MESSAGE FROM THE PRESIDENT AND CEO

A FOCUS ON CLINICAL TRANSLATION

TRULY GLOBAL

CONNECT. COMMUNICATE. TRANSLATE: OUR MEETINGS

EDUCATING AND EMPOWERING STAKEHOLDERS

TRAINING THE NEXT GENERATION

RECOGNIZING ISCT CHAMPIONS

PEER-REVIEWED PUBLISHING

FINANCIAL SUSTAINABILITY

GET INVOLVED
MESSAGE FROM THE PRESIDENT AND CEO

Moving ISCT Into a New Era

2018 was a special year. It was significant because we changed our name to broaden the scope to include gene therapies. We had also recently transitioned to an independently run society and expanded the head office in Vancouver, empowering ISCT to branch out on new initiatives. This really allowed our society to connect with cell and gene therapy professionals across the globe.

In August 2017, the FDA historically approved CAR T-cell therapies and for the first time ever, North Americans had access to these revolutionary treatments. That put ISCT on a real trajectory of dramatically increasing both partnerships and enthusiasm within the cell and gene therapy industry. Serving on the FDA ODAC and as the ISCT president at the time, it felt like the beginning of something highly exciting – the beginning of a new era. It really was an energizing time for ISCT and the cell and gene therapy field as a whole.

It’s critically important that ISCT serves different regions across the globe and continues to serve more countries and regions developing cell and gene therapies. Our slogan, “Connect. Communicate. Translate.” is appropriate because that is exactly what ISCT does, connecting and engaging a diverse global network of cell and gene therapy professionals so they can produce new, safe therapies for you and me.

2018 was also the year my presidency at ISCT sadly ended in May. My memorable time as president was highly enriching, both professionally and personally. I have since passed the torch onto Dr. John Rasko, who I am sure will continue to connect with cell and gene therapy professionals across the globe.

Celebrating a Golden Age of Cell and Gene Therapy

In 2018, ISCT scientific committees published four papers outlining innovative ideas and work taking place in cell and gene therapy.

NUMBER OF REGULATORY GUIDANCE COMMENTS MADE BY ISCT

FDA CELL THERAPY LIAISON MEETING (CTLM)

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION (ISO) CATEGORY A LIAISON

advancing standards for regenerative medicines as well as day-to-day operations in a stem cell lab.

The 2018 meetings were held on April 24th and December 4th in Ottawa, Canada.

For some, the commercialization of cell and gene therapies could be the biggest revolution in the field. The wealth of opportunities it offers is exciting, especially for those who focus on clinical translation.

At the ISCT 2018 Annual Scientific Meeting in Montreal, Quebec, the Society held a Strategies for Commercialization Track. A popular issue around cell and gene therapies is the commercialization of these products and increasing access of these innovative medicines for people in need – it is the commercialization that enables that.

The ISCT authors also proposed that MSC terminology promotes deceit by medical tourism groups by specifically appropriating the key word “stem” as a means to confuse the public, calling for the adoption of the term “mesenchymal stromal cell” to promote transparency and accuracy.

In response to a controversial article printed in Nature International Journal of Science, ISCT members published a response, applauding the article’s effort to discuss the vexing issue of stem cell tourism.

The biggest revolution in commercialization is the wealth of opportunities for long-term benefit through cell and gene therapies. This is a major revolution because we go from managing attempts of live replicating cell products. Attendees of the invite-only event include members of industry, academia and other leaders from the cell and gene therapy field, all with the objective of tackling and discussing high-profile issues in the field. Read the Meeting Report.

The ISCT Commercialization Committee Signature Series is dedicated to educating technical and quality professionals in the cell and gene therapy field. At the 2018 ISCT Annual Scientific Meeting, this series brought together experts from around the world to provide in-depth discussions on critical topics, including regulatory affairs, clinical translation, and commercialization strategies.

The second ISCT Commercialization Committee Signature Series was held this past January at the Phacilitate meeting. This special event focused on product development and strategy, with speakers from leading companies sharing insights on how to navigate the complex landscape of regulatory, clinical, and commercial challenges.

The ISCT JAPAN SERIES WEBINAR PROGRAM and ISCT COMMERCIALIZATION SIGNATURE SERIES have been instrumental in fostering partnerships and advancing the field, particularly in the context of global regulatory and standardization efforts.

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Dr. Carl June presenting in the Strategies for Commercialization
ISCT is a truly global organization with five distinct regions: North America, Europe, Asia, Australia and New Zealand, and South and Central America.

**1,425 Members in 2018**

**Membership: 51% outside of the United States from 60+ countries**

**MEETING REGIONAL MEMBERSHIP NEEDS**

ISCT’s global structure is designed to address the region-specific needs of its members. Each region, guided by its regional leadership, develops region-specific programs and initiatives for the benefit of its members.

Meet your regional leaders and learn more about activities in your region.

**GLOBAL MEETING STRATEGY**

With education as the core of ISCT’s value proposition to our members and the cell and gene therapy community, ISCT delivers highly curated scientific programming around the globe through its annual and regional meetings. The rotation of these meetings throughout the world provides its members with leading-edge education and networking opportunities to advance the field and drive the clinical translation of cell and gene therapies to patients.

- Upcoming Annual Meetings
- Upcoming Regional Meetings

**GLOBAL COLLABORATIONS**

ISCT works globally with organizations that share a common vision to drive the translation of cell and gene therapies for the benefit of patients worldwide.

**Asia**
- Council for Advanced Regenerative Medicine (CARM)
- Forum for Innovative Regenerative Medicine (FIRM) – 2018 Partner Organization Report
- Japanese Society for Regenerative Medicine (JSRM)
- Strategic Center for Regenerative Medicine (SCRM)

**Australia and New Zealand**
- Biotherapeutics Association of Australasia (BAA) – 2018 Partner Organization Report

**Europe**
- European Infrastructure for Translational Medicine (EATRIS)
- Joint Accreditation Committee – ISCT & EBMT (JACIE) – 2018 Partner Organization Report

**Global**
- Alliance for Harmonization for Cellular Therapy Accreditation (AHCTA) – 2018 Partner Organization Report
- International Council for Commonality in Blood Banking Automation (ICCBBA)
- International Organization for Standardization (ISO) – 2018 Partner Organization Report
- Worldwide Network for Blood & Marrow Transplantation (WBMT) – 2018 Partner Organization Report

**North America**
- Alliance for Regenerative Medicine (ARM) – 2018 Partner Organization Report
- American Society for Transplantation and Cellular Therapy (ASTCT) – 2018 Partner Organization Report
- Foundation for the Accreditation of Cellular Therapy (FACT) – 2018 Partner Organization Report
- United States Pharmacopeal Convention (USP) – 2018 Partner Organization Report

Visit the Annual Report Online
Since 1992, ISCT has connected more than 17,000 delegates through our Annual Meetings and communicated with more than 30,000 cell and gene therapy professionals at cutting-edge meetings, events, webinars and seminars to translate the advancement of research into clinical adoption and standard of care over the past 26 years.

**ISCT ANNUAL SCIENTIFIC MEETINGS**

**ISCT 2018 Montreal**

- **1600+ Delegates**
- **13 Dedicated Networking Sessions**
- **250+ Speakers**
- **70+ Scientific Sessions**

53 Countries Represented

**ISCT REGIONAL MEETINGS**

- **ISCT 2018 Montreal Top 10 Countries**
  - United States: 759
  - Canada: 333
  - United Kingdom: 64
  - South Korea: 62
  - Germany: 55
  - Australia: 40
  - Japan: 38
  - France: 35
  - Taiwan: 22
  - Singapore: 21

**ISCT ANZ 2018**

- **136 Delegates in Attendance**

**ISCT EU 2018**

- **263 Delegates in Attendance**

Visit the Annual Report Online


The ISCT Presidential Task Force on the Use of Unproven and/or Unethical Cell and Gene Therapies (PTF) is a contingent of colleagues focused also on the ethical implications of these unproven cell and gene therapy strategies. To increase the safety of cell-based therapies for patients, the PTF collaborates with other cell and gene therapy groups, all working towards the development of education and patient resources.

"With the increase in approvals of cell and gene therapies around the world and the resultant expectations of the public, we felt the need to consolidate the activities of the PTF to anticipate possible issues of a looming industry and to protect patients. There are many good products available but there are some that are not.

Dr. Dominici says that the strength of the PTF lies in its collaborative, cross-sectorial nature, representing the world’s leading patient advocacy groups, regulatory bodies, foundations, companies, universities, government, and other organizations.

"What makes ISCT and our task force special is that we have a large contingent of colleagues focused also on the ethical implications of these unproven cell and gene therapy strategies. To increase the safety of cell-based therapies for patients, the PTF collaborates with other cell and gene therapy groups, all working towards the development of education and patient resources. This global guide addresses the issue of unproven cell and gene therapies, which are currently being advertised, sold and administered to patients, although they fail to achieve recognized medical standards of safety and efficacy. These unproven treatments are often marketed and offered outside of normal care settings. This is one of a series of comprehensive and best regulatory approaches. With this document, the ISCT Presidential Task Force hopes to educate patients and health care professionals, providing resources to determine whether a therapy has been deemed safe and effective by the appropriate governing bodies.

Patients

The World Bank on Blood & Marrow Transplantation (WBMTP) in partnership with the ISCT Presidential Task Force on the Use of Unproven and/or Unethical Cell and Gene Therapies (PTF) on the Use of Unproven and/or Unethical Cell and Gene Therapies has developed the Patient Reference Document, a comprehensive, in-depth guide for professionals and patient advocacy groups to navigate safe and ethical cell and gene therapy treatments. To address this issue, the Society created the ISCT Presidential Task Force on the Use of Unproven and/or Unethical Cell and Gene Therapies.

The Patient Reference Document is a reliable, up-to-date resource that will help practitioners and patients to better understand and make informed decisions regarding the use of unproven cell and gene therapies. We hope that this guide will increase the safety of cell-based therapies for patients and improve the care of patients with cancer and other serious diseases in need of innovative treatments.

Patient Reference Document

View the Reference Documents here.
Training the Next Generation

With the dramatic growth in the cell and gene therapy field, there is an urgent need to train the next generation of professionals. ISCT is playing a key role in developing the careers of Early Stage Professionals (ESP) as they enter the CBT field in record numbers.

“The biggest problem facing the growth around the world is a shortage of qualified people — it is a global, industry-wide issue.”
— Bruce Levine, PhD, President-Elect, ISCT

Over the past 10 years, the cell and gene, and regenerative therapy field has been experiencing unprecedented growth around the world. The US Food and Drug Administration predicts that, incredibly, the approval of new cell and gene therapies will increase up to 900 percent in the next 10 years.

Long-time ISCT member and President-Elect Bruce Levine believes the field is going through a very pivotal phase at the moment.

“I think that we have a huge amount of seed and young plants spread around and there is going to be a weeding-out process,” he says. “We’re all going to grow and some are going to be successful and some are not. The ones given sunshine and water and sustenance will grow and flourish — the ones in the shade without water will die away. We’re in a very unique phase of innovation where there are many new ideas coming out from academia now being developed by industry — the way to effective therapies is through different approaches.”

Even though there are challenges in the cell and gene therapy field, there are also opportunities for the career development of the qualified human resources available. This is an opportunity to receive professional guidance from leaders in the field.

In August 2018, the ESP Committee launched the ISCT Mentoring Program following a successful pilot program in 2017. Mentors and mentees represented all five ISCT regions. The program provides ESPs with a unique opportunity to receive professional guidance from leaders in the cell and gene therapy field. The program pairs an experienced cell and gene therapy leader with two mentees who are mentored by an experienced cell and gene therapy leader from each of their respective regions.

2018 Mentors:

Australia and New Zealand
- Janet Macpherson, Product Specialist – Cell & Gene Therapy ANZ, GCS Healthcare Life Sciences
- Dominic Wall, Director, Pathology, Operations, Peter MacCallum Cancer Center and CEO, Cell Therapies Pty Ltd

Europe
- Tatiana Amelina, Head of Center for Biomedical Technologies, State Research Center Burnasyan Calmettes Federal Medical Biophysical Center FMBA of Russia
- Christian Chabannon, Head and QP, Cell Collection and Processing Facilities, Institut Paoli-Calmettes
- Cornelia Kasper, Professor, Department for Biotechnology, BOKU

North America
- Ali Mohamed, VP of CME, Innate Biototechnologies
- Anthony Ting, VP of Regenerative Medicine, Athersys, Inc
- Bruce Levine, Professor and Director of the Clinical Cell and Vaccine Production Facility, University of Pennsylvania
- Ed Hortwitz, Acting Professor of Pediatrics, Director of Transplantation Biology and Therapeutics, Emory University School of Medicine
- Nadim Mahmud, Associate Professor of Medicine, University of Chicago Illinois School of Medicine
- Sandeep Som, Associate Professor of Pediatrics, Stanford University
- Shirley Bartido, Director, Regulatory Affairs, Collectis, Inc

South & Central America
- Roberto Fanganello, Consultant, R-Crio, InnovaSpace, STAR Associates

Training the Next Generation

Training the Next Generation is a part of the ISCT Strategic Plan to develop and train the next generation of cell and gene therapy professionals.
Abstract: Targeted Stromal Cells Expressing Trail as a Treatment of Age-related Macular Degeneration and Diabetic Human Mesenchymal Stromal Cells Administered

Abstract: Human Placental-Derived Adherent Stromal Cells Co-Induced with TNF-α and IFN-γ to help up-and-coming scholars in cell and gene therapy field, the Society presents the ISCT Abstract Awards, which awards thousands of dollars to emerging scholars and an opportunity to showcase their work. As to success, the journal metrics speak for themselves. First, the volume of papers published has increased three-fold. In 2000 we had six issues per annum and published 41 papers. In the last 12 months we have published 26 reviews, commentaries, and 123 regular papers. In 2000 we had six issues per annum and published 141 papers. The contents have broadened from the solid base of mesenchymal stromal cells to cover the development of a huge spectrum of cell types used in therapy, including iPS cells, endothelial cells, and immune cells. In particular, the ISCT journal is leading the way in the area of cell and gene therapy for age-related macular degeneration. We need to have strong communications between the research and medical communities, the regulatory bodies – they need to be consulted and we need experts to help each other. ISCT is the central forum that connects all of these groups in order to create new therapies for people around the world.

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2018 was a big year for Cytotherapy, the official journal for ISCT. An essential resource for cell and gene therapy clinical researchers, oncologists, hematologists, physicians, and regulatory experts, the publication named Dr. Donald Phinney as the new senior editor as well as Dr. Oscar Lee, Dr. Luis Ortiz and Dr. Sowmya Viswanathan as the new associate editors. The new editorial staff brings a wealth of experience to the journal, undoubtedly reinforcing Cytotherapy as a premier source for cutting-edge findings, clinical trials of cell-based therapies, and news and opinion pieces on all aspects of the rapidly expanding field of cell-based treatments for cancer, degenerative disorders, immunotherapy and stem cell transplantation.

You can read issues of Cytotherapy here.

129 PUBLISHED PAPERS

92

SCIENTIFIC ARTICLES

14

REVIEWS

14

REPORTS

7

CORRESPONDENCE

2

EDITORIALS

Available to ISCT members around the world, Telegraft is the Society's leading global cell therapy newsletter which updates readers on new cell and gene therapy developments, regulatory updates, and regular columns on related meetings, organizations, and events, summaries of work being done in both academic and industry labs around the world. In 2018, not only was Telegraft redesigned with a fresh new look, but the bi-monthly e-newsletter named Dr. Nancy Collins as its new senior editor, a prominent researcher, mentor and leader in the cell and gene therapy field. Telegraft also recruited two Early Stage Professionals (ESPs) Dr. Alireza Abazari and Dr. Satyam Arora, as the new junior associate editors, bringing fresh perspectives to the publication.

You can read issues of Telegraft here.
FINANCIAL SUSTAINABILITY

2018 Operating Revenues:
- 25% Programs and Projects
- 6% Cytotherapy
- 6% Regional Meeting

2018 Audited Expenses:
- 40% Annual Meeting
- 23% Member Services/Projects
- 7% Regional Meeting
- 7% Cytotherapy
- 12% Operations
- 9% Facility
- 2% Other Programs

Visit the Annual Report Online
ISCT MEMBERSHIP: BE PART OF A TRULY GLOBAL COMMUNITY ADVANCING CELL AND GENE THERAPY

ISCT membership benefits your cell and gene therapy career in a number of valuable ways with exclusive access and complimentary subscriptions to Telegraft and Cytotherapy, as well as networking opportunities to collaborate with key opinion leaders, government regulators, commercial partners and cell therapy technologists. An ISCT membership also provides:

- Reduced rates at ISCT-sponsored events, including webinars, technical workshops, research and clinical symposia, and the ISCT meetings.
- Access to members-only web resources, including the ISCT Member Networking Database and online discussion boards.

To learn more about ISCT memberships and how to join, visit our website.

UPCOMING MEETINGS

ISCT COMMITTEES

ISCT has 41 stakeholder committees, working in a number of scientific, commercial and regulatory disciplines within cell and gene therapy. Joining an ISCT committee is an invaluable networking opportunity, allowing you to connect with cell and gene therapy professionals from all over the world. If you would like to bolster your career by joining an ISCT committee, visit our Committees page to see how.

ISCT CAREER CENTER

Are you interested in recruiting for a cell therapy-related position in your company or institution? The ISCT Career Center is the perfect opportunity to highlight your organization, profile open positions, and recruit highly qualified cell therapy professionals from a targeted audience of cell therapy experts, including scientists, technologists, and business professionals.

RESOURCES

ISCT has a large number of valuable and comprehensive resources for ISCT members and cell and gene therapy professionals. This toolbox of resources includes a useful glossary of cell therapy terms, the ISCT Cell Therapy Bioprocessing Tools and Reagents Database, a centralized catalogue of available products for use in cell therapy processing, manufacturing, and research, as well as valuable patient resources from the innovative ISCT Presidential Task Force (PTF) on the Use of Unproven and/or Unethical Cell and Gene Therapies website, which was launched in 2018.

Visit the Cell Therapy Community Resources page to learn more.

FOLLOW US

To stay up to date with the latest and most relevant news and developments on ISCT and the cell and gene therapy field, follow our busy social media channels and app:

PUBLISH YOUR RESEARCH TO A GLOBAL AUDIENCE

Cytotherapy, the official journal of ISCT (International Society for Cell and Gene Therapy), publishes novel and innovative results from high-quality scientific and clinical studies in the fields of cell and gene therapy. Reaching a global audience of cell and gene therapy professionals each month, content published in Cytotherapy is an essential and reliable resource for clinical researchers, oncologists, hematologists, physicians, and regulatory experts around the world.

Aims and Scope

Studies evaluating the potency of experimental cell and gene therapies in clinically relevant animal models of disease and describing important advances in cell/gene-based product manufacturing and validation are welcomed. Results of clinical studies evaluating the safety and efficacy of cell and gene therapies in early- and late-phase trials are also of interest. In addition to short reports and full-length articles, the journal also accepts editorials addressing emerging trends and potential controversies in the field, and review articles summarizing bodies of work that have made lasting impacts in the field.

Journal Format

- Editorial
- Reviews
- Short Reports
- Full-Length Articles on:
  - Translational Studies
  - Cell Therapy
  - Immunotherapy
  - Gene Therapy
  - Regenerative Medicine
  - Manufacturing
  - Regulatory

Please visit the journal submission page for more information.

Visit the Annual Report Online