Leidos Biomedical Research, Inc.

Frederick National Laboratory for Cancer Research

July 17, 2019

Mr. Scott Keasey, Contracting Officer
Dr. Toby Hecht, COR
9609 Medical Center Drive
Bethesda, MD 20892

Reference: Contract HHSN261201500003I

Subject: Task Order HHSN26100076

NCI Action: Review and Acceptance of Task Order Deliverable

Dear Dr. Hecht:

In accordance with the above referenced contract and task order, the deliverable summarized below is provided for your review and acceptance.

Table 1: Deliverable Summary

Task Order Number:	HHSN26100076	**Project Title:**	Development of an Integrated Canine Data Commons (ICDC)
Deliverable Item Number:	2	**Deliverable Description:**	Quarterly CSP Report
Reporting Period:	4/21/2019 – 7/20/2019	**Quantity:**	1
Primary Program Manager (PPM):	John Otridge	**Contracting Officer's Representative (COR):**	Toby Hecht
PPM Email:	John.Otridge@nih.gov	**COR Email:**	Toby.Hecht@nih.gov
PPM Phone:	240.276.5653	**COR Phone:**	301.435.9162

Respectfully,

Connie Suders
Contract Administrator

HHSN26100076: Development of an Integrated Canine Data Commons (ICDC)
Cost/Schedule/Performance Quarterly Report
July 2019

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	$1,959,337	**Project Type**	Applied/ Clinical	**Tier**	3	**Period of Performance**	2018-09-24 to 2020-09-23

PID	Milestone Planned Amount	LBR Project Expenses to Date	LBR Open Obligations	LBR Project Costs Invoiced to Government
400.041.0076.0001.001	$1,959,336.71	$324,492.01	$681,631.80	$326,456.62
Total as of:	6/28/19	$324,492.01	$681,631.80	$326,456.62
Percent Spent:	17%		**Percent Committed:**	51%

Milestone No. and Name	Description	POP	
		Start Date	End Date
1 – Base: Complete Prototype	Initial and incremental development of a prototype ICDC using existing data and implement	9/24/2018	9/23/2020

LBR Subcontracts Administrator	Name	Email	Phone
	Nick D'Abbraccio	dabbraccionn@nih.gov	301-228-4323

Subcontractor or Supplier	Subcontract Amount
Essential Software, Inc.	$925,000

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Project Status		
Assessment Type	**Current Status**	**Future Plans**
Technical Scope and Status	The Steering Committee has met four times since February 2019 and has appointed a chair (Deborah Knapp) and two subcommittees: Data Governance Advisory Board (DGAB) (Chair: Warren Kibbe) and Best Practices SubCommittee (BPSC) (Chair: Jeff Trent). The DGAB is focused on determining procedures and criteria for new data submissions during the prototype phase of the project. The BPSC is focused on providing guidelines for data collection and sharing to investigators and data submitters with an emphasis on determining standards for data in the ICDC. The Data Team has explored transformation of data in preparation for ingestion into the upcoming data system with an emphasis on integration on the Cloud. They have completed rough data modeling for two data sets, identified issues needing improvement (to feed back to the BPSC for standards determination), are beginning to process of defining detailed constraints for data fields and are mapping that data model to BRIDG. They are also working closely with the front-end developers of the system infrastructure to ensure that user stories are translated into wireframes and subsequent functionality. They will assist with ingestion of new data submissions once decided upon by the DGAB. The System Infrastructure Team have acquired a Sandbox in the NCI Cloud One and have setup the initial version of system/database. We are currently constructing wireframes to illustrate user stories with user feedback, developing corresponding webpages, creating and populating the Neo4J graph database to hold the data, and developing the APIs to connect the front-end and back-end systems. Automated testing is being developed simultaneously to ensure quality control.	The SC will meet in August and consider the work of the subcommittees. A call for data submissions should be forthcoming after that. The data team will process those submissions and work with the DGAB to help determine which data sets get the highest priority for entry. The system infrastructure team will continue to develop and produce a DEV environment for testing and user feedback. This will include the data from the two initial data sets (COTC007B and NCATS). They will also establish guidelines and needs for interoperability with the Cloud Resources and NCI Cloud One to ensure a smooth flow of data for users.

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Assessment Type	**Current Status**	**Future Plans**
Schedule Milestones and Status	The project is still on track with regards to period of performance and schedule.	The project has pivoted to mostly software development for the next several months and is expected to produce a minimum viable product by end of December 2019.
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	The increased software development mentioned previous has been realized and will consume project reserves closer towards the end of the period of performance than evenly throughout the project. We are, however, on target for spending appropriately according to the budget.	No change.

Cost Status Overview

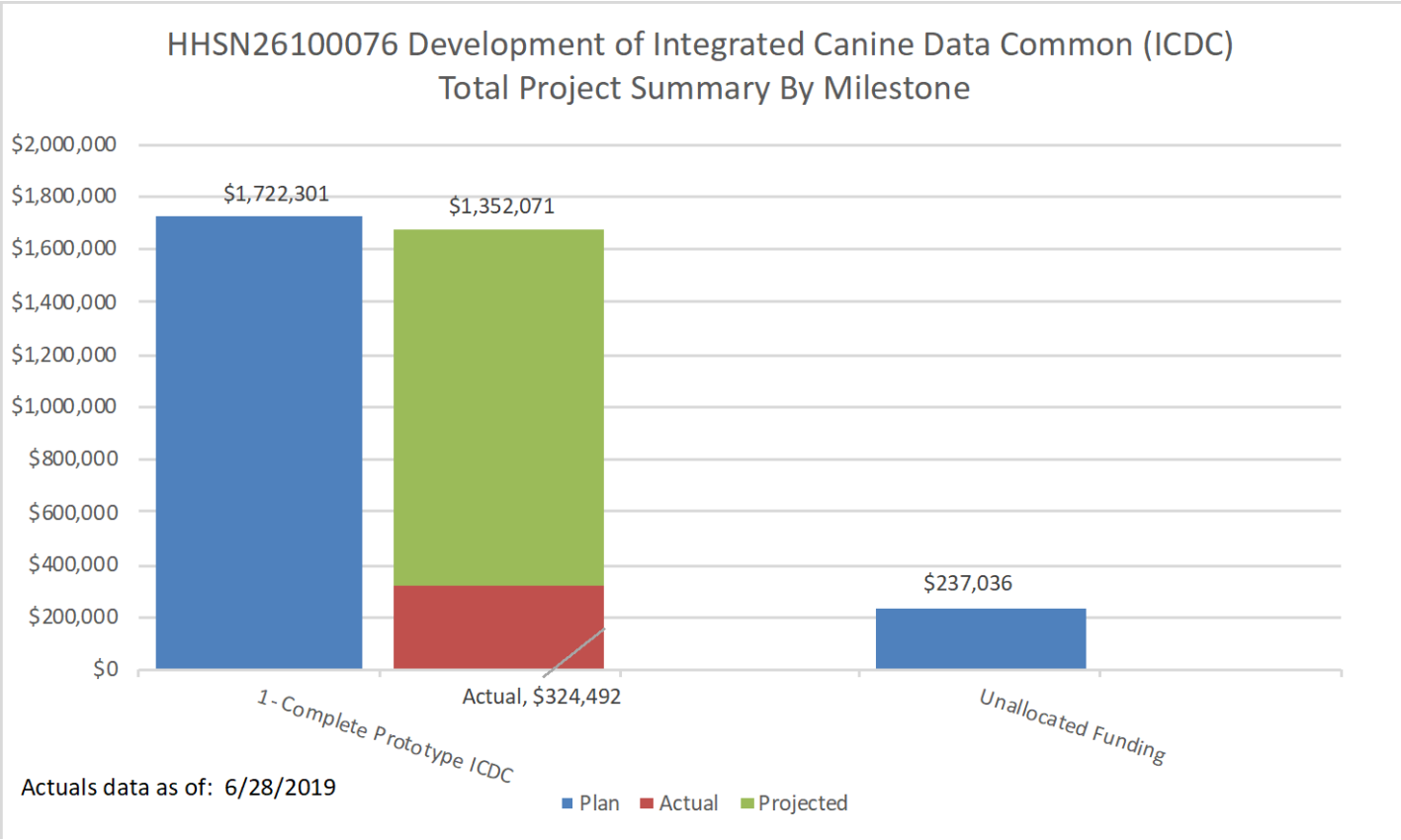

Figure 1. Bar graph shows Planned Spend compared to Actual and Projected expenses by milestone as of July 2019.

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Cost Status Overview

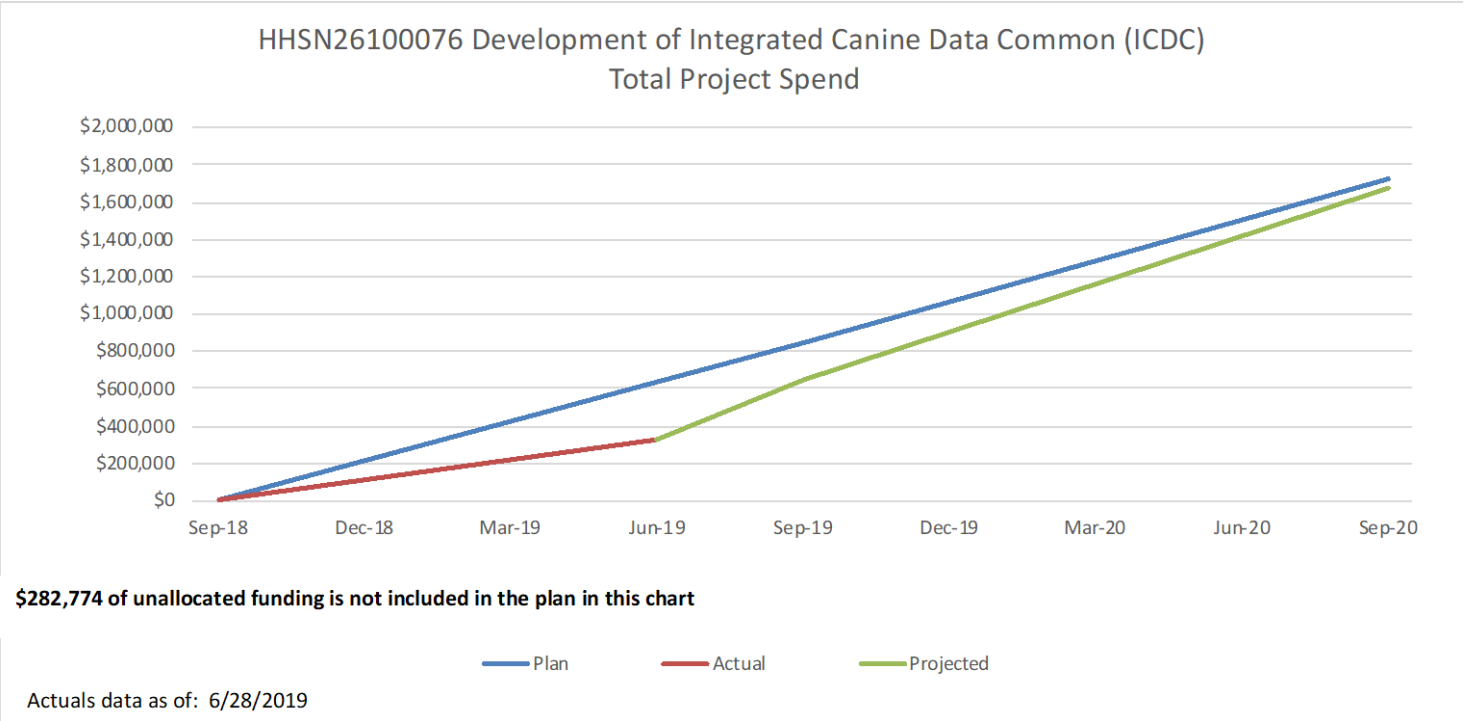

Figure 2. Line Graph showing the Actual and Projected costs compared to the Planned Spend by month and year as of July 2019.

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.

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Project Performance Status				
Assessment Area	**Past**	**Present**	**Future**	**Comments**
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

- 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.

Open Red Risks & Mitigation Plans

- 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

- 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

Risk	
	• 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. • Unable to staff the project in a timely fashion with either/or FNL or subcontractor staff. This could delay progress towards meeting milestones. Probability: Low; Impact: Moderate; Mitigation: The initial phases will focus on activities such as data inventory, harmonization and use case definition that utilize existing or soon to be hired staff (anticipated to be onboard before project starts). This will allow time to find any additional staff or subcontractors to staff up.
Open Issues, Action Items and Resolution Plans	
	No Open Issues

Original Schedule

ID	Task Name	Duration	Start	Finish	% Complete
1	Complete Prototyp	523 days	Mon 9/24/18	Wed 9/23/20	7%

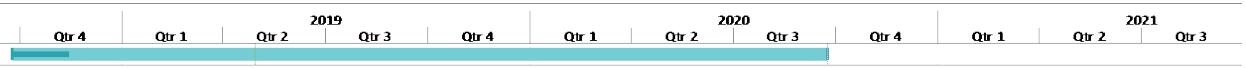

Figure 3. Project schedule based on the milestones and progress to date as of July 2019.