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

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:	November 4, 2019
Reporting Period:	7/21/2019 through 9/20/2019
Primary Program Manager (PPM):	Dr. John Otridge
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COR Email:	toby.hect@nih.gov
COR Phone:	301-435-9162
Leidos Biomed Contracts Representative:	N/A

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

Frederick National Laboratory is operated by Leidos Biomedical Research for the National Cancer Institute.

HHSN26100076: Development of an Integrated Canine Data Commons (ICDC)
Cost/Schedule/Performance Quarterly Report
October 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	$1,959,336.71	**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	$620,839.96	$496,411.44	$614,871.88
Total as of:	10/18/19	$620,839.96	$496,411.44	$614,871.88

Percent Spent:	31.7%	**Percent Committed:**	57%

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

Project Status		
Assessment Type	**Current Status**	**Future Plans**
Technical Scope and Status	Since July 2019, the SC has met twice more and has been reviewing the guidelines being produced by the Data Governance Advisory Board. These are nearing approval with the next Steering Committee meeting planned for Oct. 16, 2019 and we planned to begin accepting submissions for review in October 2019. The Best Practices SubCommittee (BPSC) has been examining standards and meeting with the NCI's Semantic Infrastructure team to being looking at standard terms and pipelines. The Imaging working group of the BPSC is currently conducting a pilot study of scripting MRI images from Virginia Tech into The Cancer Imaging Archive (TCIA) and are going to use that as a standard for de-identifying and tagging MRI images.

The ICDC Data Team has completed its transformation routines and has loaded the current data for two studies; COTC007B and NCATS. The data is incomplete is parts and inaccurate/imprecise in others so will need correcting by the submitters prior to reloading before the data is released to the public. There is also some delay in having complete data due to patent and publication issues. These data issues have been discussed with the COR and she approved holding off on a "public release" until such time as the data is reasonable, complete, accurate and voluminous enough to be useful. We have started working on two new projects, PRECINCT and Canine Glioma, with our first steps focused on understanding their data dictionaries and anticipating the impact on our current data model. Finally, the ICDC Data Team are also working with the NCI Semantics Infrastructure team to identify terminology so that the ICDC data can be better shared and searched. | The SC will meet in November 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. We will work closely with the semantics infrastructure team at NCI and the BPSC to begin defining the backbone of semantics for ICDC.

System infrastructure team is planning to release the minimum viable product in early 2020 as a soft launch. Data in the system needs to be cleaned and enhanced before a formal launch. |

Project Status		
Assessment Type	**Current Status**	**Future Plans**
	The ICDC's System Infrastructure team has produced the Dev, QA and Staging environments. We are in progress with CBIIT, who host ICDC on their CloudOne Amazon instance, on defining the deployment routine for Production. While backend and front-end development continues and we have started to focus more on front-end design. The team have also been working with Seven Bridges Genomics (where end-user defined bioinformatic analysis of ICDC data will occur) to develop the manifest for virtual file transfer/integration of data from ICDC to Seven Bridges Genomics. Testing continues as we develop and we have identified those tests which can be automated. We are aiming for an early 2020 soft launch which will be data quality dependent.	
Schedule Milestones and Status	The project is still on track with regards to period of performance and schedule, intending to produce a prototype by September 2020.	The project is expected to produce a minimum viable product (MVP) 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	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

HHSN26100076 Development of Integrated Canine Data Common (ICDC) Total Project Summary By Milestone
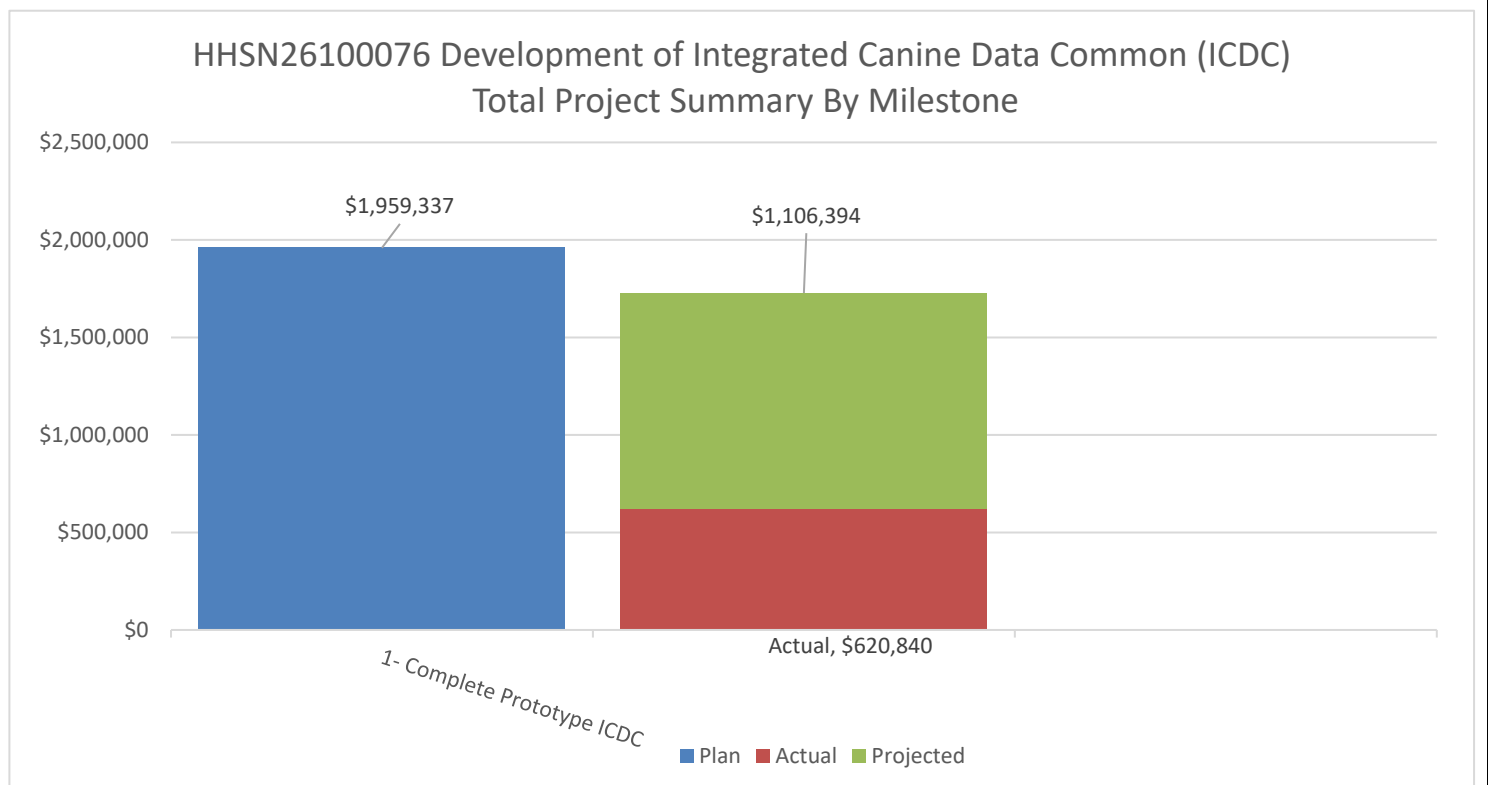
Figure 1. Bar graph shows Planned Spend compared to Actual and Projected expenses by milestone as of October 2019.

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

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

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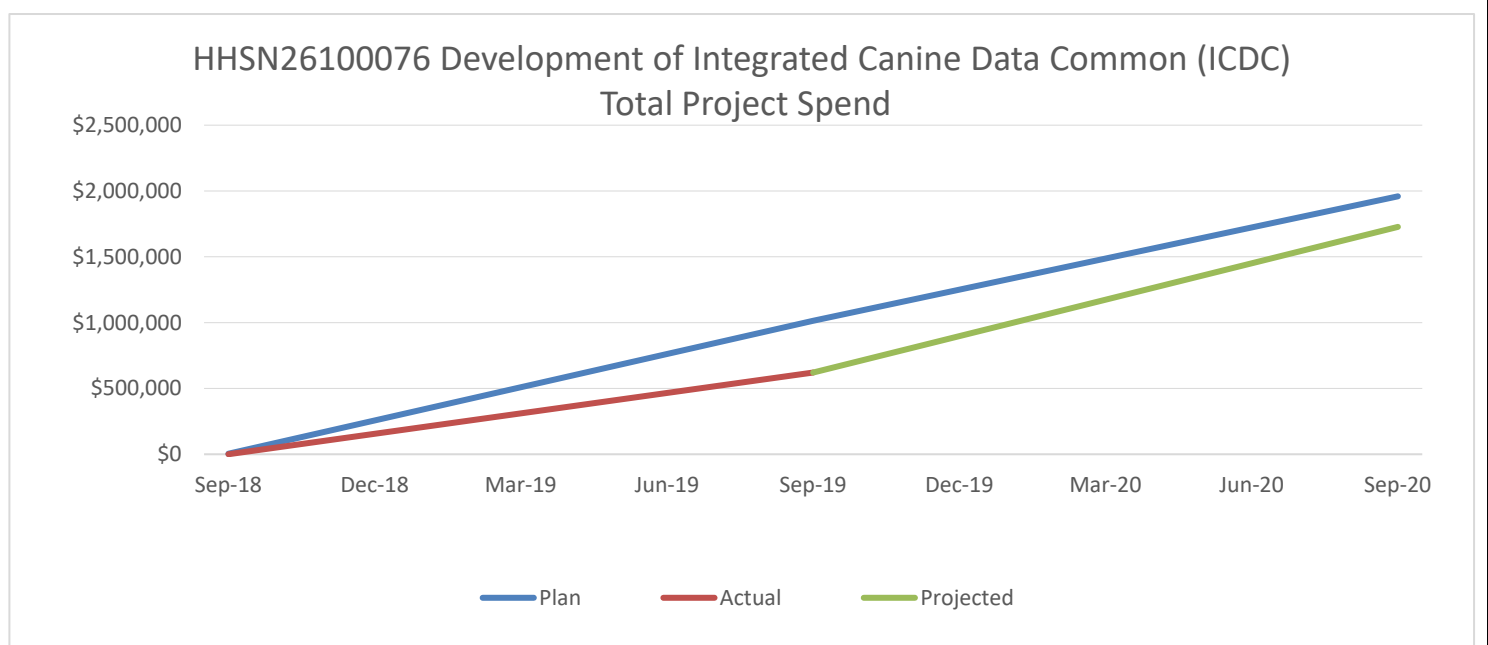## Cost/Schedule/Performance Quarterly Report
October 2019

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.
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				

Risk	
	• 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	
	• 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. • Seven Bridges Genomics will not develop their interactions with the ICDC in time for our MVP release (Dec. 31, 2019). SGB has been delaying a decision about the manifest and whether that should be a complete copy of the study or simply a reference to the files of interest. Without knowing their desired strategy, we will not be able to provide interoperability between the two systems until it is decided. Probability: Low; Impact: Low; Mitigation: Continue open communication with SBG and accept timeline - a delay of 3-6 months is acceptable as it is still prior to our prototype deadline of Sept. 2020.
Open Issues, Action Items and Resolution Plans	

Risk
No Open Issues

Original Schedule

ID	Task Name	Duration	Start	Finish	% Complete	2018 Qtr 2	Qtr 3	Qtr 4	2019 Qtr 1	Qtr 2	Qtr 3	Qtr 4	2020 Qtr 1	Qtr 2	Qtr 3	Qtr 4	2021 Qtr 1	Qtr 2	Qtr 3
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 October 2019.