



Leidos Biomedical Research, Inc.

Frederick National Laboratory for Cancer Research

The enclosed deliverable summarized below is provided for your review and acceptance.

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| Contract #: | HHSN2612015000031 |
| Task Order #: | HHSN26100076 |
| DOC: | N/A |
| Unit of Work: | N/A |
| Project Title: | Development of an Integrated Canine Data Commons (ICDC) |
| Deliverable Item #: | 2 |
| Deliverable Description: | Quarterly CSP Report |
| Deliverable Due Date: | February 4, 2020 |
| Reporting Period: | 10/21/2019 through 1/20/2020 |
| Primary Program Manager (PPM): | Dr. John Otridge |
| PPM Email: | john.otridge@nih.gov |
| PPM Phone: | 240-276-5653 |
| Contracting Officer Representative (COR): | Dr. Toby Hecht |
| COR Email: | toby.hecht@nih.gov |
| COR Phone: | 301-435-9162 |
| Leidos Biomed Contracts Representative: | Matt DeSantis |

Should you have any questions related to this deliverable, please contact the Primary Program Manager identified above.

HHSN26100076: Development of an Integrated Canine Data Commons (ICDC)
 Cost/Schedule/Performance Quarterly Report
 January 2020

| Project Information | | | | | | | |
|--|--|---------------------|-------------------------------------|--|-------------------------------|---|--------------------------|
| Project Title | HHSN26100076: Development of an Integrated Canine Data Commons (ICDC) | | | | | Project Overall Status: RYG | G |
| Project Description and Deliverables | The objective of this project is to leverage the Center for Biomedical Informatics and Information Technology's (CBIIT) NCI Cancer Research Data Commons (CRDC) experience and knowledge, and its development of Data Commons Framework Services (DCFS), to create a new, dynamic data commons for canine cancer data, including not only clinical outcomes and genomics findings from canine clinical trials being conducted by the Comparative Oncology Program (COP) in collaboration with NCI's Division of Cancer Treatment and Diagnosis (DCTD), but also the trials' molecular, pharmacological, microenvironment, medical imaging and other study data. Reporting deliverables include quarterly CSP reports and monthly meeting minutes. | | | | | | |
| LBR PM | Matthew Beyers | | LBR Directorate | BIDS/ADRD | LBR Change Control Rep | Eric Stahlberg | |
| Total Funded Amount | \$1,959,336.71 | Project Type | Applied/Clinical | Tier | 3 | Task Order Period of Performance | 2018-09-24 to 2020-09-23 |
| PID | Milestone Planned Amount | | LBR Project Expenses to Date | | LBR Open Obligations | | |
| 400.041.0076.0001.001 | \$1,959,336.98 | | \$856,600.77 | | \$310,294.64 | | |
| Total as of 12/27/2019: | \$1,959,336.98 | | \$856,600.77 | | \$310,294.64 | | |
| Percent Spent: | 44% | | | | Percent Committed: | 60% | |
| *Total Task Order Invoiced Amount: | \$806,091.81 | | | | | | |
| Invoice Number: | INV-0000003170 | | | Invoice Cost through Date: | 12/6/2019 | | |
| *The variance between the LBR Project Expenses-to-Date and the Total Task Order Invoiced Amount is related to: 1) Fixed fee included solely in the invoiced amount; and 2) Difference between target and provisional indirect cost rates used to calculate the indirect cost allocations for the project expenses-to-date and the total invoiced amount, respectively. | | | | | | | |
| Milestone No. and Name | Description | | | Original Estimated date of completion | | Revised Estimated date of completion | |
| 1 – Base: Complete Prototype | Initial and incremental development of a prototype ICDC using existing data and implement | | | 9/24/2018 | | 9/23/2020 | |
| | Name | | | Email | | Phone | |

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|---------------------------------------|------------------|--|--------------|
| LBR Subcontracts Administrator | Nick D'Abbraccio | dabbraccionn@nih.gov | 301-228-4323 |
| Subcontractor or Supplier | | Subcontract Amount | |
| Essential Software, Inc. | | \$925,000 | |

| Project Status | | |
|----------------------------|--|---|
| Assessment Type | Current Status | Future Plans |
| Technical Scope and Status | <p>Since October 2019, the SC has met twice more and finalized the guidelines for the Data Governance Advisory Board. The finalized document was published to the Steering Committee and the first data submission proposal was received Dec. 31, 2019. The Best Practices SubCommittee continues to develop standards for genomic, imaging and pathology data collection. We continue to meet with the COR on a monthly basis to review progress and ensure agreement. Because of excellent performance and COR confidence, as well as need for continued support, Options 1 and 2 have been exercised by the government.</p> <p>The ICDC Data Team continued to work with the new projects, Glioma and PRECINCT, as reported last quarter, and also continued to meet with the NCI Semantics Team to look at CDISC and BRIDG and what integration with them means and looks like. The Data Team also completely tested the data load for the two existing studies in an end-to-end test prior to release of the system to Production.</p> <p>The System Infrastructure team worked diligently to produce the Minimum Viable Product, which was released to the public on Dec. 16, 2019. During this last period, the team worked with a designer to revise the UI, developed integration with Seven Bridges Genomics, implemented a faceted search interface, designed and tested a disaster recovery process, designed a data upload and validation process, and acquired the Authority To Operate (ATO). The system was demonstrated</p> | <ol style="list-style-type: none"> 1. Meet with COP/NCATS to correct existing studies. 2. Acquire more data from NCATS to fill out the existing study (only 12 of 60 dogs currently have genomic data due to publishing and patent issues.) 3. Acquire pharmacokinetic/pharmacodynamic data from COP to add to existing study. 4. Develop a submission guide for potential data submitters so that they can plan what changes to their data are required to comply with ICDC. 5. Work with TCIA to develop image transfer, deidentification and linkage procedures. 6. Work with Canine Glioma data set submitters to get their data into the system (once proposal to DGAB is prioritized) |

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| Project Status | | |
|--------------------------------|---|---|
| Assessment Type | Current Status | Future Plans |
| | to the COR on Dec. 23, 2019 and feedback was very positive. CBIIT leadership was also shown the system and responded similarly. | |
| Schedule Milestones and Status | The project is still on track with regards to period of performance and schedule. The Minimum Viable Product (MVP) was released on Dec. 16, 2019. | The project is in a status of acquiring feedback from users of the MVP, processing new data and identifying and developing additional features. |
| Cost Status | The project is currently spending at projected rate. | No change. |
| Terms and Conditions | No change. | No change. |
| Assumptions | No change. | No change. |
| Subcontractor Status | The subcontractor has performed at or above expectations and is within budget and schedule. | Because of excellent past performance, we expect this subcontractor to continue to provide the same level of effort as we move forward. |
| Risk Status | No new risks are foreseen which would affect scope, schedule or budget. | See risk assessment below - no risks are expected to affect project performance. |

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Cost Status Overview

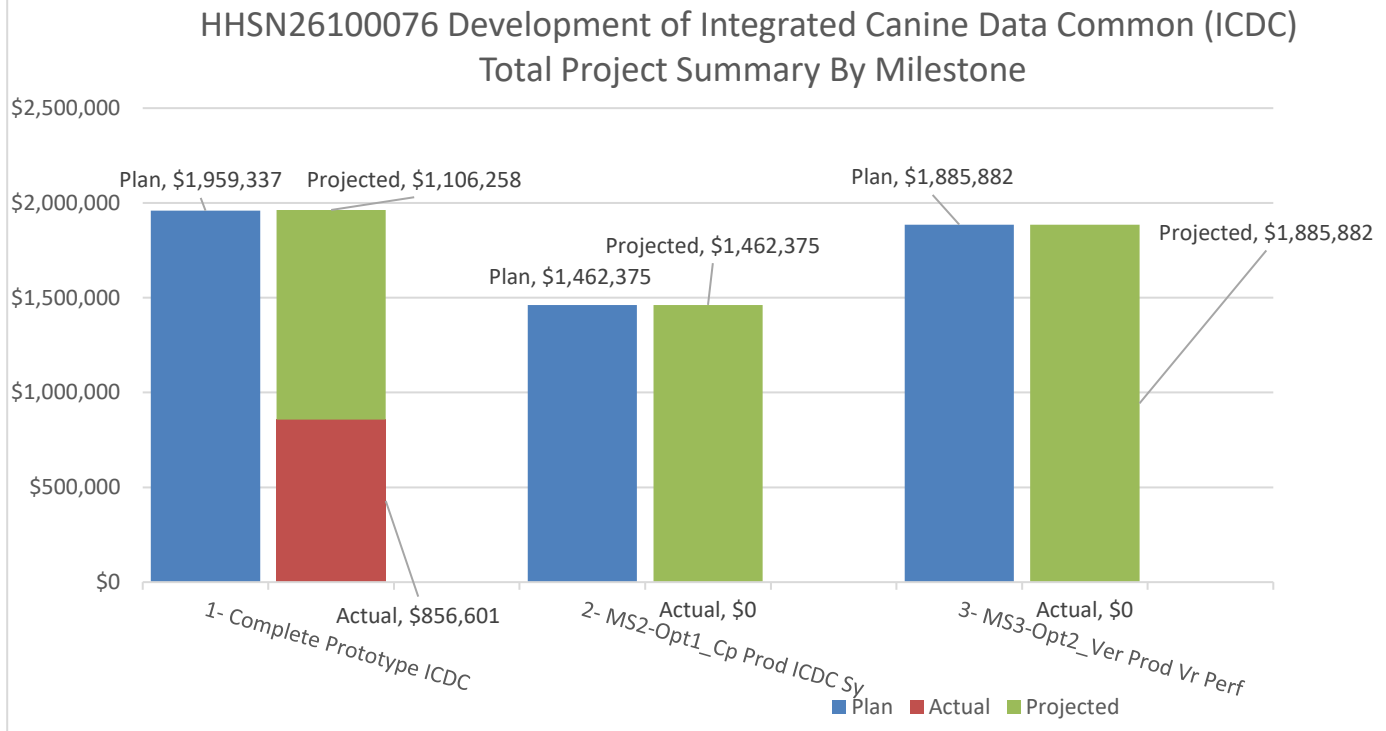


Figure 1. Bar graph shows Planned Spend compared to Actual and Projected expenses by milestone.

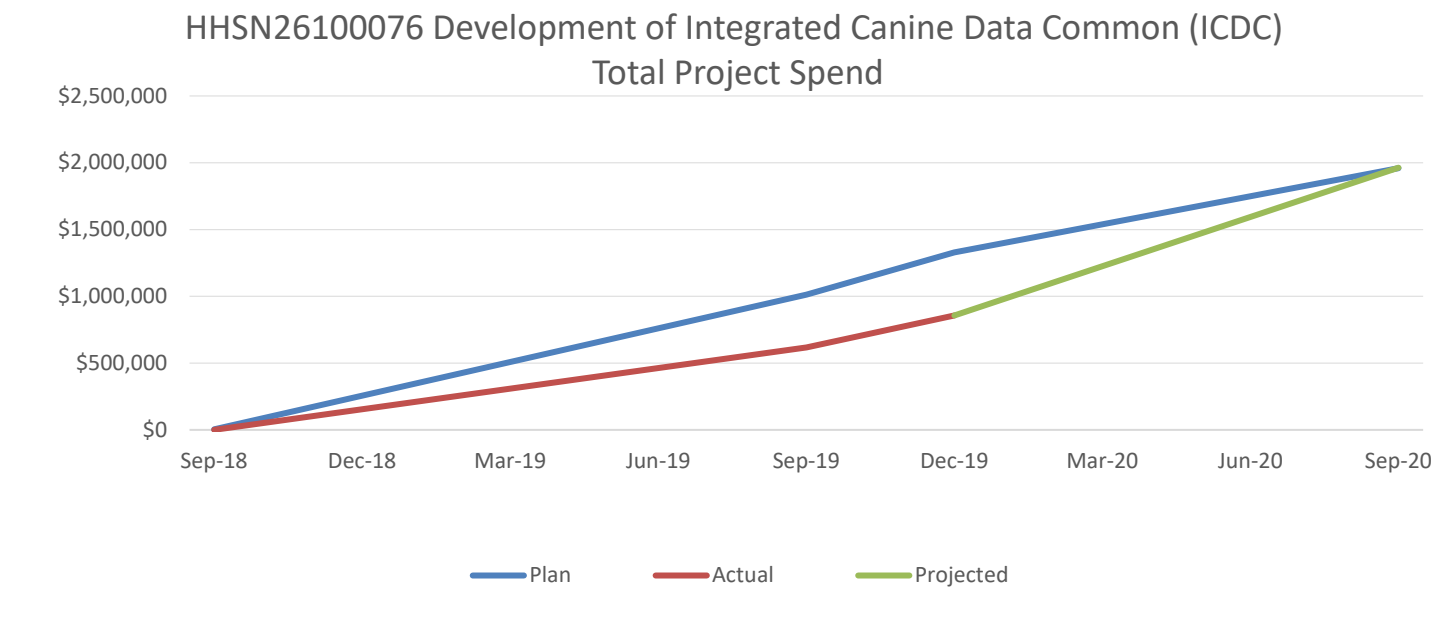


Figure 2. Line Graph showing the Actual and Projected costs compared to the Planned Spend by month and year.

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| Project Performance Status | | | | |
|----------------------------------|------|---------|--------|---|
| Assessment Area | Past | Present | Future | Comments |
| Overall Assessment | G | G | G | Two or less yellows, no red |
| Technical/Scientific | G | G | G | Demonstrated or projected ability to meet all technical metrics and no open unresolved technical issues. |
| Schedule | G | G | G | Ability (actual and projected) to meet all schedule milestones. |
| Cost | G | G | G | Costs are being tracked and projected to show actuals versus plan/forecast. |
| Contract | G | G | G | Change Control Board running well and managing technical direction changes. And no significant contractual issues. |
| Subcontractors & Suppliers | G | G | G | Demonstrated or projected ability for supplier to meet all technical metrics. |
| Customer Environment | G | G | G | Customer perceptions aligned with PM perceptions. |
| Team Compliance & Fraud Concerns | G | G | G | No unusual circumstances that would give rise to fraud/corruption concerns. |
| Staffing | G | G | G | All key positions filled; no significant staffing shortfalls. Project team working effectively together. Good line management and functional support. |
| Infrastructure & Facilities | G | G | G | No Infrastructure needs. |
| Data Security | G | G | G | Required security and privacy plans current, self-assessment has been completed, employees have completed required training. |

| Risk | |
|--|---|
| Accepted or Realized Risks & Impact | |
| | <ul style="list-style-type: none"> There was a risk that the Gen3 architecture was going to be found to be less mature than needed for the purposes of ICDC. We expected that installing and configuring the system would be challenging and that there would be specifics that related to the Genomic Data Commons that were not relevant to ICDC. Upon examination, we determined that there were many aspects of Gen3 that were incompatible with our needed functionality, in particular the ability to capture and store clinical trial data models and data. We also discovered that there was a high degree of “hard coding” that would require significant re-writes. Probability: High; Impact: Minor; Mitigation: Software development to customize was anticipated to be needed for this purpose and budgeted. This risk is currently realized and mitigated. |

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| Risk | |
|--|---|
| Open Red Risks & Mitigation Plans | |
| | <ul style="list-style-type: none"> The known Use Cases may only be a small fraction of the Use Cases the community requires. As such, our level of efforts estimates may not be enough to cover the effort required to meet the new use cases. Probability: High; Impact: Minor; Mitigation: Frequent communication with the NCI program leadership to prioritize Use Cases to use in the Prototyping and Production stages. |
| Open Yellow Risks & Mitigation Plans | |
| | <ul style="list-style-type: none"> The level of detail in the SOW is low and the Data Commons concept is new. So, there are a lot of unknowns that will only be encountered during implementation. So, this adds a lot of uncertainty to the timelines and the effort estimates. Probability: Medium; Impact: Moderate; Mitigation: Focus on uncovering those unknowns during the Prototyping stage so they do not arise late in the project at Production. At the completion of the Prototyping phase we will conduct an assessment of costs and schedule for the development of the Production system. |
| Open Green Risks | |
| | <ul style="list-style-type: none"> Amount of data to be stored is larger than the free-storage can handle, so could exceed our estimated costs. Probability: Low; Impact: Moderate; Mitigation: Work with the NCI programs to identify this issue if it arises and evaluate options before implementing a solution. |
| Open Issues, Action Items and Resolution Plans | |
| | <ul style="list-style-type: none"> The current subcontractor has been performing exceptionally and, in coordination with the ADRD directorate, we will allocate additional funds for further development. Some of the funds which has been previously reserved for data submission assistance will be allocated for development as we do not anticipate a need for all of them at this time. An IAR will need to be completed to increase the contract ceiling for additional development. |

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| Project Schedule | | | | | | | | | | | | | | | | | |
|------------------|---|-------------------|----------|-------------|-------------|------------|---|-----|-------------|-----|-----|-------------|-----|-----|-------------|--|--|
| ID | Task Mode | Task Name | Duration | Start | Finish | % Complete | Nov | Jan | 1st Quarter | May | Jul | 3rd Quarter | Nov | Jan | 1st Quarter | | |
| | | | | | | | | | Mar | | | Sep | | Mar | | | |
| 1 |  | Complete Prototyp | 523 days | Mon 9/24/18 | Wed 9/23/20 | 44% |  | | | | | | | | | | |

Figure 3. Project schedule based on the milestones and progress to date.