International Cancer Patient Coalition

From Global Declarations to Practical Delivery

May 30-31, 2025

SCHR 1001 (Schreiber Center)
Schreiber Center
16 E. Pearson St.
Chicago, United States

The Imperative

Breakthroughs in precision oncology—**HER2-low classification, ctDNA-guided therapy, and radioligand theranostics**—are transforming cancer care. Yet systemic gaps in diagnostics, reimbursement, and infrastructure persist, leaving patients behind. Urgent challenges include:

- **HER2-low breast cancer:** 30–50% diagnostic variability and 70% reimbursement gaps in LMICs
- **NSCLC resistance:** 14-month delays in next-line therapy access
- **MRD adoption:** 80% uncovered despite 42% trial cost reductions
- **Radioligand therapy:** Fragmented regulatory pathways and nuclear medicine shortages

Our Approach

Over two days, this working meeting will translate commitments into action through:

1. **Cancer-Specific Policy Sessions:**
    - *Day 1:* HER2-low diagnostics, NSCLC resistance solutions, MRD reimbursement, liquid biopsy equity
    - *Day 2:* Universal HER2 standards, radioligand therapy scaling
2. **Regional Roadmaps:** Tailored plans for Latin America (30% genomic testing rates) and MENA (22-month therapy delays)
3. **Policy Frameworks:**
    - **Harmonized Diagnostics:** Lab certification, tumor-agnostic HER2 standards
    - **Equitable Access:** LMIC pricing models, decentralized trial infrastructure
    - **Theranostic Readiness:** Bundled payments, radiopharmacy hubs

Target Audience

This meeting convenes stakeholders critical to driving systemic change:

- **Policymakers & Regulators:** Shape reimbursement frameworks and harmonize standards
- **Oncologists & Pathologists:** Implement testing protocols and clinical guidelines
- **Patient Advocates:** Ensure equity in care delivery and trial design
- **Industry Leaders:** Develop sustainable pricing and infrastructure solutions

- **Researchers:** Translate innovations into real-world practice

Anticipated Impact

- **Standardized Testing:** Reduce HER2 diagnostic variability by 50% through lab certification
- **Faster Access:** Cut NSCLC therapy delays by implementing "pipeline reimbursement" models
- **Expanded MRD Adoption:** Triple testing coverage in LMICs via mobile units and tiered pricing
- **Theranostic Scale-Up:** Establish 3 regional radiopharmacy hubs to address infrastructure gaps

By bridging the gap between innovation and implementation, this convening will deliver actionable policies to ensure precision oncology benefits **all patients—regardless of geography or resources**

Session 1: **Scaling HER2-Low Diagnostics & ADCs Worldwide**

May 30, 2025 | **9:30 AM – 11:00 AM**

The discovery of HER2-low breast cancer (IHC 1+/2+ ISH-) has revolutionized treatment for previously ineligible patients, but geographic and resource disparities threaten equitable access to life-changing ADCs. This session brings together experts to tackle key challenges: standardizing HER2-low diagnostics (reducing 30–50% inter-lab variability), expanding ADC access in LMICs (addressing reimbursement gaps for 70% of underserved regions), and accelerating implementation in areas where delays prove deadly—ensuring this breakthrough reaches all who need it.

Moderator: **Denis Horgan**, *PhD, Secretary General, International Cancer Patient Coalition*

Setting the Scene: **Ana Garrido-Castro,** *Medical Oncologist, Dana-Farber Cancer Institute and Assistant Professor of Medicine at Harvard Medical School.* (Confirmed)

Standardization & Innovation

- **Dr. Frederique Penault-Llorca,** *Jean Perrin Center.* *(Confirmed)*
  Topic: How must regulators adapt to ensure AI-driven diagnostics meet clinical and ethical standards?
- **Arturo Loaiza-Bonilla,** *Systemwide Chief of Hematology and Oncology, SLUHN | Co-Founder, Massive Bio* Confirmed)

Reimbursement & Equity

- **Dr. Emina Torlakovic,** *Professor in Department of Laboratory Medicine and Pathobiology, University of Toronto* (Confirmed)
- **Lorenzo Gerratana, MD,** *Associate Professor of Medicine, Medical Oncology, Scientific Lead, Breast Medical Oncology, Department of Medicine (DMED) - University of Udine* *(Confirmed)*

Infrastructure & Policy

- **Dr. Hesham Elghazaly**, *Professor of Clinical Oncology, Ain Shams University* (Confirmed)
  Topic: How can emerging economies lead in shaping HER2-low guidelines?
- **Dr. Dario Trapani,** *Oncologist, European Institute of Oncology* (Confirmed)
  Topic: What minimum infrastructure benchmarks should national cancer plans adopt?

Discussion

Q&A

Session 2: **Surviving Success: Policy Solutions for Resistance Mutations in Extended NSCLC Survival**

May 30, 2025 | **11:30 AM – 1:00 PM**

As targeted therapies transform NSCLC into a chronic condition, this session addresses the policy bottlenecks in resistance mutation management—from re-testing protocols to global data sharing.

Core Questions:

1. Should serial biomarker testing be mandated at progression—and how?
2. Can "pipeline reimbursement" prevent delays for resistance therapies?
3. What minimum survivorship infrastructure should all health systems provide?

Setting the Scene: **Tony S.K. Mok, MD**, *Professor of Clinical Oncology, Chinese University of Hong Kong (Confirmed)*

Key Challenges & Speaker-Led Solutions

1. Re-Testing Infrastructure & Standards

How to institutionalize biomarker surveillance?

- **Clare Thibodeaux,** *President & CEO, Cures Within Reach.* *(Confirmed)*
  Topic: Repurposing therapies for resistance mutations
- **Nicola Normanno,** *Director, IQN-Path.* *(Confirmed)*
- **Robert Palmer,** *Head of Market Access Oncology, Boehringer Ingelheim International GmbH* *(Confirmed)*
- **Nisha Mohindra**, *MD, Thoracic oncologist, Northwestern University.* *(Confirmed)*

2. Accelerating Access to Next-Line Therapies

Bridging the 14-month approval-delay gap:

- **Benjamin Besse**, *MD, PhD, Head of Clinical Research, Gustave Roussy, France.* *(Confirmed)*
  Topic: Clinical trial designs for resistance-targeted drugs

3. Redesigning Survivorship Systems

From acute care to chronic management:

- **Alessio Cortellini,** *MD, PhD, Assistant Professor, Campus Bio-Medico University of Rome* (Confirmed)
  Topic: Real-world evidence for adaptive guidelines
- **Clarissa Baldotto**, President-Elect of the Brazilian Society of Oncology (SBOC):
- **Melinda Hsu,** *Assistant Professor of Medicine at Case Western Reserve University,*
- **Cristiano Ferrario**, *MD, Assistant Professor, McGill Univ.* (Confirmed)
  Topic: Rural/underserved region adaptations

Moderated Policy Debate

Guided by:

- **Denis Horgan**, *Secretary General, International Cancer Patient Coalition*

Session 3: **The MRD Imperative – Policy Solutions for Detection, Surveillance & Reimbursement**

May 30, 2025 | **2:00 PM – 3:30 PM**

The emergence of ctDNA-based MRD testing is transforming early-stage cancer management, but inconsistent adoption risks creating inequities. This session gathers global experts to address key policy priorities: regulatory harmonization (aligning FDA/EMA/PMDA standards and mutual recognition of clinical validity studies), clinical integration (standardizing surveillance protocols and telemedicine-enabled testing), sustainable reimbursement (implementing outcomes-based contracts and tiered pricing for LMICs), and equitable access (deploying mobile units for rural/LMIC regions) to bridge implementation gaps across solid and hematologic tumors.

Key Policy Priorities

1. What constitutes sufficient evidence for MRD assay approval across regions?
2. How can decentralized testing maintain quality in resource-limited settings?
3. Which reimbursement models best balance innovation and sustainability?
4. What global coordination mechanisms are needed for real-world data sharing?

Setting the Scene: **Vivek Subbiah**, M.*D.,Chief,, Early-Phase Drug Development, Sarah Cannon Research Institute (SCRI) (Confirmed)*

Translational Science Leaders

- **Naureen Starling**, *Consultant Medical Oncologist, The Royal Marsden NHS Foundation Trust, United Kingdom (Confirmed)*
  Topic: *Integrating MRD surveillance into standard GI oncology care: Evidence, protocols, and system readiness*
- **Jeff Allen,** *PhD, President & CEO, Friends of Cancer Research, USA* (Confirmed)
  Topic: Policy innovations for accelerated adoption
- **Carolina Reduzzi,** *Assistant Professor of Cancer Biology Research in Medicine, Weill Cornell Medicine* (Confirmed)

Implementation Pioneers

- **Brittany McKelvey,** *Regulatory lead, LUNGevity Foundation, USA* (Confirmed)
  Topic: Patient advocacy-driven implementation
- **Ghassan Abou-Alfa**, *MD, Medical Oncologist, Memorial Sloan Kettering Cancer Center, USA* (Confirmed)
  Topic: Translational biomarkers for early detection

Equity Advocates

- **Dr. Pratheesh Sathyan**, *PhD, Head, Illumina AMR Oncology Medical Affairs.* *(Confirmed)*
  Topic: ctDNA testing access and MRD reimbursement frameworks for resource-limited settings

- **Andrew Davis,** *MD, Assistant Professor of Medicine | Section of Medical Oncology | Division of Oncology, Washington University (Confirmed)*

Moderator: **Denis Horgan**, *PhD, Secretary General, International Cancer Patient Coalition*

Session 4: **Liquid Biopsy for All – Expanding Access, Equity, and Efficiency in Oncology Trials**

May 30, 2025 | **4:00 PM – 5:30 PM**

Liquid biopsy is revolutionizing clinical trials by eliminating geographic barriers through remote monitoring, increasing underserved enrollment by 40%. Yet major gaps remain - 80% of LMICs lack reimbursement, while infrastructure and inconsistent standards hinder adoption. The path forward? Global regulatory alignment, public-private partnerships, and embedding liquid biopsy in trial designs from the start. The challenge isn't technological—it's ensuring this breakthrough doesn't leave the most vulnerable patients behind.

Key Policy Priorities

1. What financing models can sustain liquid biopsy in global trials?
2. How to harmonize ctDNA validation without compromising rigor?
3. What infrastructure support do decentralized trials require?
4. How to embed liquid biopsy in protocols for scalability?

Setting the Scene: **Don Dizon**, *MD, Brown University, USA. (Confirmed)*
Topic: Patient rights frameworks

Speakers

Trial Innovation Leaders

- **Rafal Dziadziuszk**, *Department of Oncology and Radiotherapy, Medical University of Gdańsk, Gdańsk, Poland. (Confirmed)*
- **Franesco Pepe,** *Department of Public Health, University of Naples Federico II, Naples, Italy (Confirmed)*

Equity & Implementation Experts

- **Dr. Roberto Carmagnani Pestana, MD,** *Medical Oncologist, Hospital Israelita Albert Einstein, São Paulo, Brazil (Confirmed)*
- **Kirk Tanner, PhD,** *Chief Scientific Officer, National Brain Tumor Society, Senior Vice President, Brain Tumor Investment Fund (Confirmed)*
- **Lee-Anne Zinetti,** *Executive Director, Global Oncology Portfolio Precision Medicine Strategy, Novartis (Confirmed)*

Technology & Regulatory Specialists

- **Paul Hofman**, *MD, Professor of Pathology, University Côte d'Azur, France. (Confirmed)*
  Topic: ctDNA assay standardization
- **Arielle J Medford, MD**, *Attending Physician, Mass General Cancer Center, Instructor, Harvard Medical School (Confirmed)*
- **Vanessa Teich,** *Director of Oncology and Hematology Transformation at Hospital Israelita Albert Einstein (Confirmed)*

Moderator: **Denis Horgan**, PhD, *Secretary General, International Cancer Patient Coalition* *(Confirmed)*

Day 2 - May 31, 2025.

Session 5: **Beyond Breast Cancer – Universal HER2 Testing Standards**

May 31, 2025 | **9:00 AM – 10:30 AM**

The rapid expansion of HER2-targeted therapies across multiple cancers has exposed dangerous inconsistencies in testing quality and accessibility. With 20% discordance between local and central labs and breast-centric standards failing gastric/pancreatic cancers, patients face unacceptable diagnostic lottery. This session delivers concrete policy actions:

1. **Standardizing Testing Quality** through national lab certification, mandatory secondary reviews for borderline cases, and value-based reimbursement tied to accuracy metrics
2. **Modernizing Scoring Criteria** with tumor-specific regulatory guidance and provisional standards for rare HER2+ cancers
3. **Protecting Patient Interests** via universal eligibility rules, plain-language result reporting mandates, and real-world disparity tracking

The time for diagnostic equity is now—before more lives are lost to inconsistent implementation of transformative therapies.

Policy Discussion Questions

1. Should HER2 testing reimbursement require lab certification?
2. How to harmonize scoring across tumor types without losing precision?
3. What provisional standards suit rare HER2+ cancers?
4. Which financial levers accelerate digital pathology adoption?

Moderators

- **Denis Horgan**, *PhD, Secretary General, International Cancer Patient Coalition*

Speakers

Testing Standardization Leaders

- **Iwona Ługowska,** *Consultant in Oncology, Maria Sklodowska-Curie National Research Institute and Oncology Centre (MSCI), Poland.* *(Confirmed)*
- **Sunil S. Badve,** *Vice Chair for Pathology Cancer Programs, Emory University School of Medicine* *(Confirmed)*
- **David Swartz,** *Global Oncology Diagnostics Director, AstraZeneca* *(Confirmed)*

- **Eleonora Nicolò, MD**, *Research Fellow in Medicine, Precision Medicine Research Manager, Cristofanilli CTC lab Weill Cornell Medicine*
- **Yizhuo Zhang**, *Professor, Chief of Pediatric Oncology, Sun Yat-sen University Cancer Center (Confirmed)*

Clinical Implementation Experts

- **Molly Li Siu Ching,** *Assistant Professor, Department of Clinical Oncology, The Chinese University of Hong Kong. (Confirmed)*
- **Luis Leonardo Rojas Puentes,** *Head of the GU and Thorax Functional Unit, CTIC-Luis Carlos Sarmiento Angulo Foundation. (Confirmed)*
- **Kjetil Tasken,** *Head of Institute, Institute for Cancer Research, Oslo University Hospital, Norway (Confirmed)*

Equity Advocates

- **Janice Tsang,** *MD, Specialist in Medical Oncology, The University of Hong Kong. (Confirmed)*
  Topic: LMIC access challenges
- **Navid Madani,** *Senior Scientist, Dana-Farber Cancer Institute's Department of Cancer Immunology and Virology. (Confirmed)*

Session 6: **Radioligand Therapy and Diagnostics: Policy Pathways for Scaling Theranostics in Cancer Care**

May 31, 2025 | **11:00 AM – 12:30 AM**

Setting the Scene: Radioligand therapy (RLT) is a targeted treatment that delivers radioactive particles directly to malignant cells or their tumor microenvironment, aiming to limit damage to healthy cells. RLT has the potential to improve survival and quality of life for cancer patients in Europe and worldwide, potentially making it an essential pillar of cancer care. However, RLT and the concept of theranostic approach remains poorly recognized in cancer policy frameworks due to the lack of legislative support for radiopharmaceuticals.

Research & Innovation: Theranostic concept and innovative approach of RLI/RLT concept in patient care. Discovering new molecules to expand radiopharmaceutical uses is crucial. Bridging the gap between academic research and clinical practice will help develop a framework tailored to radiopharmaceuticals' innovative nature

- **Ken Herrmann,** *Professor of Nuclear Medicine, Universitätsklinikum Essen, Germany (Confirmed)*

Awareness & Understanding:: Oncologists, clinicians, politicians, and decision-makers need to understand radioligand therapy's potential. Oncologist awareness and multidisciplinary collaboration (including referral) is key to allow this innovative RLT therapies to reach patients in the future

- **Fabrice André,** *President, European Society for Medical Oncology (ESMO) & Head of Research Division, Institut Gustave Roussy, France*

Infrastructure & Readiness: Hospitals need specialized facilities, proper waste management, technical equipment, and trained professionals to administer RLT safely. Investment in infrastructure is essential for equitable treatment delivery and meeting growing demand.

- **Desiree Deandreis,** *Chief, Nuclear Medicine Division, Institut Gustave Roussy, France (Confirmed)*
- **Nicholas Sherman,** *Deputy Head of Division for Nuclear Technology Development and Economics OECD Nuclear Energy Agency (NEA*

Harmonization: Radiopharmaceutical regulations vary widely across countries. A clear framework between radioprotection and medicinal product legislation is needed to ensure safe and timely patient access.

Panel discussion

- **Samuel Armato, PhD**: Professor of Radiology, University of Chicago;

- **Pat B. Zanzonico, PhD**: Attending Physicist, Memorial Sloan Kettering Cancer Center;
- **Sarah M. Cheal, PhD**: Research Scientist, UCSF Radiology and Biomedical Imaging;
- **Jonathan W. Engle, PhD**: Associate Professor, University of Wisconsin-Madison
- **Ami S. Patel, MD**: Assistant Professor of Radiology, University of Pennsylvania;
- **David R. Vera, PhD**: Professor of Radiology, UC San Diego;
- **Eric Rohren, MD, PhD**: Chair of Radiology, Baylor College of Medicine;
- **Kathleen H. Gage, MD**: Director of Nuclear Medicine, Cleveland Clinic
- **Todd Peterson, PhD**: Associate Professor of Radiology and Radiological Sciences, Vanderbilt University; focuses on molecular imaging and image-guided therap

Key policy questions and priorities:

- How can we recognize RLT as an essential pillar for cancer treatment?
- How can we ensure patients are tested for potential eligibility of RLT treatment?
- What approach to raise awareness among different stakeholders would be considered as most appropriate?
- What regulatory framework will support legislation to foster innovation in RLT?
- How do we secure more investments in infrastructure and hospital capacity for RLT and imaging?
- Which stakeholders should be involved to harmonize legislation, address radioprotection regulations, and facilitate new treatment models?

CLOSING