CHALLENGES TO BIOMARKER DEVELOPMENT IN CANADA

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ACKNOWLEDGEMENTS

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BACKGROUND

North American experts in medical imaging met with University of Saskatchewan health researchers and students on April 10, 2014 to discuss how advanced imaging and other biomarkers can speed up the detection and treatment of diseases that affect people and animals. Biomarkers help medical imaging specialists measure the severity or presence of disease in the body. This 'Biomarker Development" workshop focused on the challenges in developing nuclear biomarkers and nanoprobes (tiny particles used to detect, diagnose and treat disease) to better understand specific disease mechanisms and pathways.

Sixty two participants including faculty, undergraduate and graduate students, postdoctoral fellows, residents and interns from various department all across campus were able to attend. This event was funded through partnership with the College of Engineering [University of Saskatchewan], College of Medicine [University of Saskatchewan], GE Healthcare Canada, Philips Healthcare, Saskatchewan Health Research Foundation, Sylvia Fedoruk Centre, University of Saskatchewan, and the Western College of Veterinary Medicine.

Figure 1 - Biomarker Development Workshop Participants & Organizers

Speakers included: Dr. John Gore, Director, Vanderbilt University Institute of Imaging Science; Piotr Maniawski, Director, Clinical Science, Advanced Molecular Imaging, Phillips Healthcare; Dr. Ekaterina Dadachova, Professor, Albert Einstein College of Medicine of Yeshiva University; Dr. Dayan Goodenowe, President/CEO, Phenomenome Discoveries Inc. (Saskatoon); Dr. Robert Kerbel, Senior Scientist, Sunnybrook Research Institute; and Dr. Amy LeBlanc, Associate Professor, Small Animal Clinical Sciences, College of Veterinary Medicine, University of Tennessee.

Before the next generation of biomarkers can be developed, researchers must understand the unique molecular "signature" of a disease. That information is used to develop biomarkers that can be used for precise imaging or targeted drug delivery. "This workshop will foster the advancement and exchange of health research knowledge and identify pressing needs for research in the area of biomarker development for imaging conditions such as cancer," said Dr. Baljit Singh, Associate Dean (Research), Western College of Veterinary Medicine.

Figure 2 - Plenary Session, International Speaker, Dr. Ekaterina Dadachova, Professor, Department of Radiology (Nuclear Medicine), Albert Einstein College of Medicine, Yeshiva University

IDENTIFIED CHALLENGES/NEEDS

Breakout Group #1 – What are the current needs in the development of animal models?

Word Cloud #1: Breakout Group #1 Discussion

NEEDS
Better animal models
Improved success rate of current animal models
Genetic modifications to improve immune competence in animals
Control of tumor growth to facilitate study of the progression of cancer
More research dollars from funding agencies
Increase survival period to facilitate study of the progression of cancer
Facilitate integration of clinical science and animal trials
Evidence to support whether to use genetically modified or natural animals
Models to reflect human biology better
Models that can better mimic spontaneous models of human disease
Models of adjunct therapy or neo adjunct therapy
Understand physiological processes by examining more than one gene at a time
Undertake a comparison analysis of existing and new animal models
Take more advantage of genetically engineered models of cancers i.e., gastric, pancreatic, lung
Removal of bias against publishing negative results
Decrease or subsidize the costs of research (i.e., the bigger the size of the (animal) model, the increased cost of research)
To coordinate between disciplines to take advantage of xenographed spontaneous cancer models & immune compromised models using synchrotron imaging
Industry to drive research using animal models
Success stories using animal models

Breakout Group #2 – What are the Challenges Regarding Industry Engagement and Translational Technology Developments?

Word Cloud #2: Breakout Group #2 Discussion

CHALLENGES	
Markers are not available	Scheduling Issues
Need an up market	Bench top single dose cyclotron
More specific label for downstream users	Working with Gallium
Problem of shelf life	Peptide Labelling
Regulatory Issues	Few markers for magnetic resonance imaging
Logistics	Sufficient signal for detection

Breakout Group #3 – What is Needed to Build Industry/Academic Collaborations?

Word Cloud #3: Breakout Group #3 Discussion

NEEDS	
Profit or return on investment is key for industry	Interest from veterinary companies
Better interaction on the part of industry	Proper protocols for research i.e., infection control, radiation safety
Better Canadian market	Other opportunities such as metabolic profiling
Identify better animal models than rodent model	Take more advantage of funding opportunities e.g., Morris Animal Foundation
Industry needs to take responsibility/initiative/ Interest	Champion to engage industry
Emphasis on other diseases than just cancer	Commercialization model i.e., create value for companies, create patents, IP
Eliminate university & government bureaucracy	Database sharing models
Research & development investment by industry	Network with interested people that have compounds to evaluate for cancer treatment
Maintain objectivity – no bias creep	WCVM maintain/fund repository for data bank of cancer tumours from cats and dogs
Targeted therapeutics i.e., dedicated clinical trials personnel, access to patients	Pursue solid interest in nutraceuticals e.g., collaborate with the College of Agriculture and Bioresources

Breakout Group #4 – Needs Regarding Highly Qualified Personnel (HQP) Training

World Cloud #4: Breakout Group #4 Discussion

NEEDS
Needs assessment – what does industry need?
Eliminate bias – PhDs preferred over MScs
Help train PhDs – PhD required for corporate training
Training in HR, business management, marketing, entrepreneurship, etc.
Collaborate on existing programs to enhance training experience e.g., Canadian Light Source, One Health initiative, Aboriginal initiatives, THRUST program (U of S)
Interdisciplinary training opportunities e.g., synchrotron with health research
New view regarding HQP training in other countries
Collaborate more with other universities to provide enriched training opportunities for students e.g., University of Alberta, UBC
More co-supervision of students e.g., Canadian Light Source & Saskatoon Cancer Centre

BREAKOUT GROUP SUMMARIES

Summary: Development of Animal Models – Dr. Robert Kerbel

Our discussion was focused mainly on small animals, i.e., mice, and mainly in the context of oncology. But the principles apply in a number of ways to other therapeutic areas. The focus of our discussion mainly revolved around the point of the inadequacy of most current animal model in terms of their clinical relevance. So, clearly there is a compelling need to keep improving the clinical relevance of animal models, and moreover, to undertake rigorous cross comparison studies.

By way of example, interest in developing spontaneous cancers in genetically engineered mice which mimic better their human counterparts compared to tumors derived from transplanted tumor cells grown in tissue culture, continues to grow. At the same time there is significantly expanding interest in what are known as patient derived xenograft (PDX) models involving the direct transplantation of human tissue into immune deprived mice. Each of these models has advantages and disadvantages, and therefore what constitutes a "best" model depends in part on the question that one is trying to address. By way of example, if one is interested in developing and assessing a vaccine or some other kind of immunotherapeutic, this would not be possible when using immune deprived animals. So this is an area where spontaneous tumors arising in genetically engineered mouse models, or in other species where they arise naturally, such as dogs have their advantage. On the other hand, if one wanted to undertake studies of neoadjuvant or adjuvant therapy post surgery, this is extremely difficult to do with genetically engineered mouse models of cancer since these mice multiple often develop numerous primary tumors asynchronously over time. Moreover, most such models do not manifest disseminated metastatic disease in contrast to the use of transplanted cell lines. On the other hand there are questions that could be addressed using a one these sorts of model.

The focus of our discussion mainly revolved around the point of inadequacy of most current animal models in terms of their clinical relevance. So, clearly there is a compelling need to keep improving the clinical relevance of animal models, and moreover, to undertake rigorous cross comparison studies.

What we now need is some sort of very rigorous and detailed cross comparison of these models in parallel side-by-side studies examining in a retrospective comparative fashion the relative efficacy of known drugs that were previously evaluated in randomized phase III clinical trials. This would be an extremely expensive proposition, but it is one that nevertheless pharmaceutical and biotech industries should consider investing heavily in, with the aim of the development of some kind of consortium involving both industry and academia. In the long run such a collaboration could have a huge impact on lowering the incidence of failed clinical trials, which can be enormously expensive. The likely cost of such a consortium would probably be not much more than the cost of a single failed randomized phase III clinical trial sponsored by a single company. From this perspective it is hard to see why pharmaceutical companies would not want to work together with each other, and with academia, to provide the bulk of financing for the development of an animal model consortium the particular bias at the present time for one type of model over another.

Another challenge is changing the current mindset of editors of peer-review scientific journals as well as reviewers regarding the necessity for undertaking parallel studies in multiple models. While desirable, there has to be a greater appreciation and awareness of the time and money that it takes to develop new and more sophisticated models. This likely constitutes one of the reasons why, to this day, there remains an emphasis on using the least expensive but probably also the least predictive models available e.g. growth of transplanted tumors in the skin of mice and undertaking short-term therapy experiments.

Regarding imaging, whether molecular or anatomical/functional in nature, it should have an absolutely key role in the development and use of improved animal models. By way of example, one compelling criticism of cancer therapy experiments undertaken in mice, regardless of the type of model used, is the failure of many if not most investigators to use clinically relevant endpoints in their studies. Such an endpoint would be what is known as progression free survival (PFS). In humans this is always assessed by imaging, and PFS is increasingly used and accepted as an endpoint in clinical trials. Clearly, this creates a wealth of potential an exciting opportunities for many different kinds of imaging approaches, and that can obviously molecular imaging, to assess such things as whether the target of a particular drug is expressed by a tumor and to what degree, whether the target is affected by drug treatment, and how this affects ultimate clinical outcomes. In addition, greater emphasis on developments of models involving treatment of systemic metastatic disease and multiple organ sites such as the lungs, liver, bones, brain, amongst others, creates an obvious and compelling the for both functional and molecular imaging.

Summary: Industry Engagement and Translational Technology Development – Dr. Gregg Adams

The main challenge identified was the lack of availability of markers for PET, and that this situation is unlikely to change since at present, there is no incentive for commercial enterprises to develop markers. The incentive may change with anticipated up-swing in the use of PET. Specific issues regarding industry engagement and technology development are:

- More specific ligands or markers for downstream users – specific labels for specific tissues and cell types is critical for further expansion of the use of all medical imaging technologies including MRI, CT, PET, synchrotron x-ray imaging. Biomarker development itself will require a separate and concerted research program
- Short shelf life of markers, particularly for PET, is a limiting factor. The short shelf-life of biomarkers complicates the logistics and scheduling of experiments
- Regulatory issues surrounding the use of radio-isotopes is seen as an important limiting factor
- A solution for our campus is the production of isotopes from our own cyclotron. In the future, we envision bench top, single-dose cyclotrons to meet local specific requirements
- Further development of specifically labeled nano- or microspheres for use with ultrasonography has unrealized potential. Microsphere technology has greater flexibility for different types of labels.
- Sufficient signal for detection is a limiting factor for all imaging modalities; i.e., is the signal or number of signals produced per unit of tissue sufficient to be picked up by the detector?
- Detector technology – increased sensitivity is required

Although the question about encompasses how we can engage industry, any initiative that includes the issues outlined above should be of interest to the industry.

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Summary: Academic and Industry Collaborations – Dr. Amy LeBlanc

The discussion regarding academic and industry collaborations included themes on how to approach industry for collaborative efforts spearheaded by academia, how to engage existing personnel within the University with a research interest into new collaborations, and how to manage the data generated by such collaborations with respect to IP, licensing, and publication rights. In general, industry can benefit from the academic side as most new knowledge, access to animals/patients, and unique expertise is found there; academia can benefit from industry based on their ability to garner capital investment funds and/or access to unique technology.

From the industry side: a clear understanding of the expectations is needed; the pace of work is often much slower than most industry stakeholders are used to. There is a need to identify and understand benchmarks for success and how the data generated will be used to advance knowledge and thus profits for the corporation involved. Frequent face-to-face meetings are usually needed in the very beginning of collaborations to form a path forward. Having a dedicated 'point person' or 'flag carrier' is important.

From the academic side: similarly expectations should be clear from the beginning and that personnel involved in the collaboration have sufficient protected time to dedicate to the timeline of the project(s). Rights to publish/present data should be determined up front. Budgeting and indirect costs/cost sharing should be evaluated closely as the scope of work evolves. A commercialization plan for any new technologies developed within the collaboration should be considered if the data is promising.

Funding of collaborations that involve academia and industry could be supported by external granting opportunities. For example, in the US, the NIH SBIR/STTR grant mechanisms are one example.

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Summary: Highly Qualified Personnel (HQP) Training – Dr. Darrell Mousseau

BACKGROUND: A key requirement in the training of highly qualified personnel (HQP) is the need to understand what will be expected of any given HQP and how to best prepare them for their careers, all the while benefiting from them as trainees. There tends to be a bias against PhD trainees in the Industrial sector (perhaps because they are viewed as being over-qualified or perhaps because Ph.D. graduates might already be pigeon-holed in a way of thinking (they carry their graduate training Supervisor's own biases); there is a preference for hiring Master's students. In contrast, Academia prefers the Ph.D. trainee as they have a higher potential for being able to undertake independent research projects. What is becoming clear is that any individual that is anticipating a career track in Academia is now also expected to be have, in addition to their research and teaching skills, the capacity for proper management of Human Resources and Finances as well as to understand, if only at the basic level, Entrepreneurial/ Marketing management. These are unreasonable expectations, but expectations none-the-less.

The ultimate goal of any research program is to develop increasingly effective researchers who can develop more robust and satisfying outcomes for consumers, with the ultimate goal –at least in health-related research– to generate new approaches to the identification, diagnosis, and treatment of disease. Trainees will include graduate students, postdoctoral fellows, research assistants, medical residents, and early career mental health researchers.

PROGRAMS: A range of educational approaches should be considered to reach the various target groups, including (a) workshops (CME accredited?), (b) recognized certification programs, (c) co-supervision and/or exchange programs, (d) knowledge dissemination and transfer. Workshops can take on the form of the current 'Biomarker Development Workshop' and CME accreditation will have to be explored by the local CME Office and or the department that is hosting the Workshop.

<u>Co-supervision of Graduate Students</u>: Within a given academic setting, programs should facilitate establishing co-supervision roles for graduate students, postdoctoral fellows and clinical fellows. Dual degrees might be considered, but these are always limited to the degree requirements established by the home institution. Co-supervision involves providing each trainee with two supervisors, in the case of Imaging, having at least both a Ph.D. as well as an M.D. supervisor would ensure that students are familiarized Imaging in both research and clinical contexts. These days, interactions between trainees at different sites can be facilitated by interactive websites, e-mail, and video/ teleconferences. Regular assessments –consistent with the requirements of the home institution– of progress of graduate students and postdoctoral fellows will be needed.

Exchange Programs: Such programs should allow graduate students and fellows to accept placement time at centres other than their primary institution. Funding agencies will need to be included in these discussions so as to partner on stipends and travel/living expenses, thus ensuring a positive experience for trainees in their host institution, which might not be financially able to support the trainee or could be in another country and, thus, unfamiliar to the trainee(s). The impact of a given program will be reflected in the number of degrees and certificates conferred, by the rate of recruitment of new trainees, and by the number of trainees continuing on with programs and careers related to Imaging.

Research Presentations: Annual meeting of the Imaging Program/Network should include a strong trainee component for delivery of research presentations. This would be over and above their attendance at discipline-specific or broader interest National and International scientific conferences.

Knowledge Transfer: Trainees should be expected to transfer research knowledge to clinicians and, in partnership with mentors and supervisors, trainees should be provided the best opportunities to become actively involved in the writing/preparation of associated materials (articles, patents, grant applications).

"VALUE ADDED" OF TRAINEE PROGRAMS: These programs will provide increased opportunity for shared funding of graduate programs. Networking with other researchers will facilitate future partnerships (and reduce duplication of effort), and yield stronger trainees. Research dissemination will help to increase public awareness of the problems associated with disease being studied and any novel means of identification, diagnosis, and treatment of disease.

The ultimate goal of any research program is to develop increasingly effective researchers who can develop more robust and satisfying outcomes for consumers, with the ultimate goal –at least in health-related research– to generate new approaches to the identification, diagnosis, and treatment of disease.

MORE PHOTOS

Figure 3 - Workshop Participants

Figure 4 – Plenary Session, National Speaker, Dr. Robert Kerbel, Professor, Department of Medical Biophysics, Faculty of Medicine, University of Toronto

Figure 5 – Speakers: [Back Row Left to Right] Dr. Paul Babyn; Dr. John Gore; Dr. Baljit Singh; Dr. Deborah Anderson. [Front Row Left to Right] Dr. Ekaterina Dadachova; Dr. Robert Kerbel; Dr. Amy LeBlanc; Dr. Dayan Goodenowe

APPENDIX

Table 1: Workshop Participants

NAME	TITLE	ORGANIZATION	EMAIL
Sam Abeysekara	Joint Postdoctoral Fellow, Department of Medical Imaging, COM & WCVM	College of Medicine/Western College of Veterinary Medicine	saman.abeysekara@usask.ca
Darryl Adamko	Associate Professor, Department of Pediatrics, COM	University of Saskatchewan	darryl.adamko@usask.ca
Gregg Adams	Professor, Veterinary Biomedical Sciences, WCVM	University of Saskatchewan	gregg.adams@usask.ca
Oksana Akhova	Technology Transfer Officer, ILO	University of Saskatchewan	oksana.akhova@usask.ca
Deborah Anderson	Cancer Cluster Leader	Saskatchewan Cancer Centre	deborah.anderson@saskcancer.ca
Terra Arnason	Associate Professor, Department of Medicine, COM	University of Saskatchewan	tea700@mail.ca
Gurpreet Aulakh	Postdoctoral Fellow, CLS	University of Saskatchewan	gka240@mail.usask.ca
Paul Babyn	Head, Medical Imaging, COM	Saskatoon Health Region & University of Saskatchewan	paul.baby@saskatoonhealthregion.ca
Eldiko Badea	Associate Professor, COPN	University of Saskatchewan	ildiko.badea@usask.ca
Yadu Balachandran	PhD Student, Veterinary Biomedical Sciences, WCVM	University of Saskatchewan	y.balachandran@usask.ca
Kalhari Bandara	PhD Student, Veterinary Pathology, WCVM	University of Saskatchewan	kalhari.bandara@usask.ca
Bassey Bassey	PhD Student, Physics and Engineering Physics, COE	University of Saskatchewan	beb074@campus.usask.ca
Keith Bonham	Senior Research Scientist	Saskatchewan Cancer Centre	keith.bonham@saskcancer.ca
Christopher Bowman	Director, Business Development	MITACS	cbowan@mitacs.ca
Francis M. Bui	Assistant Professor, Electrical and Computer Engineering, COE	University of Saskatchewan	francis.bui@usask.ca

Hector Caruncho	Professor, Pharmacy, COPN	University of Saskatchewan	hector.caruncho@usask.ca
Dean Chapman	Professor, Anatomy & Cell Biology, Canada Research Chair in X-ray Imaging & Imaging, COM	University of Saskatchewan	dean.chapman@usask.ca
Rufael Chekol	PostDoctoral Fellow, Medical Imaging, COM	University of Saskatchewan	Rufael.Chekol@pharm.kuleuven.be
Jerry Davies	Research Associate, Anatomy & Cell Biology, COM	University of Saskatchewan	drjerrydavies@gmail.com
Humphrey Fonge	Radiopharamist	Saskatoon Health Region	humphrey.fonge@usask.ca
Kendra Furber	Postdoctoral Fellow, Neuroscience Research Cluster, COPN	University of Saskatchewan	klf615@mail.usask.ca
Kamal Gabadage	Resident, Large Animal Field Service, WCVM	University of Saskatchewan	kgabadage@gmail.com
Thushari Gunawardana	PhD Student, Veterinary Pathology, WCVM	University of Saskatchewan	tag036@mail.usask.ca
Troy Harkness	Professor, Anatomy & Cell Biology, COM	University of Saskatchewan	troy.harkness@usask.ca
Ashok Jadhav	Lecturer/Full time Faculty Member, Department of Pharmacology, COM	University of Saskatchewan	ashok.jadhav@usask.ca
Charlotte Johnston	Medical Oncology Resident, Small Animal Clinical Sciences, WCVM	University of Saskatchewan	caj311@mail.usask.ca
Danya Kordan	Senior Strategist	Innovation Saskatchewan	Danya.Kordon@InnovationSask.ca
Pankaj Kumar	Research Associate	VIDO-InterVac	pak100@mail.usask.ca
Shanika Kurukulasuriya	PhD Student, Veterinary Pathology, WCVM	University of Saskatchewan	nishadinishanika@yahoo.com
Conor Lazrou	Bioinformatic Student (2nd Yr), COAS	University of Saskatchewan	ckl594@mail.usask.ca
Neal Lemon	Technology Transfer Officer, ILO	University of Saskatchewan	neal.lemon@usask.ca

Assaf Lerer	PhD Candidate, Veterinary Biomedical Sciences, WCVM	University of Saskatchewan	assaf.lerer@usask.ca
Glenn Laba	Technology Transfer Officer, ILO	University of Saskatchewan	glenn.laba@usask.ca
Ed Lee	Physician, Nuclear Medicine, Medical Imaging, COM	Saskatoon Health Region & University of Saskatchewan	leeeddy1@yahoo.com
Liuba Lobanova	Research Technician, Anatomy & Cell Biology, COM	University of Saskatchewan	lil557@mail.usask.ca
Valerie MacDonald	Associate Professor, Small Animal Clinical Sciences, WCVM	University of Saskatchewan	valerie.macdonald@usask.ca
Karen Machin	Associate Professor, Veterinary Biomedical Sciences, WCVM	University of Saskatchewan	karen.machin@usask.ca
Piotr Maniawski	Director, AMI Clinical Science	Philips Healthcare	piotr.maniawski@philips.com
James Montgomery	Assistant Professor, Small Animal Clinical Sciences, WCVM	University of Saskatchewan	james.montgomery@usask.ca
Julia Montgomery	Assistant Professor, Large Animal Clinical Sciences, WCVM	University of Saskatchewan	julia.montgomery@usask.ca
Marc Morris	PhD Student, Nutrition, COPN	University of Saskatchewan	mwmorris11@gmail.com
Darrell Mousseau	Associate Professor, Psychiatry, COM	University of Saskatchewan	darrell.mousseau@usask.ca
Karen Mosier	Research Facilitator, WCVM	University of Saskatchewan	karen.mosier@usask.ca
Frank Nolan	Research and Innovation Development Officer	NSERC Prairies Regional Office	frank.nolan@nserc-crsng.gc.ca
Haron Obaid	Clinical Associate Professor	Saskatoon Health Region	haron.obaid1@gmail.com
Vladimir Pekar	Research Program Manager	Philips Healthcare	vladimir.pekar@philips.com
Murray Pettitt	Research Associate, Animal and Poultry Science, COAB	University of Saskatchewan	murray.pettitt@usask.ca
Nathan Pham	Masters Student, Pharmacology, COM	University of Saskatchewan	nathan.pham@usask.ca

Meena Sakharkar	Associate Professor, Chair in Rational Drug Design, COPN	University of Saskatchewan	meena.sakharkar@usask.ca
Gordon Sarty	Professor, Psychology, COAS	University of Saskatchewan	gord.sarty@usask.ca
Glen Schuler	Managing Director, ILO	University of Saskatchewan	glen.schuler@usask.ca
Pratima Shrivastava	Post Doctoral Fellow	VIDO-InterVac	prs592@mail.usask.ca
Elemir Simko	Professor, Veterinary Pathology, WCVM	University of Saskatchewan	elemir.simko@usask.ca
Baljit Singh	Associate Dean (Research), WCVM	University of Saskatchewan	baljit.singh@usask.ca
Jaswant Singh	Professor, Veterinary Biomedical Sciences, WCVM	University of Saskatchewan	jaswant.singh@usask.ca
Liz Snead	Professor, Small Animal Clinical Sciences, WCVM	University of Saskatchewan	liz.snead@usask.ca
Haresh Vachhrajanai	Interim Head, Radiation Oncology	Saskatchewan Cancer Agency	Haresh.Vachhrajani@saskcancer.ca
Emy Varughese	MSc Student, Veterinary Biomedical Sciences, WCVM	University of Saskatchewan	eev835@mail.usask.ca
Khan Wahid	Assistant Professor, Mechanical Engineering, COE	University of Saskatchewan	khan.wahid@usask.ca
Carl Wesolowski	Pediatric Radiologist, Medical Imaging, COM	University of Saskatchewan	carl.wesolowski@gmail.com
Michal Wesolowski	Post Doctoral Fellow, Medical Imaging, COM	University of Saskatchewan	mike.wesolowski@usask.ca
Sheldon Wiebe	Pediatric Radiologist, Medical Imaging, COM	University of Saskatchewan	sheldon.wiebe@usask.ca

LEGEND: CLS – Canadian Light Source; COAB – College of Agriculture and Bioresources; COAS – College of Arts and Science; COE – College of Engineering; COM – College of Medicine; COPN – College of Pharmacy and Nutrition; ILO – Industry Liaison Office; VIDO-InterVac – Vaccine and Infectious Disease Organization International Vaccine Centre; WCVM - Western College of Veterinary Medicine