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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

<table>
<thead>
<tr>
<th>Task Force</th>
<th>Standards</th>
<th>Collaborative Community</th>
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<tbody>
<tr>
<td><strong>Establishment</strong></td>
<td>Usually initiated by a government entity</td>
<td>Multiple mechanisms</td>
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<td><strong>Goals</strong></td>
<td>Provides specific recommendations to address a single issue or concern</td>
<td>One deliverable per workstream that gets updated</td>
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<td><strong>Lifespan</strong></td>
<td>Limited duration</td>
<td>Potentially sustained, intermittent</td>
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<tr>
<td><strong>Members</strong></td>
<td>Involves a more focused group, usually not all stakeholders</td>
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Potential Outcomes of a Collaborative Community

- Research Agenda or Projects
- Peer-Reviewed Publications
- Tool Development
- Best Practices
- Templates or Frameworks
- Health Care Coverage and Reimbursement Decisions
- White Papers
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
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
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.
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)
Questions?

About Collaborative Communities:
CDRHCollabCommunities@fda.hhs.gov

About Medical Device Regulation:
Division of Industry and Consumer Education
DICE@fda.hhs.gov

Slide Presentation, Transcript and Webinar
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