



DATA MODERNIZATION - COVID GUIDANCE

7/21/2021

Project C2: Data Modernization

Supported Coronavirus Aid, Relief, and Economic Security Act”
or the “CARES Act” of 2020 – *Get and Keep America Open.*

CONTENTS

Background and Purpose 1
Funding Strategy 1
Allowable Costs 3
COVID-19 Terms and Conditions..... 3
Process for Workplan and Budget Submission..... 4
Required Tasks 6
Activities 6
Performance Measures 12
Summary of Reporting Requirements..... 13
Acknowledgement Letter: Due Within Five (5) Days of NOA Receipt..... 15

**DATA MODERNIZATION - COVID
GUIDANCE
PROJECT C2: DATA MODERNIZATION**

BACKGROUND AND PURPOSE

As part of the “Coronavirus Aid, Relief, and Economic Security Act” or the “CARES Act” of 2020, ELC is awarding a total of \$200 million to our recipient base in a program-initiated component funding under *Project C2: Data Modernization of CK19-1904*, henceforth ‘*Data Modernization - COVID*’. The intention of this funding is to accelerate recipient’s implementation of data modernization efforts, including core data modernization infrastructure, implementation of electronic case reporting (eCR), and modernization of the National Vital Statistics System (NVSS) to move towards faster, more automated sharing of vital statistics between the state and national levels. Monitoring the indicators associated with these activities is intended to assist State, local, and territorial governments in efforts to achieve data modernization goals, assuring faster and more complete data sharing across the public health data ecosystem.

FUNDING STRATEGY

The \$200,000,000, under the ‘*Data Modernization - COVID*’ award, will be awarded to the current 64 ELC recipients according to the below formula.

1. Tier 1 – Core Data Modernization Infrastructure: Total award approximately \$46M

All 64 ELC recipients will receive funds for the following activities under this tier to conduct the following activities:

- a. Lead and coordinate data modernization efforts in the recipient’s health jurisdiction
- b. Document and understand workforce, data, and health information system needs and opportunities
- c. Implement workforce enhancements to accelerate data modernization
- d. Accelerate improvements to data quality, exchange, management, and use

2. Tier 2 – Electronic Case Reporting (eCR) Scale Up: Approximately \$77M – All 64 ELC recipients will be eligible with funding determinations being based on recipient eCR status.

eCR is the automated, real-time exchange of case report information between electronic health records (EHRs) and public health agencies. This capability increases the timeliness, completeness, and utility of case surveillance by moving data securely and seamlessly from EHRs in healthcare facilities to state or local health departments, and from state and local health departments through to other relevant partners, such as CDC.

With the funding, recipients will:

- a. Integrate eCR into surveillance for disease monitoring, case management, and notification to CDC

- b. Onboard healthcare providers and hospitals, including authoring information to support bidirectional communications and implement eCR using HL7 (Health Level 7) eCR standards and APHL AIMS (Association of Public Health Laboratories Informatics Messaging Services)
- c. Expand diseases and conditions utilizing eCR in the recipient's jurisdiction

All recipients will be eligible for funding, with the amount tailored to the recipient's status of eCR implementation and readiness for eCR expansion. There are two levels of funding.

1. Recipients awarded in Level 1 will have a funding range between \$200,000 to \$810,000. Level 1 recipients will focus their efforts on planning and foundational activities in Year 1 and start eCR expansion activities in Year 2 of this 2-year funding period. Level 1 financial support will be awarded to recipients that meet one or more of the below criteria.
 - a. Having an integrated surveillance system that is not yet mature;
 - b. A small percentage of labs onboard to ELR; and
 - c. Have not met the ELC CARES requirement to connect to AIMS for eCR.
 - d. Indicated a plan to implement a new surveillance system that is greater than 1 year away from implementation.
 - e. Indicated that they are deciding whether to implement a new surveillance system and have stopped all development activities on their current surveillance system until the new system is implemented for a period of at least 1 year.
2. Level 2 recipients will have a funding range between \$1,100,000 to \$1,545,000 and will be expected to initiate rapid expansion within the first year of award. Level 2 recipients have all authored for COVID-19 and have connected to APHL AIMS to receive eICR messages for COVID-19. These recipients may be implementing a new surveillance system in the two years or do significant development activities for their surveillance system, but they have expressed that their new surveillance system or system upgrade will not limit recruitment or onboarding for eCR for COVID-19. They should be able to make progress immediately on eCR and meet the full level 2 requirements for *Project C2: Data Modernization*.

3. Tier 3 – NVSS Modernization: Approximately \$77M

Modernizing the National Vital Statistics System (NVSS) will allow for faster, more automated sharing of vital statistics between the state and national levels. With this funding recipients will:

1. Support development and implementation of FHIR-based (Fast Healthcare Interoperability Resources) interoperability between recipients' Electronic Death Registration Systems and the National Center for Health Statistics (NCHS). This modernization will allow for faster, more automated sharing of vital statistics between state and national levels.
2. Support the 57 vital records recipients (evenly) through the production and development/testing phases of FHIR-based interoperability implementation.

All 57 ELC recipients who are part of the National Vital Statistics System (NVSS) (i.e., 50 states, American Samoa, Commonwealth of Northern Mariana Islands, Guam, New York City, Puerto Rico, US Virgin Islands, Washington DC) will receive funding, with an average award of \$1.35M for this funding tier.

Financial expenditures related to each Tier will be monitored and assessed with recipients monthly.

ALLOWABLE COSTS

Recipients are referred to the cost principles regulation found at [45 CFR Part 75 Subpart E – Cost Principles](#).

In determining if costs are allowable, consideration must be given to applicable regulations; the overall underlying cooperative agreement (CK19-1904); be considered necessary and reasonable; and be considered allocable (see: 45 [CFR 75.403](#)). Any questions about specific budget items should be directed to the OGS and the ELC Project Officer.

COVID-19 TERMS AND CONDITIONS

Coronavirus Disease 2019 (COVID-19) Funds: A recipient of a grant or cooperative agreement awarded by the Department of Health and Human Services (HHS) with funds made available under the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 (P.L. 116-123); the Coronavirus Aid, Relief, and Economic Security Act, 2020 (the “CARES Act”) (P.L. 116-136); the Paycheck Protection Program and Health Care Enhancement Act (P.L. 116-139); the Consolidated Appropriations Act and the Coronavirus Response and Relief Supplement Appropriations Act, 2021 (P.L. 116-260) and/or the American Rescue Plan of 2021 [P.L. 117-2] agrees, as applicable to the award, to: 1) comply with existing and/or future directives and guidance from the Secretary regarding control of the spread of COVID-19; 2) in consultation and coordination with HHS, provide, commensurate with the condition of the individual, COVID-19 patient care regardless of the individual’s home jurisdiction and/or appropriate public health measures (e.g., social distancing, home isolation); and 3) assist the United States Government in the implementation and enforcement of federal orders related to quarantine and isolation.

In addition, to the extent applicable, Recipient will comply with Section 18115 of the CARES Act, with respect to the reporting to the HHS Secretary of results of tests intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19. Such reporting shall be in accordance with guidance and direction from HHS and/or CDC. HHS laboratory reporting guidance is posted at: <https://www.hhs.gov/sites/default/files/covid-19-laboratory-data-reporting-guidance.pdf>.

Further, consistent with the full scope of applicable grant regulations (45 C.F.R. 75.322), the purpose of this award, and the underlying funding, the recipient is expected to provide to CDC copies of and/or access to COVID-19 data collected with these funds, including but not limited to data related to COVID-19 testing. CDC will specify in further guidance and directives what is encompassed by this requirement.

This award is contingent upon agreement by the recipient to comply with existing and future guidance from the HHS Secretary regarding control of the spread of COVID-19. In addition, recipient is expected to flow down these terms to any subaward, to the extent applicable to activities set out in such subaward.

To achieve the public health objectives of ensuring the health, safety, and welfare of all Americans, Recipient must distribute or administer vaccine without discriminating on non-public-health grounds within a prioritized group.

Acknowledgement of Federal Funding:

When issuing statements, press releases, publications, requests for proposal, bid solicitations and other documents -- such as tool-kits, resource guides, websites, and presentations (hereafter “statements”)--describing the projects or programs funded in whole or in part with U.S. Department of Health and Human Services (HHS) (which includes CDC) federal funds, the recipient must clearly state:

1. The percentage and dollar amount of the total costs of the program or project funded with federal money; and,
2. The percentage and dollar amount of the total costs of the project or program funded by non-governmental sources.

When issuing statements resulting from activities supported by HHS financial assistance, the recipient entity must include an acknowledgement of federal assistance using one of the following or a similar statement.

- If the HHS Grant or Cooperative Agreement is NOT funded with other non-governmental sources:

This **[project/publication/program/website, etc.] [is/was]** supported by the **[full name of the OPDIV/STAFFDIV]** of the U.S. Department of Health and Human Services (HHS) as part of a financial assistance award totaling **\$XX** with 100 percent funded by **[OPDIV/STAFFDIV]/HHS**. The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by **[OPDIV/STAFFDIV]/HHS**, or the U.S. Government. For more information, please visit **[OPDIV/STAFFDIV website, if available]**.

- If the HHS Grant or Cooperative Agreement IS partially funded with other nongovernmental sources:

This **[project/publication/program/website, etc.] [is/was]** supported by the [full name of the **OPDIV/STAFFDIV**] of the U.S. Department of Health and Human Services (HHS) as part of a financial assistance award totaling **\$XX** with **XX** percentage funded by **[OPDIV/STAFFDIV]/HHS** and **\$XX** amount and **XX** percentage funded by non-government source(s). The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by **[OPDIV/STAFFDIV]/HHS**, or the U.S. Government. For more information, please visit **[OPDIV/STAFFDIV website, if available]**.

The federal award total must reflect total costs (direct and indirect) for all authorized funds (including supplements and carryover) for the total competitive segment up to the time of the public statement.

Any amendments by the recipient to the acknowledgement statement must be coordinated with the HHS Awarding Agency.

If the recipient plans to issue a press release concerning the outcome of activities supported by HHS financial assistance, it should notify the HHS Awarding Agency in advance to allow for coordination.

Termination and/or Noncompliance

This award may be terminated in whole or in part consistent with 45 CFR 75.372.

CDC may impose other enforcement actions in accordance with 45 CFR 75.371- Remedies for Noncompliance, as appropriate.

PROCESS FOR WORKPLAN AND BUDGET SUBMISSION

Within five (5) business days of receipt of this guidance, the recipient's Authorized Official is required to acknowledge receipt of this guidance by submitting a Grant Note in GrantSolutions. The acknowledgement must be submitted on the recipient's official agency letterhead and utilize the 'Acknowledgement Letter for CK19-1904 – COVID Supplemental Funds' template provided at the end of this guidance document.

This funding will be awarded in the ELC Budget Period 3 (BP3) (i.e., August 1, 2021 – July 31, 2022) under CK19-1904. However, recipients should note that this supplemental funding is for a twenty-four (24) month project period and will end on July 31, 2023. The expanded project period coincides with the end of Budget Period 4 (BP4) (i.e., August 1, 2022 – July 31, 2023) of the ELC Cooperative Agreement (CK19-1904). Therefore, workplans and revised budgets should reflect activities and associated costs that will end on July 31, 2023. Recipients are reminded that expanded authority¹ applies, and funding may be extended to subsequent budget periods to cover the activities until July 31, 2024.

Within 90 days of receipt of the Notice of Award (NOA), the recipient is required to submit a workplan and revised budget describing its proposed activities. Upon submission, budgets and workplans will be reviewed by CDC and feedback will be provided and discussed with the recipient. Any necessary or recommended changes may be agreed upon between the recipient and CDC and documented in REDCap; and any agreed upon changes must be captured in GrantSolutions, the system of record, as necessary.

To appropriately document workplans, budgets, and facilitate recipients meeting the 90-day requirement:

1. Workplan entries will be completed in the 'Data Modernization - COVID' portal, in REDCap.
2. Revised budgets must be completed by using the Excel budget workbook template provided via GrantSolutions Grant Notes at time of NOA issuance. **Note:** If a recipient does not meet the 90-day submission requirement and has not received written approval for an extension from CDC, then the Payment Management System (PMS) account associated with this award may be restricted. The restriction will result in a manual drawdown process that requires CDC approval of each PMS charge. This restriction will remain in effect until the recipient satisfactorily meets the workplan and budget submission requirement.
 - a. Funds will be awarded under the 'Other' cost category and will be accessible in the Payment Management System (PMS) during the 90-day budget revision period for use in accomplishing activities outlined in this guidance;
 - b. Recipients will adjust the cost category allocations of awarded funds to reflect the areas where financial assistance is needed;
 - c. Recipients will upload the revised budget into GrantSolutions via a budget revision amendment, with a courtesy copy into REDCap 'Data Modernization - COVID' portal, by the 90-day post award deadline; and
 - d. The ELC Project Officer and OGS will process the budget revision amendment in GrantSolutions and the recipient will receive a revised NOA reflecting the requested cost category allocations.
3. A letter, indicating that all ELC Governance Team members (i.e., Project Director, Epidemiology Lead, Laboratory Lead, Health Information Systems Lead, and Financial Lead) have both contributed to and agreed upon the workplan and revised budget submitted, must be signed by all Governance Team Members (hard copy or digital signature) and submitted with the documents in the REDCap portal.

GrantSolutions

Within 90 days of receipt of the NOA, the recipient is required to submit a '**Budget Revision Amendment**' as part of the recipient's current award (CK19-1904), Budget Period 2.

The 'budget revision amendment' must consist of the following documents:

1. **Budget Information: SF-424A**
 - a. Recipient can use the form generated by the ELC budget workbook;
 - b. Or, recipient can submit a PDF of this form.
 - c. Please do not use the **e-form in GrantSolutions** as it creates issues when processing the revised NOA.
2. **Cover Letter** signed by the Authorized Official of record in GrantSolutions.

¹ Expanded Authority is provided to recipients through 45 CFR Part 75.308, which allows carryover of unobligated balances from one budget period to a subsequent budget period. Unobligated funds may be used for purposes within the scope of the project as originally approved. Recipients will report use, or intended use, of unobligated funds in Section 12 "Remarks" of the annual Federal Financial Report.

3. Completed revised budget using the ELC budget workbook that was provided in GrantSolutions as a Grant Note.

Note: In a cooperative agreement, CDC staff is substantially involved in the program activities, above and beyond routine grant monitoring.

CDC responsibilities include but are not limited to:

1. Provide ongoing guidance, programmatic support (including guidance on evaluation, performance measurement, and workplan changes), technical assistance and subject matter expertise to the activities outlined in this supplemental funding announcement guidance.
2. Convene trainings, meetings, conference calls, and site visits with recipients.
3. Share best practices identified and provide national coordination of activities, where appropriate.

REQUIRED TASKS

Note: If a recipient does not meet the below required tasks and has not received written approval for an extension from CDC, recipient may have their funds restricted in the Payment Management System (PMS) for specific costs/activities. Recurring or repeat non-compliance may result in additional restrictions or other actions being taken, consistent with applicable grant regulations.

In addition to the programmatic activities noted below in further detail, recipient responsibilities include but are not limited to:

1. Within **five (5) business days** of receipt of this guidance the Authorized Official is required to acknowledge receipt of this guidance by submitting a Grant Note in GrantSolutions. The acknowledgement must be submitted on the recipient's official agency letterhead and utilize the 'Acknowledgement Letter for CK19-1904 – COVID Supplemental Funds' template provided at the end of this guidance document.
2. Regular participation in calls with CDC for technical assistance and monitoring of activities supported through this cooperative agreement.
3. On-time submission of all requisite reporting. This may include but is not limited to reporting of performance measures, progress on milestones, and/or financial updates within REDCap.
4. Report expenditures and unliquidated obligations (ULOs) on a monthly basis. On the 5th day of the month, the expenditures and ULOs from the prior month shall be reported in the REDCap 'Data Modernization - COVID' portal.
5. Documentation of any necessary budget change/reallocation through GrantSolutions and REDCap.

ACTIVITIES

This award has 3 funding Tiers, with designated required activities for each funding tier.

Tier 1 – Core Data Modernization Infrastructure [Required Strategies and Activities]

Strategy 1: Understand, coordinate, and lead data modernization efforts in the jurisdiction

- 1a. Lead and coordinate data modernization efforts, funded either in this award or in other awards (e.g., ELC COVID &/or Core funding) to prevent duplication of efforts, in the health jurisdiction
 - i. Identify staff to lead data modernization efforts in the recipient's jurisdiction, and request funding for supporting staff if needed. The lead will be responsible for ensuring a gap analysis, needs assessment and workforce development plan are completed.
 - ii. The DMI Lead should ideally be placed to ensure that the recipient takes an enterprise approach to implementation of modernization activities. The DMI Lead should be able to lead and/or coordinate DMI activities across all diseases and conditions addressed by the health department. It is expected that the DMI Lead will include all offices (e.g. informatics, public health labs, reportable conditions, vital records, and others)

impacted by DMI work within the jurisdiction to appropriately select and move forward on modernization strategies in a coordinated and collaborative fashion.

1b. Document and understand workforce, data, and health information system needs and opportunities

- i. Assess and report: 1) the current state of data and health information systems and services, including data exchange and information systems supporting epidemiology and laboratory, and identify opportunities for modernization and improved interoperability, including across health department programs; and 2) workforce capacity, gaps, and opportunities to improve data and health information system modernization. This should include assessing the jurisdiction's data science capability, and workforce development program to identify opportunities for modernization and improved interoperability, including across health department programs, and details of opportunities and challenges for intra-jurisdictional and inter-state and federal data sharing.
- ii. Using the assessment outcomes, recipients are expected to develop a 1) full data modernization plan for IT and informatics infrastructure used to support epidemiology and laboratory work in the jurisdiction that includes forward-looking use of scalable, sustainable shared services and cloud-infrastructure, and 2) a workforce development plan that includes how existing gaps will be addressed and how modernization efforts will be supported. Training, fellows, direct assistance, and technical assistance should all be considered in addition to contractual and full-time staff.
- iii. When developing the implementation plan for Strategy 1b, Milestones should include performing or requesting technical assistance to complete assessments and developing plans for system(s) modernization and workforce development plan. Jurisdictions interested in requesting technical assistance should reach out to edx@cdc.gov to discuss resources. CDC is currently developing an assessment tool that will be shared with all recipients.

Strategy 2. Accelerate data and health information system modernization

2a. Implement workforce enhancements to accelerate data modernization

- i. Improve access to high-quality and technically appropriate trainings or other learning activities. Identify technical content and provide access to training to improve competencies supporting data and health information system modernization. Learning should be tailored to address gaps and opportunities to modernize data and health information systems and can include online trainings, acquisition of licenses to massive open online courses (MOOC), collaboration with academic institutions, sending staff to be trained at in-person courses, and participation in peer-to-peer learning. Outputs from strategy 1 should inform this activity in future years. The implementation plan, in the workplan, should discuss how trainings and learning activities will relate to known gaps and opportunities.
- ii. Conduct workforce enhancement activities to support data and health information system modernization aligned with competencies to ensure the recipient's workforce has the needed knowledge and skills. Explain how the results and outputs from strategy 1 will inform the proposed activities.
- iii. Propose a project to expand workforce capability through requests for technical assistance, direct assistance, or shared consultative services between one or more recipients to address identified needs to modernize data and health information systems. Technical assistance can include requests for fellows, assistance from funded partner organizations, or short-term support from CDC subject matter experts.

2b. Accelerate improvements to data quality, exchange, management, and use

- i. Propose one (1) or more projects that use shared services or infrastructure to enhance existing or facilitate new data exchange or information system functionality. Projects may include services and infrastructure located outside of the recipient's jurisdiction; existing services and infrastructure in the jurisdiction for use by others; or building new services and infrastructure. Given limited resources available, proposals should include incremental or scalable activities.
- ii. Propose other innovative projects for modernizing data quality, exchange, management, sharing, and use.

Tier 2 – eCR Scale Up [Required Activities]

The goal of this activity is to advance implementation of electronic case reporting (eCR) for all reportable conditions by healthcare organizations and accelerate the use of this data in public health to support case management and investigation, condition surveillance and monitoring and emergency response activities.

Strategy 1: Ensure that electronic Initial Case Reports (eICRs) from AIMS are delivered to the public health agency and received by epidemiologists at the local/state public health agency(s)

- 1a. Maintain connectivity with AIMS for receiving eICRs and Reportability Responses (RR). (Establishing connectivity is a requirement of *Project C1: Health Information Systems* and *ELC CARES* funding).
- 1b. Author and publish rules for all conditions available in the Reportable Conditions Knowledge Management System (RCKMS).
 - i. Each recipient should plan to author 35 conditions each quarter in year 1, with completion of all available conditions by the end of year 1 of the funding period.
 - ii. During year 2 of the funding period, the recipient should author newly available conditions within 3 months of the conditions being available in the RCKMS tool and should continue to update previously authored conditions to the latest version.
 - iii. Each recipient should plan to track the conditions authored and the version authored for each condition in order to accurately report through ELC performance measures.
- 1c. Ensure that epidemiologists/ case investigators have access to the eICR and RR in a human readable format across all condition areas within 3 months of award.
 - i. At a minimum, the eICRs and RRs should be available to epidemiologists at the state **and local** health department within 3 months of the award. More specifically, the eICRs and RRs should be available to the health department staff who currently receive faxes, paper case reports, phone case reports, or manual entry from web-portal case reports. For example, if manual case reporting currently goes to local health departments, then local health departments should have access to the eICRs and RRs in a human readable format.
 - ii. To fulfill this activity of ensuring the eICRs and RRs are available to epidemiologists, recipients can integrate the eICR and RR into the **production** surveillance environments of the integrated or secondary surveillance systems or connected database. Integration of the eICR and RRs into a test environment does not fulfill the activity of ensuring data availability to epidemiologists.
- 1d. Educate epidemiologists about the change in their workflow that they can expect from eCR.
 - i. Ensure that both epidemiologists at the state and local level are aware of changes in their workflow and data availability.
 - ii. Implement feedback mechanisms within health department to ensure that epidemiologists understand how to leverage the eICR most effectively and that there are feedback mechanisms in place.

Strategy 2: Build public health workforce capacity for electronic case reporting

- 2a. Identify a designated person as ‘eCR lead’ with the overall responsibility to lead eCR.
 - i. The eCR lead will be responsible for ensuring a work plan is developed and that eCR considerations are included in the DMI needs assessment and workforce development plan. The lead will also be responsible for long term planning for eCR in the recipient’s jurisdiction and for ensuring a plan to collect and report on the performance measures in ELC.

- ii. If the lead is already onboard and funded through other sources, please indicate which funds support this leader, and the name of the individual in the workplan.
- iii. The eCR lead should be a full-time leadership level position dedicated to electronic case reporting and able to support eCR with the appropriate authorities and at a level of effort to effect change. In the event that your jurisdiction cannot identify a dedicated eCR lead and will assign the title to someone else who also has responsibilities for another programmatic area such as ELR, please indicate the full duties of this leader and provide a justification. Recipient workplans will be reviewed and exceptions to the designation of a dedicated eCR lead will be made on a case by case basis.

2b. Propose a staffing plan to ensure that key eCR activities can be accomplished and implement eCR workforce expansion as needed.

- i. Staffing plans should be completed at the time that workplans are due. At a minimum, the staffing plan should address 1) communication with healthcare organization, including onboarding and recruitment activities; 2) authoring for conditions in RCKMS; 3) technical integration activities to ensure the eICR and RR documents are integrated into all surveillance systems; 4) data quality review of incoming messages and 5) (optional) evaluation expertise to assess performance of program.
- ii. The staffing plans should identify the individual(s) or contracts with the above responsibility, whether the individual(s) or contractor(s) will have shared responsibilities with other program areas, and which source of funding will support the staff.

Strategy 3: Communicate with healthcare organizations regarding eCR

3a. Communicate with healthcare organizations, facilities, and provider communities to ensure awareness, and compliance with case reporting for COVID-19 and for all other conditions.

- i. Communicate to healthcare organizations that eCR is a way to fulfill their mandated reporting requirements. Ensure that the recipient's website and reporting requirement material indicate that eCR is an accepted and encouraged form of reporting. CDC provides consistent messaging to recipients and can provide communication material to aide in the outreach efforts.
- ii. Formally declare readiness (indicating a willingness to receive data) for eCR on the recipient's website within 3 months of award. Readiness does not imply the ability to process the eICR.
- iii. Ensure Promoting Interoperability Program information is updated and available on the recipient's website.

3b. Communicate with healthcare organizations regarding parallel production.

- i. **[For level 1 recipients]** In the event that the recipient will not be able to integrate the eICR and RR data into the surveillance system during the first year of the grant period, then the recipient should communicate onboarded healthcare organizations within the recipient's jurisdiction that they can send eICRs instead of phone calls, faxes, or direct web entry portal, and can end parallel production of data.
- ii. **[For level 2 recipients]** Develop processes to turn off parallel production within recipient's jurisdiction and provide process documentation to CDC within 3 months of award.
- iii. **[For level 2 recipients]** Notify 75% of onboarded healthcare organizations that they can turn off parallel production by the end of the funding period. Turning off parallel production should be accomplished after epidemiologists have access to the data in the system with sufficient quality *or* after epidemiologists have access to manual case reports. Recipients should aim to provide feedback to healthcare organizations on the message quality within 4 weeks of go live date and should aim to turn off parallel production with healthcare organizations within 2 weeks of the messages being of sufficient quality to meet jurisdictional standards.

Strategy 4: Accelerate the utilization of eICR and RR in primary and secondary surveillance systems [Required for Level 2 recipients]

3a. Enhance all surveillance systems, including both primary and secondary surveillance systems, to enable the automated processing and use of eICR and RR documentation.

- i. Critical data elements from the eICR and RR should be processed into the production environment of the primary integrated surveillance system within 6 months of award.
- ii. All data elements within the eICR and RR should be integrated into the production environment of the primary surveillance system within 1 year of award and should be available to epidemiologists at the state and local health departments with access to the system.
- iii. All data elements of the eICR and RR should be integrated into the production environment of secondary surveillance systems by the end of the performance period.
 - a. The eICR and RR implementation plans submitted as part of ELC Enhancing Detection should be amended and re-submitted to include a plan to integrate eICRs and RRs into secondary surveillance systems.
- iv. Schedule and attend a meeting within the first 3 months of award date with the eCR team to explore opportunities for technical assistance, learn about available resources for eCR, and request for technical assistance within 5 months of award.
- v. As needed, integrate the eICR and RR into databases, warehouses, or data lakes, which are sometimes used for staging or “in front of” one or more surveillance systems, or used for purposes such as quality analysis, or epidemiological analysis.
- vi. Assure that eICR, RR, electronic laboratory results, and other surveillance data are reconciled or linked and then appropriate data (some data may not need to be delivered to all programs) is routed or delivered to individual PHA programs in the appropriate surveillance systems or databases.
- vii. Identify ways to automatically calculate performance metrics such as number of eICRs received from AIMS, number of case investigations in system with an associated eICR, and total number of case investigations or case reports within surveillance system in order to accurately report associated performance metrics.

Strategy 5: Accelerate onboarding of healthcare organizations to eCR using the AIMS and RCKMS infrastructure for all reportable conditions [Required for Level 2 recipients]

5a. Expand conditions implemented by healthcare organizations using AIMS and RCKMS and transition to eCR for all reportable conditions

- i. Communicate with onboarded healthcare organizations for COVID-19 and request that they implement the eCR trigger codes for all conditions within 1 year of award date.
- ii. Develop a recruitment and onboarding plan to target 75% of hospitals to onboard to eCR using the APHL AIMS shared service platform and RCKMS for decision support for all reportable conditions available in RCKMS by the end of the funding period (consider target of 40% by end of year 1). The funds provided through *Project C2: Data Modernization* can only be used for onboarding of healthcare organizations that utilize AIMS and RCKMS, use the standardized trigger code set from eRSD, use the CDA eICR v1.1 or later or FHIR eCR standard, and meet established time requirements to ensure interoperability across onboarded healthcare organizations.
- iii. Work with CDC to measure key aspects of implementation and measure progress including the number of facilities implementing, the number of conditions implemented eCR and data quality metrics.
- iv. Author or enhance supporting information for inclusion in the RR within RCKMS to be delivered to healthcare providers about reported conditions in support of bidirectional communications.

Strategy 6: Innovation and scientific advancement using eCR [Optional activity that is conditional upon sufficient progress with onboarding as measured by onboarded healthcare organizations in the recipient’s jurisdiction for the full set of RCKMS conditions]

6a. Recipients may include activity in the workplan that proposes an innovation and scientific advancement leveraging the eCR infrastructure to improve public health. These innovative projects can be conditionally approved during the workplan review, but the recipient must have onboarded at least one healthcare organization onboarded for all available conditions RCKMS conditions before innovative or scientific advancement projects are initiated. These activities are better suited for year 2 of the proposed workplan.

- i. Conduct a scientific evaluation project to show completeness, timeliness, and impact of eCR within jurisdiction. Evaluation plans funded through ELC should partner with CDC and should leverage the CDC evaluation framework for eCR. Possible activities for inclusion in the evaluation include comparisons of the eICR to manual case reports to lab reports. Partnership with a healthcare organization for a scientific evaluation with publishable results could be accomplished through this strategy. Evaluation activities could examine overall eCR impact or could focus on disease specific area.
- ii. Partner with healthcare providers to study the best way to utilize the RR and leverage the results to include supporting information in RCKMS that meets the needs of both public health and healthcare.
- iii. Collaborate with healthcare providers to improve the field completion rate for critical elements within the electronic health record, to enable the eICR to be more complete.
- iv. Stand-up the FHIR R4 API in front of Public Health Agency (PHA) systems to support the FHIR eCR payloads from healthcare organizations to public health agencies. PHAs may need to map this new FHIR data to manage this FHIR formatted data and integrate it into surveillance systems or databases. This activity may be approved for year 1 if there is a strong justification provided that this activity could expedite data processing or use of data by the recipient.

Tier 3 – NVSS Modernization [Required Activities]

Currently, none of the 57 vital record recipients are providing data to NCHS using FHIR-based interoperability. Recipients' expertise and system readiness for FHIR based interoperability vary widely. Recipients recently funded through the Vital Statistics Cooperative Program (VSCP) contract special projects to support testing/piloting of interoperability should be well positioned to successfully implement FHIR-based interoperability with NCHS in 2022. Other recipients will have made significantly less progress including some that do not yet have operational electronic registration systems. Regardless of technical maturity, each of the 57 NVSS recipients will receive the same base funding amount to work towards the required activities. More technically mature recipients that do not need the full funding to complete the required activities are asked to propose other 'optional' activities related to NVSS modernization consistent with the recipient's needs.

Required Activities:

- 1) Develop a project plan and timeline for implementation of HL7 FHIR-based interoperability with NCHS and any other optional NVSS modernization work to be undertaken with this funding. NCHS will work with awardees to establish a realistic timeline during the development and implementation period to align with each recipient's unique capabilities, with a goal of having most recipients ready to support FHIR-based interoperability with NCHS by July 2023, or having made significant progress towards that objective with the expectations of being ready to support FHIR-based interoperability within one year of the end of the funding period of this project.
- 2) Develop and maintain technical capacity and systems needed to implement FHIR-based interoperability with NCHS and any other optional modernization work to be undertaken with this funding. Development will be conducted in a phased approach that aligns with the timeline each recipient has developed in conjunction with NCHS. Development will include but not be limited to:
 - i. Making necessary upgrades to existing systems to support FHIR standards and record-level messaging
 - ii. Implement application programming interfaces (APIs) to support sending and receipt of FHIR messages

- iii. Engage in testing and piloting between recipient Electronic Death Registration System (EDRS) and NCHS
- iv. Recipients determined to be ready for production interoperability between EDRS and NCHS will be required to successfully complete a series of tests to demonstrate readiness before approved to send NCHS data using FHIR in production.
- v. Once the recipient has been approved for production, the recipient will move to sending data using FHIR and cease using the legacy feed.

3) Participate in NVSS Modernization Community of Practice.

Optional Activities

- 1) Propose and implement additional vital statistics related modernization and/or interoperability projects, including but not limited to:
 - a. FHIR based interoperability between medical examiner/coroner case management systems and electronic death registration systems
 - b. Pilot interoperability between hospital EHR and recipient's electronic birth and/or death registration systems
 - c. Interoperability between recipient's electronic death registration system and one or more surveillance systems or registries
 - d. Maintain existing information systems (e.g. electronic birth and death registration systems), including the personnel and operating environment and supporting software necessary for them to function

PERFORMANCE MEASURES

Tier 1 – Core Data Modernization Infrastructure

Strategy 1b. Document and understand workforce, data, and HIS needs and opportunities

- i. Completed assessment and identified opportunities using recommended tool or equivalent in first 90 days of award (Y/N).
 - a. If yes, provide summary of key finding and opportunities identified.
 - b. If no, describe barrier and challenges to completing the assessment.
- ii. Was assessment data used to modify the work plan for data modernization (Y/N)
 - a. If yes, describe data used and how the workplan was modified.

Strategy 2a. Implement workforce enhancement to accelerate data and HIS modernization

- i. Did trainings and other workforce activities address workforce competency gaps identified in the assessment? (Y/N).
 - a. If yes, describe how the trainings and workforce activities address identified competency gaps.
- ii. Number of trainings:
 - a. Provide a list of the trainings presented to include title of the training, intended audience, mode of delivery, number of participants, proportion of evaluations completed, and feedback provided.
- iii. Other workforce activities:
 - a. Provide details on peer-to-peer learning (if applicable) via trip report; and workforce enhancement through fellows, technical assistance, or shared consultative services.

Strategy 2b. Accelerate improvements to data quality, exchange, management, and use

- i. List of shared services used or created to enhance existing systems or data exchange.

Tier 2 – Electronic Case Reporting

There are several required activities that recipients should expect be able to report progress on as part of monitoring and evaluation activities.

- i. Level 1 recipients are expected to author for all conditions by end of Year 1; make manual eICRs available to epidemiologists; communicate with healthcare organizations (HCOs) consistently regarding parallel production, onboarding; update websites with information promoting interoperability and use of eCR as a method to fulfill case reporting requirements; have an eCR lead who is 100% on eCR and not on another activity, and develop a staffing plan. Recipients should be prepared to report which healthcare organizations have onboarded within their jurisdiction and whether they are in parallel production or are no longer submitting manual case reports. Recipients should also be prepared to report the number of eICRs received. Recipients should also be prepared to report on the number and version of conditions authored to the “published” status.
- ii. Level 2 recipients will be required to meet all level 1 requirements and also be required to integrate eICR and RR into surveillance systems; onboard all hospitals for COVID within year 1 and recruit for additional conditions in year 2; author meaningful RRs to HCOs. Recipients should be prepared to report on the number of cases within the surveillance system with at least one eICR associated and on the total number of cases within each surveillance system. The recipient should be prepared to share the percent of eICRs successfully integrated into each of the surveillance systems within the jurisdiction. Recipients should also be prepared to report on which conditions or which version of the RCTC is implemented within in-jurisdiction onboarded healthcare organizations.

Final guidance on performance measures will be communicated after funding guidance is issued. The ELC Program Office will utilize existing data sources whenever possible to reduce the reporting burden on recipients and, where appropriate, existing ELC performance measures may be used.

Tier 3 – NVSS Modernization

There are several required activities that recipients should expect be able to report progress on as part of monitoring and evaluation activities. Recipients will be required to submit a draft implementation plan 90 days after award to be reviewed by NCHS, with the implementation plan finalized and approved by NCHS at 6 months post award. Performance for required activities will be tracked by participation in the NVSS Modernization Community of Practice, timeliness of mortality data reporting to NCHS (percent of records reported to NCHS within 10 days), participation in formal and informal testing events and connect-a-thons, demonstration of capability to send data to and receive data from NCHS using APIs and FHIR messages, and ultimately successfully completing certification to send mortality data to NCHS using FHIR in production. Performance metrics for optional jurisdiction proposed NVSS modernization activities will be established for each project on a case-by-case basis.

Final guidance on performance measures will be communicated after funding guidance is issued. The ELC Program Office will utilize existing data sources whenever possible to reduce the reporting burden on recipients and, where appropriate, existing ELC performance measures may be used.

SUMMARY OF REPORTING REQUIREMENTS

The following is a summary of the reporting requirements for the ‘Data Modernization - COVID’.

1. Within five (5) business days of receipt of this guidance, the Authorized Official is required to acknowledge receipt of this guidance by submitting a Grant Note in GrantSolutions.

ELC Data Modernization COVID Award

2. Quarterly progress reports on milestones in approved workplans via REDCap.
3. Monthly fiscal reports (beginning 30 days after NOAs are issued).
4. Performance measure data.
5. CDC may require recipients to develop annual progress reports (APRs). CDC will provide APR guidance and optional templates should they be required.

ACKNOWLEDGEMENT LETTER: DUE WITHIN FIVE (5) DAYS OF NOA RECEIPT

‘Data Modernization - COVID’

Date:

Organization Name:

Subject: Acknowledgement Letter for CK19-1904 – COVID-19 Supplemental Funds – ‘Data Modernization - COVID’

Reference: Guidance for the use of supplemental funding for CK19-1904 ‘Data Modernization - COVID’ through the Coronavirus Aid, Relief, and Economic Security Act” or the “CARES Act” of 2020.

This is to acknowledge that I have received, reviewed, and understand the requirements in the attached programmatic guidance.

The federal funding received will be in support of the supplemental funding referenced herein and will be spent in accordance with the legislation and programmatic guidance.

Authorized Official