

Request for Proposal and Quote

Sentinel Data Visualization Platform

Department of Population Medicine

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Background

Sentinel is sponsored by the [U.S. Food and Drug Administration \(FDA\)](#) to monitor the safety of FDA-regulated medical products. Sentinel is one component of the [Sentinel Initiative](#), a multi-faceted effort by the FDA to develop a national electronic system that complements previously existing methods of safety surveillance. The Sentinel Coordinating Center resides within the Department of Population Medicine (DPM) at the Harvard Pilgrim Health Care Institute (HPHCI) and is funded by the FDA through the Department of Health and Human Services (HHS) Contract number 75F40119D10037. Sentinel Collaborators include Data and Academic Partners that provide access to health care data and ongoing scientific, technical, methodological, and organizational expertise.

Project Purpose and Description

The Sentinel Initiative is an FDA-funded project to conduct post-market surveillance of pharmaceuticals in the United States. Sentinel Operations Center (SOC) relies on a distributed network of healthcare insurance providers with data in a Common Data Model (CDM) format to routinely execute analytic programs on behalf of FDA to answer pharmacoepidemiologic inquiries.

The distributed nature of Sentinel's data network necessitates a certain degree of data segmentation across participating Data Partners in order to fully comply with each organization's governance policies. In pursuit of this goal, Sentinel's analytic tools were developed to return aggregated, deidentified results in SAS (Statistical Analysis Software) data table format to the SOC upon execution of each analysis. These results are in turn individually analyzed using SAS-based reporting programs.

As Sentinel has grown in terms of the volume of distributed data requests made yearly, FDA has become increasingly interested in gaining additional insight into the results of these analyses by way of data visualization and other visual representation.

In pursuit of improving the transparency and accessibility of Sentinel's analytic data, the purpose of this project is to solicit proposals for development and/or installation of a **web-based data visualization platform**. The primary purpose of this platform will be to provide FDA and internal Sentinel staff with a secure and reliable way to gain deeper insight into Sentinel's analytic data by way of data visualization.

The project goals are as follows:

- Work with SOC staff to deploy a pilot data visualization platform, either by building a custom application, or by deploying and customizing an off-the-shelf product in cooperation with SOC
- Develop a data model based on the current and projected format of Sentinel's SAS analytic output datasets
- Develop an ETL (extract, transform, load) process by which Sentinel SAS analytic output datasets may be transformed and loaded into the data visualization platform
 - This effort will focus specifically on preprocessed datasets produced by Sentinel's local reporting tools (See Appendix A).

- Develop a series of interactive data visualizations which highlight metrics and/or insights of specific interest to FDA, based on Sentinel distributed data request results
 - As above, this effort will focus on utilizing preprocessed data sets produced by Sentinel's local reporting tools (See Appendix A) to produce visualizations (See Appendix B).
- Empower Sentinel Operations staff to administer and provide self-service for the data visualization platform, allowing for the development of future data visualizations and/or data model updates without direct vendor intervention
- Develop the visualization platform with FDA and internal Sentinel staff as primary users, while providing potential opportunity for portions of the platform to be public-facing.

Proposal Guidelines

This RFP represents the requirements for an open and competitive bidding process. **Proposals will be accepted up until December 18, 2020 at 11:59 pm ET.** Please submit your proposals to DataVisualizationInquiry@sentinelssystem.org. Any proposals received after this date and time will not be considered. All proposals must be signed by an official agent or representative of the company submitting the proposal.

If the organization submitting a proposal must outsource or contract any work to meet the requirements contained herein, this must be clearly stated in the proposal. Any proposals which call for outsourcing or contracting work must include a name and description of the organizations being contracted. Additionally, proposals must be all-inclusive to cover any outsourced or contracted work.

Contract terms and conditions will be negotiated upon selection of the winning bidder for this RFP. All contractual terms and conditions will be subject to review by HPHCI and will include scope, budget, schedule, and other necessary items pertaining to the project.

Please note that SOC reserves the right to decline to select a winning bidder if submitted proposal(s) are determined to not meet project specifications as outlined in this document, or if otherwise warranted.

Proposal Contents

Each proposal should contain the following information.

- A detailed description of the proposed data visualization system, addressing all initial platform requirements as indicated in the Requirements section of this document
- Answers to all questions indicated in the Bidder Questionnaire section of this document
- Examples or case studies which showcase the Bidder's expertise in creating attractive, interactive, and flexible visualizations of healthcare data
 - Preference will be given to prototype or example visualizations based on the provided data sets and visual mock-ups (see Appendices A and B, respectively)
- Up to three (3) prior customer referrals. These referrals may be associated with the provided examples and/or case studies.

- Estimated timeline of engagement
- Estimated budget by role, including hourly rate by role
 - Please use the table in Appendix C to indicate budget and time estimates
- Number of anticipated resources you will assign to this project (total number, role, title, prior experience, (optional) areas of expertise)
- Detail on project management methodologies to be used

Evaluation Criteria

Proposals that provide the above specified information will be evaluated on the following criteria:

- **Overall proposal suitability:** Each proposal will be evaluated based on how clearly it addresses the scope and needs described herein.
- **Organizational experience:** Bidders will be evaluated on their experience as it pertains to the scope of this project.
- **Case studies and examples:** Bidders will be evaluated on the quality of the provided example projects, applications, and/or case studies, with a focus both on stylistic elements and usability. As noted in the previous section, strong preference will be given to examples and/or prototypes which utilize the specific synthetic datasets and visual mock-ups provided in Appendices A and B.
- **Cost and timeline:** Bidders will be evaluated on the projected cost of their proposed solution.
- **Technical expertise and experience:** Bidders will be evaluated on documented staff technical expertise and experience.

Open Q&A Session

A question and answer session will be held on December 3, 2020 at 12 pm - 1:30 pm ET.

This session will be open to all prospective bidders to ask any questions they may have about this project.

Please contact DataVisualizationInquiry@sentinelssystem.org if you're interested in attending the Open Q&A Session, providing the names and contact information of any attendees. Please refer to Appendix D for response format.

Additionally, prospective bidders may contact DataVisualizationInquiry@sentinelssystem.org in advance of the scheduled session with any written questions they wish to have covered during the session. *Please note that all questions must be submitted by November 20th at 11:59 pm ET* in order to ensure that SOC can respond to all questions and share with all prospective bidders for review prior to the open session. Please refer to Appendix D for question format.

Questions may also be raised during the open session.

Terms and Definitions

- Common Data Model (CDM): A standard data structure that allows a distributed network of healthcare insurance providers with data to quickly execute distributed programs against local data.
- Sentinel Operation Center (SOC): The SOC is a center within the Sentinel Initiative. It relies on a distributed network of healthcare insurance providers with data in a Common Data Model (CDM) format to routinely execute analytic programs on behalf of FDA to answer pharmacoepidemiologic inquiries.

Project Requirements

Functional Requirements (FDA)

As an FDA Team Member, I need a web-based user interface that will allow me to compare and visualize data elements contained within the Propensity Score Analysis (PSA) analytic module query results. This will allow me to better inform FDA leadership about the findings associated with a specific request.

The user interface for this pilot needs to provide me with the ability to easily view the output data from the Propensity Score Analysis (PSA) and Covariate Stratification (CS) Reporting Tool to facilitate query results analysis. For that to be achieved, the user interface must have the following:

Business Requirements	Summary of Requirement
The solution shall be easily accessible via a web link on the Query Portal	Accessibility from existing platform
The solution shall allow me to specify which columns from the PSA and CS Reporting Tool output data are brought into my active view	Dimensions which can be pulled in by the user
The solution shall allow me to expand, contract, and manipulate the volume of the PSA and CS Reporting Tool output data brought into active view	Minimize, maximize, limit visually
The solution shall allow me to limit visible results using criteria that I define that are not related to graphical representation	Define additional criteria that limit data (for example, filter a column with values > 5)

Business Requirements	Summary of Requirement
The solution shall allow me to easily navigate between available PSA and CS Reporting Tool output data	Seeing a list of all output tables available for viewing
The solution shall allow me to view different PSA and CS Reporting Tool output data of my choosing in the same view	Being able to collapse data into a single table in the same view
The solution shall allow me to view all available PSA and CS Reporting Tool output data associated with one query	The entirety of an output must be available within the tool
<p>The solution shall allow me to view user defined elements across multiple and different PSA and CS Reporting Tool output data in the same view</p> <ul style="list-style-type: none"> • Example # 1 - Show me user-defined effect estimates and/or subgroup with respect to one analysis group (an exposure pair & outcome) across different analysis types and/or within different subgroups • Example # 2 - Show me user-defined effect estimates with respect to multiple analysis groups (multiple exposure pairs & outcomes) across different analysis types and/or within different subgroups • Example # 3 - Show me user-defined comparisons for cohorts, drugs, and methods 	Manipulation of the data itself and part of the core functionality of the tool
The solution shall allow me to easily redefine text and diagram descriptions to something of my choosing that can viewed by other users	Aliasing and describing data sets with text
The solution shall allow me to highlight and consolidate a list of all queries I have access to	User accessibility
The solution shall allow me to bookmark / save previously viewed queries or created reports for future reference	User accessibility
The solution shall allow me to export created reports with user-defined elements to Excel and PDF files	Export functionality

The user interface for this pilot needs to provide me with the ability to easily create visualizations based upon PSA and CS Reporting Tool output data to facilitate query results analysis. For that to be achieved, the user interface must have the following:

Business Requirements	Summary of Requirement
<p>The solution shall allow me to create industry standard visualizations of my choosing</p> <ul style="list-style-type: none"> • Subgrouping by a data dimension of choice • Data attrition tables <ul style="list-style-type: none"> • The tables should display exclusion criteria • The tables should display subtotals of subjects remaining for each exclusion criteria applied • Number of eligible new users • Propensity score distributions (before and after adjusting) • Love plots that show standardized mean differences for each covariate before and after confounding adjustment using propensity scores 	<p>Visualization creation for existing business needs</p>
<p>The solution shall have the flexibility to allow for the user-driven addition of customized visualization types</p>	<p>Visualization variety in anticipation of future customer needs</p>
<p>The solution shall allow me to take multiple user-generated graphics and view them together on the same screen</p>	<p>Seeing visualizations side by side</p>
<p>The solution shall allow me to create interactive dashboards which can contain multiple graphics that can easily be shared with other SOC & FDA users</p>	<p>Centrally controlled, shareable, side by side visualizations</p>
<p>The solution shall allow me to bookmark / save previously created visualizations & dashboards for future reference</p>	<p>User accessibility</p>

Business Requirements	Summary of Requirement
The solution shall allow me to export created visualizations and dashboards to Excel and PDF files	Export functionality
The solution shall have exports of a given data set tracked and their history available for viewing within a list/log	Export functionality & privacy
When export functionality is used, the system shall prompt/warn the user about exporting business sensitive information such as small cell counts or Data Partner information	Export functionality & privacy
The solution shall make these visualizations available to the general public after standardized clearance processing	Information sharing
The solution shall allow me to mask visualizations metrics at a user-defined threshold	Privacy and DUA

Functional Requirements (SOC)

As an SOC Team Member, I need a web-based user interface that will allow me to compare and visualize data elements contained within Propensity Score Analysis (PSA) analytic module query results. This will allow me to better assist FDA in completing PSA queries.

The user interface for this pilot needs to provide me with the ability to easily view PSA and CS Reporting Tool output data to facilitate query results analysis. For that to be achieved, the user interface must have the following:

Business Requirements	Summary of Requirement
The solution shall be easily accessible via a web link on the Query Portal	Accessibility from existing platform
The solution shall allow me to specify which columns from the PSA and CS Reporting Tool output data are brought into my active view	Dimensions which can be pulled in by the user

Business Requirements	Summary of Requirement
<p>The solution shall allow me to expand, contract, and manipulate the volume of the PSA and CS Reporting Tool output data brought into active view</p>	<p>Minimize, maximize, limit visually</p>
<p>The solution shall allow me to limit visible results using criteria that I define that are not related to graphical representation</p>	<p>Define additional criteria that limit data (for example, filter a column with values > 5)</p>
<p>The solution shall allow me to easily navigate between available PSA and CS Reporting Tool output data</p>	<p>Seeing a list of all output tables available for viewing</p>
<p>The solution shall allow me to view different PSA and CS Reporting Tool output data of my choosing in the same view</p>	<p>Being able to collapse data into a single table in the same view</p>
<p>The solution shall allow me to view all available the PSA and CS Reporting Tool output data associated with one query</p>	<p>The entirety of an output must be available within the tool</p>
<p>The solution shall allow me to view user defined elements across multiple and different the PSA analytic module output data in the same view</p> <ul style="list-style-type: none"> • Example # 1 - Show me user-defined effect estimates and/or subgroup with respect to one analysis group (an exposure pair & outcome) across different analysis types and/or within different subgroups • Example # 2 - Show me user-defined effect estimates with respect to multiple analysis groups (multiple exposure pairs & outcomes) across different analysis types and/or within different subgroups • Example # 3 - Show me user-defined comparisons for cohorts, drugs, and methods 	<p>Manipulation of the data itself and part of the core functionality of the tool</p>
<p>The solution shall allow me to easily redefine text and diagram descriptions to something of my choosing that can viewed by other users</p>	<p>Aliasing and describing data sets with text</p>

Business Requirements	Summary of Requirement
The solution shall allow me to highlight and consolidate a list of all queries I have access to	User accessibility
The solution shall allow me to bookmark / save previously viewed queries or created reports for future reference	User accessibility
The solution shall allow me to export created reports with user-defined elements to Excel and PDF files	Export functionality

The user interface for this pilot needs to provide me with the ability to easily create visualizations based upon PSA and CS Reporting Tool output data to facilitate query results analysis. For that to be achieved, the user interface must have the following:

Business Requirements	Summary of Requirement
<p>The solution shall allow me to create industry standard visualizations of my choosing</p> <ul style="list-style-type: none"> • Kaplan Meier survival curves • Histograms (regular and overlapping) • Forest plots 	Visualization creation for existing business needs
The solution shall have the flexibility to allow for the user-driven addition of customized visualization types	Visualization variety in anticipation of future customer needs
The solution shall allow me to take multiple user-generated graphics and view them together on the same screen	Seeing visualizations side by side
The solution shall allow me to create interactive dashboards which can contain multiple graphics that can easily be shared with other internal SOC & FDA users	Centrally controlled, shareable, side by side visualizations
The solution shall allow me to bookmark / save previously created visualizations & dashboards for future reference	User accessibility

Business Requirements	Summary of Requirement
The solution shall allow me to export created visualizations and dashboards to Excel and PDF files	Export functionality
The solution shall have exports of a given data set tracked and their history available for viewing within a list/log	Export functionality & privacy
When export functionality is used, the system shall prompt/warn the user about exporting business sensitive information such as small cell counts or Data Partner information	Export functionality & privacy
The solution shall make these visualizations available to the general public after standardized clearance processing	Information sharing
The solution shall allow me to mask visualizations metrics at a user-defined threshold	Privacy and DUA

Non-Functional Requirements

As a Systems Development Team member, I need to provision technical infrastructure and support for a web-based user interface tool. This tool will allow SOC Team Members and FDA to compare and visualize Propensity Score Analysis query results.

For this to be provisioned, we need to provide the following:

Business Requirements	Summary of Requirement
The new system shall maintain all existing functionality for Query Portal and any resulting data exported to Excel or PDF	Existing export functionality for other products must be maintained
The new system shall be permissions-based and managed by Crowd. Permissions shall be tiered for tool access and exporting capabilities.	User management

Business Requirements	Summary of Requirement
The new system shall provide internal users Single-Sign-On access to the tool using existing JIRA credentials	User management & user accessibility
The new system shall be accessible via a link from the Query Portal	User accessibility
The new system shall load user-defined PSA query result which occur post PSA and CS Reporting tool and report SAS function processing	Data Management
The new system shall make the entirety of the loaded data set available to internal users in a read-only form	Data Management
<p>The new system shall provide flexibility for inputs due to a non-static QRP data model</p> <ul style="list-style-type: none"> • Additional columns • Additional metrics • Additional tables / output data 	Data management
The new system should have enough ETL flexibility that it can provide an equivalent level of data manipulation functionality to current and existing QRP, PSA and CS local reporting tools	Data management
The new system shall be able to easily integrate with our existing Continuous Integration / Continuous Development pipeline	Integration into existing technical ecosystem
The new system shall be established to work with Microsoft Azure	Integration into existing technical ecosystem
The new system shall exist in compliance with all Data Partner level contracts and agreements	Privacy & compliance
The new system shall exist in compliance with all patient privacy and FISMA security requirements	Privacy & compliance

For this project, thoughtful technical infrastructure development should occur which will allow for the expansion of the platform to other query types in the future. To meet this need, the system shall be developed in accordance with the following:

Business Requirements	Summary of Requirement
The platform shall be flexible enough to work with different data set inputs, which will accommodate additional query types	Future customer needs
The solution shall have a large selection of visualization types to account for future development based around other available query types at Sentinel	Future customer needs

Bidder Questionnaire

In your response, please provide answers to the following questions regarding the characteristics of your organization and of your proposed solution. Please note that any additional detail or explanatory materials required should be attached to your formal proposal in the form of appendices and referenced below.

Responses to these questions will be reviewed by SOC during the RFP review process and will be graded according to a predetermined qualitative scale.

#	Question	Bidder Response
1	<p>SOC is open to both custom-developed solutions and customized off-the-shelf solutions in pursuit of fulfilling the stated data visualization requirements of this project.</p> <p>Please describe whether your organization’s proposed solution will be developed specifically for this project, or purchased and deployed as a customized existing offering, providing as much contextual detail as appropriate to fully characterize the proposed solution.</p>	
2	<p>SOC expects to assign business analyst resources to work directly with the selected bidder in order to help elicit and/or refine granular requirements for specific visualization functionality requested by internal and external stakeholders.</p> <p>Please indicate and explain how your organization has managed these types of cooperative analytic engagements in the past, providing examples if applicable.</p>	
3	<p>The nature of the proposed data visualization system necessitates that both internal and external Sentinel collaborators access potentially sensitive information, including regulatory information. Additionally, providing public access to areas of the application is of high interest and the data will need to be curated/masked for public viewing.</p> <p>Please articulate how your proposed solution will safeguard information while simultaneously providing simplified web-based access to internal and external collaborators.</p>	
4	<p>SOC has identified multiple potential future use cases for a data visualization platform which may increase the scope of the data contained in the system, both in terms of the types of data which may be stored (model) and the overall volume of data present in the system.</p>	

	<p>Please explain how your solution will account for potential future changes in the type, scope, and/or model of the data that will be visualized.</p>	
5	<p>Self-service is a principal concern for Sentinel users, particularly internal “power users” who wish to use the proposed visualization platform to explore the wealth of analytic data available to Sentinel.</p> <p>Please indicate how your solution accounts for providing both standardized and customized visualization and querying capabilities to the various types of end users who will be using the system.</p>	
6	<p>Due to FISMA compliance requirements, SOC requires that any solution that requires the storage of sensitive FDA data be hosted in a FISMA-compliant hosting environment. Ideally, any solution should be co-located in the existing Sentinel cloud hosting environment.</p> <p>Please indicate how the proposed solution and/or your organization’s capabilities will allow SOC to continue to meet its compliance obligations.</p>	
7	<p>SOC expects to be able to administer and support the proposed visualization platform after it is deployed for use.</p> <p>Please articulate how your solution will empower SOC operational staff to maintain appropriate centralized control of the proposed solution, both in terms of active troubleshooting and issue resolution.</p>	
8	<p>Emergent requirements during the process of a vendor engagement can sometimes complicate the process of solution delivery.</p> <p>Please indicate how your team will manage the possibility of emergent requirements throughout the period of performance for this project.</p>	
9	<p>Please indicate how your organization’s specific focus and primary technical competencies align with the proposed project and will support delivery of a robust solution.</p>	
10	<p>SOC requires that any solution developed is fully integrated with Sentinel’s existing suite of web tools, specifically including Atlassian JIRA (as a data source) and Atlassian Crowd (as an access management platform).</p>	

Please indicate how the proposed solution can be integrated with these (or other) external systems, with a principal focus on access and identity management, single-sign-on, and user experience.	
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Request for Proposal Timeline

All proposals in response to this RFP are **due no later than December 18, 2020 at 11:59 pm ET.**

Evaluation of proposals will be conducted from December 19, 2020 through February 26, 2021. If additional information or discussions are needed with any bidders during this window, the bidder(s) will be notified.

If there are more than 10 proposals submitted across all bidders, the top 3 finalists will be invited to meet with SOC and present their proposal to the SOC evaluation team by February 8, 2021.

A selection decision for the winning bidder will be made no later than April 30, 2021.

Notifications to bidders who were not selected will be completed by April 30, 2021.

Upon notification, contract negotiation with the winning bidder will begin immediately.

As noted in the Proposal Guidelines, SOC reserves the right to decline to select a winning bidder if submitted proposal(s) are determined to not meet project specifications as outlined in this document, or if otherwise warranted.

Ownership

This activity is Work for Hire (WFH). All functionality generated by this activity is property of FDA. HPHC owns all intellectual property.

Contact Information

Each bidder must submit their proposal to DataVisualizationInquiry@sentinelssystem.org

by December 18, 2020 at 11:59 pm ET.

Appendices

Appendix A: Sample Sentinel Reporting Datasets

Refer to the provided CSV files with the filename prefix “Appendix_A” (9 total).

These files are synthetic datasets produced by Sentinel’s local reporting tools.

The synthetic datasets provided in Appendix A correspond to the visualizations in Appendix B (“Appendix_B_Sample_Visualizations.pdf”) according to the following mapping:

Synthetic dataset name(s)	Visualization
Appendix_A_table1_agg_1_1.csv Appendix_A_table1_agg_2_1.csv Appendix_A_table1_dp_1_1.csv Appendix_A_table1_dp_2_1.csv	Table 1, Baseline table (pgs. 1-5)
Appendix_A_Estimates_1.csv	Table 2, Effect estimates table (pg. 6)
Appendix_A_Histogram_1_1.csv Appendix_A_Histogram_2_1.csv	Overlapping Histogram (pgs. 7-9)
Appendix_A_kmtable_unadjusted_1.csv Appendix_A_kmattrmap_unadjusted_1.csv	Kaplan-Meier Plot (pg. 10)

Appendix B: Sample Visualizations

Refer to the provided file “Appendix_B_Sample_Visualizations.pdf”.

Visualization Name(s)	Page Reference
Table 1, Baseline table	Pages 1-5
Table 2, Effect estimates table	Page 6
Overlapping Histogram	Pages 7-9
Kaplan-Meier Plot	Page 10

Guidance on variables used in datasets to create Histogram and Kaplan Meier Plot

Overlapping Histogram: In files “Appendix_A_Histogram_1_1.csv” and “Appendix_A_Histogram_2_1.csv”, the variables “Histogram of Typical Antipsychotics” and “Histogram

of Atypical Antipsychotics" are used as the x variables. The variables "_typ_is" and "_atyp_is" are used as the y variables.

Kaplan-Meier Plot: In files "Appendix_A_kmtable_unadjusted_1.csv" and "Appendix_A_kmattrmap_unadjusted_1.csv", the stepwise plot component uses "time" as the x variable, and "graphed" as the y variable which is also grouped by the "group" variable. The scatter component uses "time" as the x variable and "censored" as the y variable, along with it being grouped by the variable.

Appendix C: Budget Templates

IMPLEMENTATION				
LABOR:				
Name	Role	Rate	Hours	Cost
		\$0.00	0	\$0.00
		\$0.00	0	\$0.00
		\$0.00	0	\$0.00
		\$0.00	0	\$0.00
		\$0.00	0	\$0.00
		\$0.00	0	\$0.00
TOTAL LABOR			0	\$0.00
Other Costs:				
				\$0.00
				\$0.00
				\$0.00
TOTAL Other Costs				\$0.00
TOTAL DURATION (Weeks)				
TOTAL COSTS				\$0.00

Maintenance				
LABOR:				
Name	Role	Rate	Hours	Cost
		\$0.00	0	\$0.00
		\$0.00	0	\$0.00
		\$0.00	0	\$0.00
		\$0.00	0	\$0.00
		\$0.00	0	\$0.00
		\$0.00	0	\$0.00
TOTAL LABOR			0	\$0.00
Other Costs:				
				\$0.00
				\$0.00
				\$0.00
TOTAL Other Costs				\$0.00
TOTAL DURATION (Weeks)				
TOTAL COSTS				\$0.00

Appendix D: Open Forum Response Template

Refer to file “Appendix_D_Open_Forum_Response.pdf”

Please use this template (or include all information noted as required) when submitting written questions for the RFP Open Forum.