

From Discovery to Clinical Impact: Translational Science Forum

[After TCR-SIG Vision Event](#), this forum brings together communities across the translational research spectrum to showcase how scientific discoveries are transformed into meaningful clinical outcomes. Spanning the full continuum—from gene discovery and next-generation human models to pre-IND development and first-in-human studies—the program highlights integrated efforts that accelerate innovation and improve patient care.

Sessions will feature advances in genomics, organoid and 3D model systems, and New Approach Methodologies (NAMs), alongside perspectives on regulatory science and clinical development. Speakers from the National Center for Advancing Translational Sciences, the NIH Clinical Center, and the broader scientific community across NIH, FDA, academia, and industry will illustrate how multidisciplinary approaches enable efficient translation from bench to bedside.

By connecting discovery science, enabling technologies, and clinical execution, this forum aims to foster collaboration, inspire innovation, and advance clinical excellence—ultimately delivering greater impact for patients and communities.

Date & Time: May 29, 2026 | 12:30 PM – 5:00 PM

Venue: Lipsett Amphitheater (NIH Clinical Center)

Date & Time: June 1, 2026 | 9:00 AM – 5:00 PM

Venue: Masur Auditorium (NIH Clinical Center)

Registration Link:

<https://forms.cloud.microsoft/g/Ye4DQRBizR>



Day 1 (May 29, 2026)

TCR-SIG Vision Event:

“Leading the Way: Strategic Directions for the TCR-SIG”

Venue: Lipsett Amphitheater (NIH Clinical Center)

Date & Time: May 29, 2026 | 12:30 PM – 2:30 PM

Please join us for a unique session of the Translational and Clinical Research Special Interest Group (TCR-SIG). This event presents a distinct blend of forward-looking strategic vision and a heartfelt tribute to outstanding leadership in translational research. Dr. Carlos Ferreira will open the event by outlining the mission and future trajectory of the TCR-SIG, focusing on advancing clinical excellence through cross-disciplinary collaboration. **Your voice matters.** We actively encourage attendees to help shape the future of the TCR-SIG. We want to know what resources will serve you best—whether that means monthly meetings, annual symposia, expanded resource sharing, or new networking opportunities.

Dr. Ben Solomon will lead a special tribute to Dr. Daniel Kastner, a trailblazer in rare disease research and a true role model for physician-scientists. A featured video presentation will highlight his groundbreaking scientific contributions and enduring legacy. Former trainees and collaborators will share personal perspectives on Dr. Kastner's impactful mentorship and leadership.

The event will wrap up with remarks aimed at promoting continued information exchange and collaboration across the TCR-SIG.

Speakers:

- Carlos Ferreira, MD (NIH/NICHHD)
- Benjamin Solomon, MD (NIH/NHGRI)
- Dan Kastner, MD, PhD (NIH/NHRGI)
- Ivona Aksentijevich, MD (NIH/NHGRI)
- Amanda Ombrello, MD (NIH/NHGRI)

Program:

- TCR-SIG vision by Dr. Ferreira (30 min)
- Remark: Dr. Solomon's introduction of Dr. Dan Kastner (10 min)
- Dr. Kastner video highlight: Cutting the gordian knots of inflammation with the shears of genomics (40 min)
- Post-video remarks with slides by Drs. Aksentijevich and Ombrello (30min)
- Conclusion by Dr. Ferreira (5min)

Break Time: 2:30 PM – 3:00 PM

Forum:

Session 1. “ Organoids and Technologies: Advanced 3D Human Models”

Venue: Lipsett Amphitheater (NIH Clinical Center)

Date & Time: May 29, 2026 | 3:00 PM – 5:00 PM

This session highlights emerging advances in organoid systems, microphysiological platforms, and enabling technologies that are transforming human-relevant disease modeling and translational research.

Speakers will present foundational and next-generation organoid platforms that have advanced in vitro modeling of human tissues and diseases. Special invited speakers from the Microphysiological Systems (MPS) community will showcase innovative technologies, including scalable organoid-based systems and advanced label-free 3D imaging platforms capable of real-time, high-resolution analysis of living cells and complex tissue models.

Industry perspectives will further demonstrate how pharmaceutical pipelines are integrating organoid and 3D human model systems to improve translational predictability, drug discovery, and therapeutic development. In addition, the Standard Organoid Model (SOM) initiative will highlight collaborative and interdisciplinary efforts that bridge academia, technology innovation, and clinical translation.

Together, this session illustrates how organoids, advanced imaging, and human-based model systems are reshaping precision medicine and accelerating the translation of scientific discovery into clinical impact.

Speakers:

- Fnu Ruchi, PhD (NIH/NEI) (15 min)
- Brian Bui, PostBac (NIH/NCI) (5 min)
- Dong Sung Kim, PhD (Celloid) (15 min)
- Sumin Lee, PhD (Tomocube) (15 min)
- Holly Kimko, PhD, FAAPS (Astrazeneca) (15 min)
- Srivatsan (Sri) Kidambi, MS, PhD (NIH/NCI/NIAID) (15 min) – SOM Vision & Mission
- Steven M. Ferguson, CLP (NIH/OD/OTT) (15 min) - How to Collaborate with NIH
- All speakers: Q+A

Network Event: 6:00 PM – 9:00 PM (BabyCat Bethesda, 4850 Del Ray Ave, Bethesda)

Day 2 (June 1, 2026)

Session 2. “Translational Science to First-in-Human”

Venue: Masur Auditorium (NIH Clinical Center)

Date & Time: June 1, 2026 | 9:00 AM – 10:30 AM

This session highlights how collaborative efforts across NIH and FDA are accelerating the translation of scientific discoveries into meaningful clinical and patient outcomes.

A speaker from the National Center for Advancing Translational Sciences (NCATS) will present innovative translational science strategies that bridge preclinical discovery and clinical application, including emerging approaches that support therapeutic development, translational efficiency, and regulatory advancement.

A speaker from the NIH Clinical Center (CC) will discuss pre-IND enabling efforts and the clinical research infrastructure that supports regulatory readiness, multidisciplinary collaboration, and first-in-human studies. Speaker from the NIH Clinical Center (CC) / the Division of Transfusion Medicine (DTM) will highlight collaborative work in developing and translating advanced cellular therapies, including your efforts to improve potency and stability testing through high-throughput technologies and to establish GMP-compliant methods to produce novel cellular and gene therapies. In addition, a speaker from the National Institute of Neurological Disorders and Stroke (NINDS) will highlight mitochondrial dysfunction and stress responses in neurodegeneration that exemplify the successful translation of laboratory discoveries into therapeutic interventions and patient-centered care.

Together, this session presents an integrated translational ecosystem—spanning discovery science, translational innovation, regulatory science, and clinical execution—designed to advance clinical excellence, accelerate bench-to-bedside research, and improve outcomes for patients and communities.

Speakers:

- Elizabeth Ottinger, PhD (NIH/NCATS) (15 min)
- Lisa Goldfeder, RAC, CCRP (NIH/CC) (15 min)
- David Stroncek, MD (NIH/CC) (15 min)
- Derek Narendra, MD, PhD (NIH/NINDS) (15 min)
- Q+A with Jake Juip

Session 3. “Voices of Hope: Jake Juip & EchoBloom Ullim Ensemble”

Venue: Masur Auditorium (NIH Clinical Center)

Date & Time: June 1, 2026 | 10:30 AM – 12:00 PM

This special session will highlight the power of patient advocacy, community connection, and the healing role of voices in translational and clinical research communities.

Participants will have the opportunity to meet Jake Juip, a young advocate living with Friedreich's ataxia, whose journey reflects resilience, hope, and the importance of rare disease awareness and research. Through personal storytelling and community engagement, the session aims to inspire a deeper understanding of patient-centered care and the real-world impact of translational science.

The session will also feature a special healing performance by the EchoBloom Ullim Ensemble, bringing together voices, empathy, and community to foster encouragement and connection among patients, families, researchers, clinicians, and NIH staff.

Together, this session celebrates the human side of clinical excellence—where science, advocacy, and the arts unite to advance healing, compassion, and hope.

Speakers:

- Jake Juip (Young advocate living with Friedreich's ataxia)
- **EchoBloom Ullim Ensemble:** Misook Kim (Soprano), Hyangje Seong (Soprano), Jiyeong Choi (Messo-soprano), Hyunmi Ji (Alto), Byungkun Chae (Tenor), Seunghwan Kim (Baritone), and Hyosoon Oh (Piano)

“Voices of Hope”

Masur Auditorium
June 1
10:30 AM – 12:00 PM

This inspiring program will feature Jake Juip, a young advocate living with Friedreich's ataxia, alongside a special vocal performance by the EchoBloom Ullim Ensemble. Together, the session highlights how voices, compassion, and community can inspire hope and strengthen the human side of translational and clinical research.



Session 4. “From Gene Discovery to Precision Medicine”

Venue: Masur Auditorium (NIH Clinical Center)

Date & Time: June 1, 2026 | 1:00 PM – 2:00 PM

This session explores the evolution of gene discovery technologies and their integration into clinical research and precision medicine initiatives across NIH.

Beginning with foundational advances in gene discovery—including Positional Cloning, Microarray, and Next-Generation Sequencing—the session will highlight how these transformative technologies have advanced the identification of disease-causing genes and molecular pathways. Large-scale national initiatives, including the Undiagnosed Diseases Program (UDP) will further demonstrate how integrative genomics and patient-centered research are advancing diagnosis, disease understanding, and precision medicine. Autoinflammatory diseases are a group of rare immune dysregulatory syndromes that present with unexplained fevers, rashes, joint pain, and inflammation in multiple organs, such as the central nervous system, the eyes, inner ears, bones, fat, blood vessels, lungs and muscles. Precision medicine efforts highlight that the team applies a diagnostic approach that includes careful clinical evaluation, and genetics and immune evaluations to characterize the immune dysregulation with the ultimate goal of finding better treatments for these patients.

Together, this session connects the past, present, and future of genomics—highlighting how multidisciplinary collaboration drives clinical excellence and meaningful patient impact.

Speakers:

- Settara Chandrasekharappa, PhD (NIH/NHGRI) (15 min)
- May Christine Malicdan, MD, PhD (NIH/NHGRI) (15 min) - UDP
- Raphaela Goldbach-Mansky, MD, MHS (NIH/NIAID) (15 min)
- Q+A with Jake Juip

Session 5. “Next-Generation Human Models and FDA Contributions: From Drug Discovery to Clinical Impact”

Venue: Masur Auditorium (NIH Clinical Center)

Date & Time: June 1, 2026 | 2:30 PM – 3:30 PM

This session highlights pioneering advances in biomaterials and functional technologies that are transforming translational research and New Approach Methodologies (NAMs) across NIH and how FDA regulatory pathways contribute to advancing translational science and accelerating clinical impact.

A speaker from the National Center for Advancing Translational Sciences (NCATS) will showcase emerging 3D bioprinting technologies that support scalable, physiologically relevant human tissue models. Industry perspectives will further highlight advanced functional assay platforms integrating engineered tissues with real-time performance analysis for drug discovery and safety evaluation. This will conclude with an overview of NIH-wide NAMs efforts, emphasizing cross-institute strategies to advance human-based model systems and accelerate translational innovation. Speaker will introduce the overview of the process for Drug & Clinical Development. This opportunity will help strengthen connections between the NIH and FDA communities in advancing clinical excellence for patient care.

Objective: Provide an Overview of New Approach Methodologies (NAMs), Drug Development, and Clinical Development

Speakers:

- Marc Ferrer-Alegre, PhD (NIH/NCATS) (15 min)
- Greg Luerman, PhD (curibio) (15 min)
- Christine Happel, PhD (NIH/NCATS) (15 min) - Complement-ARIE
- Sang Mok Chung, PhD (Nature Cell America, former FDA) (15min)

Networking & Booth Exhibition:

Date & Time: May 29, 2026 | 10:00 AM – 4:00 PM

Date & Time: June 1, 2026 | 10:00 AM – 4:00 PM

Venue: FAES Terrace

Networking & Individual Meeting:

Date & Time: May 29, 2026 | 12:00 PM – 4:00 PM

Venue: FAES Class Room # 6 (NIH Clinical Center)

Date & Time: June 1, 2026 | 9:00 AM – 4:00 PM

Venue: FAES Class Room # 2 (NIH Clinical Center)

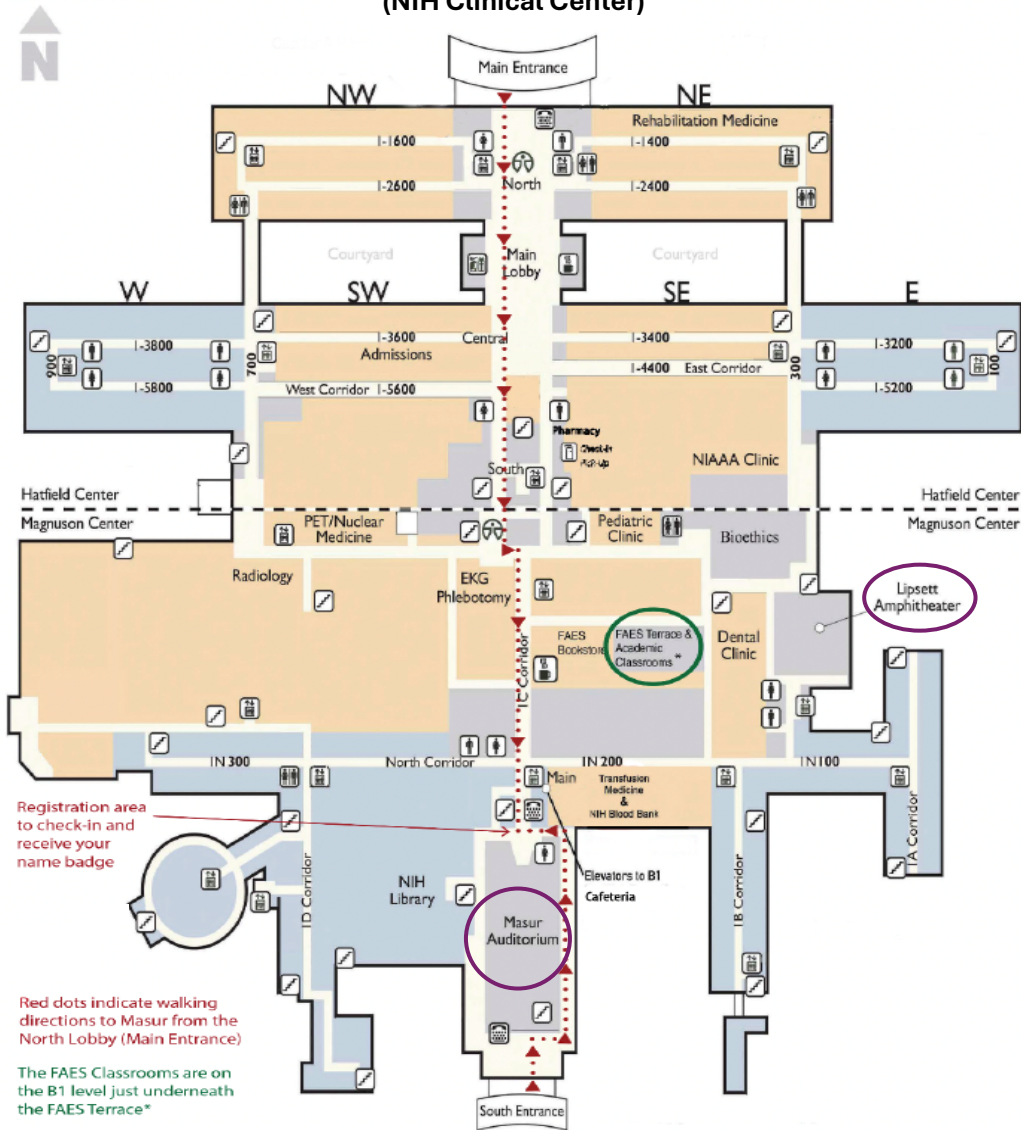
Date & Time: June 1, 2026 | 9:00 AM – 2:00 PM

Venue: FAES Class Room # 6 & 7 (NIH Clinical Center)

❖ **Expand your network, exchange ideas, and broaden your vision of Translational and Clinical Research!**

Map of Building 10

(NIH Clinical Center)



Registration area to check-in and receive your name badge

Red dots indicate walking directions to Masur from the North Lobby (Main Entrance)

The FAES Classrooms are on the B1 level just underneath the FAES Terrace*

-  Restrooms
-  Hospitality
-  Patient Areas
-  Stairs
-  Research/Lab Areas
-  Elevators
-  TTY Phone
-  Coffee Shop
-  Gift Shop



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- Brian Bui, PostBac (NIH/NCI) (5 min)
- Dong Sung Kim, PhD (Celloid) (15 min)
- Sumin Lee, PhD (Tomocube) (15 min)

Title: Label-free Quantitative Imaging of Live Organoids and Complex 3D Models by Holotomography

Abstract: This talk introduces holotomography (HT), a label-free 3D quantitative phase imaging modality that uses refractive index as endogenous biophysical contrast across scales from single cells to 3D tissue models. Recent applications—including organoid drug response, tissue architecture, oocyte and embryo assessment, and immune cell dynamics—demonstrate sub-micron 3D resolution with continuous live imaging over hours to days without labels or phototoxicity. The talk will also examine how HT complements fluorescence imaging and downstream molecular assays for reproducible, longitudinal 3D biology.

- Holly Kimko, PhD, FAAPS (Astrazeneca) (15 min)

Title: Quantitative Systems Toxicology Modeling for Translating Microphysiological Systems Data for Clinical Dosage Decisions

Abstract: This presentation describes how quantitative systems toxicology (QST) can translate microphysiological system (MPS) data, including organs-on-chip and organoids, into predictions that support clinical dosage decisions. It outlines the rationale for combining mechanistic modeling with advanced human-relevant in vitro systems and presents case studies in bone marrow hematotoxicity and gastrointestinal toxicity. The examples show that integrating MPS data with QST can improve clinical toxicity prediction, inform dosing strategies, reduce animal experimentation, and strengthen decision-making in drug development.

- Srivatsan (Sri) Kidambi, MS, PhD (NIH/NCI/NIAID) (15 min)

Title: The NIH Standardized Organoid Modeling (SOM) Initiative: Building a Reference Framework for Reproducible and Fit-for-Purpose Organoid Platforms

Abstract: This presentation will highlight the NIH Standardized Organoid Modeling (SOM) Initiative and its efforts to establish scalable, reproducible, and AI/ML-enabled organoid infrastructure for biomedical research and translational science. The talk will focus on

challenges surrounding standardization, benchmarking, qualification, and regulatory readiness of organoid systems, while outlining how NIH SOM aims to build fit-for-purpose human-relevant platforms that support drug development, disease modeling, and precision medicine. Attendees will gain insight into how coordinated infrastructure, data integration, and cross-sector collaboration can accelerate broader adoption of organoid technologies.

- Steven M. Ferguson, CLP (NIH/OD/OTT) (15 min) - How to Collaborate with NIH

Title: Strategic Partnerships with NIH: New Pathways for Clinical & Translational Development

Abstract: Companies and institutions looking to bring innovative and novel medical products to market should not overlook the NIH as a strategic partner for their discovery, translational and clinical research development programs. NIH has a long history of success in working with companies and other organization to bring new products forward to the clinic and medical practice and has several important programs that companies should be utilizing as part of their overall business strategies. This presentation will outline some of the key programs for these collaborations and cite some important success stories to date for both commercial development and public health.

Session 2. “Translational Science to First-in-Human”

- Elizabeth Ottinger, PhD (NIH/NCATS) (15 min)
- Lisa Goldfeder, RAC, CCRP (NIH/CC) (15 min)

Title: Working With the ORSC Regulatory Support Section: Who We Are and How We Collaborate Across the NIH IRP

Abstract: The Office of Research Support and Compliance (ORSC) holds a mission to ensure the quality and integrity of clinical research across the intramural research program at the NIH. The Regulatory Support Section within ORSC works with the ICs in their sponsorship of FDA regulated research. An overview of this section will be provided, including how the RSS supports both the clinical directors and research teams.

- David Stroncek, MD (NIH/CC) (15 min)
- Derek Narendra, MD, PhD (NIH/NINDS) (15 min)

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Program QR here

Session 4. “From Gene Discovery to Precision Medicine”

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Session 5. “Next-Generation Human Models and FDA Contributions: From Drug Discovery to Clinical Impact”

- Marc Ferrer-Alegre, PhD (NIH/NCATS) (15 min)
- Greg Luerman, PhD (curibio) (15 min)

Title: Accelerating NAMs Adoption through MOA Specification and Functional Correlation

Abstract: The transition away from animal models towards New Approach Methodologies (NAMs) remains hampered by uncertainty around mechanism of action (MOA) alignment between in vitro systems, in vivo models, and clinical outcomes. Critically, NAMs are not a one-size-fits-all solution — meaningful adoption requires defining the specific, well-characterized MOA a given model is designed to interrogate, matched to the appropriate tissue context, biological maturity, and clinical endpoint.

- Christine Happel, PhD (NIH/NCATS) (15 min) - Complement-ARIE
- Sang Mok Chung, PhD (Nature Cell America, former FDA) (15min)