FDA Webinar: Collaborative Communities

Moderator: Irene Aihie
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3:00 pm ET

Coordinator: Welcome and thank you for standing by. At this time all participants will be on a listen only mode until the question and answer session of today's call. At that time please press star followed by number one, unmute your line and record your name clearly as prompted to be introduced.

Today's conference is being recorded. And if you have any objections you, may disconnect. I would like to introduce Irene Aihie. You may begin.

Irene Aihie: Hello. And welcome to today's FDA webinar. I am Irene Aihie at CDRH's Office of Communication and Education. Participating in collaborative communities is one of the Center for Devices and Radiological Health three strategic priorities for 2018 through 2020.

CDRH envisions collaborative communities as an ongoing forum where public and private sector members proactively work together to achieve prominent objectives in outcomes, to solve shared challenges and to leverage collective opportunity in an environment of trust, respect, empathy and openness.

Today, Michelle Tarver, Director of Patient Science and Engagement here in CDRH will discuss CDRH's definition of a collaborative community, outline considerations for CDRH's participation in a collaborative community, review the collaborative community toolkit and address frequently asked questions.

After the presentation we will open the line for your questions related to information provided during the presentation. Now, I give you Michelle.

Dr. Michelle Tarver: Good afternoon. This is an overview of what we will cover during today's agenda. We will start by discussing the FDA's concept of a collaborative community.

We'll talk about when CDRH may consider participating in a collaborative community and current collaborative communities in which CDRH is already participating.

We'll also talk about the collaborative communities toolkit, which is a resource posted on the collaborative community’s section of the fda.gov Web site.

And finally we'll wrap-up with some frequently asked questions, share available FDA resources and open the lines for your questions.

We recognize that there may be others using the term collaborative community. So let's start out by defining the FDA's concept of a collaborative community, including what is a collaborative community? What collaborative communities are not? Other collaborative groups compared to a collaborative community and potential outcomes of a collaborative community.

Collaborative communities are convened by interested stakeholders and appear organically rather than at the direction or request of the FDA. They may exist indefinitely, produce deliverables as needed and tackle challenges with broad impacts.

This mutually beneficial relationship is reinforced by shared responsibility and accountability for achieving results toward common goals. Participation in at least 10 collaborative communities by December 31, 2020 is one of the Center for Devices and Radiological Health's strategic priorities.

We encourage medical device stakeholders to consider forming collaborative communities and to consider requesting CDRH’s participation in appropriate cases.

The FDA does not establish, lead or operate collaborative communities nor are these communities intended to advise the FDA. Instead, the FDA may participate as a member of a collaborative community and will consider adopting the solutions developed by the community if doing so is in the best interest of public health and consistent with the law.

In addition membership and governance of a collaborative community is not directed by the FDA. And finally collaborative communities are not task forces, working groups or commissions, which typically address narrowly defined problems and disband after developing a final deliverable. These communities are envisioned to be sustained entities.

Collaborative communities are distinct from other types of collaborative groups. They are unique in how they are established, their goals, their lifespan and their membership. Let's compare the features of a collaborative

community to other collaborative groups with which you may be more familiar.

We'll start with the establishment of the group. Remember a collaborative community may be established and convened only by an external partner and not by the FDA. The FDA may participate only as a member of the community.

Next, let's look at the goals of a collaborative community versus other collaborative groups.

Collaborative communities focus on broad outcomes and impacts and may have multiple deliverables that benefit its members. In contrast, the other collaborative groups noted above have a narrow focus on the goal of achieving one or few specific deliverables.

Another hallmark of a collaborative community is its lifespan. Collaborative communities, by the very nature of their goals, are intended to be long-term forums that could exist indefinitely.

Most other collaborative groups have a limited lifespan which typically lasts the length of time it takes to complete their deliverables.

And last but not least one of the most unique features of a collaborative community is its membership. Collaborative communities would typically be composed of appropriate representatives from a full range of stakeholder communities impacted by a topic.

Participants could include, but are not limited to patients, caregivers, academicians, health care systems, payers, government agencies, international regulatory bodies and product developers.

Unlike collaborative communities, task forces are workgroups typically comprising experts in specified areas of knowledge or practice. Task forces are small groups of people and resources brought together to accomplish a specific objective with the expectation that the group will disband when the objective has been completed.

Whereas, collaborative communities are typically defined by organizational laws, bylaws, charters and other formal documents, task forces are often created on an as needed basis.

The impetus for the creation of a task force is often the result of some event, often unexpected or unanticipated, causing the need for an organization to acquire knowledge as to how to best respond to the event, related event or to a similar situation quickly.

This is not an exhaustive list of possible outcomes that could come out of a collaborative community. The types of things a collaborative community chooses to work on will be unique to the goals set by the community's members and may take many forms, such as developing regulatory or clinical best practices, evidence generation to inform health care coverage and reimbursement decisions, other clinical and non-clinical research projects, peer reviewed publications, white papers, templates and framework.

As stated earlier, the FDA may consider adopting solutions developed by a collaborative community if doing so is in the best interest of public health and consistent with the law.

Established collaborative communities may wish to invite CDRH to participate. CDRH's decision to participate as a member is influenced by the public health impact of the community, its alignment with CDRH's regulatory mission, current priorities and resources.

The FDA's collaboration with diverse stakeholders is a key to achieving our goal of assuring patients and providers have timely and continued access to safe, effective and high quality medical products.

We know that we can achieve better outcomes in protecting public health when we integrate different perspectives, experiences, resources and expertise from each participant in the medical device ecosystem.

The FDA currently participates as a member in two collaborative communities, which have been established and are managed and controlled by external stakeholders.

The Ophthalmic Imaging Collaborative Community will seek to identify and clarify important challenges, clarify best practices, strategies and standards and drives innovation within the general area of ophthalmic imaging.

This collaborative community has domestic and international stakeholders in the health care ecosystem committed to developing scientific solutions that can aid and clarify the use of natural language processing and other emerging technological advances that can refine the diagnosis, management and treatment of patients with eye diseases as well as other medical conditions.

Since this is a newly established collaborative community that doesn't yet have a public-facing Web site. If you're interested in this community, please

contact us at the CDRH collaborative community's email address on the question slide and we're happy to put you in touch with them.

The National Evaluation System for Health Technology Coordinating Center Collaborative Community, also known as the NEST Collaborative Community, is a national network intended to help develop methodologies designed to drive down the time and the cost of real world data collection and analysis and increase the value and use of real world evidence to meet the needs of patients, payers, the medical device community, industry, health care professionals and other regulatory bodies.

The members of this collaborative community include stakeholders that reflect the entire NEST ecosystem. As members, individuals will represent their own perspective as well as the larger communities, such as the professional organizations to which they belong.

While this is an existing collaboration dating back to the establishment of the NEST Coordinating Center in 2015, the NEST Coordinating Center has now achieved recognition as a collaborative community as described in CDRH's 2018, 2020 strategic priority.

One of the resources you can find on our collaborative communities Web page is the collaborative community’s toolkit. We compiled the toolkit as a resource for potential collaborative communities who are interested in establishing their communities on a firm foundation.

Collaborative communities are invited to use the toolkit developed with public feedback as well as input from the FDA's Patient Engagement Advisory Committee to establish themselves and to encourage collaboration to take on health care challenges.

The toolkit is not meant to be prescriptive and does not constitute agency policy or guidance. So we'll pick some frequently asked questions.

The first one is when should I talk to the FDA about a collaborative community? We always encourage members of the public who are interested in tackling a matter of public health importance to engage in conversation with the FDA. We understand that each collaborative community will evolve from its earlier stages of surveying the landscape to see what's out there and better understand the area that it should focus on to the designing phase, where their critical problems are designed and a charter has been drafted.

If you are interested in having FDA join as a newly developed or an existing collaborative community, we welcome you to contact us at the email address below.

If CDRH decides to participate in your collaborative community, we will designate at least one CDRH liaison who will be the point of contact and who will represent CDRH.

The next question that we typically get is does the FDA establish a fund collaborative community? The answer is no. The FDA does not establish, manage or control collaborative communities.

It does not provide funding, define the membership, schedule meetings or set agendas or control the community's operations. We understand the collaborative communities can exist without FDA's participation.

Another question that we commonly receive is, are collaborative communities an alternative to standard federal advisory committees or other established regulatory processes?

And the answer is no. They do not replace established regulatory mechanisms. The FDA will follow good guidance practices, ethics, standards and other existing processes for conducting its business.

The FDA's participation in collaborative communities must conform with these existing obligations.

We also want to note that a collaborative community is not a federal advisory committee. And if you have questions about the advisory committees, we welcome you to visit our FDA Web site.

If you have questions about other federal laws as well as laws of other jurisdiction, we would encourage you to seek the legal advice of legal counsel to get answers to those questions.

Another question that we receive is why would I want to be part of a collaborative community? And the answer to that is we believe collaborative communities can contribute to the improvement in areas that affect U.S. patients and health care and result in wide ranging benefits to public health.

For example, collaborative communities could help accelerate the development of science-based solutions to policy challenges related to assuring the safety and effectiveness of new novel areas of medical device innovation.

We have looked at some of the resources that are available to the public on our collaborative communities Web page, which includes the toolkit as well as a listing of collaborative communities in which we are currently participating.

So while we wait for callers with questions to come into the queue, let's start with some questions that we've received by email.

Irene Aihie: Operator, we will now take questions.

Coordinator: Thank you. At this time to ask a question, please press star followed by number 1. Please unmute your line, record your name clearly as prompted. Again to ask questions from the phone line, please press star followed by number 1.

Dr. Michelle Tarver: One of the first questions that we received by email is what roles can FDA establish through a collaborative community?

And the answer is that any FDA staff member can be a member of a collaborative community in a manner similar to that of other members. However an FDA staff member cannot chair or convene a collaborative community but they can participate in the work stream as well as lend a regulatory perspective to the discussion.

Another question frequently asked is how can CDRH get involved in a collaborative community? And we encourage interested stakeholders to convene their collaborative community, establish their charter and then invite us or request for CDRH to participate.

Our decision to participate as a member is influenced by the public health impact of the community, its alignment with CDRH's regulatory mission and its current priorities and resources.

It is ultimately CDRH's decision whether and to what extent to participate in a collaborative community as well as how to leverage information generated in that collaborative community.

And one of the last questions that we've gotten by email is well, what does CDRH actually do in a collaborative community? Do we actively participate or are we there in a listening mode?

And we, as I have just said before, are members. And as members we participate. We lend a regulatory perspective as well as scientific perspective to the discussions that may be taking place in the community.

The CDRH liaisons that are participating in that collaborative community represent CDRH's regulatory perspective during the meeting. And they will gather information from other CDRH sources to help inform those discussions.

We can take questions now if there are any questions.

Coordinator: Once again on the phone line, if you have a question, please press star followed by number 1, unmute your line and record your name clearly as prompted.

Again, with questions, please press star followed by number 1. I'm showing no questions from the phone line at this time.

Dr. Michelle Tarver: So we really encourage people to consider a collaborative community framework. This approach to solving some of the challenges that exist in different health care communities.

We do know that there are a lot of discussions underway about potential collaborative communities. And we encourage you to reach out to us at CDRH if you are interested in us being members of those collaborative communities.

Thank you for your time and attention today.

Coordinator: We did have a question that came in if you would like to go ahead and take that at this time.

Dr. Michelle Tarver: Please.

Coordinator: Thank you. (Patricia Lehman), your line is open.

(Patricia Lehman): Hi. Thank you for taking my question. I was just interested in knowing how can manufacturers play an active role in the collaborative group?

Dr. Michelle Tarver: So we truly believe that it's important to have all the relevant stakeholders. And as you alluded to, manufacturers are a pertinent stakeholder in that conversation.

There are collaborative communities that I said we have listed on our Web site. And you could send an email to us if there's not a contact information for the collaborative community in which you are participating and we would be happy to connect you with them.

If there are conversations happening with other stakeholders that you know that are interested in tackling a challenge, we encourage you all to consider forming a collaborative community to better address that challenge and invite CDRH to be a participant in that community.

(Patricia Lehman): Thank you.

Coordinator: Thank you. We do have another question. Please stand by. (Allison Kobiana), your line is open. You may ask your question.

(Allison Kobiana): Hi. Thanks so much for this webinar. I know there's a lot of us that are very interested in the collaborative communities and what they might hold for manufacturers.

My question is for pre-submission we have clients currently that are interested in maybe having some members from the collaborative community as part of a pre-submission meeting. How would you go about recommending we request FDA members be included in those meetings?

Dr. Michelle Tarver: So if it's a pre-submission for our consideration, we keep that very separate from the collaborative community effort. We will not be participating in the part - if the collaborative community is working on a medical product, let's say, we would not be participating in that at all.

Obviously anything that is going to come to us for our review is not something that we could provide input on except through our formal recognized mechanisms. So we would work within the same mechanisms that currently exist.

However, if there was a need for a certain tool to be developed that many people in that stakeholder community would need to better understand how a certain device, let's say, could work. That would be something that we could potentially participate in if in a collaborative community if it's not something that would come in for us to regulate.

(Allison Kobiana): Okay. So maybe like an MDDT or something that's a tool that would be useful for that community.

Dr. Michelle Tarver: Correct. Like a questionnaire development or analytic approach.

(Allison Kobiana): Excellent. That's really helpful. Thank you.

Coordinator: And thank you. Once again, if there's any further questions, please press star followed by 1. And I'm showing no further questions.

Irene Aihie: Thank you. This is Irene Aihie. We appreciate your participation and thoughtful questions. Today's presentation and transcript will be made available on the CDRH Learn Web page at ww.fda.gov\training\cdrhlearn by Wednesday, November 6.

If you have additional questions about today's presentation, please use the contact information provided at the end of the slide presentation. As always, we appreciate your feedback.

Following the conclusion of today's live webinar, please complete a short 13 question survey about your FDA CDRH webinar experience. The survey can be found at www.fda.gov\cdrhwebinar immediately following the conclusion of today's live webinar.

Again, thank you for participating. This concludes today's webinar.

Coordinator: And thank you. At this time you may disconnect your lines and thank you for your participation.

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