MULTI-REGIONAL
CLINICAL TRIALS

THE MRCT CENTER OF
BRIGHAM AND WOMEN'S HOSPITAL
and HARVARD

2025

Year in Review

About the MRCT Center

For more than 16 years, the Multi-Regional Clinical Trials of Brigham and Women's Hospital and Harvard (MRCT Center) has worked to strengthen the **integrity, safety, and rigor of global clinical research.**

We operate as an independent, multidisciplinary convener, bringing together stakeholders from industry, academia, government, non-profits, and patient communities to address complex ethical, scientific, and regulatory challenges. Our work focuses on areas where collaboration is essential and practical guidance can make a measurable difference in real-world research.

"Progress depends on collaboration.

No single institution can solve the ethical and regulatory challenges of global clinical research alone.

- BARBARA BIERER

Our Work This Year

Over the past 12 months, we have continued to foster productive conversations with our expert collaborators across sectors and to develop ethical and actionable tools for the global clinical research community.

This year's work emphasized:

- Translating emerging research challenges into actionable guidance
- Supporting consistent, transparent research oversight across regions
- Advancing tools and frameworks that can be applied in real-world research settings

This year also marked continued growth in our convening and dissemination efforts, extending the reach of MRCT Center resources to research professionals and institutions worldwide.

Resources

8 Guidances, Frameworks, and Toolkits

15 Webinars and Workshops

6 Trainings

11 Forum Meetings

28 Presentations

2 Podcasts

13 Publications

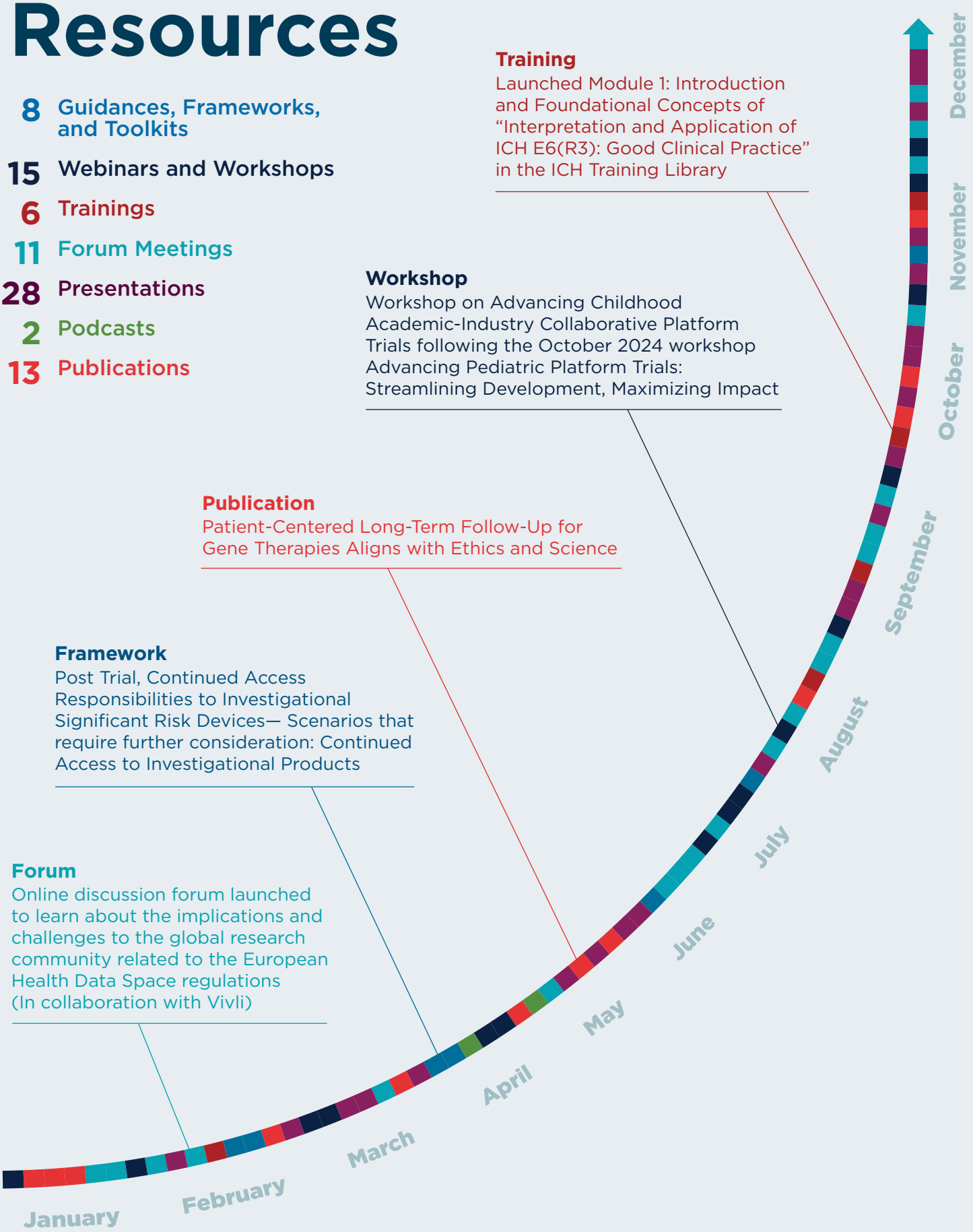
Training
Launched Module 1: Introduction and Foundational Concepts of "Interpretation and Application of ICH E6(R3): Good Clinical Practice" in the ICH Training Library

Workshop
Workshop on Advancing Childhood Academic-Industry Collaborative Platform Trials following the October 2024 workshop Advancing Pediatric Platform Trials: Streamlining Development, Maximizing Impact

Publication
Patient-Centered Long-Term Follow-Up for Gene Therapies Aligns with Ethics and Science

Framework
Post Trial, Continued Access Responsibilities to Investigational Significant Risk Devices— Scenarios that require further consideration: Continued Access to Investigational Products

Forum
Online discussion forum launched to learn about the implications and challenges to the global research community related to the European Health Data Space regulations (In collaboration with Vivli)



8 Toolkits

Delivering actionable guidance for real-world oversight

Supporting the Design, Conduct, and Reporting of Long-Term Follow-Up Studies for Gene Therapies

Released for public comment in November 2025, this toolkit provides practical guidance on best practices for long-term follow-up studies of investigational and approved gene therapies. It supports the generation of critical safety and efficacy data while seeking to minimize burden on participants, caregivers, sponsors, and investigators.

Review of Clinical Research Involving Artificial Intelligence

In collaboration with WCG Clinical

Co-developed by the MRCT Center and WCG through a multi-stakeholder collaboration, the Framework for Review of Clinical Research Involving AI provides IRBs and other oversight bodies with a practical approach to reviewing AI-enabled research. The framework addresses key ethical and regulatory issues, such as bias, adaptive learning, data identifiability, and human oversight.

Post Trial, Continued Access Responsibilities to Investigational Significant Risk Devices

Scenarios that require further consideration: Continued Access to Investigational Products

This framework highlights key milestones, scenarios, and considerations to support equitable, transparent decisions around continued access to investigational significant-risk devices. It complements the existing framework for investigational medicines and aligns with the MRCT Center's Principles of Post-Trial Responsibilities.

15 Webinars

Exploring emerging issues

featuring **13** expert panelists

with **5494** unique registrants

attending from **64** unique countries

HIGHLIGHTS

Innovative Approaches for Gene Therapy Long-Term Follow-Up

This webinar explored innovative long-term follow-up strategies for gene therapy, including registries and platform trials, addressing scientific and logistical challenges in monitoring safety and efficacy over years or decades. Expert panelists shared global and collaborative approaches, highlighting efforts like the World Federation of Hemophilia and CIBMTR registries, and advanced study designs to support long-term outcomes.

On-going Series on AI Digital Twins and Synthetic Data

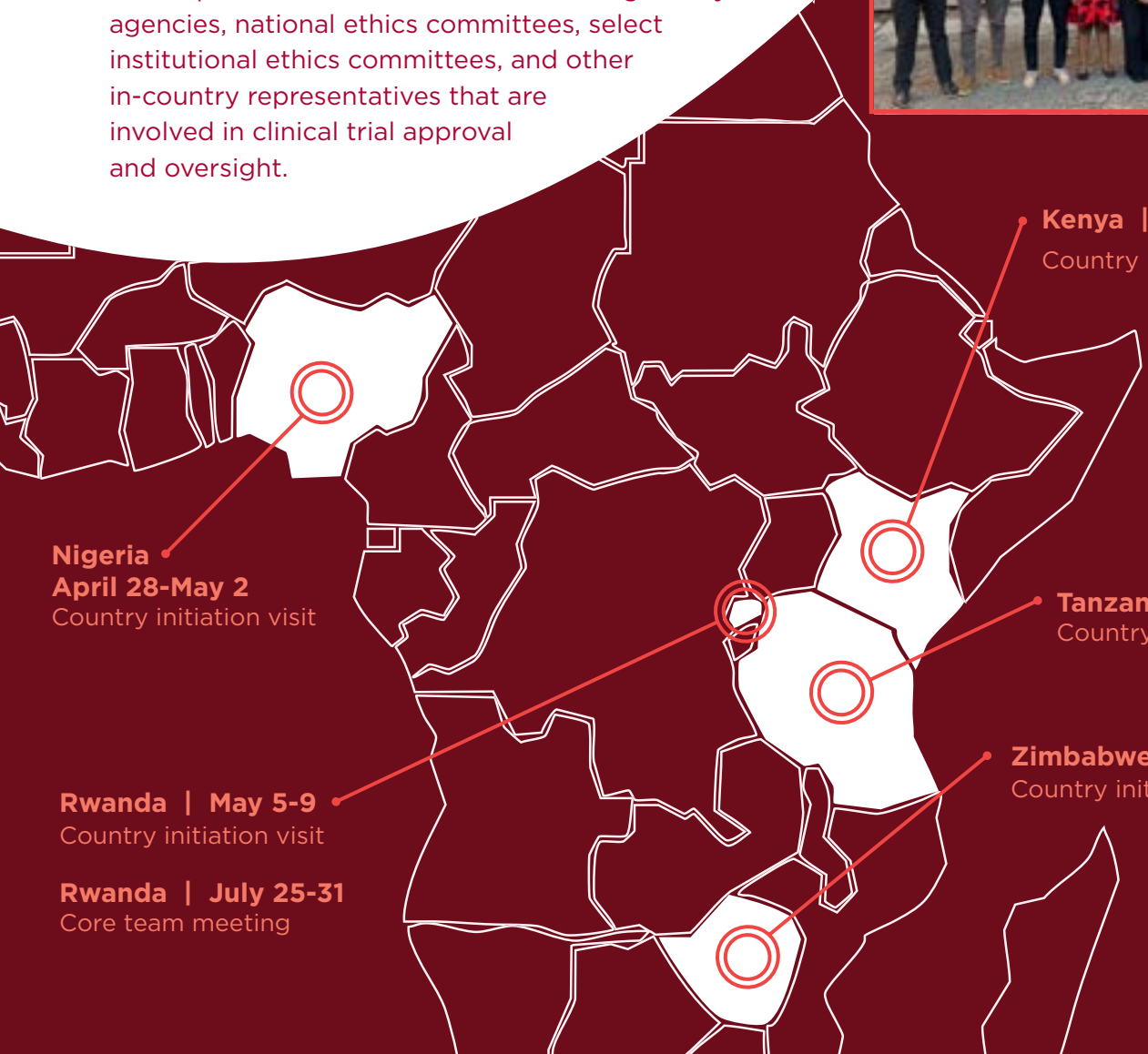
This webinar series highlighted responsible AI in clinical research, covering digital twins and synthetic data, and introduced the MRCT Center and WCG's Review Framework for Protocols Involving AI.

The series provided IRBs with practical, ethics- and regulation-based guidance to assess risks, benefits, and oversight needs for AI-driven research, while addressing implementation and governance issues.

5 On-site Global Capacity Building Meetings

Our Work in Africa

The TRACE (Trial Regulatory and Clinical Ethics Optimization) Project supports the development of competent, efficient, predictable, and transparent ethics and regulatory systems in select countries across Africa. The MRCT Center, in partnership with the African Vaccines Regulatory Forum (AVAREF) and Garnet Partners, leads capacity-building, system assessments, and sustainable regulatory and ethics systems solutions, with work underway in Rwanda, Tanzania, Zimbabwe, Nigeria, and Kenya. The MRCT Center visited each country in 2025 to work directly with representatives from the national regulatory agencies, national ethics committees, select institutional ethics committees, and other in-country representatives that are involved in clinical trial approval and oversight.



Kenya | December 13-19
Country initiation visit

Nigeria
April 28-May 2
Country initiation visit

Tanzania | June 23-25
Country initiation visit

Zimbabwe | June 16-19
Country initiation visit

Rwanda | May 5-9
Country initiation visit

Rwanda | July 25-31
Core team meeting

11 Forum Meetings

Fostering collaborative problem-solving among global leaders

Three forums convened senior leaders across industry, academia, government, and ethics committees to address complex, pre-competitive challenges in clinical research and development. These closed-door discussions created space for candid exchange, collaborative problem-solving, and forward-looking dialogue on high-impact issues shaping research practice and oversight.

MULTI-REGIONAL CLINICAL TRIALS
BIOETHICS COLLABORATIVE

The Bioethics Collaborative met **four times** in 2025 to examine evolving ethical questions in multinational clinical trials. This year, discussions focused on topics such as risk in control arms, ethical considerations in rare disease research, therapeutic misconception, and how research priorities are set, fostering shared learning and practical insights across diverse perspectives.

GO

Research, Development, & Regulatory Roundtable

The Research, Development, & Regulatory Roundtable convened **three times** in 2025 to explore legal, regulatory, and policy developments affecting drug and device development and human subjects research. Sessions addressed recent FDA guidance, confidentiality and data protection, regulatory oversight trends, and the broader policy environment impacting clinical research.

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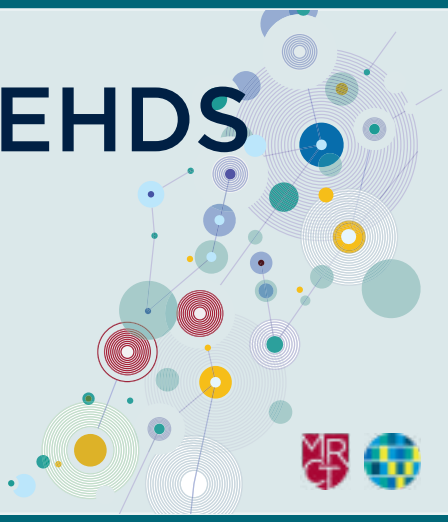
EHDS



The MRCT Center and Vivli co-hosted **six meetings** on the European Health Data Space (EHDS) that convened global stakeholders to track policy and framework developments, foster dialogue on data sharing and governance, and coordinate efforts. The forum supported collaboration toward a harmonized system for the secondary use of health data, aligned with ethical, regulatory, and compliance standards that advance clinical research and healthcare innovation.

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28 Presentations

Across global conferences, summits, and policy forums

HIGHLIGHTS

2nd WHO Global Clinical Trials Forum [4/2–4/3]

Barbara Bierer attended The 2nd WHO Global Clinical Trials Forum: *Action for Impact* in Geneva, Switzerland. Discussions focused on advancing the implementation of World Health Assembly Resolution 8 (WHA75.8) and included a specific review of the Global Action Plan.

SOCRA Annual Conference [9/26–9/28]

Sylvia Baedorf Kassis delivered a plenary session at the Society of Clinical Research Associates (SOCRA) Annual Conference in Chicago, sharing insights on patient-centered consent processes and strategies to enhance clinical trial participation.

First Open Expert Meeting on the Revision of the WMA Declaration of Taipei [12/4–12/6]

Barbara Bierer attended the inaugural in-person meeting focused on revising the Declaration of Taipei. Discussions addressed evolving ethical challenges related to health data, biospecimens, and Artificial Intelligence. She will continue to engage in this work as the effort unfolds.

The

MRCT CENTER PODCAST

April 2024

Advancing Pediatric Platform Trials: A Conversation with Dr. Danny Benjamin

May 2025

Clinical Trials in Latin America—Aligning Global Research with Local Realities

18 Journal Articles

Contributing to Peer-Reviewed Scholarship

In addition to developing applied guidance and convening global stakeholders, the MRCT Center contributes to peer-reviewed scholarship that shapes clinical research ethics, policy, and practice. These publications extend our collaborative work into the academic literature, informing ongoing dialogue and future research worldwide.

WHERE OUR WORK SHOWS UP