MULTI-REGIONAL CLINICAL TRIALS

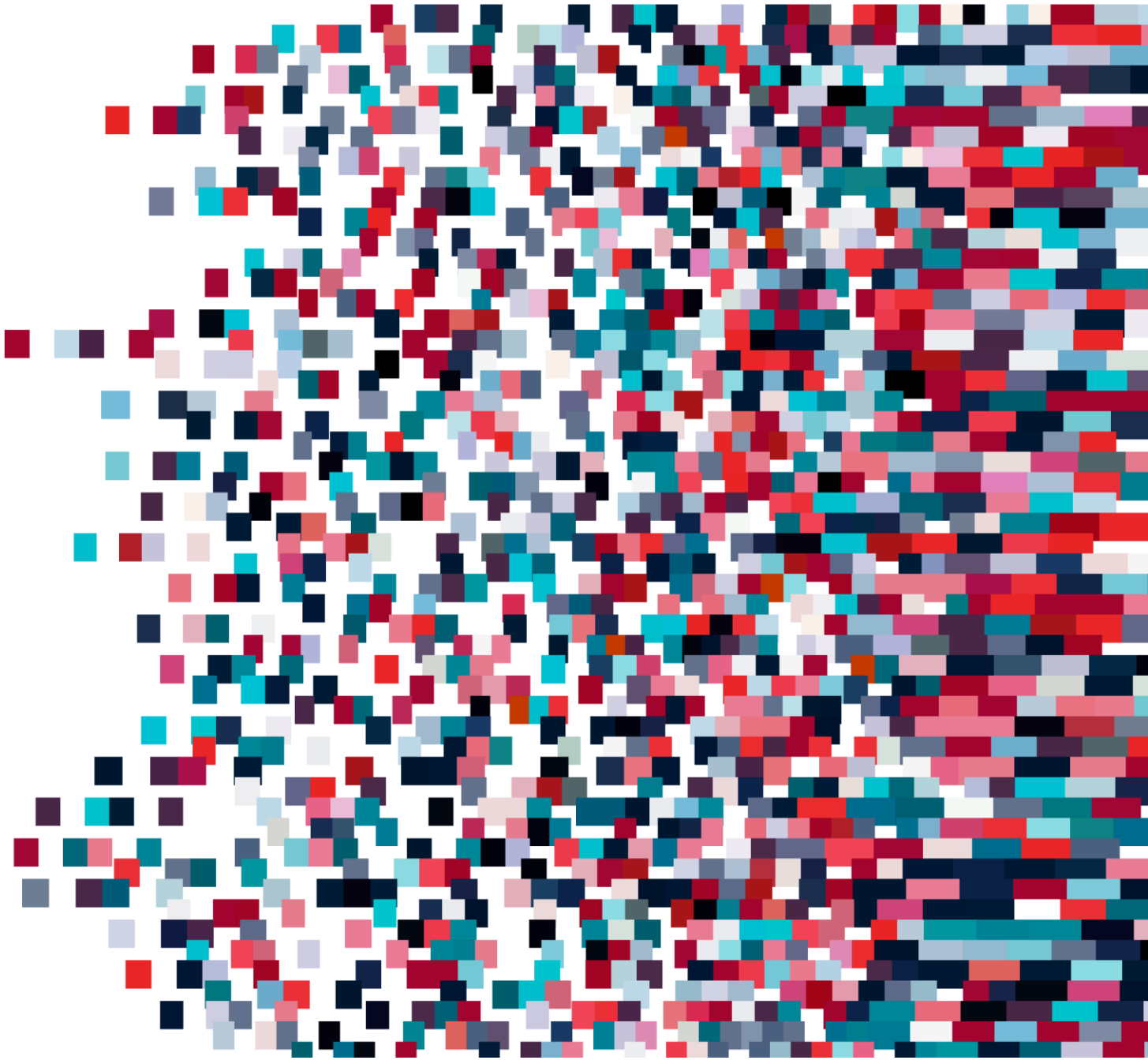
THE MRCT CENTER OF BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

Webinar:

Global Development of a Clinical Research Workforce: Tools and Resources

APRIL 3, 2025
9:00 - 10:00 AM ET

REGISTER NOW



This Meeting

We are recording this webinar, and we plan to post the recording for our international audience.

We will follow up regarding permission with the presenters.

Disclaimer

The opinions contained herein are those of the presenters and are not intended to represent the position of Brigham and Women's Hospital, Mass General Brigham, Harvard University, or any of the institutions or organizations represented today.

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We are committed to autonomy in our research and to transparency in our relationships. The MRCT Center leadership retains responsibility and final control of the content of any products, results, and deliverables.

We have no personal financial conflicts of interest with the content of this presentation

About Us

MRCT Center is an applied policy center focused on addressing the conduct, oversight, ethics and regulatory environment for clinical trials around the world.

Our Vision

Improve the integrity, safety, and rigor of clinical trials around the world.

Our Community

We engage diverse stakeholders to define emerging issues in global clinical trials and to create and implement ethical, actionable, and practical solutions.

Agenda

Time	Title	Presenter
9:00 AM EDT	Welcome and Introduction	Barbara E. Bierer, MD Faculty Director, MRCT Center Co-Chair, JTF Stephen Sonstein, PhD Co-Chair, JTF
9:05 AM EDT	Keynote Product development and need for education of stakeholders: focus on health professionals	Lembit Rago Secretary General, CIOMS
9:25 AM EDT	PRAXIS Australia: Global Development of a Clinical Research Workforce	Sally Armstrong CEO, PRAXIS Australia
9:40 AM EDT	Let's Talk About the Clinical Research Workforce	Susan Landis Executive Director, ACRP
9:55-10:00 AM EDT	Discussion Wrap-up	Stephen Sonstein, PhD Co-Chair, JTF

Global Standards for Clinical Research Professionals

JOINT TASK FORCE FOR CLINICAL TRIAL COMPETENCY

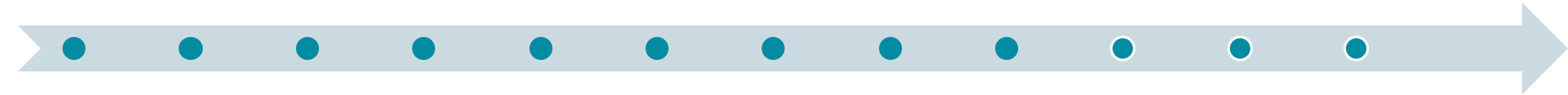
The JTF has identified the knowledge and skills required for **safe, ethical, and high-quality clinical research.**

We are committed to providing all members of the research team worldwide with **guidance and tools to ensure necessary competencies**.

www.mrctcenter.org/clinical-trial-competency

Timeline of JTF Clinical Trial Competencies

Download
the Framework



2013 — Launched JTF Task Force

2014 — Version 1.0 JTF Framework

2015

2016

2017 — Version 2.0 JTF Website created

2018 — Version 3.0 JTF (Fundamental, Skilled, Advanced); Spanish Translation

2019

2020 — Version 3.1 JTF (Project Management); Japanese Translation

2021 — Global survey of self-assessed competencies and recommendations

2022 — Bi-annual global meetings

2023 — 12 Translations

2024 — Patient partners And data management workgroups

The 8 JTF Competency Domains

Scientific Concepts and Research Design

Knowledge of scientific concepts related to the design and analysis of clinical trials

Ethical & Participant Safety Considerations

Care of patients, human participant protections, and safety in the conduct of a clinical trial

Medicines Development and Regulation

Knowledge of how drugs, devices, and biologicals are developed and regulated

Clinical Trial Operations (GCPs)

Study management and GCP compliance; safety management and handling of investigational product

Study and Site Management

Content required at the site level to run a study including site and study operations

Data Management and Informatics

How data are acquired and managed during a clinical trail, including source data, data entry, queries, etc.

Leadership and Professionalism

The principles and practice of leadership and professionalism in clinical research

Communication and Teamwork

All communication within the site and between sites, sponsor, & CRO

Under each domain are specific competency statements

FOR EXAMPLE:

Domain 1: Scientific Concepts and Research Design

Encompasses knowledge of scientific concepts related to the design and analysis of clinical trials

1.1 Apply principles of biomedical science to investigational product discovery and development and health- related behavioral interventions

1.2 Identify scientific questions that are potentially testable clinical research hypotheses

1.3 Identify the elements and explain the principles and processes of designing a clinical study

1.4 Maintain awareness of new technologies, methodologies, and techniques that enhance the conduct, safety, and validity of the clinical study

1.5 Critically analyze clinical study results

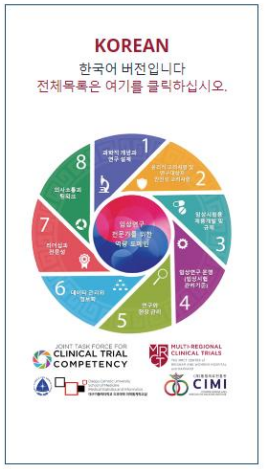
Fundamental, Skilled, and Advanced Level Competencies

1.1 Apply principles of biomedical science to investigational product discovery and development and health-related behavioral interventions

Fundamental Level	Skilled Level	Advanced Level
A1. Recognize the need to apply scientific principles to discovery and development of biomedical investigational products and health-related behavioral interventions	**B1. Apply** scientific principles when implementing a clinical or behavioral study	**C1. Plan** biomedical research according to scientific principles
A2. Explain the basic scientific principles that should be applied during development of biomedical investigational products and health-related behavioral interventions	**B2. Implement** data collection according to scientific principles and based on protocol design	**C2. Develop** a data management plan according to scientific principles.
Example: When reviewing a clinical research protocol, researcher describes the objective and scientific techniques used to design and implement biomedical research.	**Example:** When given a clinical research protocol, researcher differentiates what principles could affect how the data should be collected and implement best practices accordingly.	**Example:** Given a clinical research protocol and data collected, the researcher evaluates the findings to assess results via a scientific framework.

Translations that are currently available:

- English
- Spanish
- Japanese
- French
- Thai
- Bahasa Indonesia
- Italian
- Vietnamese
- Chinese
- Korean
- Arabic
- Portuguese



https://mrctcenter.org/clinical-trial competency/framework/translations/

How to reference the MRCT Center when using the JTF Framework

Product development and need for education of stakeholders: focus on health professionals

Global Development of a Clinical Research Workforce: Tools and Resources
Webinar
April 3, 2025

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MULTI-REGIONAL CLINICAL TRIALS
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CIOMS – Introduction (https://cioms.ch/)

Council for
International
Organizations of
Medical
Sciences (41 member organizations)

Founded in Belgium in 1949, today Swiss Association in Geneva

In official relations with WHO

UNESCO associated partner

ICH Observer since 2016

Our link to regulatory science

Mission Statement

CIOMS mission is to advance public health through guidance on health research including ethics, medical product development and safety

1 Product development – a life-cycle continuum

- To get better medicines - **DATA** is what we need!

In God We Trust. All Others Must Bring Data.

William Edwards Deming/Also a common saying at the US FDA

- Medicinal product development is **DATA centric**
- Medicinal product development should also be **PATIENT centric** and enabled by **well educted** stakeholders
- *Medicinal product scientific development includes all processes and activities necessary to develop and assess **data** with the aim of bringing the product to the market and supporting its safe and effective use until it stays on the market*

2 Regulatory science – what is it?

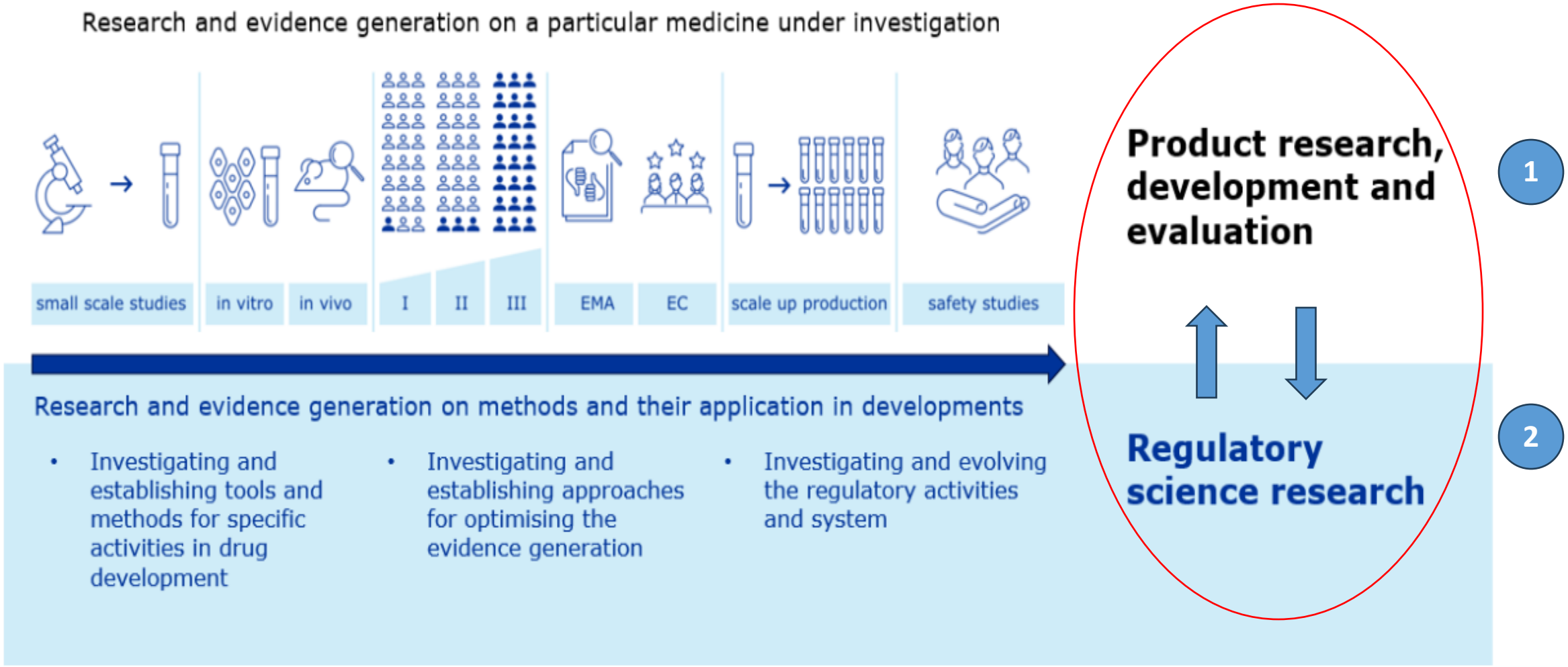
Multiple sciences/scientific disciplines joined by application purpose

- A range of scientific disciplines that are applied to the quality, safety and efficacy assessment of medicinal products and that inform regulatory decision making throughout the lifecycle of a medicine. It also contributes to developing regulatory standards and tools.
  - ❖ EMA: https://www.ema.europa.eu/en/documents/other/draft-concept-paper-european-platform-regulatory-science-research_en.pdf

- Regulatory Science is the science of developing new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of some FDA-regulated products.
  - ❖ US FDA: https://www.fda.gov/science-research/focus-areas-regulatory-science-report/focus-areas-regulatory-science-introduction

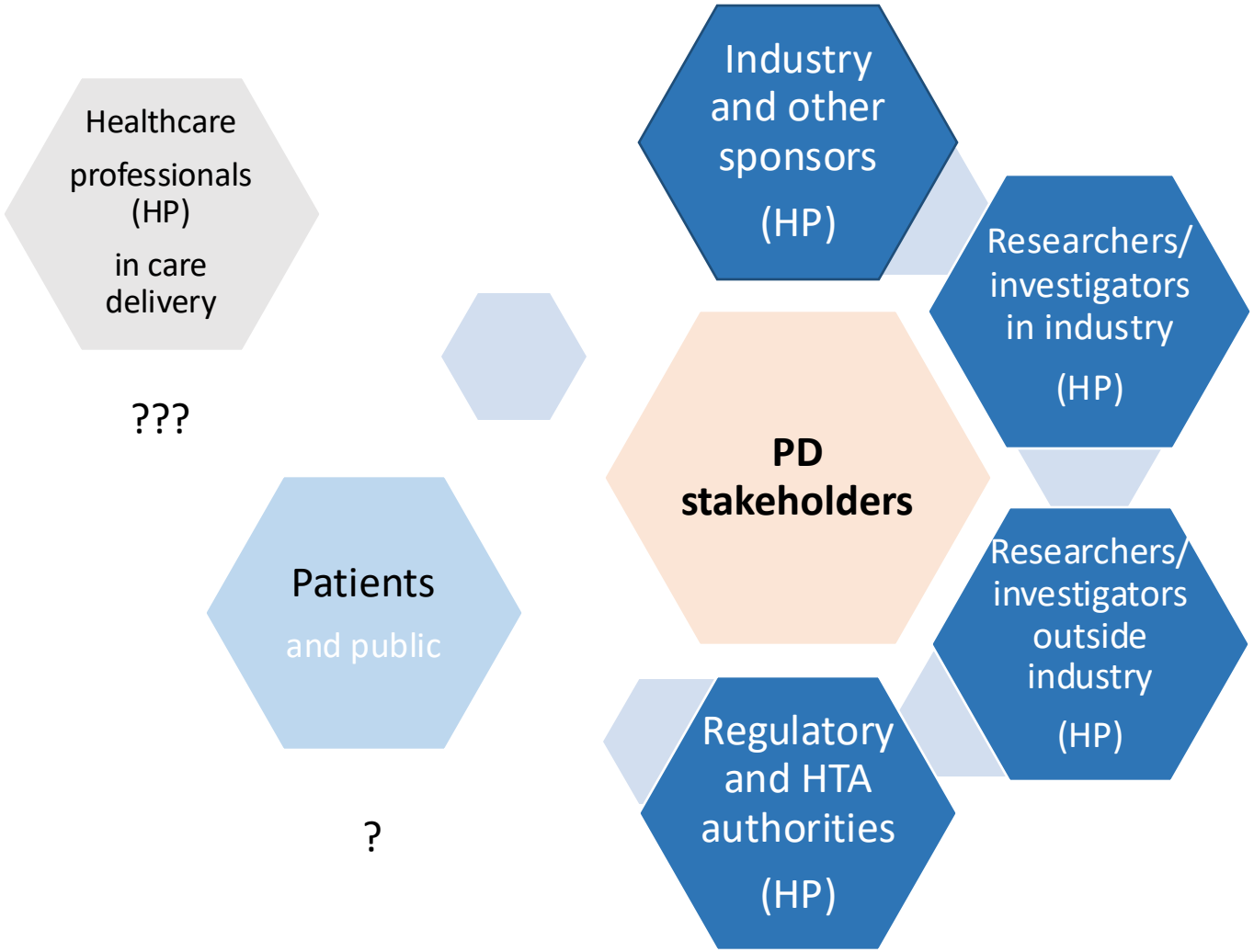
- Regulatory science is a multidisciplinary field that ensures the safety, efficacy, and quality of products within regulated industries, including pharmaceuticals, medical devices, biotechnology, cosmetics, and food. These industries are governed by regulations, policies, and standards that apply from the product research and development stage to product marketing and use.
  - ❖ Johns Hopkins University: https://advanced.jhu.edu/about/on-the-advance/mastering-your-future/what-is-regulatory-science/

Product development and regulatory science



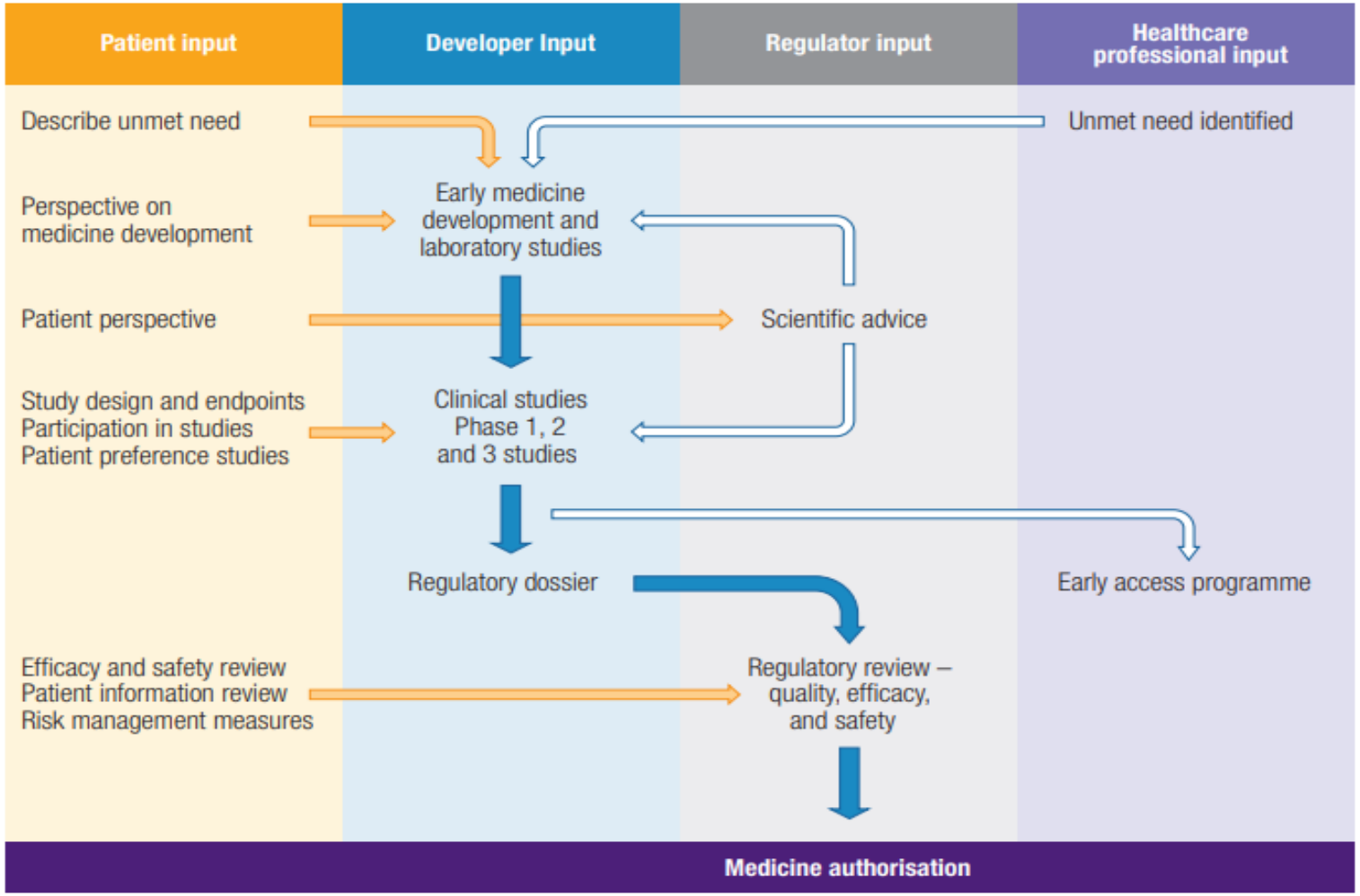
Reference: https://www.ema.europa.eu/en/documents/other/draft-concept-paper-european-platform-regulatory-science-research_en.pdf

Product development (PD): are all stakeholders equally on board?



Patients as active partners during the whole life-cycle of medicines

Example: Figure 1a: Patient involvement during a medicine life-cycle. Pre-authorization period



Source: CIOMS Working Group XI

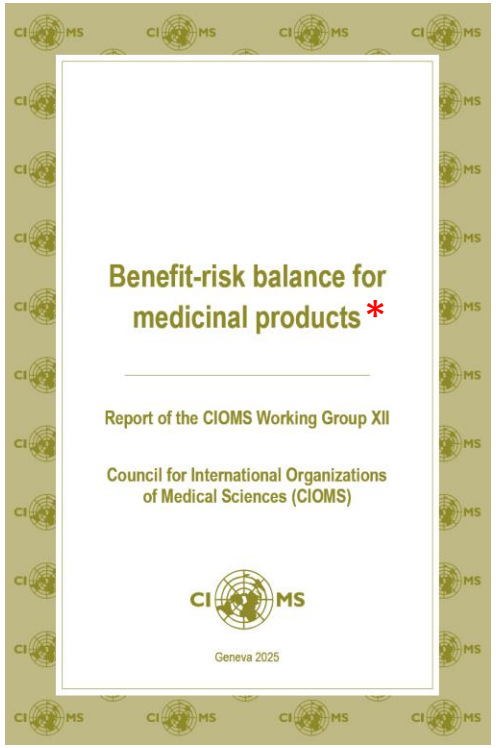
https://doi.org/10.56759/iiew8982

Benefit-risk assessment : value of patient input

In drug regulatory sciences, the question on how to assess and justify a positive benefit–risk of a medicine remains at the center of many research activities

CIOMS WG XII report on “Benefit-risk balance for medicinal products” will soon be published. Among others it points out:

- The relative importance to patients of different attributes of benefit and risk, including impact on quality of life
- Patient perspective of risk, which of the medicine’s identified risks are patients willing or unwilling to accept
- How patients trade-off key benefits against key risks for a given medicine and how that informs minimum clinically important benefit and effect size
- The heterogeneity or distribution of patient preferences regarding benefits and risks of various medicinal products, incl. identification of patient subgroups for benefit-risk assessment



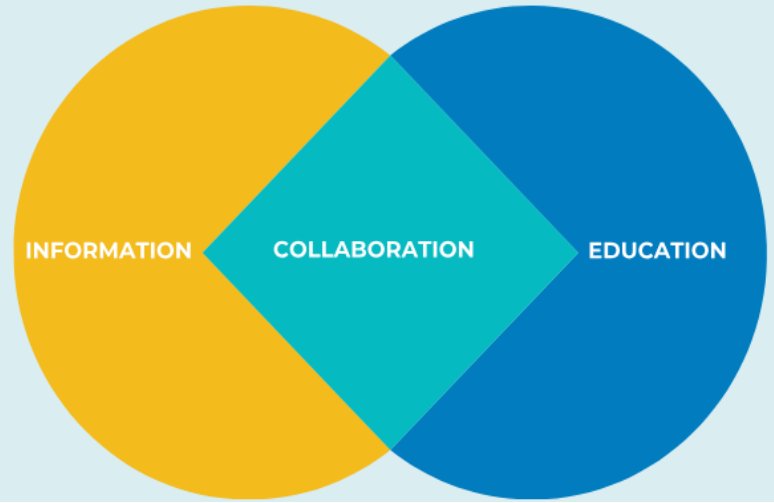
** Note: In press, expected April 2025*

Do patients know enough about product development (PD) ?

- Do they need to know? No doubt it would help both product development and treatment
- How can they get to know?
- The **E**uropean **P**atients' **A**cademy on **T**herapeutic **I**nnovation – EUPATI at https://eupati.eu/

Taking the future healthcare and patient involvement trends into account, EUPATI aims to anchor it's growth strategy in the 'ICE' structure, comprising of three fundamental pillars:

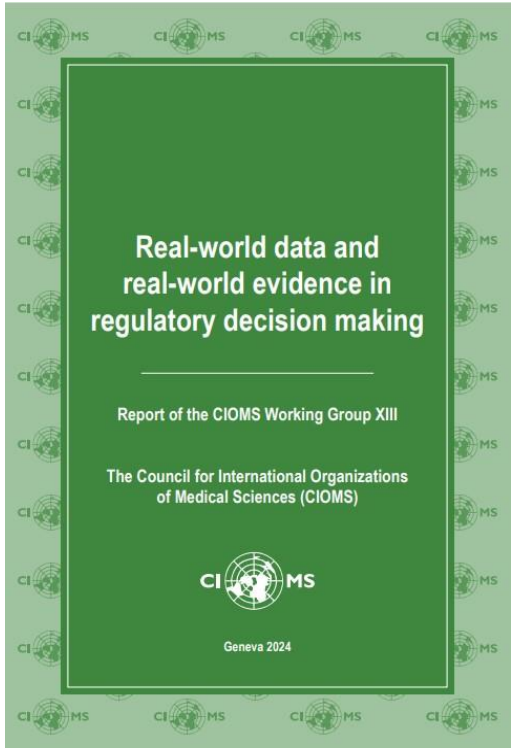
Information: To enhance the availability of impartial, dependable, and openly accessible information about medical research and development and other health technologies.
Education: To broaden educational and training initiatives for both patients and researchers.
Collaboration: To integrate and enhance interaction and cooperation between patients and researchers within the above two pillars.



Do health professionals know enough about PD?

- Those who work in the industry – YES (perhaps)
- Those who are involved in clinical trials – YES (but mostly their domain)
- What about those involved in patient care and NOT involved (directly) in product development? Mostly/most likely NOT

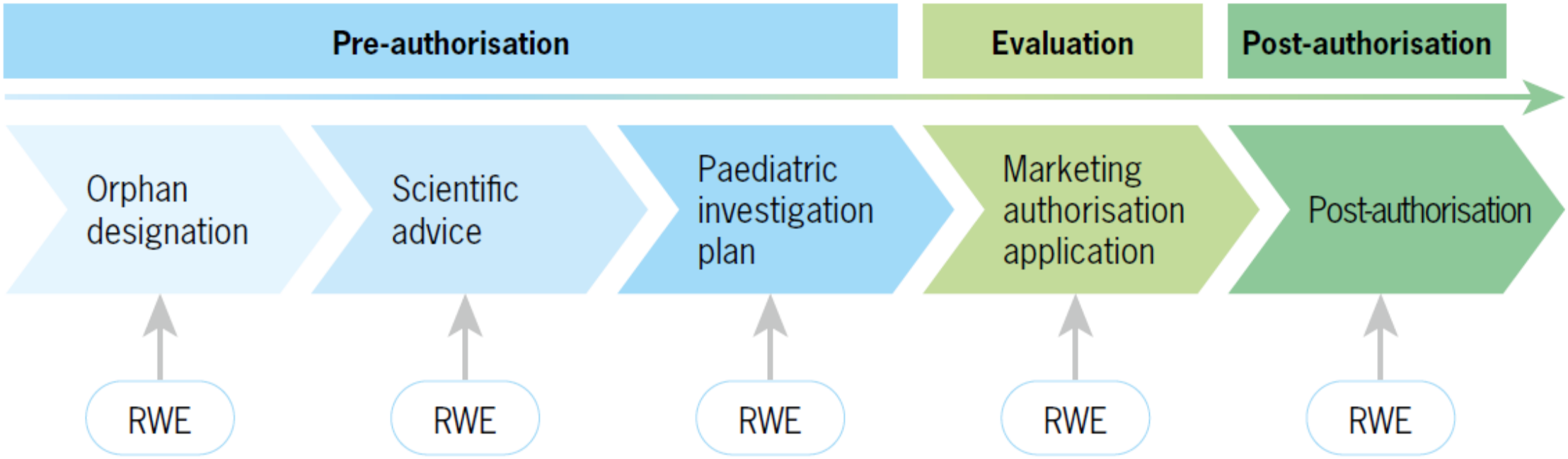
- One hot topic of regulatory science is how real-world data (RWD) could be best used to generate real-world evidence (RWE) for safety and efficacy claims
- The more we use RWD the more health professionals NOT directly involved in product development start to be involved as they produce and document DATA in care delivery



https://doi.org/10.56759/kfxh6213

*Fig. 1 Potential use of RWE in each core regulatory review process**

Source: Modified from an original EMA figure.[29]



*Modified. *Source*: *DARWIN EU (Data Analytics and Real World Interrogation Network) PCWP and HCPWP Data workshop 23 September 2020. Peter Arlett EMA Head of EMA Data Analytics and Methods Taskforce Co-chair HMA-EMA Big Data Steering Group. Slides 7-9. (PDF accessed 2 June 2023)*

CIOMS initiative about health professionals' (HP) education

- CIOMS started the new working Group (WG) on education of health professionals about medicines development in April 2021
- The main objective of this working group was to discuss and develop a consensus report giving recommendations on the principles of competency-based knowledge needed for healthcare professionals working in medicines development.
- Since 2021 nine in person WG meetings have taken place and now the draft is with the Editorial Committee

Health professional definition

- *Healthcare professional, health professional, health worker* – often used as synonyms. Definitions are many, sometimes controversial. Some are 'open ended', some more restrictive in terms of professionals included

Option considered *(defining what they do without defining who they are)*

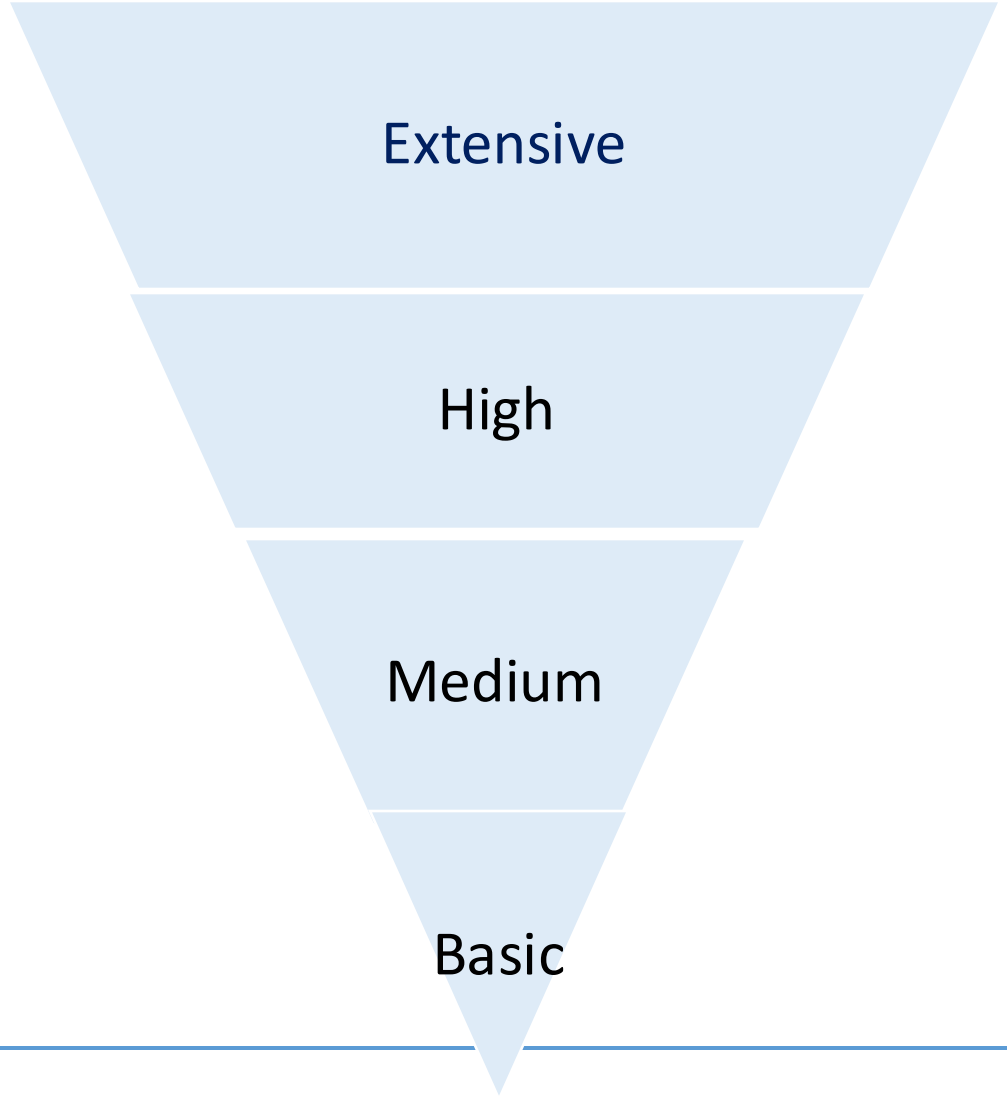
- ***Health professionals**** *maintain health in humans through the application of the principles and procedures of evidence-based medicine and caring. Health professionals study, diagnose, treat and prevent human illness, injury and other physical and mental impairments in accordance with the needs of the populations they serve. They also conduct research and improve or develop treatments, concepts, theories and operational methods to advance evidence-based health care*

- *Note*: **World Health Professionals Allience** (WHPA) brings together the global organizations representing the world's *dentists, nurses, pharmacists, physical therapists and physicians* – stating who HP are?

* *Adapted from: Transforming and scaling up health professionals' education and training. WHO 2013 - adapted from ILO 2008; WHO 2010; Gupta 2011*).

HP's educational needs of medicinal product development

Extent of knowldge needed in medical product development (PD)



Numbers of Health Professionals (HPs)

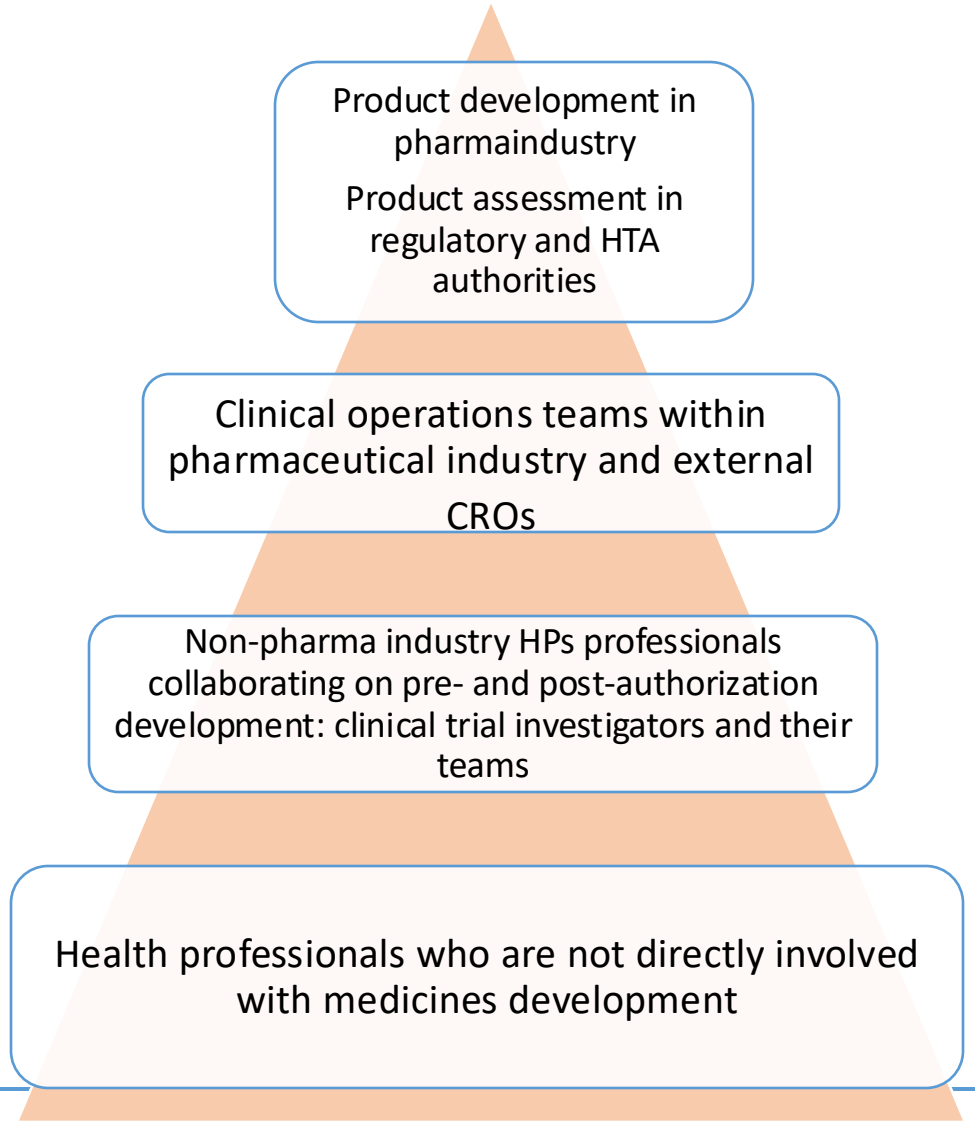


Table of contents (1)

Table of contents (2)

- **INTRODUCTION**

  Background, The CIOMS Working Group, Structure and content of this report etc.
- **CHAPTER 1. Medicines development landscape**
- **CHAPTER 2. Needs and benefits for education about medicines development**
- **CHAPTER 3. Education strategies and tools**
- **CHAPTER 4. Principles of educating health professionals** *(several subgroups, more detailed)*
- **CHAPTER 5. Principles of educating other interested parties** *(high level, with some examples referred to)*
- **CHAPTER 6. Conclusions and recommendations**
- **REFERENCES**
- **ANNEX 1.**
- **….**
- **ANNEX X. CIOMS Working Group membership and meetings**
- **ANNEX Y. Commentators**

All parties need better education on PD!

Chapter 4: HP* involved in PD : Groups 1 to 5

For Groups 1-5 *PharmaTrain** syllabus sections and topics serve as a basis

Group1. Health professionals working within pharma industry

- 1A. Medical product developers
- 1B. Clinical operations teams within pharmaceutical industry and external Contract Research Organizations (CROs)

Group 2. Medical product regulators and health technology assessment experts

Group 3. Health professionals collaborating on pre- and post-authorization development: clinical trial investigators and their teams etc.

Group 4. Health professionals in research ethics committees

Group 5. Health professionals involved in patient care and indirectly involved in medical product development – *for Groups 1-5 PharmaTrain*

Also these HP need better education on PD

* *PharmaTrain*: https://www.pharmatrain.eu/

Note: The CIOMS WG was dominated by experts with physician background

Some points raised during the WG meeting:

- *Building trust in medicines development*
- *Supporting dialogue with patients and caregivers on their treatment*
- *Ethical principles of clinical research and definition of study medication*
- *Framework of medicines development (ICH, GCP and other relevant guidelines, methodology of clinical trials, academic research)*
- *Regulatory concepts for Marketing Authorization*
- *Benefit Risk concepts – life-cycle approach, individual benefits and risks*
- *Post approval safety monitoring and reporting*
- *Importance of collecting health data – increasing use of RWD/RWE for patient centered PD*

Group 6. Other stakeholders/interested parties who need education in medicinal product development (General public, patients, patient experts, patient advocacy groups, clinical trial participants) - *EUPATI example to be used*

6A. General public

6B. Patient experts

6B. Patient advocacy groups

6D. Clinical trial participants

Challenges

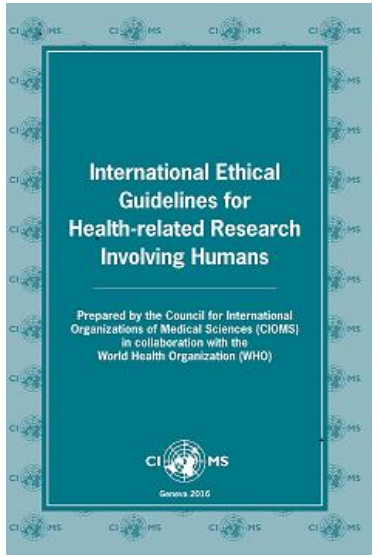
- Definitions, scope …
- Five major groups of health professionals identified by WG – how to describe their educational needs considering the complexity of issues? Ideal would be to have common high-level domains and sections, topics could differ by title or content
- Health professionals – physicians/medical doctors involved in care deliver (not directly involved in PD, but increasingly important as RWD generators)
  - ✓Some relevant to PD topics may be covered during undergraduate and postgraduate/specialist training
  - ✓Additions to undergraduate training are not realistic
  - ✓What about adding a module on medicinal products development to specialist training?
- How to convince medical community and education providers about the need to provide more education about the medicinal product development?

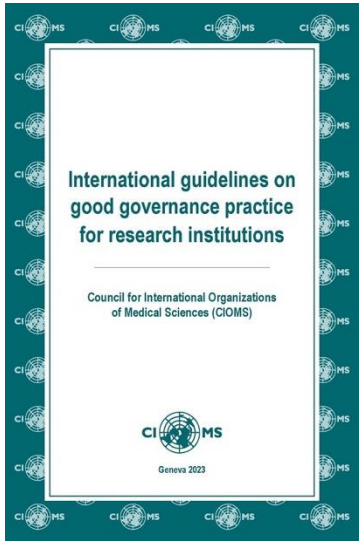
Conclusions

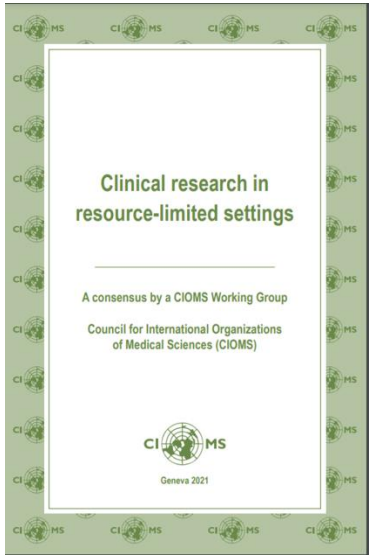
- There is a need to promote better education about medicinal product development to all product development stakeholders
- The report under development focuses on educational needs of health professionals depending on their role during product development life-cycle
- The report is emphasizing the importance of providing more education not only for those health professionals who are directly involved in product development, but also to those who are NOT directly involved (those involved in care delivery)
- The report promotes the need of having a module on medicinal product development for medical doctors during their specialist training
- …

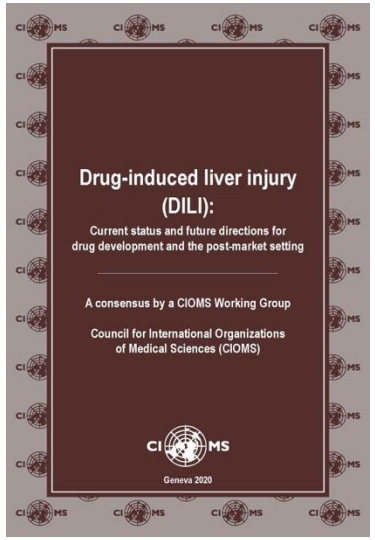
CIOMS publications are available at : https://cioms.ch/publications/

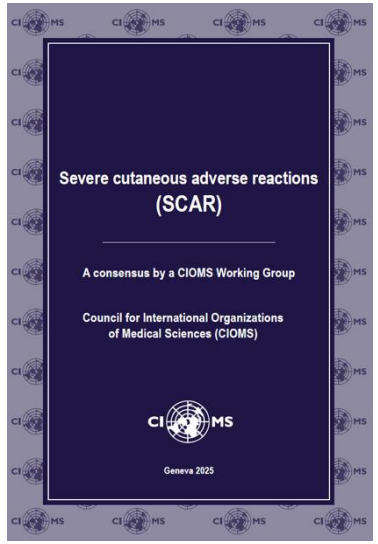
- Some CIOMS publications of potential interest:

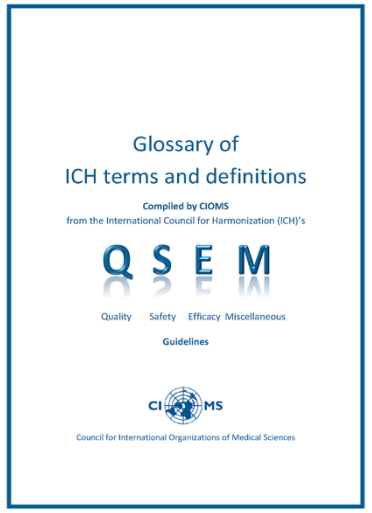












- *Note: SCAR report is in press* (will be out in April 2025)

Instead of conclusion

Working for public health and patients has a "little difficulty"

No matter how good we are we can and should always do better!

How can we do better tomorrow?

Image by Gordon Johnson from Pixabay


CIOMS
Thank you!

Sally Armstrong

"**PRAXIS Australia: Global Development of a Clinical Research Workforce**"

Sally Armstrong
CEO
PRAXIS Australia

Barbara Bierer
Faculty Director
MRCT Center

PRAXIS AUSTRALIA

Promoting Ethics and Education in Research

PRAXIS Australia: Global Development of a Clinical Research Workforce

Sally Armstrong
CEO, PRAXIS Australia
3 April 2025

About PRAXIS Australia

- 10 years sector experience
- Supporting Over 15,000 clinical trials, research and ethics staff (Australia, New Zealand & Internationally)
- Delivering 4 national programs for the CT sector (2023 – 2025)
- Competency-based training
- Aligned to the Harvard Multi-Regional Clinical Trials (MRCT) Centre JTF Competency Framework and the National Health and Medical Research Council (NHMRC)

PRAXIS AUSTRALIA

Promoting Ethics and Education in Research

World class education and training for Research and Clinical Trials staff

Research Essentials

A world class, self-paced research training program composed of online modules and electives.

HREC Essentials

Australia's most comprehensive HREC training model.

Virtual workshops

A diverse menu of interactive, expert-led workshops that cover a range of areas in research, ethics and clinical trials.

Bespoke solutions

Developing customised, high quality, education solutions for organisations, including our Immersive Staff Development Programs, national collaborations and major projects (NCTGF, Health NZ)

All education and training underpinned by the JTF Framework

PRAXIS AUSTRALIA

Promoting Ethics and Education in Research

National and International Projects

National Clinical Trials Governance Framework (NCTGF)

Health New Zealand – Clinical Trial Courses

Immersive programs (MTP Connect/ PrOSPeCT/PROgress)

Health New Zealand
Te Whatu Ora

Omico.
Australian Genomic Cancer Medicine

AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE

MTP Connect
MedTech and Pharma Growth Centre

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PRAXIS Immersive On-site Training Programs

REDI Initiative – Clinical Trial Coordinator Internship
10-months, 3 states
Pilot program: 14 participants
Introductory course for new CTCs
High employment rate

DISR / Omico PrOSPeCT Staff Development Program
5-months, national delivery
2 cohorts: 40 participants
2 levels – junior and advanced
Increased trial capacity and site quality

PROgress Program: Immersive Career Accelerator Program
3-months, national delivery
2 parts:
1. PROgress Foundations Course
2. PROgress Program, immersive component with practical placement

Benefits to Sites

- Greater return on investment with proven goal setting and achievement frameworks.
- Accelerate the development of teams, increasing clinical trials skills, confidence and capability.
- Fast-track project success with more effective and efficient skill development.
- Site mentors / supervisors develop leadership skills in a supported program.
- Career development for site staff (program participants and mentors).

Benefits to Participants

- Accelerated development, engagement and accountability vital in today's landscape
- Comprehensive training and education, supported by practical application
- Mentoring support for accountability and accelerated development
- Tailored guidance and encouragement towards their professional development goals
- Networking opportunities to support ongoing development

Sector Impacts

- Filling the critical clinical trials skill gap
- Capacity building for the sector
- Increased staff confidence in clinical trial skills
- Career pathway into the sector
- Improved leadership development opportunities
- Regional, rural and remote staff access to career development

> *"I gained valuable hands-on experience in clinical research whilst receiving the background theoretical training. The PRAXIS workshops and modules give a great overview of the different elements of the clinical trials sector, even with no prior experience."* Rafha Rafeeu, **Participant**
>
> *"Our experience has been very rewarding. It is a great opportunity to contribute to the development of capable staff in the sector, and especially in regional Queensland."* Jessica Baird, **Site**

PRAXIS AUSTRALIA

Promoting Ethics and Education in Research

Future Focus – Where to next?

- PRAXIS International
  - Growth and further interest increasing in New Zealand, US, UK, Singapore
  - Collaboration with Global partners to develop tailored programs

Sally Armstrong, CEO, PRAXIS Australia
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PRAXIS AUSTRALIA
Promoting Ethics and Education in Research

“Let’s Talk About the Clinical Research Workforce”

Susan Landis
Executive Director, ACRP


ACRP
ADVANCING PEOPLE
ADVANCING HEALTH™

With more than 17,000 members, the Association of Clinical Research Professionals (ACRP) is the only non-profit organization solely dedicated to representing, supporting, and advocating for clinical research professionals.

Advancing People Advancing Health™

ACRP is moving the people and practice of clinical research forward™ by:

- Being the Most Passionate Advocate for the Clinical Research Profession
- Providing the Tools Clinical Research Professionals Need to Build Their Own Career Journeys
- Creating Connections through Community
- Empowering Organizations to Trust that Their Studies Are in the Hands of Qualified Professionals
- Leading the Way for Workforce Development in Clinical Research

ACRP Core Competency Guidelines for Clinical Research Coordinators (CRCs)™

Domain	Communication and Teamwork: Encompasses All Elements of Communication Within the Site and Between the Site and Sponsor, CRO, and Regulators. Understanding of Teamwork Skills Necessary for Conducting a Clinical Trial							
	X when Proficiency / Competency is Achieved and/or Relevant Training Completed							
Level	Entry Level CRC			Intermediate CRC			Senior CRC		
General Competency Expectations	Explain the variety of communication channels, roles and relationship and outlets for study results that impact the conduct of clinical research.	Self Assmt.	Mgr. Assmt.	Apply good communication and team work practices as well as effective presentation and communication of study results.	Self Assmt.	Mgr. Assmt.	Train and support study team members on a range of communication and teamwork best practices.	Self Assmt.	Mgr. Assmt.
8.1 Discuss the relationship and appropriate communication between Sponsor, CRO and clinical research site	*Explain the relationship between Sponsor, CRO and clinical research site personnel, trial participants and their family members, the subjects' Primary Care Physicians (PCPs) or treating physicians including the basics of appropriate communication chains of command. Describe the general types of correspondence that take place during a study and provide examples of situations requiring expedited communication.*			*Demonstrate the ability to coordinate and manage communications with multiple stakeholders (e.g., Sponsor and CROs, other site departments, IRBs/IECs, etc.).*			*Demonstrate an understanding of when the sponsor/CRO needs to be alerted to a concern or when questions should be directed to the sponsor/CRO vs. the internal site study team. Demonstrate the ability to train, support and guide study team members on communication practices amongst different stakeholders.*		
8.2 Describe the components of a traditional scientific publication	*Identify where clinical study results may be published (e.g., clinicalstudies.gov, scientific publications) and locate such results.*			*Demonstrate the ability to identify a relevant scientific publication and describe how the results translate into changes in treatment paradigms and future study design considerations.*			*Develop, contribute to or lead the development of a relevant scientific publication.*		
8.3 Effectively communicate the content and relevance of clinical research findings to colleagues, advocacy groups and the non-scientist community	*Describe methods to communicate study findings to subjects, colleagues, advocacy groups and non scientist community.*			*Demonstrate the ability to present clinical research findings across the various stakeholders and in particular subjects and their family members.*			*Demonstrate the ability to train, guide and support study team members on how to effectively communicate with various stakeholders in a manner that is relevant to the audience.*		

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LET'S TALK ABOUT THE CLINICAL RESEARCH WORKFORCE

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STATS THAT MATTER

Unprecedented Staff Turnover
In 2022, the resignation rate was **60%** higher than in 2020

Lack of Diversity
Under-representation in demographic groups in site staff leads to **under-representation** in clinical trial participants

Increasingly Specialized Roles
Technological innovations create new requirements for specialized skills with only **30%** of new clinical research postings matching typical job descriptions

Increasing Protocol Complexity
Data points have increased in Phase III trials **3x** over the past decade

Major Shortfall in Applicants
In 2022, there was a shortfall of almost **1 million** applicants compared to the amount of posted clinical research positions

Growing Number of Trials
Registered clinical trials have risen from **2,119** in 2000 to **433,207** in 2022

U.S. FOOD & DRUG ADMINISTRATION

"We can't have high quality data, and adequate protection for subjects, without an adequately staffed, properly trained, knowledgeable, and experienced research staff.

The FDA may only regulate the clinical investigator and sponsor, but the clinical research staff are the beating heart of the industry — and to the extent we may be able to support the continued development of clinical research staff, we are also going to be supporting the quality conduct of clinical research." (2023)

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SHARING A VISION FOR THE FUTURE

Increased awareness of the profession, career pathways, and how to get the training and experience needed to advance your career in clinical research

Greater collaborations across industry groups (e.g., ACRP, CTTI, SCRC, Avoca, TransCelerate, etc.)
to align efforts, share best practices, develop standards

Globally recognized entry-level competencies established with registered site organizations accepting this as their standard

Pipelines between grade schools, high schools, and colleges or training programs; pipelines between colleges and employers; more internships and mentorship

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CURRENT PACRW PROGRAM MEMBERSHIP

FUNDERS

MERCK

Genentech
A Member of the Roche Group

AdventHealth

Biogen

Duke
UNIVERSITY

florence.

HCA Healthcare®

Michael Smith
Health
Research BC

North Carolina
Biotechnology Center®

Northwell
Health®

parexel®

RUTGERS
THE STATE UNIVERSITY
OF NEW JERSEY

Jefferson
Thomas Jefferson University
HOME OF SIDNEY KIMMEL MEDICAL COLLEGE

UCDAVIS
UNIVERSITY OF CALIFORNIA

THE UNIVERSITY
of NORTH CAROLINA
at CHAPEL HILL

Veeva

COLLABORATORS

CONSORTIUM OF ACADEMIC PROGRAMS
IN CLINICAL RESEARCH

FDA U.S. FOOD & DRUG
ADMINISTRATION

ARCS
AUSTRALIA

EUCROF
European CRO Federation

NIH National Institutes of Health
Turning Discovery Into Health

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PARTNERS ADVANCING THE CLINICAL RESEARCH WORKFORCE

Ensure a diverse, research-ready and sustainable clinical research workforce essential to advancing therapies that improve global human health

STRATEGIC PRIORITIES

BUILD AN IDENTITY

Build a powerful brand and professional identity for the clinical research profession

CHANGE HOW WE HIRE

Drive industry-wide adoption of a [competency-based] approach to hiring entry-level clinical research professionals

OPEN DOORS TO A NEW CAREER

Ensure access for all to education, training, and professional development in the clinical research industry

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Thought Leadership

This white paper explores the growing workforce shortage in clinical research, its root causes, and disruptive ways to turn barriers into bridges.

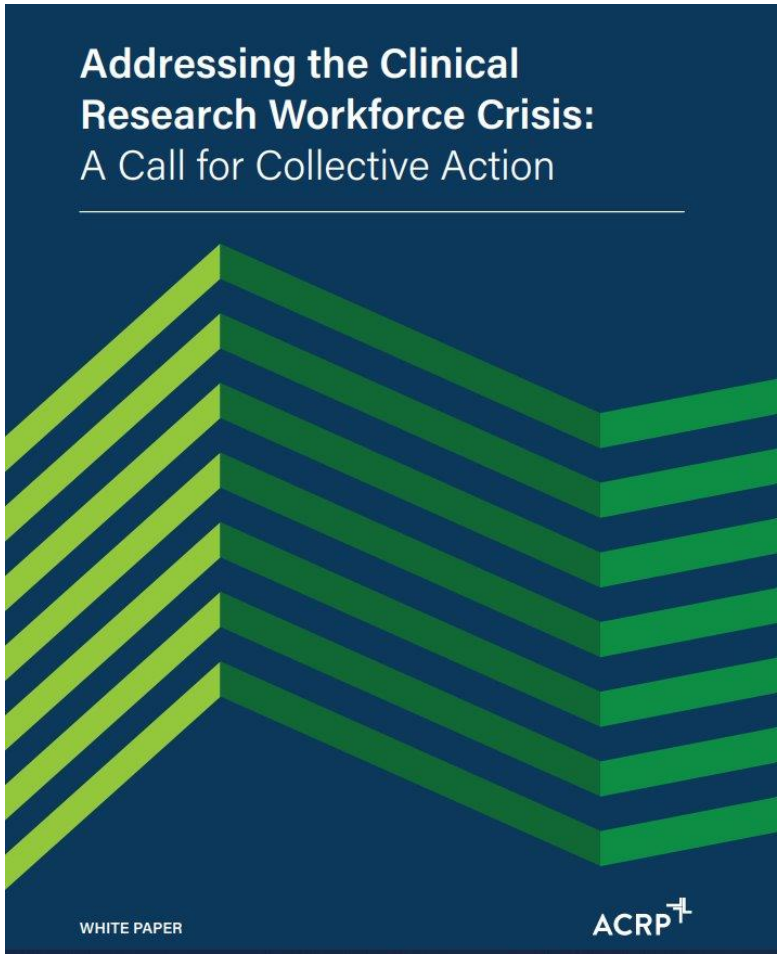
Thought Leadership

"A glaring disconnect is evident between the visionary discourse on how to revolutionize the clinical research enterprise and the sober recognition that operationalization of any such vision rests on the shoulders of a workforce that's in dire straits."

"Just as clinical research is the bedrock of drug and device development, sites are the bedrock of clinical research operations so, when sites cannot perform, the entire industry suffers."

"Alongside these costly delays, the workforce crisis imperils the quality of clinical research, including compliance with good clinical practice and the integrity of the data generated."

Thought Leadership



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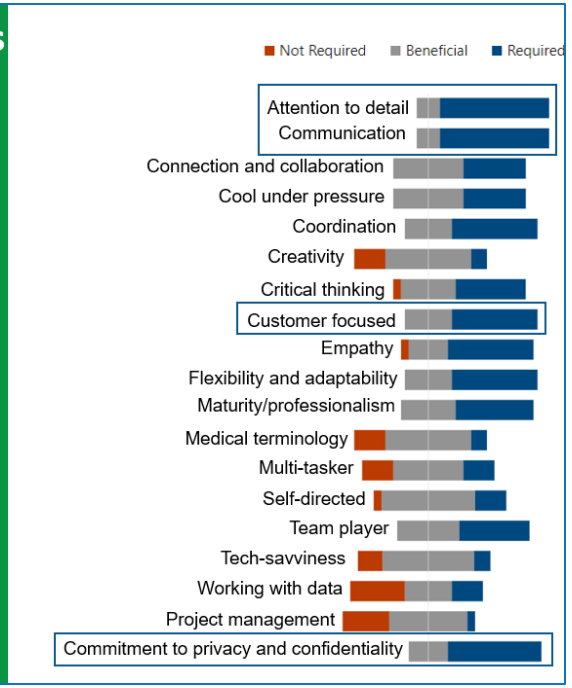
Defining A Skill-Set Based Approach

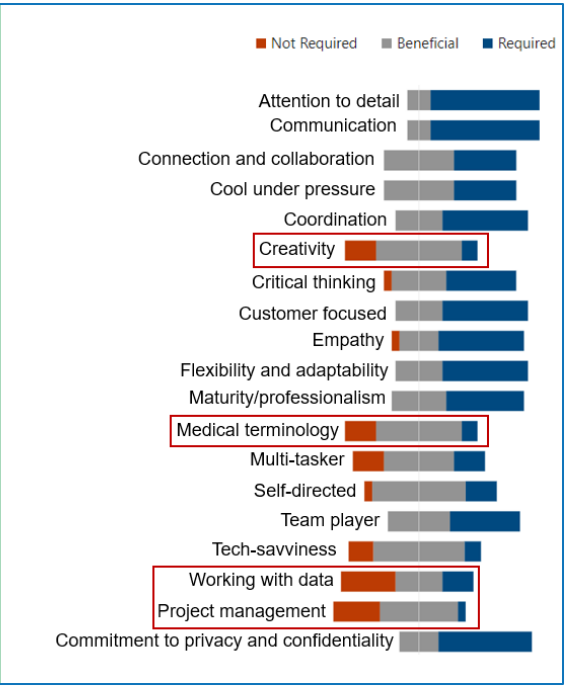
Results - Most Required Skills/Abilities

- **Attention to detail:** The ability to demonstrate thoroughness and accuracy when accomplishing a task; ensures accuracy in data collection, documentation, and adherence to protocols, which is essential for maintaining the integrity of clinical trials.
  0% Not Required; Beneficial 17.6%; Required 82.4%
- **Communication:** Excellent verbal and written communication skills are important for interacting with study participants, healthcare professionals, and team members, as well as for preparing documents and correspondence.
  0% Not Required; Beneficial 17.6%; Required 82.4%
- **Commitment to privacy and confidentiality, professionalism:** Demonstrated understanding of the importance of maintaining confidentiality of sensitive information, adherence to professional standards, and ethical conduct in handling patient data and interactions.
  0% Not Required; Beneficial 29.4%; Required 70.6%
- **Customer Focused:** Prioritizes the needs and experiences of research participants, ensuring their safety, comfort, and understanding throughout the study.
  0% Not Required; Beneficial 35.3%; Required 64.7%



Results – Least Required Skills/Abilities

- **Project management with long-term projects:** Ability to assist in managing long-term projects, which may involve coordinating various tasks, tracking milestones, and ensuring timely completion.
  35.3% Not Required; Beneficial 58.8%; Required 5.9%
- **Working with data, including preparation of quality graphs and tables:** Comfort with handling data, including organizing, analyzing, and presenting data in a clear and concise manner.
  41.2% Not Required; Beneficial 35.3%; Required 23.5%
- **Creativity:** The ability to think outside the box when addressing problems and identifying solutions.
  23.5% Not Required; Beneficial 64.7%; Required 11.8%
- **Medical terminology:** Understanding medical terminology is necessary for effectively communicating with healthcare professionals and accurately documenting study-related information.
  23.5% Not Required; Beneficial 64.7%; Required 11.8%



Classification, Recognition Through Data

- Clinical research workforce lacks clear classification and recognition
- Need trusted workforce data to support recruitment, training, and career pathways
- Insights will help shape future policies and initiatives

U.S. BUREAU OF LABOR STATISTICS

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Bureau Labor Statistics & Standard Occupational Classification Code

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Docket ID (BLS-2024-0001). Stand
Classification (SOC) – Updates fo

Executive Summary

The Association of Clinical Research Profess
Bureau of Labor Statistics (BLS) recognize th
researcher by introducing a detailed occupat
Healthcare Professionals classification. Our

Clinical research brings us new medicines

- Clinical research is the global industry be
health research. This industry drives the
medicines and new medical devices for h
their safety and effectiveness. Apart from
clinical research is the world's most glob
- The clinical research industry is growing
clinical trials rose from 2,119 in 2000 to 4
to increase still further to keep pace with
discovery powered by artificial intelligen
- The U.S. clinical trials market is forecast
expected to increase to $41.57 billion by 2033, growing at a compound annual growth rate (CAGR) of 4.88% over this period.[2]

Clinical researchers are distinct from other healthcare workers

- Clinical research professionals are specifically trained professionals who conduct and oversee clinical research. The remit of clinical researchers is to ensure that clinical research is conducted in accordance with rigorous scientific and ethical laws and guidelines, designed to protect trial participants and to safeguard data quality. To the best of our knowledge, the BLS SOC categories provide no indication of the existence of a large group of interrelated jobs dedicated to the field of clinical research.
- Clinical research is a distinct grouping of jobs with distinguishable competencies and responsibilities that require bespoke training and certification.
- The occupation includes physicians, nurses, pharmacists, scientists, project managers, coordinators, and others who may design study protocols, recruit patients, monitor study conduct, collect and analyze data, and prepare study reports and scientific publications.
- Most clinical researchers do only clinical research and do not have concurrent roles in healthcare. Their work is therefore distinct from that performed in occupations that already have a code.

We believe a new code is warranted by the existence of a large and distinct grouping of jobs within the clinical research occupation and by the substantially distinguishable competencies, training, and responsibilities demanded of the occupation. Many of the skills required of today's clinical researchers reflect transformational technological advances in drug and device development over the past decade. With the exception of Principal Investigators, who are physicians that mostly provide routine care to patients in parallel with their work on clinical trials, all other roles often perform only clinical research. The exceptional contribution of clinical researchers to the development of COVID-19 vaccines and antivirals at unprecedented speed[17] illustrated the essential nature of this workforce.

Clinical Research Competencies: Education and training for the clinical research profession is built upon a framework that defines the knowledge, skills, and attitudes necessary for conducting safe, ethical, and high-quality clinical research. The Joint Task Force for Clinical Trial Competency (JTF) has developed a framework that is distinct to the clinical research occupation (*Figure 5*).[3] This is used to define professional roles and performance evaluations, education and training requirements, and certification criteria and continuing professional development needs, and to facilitate regulatory compliance, quality improvement, and financial status of the clinical research process.

Figure 5: Joint Task Force for Clinical Trial Competency (JTF) Framework: Core Competencies

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Workforce Data & Labor Market Information

Workforce Visibility

Highlights the size, scope, and impact of the clinical research workforce, demonstrating its importance within healthcare and innovation

Defining the Profession

Clarify distinct roles, responsibilities, and competencies of clinical research professionals, supporting ACRP's push for a dedicated "Clinical Researcher" occupation code.

Addressing Workforce Gaps

Identify shortages and skills gaps and enable evidence-based advocacy for workforce development initiatives

Justifying Investment

Provide a foundation for industry, academia, and policymakers to invest in clinical research workforce training and professional growth

Building Professional Recognition

Reinforce the value of clinical research professionals, enhancing visibility, credibility, and recognition within healthcare systems and the broader labor market

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Workforce Data Survey

- Build trusted source for data about the clinical research workforce
  - Identify where CRPs are needed most and what skills are in demand
  - Support targeted training programs, recruitment strategies, and the development of clear career pathways
  - Highlight opportunities to promote workforce diversity, leading to more inclusive and representative clinical research
- Phase I: Focus groups with employees and employers about what should be included in the survey

Fitzhugh Mullan Institute for Health Workforce Equity
THE GEORGE WASHINGTON UNIVERSITY

ACRP

Focus Group Design

Discussion Themes	Career pathways and training
	Workforce challenges: pay, workload, retention
	Recruitment strategies and workforce diversity
	Industry needs and future workforce planning

Key Questions for CRPs

- How did you enter the clinical research field?
- What does a typical workday look like for you?
- Career development opportunities & challenges?
- Biggest workforce issues (burnout, workload, compensation, career advancement)?

Key Questions for Employers and Supervisors

- What roles are critical to your research operations?
- How do you recruit and retain CRPs?
- What are the biggest hiring challenges?
- Is there a clear career ladder for CRPs in your organization?
- What data would be useful in a workforce survey?

Scholarships For Access & Advancement

Access for Students to Clinical Research Training (ASCRT) Scholarships

- Provides minority students with financial support for education and training
- 2025: 33 applications from 7 countries; 4 candidates were awarded $5,000 scholarships in Career Entry and Professional Growth Pathway

Continuing Education Grants

- $2,000 to clinical researchers from minority groups to attend the ACRP 2025 Annual Conference
- 83 applications were received and 15 candidates awarded 2025 ACRP Continuing Education Grants

Transformation of the Clinical Research Enterprise Survey

Clinical researchers say clinical trials are better conducted today compared to 5-10 years ago, but the majority agree that clinical trials are still inefficient.

- The top area of improvement in the past 10 years has been trial data quality, with 50% of respondents identifying it as improved
- Yet, 52% note that hiring and retaining staff has gotten worse

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Thank You!

The industry has the opportunity to address the workforce issue in a way that it never has looked at it before.

FDA U.S. FOOD & DRUG ADMINISTRATION

“Solve difficult problems with great people.”

PARTNERS ADVANCING THE CLINICAL RESEARCH WORKFORCE

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MULTI-REGIONAL CLINICAL TRIALS
THE MRCT CENTER OF BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

Discussion

Barbara Bierer, MD
Faculty Director, MRCT Center
Co-Chair, JTF
Stephen Sonstein, PhD
Co-Chair, JTF

Joint Task Force for Clinical Trial Competency (JTF)

Biannual Global Meeting

June 2, 2025
9:00 – 11:00 AM ET

MULTI-REGIONAL CLINICAL TRIALS
THE MRCT CENTER OF BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

To register: https://mrctcenter.org/tribe-events/joint-task-force-for-clinical-trial-competency-jtf-global-biannual-meeting-2/

MULTI-REGIONAL CLINICAL TRIALS
THE MRCT CENTER OF BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

Thank you!

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