

CDC/ATSDR
Formative Research and Tool Development

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CDC OneLab Formative Evaluation

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Supporting Statement A

Contact:

Amber Eberhardt
Health Scientist/ Program Evaluator, TWDB
Division of Laboratory Systems
Centers for Disease Control and Prevention
1600 Clifton Road, NE
Atlanta, Georgia 30333
Phone: (571) 484-8131
Email: oev8@cdc.gov

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Goal of the data collection: Information gleaned from this data collection will provide rich insights to better understand the effectiveness of the overall OneLab and five out of seven elements (i.e., OneLab REACH, OneLab Network, OneLab TEST, OneLab VR, and OneLab Summit). Understanding the overall OneLab user experience and the user experience of each OneLab element will allow CDC to better serve and address the training and development needs among laboratory workforce and testing community.

Intended use of the resulting data: Explore how the overall OneLab increases access to laboratory trainings, resources, materials, and communities of practice among laboratory professionals and the testing community in order to better meet their needs. In addition, the collected data will drive insights to support the planning and creation of future OneLab resources, trainings, and events as well as opportunities to improve OneLab as a whole.

Methods to be used to collect data: Qualitative data will be collected via Focus Group Interviews and Key Informant Interviews.

The subpopulation to be studied: Clinical and public health laboratory professionals, testing professionals across the US.

How data will be analyzed: Qualitative data analysis (and additional quantitative analyses where appropriate)

A. Justification

A.1. Circumstances Making the Collection of Information Necessary

CDC requests approval for a new GenIC OneLab Network Evaluation under OMB Control No. 0920-1154.

Information collection activities are limited to formative work that will result in overall program improvement for CDC OneLab.

In 2021, CDC OneLab was developed to bridge, train, and sustain a capacity-building community among laboratory professionals and testers to collectively support rapid, large-scale responses to public health emergencies. CDC OneLab includes the following elements: OneLab REACH, OneLab Network, OneLab TEST, OneLab VR, OneLab Summit, OneLab Resources, and OneLab Assessments. The seven elements together address the goal of building capacity and establishing a sustainable learning community that equips the laboratory workforce and testing community with essential tools and resources to improve public health and patient outcomes. This formative evaluation will help us better understand the effectiveness of the overall OneLab and five out of seven elements (i.e., OneLab REACH, OneLab Network, OneLab TEST, OneLab VR, and OneLab Summit).

A.2. Purpose and Use of Information Collection

The purpose of the OneLab qualitative data collection through the focus group interview and the key informant interview is to gather information to help:

- Understand the overall OneLab user experience and the experience of each OneLab element to better serve the training and development needs among laboratory workforce and testing community.

- Identify opportunities to improve OneLab’s development and dissemination of relevant and timely education and training resources.
- Determine how effective each individual OneLab element and the overall OneLab initiative contributes to the strengthening of partnerships and connections between clinical laboratories, public health laboratories, testing communities, and CDC.
- Identify opportunities for real-time program improvements for each OneLab element and OneLab as a whole.
- Determine how each OneLab element and the OneLab as a whole sustains learning communities that facilitate the exchange of necessary tools, resources, and networks in order to eventually improve public health and patient outcomes.

The participants of the focus group and key informant interviews will consist of laboratory professionals who have experience with OneLab. Further inclusion and exclusion criteria of the participant selection details are provided in Supporting Statement B (SSB). Summary reports will be comprised of anonymized, aggregated data. CDC will share information gathered in presentations and reports to support further development of the CDC program and similar efforts.

A.3. Use of Improved Information Technology and Burden Reduction

Focus groups and key informant interviews will be hosted on a virtual video conferencing platform (e.g., Microsoft Teams). OneLab focus group interview and key informant interview participants will include varying levels of laboratory working professionals across the US. The anticipated number of participants is a maximum of 25 for the key informant interviews and a maximum of 25 for the focus group interviews. The evaluation team will identify participants based on their level of involvement of OneLab elements. Additionally, participant eligibility will be assessed by a participant intake form that will be emailed to identified OneLab members. Only eligible participants will be invited for either a key informant interview or a focus group interview, which will take participants approximately 97 minutes and 107 minutes, correspondingly.

Both key informant interview and focus group interview questions were reviewed by 4 evaluation experts and pilot-tested to collect the minimum information necessary for the purposes of this formative evaluation.

Participation in all key informant interviews and focus group interviews will be voluntary. Interview data will be recorded, aggregated, and deidentified.

A.4. Efforts to Identify Duplication and Use of Similar Information

CDC is not aware of the availability of any similar information. CDC OneLab was established by CDC/DLS as a one-of-a-kind innovative program that has not been previously evaluated. Therefore, no duplicate or similar information evaluating the program exists.

A.5. Impact on Small Businesses or Other Small Entities

This data collection will not involve small businesses.

A.6. Consequences of Collecting the Information Less Frequently

The key informant and focus group data is a one-time information collection per participant.

A.7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request fully complies with the regulation 5 CFR 1320.5.

A.8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A. A *Federal Register* notice was published for this generic package on August 23, 2019, Vol. 84, No. 164, pp. 44308. No public comments were received.

B. “No consultations outside of CDC occurred.”

CDC project staff will solely be responsible for this project.

A.9. Explanation of Any Payment or Gift to Respondents

No incentives will be provided for participation in the surveys proposed.

A.10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

CDC is not collecting information in identifiable form (IIF) and will not be retrieving the data by IIF data elements.

A.11. Institutional Review Board (IRB) and Justification for Sensitive Questions

This project was reviewed by Office of Laboratory Systems and Response (OLSR) Division of Laboratory Systems (DLS) human subjects contact and determined to not meet the definition of research under 45 CFR §46.102(l). IRB review is not required (see attachment 6).

A.12. Estimates of Annualized Burden Hours and Costs

Exhibit A.12. Estimated Annualized Burden Hours

The length of time for participants to complete each key informant interview is estimated for about 97 minutes per individual and the estimated completion time for focus group interview is about 107 minutes. It is expected that up to 25 respondents will complete the OneLab key informant interviews and another 25 respondents will finish the OneLab focus group interviews. There is no cost to participants beyond the participation burden time. The table below provides the burden estimates for this study.

Category of Respondent	Form Name	No. of Respondents	No. Responses per Respondent	Participation Time (hours)	Burden in Hours
Individuals or Households	OneLab Key Informant Semi-Structured Interviews	25	1	97/60	40.4
Individuals or Households	OneLab Focus Group Discussion	25	1	107/60	44.6

Individuals or Households	Participant Intake Form	50	1	10/60	8.3
Totals		100			93.3

Exhibit B.12. Estimated Annualized Burden Costs

The estimates of the annualized cost to respondents for the burden hours for the collection of information is derived from the 2023 mean hourly wage of \$30.22 for Clinical laboratory technologists and technicians (29-210), per the [Department of Labor website](#). This estimate will be used as a proxy to provide the total respondent cost for other participants (such as public health laboratories, large commercial laboratories, and manufacturers).

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Individuals or Household (Laboratory Professional)	OneLab Key Informant Semi-Structured Interviews	40.4	\$30.22	\$ 1220.89
Individuals or Household (Laboratory Professional)	OneLab Focus Group Discussion	44.6	\$30.22	\$ 1347.81
Individuals or Household (Laboratory Professional)	Participant Intake Form	8.3	\$30.22	\$ 250.83
Total				\$2,819.53

A.13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no costs to respondents other than their time to participate.

A.14. Annualized Cost to the Government

The cost to prepare for, administer, and report the results is \$ 41,144.20. This cost includes salaried labor for contractor staff and other direct costs associated maintaining survey data. Federal staff responsibilities include overall management and oversight of the project, provision of content matter expertise in the development of the research strategy and data collection instruments and overseeing all data analyses and dissemination activities.

Cost Category	Estimated Annualized Cost
Contractor labor	\$30,000

Federal Government Personnel Costs	CDC Health Scientist (GS-13)	5% time	\$5,572.10
	CDC Health Scientist (GS-13)	5% time	\$5,572.10
Total Annualized Cost to Government			\$41,144.20

A.15. Explanation for Program Changes or Adjustments

No change in burden is requested as this is a new generic information collection.

A.16. Plans for Tabulation and Publication and Project Time Schedule

Project Time Schedule	
Activity	Time Schedule
Focus Group and Key Informant Interviews	
Obtain updated list of OneLab Members	immediately after OMB approval
Begin recruitment of participants for Focus Group and Key Informant Interviews (using the participant intake form)	2 weeks after OMB approval
Conduct Focus Group and Key Informant Interviews among selected participants	2 months after OMB approval
Analyze data and produce summary report	10 months after OMB approval

A.17. Reason(s) Display of OMB Expiration Date is Inappropriate

The display of the OMB Expiration date is not inappropriate.

A.18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

List of Attachments

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