Cell Therapy – TRAcking, Circulation, and Safety (CT-TRACs)

OUR MISSION
The committee’s mission is to facilitate the translation of cell-based therapies to the clinic by driving the development of tools, methods, and knowledge required to evaluate the safety and fate of therapeutic cells. We do that by identifying gaps/unmet needs and designing strategy to fill, aligning “tools required” to available technology, understanding “cell fate” in vivo, addressing concerns regarding the potential for tumorigenicity, and developing scientific knowledge needed to help support international standards development.

CHAIRS
Public Chair
Dr. Tineke van den Hoorn
(Medicines Evaluation Board, The Netherlands)

Private Chair
Dr. William (Bill) Shingleton
(GE Healthcare)

HESI STAFF
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2019 COMMITTEE HIGHLIGHTS

Participating Organizations
- 8 government/regulatory agencies
- 5 academic/research institutes
- 3 nonprofit organizations
- 13 industry

Publications
- 1 published
- 1 in progress

Scientific Meetings and Trainings
- 1 committee meeting (September 2019 in Washington, DC)
- 1 advisory/other meetings (Human Pluripotent Stem Cells Meeting; June 2019 in Los Angeles, California; organized jointly with the Global Alliance for iPSC Therapies [GAiT], California Institute for Regenerative Medicine [CIRM], International Stem Cell Banking Initiative [ISCBI], and International Society Cell & Gene Therapy [ISCT]; presented session on tumorigenicity testing)

Outreach
- 2 posters (Safety of Stem Cell-Derived Therapies: Trends and Future Technologies meeting, October 2019 in Edinburgh, Scotland; and RESTORE 1st Advanced Therapies Science Meeting, November 2019 in Berlin, Germany)
- 2 presentations (Phacilitate Leaders World & World Stem Cell Summit (January 2019 in Miami, Florida)

Collaborations
- 5 external (GAiT, ISCT, CIRM, ISCBI, and FIRM/CoNCEPT [Forum for Innovative Regenerative Medicine/Committee for Non-Clinical Safety Evaluation of Pluripotent Stem Cell-derived Product, Japanese consortium])

Geographic Representation
- Japan, Netherlands, Switzerland, United Kingdom, United States

Awards and Recognition
The PoA/BD Working Group was cited in a recent Cell & Gene Therapy Insights article (2019;5:629–638; “Broadly-Applicable Imaging Platforms Are Necessary For Optimizing Cell Therapies In Solid Tumors,” co-authored by committee members David Morrow (EATRIS) and Mangala Srinivas (Radboud University) among others. The Tumorigenicity Working Group was cited in a Biologicals article (2018;56:67–83), titled “Report of the international Conference on Manufacturing and Testing of Pluripotent Stem Cells.”
WORKING GROUPS

- **Point of Administration - Biodistribution (PoA/BD) Working Group (Cell Tracking).** This working group aims to identify current approaches, gaps, and needs in monitoring/evaluating the fate and activity of cells after their administration *in vivo*, to assess the safety of cell-based therapies.

- **Tumorigenicity Working Group.** This working group aims to address concerns regarding the potential for tumorigenicity of pluripotent stem cell (PSC)-derived products by assessing and/or developing methodologies and approaches that could support tumorigenicity evaluation.

AREAS OF FOCUS FOR 2020

- **PoA/BD Working Group.** (1) Release the cell tracking database: a public database of clinical studies (later iterations may include preclinical studies as well) using cell tracking technologies in safety studies as a way to track biodistribution, cell fate, and cell therapy outcomes is in development. (2) Initiate a public webinar series as a way to train/educate stakeholders on available technologies to track human cell therapy products *in vivo*. (3) Present a scientific session at the ISCT Annual Meeting 2020 (27–30 May 2020 in Paris, France).

- **Tumorigenicity Working Group.** (1) Launch a new international multisite study to test predictive *in vitro* methodologies for assessing potential tumorigenicity of cellular therapies (iPSC-based therapies); conduct a scoping activity to identify potential new projects of interest and value for stakeholders working on cell therapies other than those that are iPSC based. Disseminate the working group position paper (Sato et al., 2019) and new initiative (multi-site study) through presentations at symposia and society meetings.

STRATEGIC IMPACT AREAS

**Catalysis of New Science**

In 2019, the committee released a public call for participants to launch a new international multisite experimental study, resulting in 10 applications with letters of interest from public and private sector organizations from Germany, Italy, Japan, Switzerland, the United Kingdom, and the United States.

**Increasing the Audiences for Collaborative Safety Science**

CT-TRACS brought new visibility of HESI as a platform for collaborative safety science in an emerging field in rapid evolution. New collaborators currently engaged in CT-TRACS were not familiar with HESI previously but are now actively contributing to and disseminating the committee’s work, including Cell and Gene Therapy Catapult (United Kingdom), EATRIS (European Infrastructure, based in the Netherlands), Emmes/PACT Program, Athersys, Celsense, VisiCell (new member in 2019), the National Institutes of Health (NIH) National Heart, Lung, and Blood Institute, and the NIH National Center for Advancing Translational Sciences. In 2019, collaboration with external collaborators continued through the organization of joint events with GAIT, CIRM, ISCT, and ISCBI.

PUBLICATIONS


PARTICIPATING ORGANIZATIONS

**Government/Regulatory Agencies**
- Medicines & Healthcare Products Regulatory Agency (UK)
- Medicines Evaluation Board (The Netherlands)
- National Institute for Public Health and the Environment (RIVM, The Netherlands)
- National Institutes of Health, National Cancer Institute
- National Institutes of Health, National Center for Advancing Translational Sciences
- National Institutes of Health, National Heart, Lung, and Blood Institute
- National Institute of Health Sciences (Japan)
- US Food and Drug Administration

**Academic/Research Institutes**
- King’s College London
- Memorial Sloan Kettering Cancer Center, Sloan Kettering Institute
- Radboud Institute for Molecular Life Sciences
- Stanford University, Cardiovascular Institute
- University College London

**Nonprofit Organizations**
- Cell and Gene Therapy Catapult
- EATRIS
- Emmes

**Industry**
- Astellas Pharma Inc.
- Athersys, Inc.
- Boehringer Ingelheim Pharmaceuticals
- Cellular Dynamics International, A Fujifilm Company
- Celsense
- Charles River Laboratories
- GE Healthcare
- Janssen Pharmaceuticals
- Novartis
- Sumitomo Dainippon Pharma
- Taconic Biosciences
- Takeda Pharmaceutical Company Limited
- VisiCell Medical