

Candidate: Regional Treasurer, North America (2023-2026)



Sowmya Viswanathan, PhD

Scientist
University Health Network
Canada

Summary of academic and professional background:

I am an Associate Professor at the University of Toronto with the Institute of Biomedical Engineering and Department of Medicine, and a Scientist at the Krembil Research Institute at the University Health Network (UHN). I have a dual industry and academic background, having worked in Regenerative Medicine at Johnson and Johnson from 2005-2008 and moving back to academia since 2009. Between 2009 and 2015, I led the Cell Therapy Program at UHN initiating multiple cell and gene-modified cell therapy trials for academic and industry partners. I oversaw the CMC aspects at our institutions' GMP facility. I was also involved in filing the regulatory dossiers with Health Canada, a role that saw me co-chair a Cell Therapy Stakeholder Group with Health Canada from 2015 to 2021. My biomedical engineering and industry background has served me well since I established my own lab in 2015. My lab has been focused on i) developing mesenchymal stromal cells (MSCs), particularly engineered MSCs and ii) monocyte/macrophage immunotherapies. The primary focus is in applying these cellular/immunotherapies in osteoarthritis. My lab has also developed in vitro human arthritis joint-on-chip and murine arthritis models that we can use to test novel cellular/immuno therapies for their efficacy in mitigating cartilage degradation and synovial inflammation.

Affiliated professional and commercial associations and any perceived or potential conflict of interests:

I have 60% equity stake in my own regulatory consulting company, Regulatory Cell Therapy Consultants Inc.

I have previously served on ISCT's BoD and familiar with COI and fiduciary responsibilities and have no conflicts with these roles.

List of top notable contributions to the field (e.g. publications, patents, reports, products advanced to clinical trial or regulatory approval, asset development, mergers, acquisitions, etc.) from the last 10 years:

1. Co-PI for a North American first dose escalation clinical trial using bone marrow-derived autologous MSCs in patients with knee osteoarthritis
2. This study was published in Stem Cells Translational Medicine in 2019 and was cited the top downloaded paper of 2019 (<https://stemcells.journals.onlinelibrary.wiley.com/doi/full/10.1002/sctm.19-0437>)
3. Recognized for this study as one of the Top 10 Research Accomplishments by The Arthritis Society (Canada, <https://arthritis.ca/about-us/what-we-do/research/top-10-research-advances-of-2019>)

4. PI for a minimally manipulated cellular therapy randomized, placebo-controlled, double-blinded clinical trial investigates heterogeneity in basal inflammation profile as a key predictor of response to autologous anti-inflammatory therapies (NCT05517434; clinicaltrials.gov)
5. Recognized for my lab's novel joint-on-dish model (Chan et al., Osteoarthritis and Cartilage 2022) as one of the Top 10 Research Accomplishments by The Arthritis Society (Canada, <https://arthritis.ca/about-arthritis/arthritis-in-the-news/news/top-10-research-advances-of-2021>)
6. I have published 50 full manuscripts with 2,160 citations and an h-index of 19
7. I co-chaired the Cell Therapy Stakeholder Group with Health Canada for 5 years (2015-2021)
8. I am co-director of a recently formed Orthobiologics centre at the Schroeder Arthritis Institute and responsible for creating and developing an orthobiologics research and clinical translation program (<https://www.uhn.ca/orthobiologics>)
9. I am elected ISCT liaison to the International Standards Organization (ISO) Technical Committee (TC) on Biotechnology 276 and led the development and publication of two MSC biobanking and characterization standards that were issued in 2022 (<https://www.iso.org/standard/74052.html?browse=tc>; <https://www.iso.org/standard/79141.html?browse=tc>)

Summary of involvement with ISCT in the past five years:

I am recently nominated co-chair of ISCT's MSC Scientific Committee (07/2022), and have been an active member since 2018. As part of the MSC's Scientific Committee, I chaired the MSC plenary session at ISCT 2020 (Paris/virtual) and an MSC satellite plenary session at ISCT 2021 (New Orleans/virtual). I have first-authored three ISCT MSC committee position papers (one in review), and co-authored other committee publications. I am actively involved in planning committee activities including participation at the 2023 ISCT (Paris) roundtable sessions.

I have been an expert member of the NA LRA since 2015 and was co-chair of the Cell Therapy Stakeholder Group with Health Canada 2015-2021. I have last-authored a committee publication (Chisholm et al., Cytotherapy 2019) on regulatory landscape. I co-chaired the Quality & Operations tracks at ISCT 2019 (Melbourne) and individual Q&O session at ISCT 2018 (Montreal)

I am an Associate Editor at Cytotherapy since 2018 and serving my second 3-year term. I mainly handle manufacturing, regulatory and MSC manuscripts

I served a two year term as Elected PhD representative on ISCT BoD from Jan 2020-Jan 2022

Summary of strategic vision for the Global Society:

ISCT is well positioned to address scientific, technical, commercial and regulatory challenges in a shifting landscape of cellular and gene therapies. To continue to do this, it must attract and retain members and stay relevant by i) publishing updated policy/position papers that reflect current thinking and norms and science; ii) hosting practical webinars and training workshops that help users address their current bottlenecks; iii) hosting regional meetings which provide opportunities for learning, networking, mentorship and updating knowledge and skills. I would work with my ISCT committees to continue to deliver on i) and ii) and be actively involved in planning and organizing American regional meetings in 2023 (Houston) and Annual Meetings in 2024 and beyond.