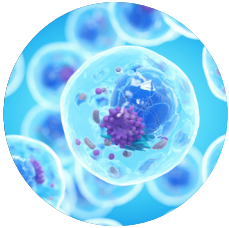


Cell Therapy – TRACKing, Circulation, and Safety (CT-TRACS)



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 by identifying gaps/unmet needs and designing strategies to fill them, 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 Chairs

- Dr. Tineke van den Hoorn
(Medicines Evaluation Board,
The Netherlands)
- Dr. Vladimir Ponomarev, Point of
Administration–Biodistribution
Working Group Co-Chair
(Memorial Sloan Kettering
Cancer Center)
- Dr. Charlotte de Wolf,
Tumorigenicity Working Group
Co-Chair (Medicines Evaluation
Board, The Netherlands)

Private Chairs

- Dr. William (Bill) Shingleton
(Cytiva)
- Dr. Brooke Helfer (Celsense), Point
of Administration–Biodistribution
Working Group Co-Chair
- Dr. Hiroto Bando (Fujifilm Cellular
Dynamics, Inc.), Tumorigenicity
Working Group Co-Chair

HESI Staff

- Dr. Lucilia Mouriès (lmouries@hesiglobal.org)
- Dr. Connie Chen (cchen@hesiglobal.org)

2020 Committee Highlights



Participating Organizations

7 government/regulatory agencies, **6** academic/research institutes, **15** industry, and **3** others



Publications

1 submitted



Scientific Meetings and Trainings

2 scientific sessions

- [International Society Cell and Gene Therapy \(ISCT\) Virtual Paris 2020](#) (May 2020 in Paris, France; 2024 attendees)
 - [Scientific session](#) on Imaging Cellular Therapeutics, chaired by CT-TRACS PoA/BD Working Group Co-Chair Brooke Helfer
- [Joint webinar](#) on Methods for Cellular Therapies: Tracking Cells *In Vivo* and Assessing Biodistribution in Patients–What Are Your Cells Doing? Where Do They Go? (September 2020, virtual; 160 attendees): organized jointly with the National Heart, Lung, and Blood Institute (NHLBI) PACT Program



Web Tools and Assays

1 database and **2** assays

- Cell Tracking Database: release anticipated by end of 2020/early 2021
- ddPCR assay: for detection of residual induced pluripotent stem cells (iPSCs) in cell therapy products derived from iPSCs (tumorigenicity assay)
- High efficiency culture (HEC) assay: for detection of residual iPSCs in cell therapy products derived from iPSCs (tumorigenicity assay)



Outreach

1 poster presentation, **2** oral presentations, and **1** scientific session

- [Fifth International Alliance for Biological Standardization \(IABS\) Cell Therapy Conference](#) (February 2020 in Tokyo, Japan; approximately 150 attendees)
 - HESI staff co-chaired Session 3 dedicated to tumorigenicity assessment and presented a talk titled “HESI CT-TRACS’ Tumorigenicity International Experimental Consortium: A Collaborative Effort to Address Collective Challenges and Needs”
- [ISCT Virtual Paris 2020](#) (May 2020 in Paris, France; 2024 attendees)
 - Poster presentation on “Safety of Cell Therapy Products: *In-Vitro* Methods to Assess the Tumorigenicity of Human Cell-Based Therapeutic Products”

2020 Committee Highlights (continued)

- Oral presentation: Dr. Yoji Sato (National Institute of Health Sciences, Japan) introduced the activities of MEASURE and the CT-TRACS Tumor Working Group to the Chinese National Stem Cell Resource Center



Collaborations

2 internal and 3 external

- Immuno-Safety Committee (ITC): formed the HESI Advisory Core Group for Engineered T-Cell Safety, with the possibility to extend collaboration to other committees in the near future
- Genetic Toxicology Technical Committee (GTTC): exploring potential synergies with the Duplex-Sequencing Working Group
- Global Alliance for iPSC Therapies (GAiT): developing a report from the joint 2019 pluripotent stem cell (PSC) workshop
- ISCT: held a joint session at the 2020 Annual Conference (virtual)
- NHLBI PACT Program: held a joint webinar at ISCT Paris 2020



Geographic Representation

Japan, Netherlands, Sweden, Switzerland, United Kingdom, and United States

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 PSC-derived products by assessing and/or developing methodologies and approaches that could support tumorigenicity evaluation.

Areas of Focus for 2021

- With the submission of the PoA/BD Working Group review manuscript, the working group will focus on concluding and releasing the Cell Tracking Database, leveraging the data in this public resource to identify new project areas and continuing collaboration with external partners such as ISCT for outreach to the broader cell and gene therapy scientific community.
- The Tumorigenicity Working Group will continue its focus on the experimental multi-site study (a multi-year project with anticipated end date in 2022). Two arms of the study are in progress: ddPCR assay and HEC assay, both for iPSC-derived cell therapies.
- The committee is currently evaluating proposals to address needs specific to chimeric antigen receptor T (CAR-T) cells and other gene therapies (two proposals submitted).
- CT-TRACS will continue engagement with other HESI committees, with the formation of a HESI Advisory Core Group for Engineered T-Cell Safety and its activities.

Strategic Impact Areas

Catalysis of New Science

In 2020, the committee started generating new data with the initiation of the new international multi-site experimental study. The preliminary phase of the study, conducted in three sites, contributed to the identification of markers for residual undifferentiated iPSCs which will be used in the main study.



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. The invitation from the International Alliance for Biological Standardization to feature a full session on tumorigenicity at their Fifth Cell Therapy Conference this year is a prime example. 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), and the National Institutes of Health (NIH) NHLBI. In 2020, collaboration with external partners continued through the organization of joint events with ISCT and the NIH/NHLBI PACT Program.



Publications

Submitted

Helper et al. (2020) Options for imaging cellular therapeutics *in vivo*: a multi-stakeholder perspective.

Participating Organizations

Government/Regulatory Agencies

Medicines and 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 Heart, Lung, and Blood Institute
 National Institute of Health Sciences (Japan)
 US Food and Drug Administration

Academic/Research Institutes

Imperial College London
 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

Industry

Astellas Pharma, Inc.
 AstraZeneca
 Athersys, Inc.
 Boehringer Ingelheim
 Bristol-Myers Squibb Company
 Celsense
 CSL Behring
 Cytiva
 Fujifilm Cellular Dynamics, Inc.
 Janssen Pharmaceuticals
 Novartis
 Sanofi
 Sumitomo Dainippon Pharma
 Takeda Pharmaceutical Company, Ltd.
 VisiCell Medical

Others

Cell and Gene Therapy Catapult (UK)
 Emmes
 European Infrastructure for Translational Medicine (EATRIS)