

# Stakeholder Community and Outreach Center: Operational Framework – Option Year 2

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## TASK & DELIVERABLE:

Deliverable 2.1: Deliver Final Revised Charter and Operational Framework



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# Purpose of Operational Framework

The purpose of this Operational Framework is to provide direction for the Stakeholder Community and Outreach Center (the Stakeholder Center) of the Clinical Decision Support Innovation Collaborative (CDSiC) regarding process and day-to-day matters.

The Stakeholder Center will:

- Establish four stakeholder-led Workgroups focused on key topic areas: 1) Measurement and Outcomes, 2) Implementation, Adoption, and Scaling, 3) Trust and Patient-Centeredness, and 4) CDS Standards and Regulatory Frameworks.
- Develop 12 high-quality, written products across the Center that will inform the activities of CDSiC and support the external community in advancing the design, development, implementation, and measurement of CDS.
- Provide thought leadership across CDSiC in conjunction with the CDSiC Steering Committee to inform the direction of the collaborative and its work products.

This document describes the Stakeholder Center's structure and processes, specifically the composition of the Stakeholder Center Planning Committee and the Center's four Workgroups as well as scheduling, reporting, and workflows of Stakeholder Center activities.

The primary audiences of this Framework are the Agency for Healthcare Research and Quality (AHRQ), the Stakeholder Center leadership, and the Stakeholder Center Planning Committee. The Framework will be ratified by the Project Directorate and the Stakeholder Center Planning Committee. The Framework will be publicly available on the CDSiC website.

## Stakeholder Center Structure

The Stakeholder Center will consist of three components: 1) Center leadership, including a Stakeholder Center Planning Committee, that will provide oversight, 2) four topic-focused Workgroups that will be dedicated forums for stakeholder engagement and product development, and 3) additional support staff that will ensure the timely completion of key Center activities.

**Stakeholder Center Leadership.** Priyanka Desai from NORC at the University of Chicago (NORC) will lead the Stakeholder Center. She will work collaboratively with Workgroup leadership to ensure that each Workgroup provides meaningful input to CDSiC activities and creates products to help advance CDS development and implementation. Desai, along with CDSiC Principal Investigator (PI) Prashila Dullabh, Co-Investigators Dean Sittig and David Lobach, Workgroup Chairs and Associate Leads (see below), and AHRQ project leadership will form the Stakeholder Center Planning Committee.

**Workgroup Structure and Leadership.** Each Workgroup will have up to 15 members, consisting of two Workgroup co-leaders and volunteer members. Additionally, each Workgroup will have a Support

Lead. The Workgroup leadership structure is described in Exhibit 1. The CDSiC PI, Co-Investigators, and Stakeholder Center leadership will identify appropriate volunteer members. Upon approval by AHRQ, volunteer members will be solicited for participation by Stakeholder Center leadership.

**Exhibit 1. Workgroup Leadership**

Workgroup	Proposed Leadership
<b>Measurement and Outcomes</b>	<ul style="list-style-type: none"> <li>• <b>Co-Lead: Polina Kukhareva, PhD, MPH, FAMIA (University of Utah)</b></li> <li>• <b>Co-Lead: Mustafa Ozkaynak, PhD, MS (Colorado University)</b></li> <li>• Support Lead: Rachel Kurtzman, PhD (NORC)</li> </ul>
<b>Implementation, Adoption, and Scaling</b>	<ul style="list-style-type: none"> <li>• <b>Co-Lead: Ken Kawamoto, MD, PhD, MHS, FACMI, FAMIA (University of Utah)</b></li> <li>• <b>Co-Lead: David Lobach, MD, PhD, MS (Elimu Informatics)</b></li> <li>• Support Lead: Krysta Heaney-Huls, MPH (NORC)</li> </ul>
<b>Trust and Patient-centeredness</b>	<ul style="list-style-type: none"> <li>• <b>Co-Lead: Jessica Ancker, PhD, MPH, FACMI (Vanderbilt University)</b></li> <li>• <b>Co-Lead: Angela Dobes, MPH (Crohn’s &amp; Colitis Foundation)</b></li> <li>• Support Lead: Avantika Shah, MPH (NORC)</li> </ul>
<b>CDS Standards and Regulatory Frameworks</b>	<ul style="list-style-type: none"> <li>• <b>Co-Lead: Aziz Boxwala, MD, PhD, FACMI (Elimu Informatics)</b></li> <li>• <b>Co-Lead: Rachel Richesson, PhD, MPH, MS (University of Michigan)</b></li> <li>• Support Lead: Desirae Leaphart, MPH, PMP (NORC)</li> </ul>

**Team Support Staff.** Additional support staff will work with Workgroup leadership to help with meeting planning and logistics as well as product development. They will also communicate regularly with Stakeholder Center Lead Desai about potential operational challenges or concerns. Additionally, a team of NORC staff will support the development of the Center-wide product.

## Stakeholder Center Planning Committee

**Planning Committee Primary Function.** The Stakeholder Center Planning Committee (Desai, PI Dullabh, Co-Investigators Sittig and Lobach, Workgroup Chairs and Associate Leads, and AHRQ leadership) will provide input on the overall strategic direction and coordination of the Stakeholder Center as well as the collaborative as a whole. This input will involve:

- Meeting regularly to provide strategic guidance and direction on key decisions that relate to the Workgroups, the CDSiC Innovation Center, or the collaborative.
- Facilitating cross-Workgroup synergy and coordination through regular communication.
- Providing strategic input into Operations Center and Innovation Center activities based on Workgroup activities.

**Planning Committee Meetings and Communications.** The Planning Committee will convene virtually three times throughout the Option Year to facilitate regular communication. The Planning Committee

will schedule ad hoc meetings as needed. Desai will moderate each meeting. In between meetings, the Planning Committee will use the CDSiC SharePoint Website to facilitate asynchronous work. As needed, Desai will provide a bulleted list of updates via email to the Planning Committee to highlight future meeting agenda items.

Desai will circulate a draft agenda and materials (e.g., slide decks, background documents) at least one business day prior. During the meetings, PI Dullabh and/or Co-Investigators will provide Steering Committee and Innovation Center Planning Committee updates to facilitate cross-communication among CDSiC activities. Within 14 days of each meeting, Desai will provide AHRQ with meeting minutes and materials.

## Stakeholder Center Workgroups

**Workgroups Primary Function.** Through the Workgroups, the Stakeholder Center will create forums to engage a diverse range of perspectives within the CDS ecosystem. The four Workgroups will provide CDSiC's thought leadership—developing product ideas, developing written products which may include frameworks and guidance that advance CDS for the broader community, collaborating with the CDSiC Steering Committee to inform CDSiC activities and the collaborative's strategic direction, and providing input to projects the CDSiC Innovation Center develops. This activity will involve:

- Meeting regularly to provide thought leadership and strategic input to CDSiC, particularly to the Innovation Center.
- Developing products that can inform the work of the Innovation Center and support the external CDS community.

**Workgroup Meetings.** Workgroups will meet seven times from October 2024-August 2025. The Workgroups will be virtually convened for 45-60-minute meetings using Zoom or another virtual platform. Workgroup co-leads will facilitate the discussion. Workgroups will schedule additional meetings as determined by scope of the products developed by each Workgroup. Between meetings, asynchronous Workgroup collaboration will occur on the CDSiC SharePoint site.

NORC team support staff will work with Workgroup leadership to create and distribute agendas at least one day before meetings. Across all Workgroups, the first meetings will focus on refining and finalizing ideas for products. All meeting minutes will be taken, distributed to Workgroup members and available on the project SharePoint site to improve communication across teams.

Lead Desai will be responsible for quality assurance processes across all developed products.

**Workgroup Reporting.** A summary of Workgroup activities will be included in monthly project reports. In addition, the Stakeholder Center will produce detailed quarterly reports on Workgroup progress that summarize:

- Actions taken by Workgroups since the last report;

- Items the Workgroups are exploring;
- Product development updates;
- Recommendations and next steps for consideration by the Planning Committee, Steering Committee, and AHRQ; and
- Recommendations for Innovation Center projects based on research, data collection, or work products.

Within 14 days of receiving AHRQ comments on the draft quarterly report, the Stakeholder Center will produce a 508-compliant version for posting on the CDSiC website.

## Stakeholder Center Products

**Workgroup Products.** Collectively, Workgroups will develop a total of 11 written products, which align with the expected level of efforts outlined by AHRQ (i.e., level of effort is 4-6 months [Level 3] or 9-11 months [Level 2] for product development). For Option Year 2, two goals will guide Workgroup product development: 1) further disseminate the Workgroup's efforts by developing journal article manuscripts that build upon CDSiC products (Level 2), and 2) develop resources that are shorter, more visual, and more accessible across different target audiences to engage broad swaths of the CDSiC community (Level 3). In addition to these Level 2 and 3 products, Workgroups will develop a Level 2 or 3 product that focuses on a distinct scope rather than building directly on a previous product.

The Measurement and Outcomes; Implementation, Adoption, and Scaling; and Standards and Regulatory Frameworks Workgroups will each create three standalone products, including one Level 2 manuscript, one Level 3 visual product, and a Level 3 or Level 2 product. The Trust and Patient-Centeredness Workgroup will produce one Level 2 manuscript and one Level 3 visual product. Each product has its own development timeline, needs, and challenges. Given that all products must be completed within a specific timeframe, the products should not be dependent on one another. Products may be synergistic, but they should be independent. Products will be unique to the CDSiC, capitalizing on the specific strengths of the collaborative and aligning with the mission and vision of the CDSiC.

A product must be a written material of publishable quality (e.g., peer reviewed manuscripts or reports). Potential products may include landscape analyses, gap analyses, prioritized research agendas, lists of evidence-based best practices or recommendations, and round table report outs. A product is not a demonstration or research study, new CDS standards, new CDS tools or software, or a dissemination activity. Products will inform the Innovation Center Cores and CDSiC goals, as well as be of utility for external stakeholders in the CDS field.

The target audience for Workgroup products may vary by resource, but broadly include patients/caregivers and their care team, clinicians, CDS researchers, CDS content developers, CDS vendors, policymakers, and payers.

**Stakeholder Center Product.** In addition to the 11 Workgroup products described above, the Stakeholder Center will develop a cross-cutting product that addresses areas relevant to several

Workgroups. The product will align with AHRQ's expected level of effort for a Level 1 product (i.e., 12-14 months). The target audience broadly includes policymakers, patients/caregivers and their care team, clinicians, health system leaders, CDS researchers, and payers. The Stakeholder Center team will comply with the expectations set forth for Workgroup products and will follow similar processes as described above for obtaining AHRQ approval. The CDSiC Stakeholder Center will lead this work and NORC will work collaboratively with Workgroup leads and members as well as the CDSiC Steering Committee as appropriate. To facilitate this, NORC will develop slides and other summary materials to share updates with CDSiC Workgroups, the Steering Committee, and the Stakeholder Center Planning Committee, as needed.

**Product Selection Criteria.** Initial product ideas were scoped by the CDSiC team and proposed to AHRQ, using suggestions from CDSiC partners (e.g., the CDSiC project team, Steering Committee members, Workgroup members, and Stakeholder Center Planning Committee members) at the 2024 CDSiC Annual Meeting, routine Steering Committee and Stakeholder Center Planning Committee meetings, and Workgroup meetings. Using these suggestions, CDSiC Stakeholder Center leadership, Workgroup support teams, and Workgroup leadership will develop a list of potential product topics for submission to AHRQ that meets the following selection criteria:

- **Workgroup Scope:** Does the product fit within the overall mission and vision of CDSiC as well as the scope and objectives of the Workgroup, as outlined by AHRQ and the Workgroup charter?
- **Need/Gap:** Does the product fill a critical need or gap in CDS that is within the Workgroup's area of focus? Does this product address a need that is not likely to be addressed by other CDS efforts?
- **Feasibility:** Is the product feasible to complete given Workgroup resources, estimated level of effort, and project timelines?
- **Impact:** Will the product have an impact on the field of CDS in the context of the Workgroup's focus? Does the product contribute a new, high-quality, and unique resource(s) to the field of CDS?

Products will ultimately need to approval from AHRQ.

**Product Development Workflows.** Workgroup leads will draft product proposals using a template provided by the CDSiC team. Proposals will be reviewed and approved by AHRQ. As each product plan is finalized, Workgroup leadership will work with members to determine roles and responsibilities for each product, assigning Workgroup members tasks or roles based on the scope of the product and the expertise and experience of members.

Product development will be supported by dedicated NORC team staff that will help complete individual tasks for each product (e.g., screening literature) and manage the overall timeline for the product. Product development teams will use the CDSiC SharePoint site for asynchronous collaboration and schedule virtual meetings as needed.

In consultation with the Planning Committee, Workgroup leadership will provide guidance and strategic direction for the development of each product developed under their respective Workgroup. The



Workgroup may produce reports, frameworks, and other documents that are publicly posted on the CDSiC website (“products”). In addition, the CDSiC may develop manuscripts based on Workgroup products for submission to peer-reviewed journals. Below, we describe guidelines for acknowledging contributions in Workgroup products and manuscript publications.

**Product Authorship.** Authorship for Workgroup products posted publicly on the CDSiC website will be determined following International Committee of Medical Journal Editors (ICMJE) guidelines.<sup>1</sup> The Workgroup as a whole will be included as a co-author. Workgroup members who provide input during Workgroup product development will be acknowledged for their contributions by being listed in a table of contributing Workgroup members. In order to be acknowledged in a final Workgroup product, Workgroup members must do at least one of the following: 1) attend at least one Workgroup meeting to review and provide real-time feedback on product findings or product structure, or 2) provide asynchronous feedback on Workgroup product drafts between Workgroup meetings (e.g., via email or on SharePoint)

**Manuscript Authorship Guidelines.** The CDSiC leadership (i.e., the CDSiC PI and Stakeholder Center lead), the Agency for Healthcare Research and Quality (AHRQ), and Workgroup support teams, and Workgroup leads will discuss expected contributions before manuscript development, including authorship and the anticipated order of authors. The anticipated authorship order will be determined and agreed upon before product drafting begins.

Following International Committee of Medical Journal Editors (ICJME) guidelines, authors must be able to meet the following four criteria:

1. Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
2. Drafting the work or reviewing it critically for important intellectual content; AND
3. Final approval of the version to be published; AND
4. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

All authors are responsible for fairly evaluating their role to ensure that authorship is attributed according to these standards. Authorship order will be discussed collectively as a group with the authors.

- The lead author is generally the individual responsible for writing the first draft of the manuscript.
- The co-authors will be listed in order of contribution to the conception, drafting, and review of the manuscript.
- The CDSiC Principal Investigator will be listed as the final author, reflecting their involvement throughout the manuscript development process, oversight, and overall strategic direction of manuscripts. Workgroup leads may be listed as co-senior authors to reflect their contribution to the conceptualization of a product, when appropriate.

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<sup>1</sup> International Committee of Medical Journal Editors. Defining the Role of Authors and Contributors. Available from: <http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html>

- The CDSiC PI or Stakeholder Center lead will serve as the corresponding author. The corresponding author will be responsible for manuscript submission and coordination with the journal during the peer-review and publication process.
- Each manuscript will have AHRQ co-authors.

Please note that authorship order of manuscripts may not reflect the authorship order of the corresponding Workgroup product.

**Acknowledging Workgroup Member Contributions.** Each CDSiC Workgroup will generally be included as a co-author in the manuscript (e.g., manuscripts developed under the Measurement and Outcomes Workgroup will include “Measurement and Outcomes Workgroup” in the list of authors). Ahead of selecting a journal, NORC will reach out to target journals to confirm the Workgroup can be submitted as a co-author. In accordance with ICJME and journal guidelines, Workgroup members will be acknowledged for their valuable contributions to the work. Individual members will be named in the article’s acknowledgments or contributors section. To be included in the list of Workgroup members noted in the manuscript, Workgroup members must have either:

- contributed to the development of the original product(s) that undergird(s) the manuscript (i.e., the Workgroup member is listed as a contributor in the report), OR
- contributed directly to manuscript development by participating in Workgroup meetings where manuscript-related activities (such as additional research activities to inform the manuscript) were discussed or providing asynchronous feedback on manuscript-focused activities.

## Roles and Responsibilities

Each component of the Stakeholder Center will have a distinct role and responsibilities, which are summarized in Exhibit 2:

- Working with the Planning Committee, Desai will provide operational leadership and establish logistics, expectations, and staffing for each Workgroup. They will also be responsible for overall quality assurance.
- Workgroup leadership will set the overall direction for the development of Workgroup products, facilitate meetings, lead product development, assign roles and responsibilities to members, monitor progress, ensure products are developed consistent with proposed timelines and communicate regularly with Stakeholder Center leadership.
- Support staff will work with Workgroup leadership to support meetings and execute all products. They will also ensure that Desai is aware of any operational concerns.

**Facilitating Communication Across CDSiC Centers.** CDSiC PI Dullabh will be responsible for communicating and coordinating with Desai to provide updates from the Operations and Innovation Center. Dullabh will also work with Desai and Workgroup co-leads to identify items that should be added to the Workgroup agendas, communicate requests for input from the Workgroup members on Innovation Center activities, and coordinate the timely review of any documents by Workgroup

members. As needed, Innovation Center leadership will join Workgroup meetings to obtain direct feedback on projects and engage Workgroup leads to help prioritize issues that need to be addressed.

**Exhibit 2. Stakeholder Center Roles and Responsibilities**

Role	Responsibilities
<b>Stakeholder Center Leadership</b>	<ul style="list-style-type: none"> <li>• Contribute to overall strategic direction and coordination of the Stakeholder Center and provide strategic input into Operations Center, Innovation Center, and broader CDSiC activities based on Workgroup activities</li> <li>• Facilitate cross-Workgroup synergies through regular communication</li> <li>• Inform Steering Committee, Innovation Center, and AHRQ of Center and Workgroup activities</li> <li>• Establish Workgroup meeting schedules and private Workgroup collaboration spaces</li> <li>• Establish consistent expectations and processes for individual Workgroups as well as expectations for timelines and products</li> <li>• Ensure adequate staffing Workgroup support</li> <li>• Establish review and quality assurance processes</li> </ul>
<b>Workgroup Leadership (Workgroup Leads and Support Leads)</b>	<ul style="list-style-type: none"> <li>• Facilitate Workgroup meetings</li> <li>• Lead product development (e.g., refining ideas, developing outlines and timelines)</li> <li>• Assigning roles and responsibilities among Workgroup members for products</li> <li>• Work with NORC team support staff to ensure timely execution and delivery of all products</li> <li>• Communicate Workgroup needs/challenges to Center Leads</li> </ul>
<b>Workgroup Members</b>	<ul style="list-style-type: none"> <li>• Participate actively during Workgroup meetings and over asynchronous collaboration platforms</li> <li>• Inform, plan, and contribute to the development and refinement of Workgroup products</li> <li>• Complete assigned tasks in consultation with Workgroup leadership</li> <li>• Provide input on Innovation Center activities</li> <li>• Assist in disseminating and amplifying the work of CDSiC</li> </ul>
<b>Team Support Staff</b>	<ul style="list-style-type: none"> <li>• Work with Workgroup leadership to support meetings (e.g., agenda, meeting materials, notes)</li> <li>• Support the execution of all Workgroup products under the direction of Workgroup leadership (e.g., conduct literature reviews, develop draft reports)</li> <li>• Communicate with Center Leads about operational concerns</li> </ul>

## Synergies, Challenges, and Mitigation Strategies

To ensure synergy and proactively address potential challenges, the Stakeholder Center Planning Committee will ensure mitigation strategies are in place for all Center activities. These include:

- Regular review and discussion of challenges encountered by Workgroups, using decision-making frameworks to solve problems.
- Regular agenda items for Planning Committee meetings to review and discuss Workgroup activities, challenges encountered, and mitigation strategies.
- Dedicated experienced Workgroup support staff to ensure the smooth operation of all meetings and timely development of products.
- Regular communication with Workgroup members to obtain buy-in and foster continuous engagement and participation.
- Cross-Workgroup and cross-CDSiC discussions to ensure alignment in activities and overall strategic approach.