

Collaborative Communities Toolkit

September 2019

PREAMBLE

The Food and Drug Administration's (FDA's) Center for Devices and Radiological Health (CDRH) compiled this toolkit as a resource for potential collaborative communities who are interested in establishing their nascent communities on a firm foundation. This toolkit provides a collection of helpful ideas to foster effective collaboration, which can lead to stronger collaborative communities that are well-prepared to take on healthcare challenges. Each component of this toolkit may help existing as well as burgeoning communities effectively interface with their membership, including potentially FDA CDRH in appropriate circumstances.

The toolkit is not meant to be prescriptive and does not constitute agency policy or guidance. In addition, the references cited herein are for informational purposes only and should not be construed as endorsements. We hope that this toolkit will be helpful to those who wish to consider forming a collaborative community.

Table of Contents

- DEFINITION OF COLLABORATIVE COMMUNITIES 3
- BEST PRACTICES FOR ESTABLISHING AND MAINTAINING COLLABORATIVE COMMUNITIES 4
 - Planning the Collaborative Community 4
 - Vision-setting Generated Collectively 5
 - Casting the Membership Net Broadly and Strategically 5
 - Clear Roles and Responsibilities..... 6
 - Distributed Leadership..... 7
 - Effective Communication 7
 - Decision-making Approach Clearly Defined and Consistently Applied..... 8
 - Transparency of Process and Outcomes..... 8
 - Clear Charter 9
 - Assessing the Effectiveness, Value and Impact of the Collaborative Community..... 9
 - Assessing Effectiveness of a Collaborative Community..... 10
 - Assessing Impact and Outcomes of a Collaborative Community 11
 - Assessing Value of a Collaborative Community 12
- CONCLUSION..... 14

DEFINITION OF COLLABORATIVE COMMUNITIES

Collaborative communities are 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.

Purpose

Collaborative communities are equipped to perform activities such as developing best practices and robust strategies for addressing challenges; generating and evaluating evidence that supports novel approaches; and disseminating and implementing solutions. The communities may also work to clarify ill-defined challenges or generate consensus on the definition and scope of the challenge which will aid in tailoring appropriate strategies to tackle those challenges. By leveraging the wide variety of resources, power and expertise of the community members, collaborative communities can help address challenges and opportunities related to medical devices.

Members

Collaborative communities 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.

While the leadership of a collaborative community is typically distributed among all members and not hierarchical, the community may have a convener to coordinate and facilitate effective collaboration. Collaborative communities are not led by the FDA and do not exist to advise the FDA. Collaborative communities do not replace established regulatory mechanisms. FDA might choose to participate as an active member of a collaborative community and help foster progress toward the community's goals. 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.

BEST PRACTICES FOR ESTABLISHING AND MAINTAINING COLLABORATIVE COMMUNITIES

There are many resources that describe practices that help to foster collaboration.^{1,2,3,4,5,6,7} While we have not generated a comprehensive bibliography of all potentially useful references about collaborations, the ones listed below cross various sectors in which collaborations have been employed. The best practices listed below reflect those recurrent themes that have been identified as contributing to successful collaborations. We encourage collaborative communities to consider these factors when establishing and developing sustained collaborative communities.

Building trust is a core value of many collaborations. Without purposeful and consistent efforts to foster trust, well-designed collaborations may not be successful. This might include airing perceptions of bias, clarifying expectations, and closing the perceived space between members' viewpoints. Trust can only exist in the setting of mutual respect, a shared vision, clear roles, and transparency.

Planning the Collaborative Community

Collaborative communities allow for multiple stakeholders to work collectively to achieve shared outcomes and address shared challenges relevant to medical devices. In preparation for forming a collaborative community, best practices encourage clear identification of the challenge or opportunity, and clear definition of the scope of involvement. Some steps for consideration involve determining whether a long-term investment of time and resources is needed to achieve success or whether a different approach may be more appropriate for tackling the identified challenge. Planning also involves identifying the relevant members (which may be modified over time), goal setting, identifying potential road blocks (e.g., financial resources), determining what skills are needed to accomplish goals, and determining how the outcomes of the collaborative community are communicated to the wider community. Appropriate prospective planning is viewed as critical and may impact the trust that members have in the overall effort.

To foster trust, it is often suggested that the initial contact with members be made in person to facilitate the development of interpersonal relationships among the members. This step not only helps to generate trust but also to establish behavioral norms. In addition, clearly defining explicit and implicit roles, and eliciting the

¹ London S. Building Collaborative Communities. In *On Collaboration*, edited by MB Mortenson and J Nesbitt. London: Tate, December 2012.

² Adler P, Heckscher C, Prusak L. Building a Collaborative Enterprise. *Harvard Business Review* (2011) 89: 94.

³ Collaboration for Impact. Available at www.collaborationforimpact.com. Accessed 18 September 2018.

⁴ Valaitis R, Meagher-Stewart D, Martin-Misener R, et al. Organizational Factors Influencing Successful Primary Care and Public Health Collaboration. *BMC Health Services Research* (2018) 18: 420.

⁵ Ehrlichman D, Sawyer D, Spence M. Cutting Through the Complexity: A Roadmap for Effective Collaboration. *Stanford Social Innovation Review*. March 15, 2018.

⁶ Huggett J. Why Collaborations Fail. *Stanford Social Innovation Review*. June 4, 2018.

⁷ Social Entrepreneurs, Inc. Building and Sustaining Effective Collaborations. Available at <https://alliancefornevadanonprofits.com/wp-content/uploads/2011/09/Research-Brief-Building-and-Sustaining-Collaborations.pdf>. Accessed 18 September 2018.

expectations of the members during the early stages of forming the collaboration may mitigate downstream relationship challenges.

The establishment process of a collaborative community may not be linear from birth to maturity but rather cyclical, going through phases of exploration, development, and creative destruction or transformation on its way to maturity. Remaining flexible and open through the planning process is key, and members may opt to revisit the collaborative community's goals and objectives over time. Reassessment of the status of the community is not viewed as an indicator of failure, but instead a marker of the members' willingness to evaluate and strengthen the community and help ensure its success.

Vision-setting Generated Collectively

The collaborative community is focused on tackling complex challenges that impact multiple stakeholders with potentially different perspectives about the causes and solutions. Therefore, one important initial step may be the creation of a shared vision and the plan to sustain that vision for the collaborative community. To come to a common vision, it is helpful if all members actively participate in shaping the vision of the community. These visionary meetings can clearly delineate group and individual goals, aid in fleshing out the needed stakeholders and facilitate commitment to accomplishing the goals.

Casting the Membership Net Broadly and Strategically

At the start of the collaborative community, it is important to identify the perspectives, knowledge, and skills of potential members needed to address and implement the collaborative effort. Ideally, members of the collaborative community

- Care about the issue being addressed;
- Are impacted by the issue; and/or
- Have knowledge and skills to help address the issue.

Integral to any collaborative effort is identifying the relevant members who are invested in solving the community's challenges and providing diverse perspectives. The following is a list of sectors from which potential members of a collaborative community might be selected. The following list is not intended to be all-inclusive or exhaustive:

- Patients and Care-partner Organizations
- Hospitals/Hospital Systems
- Public-Private Partnerships
- Trade Associations
- Technology Manufacturers
- Medical Device Distributors

- Professional Societies/Associations/ Organizations
- Payers
- Research Institutions
- Academic Institutions
- Other State & Federal Agencies
- International Organizations
- Foundations & Other Non-profits

It is important that the size of the collaborative community's membership roster be adequate to elicit diverse perspectives and generate thoughtful discussions; but not too large that it impedes efficient and effective group functioning. Although suggestions of membership size ranging from 6 – 20 members have been made by other collaborative groups, the ideal number for the community may be related to the forum through which the community meets (e.g., in-person, online), the scope of the topic to be addressed by the community, and the need for adequate representation and buy-in of key stakeholder communities.

Multidisciplinary membership may help avoid systematic biases and foster an appreciation for all voices.⁸ The collaborative community may also want to include certain types of members with expertise suited to particular issues, such as methodologists to help generate and appraise evidence, and health economists to help with value assessments, if applicable. By also including patients and healthcare consumers, the collaborative community can integrate unique insights and provide some assurance that the work products were developed with input from those who may be most affected. Patient training may empower the patients and healthcare consumer members to more fully participate.

Clear Roles and Responsibilities

An important characteristic of a high performing collaborative community is a results-driven structure. This characteristic reflects the need of every group to organize itself in a way that enables it to be productive and, ultimately, to achieve what it has set out to do. Clear roles and responsibilities are considered by many to be a necessary feature of such a structure. To effectively accomplish the collaborative community's objectives, each member would typically have a clear understanding of her or his function and the tasks and activities for which each member is responsible. At the outset of a community's work and as new members are invited to participate, members' roles and responsibilities are discussed and clarified. While there is no one approach to

⁸ Shekelle PG, Woolf SH, Eccles M, et al. Clinical guidelines: Developing Guidelines. *BMJ* (1999) 318:593.

determining the roles, various organizations have amassed helpful information about roles that have been used in other successful collaborative efforts.^{9,10}

Working together is the hallmark of a successful collaborative community. Communities are most successful when all members actively contribute by sharing their ideas and concerns, creating solutions and back up plans, pursuing needed resources, and contributing their perspective, experience, and skills to help accomplish collective goals. Questions are encouraged and can facilitate a deeper understanding of the challenges and opportunities at hand. Communication among members is essential with ongoing communication set as an expectation to further foster trust and maintain engagement.

Distributed Leadership

Many models of leadership have been suggested for collaborative efforts. One potential leadership model for the collaborative community is a distributed model instead of a hierarchical one, with all members sharing the responsibility of ensuring the work progresses.¹¹ One potential approach to distributing leadership is having a chair that changes every 6 months to 1 year, thereby, giving everyone ownership of advancing the community's objectives. In addition, a facilitator model may help build trust and ensure that all members are equal partners in the effort. Using a skilled facilitator who may not be an expert in the topic area might help to maintain a neutral position during discussions, ensure all members have an opportunity to contribute, and help resolve conflicts should they arise. The meeting facilitator position could potentially rotate as well depending on the work stream.¹²

It may be useful to identify a convener or project management team to handle the logistics of holding meetings, assembling the necessary documents and keeping the minutes. The convener might also help with determining the need for additional resources (e.g., contracts, other formal agreements) that may be needed for intellectual property generated by the collaborative community or exchange or handling of confidential information.

Effective Communication

Respect, trust, and empathy are integral to successful collaborations. Creating an environment where members feel safe and respected enhances sharing ideas, discussing challenges, and developing solutions, which can lead to sustained collaborative communities. Collaborative communities are working environments where sensitive information may be discussed. Encouraging members to collectively agree upon what, when,

⁹ Collaborative Leaders Network. 2018. *What is a Convener?* Available at <https://collaborativeleadersnetwork.org/leaders/the-role-of-the-convener/>. Accessed 19 September 2018.

¹⁰ Collaborative Leaders Network. 2018. *Should We Be Using a Facilitator?* Available at <https://collaborativeleadersnetwork.org/leaders/should-you-be-using-a-facilitator/>. Accessed 19 September 2018.

¹¹Ogden C. Roles of Collaborative "Leadership". *Interaction Institute for Social Change*, 2011. Available at <http://interactioninstitute.org/roles-of-collaborative-leadership/>. Accessed 18 September 2018¹²Principled Leadership. Center for Effective Public Policy, 2013. Available at <http://www.collaborativejustice.org/how/leadership.htm>). Accessed 18 September 2018.

¹²Principled Leadership. Center for Effective Public Policy, 2013. Available at <http://www.collaborativejustice.org/how/leadership.htm>). Accessed 18 September 2018.

and how information will be shared in their community, and how any outcomes generated by the community are communicated outside of community members, may help build and foster trust in the collaborative community.

Effective communication is often accomplished with the assistance of digital platforms and collaborative software. Functions such as real-time collaborative editing and version control platforms as well as scheduling and conferencing tools allow for efficiencies in achieving common goals. When choosing which collaborative software to use, the collaborative community may want to survey the members to identify any barriers to effective communication.

Decision-making Approach Clearly Defined and Consistently Applied

Regardless of the decision-making framework for a collaborative community, clearly defining how decisions will be made within the collaboration and consistently applying the approach may help sustain the collaboration. While the decision-making could involve a group consensus, the collaborative community is encouraged to determine the process by which consensus may be reached. Formal techniques such as the Delphi method¹³ or balloting may be applicable for some decisions, but a more informal approach may be warranted for other decisions. The collaborative community could create a visual ‘road map’ which illustrates the process by which decisions are made, implemented, and reassessed.

Transparency of Process and Outcomes

Financial and non-financial conflicts of interest can compromise the exchange of ideas and trust of those ideas within a community.¹⁴ Consistent with published recommendations to disclose financial and non-financial conflicts of interest, collaborative communities also may seek to share and manage any potential conflicts or appearances of conflicts of interest in a transparent manner. These conflicts may include, but are not limited to, personal convictions, leadership board memberships, and consulting arrangements. To mitigate any concerns about the integrity of the process, the collaborative community may want to consider determining proactively how to handle conflicts of interest and prevent them from impeding the creation or implementation of solutions.

Transparency of the community’s recommendations or the work product and the process by which it was generated can foster implementation of those recommendations. Depending on the intended end-user of the work product, greater granularity may be desired, regarding how the decision was made (e.g., clinical guideline/guidance may need to clearly disclose what information/process led to each recommendation).¹⁵

¹³ Linstone HA and Turoff M. *The Delphi Method: Techniques and Applications*. Reading, MA: Addison-Wesley Publishing Co., Advanced Book Program, 1975. Available at <http://is.njit.edu/pubs/delphibook/> . Accessed 19 September 2018.

¹⁴ Institute of Medicine of the National Academies. *Conflict of Interest in Medical Research, Education, and Practice*. Editors Lo B and Field MJ. Washington, DC: The National Academies Press, 2009.

¹⁵ Shekelle PG, Woolf SH, Eccles M, et al. Clinical Guidelines: Developing Guidelines. *BMJ* (1999) 318:593.

Clear Charter

Charters are often developed to describe the collaborative arrangements, the rationale, goals and roles and responsibilities of participants. Charters are a tool used to align the expectations of all the members of any collaborative effort. Charters typically document the following:

- reasons for establishing the community, including what events or policies prompted the members to believe a collaborative community was needed;
- the shared outcomes/challenges on which the collaborative community is focused to contribute solutions;
- objectives and constraints of the collaboration;
- in-scope and out-of-scope items or topics;
- the relevant stakeholders;
- governance structure which may include the meeting frequency, decision-making framework, and the high-level budget for the community; and
- timelines for the effort.

The charter may include other components as well. Community members may collectively generate a charter that reflects their values and priorities.

Assessing the Effectiveness, Value and Impact of the Collaborative Community

In comprehensively evaluating itself and the members, a collaborative community may consider three perspectives:

- 1) assessment of whether the group of diverse stakeholders that make up a community are working **effectively** in a collaborative manner;
- 2) assessment of the **impact** that the collaborative community is having on the larger ecosystem through solving identified challenges and proactively building for the future; and
- 3) assessment of the **value** that participating in the collaborative community generates for each contributing member.

Assessment of each of these perspectives may occur concurrently or progressively during the evaluation process. **Table 1** below outlines a framework for consideration which may be used to develop each of these assessments.

Table 1. Sample Assessment Framework: Three Perspectives for Evaluating a Collaborative Community and the Value of Participation.

Evaluating the Effectiveness, Outcomes/Impact and Value of a Collaborative Community	
<p>Effectiveness of a Collaborative Community</p> <p><i>Is a collaborative community advancing collaboration maturity?</i></p>	<p>The intention of a collaborative community is to provide a forum built and operating through:</p> <ul style="list-style-type: none"> • Engagement • Trust • Transparency • Democracy and Inclusiveness • Reciprocity <p>Each collaborative community will assess its development and execution of these attributes.</p> <p>Measuring: Progress towards advancing the values and practices that enable collaboration maturity and success in a collaborative community.</p>
<p>Outcomes & Impact of a Collaborative Community</p> <p><i>What impact is a collaborative community having on the focus area?</i></p>	<p>A collaborative community has the greatest impact when the members work collectively to identify and solve problems that directly impact or are of importance to their focus area.</p> <p>Each collaborative community will identify an important problem, define the purpose of solving it, and clarify how it will collectively make progress.</p> <p>Measuring: Impact, outcomes and progress of a collaborative community in a focus area.</p>
<p>Value of Collaborative Communities</p> <p><i>How well is the collaborative community contributing to achieving the member's vision?</i></p>	<p>The member's participation in and support of a collaborative community directly contributes to more effectively accomplishing the vision of the member's organization and helping meet its commitments.</p> <p>The member intends to develop and utilize a set of performance measures to better understand how collaborative communities directly contribute to the mission of his or her organization.</p> <p>Measuring: Value to the member of collaborative communities.</p>

Assessing Effectiveness of a Collaborative Community

When a collaborative community is initially convened, it is essentially collaborative in name only. According to one commentator,¹⁶ every team or community will go through different stages of development before reaching the desired stage of performing effectively in a collaborative manner. Recognizing this, a collaborative community may seek to understand and assess the progress of the community as it moves towards a collaborative state which would be characterized by such factors as open communication, sharing of information, **high levels of trust, active engagement**, and joint decision-making. Global, validated

¹⁶ Tuckman B. Developmental sequence in small groups. *Psychological Bulletin* (1965) 63: 384. Also in https://en.wikipedia.org/wiki/Tuckman%27s_stages_of_group_development. Accessed 19 September 2018.

collaboration measurement tools are one way of consistently and reliably assessing the effectiveness of a collaborative community. One example of a validated tool is *the Wilder Collaboration Factors Inventory*¹⁷ which can be used to gauge which components contribute to a productive and thriving collaboration over time. This tool can be used separately or in addition to the *Collaboration Evaluation and Improvement Framework (CEIF)*. The CEIF is a theoretical framework for evaluating collaboration across a continuum of stages of organizational development, including (1) operationalizing the construct of collaboration, (2) identifying and mapping stakeholder communities, (3) monitoring the stages of development, (4) assessing the levels of organizational integration over time, and (5) assessing cycles of inquiry.^{18, 19} These tools are detailed in **Table 2** and may be adapted to more adequately reflect unique aspects of a particular collaborative community.

Information gleaned from these tools may be augmented with other metrics such as the completion of key milestones (e.g., charter establishment, vision setting, consensus challenge/problem statements). Metrics may be useful to guide the community's efforts.

Assessing Impact and Outcomes of a Collaborative Community

Each collaborative community establishes itself around areas where challenges exist that require the active engagement of different stakeholders in the ecosystem. Focus areas may include those that contribute to ensuring that patients in the US ultimately have access to high-quality, safe, and effective medical devices of public health importance first in the world. As these communities stand up, they task themselves with clearly articulating their purpose and outlining their course of action to measure the **acceptance levels** and ultimately the **adoption levels** of their work products within the ecosystem. A collaborative community may decide to develop a measurable purpose based on a challenge they seek to solve, as well as outline specific deliverables or work products that would contribute to achieving its purpose. Collaborative communities may decide to include some measures of success to capture the extent to which the measurable purpose, desired result or changed state is achieved.^{20,21}

¹⁷ Mattessich, P. W., Murray-Close, M., Monsey, B. R., & W., M. P. *The Wilder collaboration factors inventory: Assessing your collaborations strengths and weaknesses*. Saint Paul, MN: Fieldstone Alliance, 2001.

¹⁸ Gajda, R.H. (2004). Utilizing Collaboration Theory to Evaluate Strategic Alliances. *Journal of Research in Crime and Delinquency*, journals.sagepub.com/doi/abs/10.1177/109821400402500105.

¹⁹ Woodland, R. H., & Hutton, M. S. Evaluating Organizational Collaborations. *American Journal of Evaluation* (2012) 33: 366.

²⁰ See, for example, US Environmental Protection Agency. *Program Evaluation and Performance Measurement at the EPA*. Available at <https://www.epa.gov/evaluate/program-evaluation-and-performance-measurement-epa#programevaluation>. Accessed September 9, 2019.

²¹ See, for example, US Department of Health and Human Services, Health Resources and Services Administration. *Performance Management and Measurement*. April 2011. Available at <https://www.hrsa.gov/sites/default/files/quality/toolbox/508pdfs/performanceandmeasurement.pdf>. Accessed September 9, 2019.

For example, one approach to developing measures of success is **outcome-based** planning (shown in **Figure 1**).

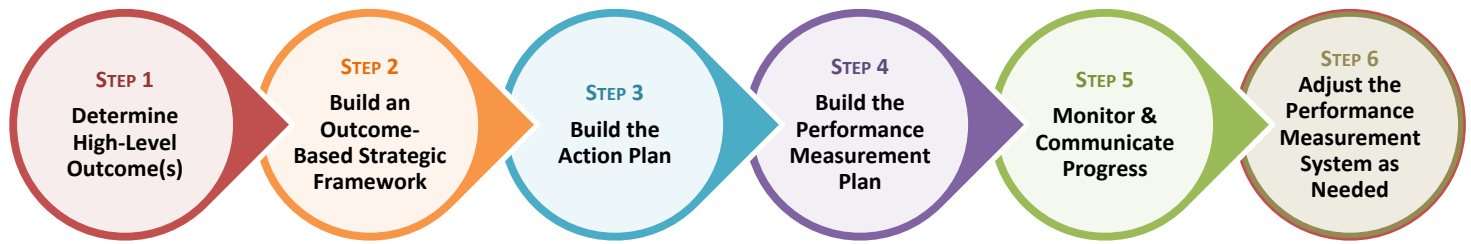


Figure 1. Process from Determining the High-Level Outcome to Implementing the Performance Management System.

This approach may help:

- Build consensus and accountability with key partners and stakeholders around shared outcomes;
- Ensure that the planned activities reflected in the collaborative community’s action plan are aligned with the high-level outcomes;
- Facilitate appropriate adjustments to activities or strategies based on measurable progress; and
- Provide an effective communication tool that succinctly expresses the key elements of the community’s intent and activities.

Other approaches could be used to develop measures of success for the collaborative community, and it is important that all stakeholders are empowered to engage in those discussions.^{22, 23}

Assessing Value of a Collaborative Community

Although the interests of each participating organization might be different, each member will actively assess the **benefits** that participating in a collaborative community provides to them as well as the **cost** level (financial or otherwise) to ensure that a compelling **value proposition** is maintained for each member and his or her organization. Being clear on these two pieces of information (benefits and investments) allows all members to make informed decisions about how to proceed moving into the future, which could include such decisions as maintaining, increasing or decreasing involvement with the community.

²² Centers for Disease Control and Prevention, P. P. (2018, March 26). *CDC Evaluation Documents, Workbooks and Tools*. Retrieved from CDC Evaluation Resources: Available at <https://www.cdc.gov/eval/tools/index.htm>. Accessed September 11, 2019.

²³ NOAA Office for Coastal Management. (2019, August 26). *How to Write a Strategic Plan*. Retrieved from NOAA Office for Coastal Management. Available at <https://coast.noaa.gov/digitalcoast/training/write-strategic-plan.html>. Accessed September 11, 2019.

Table 2. Sample Tools for Measuring Collaborative Communities.

Selecting A Framework and Methodology

Evaluation or Assessment Framework	Description	Suggested Uses
<p><i>Wilder Collaboration Factors Inventory</i>²⁴</p>	<p>The Wilder Collaboration Factors Inventory is based on research by Wilder Research Center to establish what components contribute to a productive and thriving collaboration. The researchers identified twenty factors that influence the effectiveness of collaboration.</p>	<p>The Wilder Collaboration Factors Inventory is best used when planning a collaboration as well as throughout the course of a collaboration. It can be taken by a small group of collaborators or by multiple people or numerous collaborating organizations. The Inventory can be used at the inception of a collaboration and then either every six months or annually to assess the strengths and weaknesses of an ongoing collaboration. The Inventory and scoring sheet are available electronically. It is designed for group leaders or members to use as a self-assessment and may be used to guide best practices and improvements.</p>
<p><i>Collaboration Evaluation and Improvement Framework (CEIF)</i>²⁵</p> <ul style="list-style-type: none"> • <i>Operationalizing Collaboration</i> • <i>Membership Inventory and Mapping</i> • <i>Data Collection or Discussion Questions</i> • <i>Levels of Organizational Integration Rubric (LOIR)</i> • <i>Team - Collaboration Assessment Rubric (TCAR)</i> 	<p>The Collaboration Evaluation and Improvement Framework (CEIF) is a theoretical framework for evaluating collaboration across five developmental phases, including a) operationalizing the construct of collaboration, 2) identifying and mapping communities of practice, 3) monitoring stage(s) of development, 4) assessing levels of integration, and 5) assessing cycles of inquiry.</p> <ul style="list-style-type: none"> • Operationalizing Collaboration actions involve improving evaluator and stakeholder collaboration literacy. • Membership Inventory and Mapping is a process activity within Phase 2 of the CEIF. The goal is to identify and map groups within an organizational partnership, with a focus on those that are responsible for the central work of the Community. • Data Collection and Discussion Questions are intended to help monitor stages of collaboration development. • LOIR is a rubric, or scoring tool, used to gauge levels of organizational integration over time. It describes five levels (from zero to four) and the associated 	<p>CEIF includes suggested actions and tools that can be used to a) define and describe a collaboration, b) measure the attributes of organizational collaboration, and c) increase stakeholder capacity to apply efficient and effective collaborative behaviors. It is intended to be used by evaluators but also includes qualitative and quantitative data collection strategies and measurement tools that can be used for self-assessment in different contexts. Using the CEIF to operationalize and assess a collaboration may help connect collaborative efforts to desired impact and outcomes.</p> <ul style="list-style-type: none"> • Operationalizing Collaboration actions are intended to provide a theoretical framework to inform planning and evaluation efforts. • Membership Inventory and Mapping can be used to identify high leverage groups within a Collaborative Community, as well as understand team and individual member involvement to inform decision-making. This may also be used to reconfigure team membership to improve Collaborative Community performance. • The Data Collection Discussion Questions can be used for face-to-face or virtual interviews with Collaborative Community leaders or members. They can also be used to conduct an electronic survey or

²⁴ Mattessich, P. W., Murray-Close, M., Monsey, B. R., & W., M. P. *The Wilder collaboration factors inventory: Assessing your collaborations strengths and weaknesses*. Saint Paul, MN: Fieldstone Alliance, 2001.

²⁵ Woodland, R. H., & Hutton, M. S. Evaluating Organizational Collaborations. *American Journal of Evaluation* (2012) 33: 366.

Evaluation or Assessment Framework	Description	Suggested Uses
	<p>purposes, strategies and tasks, leadership and decision making, and communication features that are typically present at each level of integration.</p> <ul style="list-style-type: none"> • TCAR is a survey tool and rubric to assess the quality of interprofessional collaboration within individuals, teams, and Collaborative Communities. 	<p>simply to generate a team discussion during a meeting. This may help stakeholders manage a Community's progression through each of the partnership development stages and ensure that the Community meets its shared goals.</p> <ul style="list-style-type: none"> • LOIR can be used to understand levels of linkages between partners to informal opportunities for improvement and directions for future growth. This rubric can be used for summative or formative assessment, and best practices encourage reassessment every six months during a collaboration. It is intended to be used by an evaluator but can also be used for group self-assessment. • TCAR can be used to assess quality of team dialogue, decision-making, action-taking, and evaluation, to improve performance. This rubric can be used for summative or formative assessment, and best practices encourage reassessment every six months during a collaboration. It is intended to be used by an evaluator but can also be used for group self-assessment.

CONCLUSION

Each collaborative community establishes itself around challenges that benefit from active engagement of diverse stakeholders in the ecosystem. FDA CDRH believes collaborative communities can contribute to improvements in important areas affecting U.S. patients and healthcare. In addition, FDA CDRH participation in a collaborative community may help advance the agency's goals of ensuring that patients in the US ultimately have access to high-quality, safe, and effective medical devices of public health importance first in the world. While each community may be unique, they may encounter similar needs and challenges as they work through early stages of formation. FDA CDRH compiled this toolkit as one potential resource for new and emerging collaborative communities to aid in positively impacting public health.