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Collaborative Communities: Addressing Healthcare Challenges Together

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Agenda

- The FDA's Concept of a Collaborative Community
- When CDRH May Consider Participating in a Collaborative Community
- Current Collaborative Communities with CDRH Participation
- Overview of the Collaborative Communities Toolkit
- Frequently Asked Questions
- Resources
- Q&A

The FDA's Concept of A Collaborative Community

- What Is a Collaborative Community?
- What Collaborative Communities Are Not
- Other Collaborative Groups Compared to a Collaborative Community
- Potential Outcomes of a Collaborative Community

What Is a Collaborative Community?



Collaborative communities are continuing forums where public and private sector members proactively work together to:

- Achieve common objectives and outcomes
- Solve shared challenges
- Leverage collective opportunities in an environment of trust, respect, empathy and openness.

What Collaborative Communities Are *Not*

- They are NOT led by the FDA.
- They are NOT convened by the FDA.
- They do NOT exist to advise the FDA.
- Their membership and governance are NOT directed by the FDA.
- They are NOT task forces, working groups, or commissions.

Other Collaborative Groups Compared to a Collaborative Community

	Task Force	Standards	<i>Collaborative Community</i>
Establishment	Usually initiated by a government entity	Multiple mechanisms	<i>Convened by external partner, but the FDA may be a member of the community</i>
Goals	Provides specific recommendations to address a single issue or concern	One deliverable per workstream that gets updated	<i>Focused on broader outcomes and impacts May have multiple deliverables for each work stream</i>
Lifespan	Limited duration	Potentially sustained, intermittent	<i>Sustained duration with a potentially indefinite lifespan</i>
Members	Involves a more focused group, usually not all stakeholders	Involves a more focused group, usually not all stakeholders	<i>All stakeholders are brought into the effort and have an equal voice in decisions</i>

Potential Outcomes of a Collaborative Community



When CDRH May Consider Participating in a Collaborative Community

- CDRH makes participation decisions on a case-by-case basis, based on:
 - Public health impact
 - Alignment with CDRH mission, priorities and resources
- To help determine whether we will participate, we may consider, for example, whether the community has:
 - A governance structure
 - A convener
 - A plan to measure success
 - A mechanism for sustained engagement

Current Collaborative Communities with CDRH Participation

- Ophthalmic Imaging Collaborative Community
- National Evaluation System for health Technology Coordinating Center (NESTcc) Collaborative Community
 - www.nestcc.org

Overview of the Collaborative Communities Toolkit



Includes best practices for establishing and maintaining collaborative communities:

- Planning the collaborative community
- Gathering members
- Decision making
- Assessing the effectiveness, value and impact of the collaborative community



Frequently Asked Question

Q: When should I talk to the FDA about a collaborative community?

Answer: 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.

If you're interested in having the FDA join as a member of a newly developed or existing Collaborative Community, contact us at CDRHCollabCommunities@fda.hhs.gov

Frequently Asked Question

Q: Does the FDA establish or fund collaborative communities?

Answer: No. The FDA does NOT:

- Establish, manage, or control collaborative communities.
- Provide funding, decide the membership, schedule meetings or set agendas, or control the community's operations.

Collaborative communities can exist without the FDA's participation.

Frequently Asked Question



Q: Are collaborative communities an alternative to standards, federal advisory committees, or other established regulatory processes?

Answer. No. Collaborative communities do not replace established regulatory mechanisms. The FDA will follow good guidance practices, ethics, standards, and other existing process for conducting its business. The FDA's participation in collaborative communities must conform with these existing obligations.

Note that a collaborative community is not a federal advisory committee. For more information on the FDA's advisory committees:

<https://www.fda.gov/advisory-committees/about-advisory-committees>

Frequently Asked Question

Q: Why would I want to be a part of a collaborative community?

Answer: We believe collaborative communities can contribute to improvement in areas affecting U.S. patients and healthcare and result in wide-ranging benefits for public health.

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

Resources

- FDA's Collaborative Communities webpage (includes the toolkit)

<https://www.fda.gov/about-fda/cdrh-strategic-priorities-and-updates/collaborative-communities-addressing-healthcare-challenges-together>

Questions?

About Collaborative Communities:

CDRHCollabCommunities@fda.hhs.gov

About Medical Device Regulation:

Division of Industry and Consumer Education

DICE@fda.hhs.gov

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<http://www.fda.gov/training/cdrhlearn>

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