

COLLEEN MARIE O'CONNOR, PH.D.

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Innovative scientific and clinical research professional with demonstrated ability to build high profile collaborative relationships with Key Opinion Leaders (KOLs), academic institutions, and other researchers in the field of cancer research and treatment. Expertise includes protocol development, clinical trial design, data analysis, and oncology research. Dynamic communicator with a strong history of presentations, publications, and media appearances.

PROFESSIONAL EXPERIENCE

CAVU Biotherapies, Houston, TX

May 2015 - Present

Founder and CEO (May 2015 - Present)

- Collaborated with Cooley, LLP law firm to submit patents and trademarks.
- Developed 5-year budgets.
- Developed monthly financial projections
- Wrote grants.
- Identified potential investors.
- Expanded network.
- Developed marketing strategies.
- Identified potential customers and markets.
- Developed scientific plan and protocols.
- Wrote business plans and executive summaries.
- Prepared decks and pitched to private investors, venture capitalists, angel networks, and business incubators.
- Performed market analysis.
- Accepted into Houston Technology Center's (HTC) incubator.
- Completed HTC MBA Ignition Bootcamp.
- Acquired mentors, business advisors and interim management.
- Met with veterinarian oncologists to secure pre-orders.
- Managed executive and advisors.
- Created website, Facebook page, and Twitter account.
- Raised awareness of canine cancer through media interviews.

The University of Texas MD Anderson Cancer Center, Houston, TX

2008 – March 2015

Research Investigator, Department of Pediatric Research (09/2013 – March 2015)

Develop the use of genomic T-cell biomarkers to aid in cancer prognosis and quantification of immune health as it relates to cancer.

- Enroll, accrue, and initiate follow-up flow cytometry studies on companion canines diagnosed with lymphoma who received T-cell therapy post bone marrow transplants.
- Managed and completed greater than 50 companion canine T-cell infusions.
- Wrote and submitted grants on canine CAR T-cell therapy.
- Genetically modified canine and human T cells to express CAR.
- Analyze data collected from activated T-cell therapy post bone marrow transplant protocol.
- Analyze single-cell and nanostring genomic data.
- Develop statistical analysis to describe Nanostring data as relates to disease prognosis and cellular therapy.
- Developed computer scripts for machine learning and system dynamics as it relates to immune health.
- Developed translational models to predict T-cell and immune system behavior in canines post T-cell infusions to improve survival and quality of life through anticipatory treatments.

- Collaborate with commercial, private, and government agencies to further T-cell therapy research.
- Enroll, accrue, and initiate follow-up flow cytometry studies on companion canines diagnosed with solid tumors who received T-cell therapy post radiation.
- Expand and cryopreserved T-cells for infusion.
- Performed next generation sequencing and analysis of data.
- Counsel private practice veterinarians on infusion and study protocols across the United States.
- Work with academic and commercial entities to track infused T-cells by MRI in companion canines.
- Identified new tumor antigen targets using T-cell Receptors for treatment of canine lymphoma.
- Assisted in regulatory matters concerning T-cell therapy in canines.
- Submitted abstracts to conferences.
- Participated as an invited speaker and panelist on canine immunotherapy.
- Mentored graduate students.
- Managed technicians.
- Wrote and submitted manuscripts.
- Worked with Development Office to procure private donations.

Post-Doctoral Fellow, Department of Pediatric Research (03/2008 – 09/2013)

Designed and conducted research projects developing the companion canine comparative oncology model to inform on adoptive CAR⁺ and CAR^{NEG} T-cell therapy as a viable treatment model for human non-Hodgkin's Lymphoma. Worked in the laboratory of Dr. Laurence Cooper, M.D., Ph.D.

- Designed protocols and conducted clinical trials to study adoptive CAR⁺ and CAR^{NEG} T-cell therapy for human non-Hodgkin's Lymphoma, osteosarcoma, and glioblastoma.
- Published research findings in peer-reviewed journals.
- Developed canine T-cell flow cytometry protocols and data analysis.
- Utilized hybridomas to develop anti-canine tumor antigen antibody.
- Compiled, analyzed, and presented research findings at meetings, conferences, and lectures.
- Initiated and managed collaborations with Key Opinion Leaders (KOLs), academic institutions, and private organizations to accomplish research goals.
- Wrote and submitted grant applications.
- Managed technicians.
- Trained and mentored undergraduate and graduate students.
- Worked with Development Office to procure private donations.
- Participated in grant review study sections.

InCellerate 2, Houston, TX

2011 – 2012

Chief Scientific Officer

Developed scientific protocols for the scale-up production of T-cell Therapy for companion canines diagnosed with cancer and redesigned protocols to include cost-saving steps and developed infusion protocols for commercial use. Developed biomarker and follow-up studies for commercial use.

- Advised on patent related issues.
- Assisted in the development and writing of business and scientific plans.
- Created budgets relating to personnel, equipment, and manufacturing.
- Wrote and submit grants to fund start-up company.
- Collaborated with KOLs and other key executives on financial aspects of scale-up as well as determination of product demand in the veterinary oncology world. Explained how and why T-cell therapy works and what future products could be built upon this initial offering.

Newport Aquarium, Newport, KY

1999 – 2002

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Independent Aquatic Biologist (03/2000 - 07/2002)

Conducted husbandry and research of venomous/poisonous marine/freshwater animals, penguins, cartilaginous fish (sharks/stingrays), reptiles/amphibians, cnidarians, and invertebrates.

- Developed and delivered educational presentations to the public on marine science and ocean conservation.
- Organized and directed small tank Veterinary Quarantine Facilities.
- Oversaw the formation and daily care of cnidarian propagation systems.

Trainee Aquatic Biologist (08/1999 - 03/2000)

- Conducted husbandry of venomous/poisonous fish, cnidarians, invertebrates, reptiles, amphibians, and cartilaginous fish.

Intern (Summer 1999)

- Assisted with cnidarians, fish, reptile, and amphibian husbandry.
- Learned the intricacies of self-contained life support.

EDUCATION & PROFESSIONAL DEVELOPMENT

Ph.D., Toxicology with Specialization in Immunology, 2008

University of Kentucky, Lexington, KY

- Dissertation Title: IL-10-Mediated Changes in Lung Tumor Cells: Possible Effect on Tumor Growth *in vivo*

B.S., Marine Science and Biology, Minor Chemistry (Double Major), 1999

University of Miami, Florida, Coral Gables, FL

Patents and Technology License:

Expired:

- T-cell Therapy for B-cell Lymphoma, File No. TAMC:016US, 2011-2012

Filed:

- US 62/187,493 Compositions and Methods for Treating Immunological Dysfunction, July 1, 2015

AWARDS, PROTOCOLS & MEMBERSHIPS

Honors and Awards:

- Entrepreneur of the Year Finalist, CAVU Biotherapies, Business Excellence Forum and Awards, 2017
- National and Regional Comcast Business I4E Start-up Award Winner, CAVU Biotherapies, 2016
- The Ben F. Love Fellowship in Innovative Cancer Therapies from the Walter Frank Foundation, University of Texas MD Anderson Cancer Center, 2013
- Trainee of the Quarter Winner for Meritorious Work, University of Texas MD Anderson Cancer Center, 2012
- Immunology Poster Contest Winner, University of Texas MD Anderson Cancer Center Immunology Retreat, 2011
- The Janice Davis Singletary Lymphoma Fellowship, University of Texas MD Anderson Cancer Center, 2010
- Graduate Academic Year Fellowship, University of Kentucky, 2002
- Henry King Stanford Academic Scholarship, University of Miami, Florida, 1995 - 1999

Grants:

- American Kennel Club Canine Health Foundation, 2016 - 2017

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- American Kennel Club Canine Health Foundation, 03/2010 - 2014
- Lymphoma SPORE Career Development Grant Award, 2011 - 2012
- T32 NIH Training Grant in Cancer Immunobiology, 2008 - 2011
- NCI/NIHS Training Grant in Toxicology/Immunology, 2004 - 2008
- NIEHS Training Grant, 2003 - 2004

Clinical Protocols Developed:

- IBC # RM0511-378-1 MD Anderson Cancer Center
- P.E.T. (Providing Engineered T-cells) 1.5 Trial Document, 2013
 - Autologous and Allogeneic T-cell Infusions into Pet Dogs with NHL Post HSCT
- P.E.T. 3.0 Trial Document, 2012
 - Autologous CD20R CAR⁺ T-cell Infusions into Pet Dogs with NHL
- P.E.T. 2.0 Trial Document, 2011
 - Autologous T-cell Infusions into Pet Dogs with NHL Treated with Prednisone
- AUP 2011-091 Texas A&M University
 - Autologous T-cell Infusions into Pet Dogs with NHL Treated with Prednisone
- AUP 2011-150 Texas A&M University
 - Autologous 19F labeled T-cell Infusions into Healthy Colony Dog for Tracking
- AUP 2009-184 Texas A&M University
 - Autologous T-cell Infusions into Pet Dogs with NHL Post CHOP
- P.E.T. 1.0 Trial Document, 2008
 - Autologous T-cell Infusions into Pet Dogs with NHL Post CHOP

Professional Affiliations

- Houston Technology Center, Client Company, 2015-Present
- American Society of Hematology, Associate Member, 2012-2014
- American Society of Gene and Cell Therapy, Member, 2010-2015
- International Society of Cellular Therapy, Member, 2010-2011

PUBLICATIONS, PRESENTATIONS & INVITATIONS

Publications:

- Panjwani1 MK, Smith J, Schutsky K, Gnanandarajah J, **O'Connor CM**, Powell DJ, Mason NJ. Feasibility and safety of RNA-transfected CD20-specific Chimeric Antigen Receptor T cells in dogs with spontaneous B cell lymphoma. (*Manuscript in Submission to Molecular Therapy* 2016).
- **O'Connor CM**, Ang S, Maiti SN, Cooper LJN. Adoptive Therapy of Activated T cells Influences T-cell Gene Signatures in Companion Canines Diagnosed with Non-Hodgkin Lymphoma. (*Manuscript in Preparation*)
- **O'Connor CM**, Wilson HM. Developing T-cell Cancer Immunotherapy in the Dog with Lymphoma. *ILAR Journal* 2014 55 (1): 169-181.
- **O'Connor CM**, Sheppard S, Hartline CA, Huls H, Johnson M, Palla SL, Maiti SN, Ma W, Davis RE, Craig S, Lee DA, Champlin R, Wilson H, Cooper LJN. Adoptive T-cell Therapy Improves Treatment of Canine Non-Hodgkin Lymphoma Post Chemotherapy. *Scientific Reports* 2012 (2):249. *Epub* 2012 Feb 15.
- Zeng L, **O'Connor C**, Zhang J, Kaplan AM, Cohen DA. IL-10 promotes resistance to apoptosis and metastatic potential in lung tumor cell lines. *Cytokine*. 2010 Mar;49(3):294-302.
- Hilgarth RS, Murphy LA, **O'Connor CM**, Clark JA, Park-Sarge OK, Sarge KD. Identification of *Xenopus* heat shock transcription factor-2: conserved role of sumoylation in regulating deoxyribonucleic acid-binding activity of heat shock transcription factor-2 proteins. *Cell Stress Chaperones*. 2004 Summer;9(2):214-20.

Invited Oral Presentations:

- *CAVU Biotherapies, Inc Pitch*, Texas Life Science Investment Forum, Houston, TX, May 2016.
- *Chimeric Antigen Receptor T-Cell Therapy for Companion Canines with Spontaneous B-Cell Non-Hodgkin Lymphoma*, American College of Veterinary Internal Medicine Forum, Nashville, TN, June 2014.
- *Personalized Canine Cancer Therapy*, 3rd Annual Post Doc Symposium, MD Anderson Cancer Center, Houston, TX, August, 2013.
- *Personalized Canine Cancer Therapy*, American Veterinary Medical Association Annual National Conference, Chicago, IL, July, 2013.
- *The Canine T-cell Therapy Model for Pediatric Lymphoma*, Technical Speaker Breakfast Seminar, International Society for Cellular Therapy Conference, Philadelphia, PA, May, 2010.

Invited Panelist:

- *National Women's Small Business Month*, Panelist, Comcast Business, Philadelphia, PN, Nov 2016.
- *Tech Week PodCast*, Panelist, Comcast Business, Philadelphia, PN, August 2016.
- *Immunotherapy for the Canine with Lymphoma*, Panelist, American College of Veterinary Internal Medicine Forum, Nashville, TN, June 2014.

Oral Abstracts:

- *P.E.T., Vets, and CARcinoma: Adoptive T cell Therapy for the Canine Companion with Non-Hodgkin's Lymphoma*, Veterinary Cancer Society Annual Conference, San Diego, CA, October, 2010.
- *IL-10 Increases Resistance in Lung Tumor Cells to Apoptosis*, Autumn Immunology Conference, Chicago, IL, November, 2006.
- *IL-10 Mediated Changes in Lung Tumor Cells: Possible Effects on Tumor Growth in vivo*, Autumn Immunology Conference, Chicago, IL, November, 2005.
- *Expression of IL-10 and IL-10R by Lung Tumor Carcinoma Cells: Effect on Tumor Growth*, Autumn Immunology Conference, Chicago, IL, November, 2004.

Posters:

- **O'Connor CM**, Ang S, Maiti SN, Cooper LJN. Of States and Fates: Predicting T-cell Immunity by the Numbers. American Society of Gene and Cellular Therapy National Conference, New Orleans, LA, May 2015.
- **O'Connor CM**, Ang S, Maiti SN, McNamara G, Sheppard S, Miller T, Huls H, Champlin R, Wilson H, Cooper LJN. Adoptive Therapy of Activated T cells Influences T-cell Gene Signatures in Companion Canines Diagnosed with Non-Hodgkin Lymphoma. Genomic Medicine Conference, MD Anderson Cancer Center, Houston, TX, October 2013.
- Maiti SN, Zhuang Z, Deniger D, **O'Connor CM**, Bueso-Ramos C, Pappanicken K, Singh HS, Ang S, Torikai H, Huls H, Lee DA, Radvanyi L, Cooper LJN. Amplification-free multiplexed high-throughput digital profiling of low abundance transcripts and non-coding miRNAs in small amounts of biological samples. Genomic Medicine Conference, MD Anderson Cancer Center, Houston, TX, October 2013.
- **O'Connor CM**, Ang S, Maiti SN, McNamara G, Sheppard S, Miller T, Huls H, Champlin R, Wilson H, Cooper LJN. Immune Reconstitution with Activated T cells Significantly Improves Survival in Companion Canines Post Various Treatment Modalities. American Society of Hematology Annual Conference, New Orleans, LA, December 2013.
- **O'Connor, CM**; Olivares, S; Ang, S; Champlin, RE; Wilson-Robles, HM; Cooper, LJN. Chimeric Antigen Receptor T-cell Therapy for Companion Canines with Spontaneous B-cell Non-hodgkin Lymphoma. American Society of Gene and Cell Therapy, Salt Lake City, UT, May 2013.
- Olivares, S; **O'Connor, CM**; Ang, S; Kean, L; Hackett, P; Najjar, A; Singh, H; Huls, H; Shpall, EJ; Cooper, LJN. The specificity of rhesus T cells can be redirected to CD20 using the *Sleeping Beauty*

transposon/transposase system to express a chimeric antigen receptor. American Society of Gene and Cell Therapy, Salt Lake City, UT, May 2013.

- **O'Connor, CM;** Sheppard, S; Hartline, CA; Huls, H; Johnson, M; Palla, SL; Maiti, S; Ma, W; Davis, R.E.; Craig, S; Lee, D A; Champlin, RE; Wilson, HM; Cooper, L J N. T-cell Therapy for Non-Hodgkin Lymphoma in the Companion Canine: A Comparative Oncology Model. The University of Texas MD Anderson Cancer Center Immunology Retreat. The Woodlands, TX, November 6, 2011.
- **O'Connor, CM;** Sheppard, S; Huls, H; Johnson, M; June, C; Craig, S; Lee, D A; Champlin, R E; Wilson, H M; Cooper, L J N. P.E.T. THERAPY: T-cell Therapy Model for Companion Canines with B-cell Lymphoma. Cancer Prevention Research Institute of Texas. Austin, TX, November 17-18, 2010.
- **O'Connor, CM;** Sheppard, S; Huls, H; Johnson, M; June, C; Craig, S; Lee, D A; Champlin, R E; Wilson, H M; Cooper, L J N. P.E.T. THERAPY: T-cell Therapy Model for Companion Canines with B-cell Lymphoma. Second International Conference on Immunotherapy in Pediatric Oncology, Houston, TX, November 10-11, 2010.
- **O'Connor, CM;** Sheppard, S; Huls, H; Johnson, M; June, C; Craig, S; Lee, D A; Champlin, R E; Wilson, H M; Cooper, L J N. T-cell Therapy for Out-Bred Canines with Spontaneous B-cell Non-Hodgkin Lymphoma. ISCT Conference, Philadelphia, PA, 2010.
- **O'Connor, CM;** Kaplan, AM; Cohen, DA. IL-10 Increases Resistance of Lung Tumor Cells to Apoptosis *in vivo*. University of Kentucky Cancer Research Day, Lexington, KY, September 2007.
- **O'Connor, CM;** Kaplan, AM; Cohen, DA. IL-10 Increases Resistance in Lung Tumor Cells to Apoptosis. Autumn Immunology Conference, Chicago, IL, November 2006.
- **O'Connor, CM;** Kaplan, AM; Cohen, DA. IL-10 Mediated Changes in Lung Tumor Cells: Possible Effects on Tumor Growth *in vivo*. Autumn Immunology Conference, Chicago, IL, November 2005.
- **O'Connor, CM;** Kaplan, AM; Cohen, DA. Expression of IL-10 and IL-10R by Lung Tumor Carcinoma Cells: Effect on Tumor Growth. Autumn Immunology Conference, Chicago, IL, November 2004.
- **O'Connor, CM;** Ryals, N; Glynn, P. Effects of Extreme Temperature and Light Changes on Zooxanthellae Populations in *Cassiopeia xamachana*. Sigma XI Biology Poster Presentation, University of Miami, Florida, Spring 1998.

Media Recognitions:

- Comprehensive list of national and worldwide media recognitions available upon request.

Civic Involvement:

- Christian Community Service Center
 - Chairman of Hygiene Distribution for Back to School Event, 2014-2016.
- University of Kentucky Alumni Chapter, Houston, TX, 2008-Present
 - President, Board of Directors, 2014-Present
 - ❖ Best Contribution to Scholarships Out of State Award, 2014-2016
 - ❖ Best Contribution for Service Out of State Award, 2014-2016
 - President-Elect, Board of Directors, 2012-2014
 - Club Secretary, Board of Directors, 2011-2012
 - College Fair Representative, 2008-Present
- Junior League of Houston, 2008-Present
 - Sustainer, 2017
 - Community Placements: Bo's Place, Done-In-A-Day, Memorial Hermann Hospital Heart and Vascular Unit, Ronald McDonald House Activities and Dinner Leader, Child Advocates
 - Transfer Advisor, 2013

- Provisional Advisor, 2013
- Junior League of Lexington, KY, 2004-2008
 - Community Placements: University of Kentucky Pediatric Oncology Clinic, University of Kentucky Children's Hospital Rolex Three Day Event, God's Pantry, American Heart Association, Lexington Gallery Hop, Baby Health Services, Junior League Saddle-bred Horse Show
- Young Friends of Ronald McDonald House Houston Chapter, 2012-2013
- Science Fair Judge: Elementary and Middle School, Lexington KY, 2002-2008
- Guest Speaker: Career and Science Lecturer in Marine Science, 1999-2003

Committee Service:

- University of Kentucky Toxicology Student Forum, Secretary, 2003-2004
- Junior League of Lexington
 - Placement Counselor, League Newsheet Writer, Inaugural Holly Day Market Decorations Committee, Horse Show Office, 2007
 - Public Affairs, Horse Show Exhibitor Liaison, 2006
 - Past Funded Agencies, Horse Show Sponsorship, 2005
 - Horse Show Grounds, 2004