Sentinel Community Building and Outreach Center Master Plan

Sentinel Community Building and Outreach Center

Version 1

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History of Modifications

Version	Date	Modification	Author
1.0	02/10/2021	Original Version	Sentinel Community Building and Outreach Center

I. Executive Summary

The Community Building and Outreach Center (CBOC) Master Plan will advance the United States Food and Drug Administration's (FDA) strategic vision of creating a more robust Sentinel System. The CBOC aims to deepen stakeholder involvement in Sentinel and broaden awareness of and access to Sentinel tools and infrastructure, especially for stakeholders outside of Sentinel's core userbase.

By combining input from stakeholders with CBOC's expertise, the goals of the Sentinel Operations Center (SOC) and Innovation Center (IC), and FDA's vision for the future of the Sentinel Initiative, the CBOC identified three key findings regarding stakeholders beyond its core userbase:
- Stakeholders desire a deeper understanding of the origins of the Sentinel System's design and the factors that shaped its development.
- Stakeholders would like to understand how they can use the Sentinel System, including the Sentinel tools and infrastructure, to inform their work.
- Stakeholders would like to widen their opportunities to engage with FDA and the Sentinel System, particularly through training sessions and scientific forums, and to better understand how their work relates to Sentinel reports and assessments posted online.

The purpose of the CBOC is to broaden and activate a strong scientific community to advance the Sentinel Initiative. The CBOC has integrated these findings to develop a portfolio of community building projects. The CBOC will implement these projects to increase awareness of the Sentinel Initiative to a more diverse scientific community, improve usability of the Sentinel tools and infrastructure, and enable stakeholders to more effectively contribute to advancing the scientific foundation of the Sentinel System. The CBOC will implement projects across two areas: 1) Communications and Training, and 2) Bidirectional Engagement. Details of these projects are included in *Section VI. Proposed Projects*. The CBOC Master Plan, including the projects to be implemented, is a living document and will be updated regularly by the CBOC with direction from FDA and Sentinel leadership.

II. Introduction

The CBOC Master Plan will advance FDA's strategic vision of creating a more robust Sentinel community with deep and diverse partnerships. This document outlines a series of projects that will build a community around a common purpose: to advance the Sentinel System's capabilities by broadening its scientific collaborations, identifying use cases beyond drug safety and capitalizing on new technologies and approaches. The activities of the CBOC Master Plan were selected expressly to support and complement the ongoing activities in the SOC and IC. The CBOC Master Plan identifies stakeholder priorities, describes the action plan, and proposes ways to evaluate project impact. The CBOC Master Plan will be updated regularly by the CBOC with direction from FDA and Sentinel leadership.

A. Background

In 2008, FDA created the Sentinel Initiative to meet congressional requirements in FDA Amendments Act (FDAAA),[1] which mandated FDA to establish an Active Post-market Risk Identification and Analysis (ARIA) system.[2] FDA launched the Sentinel Initiative to create a national electronic system, the Sentinel System, for medical product safety surveillance.[3]

FDA continues to develop Sentinel in stages to create a long-term, sustainable system. FDA released the *Sentinel System Five-Year Strategy: 2019-2023* to guide the advancement of Sentinel over five years.[4] This plan contained five strategic aims, each of which were assigned to one or more of the three Sentinel Centers: SOC, IC, and CBOC.

The SOC leverages organizational partnerships in various scientific areas including epidemiology, clinical medicine, and data science. Through these partnerships, the SOC enhances core data sources, evolves the Sentinel Common Data Model (SCDM), develops new distributed analysis tools, enhances capabilities in signal detection and other areas, and leads real-world evidence (RWE) demonstration projects.[5] The IC focuses on developing innovative methods to further advance Sentinel, including exploring new ways to extract and structure information from electronic health records (EHR).[6] The CBOC focuses on communications and collaboration by deepening stakeholder involvement and broadening awareness of and access to Sentinel tools and data infrastructure.[7] Throughout this CBOC Master Plan, the term "Sentinel tools and infrastructure" is used to refer to the Sentinel specific analytic and Extract Transform Load (ETL) programs, methods for analysis, common data model, and other resources that are provided by the Sentinel Initiative. This does not include the data held by Sentinel's Data Partners. This data will continue to be accessed only by the SOC and will not be accessible by other groups.

This Master Plan focuses on the activities of the CBOC and is designed to build upon and complement the projects in the SOC and IC's Master Plans. To the fullest extent possible, the projects in the CBOC Master Plan will be done in collaboration with the SOC and IC.

B. Sentinel Strategic Aims

In the *Sentinel System Five-Year Strategy 2019-2023*, FDA outlined five strategic aims, the last three of which (Strategic Aims C, D, and E) shape the CBOC's mission:[8]

- **Strategic Aim A:** Enhance the foundation of the Sentinel System

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[1] Food and Drug Administration Amendments Act (FDAAA) of 2007. Available at: https://www.fda.gov/regulatory-information/selected-amendments-fdc-act/food-and-drug-administration-amendments-act-fdaaa-2007. Accessed: November 6, 2020.

[2] About the Food and Drug Administration (FDA) Sentinel Initiative: History of the Sentinel Initiative. Available at: https://www.sentinelinitiative.org/about. Accessed: November 6, 2020.

[3] Ibid.

[4] US Food and Drug Administration: Sentinel System Five-Year Strategy 2019-2023. January 2019. Available at: https://www.fda.gov/media/120333/download. Accessed: November 6, 2020.

[5] Sentinel Structure: Sentinel Operations Center (SOC). Available at: https://www.sentinelinitiative.org/about/sentinel-structure. Accessed: November 6, 2020.

[6] Sentinel Structure: Sentinel Innovation Center (IC). Available at: https://www.sentinelinitiative.org/about/sentinel-structure. Accessed: November 6, 2020.

[7] Sentinel Structure: Community Building and Outreach Center (CBOC). Available at: https://www.sentinelinitiative.org/about/sentinel-structure. Accessed: November 6, 2020.

[8] US Food and Drug Administration: Sentinel System Five-Year Strategy 2019-2023. January 2019. Available at: https://www.fda.gov/media/120333/download. Accessed: November 6, 2020.

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- **Strategic Aim B:** Further enhance safety analysis capabilities
- **Strategic Aim C:** Accelerate access to and broader use of real-world data to evaluate effectiveness
- **Strategic Aim D:** Create a national resource by broadening the Sentinel userbase
- **Strategic Aim E:** Disseminate knowledge and advance regulatory science to enable innovation

III.   Methodology

The CBOC Master Plan was greatly informed by the *Sentinel System Five-Year Strategy: 2019-2023*. The CBOC supplemented the direction provided by this strategy with targeted outreach to a stakeholder community outside of Sentinel's core userbase. The CBOC conducted discussions with stakeholders who were asked about their experiences with RWE and the Sentinel Initiative. Through conversations with FDA leadership, three target stakeholder groups were identified: epidemiologists, informaticists, and patient advocates. Informaticist and patient advocates are two groups on which the Sentinel Initiative has not previously focused, but which have the potential to contribute to the advancement of the Sentinel System. Epidemiologists represent the current system's core userbase and we selected those who were not currently using Sentinel to provide an external perspective. The CBOC worked with the FDA to identify individual stakeholders with whom the CBOC conducted interviews. These people were selected based on previous experience with Sentinel, potential for future engagement, and coverage of key stakeholder sub-groups (e.g., academia, other Federal health agencies). Preliminary recommendations and projects were made using these observations as well as expertise from members of the CBOC and FDA. The CBOC, along with Sentinel and FDA leadership, then prioritized initial projects based on the shared future vision for the Sentinel Initiative, ultimately placing emphasis on projects relating to communications and training. Finally, the selected projects were compiled into the CBOC Master Plan.

IV.   Observations and Findings

The CBOC identified an opportunity for enhanced communications and training efforts using modernized technologies. This opportunity was identified via discussions with individuals from each stakeholder group with which interviews were conducted (epidemiologists, informaticists, and patient advocates). These discussions illuminated key observations across many areas, including communications and engagement. Specifically related to communications and engagement, the CBOC found that stakeholders (1) showed a high level of excitement for the potential of Sentinel, (2) were eager to better understand how they may be able to use the Sentinel tools and infrastructure, and (3) wanted to learn more about the design decisions that informing the development of the current Sentinel System.

A.   Stakeholders showed excitement for the potential of Sentinel

Stakeholders expressed a high level of respect for and trust in Sentinel. They specifically called out Sentinel's high degree of scientific and analytic rigor. Stakeholders who were familiar with Sentinel acknowledged the system's utility for FDA in post-market surveillance and expressed excitement for the potential of Sentinel in the future. Sentinel's reputation as a scientifically rigorous system for analyzing post-market safety and effectiveness and FDA's use of the Sentinel System contributed to this excitement.

B. Stakeholders were eager to understand how they can use Sentinel

Individuals who were not currently working with Sentinel also expressed an eagerness to learn more about the Sentinel tools and infrastructure, especially with regard to how Sentinel's tools and infrastructure may be used to support the work that these stakeholders do. They wanted to understand how individuals outside of FDA could use the Sentinel analytic tools on their own data sets. Patient advocates were also very interested in understanding how they could use Sentinel's reports and assessments to inform their work. Individuals within the FDA, but outside of Sentinel's core userbase, wanted to better understand the types of questions that they could use Sentinel to answer.

C. Stakeholders wanted to learn more about the design decisions informing Sentinel

Some stakeholders who were less familiar with Sentinel demonstrated different levels of understanding of the design decisions that inform the current Sentinel System. This extended to the stakeholders' level of understanding of the core uses of the current Sentinel System, namely for the FDA [and some pharmaceutical industry stakeholders through the Innovation in Medical Evidence and Development Surveillance program (IMEDS)] to perform post-market safety analyses. Many of the features that were lauded by stakeholders are the result of intentional design decisions. This presents an opportunity for the CBOC to use modern tools to educate new and existing stakeholders on the history of Sentinel and to clearly communicate the existing use cases of Sentinel.

D. Key Findings

By combining input from stakeholders with CBOC's expertise, the goals of the SOC and IC, and FDA's vision for the future of the Sentinel Initiative, the CBOC identified three key findings regarding stakeholders beyond its core userbase:

- Stakeholders desire a deeper understanding of the origins of the Sentinel System's design and the factors that shaped its development.
- Stakeholders would like to understand how they can use the Sentinel System, including the Sentinel tools and infrastructure, to inform their work.
- Stakeholders would like to widen their opportunities to engage with FDA and the Sentinel System, particularly through training sessions and scientific forums, and to better understand how their work relates to Sentinel reports and assessments posted online.

V. Target Outcomes and Stakeholders

Through the projects outlined in this Master Plan, the CBOC aims to achieve three outcomes related to the key findings discussed in the previous section. Projects implemented by the CBOC will increase awareness of the Sentinel Initiative and the design of the Sentinel System, improve usability of the Sentinel tools and infrastructure, and increase stakeholder contribution to the Sentinel community (**Figure 1**).

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Figure 1. CBOC's target outcomes

While the CBOC will work toward each outcome simultaneously, **awareness** of the Sentinel Initiative and the design decisions that led to the current Sentinel System may serve as a foundation for the other outcomes. The CBOC will target awareness activities toward individuals or groups who may be able to benefit from the tools, infrastructure, and outputs of the Sentinel System, as discussed later in this section. Increased awareness extends beyond familiarity; for the CBOC to achieve this outcome, stakeholders should demonstrate an understanding of the Sentinel System's capabilities and the decisions that led to those capabilities, the core userbase of the Sentinel System, and how Sentinel's analytic tools may be used by stakeholders outside of the core userbase.

Increasing the **usability** of the Sentinel's tools, infrastructure, and outputs can be achieved by increasing the capacity of the users (e.g., through training exercises) or by minimizing barriers preventing the use of these resources. To achieve this outcome, the CBOC will enable easier access to and increase digestibility of resources and materials that facilitate the use of the Sentinel System. The CBOC will, in collaboration with the other Sentinel centers, update and modernize existing resources.

Finally, the CBOC will increase **contribution** to the Sentinel community by creating new ways for stakeholders to engage. The current channels of engagement were designed specifically to target Sentinel's core userbase within FDA. Although some of these channels may be appropriate for new stakeholder groups (e.g., informaticists and patient advocates), additional forums may be better suited to integrate these stakeholders into the larger Sentinel community.

Four key groups of stakeholders were selected to achieve the vision set forth in the *Sentinel System Five-Year Strategy: 2019-2023*. These groups, shown below in **Figure 2**, were selected based on their alignment to Sentinel's strategic aims and their ability to contribute to the advancement of the Sentinel System. The CBOC will seek to increase the level of engagement from US Health Agencies (excluding FDA) significantly by targeting select projects to this audience and working with key points of contact from these agencies. Patient advocacy organizations, the informatics community, and industry will also be targeted. The informatics community refers to any stakeholders whose roles are focused primarily on the use of data or data science to identify and solve problems related to human health. International regulatory agencies, academia, and members of additional groups (such as health services researchers, clinical trialists, biostatisticians, health policy researchers, and the FDA) may benefit from publicly available resources resulting from CBOC projects but will not be directly targeted by the CBOC in the near term. While international regulatory agencies may be able to contribute to the development of the Sentinel System, FDA has existing relationships with these agencies. These relationships may be used to enhance other regulatory agencies' engagement with Sentinel. Members of these groups will have access to many of the resources produced and made publicly available by CBOC. They will also be welcome to take part in webinars and forums developed by CBOC.

Stakeholder Group	Level of Engagement
US Health Agencies	
Patient Advocacy Organizations	
Informatics Community	
Industry	
International Regulatory Agencies	
Academia	
Additional Groups	

Figure 2. CBOC Target Stakeholder Groups

VI.   Proposed Projects

The initial focus of the CBOC will be communications and training. These will be used to expand the number of stakeholders engaged with the Sentinel community (through channels like the Sentinel website) and to amplify the work being done by the SOC and IC. These projects, outlined in the next section, will increase overall awareness of the Sentinel Initiative while also increasing stakeholders' abilities to use the Sentinel tools and infrastructure. The CBOC will be responsible for implementing these projects with support and input from the other Sentinel Centers, as directed by FDA. These projects vary in complexity, scope, and the stakeholder group toward which they are aimed.

After initially focusing on expanding the Sentinel community, the CBOC will explore Bidirectional Engagement projects that increase stakeholder contribution to the Sentinel community. These projects are intended to address gaps between the current Sentinel Initiative and the needs of the Sentinel community. Two such projects are proposed in this document; however, additional bidirectional engagement projects will be determined after the Sentinel community is further expanded.

Each of the projects outlined in the coming two sections (*A. Communications and Training Projects* and *B. Bidirectional Engagement Projects*) aim to address one or more of the target outcomes (see *V. Target Outcomes*). **Table 1** below summarizes which target outcome(s) each project will achieve.

Project	Description	Target Outcome(s)
Sentinel Real-World Data Forum	The CBOC will work closely with the SOC and IC to convene a forum of informaticists who will use Sentinel tools and infrastructure to conduct research.	Increased **contribution** of new stakeholders
Scientific Challenges	The CBOC will plan and execute one or more public-facing competitions aimed at addressing enduring technical challenges to incentivize stakeholder engagement with the Sentinel System.	Increased **contribution** of new stakeholders through development of new ideas to advance Sentinel
Ongoing Website Design and Implementation	The CBOC will continue to design and implement updates to the Sentinel website to promote usability and create a hub around which the Sentinel community can gather.	Increased **awareness** of the Sentinel Initiative and the System's capabilities Increased **engagement** with Sentinel events
Communications and Training Goals	The CBOC will work with FDA to define the goals for the Sentinel Initiative's communications including key messages, best practices, key performance indicators, and expected outcomes for Sentinel communications.	Increased direction to improve **awareness**, **usability**, and **contribution**
Newsletters	The CBOC will produce and distribute a series of public-facing newsletters, disseminating information about activities happening within the Sentinel Initiative, milestones achieved, and upcoming events.	Increased **awareness** of Sentinel's capabilities Increased **engagement** with Sentinel events
Templates, Standardized Presentations, & Informational Videos	The CBOC will produce templates for Sentinel presentations and complete standardized presentations, as well as short informational videos, for select topic that the SOC, IC, CBOC, and FDA present regularly.	Increased **awareness** of Sentinel's capabilities
Webinar Series	The CBOC will host a series of webinars focused on increasing awareness and understanding of the Sentinel System and the Sentinel Initiative.	Increased **awareness** of Sentinel's capabilities
Virtual Training Sessions	The CBOC will leverage existing resources to produce online training materials, such as pre-recorded training videos and training documents, to increase the technical capacity of stakeholders.	Improved **usability** of Sentinel tools and infrastructure
Simplified-language Studies	The CBOC will translate FDA-selected studies into patient friendly language that is more easily consumed by stakeholders without a technical background.	Improved **usability** of reports and assessments

Table 1. Proposed CBOC projects, descriptions, and target outcomes

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A. Communications and Training Projects

Stakeholders showed an interest in becoming more aware of Sentinel. This sentiment was expressed by stakeholders within and external to FDA. As a result, CBOC developed the projects shown in this section to increase awareness and improve the usability of the Sentinel System for stakeholders.

1. Website Design and Implementation

The CBOC successfully deployed the first iteration of the redesigned Sentinel website in July 2020, and a second, enhanced iteration in October 2020. The redesigned website includes an updated navigation menu; a new standardized table search, sort, and filter; a modernized look and feel; and significant improvements to content, search engine optimization (SEO), and usability. As the CBOC moves into the implementation of this Master Plan, the center will continue to redesign and deploy key features of the website based on usability studies. Updates to the Sentinel website will enhance the website's ability to serve as a hub for the Sentinel community—a single place where key Sentinel resources can be accessed.

The Sentinel website redesign is an ongoing activity, which will include periodic releases to enhance features and address any defects. The updated website will improve key pain points highlighted by stakeholders, such as search functionality and a lack of a dedicated page for all training materials. Stakeholders will be able to learn about Sentinel study results, upcoming events, and have their questions answered.

The CBOC will assess the success of this project based on the number of agreed-upon features that have been tested and implemented and the key performance indicators have been met.

2. Communications and Training Goals

As the CBOC begins carrying out the communications and training projects outlined in this Master Plan, the center will work with FDA to develop an overarching set of goals that will extend to the Sentinel Initiative. The project will stem from continued conversations that began during the CBOC master planning process related to FDA's long-term vision for the Center and will outline how CBOC's projects can amplify work being done by the SOC and IC. Each Sentinel Center will provide input on these goals, given their potential impact on the external perception of each Center's work. The communication and training goals will include key messages, communications best practices, key performance indicators, and measures of success. For example, which stakeholders or groups of stakeholders should be prioritized and how to effectively use social media may be included as a best practice. This project will also track the external facing communications from all three Sentinel Centers to minimize duplicative messaging.

The communications and training goals will streamline the process by which Sentinel produces and distributes materials for public consumption and will provide a set of guidelines for communications produced across all three centers. These goals will strengthen the Sentinel brand and improve users' experiences engaging with Sentinel. They will also improve awareness and public perception of aspects of the Sentinel Initiative. The communication and training goals will answer questions needed to efficiently carry out other projects outlined in this plan.

The CBOC will assess the success of this project based on the development of clear and measurable goals for the center.

3. Public-Facing Newsletters

By crafting and distributing a quarterly newsletter to the public, the CBOC will be able to highlight changes or updates to the Sentinel System, upcoming events, recently published Sentinel research, updates to the website, and other relevant information. Although developed and led by the CBOC, these newsletters will take input from SOC and IC where appropriate. The content will be aimed at improving awareness of Sentinel data, tools, and research, and increasing interest in engaging with the system among government and non-government stakeholders alike. The newsletter will also promote opportunities for stakeholders to get involved with Sentinel.

The public-facing newsletter will increase overall awareness of Sentinel and deepen stakeholder understanding of Sentinel's capabilities. The distribution of a Sentinel newsletter encourages stakeholders to interact with Sentinel, ultimately increasing traffic to the Sentinel website and increasing attendance at Sentinel events.

The CBOC will assess the success of this project based on increased levels of engagement from stakeholders with content over time (e.g., links in the Sentinel newsletter are clicked on and explored), increased traffic to the Sentinel website, and increased participation in events included in the newsletter.

4. Templates, Standardized Presentations, and Informational Videos

Templates, standardized presentations, and informational videos will create consistent materials for sharing information about Sentinel. The CBOC will create a set of templates for the Sentinel Initiative to use to deliver presentations consistent with the redesigned Sentinel website's theme. These designs will be used for future Sentinel communications and can be customized to fit the needs of the user. In addition, the CBOC will develop a set of standardized presentations for use with internal and external stakeholders. These presentations may be uploaded to the Sentinel website as PDF documents or may be pre-recorded presentations with audio. The CBOC will also create short, informational videos to guide stakeholders to relevant resources. Informational videos will be accessible via the new Sentinel website and will provide an on-demand resource for individuals to become more familiar with Sentinel. Overall, these templates, presentations, and videos will make use of modern tools to streamline the process of creating presentations and outreach material that is consistent with the redesigned Sentinel Website.

Templates, standardized presentations, and informational videos will improve consistency in Sentinel branding, from the website to communications materials. Updated and standardized presentations will help Sentinel leadership communicate topics such as the value of Sentinel, the logic behind key design decisions for the Sentinel System, and the ARIA sufficiency process. They will also help to answer stakeholder questions and improve the experience for users navigating the Sentinel website and other aspects of the Sentinel System.

The CBOC will assess the success of this project based on Sentinel leadership's use of pre-designed templates, graphics, and content to create presentations and when pre-recorded videos have been uploaded to the Sentinel website. Videos will be used by stakeholders as a go-to resource for answers to their questions.

5. Webinar Series

A webinar series will increase awareness and understanding of Sentinel's value to stakeholders. The CBOC will hold a webinar series focused on the benefits of the Sentinel System and how stakeholders can get involved. These webinars will be higher-level and will not require a technical understanding of Sentinel and its data with the aim of attracting less-technical stakeholders. The webinar series will be led by CBOC with input from SOC and IC as needed. Each webinar will be recorded and posted to the Sentinel website to allow for viewing on-demand.

The webinar series will increase awareness and understanding of various aspects of Sentinel, including the history of the initiative and current structure, data in the SCDM, and Sentinel tools. Another expected outcome is a deeper understanding of the use cases for which stakeholders from different backgrounds can leverage Sentinel tools and infrastructure.

The CBOC will assess the success of this project based on attendance of the webinars by stakeholders from a variety of backgrounds (including government, patient advocacy, academia, and epidemiology). Webinars should also generate increased traffic to the Sentinel website and increase the number of stakeholders who express interest in using Sentinel for their research.

6. Virtual Training Sessions

Virtual training sessions will improve stakeholders' capacity to use Sentinel tools and methods on their own data and to carry out other relevant activities. The CBOC will develop virtual training materials and modernize existing resources to be shared with the public via the Sentinel website. These training materials will be primarily built by the CBOC but will be informed by existing inputs from the SOC and IC, including recordings of previously hosted live training sessions. While CBOC may assist the SOC in making these materials more user-friendly, the SOC will be responsible for updating details of the technical documentation. The selected topics for training sessions will be designed based on the needs of stakeholders and will rely upon modern and innovative tools to improve the user experience. The CBOC will lead the marketing efforts to drive traffic to these training materials, which will ultimately provide support to stakeholders interested in using the Sentinel tools and infrastructure more effectively.

Virtual training sessions will lead to improved usability of the Sentinel System for stakeholders inside and outside of the government. Modernized training sessions will help individuals and groups better use Sentinel for their research purposes. This will allow them to engage with the system more seamlessly. The virtual training sessions will also be posted to the online training center on the Sentinel website, along with FAQs and other support materials.

The CBOC will assess the success of this project based on the number of training videos successfully added to the Sentinel website and the rate of viewership (as defined by FDA and CBOC). Stakeholders should be referred to these training videos as a first response to inquiries for support, reducing incoming requests for training on commonly sought topics.

7. Simplified-Language Studies

During discussions, stakeholders expressed a desire for descriptions and summaries, written in simplified language, explaining the study in question and providing key takeaways from the results. To address this, the CBOC will develop and distribute study summaries, or less technical adaptations of studies written in plain language targeted at patient-level individuals.

Developing simplified-language studies for Sentinel reports and assessments will be an ongoing activity carried out as requested by FDA, with additional work being done to add write-ups for selected past studies. Simplified-language studies will open the reports and assessments produced by the Sentinel System for use by more stakeholders, specifically those with less-technical backgrounds. Stakeholders from a wider range of backgrounds will be able to use Sentinel research to inform their decision-making, especially for issues related to patient advocacy.

The CBOC will assess the success of this project based on the number of simplified language studies published and the number of stakeholders accessing these studies. Access may be measured by the number of downloads of each study or by the number of individuals accessing the page(s) where the studies can be downloaded.

B. Bidirectional Engagement Projects

In addition to the projects described above that aim to increase awareness and usability, the CBOC will increase the ways stakeholders use the Sentinel infrastructure and tools as well as the frequency with which stakeholders turn to Sentinel to advance their work. Bidirectional Engagement projects will provide channels for stakeholders to contribute to the Sentinel community and address gaps between the current Sentinel System and the needs of stakeholders. CBOC will work with FDA, SOC, and IC to determine which projects will best meet the needs of stakeholders, with additional bidirectional engagement projects being added after the Sentinel community has been more substantially expanded.

1. Sentinel Real-World Data Forum

The CBOC will work with the SOC and IC to design and implement a virtual forum for stakeholders to rapidly explore their own data using the Sentinel infrastructure and tools. This forum may be an entirely new platform or may leverage one or more existing forums and will use inputs from the SOC and IC to build out the forum's membership. For example, the IC has an existing network of innovators that may be included in the Sentinel Real-World Data Forum. The forum may focus on a specific topic area, such as a disease or family of diseases, the use of a specific type of data, or an analytic methodology. Stakeholders participating in the forum may be required to make use of one or more components of the Sentinel infrastructure, such as the SCDM or Sentinel analytic tools and methods. The CBOC will provide recommendations, but FDA will ultimately determine which components of the Sentinel infrastructure must be used by participants. The Sentinel Real-World Data Forum project will have two phases: inception and operation. Additional details on these phases can be found in *Section VII. Implementation Plan*.

The Sentinel Real-World Data Forum will provide a space for informaticists and other participants to rapidly share their findings and to use the Sentinel tools and infrastructure to explore data. The forum will also provide a place for stakeholders to give feedback to the Sentinel Initiative and drive advancements in the Sentinel System to meet their needs.

The CBOC will assess the success of this project based on the Sentinel Real-World Data Forum's ability to serves as a center of innovation and feedback for the Sentinel Initiative with an active

membership, including new informaticists who use the Sentinel tools and infrastructure for their research. Members of the Sentinel Real-World data forum will not have access to Sentinel's data, which will continue to be stored by Sentinel Data Partners in a distributed database. However, the CBOC may work with the IC to develop a synthetic data set or data sandbox to support the Sentinel Real-World Data Forum and Scientific Challenges (see below). The SOC and IC will be able to use feedback and ideas generated in the forum to shape their innovation projects.

2. Scientific Challenges

The CBOC may also lead one or more scientific challenges, which will be structured as public-facing competitions that attract people from various backgrounds to propose and develop ideas or solutions to address one or more gaps between the current Sentinel System and stakeholder desired functionality. The focus of each scientific challenge will be selected to complement Sentinel's other activities and will be determined based on the needs of the Sentinel Initiative overall. These challenges will be designed to activate both existing Sentinel stakeholders as well as new members of the Sentinel community including from academia, industry, and the informatics community.

Scientific challenges will attract new stakeholders to the Sentinel community using the draw of a prize or recognition. While a modest cash prize increases participant excitement and engagement, recognition as a finalist or winner in a competition hosted by a prestigious agency, such as the FDA, may also be effective at galvanizing participation. CBOC may also work with IC to provide synthetic data or a data sandbox for participants to use during the competition. If determined necessary by FDA, this data set may be the same as the data set used in the Sentinel Real-World Data Forum (see previous project). In addition to attracting new stakeholders, scientific challenges will generate new ideas for consideration by the SOC and IC.

The CBOC will assess the success of this project based on the number of scientific challenges executed and the quality of ideas submitted to the challenge(s). These ideas will be packaged and shared with the other Sentinel centers and FDA.

C. Measures of Success

Each of the target outcomes will be assessed using a set of measurable criteria. These criteria will be further defined in the "Communications and Training Goals" project outlined in the previous section. **Table 2** below presents sample metrics for measuring success across each of the CBOC's target outcomes:

Target Outcome	Measure of Success
Awareness of the Sentinel Initiative and the decisions leading to the system	• Number of unique visitors to the Sentinel website and associated metrics (e.g., bounce rate) • Number of people subscribed to the Sentinel newsletter, disaggregated by stakeholder group if possible • Number of participants attending CBOC webinars
Usability of the Sentinel infrastructure and tools	• Number of stakeholders accessing the site to download toolkits • Number of stakeholders accessing virtual training materials, simplified language studies, and informational videos

Target Outcome	Measure of Success
	• Number of queries run by Sentinel users, including the number of queries from new users
Contribution to the Sentinel community	• Number of participants in the Sentinel Real-World Data Forum that produce research using Sentinel tools and infrastructure • Number of participants in Scientific Challenge(s) • Number of ideas produced during Scientific Challenge(s)

Table 2. Measures of Success

VII.   Implementation Plan

The proposed projects outlined in the previous section will be the first projects to be implemented by the CBOC following the initiation of this Master Plan. While overlap will exist between the sets of projects, Communications and Training projects will initially be prioritized to expand the Sentinel community and create greater awareness of Sentinel's value proposition. After expanding the network, the CBOC will work to strengthen the community with Bidirectional Engagement projects, such as the Sentinel Real-World Data Forum and scientific challenges.

The timeline on the next page (**Figure 3**) provides a sample plan that will be used to guide the implementation of these projects. Note that this plan is subject to change based on FDA direction, project needs, unforeseen circumstances, and other factors.
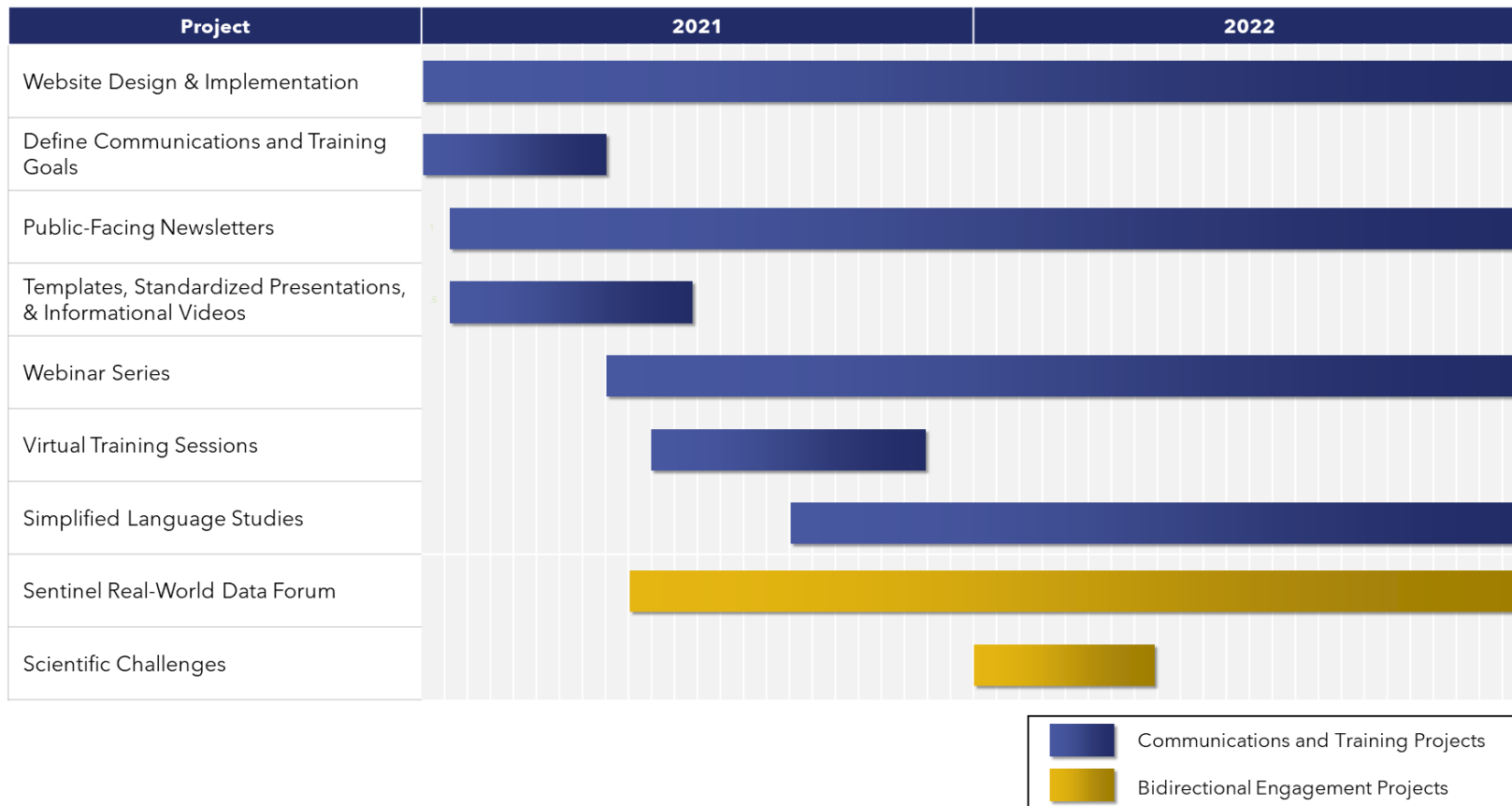
Figure 3. Proposed CBOC Project Implementation Timeline

Communications and Training projects will be the primary focus of the CBOC during the first year of this Master Plan. In many cases, the skills and resources needed to support one of these projects may be used to support others. These projects will require design, communications, and training professionals. The anticipated duration and key activities for each project is described below.

1. Website Design and Implementation

Duration: Ongoing
Implementation Overview: The process for designing and implementing enhancements to the Sentinel website was established prior to the development of this Master Plan. Activities related to the website are expected to continue through the second year of this Master Plan, with continuous enhancements taking place during this time.
Key Activities:
- Plan each technical sprint (a sprint is a period during which a technical team will perform a set amount of work)
- Design and develop sprints
- Conduct testing, including Usability Testing with stakeholders
- Deploy enhanced website as needed

2. Communications and Training Goals

Duration: 3-4 months
Implementation Overview: The development of the Sentinel Communications Plan will be a joint effort between CBOC and FDA. CBOC will gather input from SOC and other parts of Sentinel and will work with FDA to create a plan for the development and distribution of future public-facing Sentinel communications. After the development of this initial plan, it will be updated as necessary to improve processes and account for new developments.
Key Activities:
- Define long-term vision for CBOC
- Establish goals for the Communications and Training Projects
- Collaborate with FDA to identify key messages, determine best practices and the target audience, and establish key performance indicators
- Gather feedback and content from SOC and other Sentinel stakeholders
- Implement plan for future public-facing communications
- Maintain and update the plan as needed to serve the Sentinel Initiative

3. Public-Facing Newsletters

Duration: Approximately 2 months per newsletter
Implementation Overview: The initial design of a template for Sentinel public-facing newsletters will require more dedicated resources than subsequent newsletters, after the CBOC has established a regular cadence for gathering information from SOC and IC and submitting the public-facing materials for review.
Key Activities:
- Establish goals for the newsletter series
- Design reusable newsletter template

- Determine content for newsletter editions in collaboration with SOC and IC
- Craft a single newsletter each quarter providing updates on the work Sentinel is doing, updates to the website, and other relevant topics
- Distribute to target audiences and make publicly available

4. Templates and Standardized Presentations

Duration: 5-6 months
Implementation Overview: The development of templates and standardized presentations will take place in two phases. First, standardized design elements will be developed and used to produce consistent PowerPoint presentations on common topics. Next, the CBOC will work with FDA to record these presentations and upload the pre-recorded presentations to the Sentinel website.
Key Activities:
- Determine which graphics and templates will be most useful for FDA, SOC, and IC
- Design first drafts and iterate based on feedback
- Maintain graphics going forward and create new designs as needs arise and as changes are made to the website
- Gather content from FDA, SOC, and IC
- Develop standardized presentations and record videos

5. Webinar Series

Duration: 3-5 months per webinar
Implementation Overview: The success of the Sentinel webinar series will depend not only on the quality of the materials presented during these sessions, but also on the number and breadth of attendees that join the webinars. As such, the CBOC will invest significant effort in marketing and communications about the webinar series, especially ahead of the first webinar. CBOC expects that the first two webinars may take longer to plan and execute (4-5 months per webinar), while subsequent webinars may require less time (3-4 months per webinar).
Key Activities:
- Establish goals for webinars and determine target audiences
- Curate content for webinars in collaboration with SOC and IC
- Determine key performance indicators and the process for gathering metrics
- Raise awareness, generate excitement, and increase registration with promotional campaigns
- Host and record webinars

6. Virtual Training Sessions

Duration: 3-5 months per session
Implementation Overview: Virtual training sessions will be developed as a series of pre-recorded videos that can be watched on-demand by stakeholders. Many of the virtual training sessions will be created based on existing training materials from the SOC and FDA, while others will cover new topics, for which training does not already exist.
Key Activities:
- Establish goals for training sessions and determine target audiences
- Work with SOC to develop training content for sessions focused on specific aspects of the Sentinel System

- Record and process training materials
- Post training materials on the Sentinel website
- Promote videos via targeted outreach to stakeholders

7. Simplified-language Studies

Duration: 4-5 months up front and 1-2 months for additional studies
Implementation Overview: Simplified-language studies, which will begin development toward the end of the first year of this Master Plan, will be developed with input from SOC and FDA. SOC will provide technical support to the CBOC to maximize the accuracy of the summaries and key takeaways presented in these reports.
Key Activities:
- Work with SOC to develop simplified language for study descriptions as those studies are published
- Receive approval through necessary channels for simplified language
- Post descriptions (along with the full-length research reports) on the Sentinel website
- Promote descriptions using targeted outreach

B. Bidirectional Engagement

1. Sentinel Real-World Data Forum

Duration: 3-4 months for forum inception; forum operations continuous after inception
Implementation Overview: The Sentinel Real-World Data Forum will be established over three to four months during the inception phase of this project. This phase will culminate in the first meeting of the Sentinel Real-World Data Forum. The inception phase will include stakeholder outreach, the development of a charter for the forum, and the execution of planning activities.

After the forum has been established, the CBOC will continuously oversee marketing and outreach activities, hosting and convening activities (such as sending out invites and facilitating forum meetings), and other communications activities related to the Sentinel Real-World Data Forum.
Key Activities:
Establishing the Sentinel Real-World Data Forum will include the following activities:
- Develop a charter for the Sentinel Real-World Data Forum, which will outline the goals and governance of the forum
- Determine the focus of the Sentinel Real-World Data Forum
- Determine which stakeholders or groups of stakeholders should be included in the forum
- Actively and passively market the Sentinel Real-World Data Forum

The CBOC will also perform the following activities on an ongoing basis to support the operations of the forum:
- Create, share, and manage outreach and invites for upcoming forum meetings
- Convene Sentinel Real-World Data Forum meetings using a virtual meeting platform (e.g., Zoom)
- Oversee logistics related to the meeting, such as managing chats and providing transcripts

2. Scientific Challenges

Duration: 4-5 months per challenge

Implementation Overview: CBOC will host scientific challenges intended to gather new ideas for addressing gaps between Sentinel functionality and user needs. These forums will also bring new stakeholders into the Sentinel community. These challenges will be implemented by determining the topic of interest for the scientific challenge, creating a platform on which to host the challenge, planning challenges logistics, including evaluation criteria for the competition, gathering responses from participants and determining a challenge winner.

Key Activities:
- Determine, with guidance from FDA, SOC, and IC, the topic of interest for the scientific challenge
- Create a platform on which to host the challenge
- Plan challenges logistics, including evaluation criteria for the competition
- Gather responses from participants and determine a challenge winner

VIII.   Conclusion

This initial version of the CBOC Master Plan is intended to be a living document. The CBOC Master Plan should be updated approximately once per year, or as determined necessary by FDA, to reflect changes in CBOC's priorities, direction, target outcomes, or proposed projects. During the initial phases of the Master Plan implementation, the CBOC will focus primarily on Communications and Training projects. CBOC will also implement select Bidirectional Engagement projects as directed by FDA. Communications and Training and Bidirectional Engagement projects will focus on increasing awareness of the Sentinel Initiative, improving usability of the Sentinel tools and infrastructure, and increasing stakeholder contribution to the Sentinel community. The CBOC will work with FDA and Sentinel leadership to determine the types of projects that will be implemented beyond the current scope of this document.

IX. Appendix

A. Appendix A: Glossary of Acronyms

Acronym	Definition
ARIA	**Active Risk Identification and Analysis** is a component of FDA's Sentinel System that is used to conduct medical product safety surveillance.
CBOC	The Sentinel **Community Building and Outreach Center** is dedicated to developing and engaging the Sentinel community and expanding the Sentinel userbase.
EHR	Data taken from the **Electronic Health Records** of patients.
ETL	**Extract, transform, load** is a process by which data are copied from one source into a destination system.
FDA	The U.S. **Food and Drug Administration** is a federal agency of the Department of Health and Human Services. The FDA is responsible for protecting and promoting public health through the control and supervision of food safety, medications, vaccines, biopharmaceuticals, and other products.
FDAAA	The **Food and Drug Administration Amendments Act** of 2007 is the legislation that sparked the creation of the Sentinel Initiative in 2008.
IC	The Sentinel **Innovation Center** is a test bed to identify, develop, and evaluate innovative methods. Its goal is to enhance Sentinel's capabilities.
IMEDS	The **Innovation in Medical Evidence and Development Surveillance** program is a national resource for broader public health and medical evidence generation.
RWE	**Real World Evidence** refers to evidence obtained from real world data, which are observational data obtained outside the context of randomized controlled trials and generated during routine clinical practice.
SCDM	The **Sentinel Common Data Model** refers to the data to which Sentinel has access and the methods by which it is stored and maintained.
SEO	**Search engine optimization** is the process of improving the quality and quantity of website traffic to a website or a web page from search engines.
SOC	The **Sentinel Operations Center** works with the FDA to assess the risks and benefits of marketed medical products.