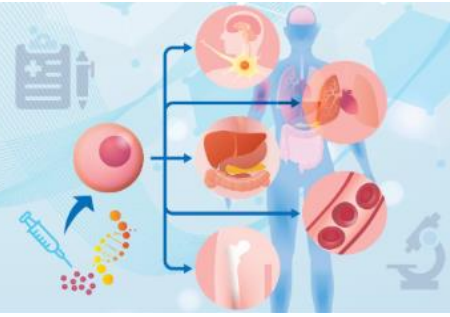


Assessing Emerging Cell and Gene Therapies for Disease-specific Therapeutic Applications: In Vivo Tracking and Biodistribution

December 2–3, 2026 | Bethesda, MD

Hybrid Meeting

Co-Organized by NIH and HESI CGT-TRACS Committee

Overall Purpose

The purpose of this workshop is to bring together multidisciplinary stakeholders to evaluate the current state of in vivo tracking and biodistribution for cell and gene therapies (CGTs) across the preclinical-to-clinical continuum. The workshop will examine how preclinical and clinical approaches are currently used to characterize the localization, persistence, and fate of CGTs, while identifying critical scientific, technical, and translational gaps between these settings. A central focus will be on how preclinical and clinical data and methodologies can be better connected to strengthen translation, inform clinical monitoring, and support regulatory decision-making. Ultimately, the workshop aims to identify priority needs and opportunities for advancing fit-for-purpose tracking and biodistribution approaches across the CGT development lifecycle.

Workshop Objectives

1. Assess the current state of knowledge for in vivo tracking and biodistribution in organ-specific and disease-specific applications
2. Identify knowledge gaps related to quantifying cells at intended engraftment sites and remote tissues
3. Detail the continuum from preclinical to clinical applications
4. Examine challenges related to accessibility and implementation across multiple sites
5. Identify future directions and funding opportunities

Key Questions to Address:

1. What information about the biodistribution, persistence, and fate of cell and gene therapies is needed across the preclinical-to-clinical continuum?
2. What can current preclinical and clinical tracking and biodistribution approaches reliably measure, and where are the most consequential scientific and technical gaps?
3. How can preclinical and clinical approaches and data be better integrated to support translation, clinical monitoring, and regulatory decision-making?
4. What technologies, standards, research priorities, and collaborations are needed to advance fit-for-purpose tracking and biodistribution assessment across the CGT development lifecycle

Day 1: December 2, 2026

7:30 AM – 8:00 AM	**Registration and Coffee**
8:00 AM - 8:15 AM	**Welcome and Meeting Goals**

Session 1: State of the Science: Cell and Gene Therapies and Imaging

Session Chair: Anne Plant, *Emerita Fellow, National Institute of Standards and Technology*

This opening session establishes the foundation for the workshop by providing an overview of the current and emerging cell and gene therapy modalities and the imaging technologies used for in vivo tracking and biodistribution.

8:15 - 8:50 AM	**Opening & State of the Science** **Speaker: Terry Flotte,** *UMass Medical School*
8:50 - 9:25 AM	**Overview of Current and Emerging Cell & Gene Therapies** **Speaker: Sadik Kassim,** *Danaher Life Sciences*
9:25 - 10:00 AM	**Overview of Current and Emerging Imaging and Biodistribution Tools** **Speaker: Jeff Bulte,** *Johns Hopkins*
10:00 - 10:15 AM	**Break**

Session 2: Disease and Organ System Applications – Case Examples

Session Chair: Terry Flotte, *UMass Chan Medical School*

This session will use case examples from diverse diseases and organ systems to demonstrate how in vivo tracking and biodistribution methods support cell and gene therapy development.

10:15 - 10:30 AM	**Pre-clinical and IND Enabling Applications** **Speaker: Alice Tarantal,** *UC Davis* ***(Virtual)***
10:30 - 10:45 AM	**Cardiac Case Example** **Speaker: Barry Byrne,** *University of Florida*
10:45 - 11:00 AM	**Liver Disease Case Example** **Speaker: Erik Shapiro,** *Michigan State University*
11:00 - 11:15 AM	**Diabetes Case Example** **Speaker: Klearchos Papas,** *University of Arizona & Co-Founder Procyon Technologies*

11:15 - 11:30 AM	**Autoimmune Case Example** **Speaker: Roberto Caricchio,** *UMass Chan Medical School* ***(Virtual)***
11:30 - 11:45 AM	**CAR-T for Oncology Case Example** **Speaker: Saad Kenderian,** *Mayo Clinic*
11:45 - 12:00PM	**Session Wrap-up/ Q&A**
12:00 - 1:00 PM	**Lunch**

Session 3: Technical Gaps and Development Needs

Session Chair: Michael Farwell, *University of Pennsylvania, Perelman School of Medicine*

This session will examine key technical gaps and development needs for in vivo tracking and biodistribution, including challenges related to sensitivity, quantification, spatial resolution, persistence, and longitudinal tracking.

1:00 - 2:15 PM	**89Zr-oxine PET Cell Labeling** **Speaker: Peter Choyke**, *NIH/NCI* **Neuro/Parkinsons - MRI** **Speaker: Amber Van Laar,** *AskBio* **CD45 CAR-T - PET Imaging** **Speaker: Mohammad Rashidian,** *Dana-Farber/Harvard* **19F - MRI** **Speaker: Eric Ahrens,** *UC - San Diego* **CAR-T PET Reporter Gene** **Speaker: Mark Sellmyer,** *UPenn* **CAR-T - MPI** **Speaker: Steve Conolly,** *UC – Berkeley*
2:15 - 2:45 PM	**Discussion Q&A**
2:45 - 3:00 PM	**Break**

Session 4: Regulatory and Public Health Perspectives

Session Chair: Richard McFarland, *Chief Regulatory Officer, Advanced Regenerative Manufacturing Institute (ARMI)*

This session will examine how tracking and biodistribution information is considered in both pre-clinical and clinical development stages and how they are applied across regulatory, industry, and

public health settings, with a focus on current expectations, decision-making needs, and areas where greater alignment may be needed.

3:00 - 4:00 PM	**Foundation Perspective** **Speaker: Marjana Marinac,** *Breakthrough T1D* **Developer Perspective** **Speaker: Howard Federoff,** *Kenai Therapeutics* **Regulatory Perspective** *Speaker: To be confirmed* **Academia/Bio-Tech Perspective** **Speaker: Mark Cohen,** *University of Illinois, Carle Illinois College of Medicine, Co-Founder REGENDO*
4:00 - 4:30 PM	**Discussion Q&A**
4:30 – 5:30 PM	**Networking Reception**

Day 2: December 3, 2026

7:30 - 8:00 AM	**Coffee and Networking**
8:00 - 8:15 AM	**Day 1 Recap and Day 2 Overview**

Session 5: Emerging Opportunities, Future Outlook, and New Approach Methodologies (NAMs)

Session Chair: Joe Wu, *Stanford University*

This session will look beyond current capabilities to explore emerging technologies and approaches that could address existing gaps and improve tracking and biodistribution assessment across preclinical and clinical applications.

8:15 - 8:35 AM	**Super Intelligence Models in Biomedical Image-Based Measurements** **Speaker: Peter Bajcsy,** *NIST* ***(Virtual)***
8:35 - 8:55 AM	**Beyond Tumor Size: Radiomic Insights into CAR T Activity in Lymphoma** **Speaker: Andrew Dunn,** *Resurface Therapeutics*

8:55 - 9:15 AM	**Reporter Gene – MRI** **Speaker: John Ronald,** *Robarts Research Institute, Western University*
9:15 - 9:35 AM	**Organoids/3D Tissues - iPSCs - COPD/AATD** **Speaker: Andrew Wilson,** *Boston University*
9:35 - 9:55 AM	**Organoids/3D Tissues - Regenerative Medicine Strategies for Human Relevant Models and the Path Towards Standards** **Speaker: Tony Atala,** *Wake Forest University* ***(Virtual)***
9:55 - 10:00 AM	**Session Wrap-up**
10:00 - 10:15 AM	**Break**

Panel Discussion: Funding Landscape, Partnerships, and the Future Ecosystem for CGTs Assessment

Session Chair: Matt Porteus, *President of the American Society of Gene & Cell Therapy (ASGCT), Stanford University*

This panel will consider what is needed to move the field forward, with a focus on funding priorities, partnerships, and opportunities for coordinated investment and collaboration.

10:15 - 11:45 AM

Regulatory Perspective
Panelist: PJ Brooks, *FNIH, NIH/NCATS*

Foundation Perspective
Panelist: Pat Furlong, *Parent Project Muscular Dystrophy*

Private VC Funding Perspective
Panelist: Meg Wood, *NYBC Ventures*

Academic – Research Perspective
Panelist: Elizabeth Hillman, *Columbia University, St. Jude Children's Research Hospital*

Academic – Clinical Perspective
Panelist: Christine Brown, *City of Hope*

Industry/Developer Perspective
Panelist: Kathy Tsokas, *BlueRock Therapeutics*

11:45 AM - 12:45 PM	**Lunch**

Breakout Sessions

The breakout sessions will address three priority areas:

- **Breakout 1: Accessibility and Implementation Across Clinical Sites**
- **Breakout 2: Technical Gaps and Research Needs**
- **Breakout 3: Future Directions and Innovation**

12:45 - 1:00 PM	**Breakout Charge & Instructions**
1:00 - 2:00 PM	**Breakouts**
2:00 - 2:15 PM	**Break**
2:15 - 3:00 PM	**Breakout Report Outs**
3:00 - 3:30 PM	**Workshop Synthesis & Wrap-up**
3:30 PM	**Adjourn**