



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

NIH-HESI Workshop on In Vivo Tracking and Biodistribution for Cell and Gene Therapies | December 2-3, 2026

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 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: Current State, Applications, Gaps, and Regulatory Context

Time	Session
7:30 – 8:00 AM	Breakfast, Coffee, and Networking
8:00 – 8:15 AM	Welcome Remarks: Workshop Objectives, and Overview Workshop Chairs: Celia Witten & Terry Flotte
8:15 – 10:00 AM	Session 1: State of the Science: Cell and Gene Therapies and Imaging 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. Purpose: 1. Establish foundational knowledge for workshop attendees. 2. Present the current state of cell and gene therapies. 3. Present the current state of imaging technologies relevant to tracking and biodistribution. 4. Serve as the workshop's de facto keynote section. Suggested topics: State of the field and importance of tracking and biodistribution; Current and emerging CGT modalities; Current and emerging biodistribution and imaging tools; Preclinical and clinical capabilities.
10:00 – 10:15AM	Break
10:15 – 12:00 PM	Session 2: Disease and Organ System Applications – Case Examples This session will present case examples across different disease and organ systems to illustrate how in vivo tracking and biodistribution approaches are being applied in cell and gene therapy development Purpose: 1. Present case examples of tracking and biodistribution across a range of CGT applications. 2. Illustrate how approaches are being applied to address specific therapeutic and clinical questions. 3. Highlight practical experiences, challenges, and lessons learned from different applications.

	4. Identify considerations that may be relevant across CGT modalities and disease areas. Suggested case-example topics: CAR-T and oncology; Cardiovascular applications; Diabetes; Neurological applications; Autoimmune disease; Lessons learned across applications.
12:00 – 1:00 PM	Lunch
1:00 – 2:45 PM	Session 3: Technical Gaps and Development Needs 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. Purpose: 1. Examine the capabilities and limitations of current tracking and imaging technologies. 2. Identify technical gaps that limit their use across preclinical and clinical applications. 3. Define development needs for improved sensitivity, quantification, spatial resolution, and longitudinal assessment. 4. Highlight priorities for advancing technologies to better meet CGT tracking and biodistribution needs. Suggested topics: Sensitivity and quantification; Spatial resolution; Longitudinal tracking and persistence; PET and MRI; Reporter gene approaches; MPI and emerging imaging platforms; Preclinical-to-clinical translation.
2:45 – 3:00 PM	Break
3:00 – 4:00 PM	Session 4: Regulatory and Public Health Perspectives This session will examine how tracking and biodistribution information is considered in both pre-clinical and clinical 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. Purpose: 1. Discuss regulatory and public health considerations for CGT tracking and biodistribution. 1. Examine what information is needed to support product development, clinical translation, and regulatory decision-making.

	- Highlight perspectives and needs across government, industry, and patient or public health stakeholders. - Identify gaps in current approaches, expectations, or interpretation of biodistribution data. Suggested topics: Regulatory/government perspective; Industry/developer perspective; Patient advocacy/foundation perspective; Clinical/public health perspective.
4:00 – 5:00 PM	Networking Reception and Poster Session
5:00 PM	Adjourn

Day 2: Future Directions, Partnerships, and Workshop Recommendations

Time	Session
7:30 – 8:00 AM	Breakfast, Coffee, and Networking
8:00 – 8:15 AM	Day 1 Recap and Day 2 Overview
8:15 – 10:00 AM	Session 5: Emerging Opportunities, Future Outlook, and New Approach Methodologies (NAMs) 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. Purpose: - Highlight emerging technologies and approaches with potential applications to CGT tracking and biodistribution. - Explore how AI, radiomics, advanced imaging, and reporter technologies may address current limitations. - Consider how NAMs, including organoids and 3D tissue models, can complement in vivo and clinical approaches. - Identify areas where further development, validation, or integration is needed to support future use. Suggested topics: AI and radiomics; Advanced imaging and data integration; Reporter technologies; Organoids and 3D tissue models; NAMs; Emerging technologies and future development needs.
10:00 – 10:15 AM	Break

10:15 – 11:15 AM	Panel Discussion: Funding Landscape, Partnerships, and the Future Ecosystem for Biodistribution Assessment 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. Purpose: 1. Discuss current and future funding needs for tracking and biodistribution research and technology development. 2. Identify areas where coordinated investment could help address shared gaps and priorities. 3. Explore opportunities for collaboration across government, academia, industry, foundations, and other organizations. 4. Consider mechanisms for supporting continued development and implementation of promising approaches. Suggested topics: Current and future funding needs; Coordinated investment; Cross-sector partnerships; Infrastructure and implementation
11:15 – 11:45 AM	Open Discussion and Audience Q&A
11:45 – 12:45 PM	Lunch
12:45 – 1:00 PM	Breakout Charge and Instructions
1:00 – 2:00 PM	Breakout Discussions
2:00 – 2:15 PM	Break
2:15 – 3:00 PM	Breakout Report-Outs
3:00 – 3:30 PM	Workshop Synthesis and Closing Remarks
3:30 PM	Adjourn