan Berstein: Thanks Kim. The first frequently asked question is, is there a submission deadline for statements of interest?

Our response to this question is, there is no specified deadline for when FDA will stop accepting statements of interest for participation in the TEMPO pilot. FDA encourages manufacturers to submit their statements of interest before March 2nd, 2026.

However, as the TEMPO pilot is a pilot, FDA plans to limit participation, and currently expects to select up to about ten manufacturers based in the United States in each of the four clinical use areas identified for the TEMPO pilot. FDA began accepting statements of interest on January 2nd, 2026, and expects to begin sending follow-up requests around March 2nd, 2026, to certain potential pilot participants who reflect a broad spectrum of manufacturers.

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Eitan Berstein: The next question is, what are the eligibility requirements for manufacturers?

Our response to this question is manufacturers must be based in the United States. FDA will select manufacturers of digital health devices that meet the definition of a device under section 201(h) of the Federal Food, Drug, and Cosmetic Act; are intended to be used in conjunction with clinician-supervised outpatient treatment to patients with conditions in one of the four CMMI ACCESS clinical use areas; do not present potential for serious risk to patient health, safety, or welfare; and have an intended use to improve patient outcomes consistent with the CMMI ACCESS program.

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Eitan Berstein: The next question is, are devices that are already FDA-cleared eligible for the TEMPO Pilot?

Our response to this question is, manufacturers of certain digital health devices that are not already authorized by FDA for an intended use to improve patient outcomes in one of the four CMMI ACCESS clinical use areas, which are early cardio-kidney-metabolic, cardio-kidney-metabolic, musculoskeletal, and behavioral health, may request to participate in the TEMPO pilot.

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Eitan Berstein: The next question is, is CMMI ACCESS participation required for TEMPO?

Our response to this question is, through the TEMPO pilot, a manufacturer may request that FDA exercise enforcement discretion and not enforce certain applicable requirements when their device is offered to or by CMMI ACCESS participants for an intended use to improve patient outcomes, to be used in providing care expected to be covered by the CMMI ACCESS model.

This may include, for example, when the manufacturer is itself a participating organization under the CMMI ACCESS model, or when the manufacturer offers the device to other entities that are participants under the CMMI ACCESS model for an intended use to improve patient outcomes.

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Eitan Berstein: The next question is, will devices in the TEMPO Pilot be expected to receive FDA authorization?

Our response to this question is, although FDA may exercise enforcement discretion and not enforce premarket authorization requirements for a device while participating in the pilot, FDA expects manufacturers participating in the pilot to ultimately seek appropriate marketing authorization from FDA, using the data collected during their participation in the pilot, along with additional information to support a marketing submission. FDA expects to discuss proposed timelines for submission of a 510(k) or other type of marketing submission with participants.

I'll now turn it back over to Kim.

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CAPT Kim Piermatteo: Thank you Eitan for presenting those frequently asked questions about the pilot. Before we conclude this module, I'll turn it back over to MiRa for some final thoughts.

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Dr. MiRa Jacobs: Thanks again Kim. For final thoughts, I'd like to leave you all with three reminders. The first, is that manufacturers should really endeavor to submit their statements of interest for participating in the TEMPO pilot before March 2nd, 2026.

Second, that these statements of interest as well as any other questions about the TEMPO pilot can be submitted to FDA-TEMPOPilot@fda.hhs.gov.

And lastly, we'd ask that you please keep an eye out, because we are currently developing a TEMPO FAQ webpage, and we will provide more information once that's available.

I think with that I will close out and turn it back to you Kim. Thanks again.

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CAPT Kim Piermatteo: Thanks again MiRa and Eitan. This module and other learning modules can be found at CDRH Learn via the link provided on this slide.

Other resources available to you that are referenced on this slide include Device Advice, for text-based information on premarket and postmarket topics, and the contact information for the Division of Industry and Consumer Education or DICE, whom you may contact for additional information on this or other medical device regulatory topics.

Thanks again for watching. This concludes the CDRH Learn module on the TEMPO pilot.

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