

Collaborative Communities

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Collaboration is Imperative

As we look around us in a new century, we realize that businesses and non-profits in today's interconnected world will neither thrive nor survive with visions confined within the walls of their own organizations. They need to look beyond the walls and find partners who can help achieve greater results and build the vital communities to meet challenges ahead.

---Frances Hesselbein & John C. Whitehead of the PF Drucker Foundation & Harvard Business School

Definitions of Collaboration



Process through which parties who see different aspects of a problem can constructively explore their differences and search for solutions that go beyond their own limited vision of what is possible

Barbara Gray

Mutually beneficial relationship between two or more parties who work toward common goals by sharing responsibility, authority and accountability for achieving results

David Chrislip & Carl Larson





Goal

Establish our participation in at least 10 new Collaborative Communities by December 31, 2020



Definition of Collaborative Communities

Continuing forums where public and private sector members proactively work together to achieve common objectives and outcomes, to solve shared challenges and to leverage collective opportunities in an environment of trust, respect, empathy, and openness.

These communities are **not convened by FDA** and are not task forces, working groups, or commissions, which typically address narrowly-defined problems and disband after developing a final deliverable. Instead, collaborative communities **are convened by interested stakeholders**.

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.



Definition of Collaborative Communities (cont.)

Include diverse, relevant organizations and individuals impacted by the topic

which may include but are not limited to the following: patients, care-partners, academicians, healthcare professionals, healthcare systems, payers, federal and state agencies, international regulatory bodies, and industry.



As appropriate, FDA may support, leverage, and/or adopt solutions that emerge from the Collaborative Communities, consistent with the statute, regulations, and agency priorities, and in the best interest of public health.



Characteristics of Collaborative Communities

Sustained

Leadership is broadly distributed

Trustworthy

Empathetic

Reciprocal

Inclusive

Cultivates an ethic of contribution

Effective informal communication



Why Collaborative Communities?

A collaborative community may be appropriate when one or more of the following conditions are met:

- Ill-defined challenges or no consensus on the definition of the challenges
- Challenges and outcomes are complex (e.g., multidimensional)
- Interrelatedness of the partners
- Incremental or unilateral efforts to address the challenge has been ineffective
- Partners seek to optimize efforts, including preventing duplication of efforts
- Could achieve better outcomes with integrating different perspectives, experiences, resources, power, and expertise





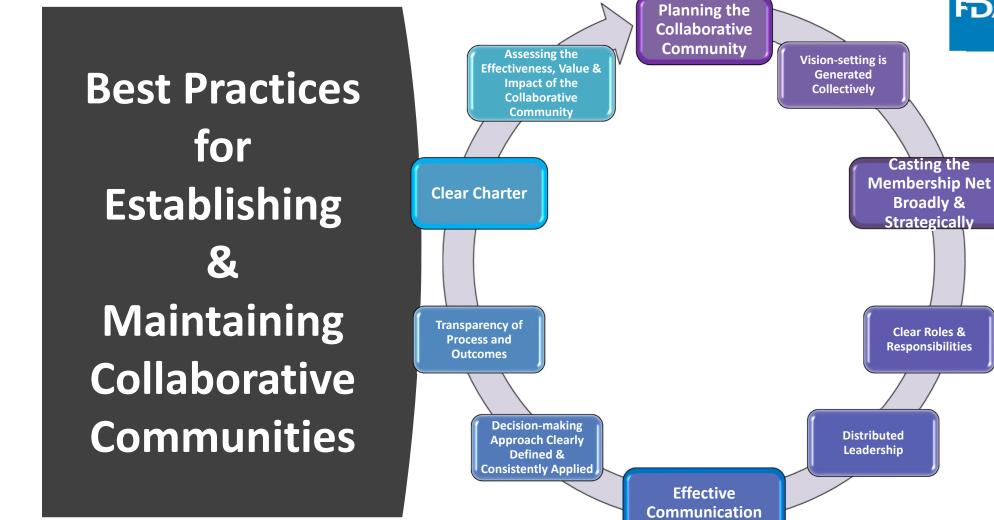
September 2018



Draft Collaborative Communities Toolkit

- A resource to help stakeholders interested in establishing Collaborative Communities
- Please visit CDRH website

(https://www.fda.gov/AboutFDA/Centers Offices/OfficeofMedicalProductsandToba cco/CDRH/CDRHVisionandMission/ucm6 21433.htm#download)



FDA

Broadly &

Clear Roles &



Sectors for Potential Members

Patient & Consumer Advocacy Organizations

Academia

Hospital Systems

Trade Associations

Device Manufacturers

Medical Device Distributors

Professional Societies/

Associations/

Organizations

Payers

Research Institutions

State, Federal and International Organizations

Foundations

Public-Private Partnerships



Example of Potential Roles & Responsibilities

Member

Participates

Convener

Coordinates and hosts meetings

Facilitator

 Executes agenda and manage deviations and or conflicts

Chair

Responsibility of ensuring objectives are met

Leaders

For subcommittees, work streams, or projects



Assessing Effectiveness, Value & Impact

1

Assessing the effectiveness of collaborating

2

Assessing the impact of outcomes from Community

3

Assessing the value of the Community for each member



Potential Deliverables

Guidance

Standard

White paper

Peer-reviewed publication

Research agenda and projects

Proposed regulation

Proposed legislation

Best practices

Tool development

Culture change

Paradigm shift





FDA

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Questions about Collaborative Communities:

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Information on Strategic Priority:

https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsand Tobacco/CDRH/CDRHVisionandMission/UCM592693.pdf

www.fda.gov

Collaborative Community



Thank You

