ASCPT American Society for Clinical Pharmacology & Therapeutics

# THE FUTURE OF CLINICAL TRANSLATIONAL PHARMACOLOGY

Summit Hosted by ASCPT
Washington DC May 27/28, 2025

## Executive Summary and Outcomes

Authored by:

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# The Future of Clinical Translational Pharmacology

**Summit hosted by ASCPT**

**May 27-28, 2025**

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# Executive Summary

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# Introduction

The ASCPT Summit on the Future of Clinical Translational Pharmacology convened a diverse, cross-sector cohort of leaders to chart a bold vision for the future of clinical translational pharmacology (CTP). In a rapidly evolving landscape marked by funding volatility, public skepticism, and scientific acceleration, participants were called to assess where the field is headed and how we can lead strategically into the next decade.

The term 'clinical translational pharmacology' is deliberately used here as a broader, more dynamic term than 'clinical pharmacology', reflecting the evolving scope of the multidisciplinary field in the modern scientific, medical, and technological landscapes. In addition, the word 'translational' underscores the bidirectional bridge between scientific discoveries and application in clinical practice across the drug discovery, development, regulation and utilization (DDRU) continuum.

Prior to the Summit, attendees were provided a framing document co-authored by the task force, which is provided here.

Summit objectives included:

- **Establish a Shared Vision for the Future of Clinical Translational Pharmacology:** Define a forward-looking vision and guiding principles that articulate the evolving role and impact of the discipline across discovery, development, regulation, and utilization (DDRU).
- **Identify Strategic Priorities and Opportunities:** Pinpoint the most critical scientific, technological, and societal priorities needed to advance the field over the next decade, including innovation, equity, global health, and multidisciplinary collaboration.
- **Develop Actionable Recommendations:** Generate strategies and tactics that capture the agreed vision, priorities, and actionable recommendations, that can be used to further develop roadmaps outlining future needs and collaboration across sectors.

Participants articulated their long-term visions for CTP that were inclusive, future-facing, and centered on patient and societal value. The visions that were shared include:

- Clinical pharmacologists develop and wield the tools to optimize drug development.
- Safe, effective, more affordable medications to patients more efficiently.
- Improve the health of all people through rapid translation of safe and effective medicines.
- Decrease time and cost and increase the probability of success of all products for all patients.
- Clinical translational pharmacology will develop innovative approaches and people to optimize drug development and utilization, bringing benefits to all people.

# Core Themes and Insights

While the Summit on the Future of Clinical Translational Pharmacology discussions were organized around structured sessions and breakout themes, several cross-cutting imperatives emerged consistently across all activities. These imperatives reflect the foundational areas in which CTP must invest to realize its 2035 vision.

**Repositioning Clinical Translational Pharmacology as a Leadership Discipline**

The field should consider shifting from its historic identity as a technical or support function to a leadership force in translational medicine. This evolution may require:

- Embedding leadership development into training and professional development.
- Rebranding clinical translational pharmacology to reflect its integrative and strategic value.
- Elevating visibility through public communication, advocacy, and cross-sector representation.

**Modernizing Education and Workforce Development**

Training models must evolve to prepare a nimble, interdisciplinary workforce. Priorities include:

- Defining and disseminating core principles of CTP within and across disciplines (e.g., PharmD, MD, PhD, data science). Consider higher education as well as professional development
- Embedding team science, regulatory strategy, innovations like AI/ML, and communication into curricula.
- Increasing the field's presence and accessibility among clinicians, patients, and the public.
- Supporting new models for experiential learning across sectors.

**Advancing Equity and Global Health**

Equity must be foundational, not an afterthought. This imperative includes:

- Promoting inclusive trial design, real-world evidence generation, and community-driven research.
- Designing context-specific training and regulatory frameworks for underserved and LMIC settings.
- Partnering with global institutions to co-develop harmonized standards and infrastructure.
- Elevating diverse voices in field-shaping conversations, not just implementation.

**Innovating Tools, Trial Design, and Patient Engagement**

The purpose of clinical translational pharmacology remains constant, but the tools, and the people who use them, are changing. The field must lead the evolution and application of next-generation translational tools, with openness to continuous advancement. Priorities include:

- Embracing decentralized, pragmatic, and adaptive trial models to increase flexibility and relevance.
- Integrating emerging technologies such as wearables, digital twins, AI-driven decision support, and real-world data, recognizing that tools will evolve.
- Engaging patients early and consistently across the drug development, review, and utilization (DDRU) continuum.
- Redefining endpoints and evidence standards to reflect what truly matters to patients.

**Shaping Regulatory Strategy and Totality of Evidence Ecosystems**

CTP must step into a more visible role in shaping what counts as evidence and how it is used. This involves:

- Advocating for process-based, lifecycle-oriented regulatory models.
- Defining evidentiary standards that are predictive, pragmatic, and equitable.
- Promoting interoperability, transparency, and reproducibility in modeling, AI, and real-world data use.

- Convening stakeholders, including regulators, developers, and patient groups, to co-create trust and clarity.

These core themes underscore the opportunity that exists, as clinical translational pharmacology is arguably among the most dynamic fields in biomedical science. This dynamism results from the interplay of three factors: 1) the broad range of scientific roles that build on the discipline of clinical translational pharmacology; 2) the diverse knowledge, skills, and experiential backgrounds of clinical translational pharmacologists; and 3) the depth and breadth of clinical translational pharmacology's application space. The range of clinical translational pharmacology activities and applications are connected across the DDRU continuum including supporting global public health (**Figure 1**).

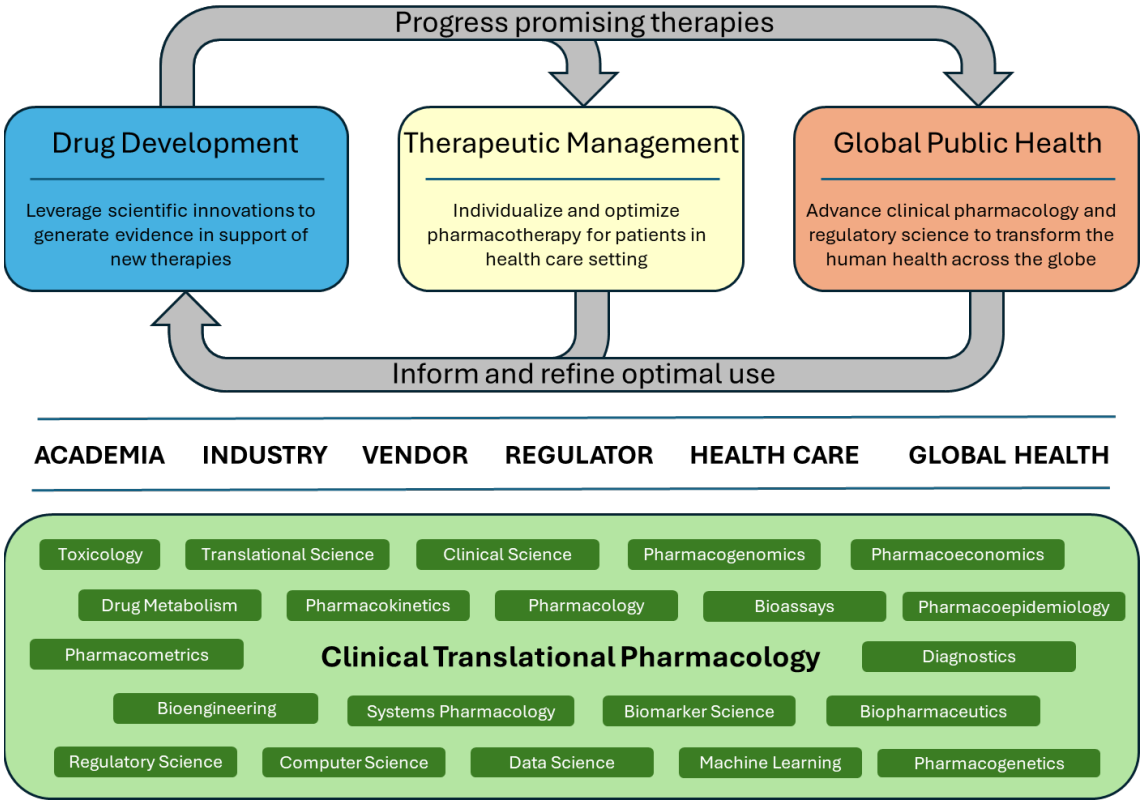


***Figure 1:*** *The clinical translational pharmacology discipline plays a large role in drug development, therapeutic management and global public health by progressing promising therapies and informing and refining their optimal use. Clinical translational pharmacology professionals bring their skills and experience into a large variety of roles across wide range of professional organizations and possess a multidisciplinary skill set that builds on expertise across many scientific areas (adapted from Zineh and Hartman).*

# Strategic Pathways Forward

Participants outlined clear priorities across three core pillars:

**Education & Training & Communication**

- Define and disseminate core CTP principles for both higher education and professional development.

- Launch leadership curricula and interprofessional programs.
- Leverage social media, podcasts, and YouTube for external engagement.

**Partnerships & Advocacy**

- Deepen ties with CTSAs, therapeutic societies, WHO, and patient groups.
- Promote open science and cross-sector work products.
- Build infrastructure for collaboration and shared training.

**Equity & Global Impact**

- Patient-centric clinical trial approaches and reducing access barriers through community-based research and including patient voices
- Design tailored education and regulatory programs for LMICs.
- Use philanthropic and public-private partnerships to address neglected diseases.

# Call To Action: Roadmaps to the Future

The Summit on the Future of Clinical Translational Pharmacology affirmed that CTP's future will be shaped by its principles. To lead in this new era, professionals in the field must elevate its visibility, expand collaborative alliances, and build capacity by cultivating a globally engaged, patient-centered, and interdisciplinary workforce.

Born from the collective insights of leaders across science, medicine, regulation, and patient advocacy, the proposed Summit Roadmaps are a shared commitment to turn the field's bold vision into reality. They reflect a future where, by 2035, clinical translational pharmacology (CTP) delivers safe, effective, and more affordable medicines to patients more efficiently; where every patient, everywhere, benefits from innovations that optimize drug development and utilization. These roadmaps are not just a list of initiatives, they are a call to the field to lead with principle, to collaborate across disciplines and borders, and to invest in a future that improves the health of all people. Both aspirational and actionable, they show how, together, we can transform vision into measurable impact.

*Clinical translational pharmacology (CTP) drives faster, safer, and more affordable medicines to all patients, everywhere.*

*By 2035, CTP principles are embedded in every stage of drug development and patient care. They guide how therapies are discovered, tested, approved, and delivered, ensuring equity, trust, and innovation are at the heart of the health ecosystem.*

*Clinical pharmacologists develop and wield the tools to optimize drug development and utilization, bringing benefits to every patient in every setting.*

Five key focus areas are identified in the Summit Roadmaps, and include Foundational, Workforce & Leadership, Innovation & Technology, Equity & Global Health, and Public Visibility & Scientific Trust, representing where CTP must act to deliver on its 2035 vision (**Figure 2**).

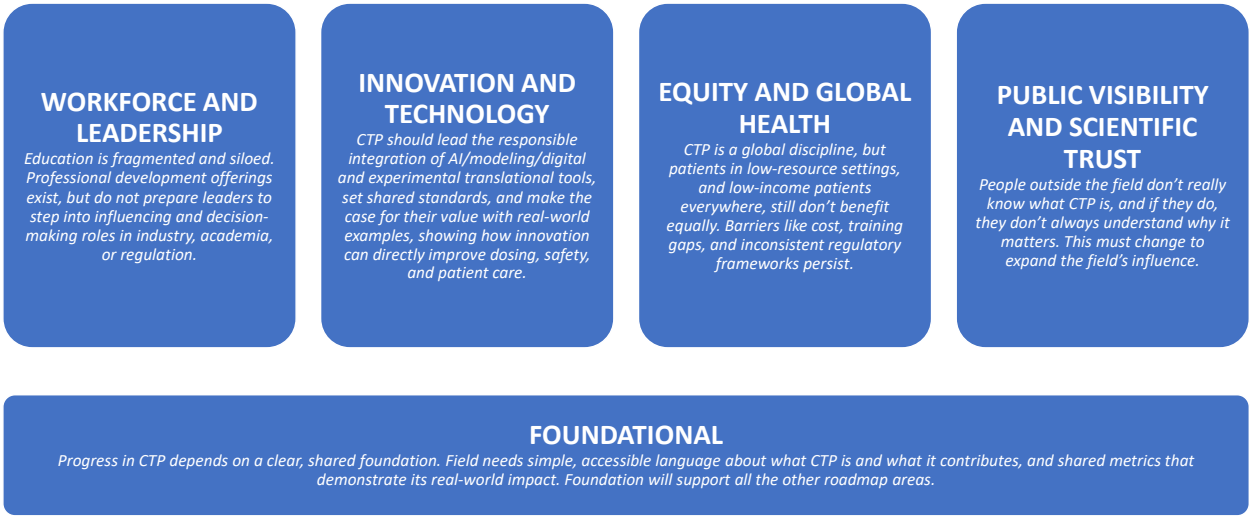


***Figure 2:*** *Focus areas to enable CTP to achieve its 2035 vision.*

## FOUNDATIONAL

**Context:** Summit participants agreed that the field's progress depends on a clear, shared foundation. Right now, CTP is used and valued across science, medicine, and regulation, but often without a unifying definition or consistent way to describe its principles. There is broad agreement that the field needs simple, accessible language about what CTP is and what it contributes, and shared metrics that demonstrate its real-world impact. This foundation will support all the other roadmap areas, from education and communication to global harmonization.

**Outcome:** CTP has a clear, shared foundation. Its core principles are defined and understood across science, medicine, regulation, and industry, forming the common language that unites the field. These principles serve as the basis for the efforts outlined in the other roadmaps, and are measured by meaningful metrics that show how CTP accelerates drug development, improves dosing, and delivers safer, more effective treatments to patients everywhere.

**Objectives:**

- Define the core principles of CTP
- Establish metrics that show CTP's impact
- Embed these principles as the field's baseline standard

## WORKFORCE AND LEADERSHIP

**Context:** Summit conversations highlighted that education is both fragmented and siloed. Students learn about pharmacology in some programs, but rarely in ways that connect to engineering, informatics, or data science. At the same time, many professional development offerings exist, but they aren't coordinated, and they rarely prepare leaders to step into decision-making roles in industry, academia, or regulation.

Participants called for two parallel tracks: embedding CTP in higher education and creating leadership and skill-building programs for professionals at every stage of their careers.

**Outcome:** By 2035, clinical translational pharmacology (CTP) is woven into the training of scientists, clinicians, and regulators at every stage of their careers. Students in pharmacy, medicine, data science, and engineering learn CTP principles early, and established professionals keep building skills through leadership, communication, and cross-disciplinary programs. CTP-trained leaders are sitting in influencing and decision-making roles in industry, academia, and government, and the field has formal pathways, from foundational education to advanced leadership training, that prepare the next generation to shape the future of drug development and patient care.

**Objectives:**

- Build CTP into the academic pipeline *(Higher Education Focus)*
- Grow leaders and equip professionals at every career stage *(Professional Development and Leadership Training)*

### INNOVATION AND TECHNOLOGY

**Context:** Innovation came up in every Summit discussion, particularly the explosion of AI, modeling, and digital tools alongside advances in wet lab translational capabilities. Participants were excited by the possibilities but clear-eyed about the risks: hype outpacing evidence, fragmented standards, and skepticism from decision-makers. They agreed that CTP should lead the responsible integration of these tools, set shared standards, and make the case for their value with real-world examples, showing how innovation can directly improve dosing, safety, and patient care.

**Outcome:** By 2035, innovative tools like AI, digital twins, and advanced modeling aren't side experiments, they are trusted, everyday drivers of how medicines are developed, tested, and prescribed. Additionally, innovation in the wet lab including development of novel translational tools, biomarkers, -omics data generation, imaging, etc. are quickly advancing our understanding of causal biology. Clinicians, regulators, and scientists across the globe use these tools seamlessly, leading to faster, safer, and more affordable treatments reaching patients. Instead of fragmented, siloed approaches, there's a unified, transparent system where technology accelerates the path from discovery to better health for all people.

**Objectives:**

- Define how CTP will lead innovation responsibly and build trust and broad adoption of digital tools
- Create the infrastructure for sustainable innovation in CTP

### EQUITY AND GLOBAL HEALTH

**Context:** Equity and access were front and center in the Summit. Participants pointed out that CTP is a global discipline, but patients in low-resource settings, and low-income patients everywhere, still don't benefit equally. Barriers like cost, training gaps, and inconsistent regulatory frameworks persist. The group called for building capacity, harmonizing standards, and making sure that CTP principles are applied equitably, so that every patient has access to the same level of innovation and care.

**Outcome:** By 2035, the benefits of clinical translational pharmacology are felt consistently across the world. Patients, regardless of income, geography, or circumstance, receive the same level of care,

innovation, and timely access to treatments. The inequities that once meant low-income patients and communities were left behind are erased, and the tools and discoveries of CTP are applied equitably, everywhere. Regulatory systems speak the same language, equity isn't an afterthought, and patients in low- and middle-income countries benefit from the same innovations, timelines, and standards as patients anywhere else in the world.

**Objectives:**

- Build global capacity and expertise so CTP principles are understood and applied everywhere
- Embed equity into how medicines are developed, tested, and regulated
- Harmonize regulatory standards and align global approaches to CTP

### PUBLIC VISIBILITY AND SCIENTIFIC TRUST

**Context:** Throughout the Summit, one theme kept resurfacing: people outside the field don't really know what CTP is, and if they do, they don't always understand why it matters. Participants said this must change to expand the field's influence. The roadmap calls for creating a clearer narrative, training scientists and clinicians to share it, and positioning CTP as a trusted voice for policymakers, funders, and the public.

**Outcome:** By 2035, clinical translational pharmacology isn't just understood within scientific circles, it's part of the broader health conversation. Policymakers, funders, clinicians, and the public recognize the value of CTP because the field tells its story clearly and consistently. The term "totality of evidence" becomes widely understood, and CTP voices are sought out in the media, in government, and on global stages. Scientists and clinicians are equipped to communicate not just data, but meaning, in order inspire trust, drive smart policy, and ensure patients see how innovation connects to their care.

**Objectives:**

- Build the narrative and raise visibility of CTP
- Equip scientists, clinicians, and leaders to communicate effectively
- Establish CTP as a go-to source for trusted information

## Further Reading

Framing document provided as a pre-read to attendees is provided here.

Selected references for further in-depth reading are provided here.