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Leidos Biomedical Research, Inc.

Frederick National Laboratory for Cancer Research

January 25, 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:	9/24/2018-1/20/2019	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
February 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 Research	Tier	2	Period of Performance	2018-09-24 to 2020-09-23

PID	Milestone Funded Amount	LBR Project Expenses to Date	LBR Open Obligations	LBR Project Costs Invoiced to Government
400.041.0076.0001.001	$1,959,336.71	$43,990.49	$115,835.22	$48,783.46

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
	Joshua Ensor	Joshua.ensor@nih.gov	301-228-4019

Subcontractor or Supplier	Subcontract Amount
Essential Software, Inc.	$112,608

Project Status

Assessment Type	Current Status	Future Plans
Technical Scope and Status	**System Infrastructure:** • Worked closely with U. Chicago team to standup full-Gen3 system, identifying gaps in documentation and configuration. The U. Chicago full-Gen3 system is more complex than is needed at this time, requiring a great deal of maintenance and configuration. Suspecting	**System Infrastructure:** • We intend to be able to show a basic working system to the client by the end of January including some minimal set of curated, representative data. Based on this, we will start to

Project Status		
Assessment Type	**Current Status**	**Future Plans**

	this, we have been working on a simpler, dockerized version simultaneously.
	• Completed dockerized version of Gen3 system which will be used for prototype. Dockerizing each of the components will also allow us to configure load balancers for the production system by distributing the work load on multiple machines without need for the complexity designed by U. Chicago.
	• Established use of NCI CloudOne (AWS) as the Prototype's cloud infrastructure.
	
	Data:
	• Identified two new areas from which to acquire data through Connie Sommers (NCI).
	• Plans have changed regarding data from NCATS - data will start flowing in late January when the investigators are available, however this does not affect our schedule as we will move forward with the data we have in hand and add more later.
	• The first draft of the Gen3 data model was completed. We have recognized the need for, and are developing, a robust program to outline the data model and then construct a graphical representation and simultaneously produce the file needed for ingestion by Gen3. The program will be ready early January and will not affect our schedule.
	• Meetings were held to discuss the projects and data that will be enter the ICDC. COTOC007b trial is first data set selected.
	    ○ Reviewed trial workflow/protocol, inventoried data.
	    ○ Reviewed image data held at FNL and began acquiring images from Jay Juiping Ji.
	    ○ Received data for a set of subjects
	    ○ Extracted and transformed data as it was made available.
		receive feedback about future improvements.
		• Finalize Gen3 shell installation and start customization/configuration.
		• Finalize ETL and database selections.
		
		Data:
		• We intend to continue to collect data from various sources and integrate it into our data model, adding to the system on a continuous basis. Eventually this will switch from our entering data to user's submitting their own data.
		• Start receiving genomic data from NCATS.
		
		Steering Committee:
		• The SC intends to have its first meeting by end of January 2019. From here, we will start getting feedback on user stories and system performance as well as getting data submitted by users. We expect a continuous feedback loop to result in continuous improvements.

Project Status		
Assessment Type	**Current Status**	**Future Plans**
	• Met with Greg Tawa and David Gerhold from the National Center for Advancing Translational Sciences (NCATS) to discuss genomic canine data. **Steering Committee:** • Project Management Plan will be completed by end of January. • Finalized proposed list of Steering Committee members and sent letters of invitation. Almost all responded in the affirmative and we will finalize the list in January. • Delivered Project Implementation Plan and held kick-off meeting with NCI	
Schedule Milestones and Status	On track for completing Prototype by end of POP.	
Cost Status	We recognize that we have allocated monies which were reserved for a contract with U. Chicago, which is no longer necessary. We have begun discussions with the COR concerning and appropriate use of this money but have not yet come to a decision.	Evaluate impact that not requiring subcontract with UChicago will have on project. Discuss impact with NCI and possible options if the funds indeed can be used for other project activities. Will follow the Task Order change request process to effect any change. We realize there is a significant cost under-run and have planned to utilize those monies within the time frame, in a subcontract mechanism, once we have a better understanding of the system design needs.
Terms and Conditions	No new Terms and Conditions.	Do not anticipate changes to Terms and Conditions.
Assumptions	No new assumptions.	Not anticipating any new assumptions.
Subcontractor Status	ESI is onboard. Subcontracting with UChicago is likely moot as their support will be provided under a different	We expect to execute new subcontracts to acquire additional staff from ESI for programming and web development. This will be absorbed by monies that were deallocated from the labor budget and

Project Status		
Assessment Type	Current Status	Future Plans
	FNL contract funded by CBIIT (Data Commons Framework).	moved to subcontracts. If this causes a need for a change in the subcontract ceiling, an Impact Analysis Report will be filed with change mangagement.
Risk Status	See risk assessment below.	See risk assessment below.

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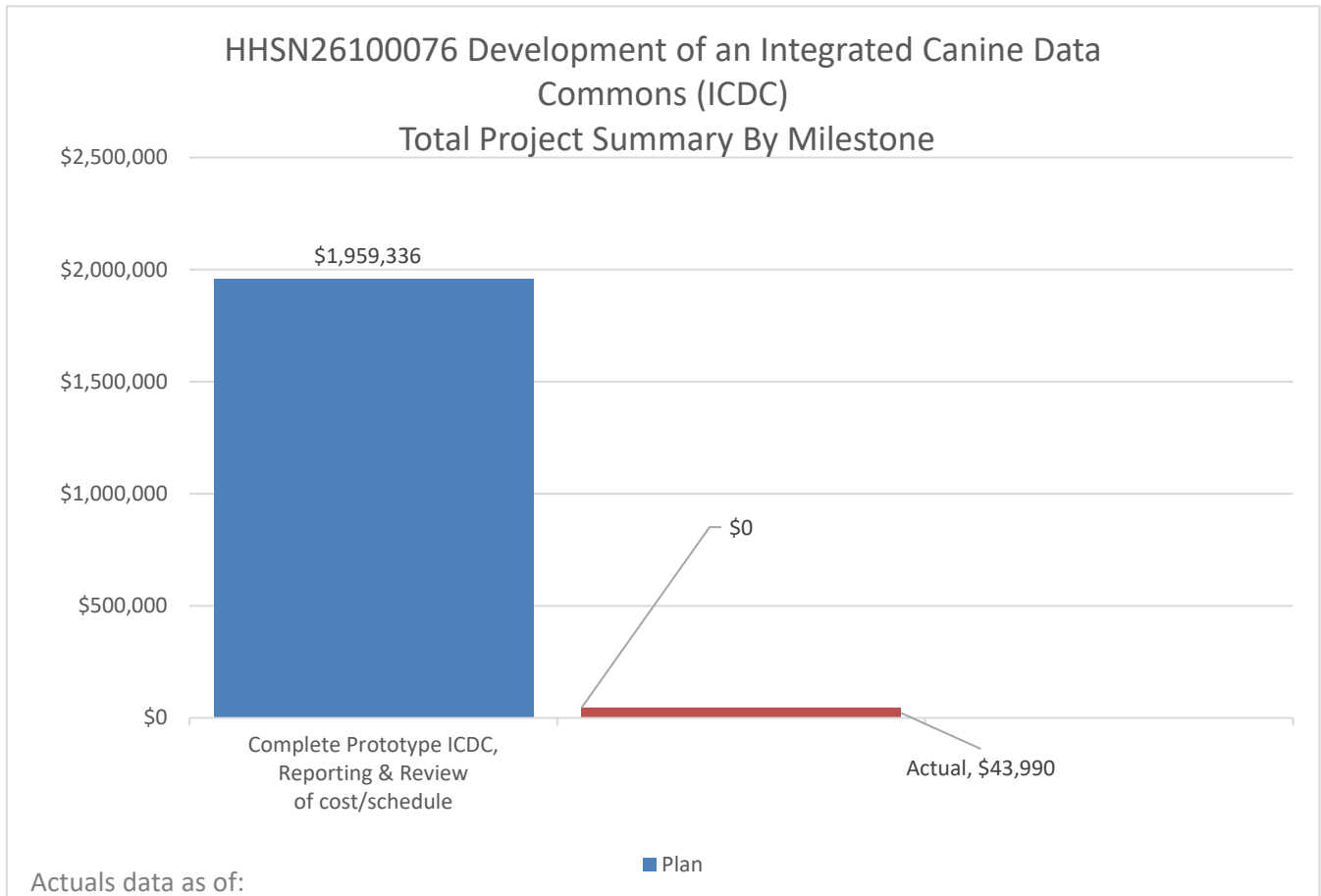## February 2019

Cost Status Overview

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

Cost Status Overview

HHSN26100076 Development of an Integrated Canine Data Commons (ICDC)
Total Project Spend

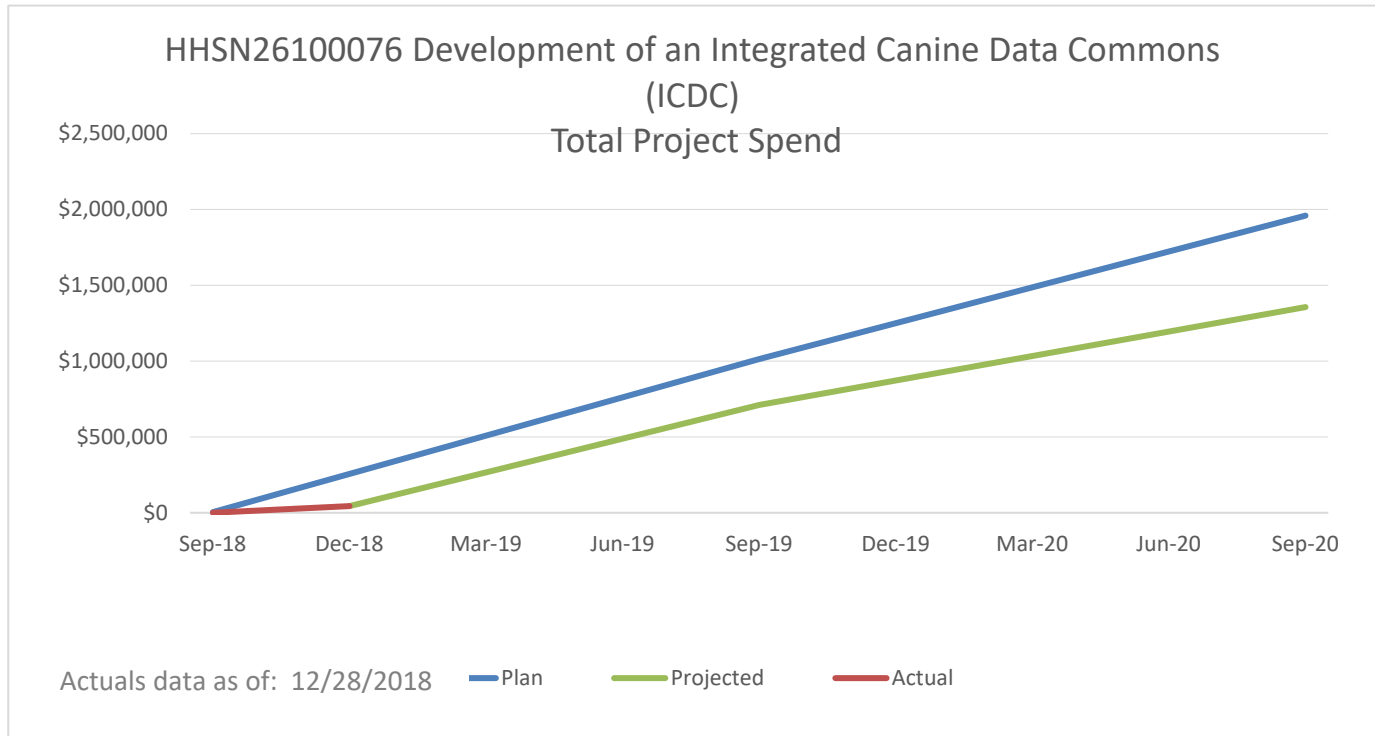Actuals data as of: 12/28/2018 — Plan — Projected — Actual

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

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. OR Costs are being managed within the annual budget allocation for the Directorate.
Contract	G	G	G	Change Control Board running well and managing technical direction changes. And no significant contractual issues.
Subcontractors & Suppliers	Y	G	G	Demonstrated or projected ability for supplier to meet all technical metrics. At the time we were yellow, we had no contract with UChicago. That became a moot point, as they supported us under the DCF contract.
Customer Environment	G	G	G	Customer perceptions aligned with PM perceptions.

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. OR no open compliance issues.
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 OR Infrastructure is in place OR Plan to install infrastructure is on schedule.
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

- Gen3 architecture is taking longer than expected to instantiate the shell, however, this is still within project schedule boundaries and is considered a negligible impact at this time. We are currently working through the issues encountered with UChicago. We will continue to monitor the situation go forward and are documenting lessons learned for future use.
- The Sheepdog code in Gen3 is very specific to the GDC data model. We will have to interitively modify our data model YAML to get Sheepdog to accept it. This may cause a delay in loading the model and therefore loading the data to the system.

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, Management Strategy: 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, Management Strategy: 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. 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. 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. • The Gen3 architecture is still new and not extensively documented or field tested. It is possible there are missing elements needed to fully support the ICDC or there are performance gaps in functionality or stability. Mitigation: Gen3 was assembled by UChicago so by using UChicago as SME(s) during development we can be guided by them with respect to what features are incomplete and if there are roadmaps to complete those features. This will enable us to determine prioritization of ICDC system development to avoid any known issues and to plan around Gen3 development releases.

Open Issues, Action Items and Resolution Plans
No Open Issues

Original Schedule

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

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