Leidos Biomedical Research, Inc.

Frederick National Laboratory for Cancer Research

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

Contract #:	HHSN261201500003I
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
Reporting Period:	1/21/2020 – 4/20/2020
Program Name:	BIDS/ADRD
Primary Program Manager (PPM):	Dr. John Otridge
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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
April 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	$5,307,594.00	**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	$1,105,064.33	$592,609.25
Total as of 3/27/2020:	$1,959,336.98	$1,105,064.33	$592,609.25
Percent Spent:	56%	**Percent Committed:**	87%

***Total Task Order Invoiced Amount:**	$1,120,473.46		
Invoice Number:	INV-0000003170	**Invoice Cost through Date:**	3/27/2019

*The variance between the LBR Project Expenses-to-Date and the Total Task Order Invoiced Amount may be related to: 1) Difference in reporting periods; 2) Fixed fee included solely in the invoiced amount; and 3) 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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Project Information			
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	Since January 2020, the SC has met twice more and was informed of the launch of the ICDC website and was provided a demonstration. The Data Governance Advisory Board received four (4) study proposals and prioritized them with agreement from the NCI Senior Advisory Committee. The Best Practices SubCommittee was actively involved in establishing Data Submission Guidelines and provided a draft for review at the April SC meeting. The draft includes guidelines for genomic, imaging, and clinical/pathology data, as well as study, subject, and visit data. A plan is in development, coordinating with NCI (DCTD and CBIIT), for a series of outreach activities and communications which will occur when the data sets that are in the pipeline. The ICDC Data Team, in concert with the data submitters, began revision of the two original studies (COTC007B and NCATS-COP-01) to bring them into compliance with the draft guidance. They have also been actively working on the recently submitted Glioma and Vemurafenib studies and working out linkage to existing sequence data with NCBI's Sequence Read Archive (SRA). They met with the Center for Cancer Data Harmonization (CCDH) and shared their data model to assist the CCDH in coming up with an aggregate data model for all of Cancer Research Data Commons (CRDC), of which the ICDC is a member. The System Infrastructure team has been evaluating the backlog of improvements, bugs and user requests to prioritize modifications. They	1. Coordinate with CBIIT/DCTD Communications team on official announcement of ICDC. 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. Load revised studies, plus Glioma, to production. 5. Develop an outreach plan to the veterinary research community. 6. Continue working with Glioma data set submitters to get their data into the system, including integration with NCBI's SRA and acquisition of images. 7. Collate and integrate the Vemurafenib study data and push to production. 8. Make and apply changes to the system based on the prioritized backlog.

Project Status		
Assessment Type	**Current Status**	**Future Plans**
	have also been monitoring of the security and usage of the system and making modifications to the data model as needed by the Data Team for incorporation of new studies.	
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.	We expect this subcontractor to continue to provide the same level of effort.
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.

Cost Status Overview

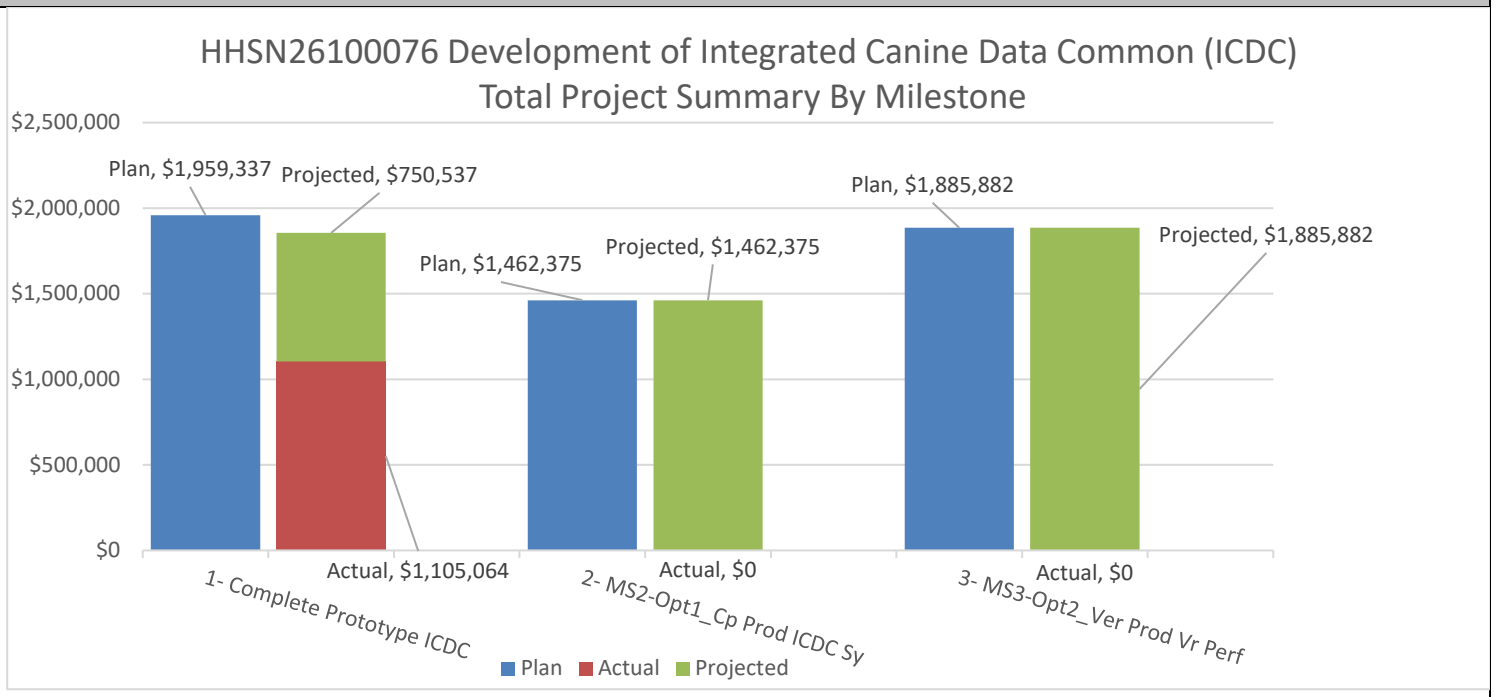

Figure 1. Bar graph shows Planned Spend compared to Actual and Projected expenses by milestone as of 3/27/2020.

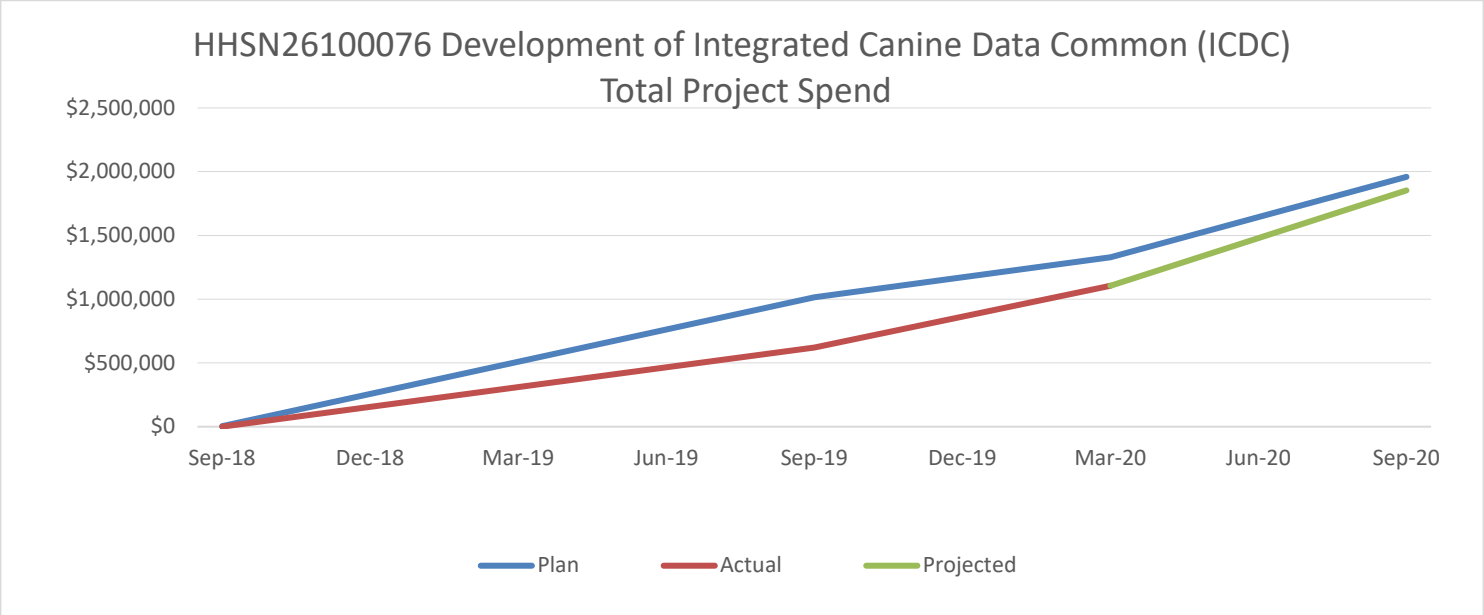

Figure 2. Line Graph showing the Actual and Projected costs compared to the Planned Spend by month and year as of 3/27/2020.

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

- 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.

Risk
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
• 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
• None at this time.

Project Schedule

ID	Task Mode	Task Name	Duration	Start	Finish	% Complete
1		Complete Prototype	523 days	Mon 9/24/18	Wed 9/23/20	87%

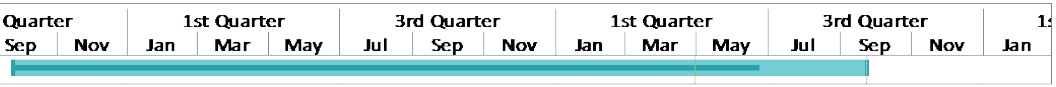

Figure 3. Project schedule based on the milestones and progress to date.