Workshop on Clinical Research in Precision Medicine, Rare Diseases, and Pharmacogenomics

Date: Monday 8 December - Thursday 11 December
Location: Alwaha Ballroom, Alwadi Hotel Doha – MGallery Collection, Qatar

About the Organizing Institutions

Principles and Practice of Clinical Research (PPCR) - Harvard T.H. Chan School of Public Health
PPCR is a globally recognized program that provides a comprehensive, interactive, and structured approach to clinical research training. Designed and led by Harvard faculty, PPCR covers the foundational principles of clinical trial design, biostatistics, data analysis, and ethical considerations, with a strong emphasis on evidence-based decision-making in research. Over the years, PPCR has built an extensive network of international researchers, fostering collaboration and advancing clinical research across diverse disciplines.

Qatar Precision Health Institute (QPHI)
QPHI is a leading national research institute dedicated to advancing genomic research, precision medicine, and translational healthcare innovations. QPHI aims to support Qatar in delivering precision health by translating research findings from laboratories into clinical applications "benchside to bedside" to benefit patients directly. This includes identifying key clinical focus areas that address Qatar's specific needs, scaling precision medicine for clinical practice, and establishing policies to guide the field of precision medicine and regulatory affairs.

Qatar University (QU)
QU stands as the nation's leading institution of higher education and a symbol of academic and research excellence in the region. The Qatar University Health Cluster is a national provider of health and medicine education, offering high-quality interdisciplinary programs that equip graduates with the skills to shape the future of healthcare in Qatar. Through collaborative efforts in teaching, research, and community engagement, the health cluster enhances knowledge, tackles local and regional healthcare challenges, and contributes to the nation's health outcomes.

About the Workshop

Qatar Precision Health Institute (QPHI) is partnering with the Principles and Practice of Clinical Research (PPCR) Program (a program from the ECE Department, Harvard T.H. Chan School of Public Health) and Qatar University through its Tanawwo' program to organize a 4-day workshop on Clinical Research in Precision Medicine, Rare Diseases, and Pharmacogenomics. This workshop delivers a unique, multidisciplinary training experience at the intersection of genomics, clinical research, and innovation.

Participants will gain in-depth knowledge of clinical research methodologies and their application to precision medicine, rare diseases, and pharmacogenomics. The program integrates classical trial design with emerging innovations in AI, big data, and multi-omics, offering both theoretical foundations and practical, hands-on exercises. Through lectures, panel discussions, and facilitated workshops, attendees will explore key themes including research ethics, regulatory frameworks, adaptive trial designs, patient registries, pharmacogenomics applications, and AI-driven approaches to clinical trials. In addition, participants who are interested will be invited to apply to the 2026 PPCR program offered by Harvard TH Chan School of Public Health to continue their training in clinical Research.
Designed for clinicians, researchers, policymakers, and early-career scientists, the workshop equips participants with practical skills, fosters collaboration, and contributes to Qatar's growing precision health ecosystem—while offering the opportunity to learn directly from world-renowned experts at Harvard, QPHI, and QU

Key Themes Covered:

- Core concepts of clinical research design, methodology, and causal inference
- Research ethics, informed consent in genomics, and WHO-aligned governance frameworks
- Innovative trial designs for precision medicine, including adaptive, basket, and pragmatic trials
- Rare disease research, from patient registries to compassionate use and surgical trials
- Pharmacogenomics: integrating gene-drug interactions into study protocols
- Leveraging AI, real-world data, and multi-omics for trial optimization and patient stratification
- Practical sessions on protocol writing, IRB submission, and AI/bias audit readiness

Who Should Attend?

This workshop is designed for:

- Clinicians and healthcare professionals involved in research and patient care
- Clinical researchers and trial coordinators
- Geneticists, molecular biologists, and bioinformaticians
- Pharmacologists and pharmacogenomics specialists
- Public health professionals and policymakers
- Graduate students and early-career researchers interested in precision medicine

Key Benefits of Attending:

- Learn from Harvard, WHO experts, and Qatar faculty and experts in clinical research and regulation
- Gain practical, hands-on experience through facilitated workshops on protocol design, consent material development, and omics-driven trials
- Understand cutting-edge innovations in trial methodology, ethics, and precision medicine applications
- Participate in interactive panels and real-world case discussions involving both HIC and LMIC contexts
- Build meaningful connections with academic, regulatory, and clinical experts from Qatar and beyond

Learning Outcomes:

By the end of this workshop, participants will:

- Build a strong foundation in clinical research methodologies and trial design
- Understand global best practices in ethics and governance, including WHO frameworks

- Acquire the ability to design and evaluate studies in precision medicine, rare diseases, and pharmacogenomics
- Gain insights into AI, big data, and omics-driven approaches for clinical research
- Be able to translate concepts into practice through structured, facilitated exercises

Workshop Short Agenda

Day 1 – Foundations of Clinical Research

Time	Session Title	Speaker/Facilitator
08:30-09:00	Opening & Welcome	Workshop Chairs & Organizers
09:00-09:45	Clinical Research Foundations: Navigating the Journey into Scientific Inquiry	Gabriela Rosa
09:45-10:30	Study Designs & Methodological Rigor – Building the Foundations of Causal Inference	Chris Polanco
10:30-10:45	**Coffee Break**	
10:45-11:30	Critical Appraisal: Internal & External Validity, Bias, and Power Understanding How to Identify and Plan Studies	Jorge Marquez
11:30-12:15	GCP & ICH E6(R3): What Practitioners Must Know	Gabriela Rosa
12:15-13:15	**Lunch**	
13:15-14:30	From Research Question to Protocol	Facilitated Workshop Session Gabriela Rosa
14:30-15:15	Panel: Real-World Barriers in Trials (LMIC/HIC Perspectives)	Panel Discussion Wadha Al Muftah
15:15-15:30	**Coffee Break**	
15:30-16:00	Synthesis & Q&A	All Faculty

Day 2 – Ethics & Global Standards

Time	Session Title	Speaker/Facilitator
08:30-09:00	Ethical Dilemmas in Research – From the Trolley Problem to Clinical Trials	Felipe Fregni
09:00-09:30	Research Ethics in Practice – Validity, Oversight, and Responsibility	Jorge Marquez
09:30-10:30	WHO Keynote: Latest Global Best Practices for Clinical Trials	Stephanie Villar
10:30-10:45	**Coffee Break**	
10:45-11:30	Regulatory & Local Governance	Amany Salama Dahir
11:30-12:15	Panel: Aligning WHO Guidance with Local Context	Panel Discussion Dima Darwish
12:15-13:15	**Lunch**	
13:15-14:00	Ethical Dilemmas in Practice	Facilitated Workshop Session Jorge Marquez
14:00-14:45	Informed Consent in Genomics & Precision Medicine	Aisha Naeem
14:45-15:00	**Coffee Break**	
15:00-16:00	Designing Consent Materials & Preparing IRB Submissions	Facilitated Workshop Session Aisha Naeem

Day 3 – Precision Medicine, Rare Diseases & Pharmacogenomics

Time	Session Title	Speaker/Facilitator
08:30-09:00	Innovative Trial Designs for Precision Medicine – Mechanistic & Adaptive Approaches	Felipe Fregni
09:00-09:30	Innovative Trial Designs for Precision Medicine – Real-World Evidence (RWE) & Pragmatic Approaches	Chris Polanco
09:30-10:30	From Registries to Compassionate Use: Research Approaches in Rare Diseases and Surgical Settings	Valeria Bustos
10:30-10:45	**Coffee Break**	
10:45-11:30	Pharmacogenomics in Trials: Design & Implementation	Hazem Elewa
11:30-12:15	Designing a PGx-Informed Trial	Facilitated Workshop Session Rania Abdellatif
12:15-13:15	**Lunch**	
13:15-14:15	Basket/Adaptive Framework for Rare Diseases	Facilitated Workshop Session Chris Polanco
14:15-15:00	Translational Genomics: From Evidence Synthesis to Return of Results (Case Study Approach)	Amal Elfatih
15:00-15:15	**Coffee Break**	
15:15-16:00	Genomics & Multi-Omics: From Discovery to Stratified Trials	Akl Fahed (Online)

Day 4 – AI, Big Data & Multi-Omics in Clinical Research

Time	Session Title	Speaker/Facilitator
08:30-09:15	AI & Machine Learning in Trial Design & Analysis – From Fundamentals to Clinical Application	Jorge Marquez
09:15-10:00	RWD, Biobanks & Digital Health: From Cohort to Trial	Radja Messai Badji
10:00-10:15	**Coffee Break**	
10:15-11:00	How Ready Is Your Trial for AI? Bias and Data Quality Audit	Facilitated Workshop Session Jorge Marquez
11:00-12:00	Career Session	Felipe Fregni
12:00-13:15	**Lunch**	
13:15-13:30	Guest Presentation Senior Author, Nature paper “Refining the impact of genetic evidence on clinical success”	Matthew R. Nelson (Online)
13:30-14:15	Opportunities & Risks of AI & Omics-Driven Trials	Panel Discussion Radja Messai Badji
14:15-15:00	**Networking Coffee Break**	
15:00-16:30	Closing, Certificates & Next-Steps Roadmap	Workshop Chair & Leads

Workshop Detailed Agenda

Day 1 – Foundations of Clinical Research

Time	Session Title	Speaker/Facilitator
08:30-09:00	Opening & Welcome	Workshop Chairs & Organizers
09:00-09:45	**Clinical Research Foundations: Navigating the Journey into Scientific Inquiry** Learning Objectives: 1. Differentiate applied practice from research by reflecting the shift from addressing individual cases to generating knowledge that benefits wider populations. 2. Describe the main phases of clinical trials (I–IV) and their purposes, with illustrative examples from each phase. 3. Identify key study designs used in early- and late-phase clinical research – including observational and experimental approaches. 4. Recognize how health professionals contribute to research and leverage their expertise to advance innovation and improve health outcomes.	Gabriela Rosa
09:45-10:30	**Study Designs & Methodological Rigor: Building the Foundations of Causal Inference** Learning Objectives: 1. Describe the main types of study designs in clinical research (randomized controlled trials, cohort studies, case–control studies, cross-sectional studies) and their key features. 2. Differentiate between descriptive and analytical study designs and recognize when each is most appropriate in clinical research. 3. Explain the concept of causal inference and how different study designs contribute to, or limit, our ability to draw causal conclusions. 4. Apply principles of study design and causal reasoning to critically interpret evidence and guide clinical decision-making.	Chris Polanco
10:30-10:45	**Coffee Break**	
10:45-11:30	**Critical Appraisal: Internal & External Validity, Bias, and Power Understanding How to Identify and Plan Studies** Learning Objectives: 1. Differentiate internal vs. external validity and explain why both are essential when evaluating or designing clinical studies. 2. Identify common sources of bias (selection bias, measurement bias, confounding, publication bias) and discuss strategies to minimize their impact in research. 3. Explain the concept of statistical power and sample size and recognize their importance in planning robust clinical studies.	Jorge Marquez

	4. Apply critical appraisal skills to real examples, assessing whether study results are credible, generalizable, and clinically meaningful. 5. Integrate clinical insight into study design and appraisal, recognizing how clinicians can contribute to improving methodological rigor in research.	
11:30-12:15	**GCP & ICH E6(R3): What Practitioners Must Know** Learning Objectives: 1. Define Good Clinical Practice (GCP) and describe its role in ensuring ethical and scientifically robust clinical research. 2. Summarize the purpose and scope of ICH E6(R3), including its recent updates and how they impact clinical research. 3. Identify the responsibilities of investigators, sponsors, and ethics committees under GCP and ICH guidelines. 4. Apply key principles of GCP in practice**,** focusing on informed consent, data integrity, participant safety, and documentation. 5. Recognize common challenges in GCP compliance and discuss practical strategies for clinicians to maintain high methodological and ethical standards.	Gabriela Rosa
12:15-13:15	**Lunch**	
13:15-14:30	**From Research Question to Protocol** Learning Objectives: 1. Translate a clinical idea into a structured research question using frameworks like PICOT. 2. Define objectives, endpoints, and key elements of study protocol development. 3. Apply critical thinking to align study designs with research questions and population. 4. Draft an outline of a research protocol in small groups with facilitator guidance.	Facilitated Workshop Session Gabriela Rosa
14:30-15:15	**Panel: Real-World Barriers in Clinical Trials** Learning Objectives: 1. Barriers to clinical research implementation. 2. Identify system-level, regulatory, and operational constraints. 3. Reflect on strategies for improving research equity, funding, and sustainability.	**Panel:** Reem Al-Sulaiman Tawfeg Ben-Omran Emmanouil Dermitzakis **Moderator:** Wadha Al Muftah
15:15-15:30	**Coffee Break**	
15:30-16:00	**Synthesis & Q&A** Learning Objectives: 1. Recap and consolidate core concepts from Day 1. 2. Engage in reflective discussion to clarify key takeaways. 3. Share participant insights and align on next steps for upcoming sessions.	All Faculty

Day 2 – Ethics & Global Standards

Time	Session Details	Speaker/Facilitator
08:30-09:30	**Part 1 (30 min): Ethical Dilemmas in Research – From the Trolley Problem to Clinical Trials** Learning Objectives: 1. Differentiate utilitarian and deontological ethical frameworks and apply them to clinical research dilemmas. 2. Explain the concept of equipoise and why it is essential for ethically justifying randomization in trials. 3. Discuss ethical considerations when patients improve during clinical trials, including continuation, crossover, and early trial stopping. 4. Reflect on how ethical reasoning guides decisions in balancing participant welfare with scientific integrity. **Part 2 (30 min): Research Ethics in Practice – Validity, Oversight, and Responsibility** Learning Objectives: 1. Summarize the foundational documents and principles of research ethics (Nuremberg Code, Belmont Report, Declaration of Helsinki). 2. Explain why methodological rigor and validity are ethical imperatives, ensuring that participant risks are justified by meaningful knowledge. 3. Identify the roles of oversight bodies (IRBs/ethics committees, DSMBs) and key processes (informed consent, monitoring, reporting). 4. Apply ethical principles to practical challenges such as vulnerable populations, bias, and conflicts of interest. 5. Integrate ethical principles into daily research practice to safeguard participants and ensure trustworthy results.	Part 1 – Felipe Fregni Part 2 – Jorge Marquez
09:30-10:30	**WHO Keynote: Latest Global Best Practices for Clinical Trials** Learning Objectives: 1. Understand recent WHO guidance on clinical trial design and governance. 2. Recognize global trends in transparency, trial registration, and equitable access. 3. Discuss how international best practices can inform local regulatory reforms.	Stephanie Villar
10:30-10:45	**Coffee Break**	
10:45-11:30	**Regulatory & Local Governance** Learning Objectives: 1. Understand the regulatory landscape governing clinical trials in Qatar. 2. Identify the roles and responsibilities of local regulatory bodies. 3. Compare local practices to international standards and explore alignment opportunities.	Amany Salama Dahir

11:30-12:15	**Panel: Aligning WHO Guidance with Local Context** Learning Objectives: 1. Analyze compatibility and gaps between WHO trial guidance and Qatar's ecosystem. 2. Explore mechanisms to localize international frameworks. 3. Foster dialogue among regulators, researchers, and ethics committee representatives.	**Panel:** Amany Salama Dahir Mohammed Ghaly Stephanie Villar **Moderator:** Dima Darwish
12:15-13:15	**Lunch**	
13:15-14:00	**Ethical Dilemmas in Practice** Learning Objectives: 1. Apply ethical frameworks to complex case scenarios. 2. Navigate real-world tensions in consent, risk-benefit tradeoffs, and oversight. 3. Practice group-based ethical reasoning in a structured discussion format.	Facilitated Workshop Session Jorge Marquez
14:00-14:45	**Informed Consent in Genomics & Precision Medicine** Learning Objectives: 1. Identify the unique challenges and essential elements of informed consent in genomic and precision medicine research. 2. Compare traditional consent approaches with broad and dynamic consent models used in biobanking and omics studies. 3. Apply best practices to design culturally sensitive and ethically robust consent materials for precision health research.	Aisha Naeem
14:45-15:00	**Coffee Break**	
15:00-15:45	**Designing Consent Materials & Preparing IRB Submissions** *IRB: Institutional Review Board Learning Objectives: 4. Understand core components of IRB-approved informed consent forms. 5. Tailor language and visuals for different participant populations. 6. Simulate IRB submission steps and anticipate reviewer concerns.	Facilitated Workshop Session Aisha Naeem
15:45-16:00	**Synthesis & Q&A** Learning Objectives: 4. Recap and consolidate core concepts from Day 2. 5. Engage in reflective discussion to clarify key takeaways. 6. Share participant insights and align on next steps for upcoming sessions.	All Faculty

Day 3 – Precision Medicine, Rare Diseases & Pharmacogenomics

Time	Session Details	Speaker/Facilitator
08:30-09:30	**Part 1 (30 min): Innovative Trial Designs for Precision Medicine – Mechanistic & Adaptive Approaches** Learning Objectives: 1. Explain the concept of precision medicine and why traditional randomized controlled trials (RCTs) often fall short. 2. Describe the role of mechanistic trials in linking interventions to biological pathways and identifying subgroups most likely to respond. 3. Recognize adaptive trial designs and how they address heterogeneity in precision medicine. **Part 2 (30 min): Innovative Trial Designs for Precision Medicine – Real-World Evidence (RWE) & Pragmatic Approaches** Learning Objectives: 1. Define real-world evidence (RWE) and distinguish it from traditional clinical trial data. 2. Explain the value of registries, electronic health records, and pragmatic trials in capturing evidence for precision medicine. 3. Discuss the integration of RWE with trial data to strengthen external validity and support regulatory and clinical decision-making. 4. Evaluate ethical and methodological considerations when using RWE in rare or heterogeneous patient populations.	Part 1 – Felipe Fregni Part 2 – Chris Polanco
09:30-10:30	**From Registries to Compassionate Use: Research Approaches in Rare Diseases and Surgical Settings** Learning Objectives 1. Describe the unique challenges of conducting research in rare diseases and surgical interventions, including small patient populations, heterogeneity, and ethical considerations. 2. Explain the role of patient registries in generating real-world evidence, monitoring safety, and informing trial design in rare and surgical populations. 3. Identify alternative research approaches (e.g., adaptive designs, N-of-1 trials, pragmatic trials) that address limitations of traditional randomized controlled trials in rare or complex clinical scenarios. 4. Discuss the ethical and regulatory framework of compassionate use and expanded access programs, and how they can provide treatment opportunities while generating valuable data. 5. Apply principles of methodological rigor and clinician insight to design and appraise research in rare disease and surgical settings.	Valeria Bustos
10:30-10:45	**Coffee Break**	
10:45-11:30	**Pharmacogenomics in Trials: Design & Implementation** Learning Objectives: 1. Identify core PGx concepts relevant to clinical trial design.	Hazem Elewa

	2. Integrate gene-drug interaction knowledge into eligibility, stratification, and outcome measurement. 3. Discuss challenges in implementing PGx trials, including ethics and analytical validity.	
11:30-12:15	**Designing a PGx-Informed Trial** *PGx: Pharmacogenomics Learning Objectives: 1. Apply PGx principles to a real-world study concept. 2. Draft a PGx-informed trial design (e.g., arms, endpoints, stratification). 3. Collaborate in groups to refine hypotheses and design elements.	Facilitated Workshop Session Rania Abdellatif
12:15-13:15	**Lunch**	
13:15-14:15	**Basket/Adaptive Framework for Rare Diseases** Learning Objectives: 1. Define basket and adaptive trials and their relevance to rare disease research. 2. Design a trial structure that accommodates small, heterogeneous populations. 3. Critically evaluate the statistical and regulatory implications of such designs.	Facilitated Workshop Session Chris Polanco
14:15-15:00	**Translational Genomics: From Evidence Synthesis to Return of Results (Case Study Approach)** Learning Objectives 1. Describe the key stages of the translational genomics pathway from discovery to clinical return of results. 2. Critically assess each step of the pipeline using a structured framework to identify strengths, limitations, and mitigation strategies. 3. Identify practical, community-engaged approaches to support ethical and equitable genomic implementation.	Amal Elfatih
15:00-15:15	**Coffee Break**	
15:15-16:00	**Genomics & Multi-Omics: From Discovery to Stratified Trials** Learning Objectives 1. Understand how multi-omics data inform patient stratification and endpoint selection. 2. Interpret omics-driven insights into actionable trial hypotheses. 3. Discuss infrastructure needs for generating and using multi-omics in clinical trials.	Akl Fahed (Online)

Day 4 – AI, Big Data & Multi-Omics in Clinical Research

Time	Session Details	Speaker/Facilitator
08:30-09:15	**AI & Machine Learning in Trial Design & Analysis – From Fundamentals to Clinical Application** Learning Objectives: 1. Explain the core principles of Artificial Intelligence (AI) and Machine Learning (ML) in accessible terms, including how algorithms learn from data and the distinction between supervised, unsupervised, and reinforcement learning. 2. Recognize the types of data used in AI/ML for clinical research, including structured (e.g., lab values, EHR data) and unstructured (e.g., imaging, text, genomics) sources. 3. Understand how AI/ML can be applied in clinical trial design and analysis, with examples such as patient recruitment, risk prediction, adaptive trial designs, and analysis of complex datasets. 4. Discuss issues of methodological rigor in AI/ML, including overfitting, bias, transparency, and reproducibility. 5. Reflect on the ethical considerations of using AI/ML in clinical research, including privacy, fairness, accountability, and the role of clinicians in ensuring responsible use.	Jorge Marquez
09:15-10:00	**RWD, Biobanks & Digital Health: From Cohort to Trial** *RWD: Real World Data Learning Objectives: 1. Describe how real-world data and digital health tools enhance trial readiness. 2. Explore the role of national biobanks in prospective and retrospective studies. 3. Identify data governance, privacy, and interoperability challenges.	Radja Messai Badji
10:00-10:15	**Coffee Break**	
10:15-11:00	**How Ready Is Your Trial for AI? Bias and Data Quality Audit** Learning Objectives: 1. Audit a hypothetical trial for AI/data readiness. 2. Identify risks of bias, model overfitting, and data leakage. 3. Apply practical tools for improving fairness, accountability, and transparency.	Facilitated Workshop Session Jorge Marquez
11:00-12:00	**Career Session** Learning Objectives: 1. Understand diverse career pathways in clinical research, translational medicine, and precision health, both in academia and industry. 2. Identify the key competencies and mindset required for successful careers in clinical and translational research. 3. Gain insights into mentorship, networking, and global collaboration as tools to advance professional growth. 4. Recognize strategies for career planning and lifelong learning in a rapidly evolving biomedical landscape.	Felipe Fregni

	5. Explore opportunities for international training and certification, including how programs like PPCR can support career development.	
12:00-13:15	**Lunch**	
13:15-13:30	**Guest Presentation: Nature paper "Refining the impact of genetic evidence on clinical success"** Learning Objectives: 1. Summarize key findings from the featured Nature paper on the predictive value of genetic evidence in drug development. 2. Understand how genetic support influences the probability of clinical trial success across therapeutic areas. 3. Reflect on the implications of integrating genetic evidence earlier in the drug discovery and development pipeline.	Matthew R. Nelson (Online)
13:30-14:15	**Opportunities & Risks of AI & Omics-Driven Trials** Learning Objectives: 1. Debate the promises and pitfalls of AI/omics integration in research. 2. Discuss bias, reproducibility, and regulatory hurdles. 3. Explore cross-disciplinary collaboration to address risk mitigation.	**Panel:** Moza Al-Kuwari Matthew Nelson (Online) Barry Solaiman **Moderator:** Radja Messai Badji
14:15-15:00	**Networking Coffee Break**	
15:00-16:30	**Closing, Certificates & Next-Steps Roadmap** Learning Objectives: 1. Reflect on workshop achievements and personal learning outcomes. 2. Define the next steps for implementing knowledge in home institutions. 3. Explore collaborative and training opportunities for continued engagement.	Workshop Chairs

Workshop Speakers, Panelists, Facilitators, and Moderators

Name	Role / Affiliation	Contact Details
Workshop Chairs		
Pr. Felipe Fregni	Professor of Physical Medicine & Rehabilitation Harvard Medical School Professor of Epidemiology Harvard T.H. Chan School of Public Health Director, Spaulding Neuromodulation Center, Department of Physical Medicine & Rehabilitation, Spaulding Rehabilitation Hospital and Massachusetts General Hospital Director, Clinical Research Collaborative Learning Training Program - Principles and Practice of Clinical Research (PPCR), ECPE Harvard T.H. Chan School of Public Health	felipe.fregni@ppcr.org
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Workshop Speakers		
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Workshop Panelists		
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