National Cancer Institute (NCI)
Integrated Canine Data Commons (ICDC) Steering Committee (SC)

Teleconference
Wednesday, May 20, 2020

Participants (*Present)

External Committee Members

Matthew Breen*
Renee Chambers
Dawn Duval*
Allison Heath
Will Hendricks*
Warren Kibbe*
Debbie Knapp, ICDC-SC Chair*
Cheryl London
Jeff Trent
Roel Verhaak*
Shaying Zhao*

Internal Committee Members (NCI, National Institutes of Health, and Frederick National Laboratory for Cancer Research [FNLCR])

Matthew Beyers*
Allen Dearry
Toby Hecht*
Paula Jacobs*
Tony Kerlavage*
Erika Kim*
Amy LeBlanc*
Christina Mazcko*
Philip Musk*
Elaine Ostrander
John Otridge
Ralph Parchment, ICDC-SC Managing Secretary*
Connie Sommers*
Greg Tawa*

Others

Anju Singh*
Lori Lydard
Tara Whipp
Mary Cerny (writer)*

Opening and Welcome

Drs. Knapp and Parchment opened the meeting at 12:02 p.m. ET and welcomed attendees.

Minutes of the April 2020 Meeting

The minutes of the April 15, 2020, ICDC-SC meeting were accepted as written.

Reports from the Working Groups (WGs)

Data Governance Advisory Board (DGAB) Chair's Report

The DGAB met in the past month to review a new data submission that takes an integrated look across whole genome sequencing, whole exome sequencing, and RNA sequencing in canine osteosarcoma. The PI on the submission is Dr. Hendricks, and the data are primarily from veterinary teams at Colorado State University and Ohio State University. The DGAB recommended that the ICDC intake group prioritize the submission; the intake group, in turn, will provide the DGAB with a recommendation for how to prioritize the submission. As part of its review, the DGAB noticed that this submission included cases and data from the CCOG repository and pointed out that animals and specimens should have a number associated with that repository attached to them. This realization prompted the DGAB to update the Canine Data Commons submission and intake form to ask all submitters whether they are getting any specimens or data from any repository and/or from more than one institution and, if so, to provide that information. The DGAB is also going back to query prior submissions about this issue. Having these details will help facilitate cross-referencing animals, data, and specimens across repositories and research organizations within the ICDC.

As discussed during prior meetings, the ICDC-SC has identified several strategies to expand outreach to a broader range of groups outside the Comparative Oncology Trials Consortium to invite them to participate in the ICDC. Dr. Singh, Dr. Kim, and Mr. Beyers have taken the lead on this effort. Dr. Singh summarized the results to date. Dr. Singh searched the Query, View, and Report (QVR) system for NIH grantees conducting canine cancer trials. She has reached out to several groups and has received a positive response from many of the grantees, who are at various stages of their respective trials. In addition, there has been a good response from the canine cancer research teams that were contacted using the list of publications provided by Dr. Hendricks. Supplement awardees have also expressed an interest in the ICDC. One group from the University of California, Davis, anticipates completing analysis of data on canine glioma, melanoma, and osteosarcoma (30 cases/cancer type) this summer. The analyses will be comprehensive and will include tissue staining, RNA sequencing, and whole genome sequencing. Additional submissions include glioma samples (through Dr. Verhaak) and data and specimens from canine B-cell lymphoma cases. Data from other groups are expected to be forthcoming as studies are finalized and data are analyzed. Feedback and data received through ongoing outreach, along with data from various repositories, are likely to lead to changes in models for how data are stored in the canine commons.

Best Practices Subcommittee (BPS) Chair's Update

Dr. LeBlanc provided updates on behalf of Dr. Trent, who was not able to attend the teleconference. The BPS meeting scheduled for May 19 was cancelled due to scheduling conflicts for several members. Dr. Heather Gardner from Tufts University has accepted an

invitation to join the BPS as an *ex officio* member and will officially join the group as of the June meeting. Dr. Gardner has already participated in discussions with the Genomics Working Group (WG) on identifying and curating genomic datasets for the ICDC. Additional WG updates were provided as follows.

Imaging WG
The Imaging WG continues to reach out to researchers who have MRIs for the canine glioma dataset. Some of the feedback has slowed as a result of logistical and other operational changes at academic institutions because of the COVID-19 situation.

Genomics WG
The draft best practices document for genomics analysis continues to circulate for review and comment. Given the diversity in how different labs do genomic analyses and the lack of reference standards (in contrast with the human research enterprise), the goal is not only to put together best practices recommendations but also to develop standardized references and tools that can be used to harmonize across datasets. Other efforts are underway to develop a common data model for genomic analysis that will synergize with the Observational Medical Outcomes Partnership (OMOP), electronic health records (EHRs), the CHOP team, the Tufts team, and other groups and platforms. These standardized tools, in turn, would be disseminated in conjunction with best practices for broader use in addition to use with the ICDC. The efforts to develop community-wide tools are still in their early stages. By the next ICDC-SC meeting, the Genomics WG hopes to have a two-page summary of what they have accomplished to date and what they are planning for the future.

Other BPS WG Updates
The other WGs continue to focus on the issues discussed at previous meetings. No additional updates on the other WGs were provided during the teleconference.

Other Issues

Presentation on Breed-specific Genomic Data
Dr. Ostrander had planned to present information on breed-specific reference genomic data available in the public domain, but she was not able to attend this meeting. She plans to make the presentation at next month's meeting.

Update: Policy/Guidelines on Use of Recombinant and Synthetic Genetic Materials in Companion Pets
Drs. Hecht and LeBlanc reported on a significant change in and clarification of NIH and FDA policy regarding use of recombinant and other synthetic nucleic acid molecules in companion pets enrolled in research studies, which has been a gray area until now.

The NIH policy states that for research subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)*, any animal administered recombinant or synthetic nucleic acid molecules may not be released from containment unless another federal agency has jurisdiction over the experiment and approves the proposed release. As stated in Section I-A-1 of the *NIH Guidelines*:

> Any nucleic acid molecule experiment, which according to the *NIH Guidelines* requires approval by NIH, must be submitted to NIH or to another Federal agency that has jurisdiction for review and approval. Once approvals, or other applicable clearances, have been obtained from a Federal agency other than NIH (whether the experiment is referred to that agency by NIH or sent directly there by the submitter), the experiment may proceed without the necessity for NIH review or approval.

The NIH Office of Science Policy (OSP) consulted FDA regarding the provision that requires approval or clearance from another federal agency. FDA reconsidered this policy and released a statement (dated 4/13/2020) that reads in part,

> CVM [FDA Center for Veterinary Medicine] advises that it will not object to release of animals to owners that are or were enrolled in this type of research when developing therapeutics solely for human use and, therefore, researchers will be considered to have the necessary "applicable clearance" for purpose of compliance with the *NIH Guidelines* [if they comply with conditions delineated in the FDA statement].

Pursuant to FDA's statement, the OSP clarified the *NIH Guidelines* regarding the release of client-owned animals after participation in research, saying that the FDA statement "fulfills the clearance required by the *NIH Guidelines*; thus, for research meeting the criteria and conditions specified in the FDA statement, institutions subject to the *NIH Guidelines* will be permitted to release animals to their owners."

The FDA statement can be found at https://www.fda.gov/animal-veterinary/resources-you/release-client-owned-animals-when-conducting-study-develop-human-therapeutics-using-recombinant-or. The OSP statement can be found at https://osp.od.nih.gov/biotechnology/release-of-client-owned-animals/. Both pages include contact information.

The Committee agreed that this is a very positive development that will allow researchers to conduct canine and other trials involving companion animals without concerns about losing NIH funding due to being out of compliance with NIH guidance. The Committee thanked Dr. Hecht for her continued advocacy on this issue.

Mr. Beyers will post the FDA and NIH statements in the ICDC-SC Box folder. Dr. LeBlanc will draft a short summary of the revised policy with OSP language and send it to Mr. Beyers to post and for wider distribution upon request. Dr. LeBlanc will also post the summary on the American College of Veterinary Internal Medicine (ACVIM) listserv to reach as many Board-certified veterinary oncologists as possible. Dr. Duval, who chairs the Clinical Review Board at Colorado State University, said that having this information to disseminate will be very helpful.

Administrative Items

June ICDC-SC Meeting

The next meeting of the ICDC-SC will be held via teleconference on Wednesday, June 17, 2020, from noon to 1:30 p.m. ET. The Committee discussed changing the official start time of the ICDC-SC teleconferences from 11:30 a.m. to noon, in part to accommodate members on the

West Coast. Dr. Parchment will forward the meeting information and materials ahead of the June teleconference.

DGAB and BPS Meetings
Dates and times for other upcoming meetings are still to be determined. Details will be distributed as they become available.

Honoraria
External members were reminded to continue to forward the paperwork for their honoraria to Ms. Lydard. Anyone having problems with the form or reimbursement should contact Dr. Parchment.

Action Items

- Regarding the update to the NIH policy on containment and release of companion animals in research:
  - Mr. Beyers will post the FDA and NIH/OSP statements to the ICDC-SC Box folder.
  - Dr. LeBlanc will draft a short summary of the revised policy with OSP language and send it to Mr. Beyers to post and for wider distribution upon request.
  - Dr. LeBlanc will post the summary on the ACVIM listserv.
- Topics for future meetings should be forwarded to Drs. Knapp and Parchment.
- Dr. Parchment will forward the logistics information and materials for the next teleconference as they become available.

Adjournment

The meeting was adjourned at 12:30 p.m. ET.