

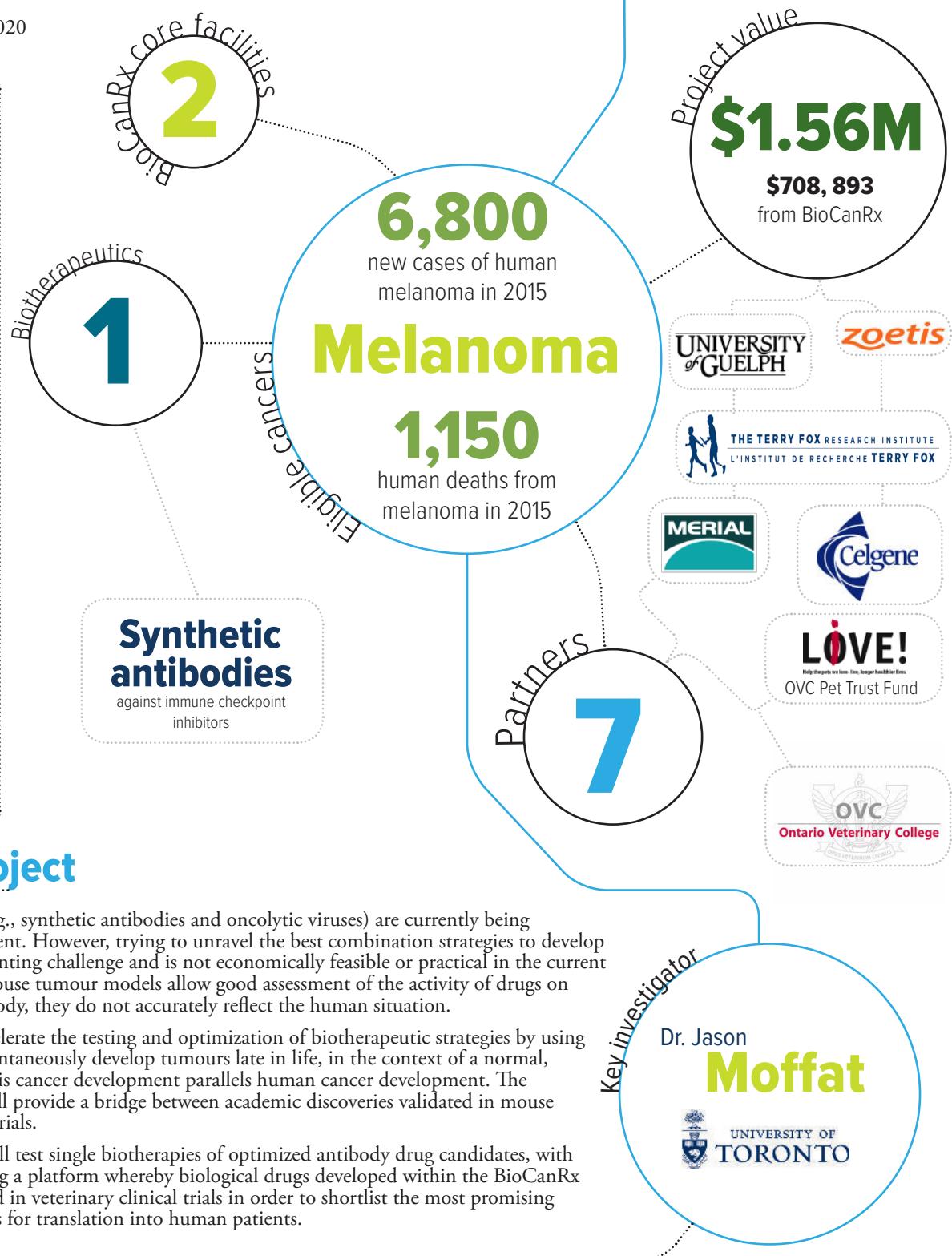
Enabling Studies Program

Development of immune regulating antibodies for use in companion animal clinical trials

July 1, 2015 to March 31, 2020

Highlights

- An innovative approach to accelerating combination cancer therapies by using companion animal clinical trials
- Companion animals are cancer patients themselves and could benefit from clinical application of novel experimental therapeutics
- This project will develop canine-active synthetic antibodies that bind to key immune modulatory molecules in development for use in human cancer patients
- This project will test the ability to rapidly assess combinations of antibodies with other innovative therapies (e.g., oncolytic viruses, T cells) in a clinical setting
- Cost effective product development



About the project

Many novel biotherapies (e.g., synthetic antibodies and oncolytic viruses) are currently being developed for cancer treatment. However, trying to unravel the best combination strategies to develop for clinical trials poses a daunting challenge and is not economically feasible or practical in the current regulatory setting. While mouse tumour models allow good assessment of the activity of drugs on biological processes in the body, they do not accurately reflect the human situation.

This project proposes to accelerate the testing and optimization of biotherapeutic strategies by using companion animals that spontaneously develop tumours late in life, in the context of a normal, outbred immune system. This cancer development parallels human cancer development. The project's proposed testing will provide a bridge between academic discoveries validated in mouse models and human clinical trials.

As a proof-of-concept, we will test single biotherapies of optimized antibody drug candidates, with the ultimate goal of providing a platform whereby biological drugs developed within the BioCanRx network can be rapidly tested in veterinary clinical trials in order to shortlist the most promising candidates and combinations for translation into human patients.

Enabling Study investigators



Guelph

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Scientific investigator

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Core facilities

**Toronto Recombinant
Antibody Centre (TRAC)**
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**Robert E. Fitzhenry Vector
Laboratory** (BioCanRx Core Facility)
McMaster University

BioCanRx

\$708,893

approved on
June 10, 2015*

*revised on June 9, 2016

July 1, 2015

- Project starts

PARTNER FUNDING

University of Guelph

\$55,000

OVC Pet Trust Fund

\$41,358

Celgene

\$680,000

Ontario Veterinary College

\$16,000

Terry Fox Research Institute

\$47,000

Merial

\$8,000

Zoetis Canada

\$4,000

- Generate human synthetic antibodies that target immune checkpoint modulators (e.g., PD1, PD-L1 and OX40) and convert these antibodies for canine clinical trials through caninization
- Characterize these synthetic antibodies, including binding profiles and blocking studies with two to three candidate antibodies (e.g., PD1, PD-L1 and OX40).
- Large-scale production of IgGs for in vivo efficacy studies

- Conduct pharmaco-kinetic and toxicity studies in pure-bred research dogs with 2-3 synthetic canine antibodies (i.e. OX40 and PD1)
- Conduct phase I clinical studies in canine malignant melanoma with anti-PD1 and anti-OX40
- Develop data packages for Phase 1 clinical trials for both OX40 and PD1 antibodies for canine melanoma

**The power to kill cancer lies within us.
Let's tell our bodies how.**

