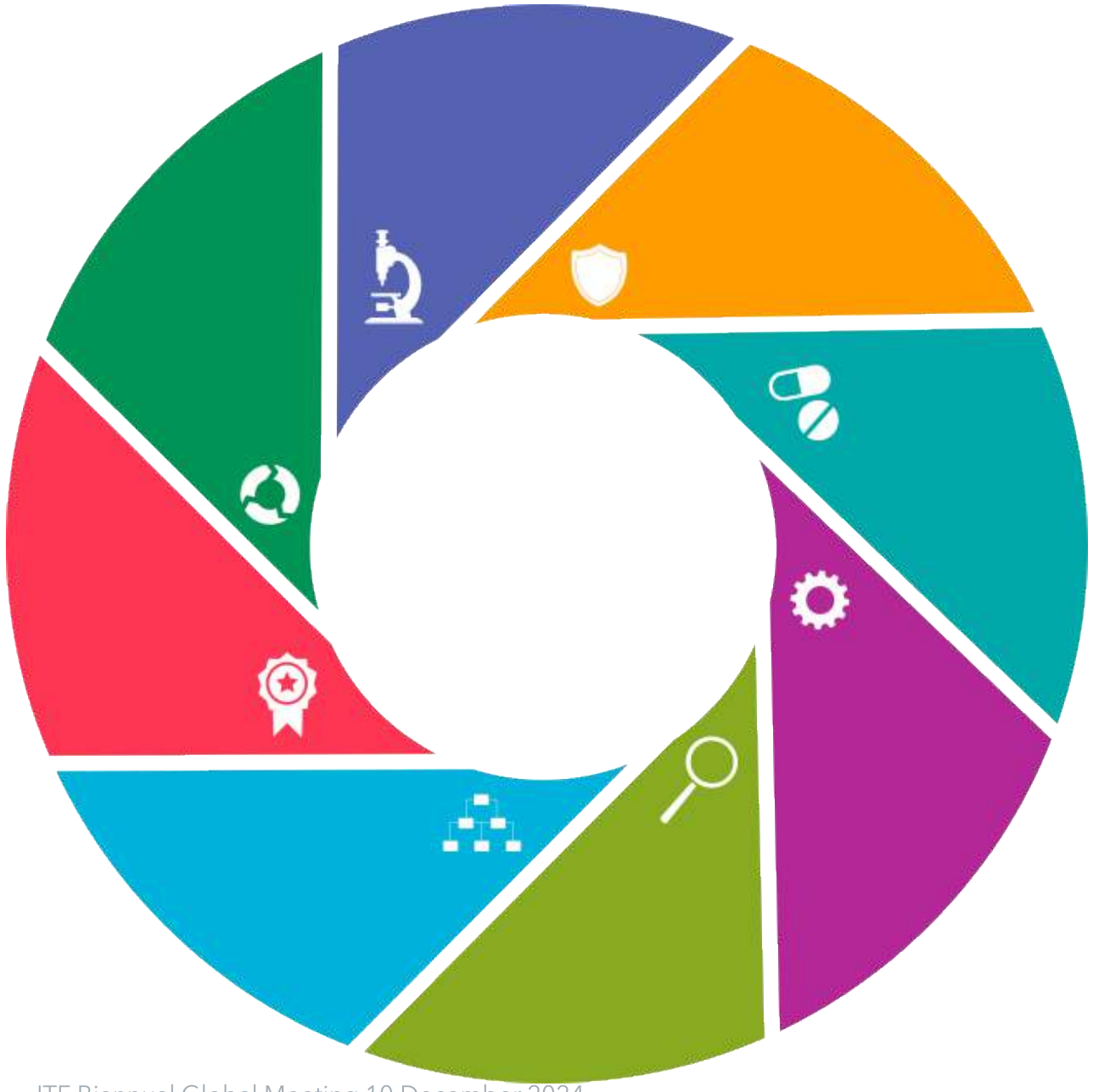
MULTI-REGIONAL CLINICAL TRIALS

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

Joint Task Force for Clinical Trial Competency (JTF)

Biannual Global Meeting

December 10, 2024



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Introduction

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

This Meeting

We are recording this meeting for note-taking purposes.

We plan to post slides and an executive summary of the meeting on the JTF website.

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, Harvard University, or any of the institutions or organizations represented today.

The MRCT Center is supported by voluntary contributions from foundations, corporations, international organizations, academic institutions, and government entities (see www.MRCTCenter.org) and by grants.

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 EST	Topic	Speaker / Facilitator
9:00-9:15	Introduction Overview JTF Slide deck JTF Webinar	**Barbara Bierer, MD** Co-Chair, JTF Faculty Director, MRCT Center **Stephen Sonstein, PhD** Co-Chair, JTF Consultant, MRCT Center
Use of the JTF Framework		
9:15-9:30	Training modules using the JTF Framework	**Benjamin P. Sablan, JR., MD, MDM** Director National Clinical Trials and Translation Center University of the Philippines Manila
9:30-9:45	How ROCHE and AICIB Used the JTF Framework to Enhance Clinical Trial Competency in Portugal	**Mónica Bogas, MD** Head of Clinical Operations Roche Farmacêutica Química, Lda Portugal
9:45-10:00	Training Community Health Workers (CHWs) for the Vital Jobs in Clinical Research and Expanding the Workforce Directly into Communities	**Amin Yakubov, MPH, MBA, ACRP-CP** Associate Director- Research Operations Clinical & Translational Science Institute (CTSI) NYU Langone Health Brooklyn **Emily Drum, MPH** Program Manager, Research Education and Strategic Initiatives Clinical & Translational Science Institute (CTSI) NYU Langone Health Brooklyn

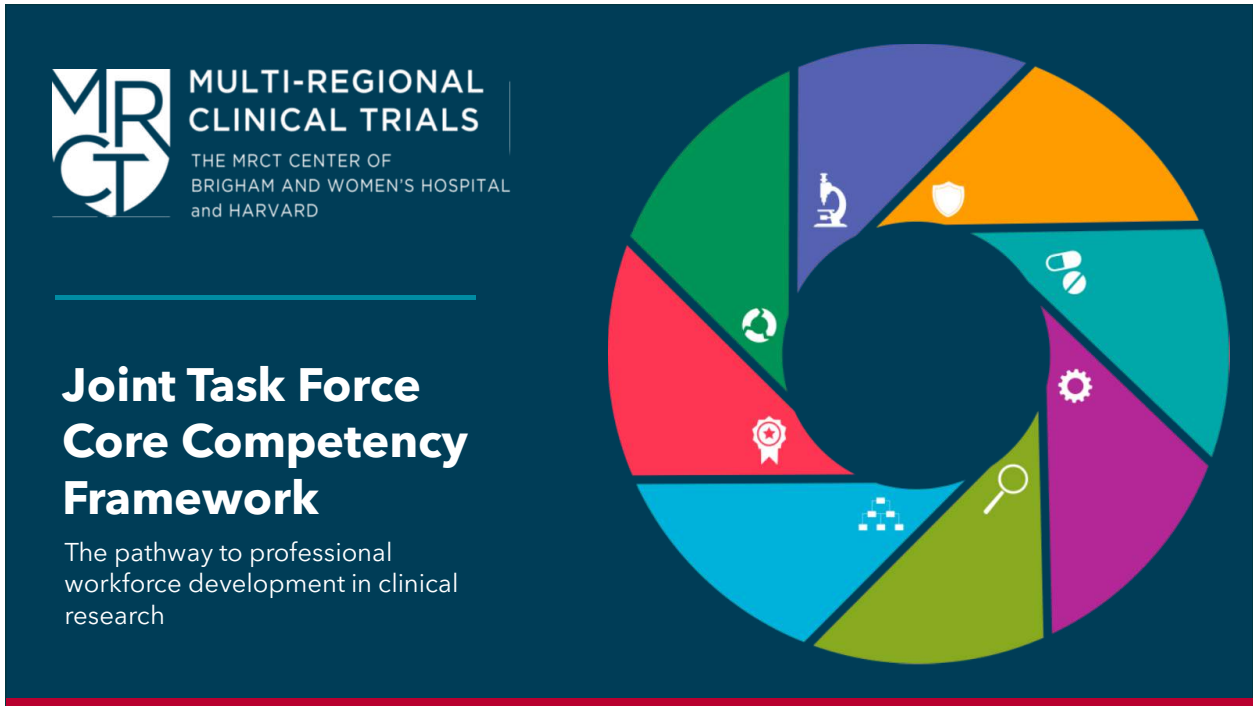
Agenda (cont.)

Time EST	Topic	Speaker / Facilitator
Updates to the JTF Framework		
10:00-10:15	Data Management update: Results from Delphi	**Meredith Zozus, PhD** Professor, Division Chief, Clinical Research Informatics University of Texas (UT) Health San Antonio, Long School of Medicine, Department of Population Health Sciences
10:15-10:30	Patient Participants Task Force	**Sylvia Baedorf Kassis, MPH** Program Director Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard
10:30-10:45	Team Science Competencies for Clinical Research Professionals: A Multi-Leveled Delphi Approach	**Carolynn Thomas Jones, DNP, MSPH, RN, CRN-BC, FAAN** Clinical Professor, College of Nursing Director, Master of Clinical Research, College of Nursing Co-Director of Workforce Development, OSU Clinical Translational Science Institute The Ohio State University
10:45-11:00	Discussion and Wrap-up	**Barbara Bierer, MD** Co-Chair, JTF Faculty Director, MRCT Center

JTF Slide Deck

The JTF has developed a PowerPoint presentation that describes the Core Competency Framework and its uses. This presentation can be used for instructional purposes and for training programs.

https://mrctcenter.org/clinical-trial-competency/resources/introductory-jtf-core-competencies-framework-powerpoint/



JTF Webinar: 3 April 2025, 9:00-10:00 AM EDT

Global development of a clinical research workforce: tools and resources

- Utilizing the JTF framework to define and develop competencies in clinical research
- Developing the education and training paradigm for the clinical research workforce
- Recruiting and retaining a diverse and representative clinical research workforce

Keynote speaker: Lembit Rägo, MD, PhD
Secretary-General, Council for International Organizations of Medical Sciences (CIOMS)

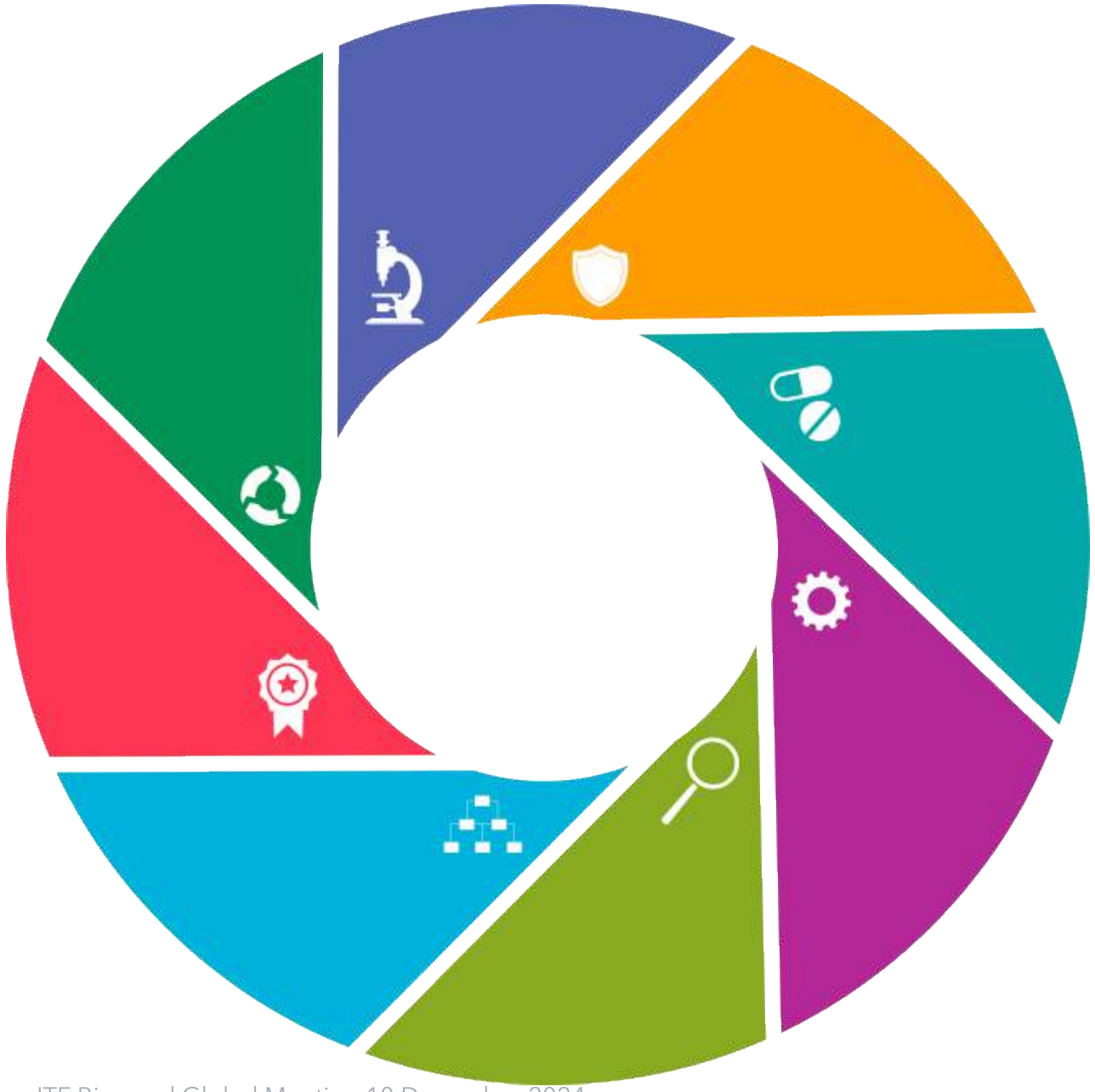
[Global Workforce Development: Tools and Resources]

Next JTF Biannual Global Meeting

29 May 2025, 1:00-3:00 PM EDT

Please note different timeframe to allow people from different time zones to participate

Registration will be available next year



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Training modules using the JTF Framework

Benjamin P. Sablan, JR., MD, MDM

Director

National Clinical Trials and Translation Center

University of the Philippines Manila

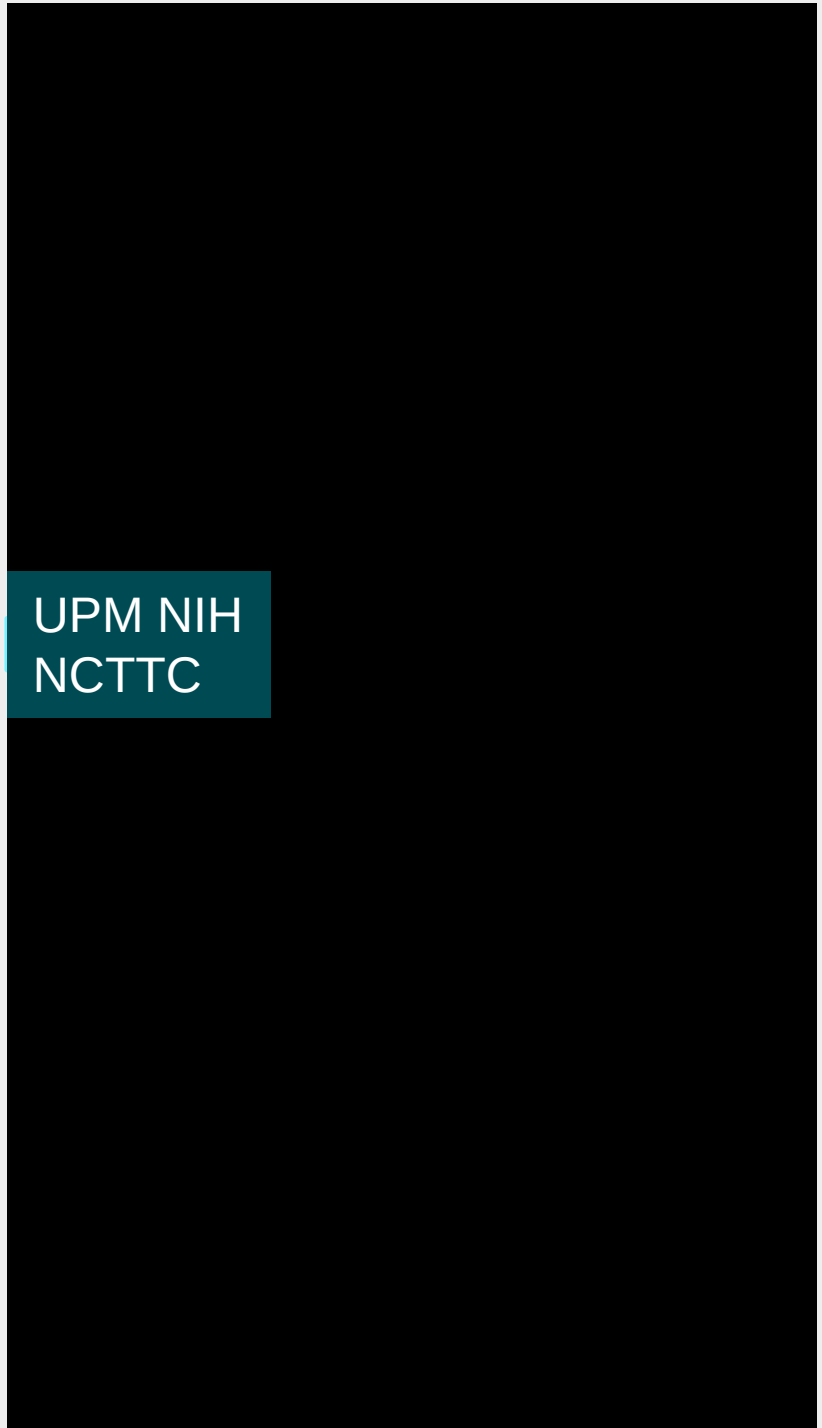
nctc

NATIONAL INSTITUTES OF HEALTH
NATIONAL CLINICAL TRIALS
AND TRANSLATION CENTER

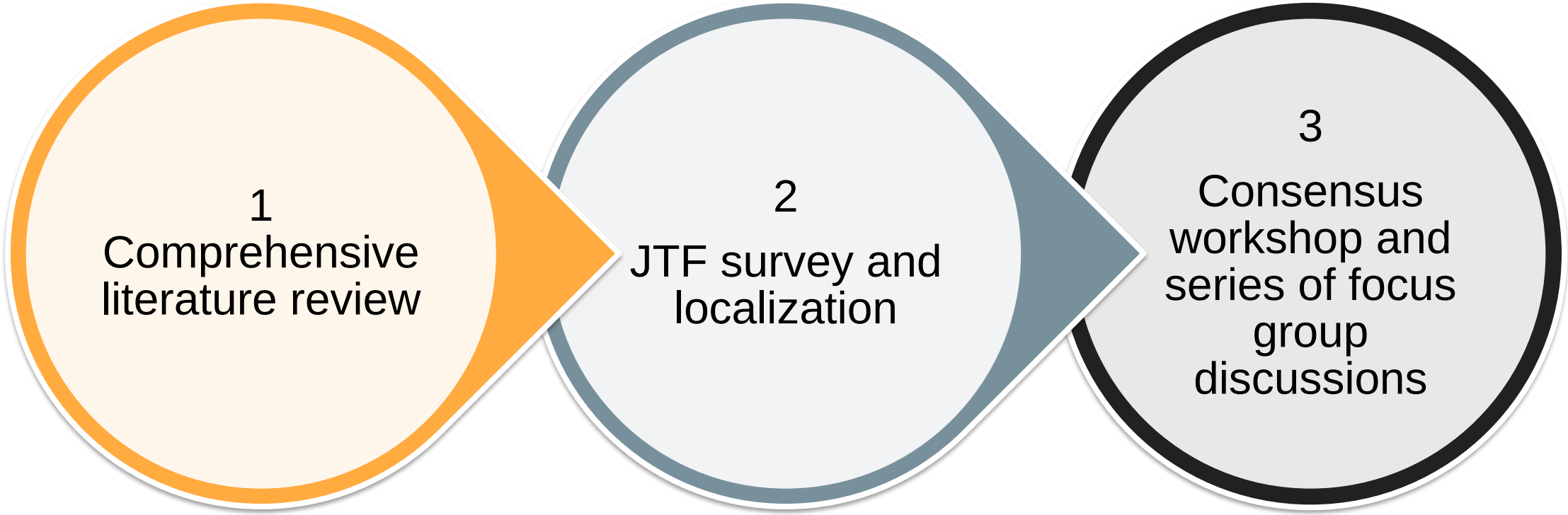
VISION

The National Clinical Trials and Translation Center of the UP National Institutes of Health is a globally recognized institution for state-of-the-art clinical trial management and resource center by 2028.

- To provide a central hub for the clinical trial operations of multicenter or multinational clinical research;
- To significantly increase Filipino participation in local and international clinical trials research;
- To encourage Filipino researchers to conduct research on new drugs, devices, and innovations; and
- To translate research findings into relevant policies, technologies, and products for improving health outcomes of the Filipinos.

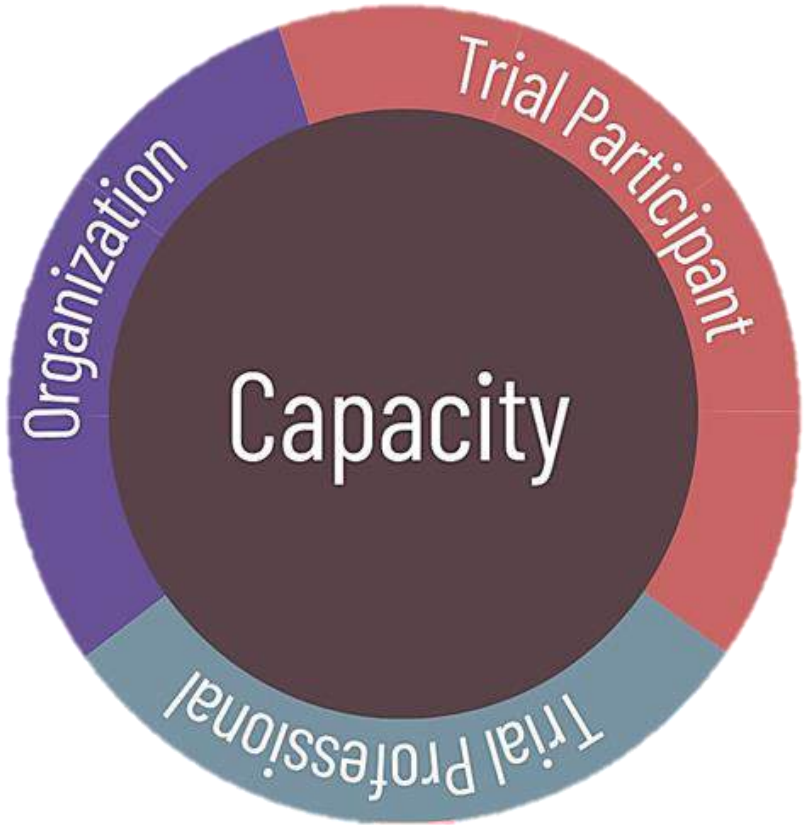


METHODOLOGY



UPM with support from AMED through the ARISE network of NCGM

NCTTC LOCALIZED CLINICAL RESEARCH FRAMEWORK

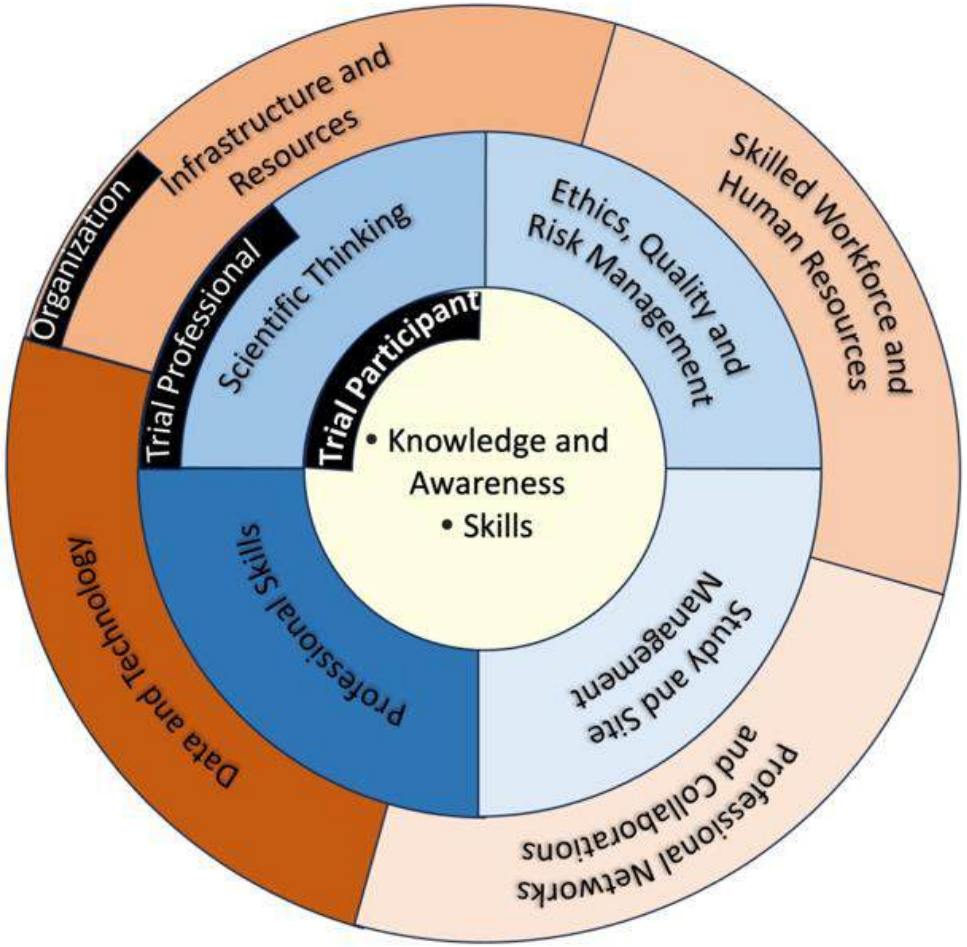


Supported through the NIH Commissioned Grants scheme and DOST GIA

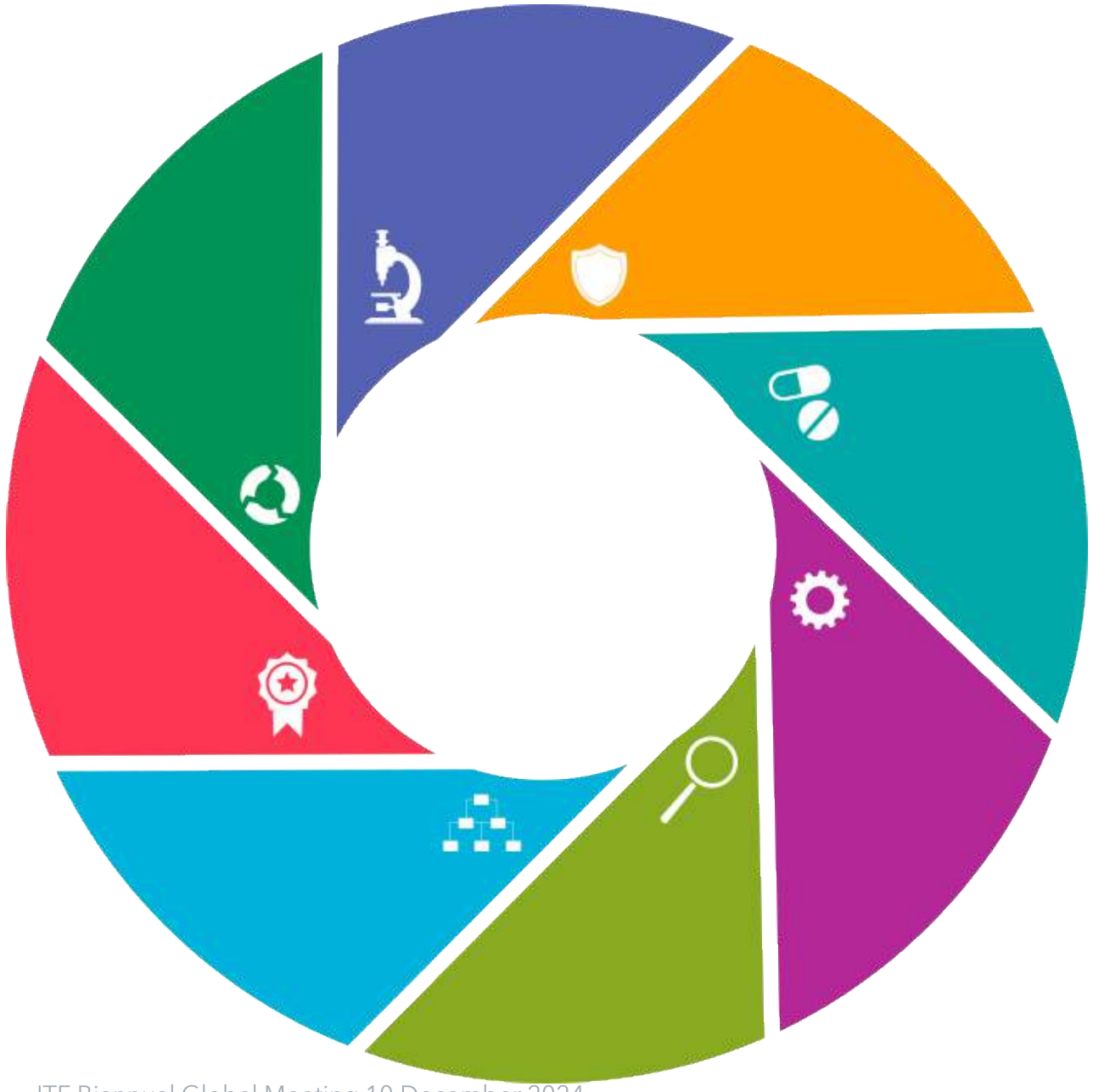
*Under embargo until publication by the authors**

* *Arianna Maever L. Amit, Edwin C. Ruamero, Anna Maria S. Ordinario, Benjamin P. Sablan*

THE NCTTC CLINICAL TRIAL TRAINING MODULES



1. Program Overview
2. Introduction to Clinical Research
3. Ethics and Regulations
4. Governance and Management of Clinical Research Studies
5. Scientific Concepts and Research Designs
6. Protocol Development
7. Data Management, Analysis, and Study Reporting
8. Good Clinical Practice
9. Protection of Clinical Research Staff
10. Budgets and Contracts



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How ROCHE and AICIB Used the JTF Framework to Enhance Clinical Trial Competency in Portugal

Mónica Bogas, MD

Head of Clinical Operations

Roche Farmacêutica Química, Lda

Portugal

How ROCHE and AICIB used the JTF Framework to enhance Clinical Trial Competency in Portugal

Mónica Bogas, MD
Country Head for Clinical Operations
Roche Portugal

Roche - A long term commitment

15+ years of partnership

I Curso de EC para Médicos

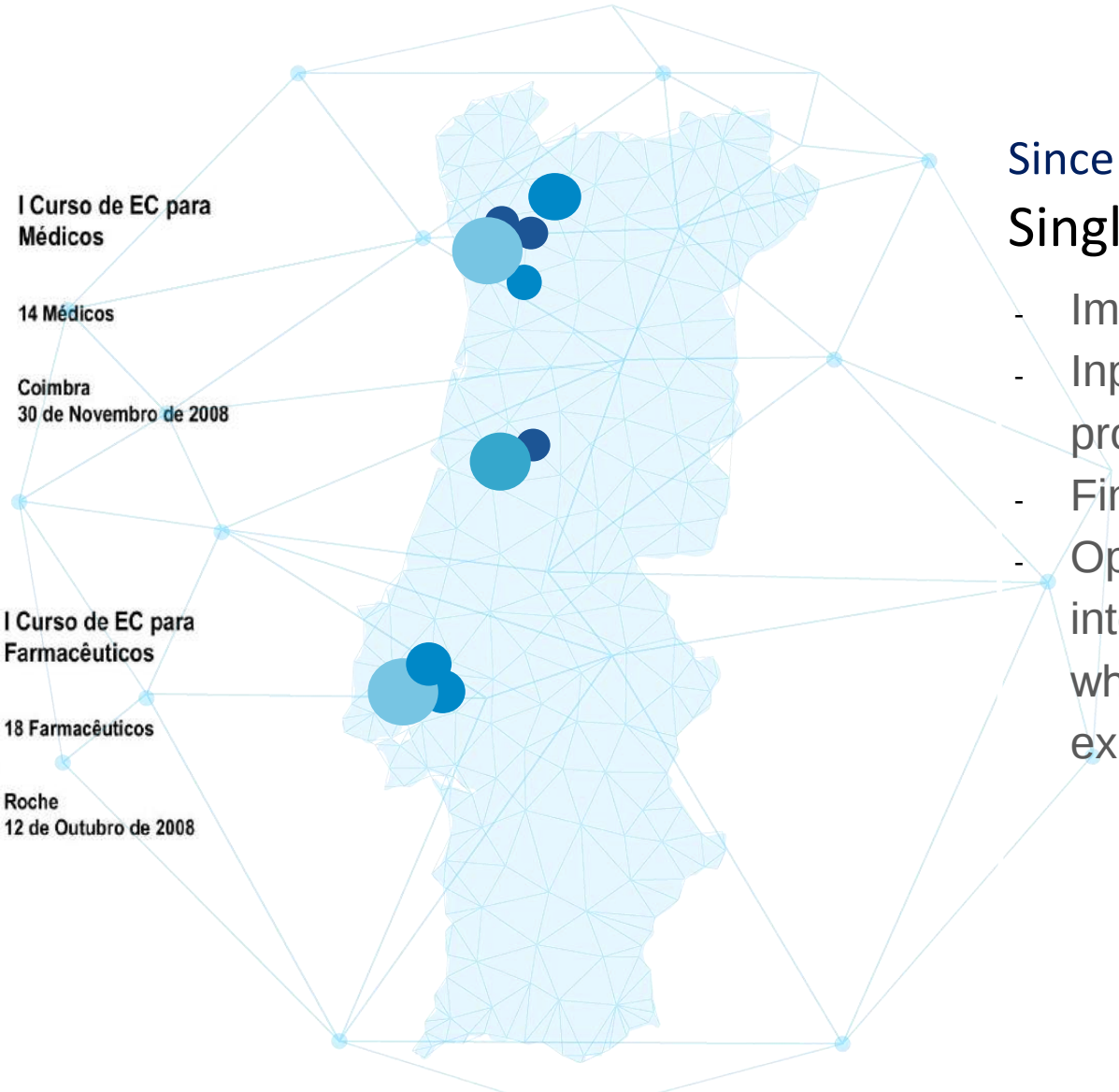
14 Médicos

Coimbra
30 de Novembro de 2008

I Curso de EC para Farmacêuticos

18 Farmacêuticos

Roche
12 de Outubro de 2008



Since 2019

Single Point of Contact

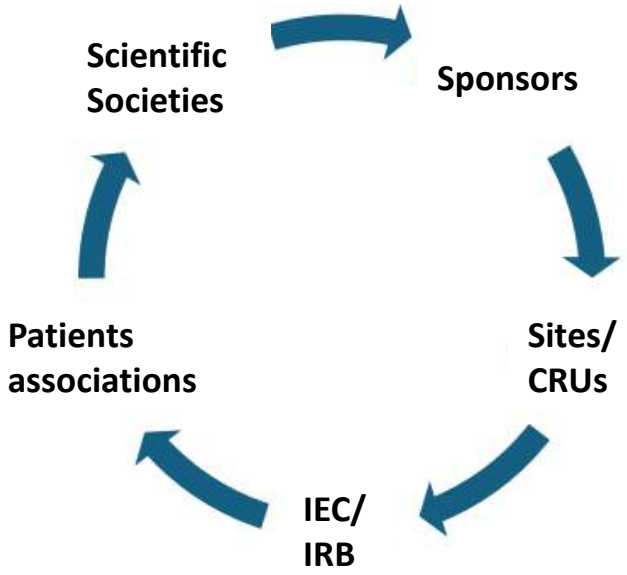
- Improved collaboration
- Inputs contributing to better process flow, metrics, quality
- Find win-win solutions
- Optimizing efficiency of the internal resources involvement while increasing site's customer experience satisfaction

Portugal Clinical Studies (*One Stop Shop*)

Act as a liason between different stakeholders, providing support, services and consultancy for clinical research

Increase Portugal competitivenss, attract investment for Clinical Research
either Industry promoted, either Investigator's initiated

Online Platform to support Clinical Research

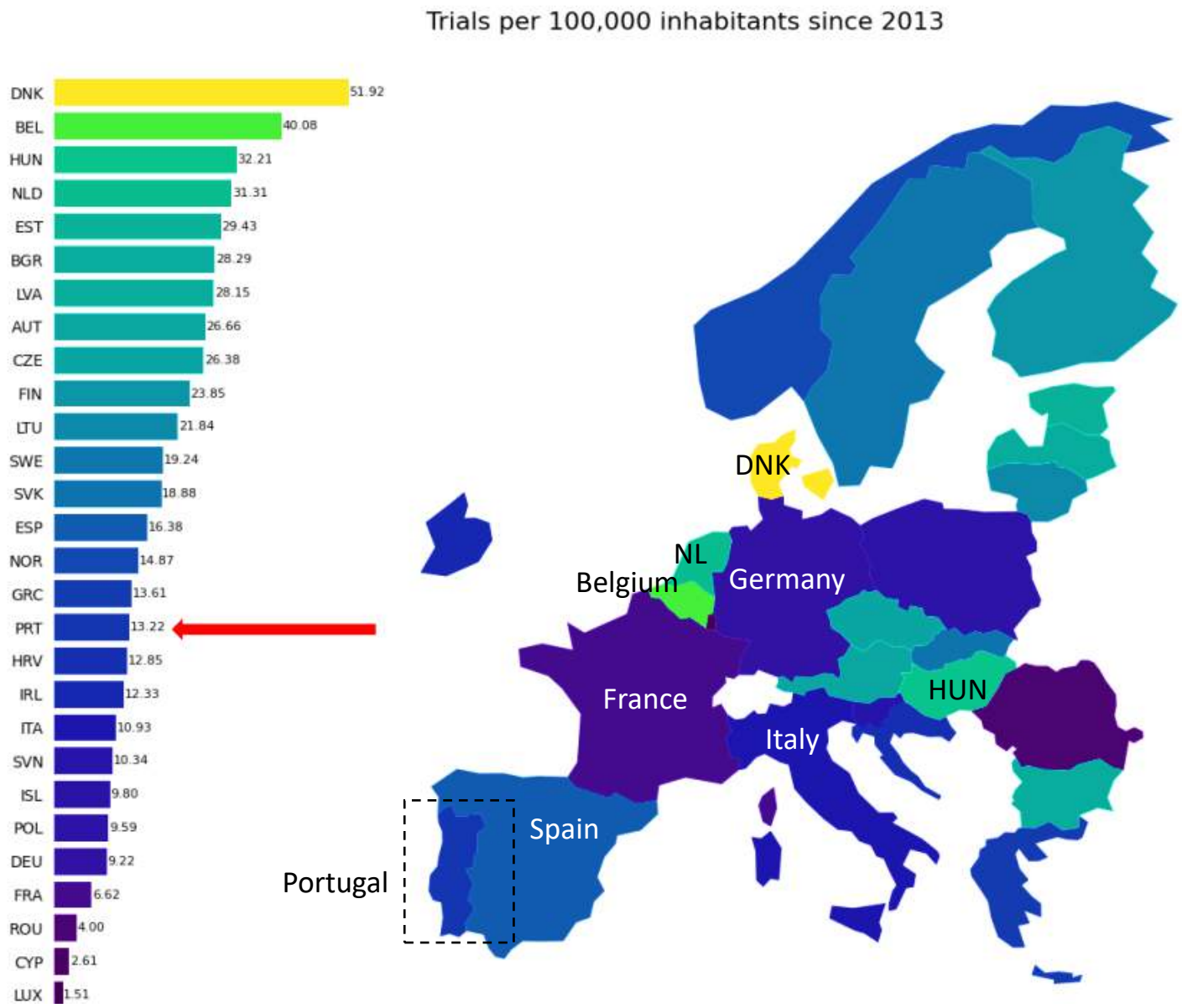


Portugal roadmap for increasing competitiveness in Clinical Trials

Actions aimed at large-scale diagnostic assessment of needs

- Actions aimed at large-scale training & empower

Human Resources & Training



No. of trials per 100,000 inhabitants – 2013 to 2024

Diagnostic assessment

- Many professionals report insufficient knowledge to conduct clinical trials with quality and in compliance with good practices
- Limited number of qualified professionals for clinical research
- High turnover of professionals in research support areas
- Need to enhance competencies for clinical research beyond good clinical practices
- Lack of career progression, training, and development opportunities

The "diagnostic" assessments conducted so far haven't focused on evaluating the knowledge/ skills of professionals involved in clinical research

JOINT TASK FORCE FOR CLINICAL TRIAL COMPETENCY

History

JANUARY 2013

The Joint Task Force for Clinical Trial Competency (JTF) was formed and the first face-to-face meeting was hosted by the Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard (MRCT Center) bringing together representatives from academic institutions, pharmaceutical companies, contract research organizations (CROs), clinical research sites, and professional societies.
The JTF established the goal of creating a universally applicable, globally relevant competency framework for the clinical research enterprise.

Brigham and Women's Hospital
Founding Member, Mass General Brigham

HARVARD UNIVERSITY

OCTOBER 2013

The JTF presented a report at the DIA Conference.

SPRING 2014

Harmonized Core Competency Framework for the Clinical Research Professional was published simultaneously in CenterWatch White Papers, Clinical Researcher, and Journal of Clinical Research Best Practices.

JOINT TASK FORCE FOR CLINICAL TRIAL COMPETENCY

History

OCTOBER 2016

Workshop on the JTF Harmonized Competency Framework—"Core Competencies in Clinical Research: Real World Applications, Convergence and Evolution of Framework"—hosted by the MRCT Center at Harvard University, Cambridge, MA. The workshop brought together clinical researchers from across the globe to discuss applications of the Framework, present real-life case studies, and collaborate on the evolution and revision of the Framework.

MARCH 2019

JTF Framework adopted as curricular basis for the accreditation of academic programs in clinical research by the Commission on Accreditation of Allied Health Education Programs.

MAY 2019

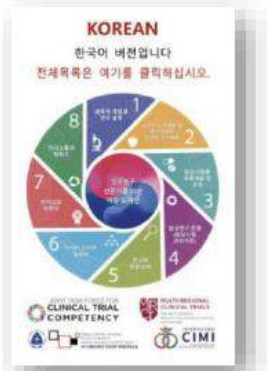
Spanish translation of the JTF Framework released.

48 publications
US and Worlwide

Center

JTF dissemination and impact

- Current translations (10):
  - English
  - Spanish
  - French
  - Japanese
  - Thai
  - Bahasa Indonesia
  - Italian
  - Chinese
  - Vietnamese
  - Korean



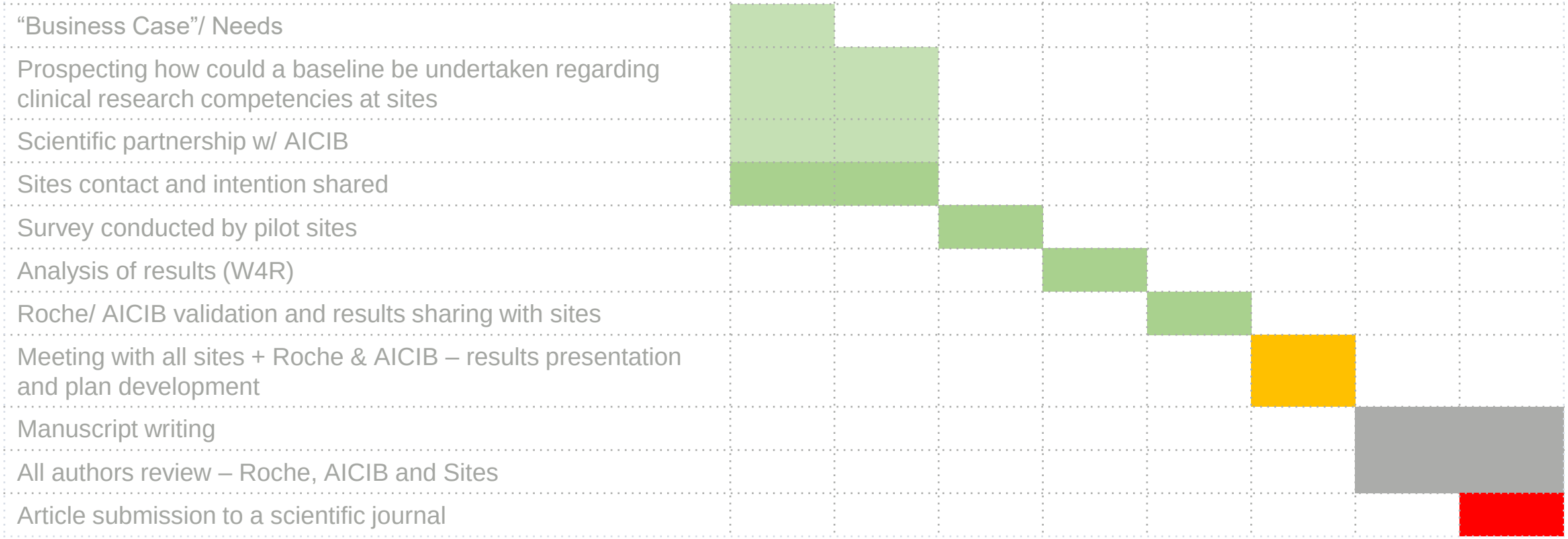
- Current CIOMS initiative:
  - *International Guidelines for Education in Medicines Development*
  - Working group has met 6 times
  - JTF has helped inform direction of competencies in education

Portuguese Translation!

Pilot: self-assessed competences of Clinical Research Professionals

Plan of actions | recommendations for advancing further

Objective of the study: to assess the competencies required to develop and/or conduct observational or interventional clinical studies – to develop recommendations/improvement plans



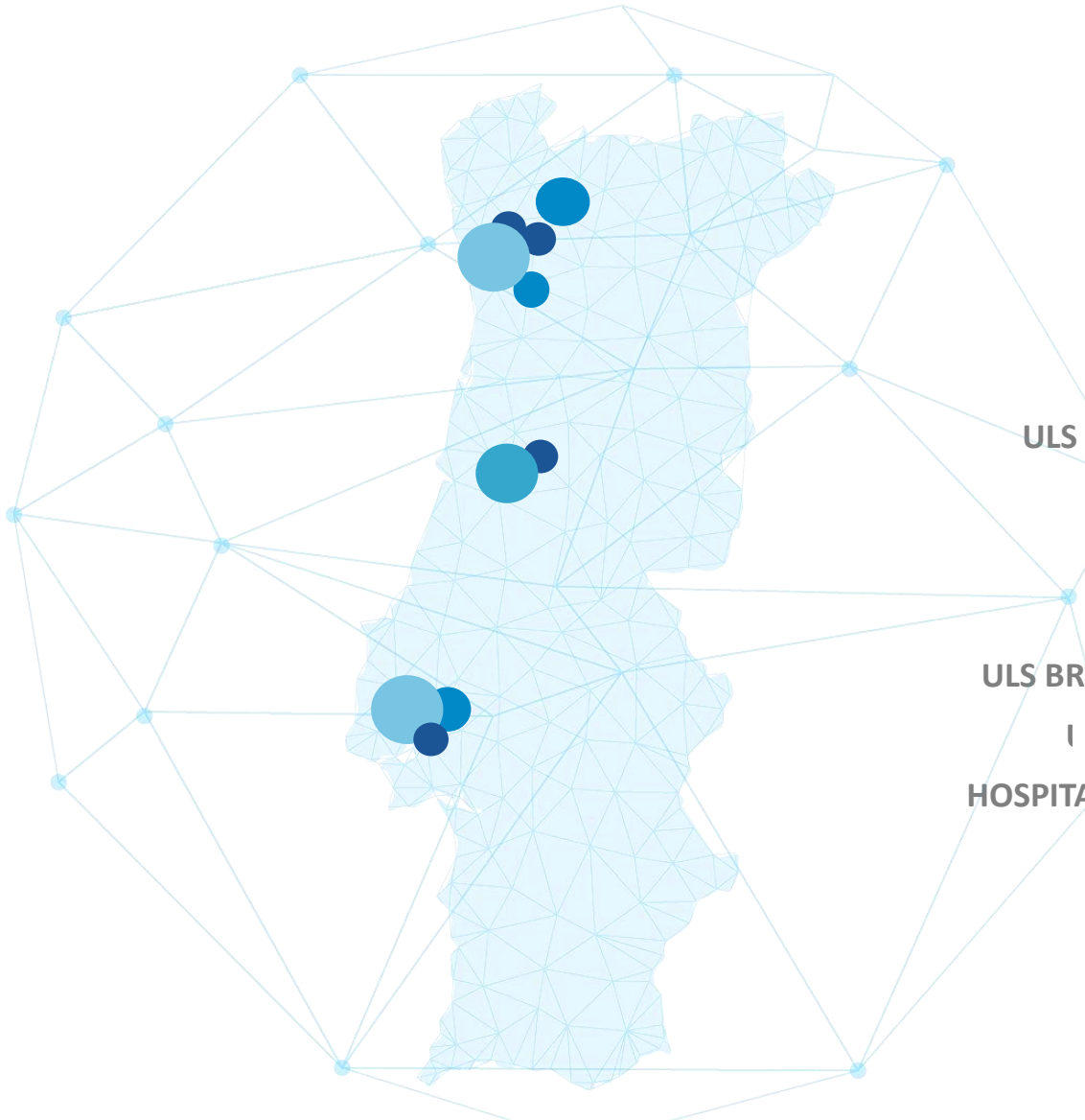
METHODOLOGY

Assessment of Knowledge and Competencies for Clinical Research

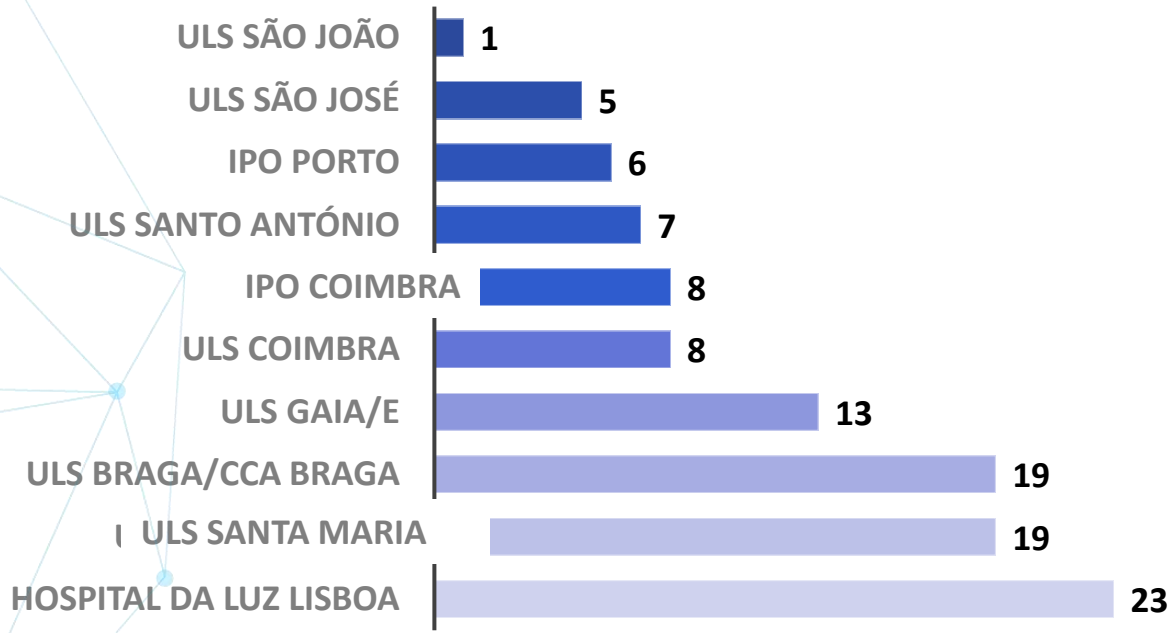
Roche-AICIB pilot using JTFCTC tool

The Joint Task Force for Clinical Trial Competency (JTFCTC) developed a tool to assess the knowledge, skills, and attitudes required to conduct clinical research in a safe, ethical, and high-quality manner

Participating Research Centers

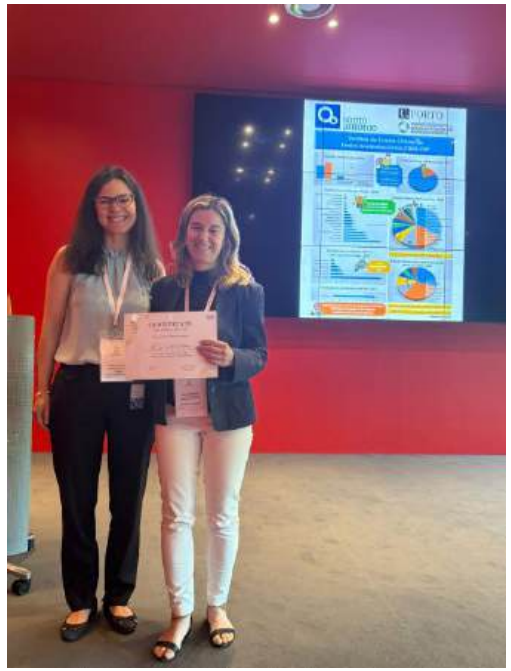


Participating sites (n=109)



RESULTS

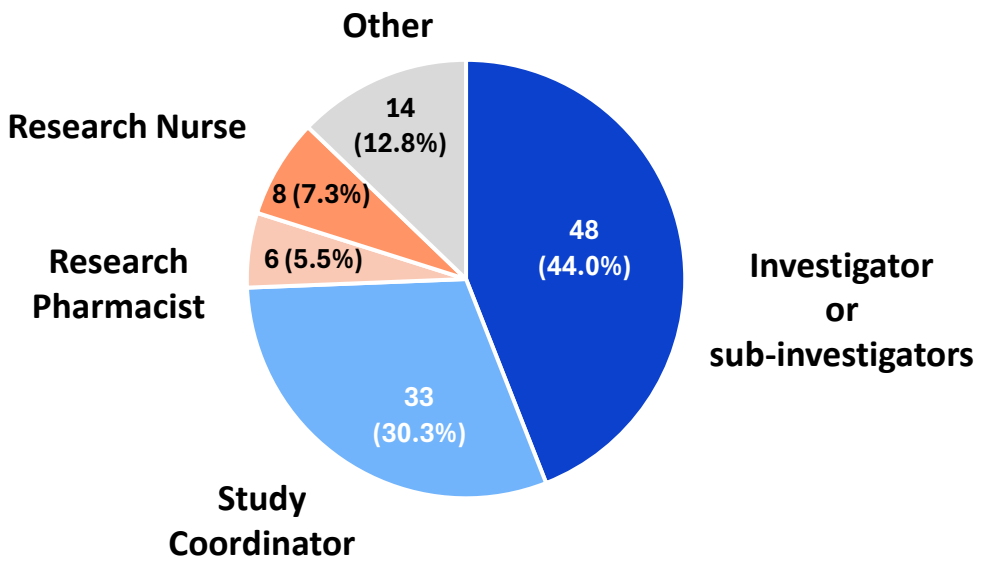
Meeting in Lisbon, June 6th



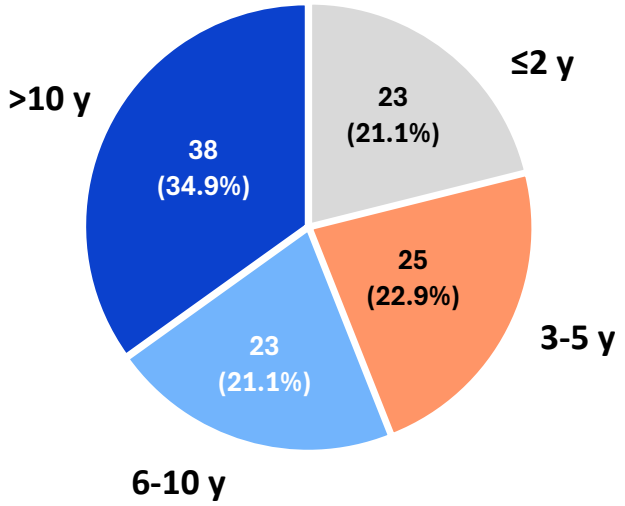
Sample

Most participants are **Investigators** (44.0%), followed by **Study Coordinators** (30.3%).
Over 50% of the participants have more than 5 years of experience

FUNCTIONAL ROLE IN THE STUDIES

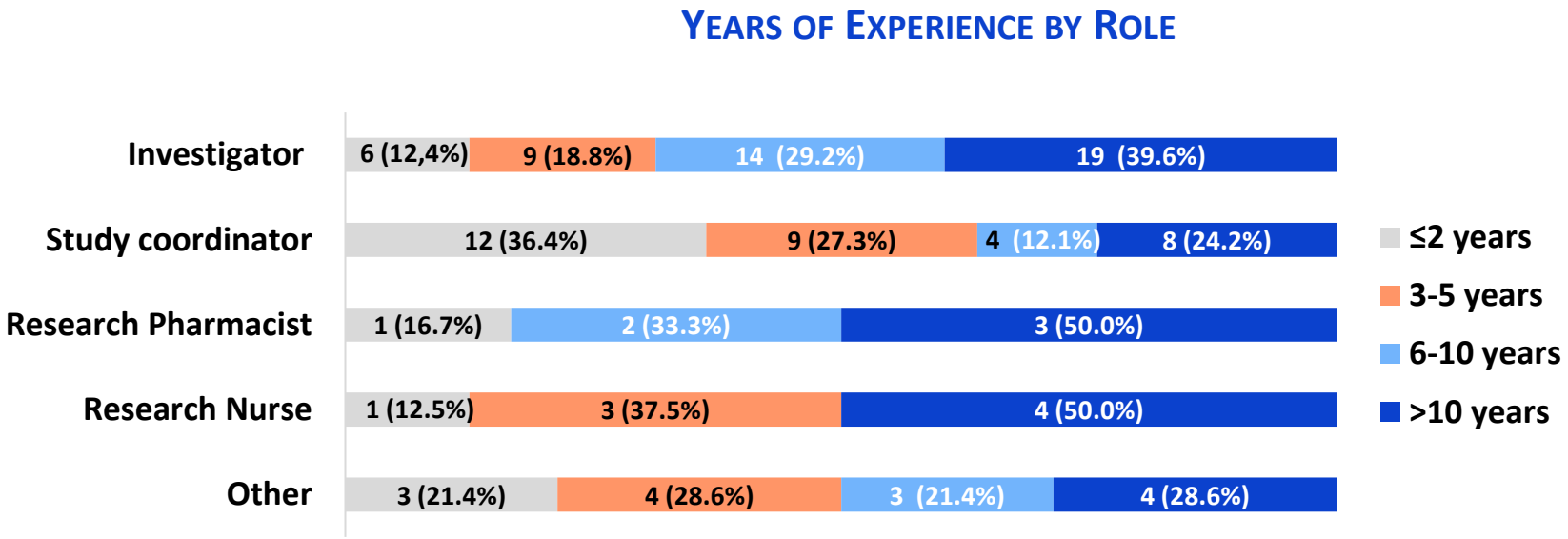


YEARS OF EXPERIENCE



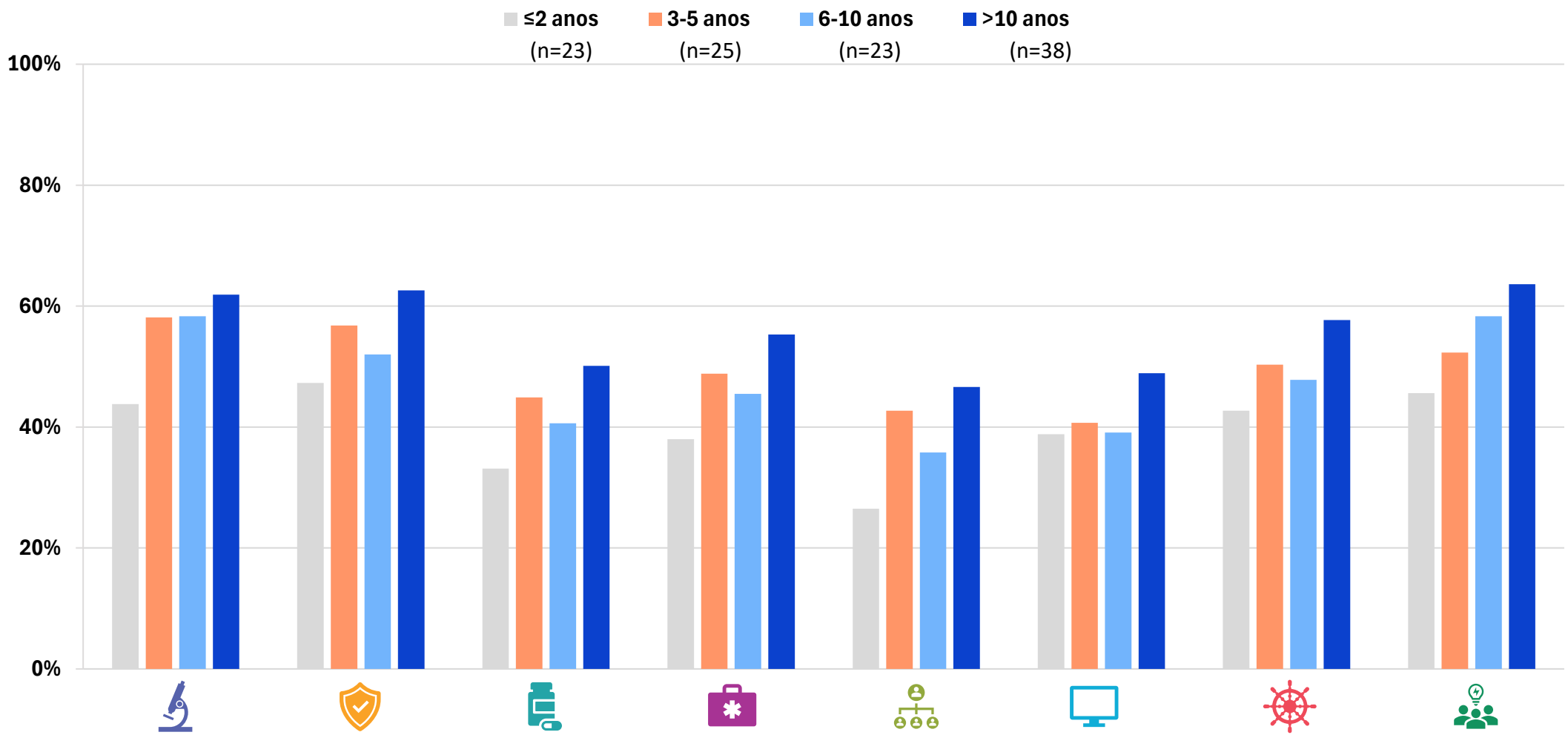
Sample

"**Study Coordinators**" group is the professional category with the least years of experience



Self-assessed Knowledge/ Competences at National Level

Knowledge/skills for clinical research increase with the **number of years of experience**



Multiple analysis

Domínio 1: Conceitos Científicos e Desenho da Investigação

As maiores dificuldades dos participantes relacionam-se com o serem capazes de manter um conhecimento atualizado das novas tecnologias, metodologias e técnicas e de fazer uma análise crítica dos resultados

Proporção de Participantes

Pontuação média

1.1 Aplicar os princípios das ciências biomédicas à

Domínio 2: Considerações Éticas e de Segurança dos Participantes

Avaliar e aplicar questões éticas relacionadas com aspetos comerciais e do produto experimental, bem como definir conceitos de equilíbrio clínico e equívoco terapêutico são os pontos que apresentam menor nível de

Pontuação

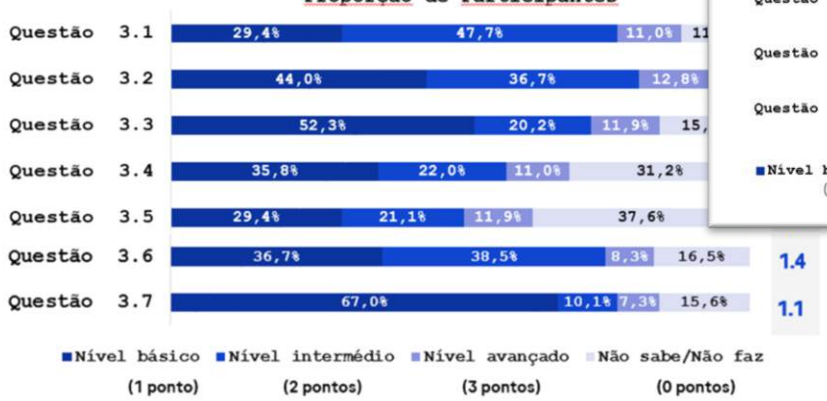
2.1 Dist
clínico

Questão
Questão
Questão
Questão
Questão
Questão
Questão
Questão

Domínio 3: Desenvolvimento e Regulament

A maioria dos participantes não sabe ou tem um nível básico de con
desenvolvimento e gestão do ciclo de vida do produt

Proporção de Participantes



3.5 Descrever as fases
autoridade regulament
mercado

3.6 Descrever requisito
segurança das agência
introdução no mercado

3.7 Avaliar questões le
na aprovação e regula

Domínio 4: Atividades dos Estudos Clínicos (Boas Práticas Clínicas - BPC)

A maioria dos participantes não sabe/ não faz ou tem um nível de conhecimento básico no que concerne a BPC

Proporção de Participantes

Pontuação média

4.1 Explicar enquadramento no objetivo de desenvolver uma nova intervenção

4.2 Descrever as funções e as responsabilidades da equipa de investigação clínica, tal como definida nas diretrizes de BPC

4.3 Avaliar o desenho, a realização e a documentação, em

rizes dos

mental

(AE) e explicar c
icação
gulamentares

lobais garantem
ante o estudo

ão de um estudo

Domínio 5: Gestão do Estudo e do Centro

O Enfermeiro e o Coordenador de estudos apresentam menor nível de conhecimento sobre a gestão de um estudo clínico
O grupo "Outro" reune maior pontuação média neste domínio

5.1 Descrever os métodos utilizados para determinar se deve promover, supervisionar ou participar num estudo clínico

5.2 Desenvolver e gerir as eficiências funcionais e operacionais e os recursos humanos necessários à realização de um estudo

s de gestão e formação para mitigar
ção de estudos clínicos.

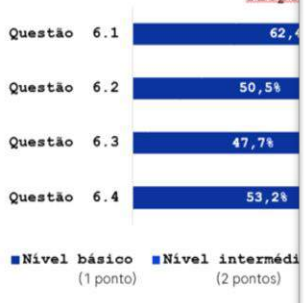
s para gerir o recrutamento e a
a conformidade e a monitorização

ação e gestão

Domínio 6: Tratamento de dados e informática

A maioria dos participantes tem um nível básico de conhecimento ou não sabe/ não desempenha funções relacionada
A maior dificuld

Propo



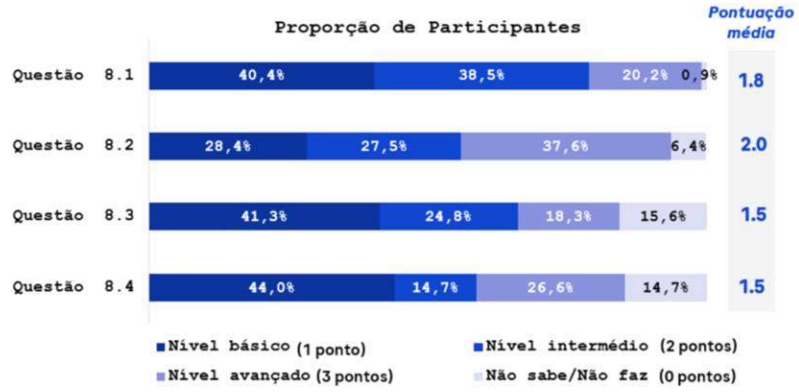
desenvolvimento e reg

Domínio 8: Comunicação e Trabalho de Equipa

+50% dos participantes revela não saber ou ter um conhecimento básico sobre a forma de comunicar o conteúdo e resultados da investigação clínica e descrever os elementos de uma publicação cientifica

Proporção de Participantes

Pontuação média



8.1 Descrever a importância do trabalho de equipa e os métodos necessários para trabalhar eficazmente com equipas de investigação transversais, multidisciplinares e interprofissionais, que podem incluir parceiros externos

8.2 Discutir a relação e a forma de comunicação adequada entre o promotor, a CRO e o centro de investigação clínica.

8.3 Comunicar eficazmente o conteúdo e a relevância dos resultados de uma investigação clínica a colegas, a grupos de defesa dos doentes e à comunidade não científica

8.4 Descrever os elementos de uma publicação científica tradicional.

Meeting in Lisbon, June 6th

Workshops to discuss ideas and proposal of recommendations

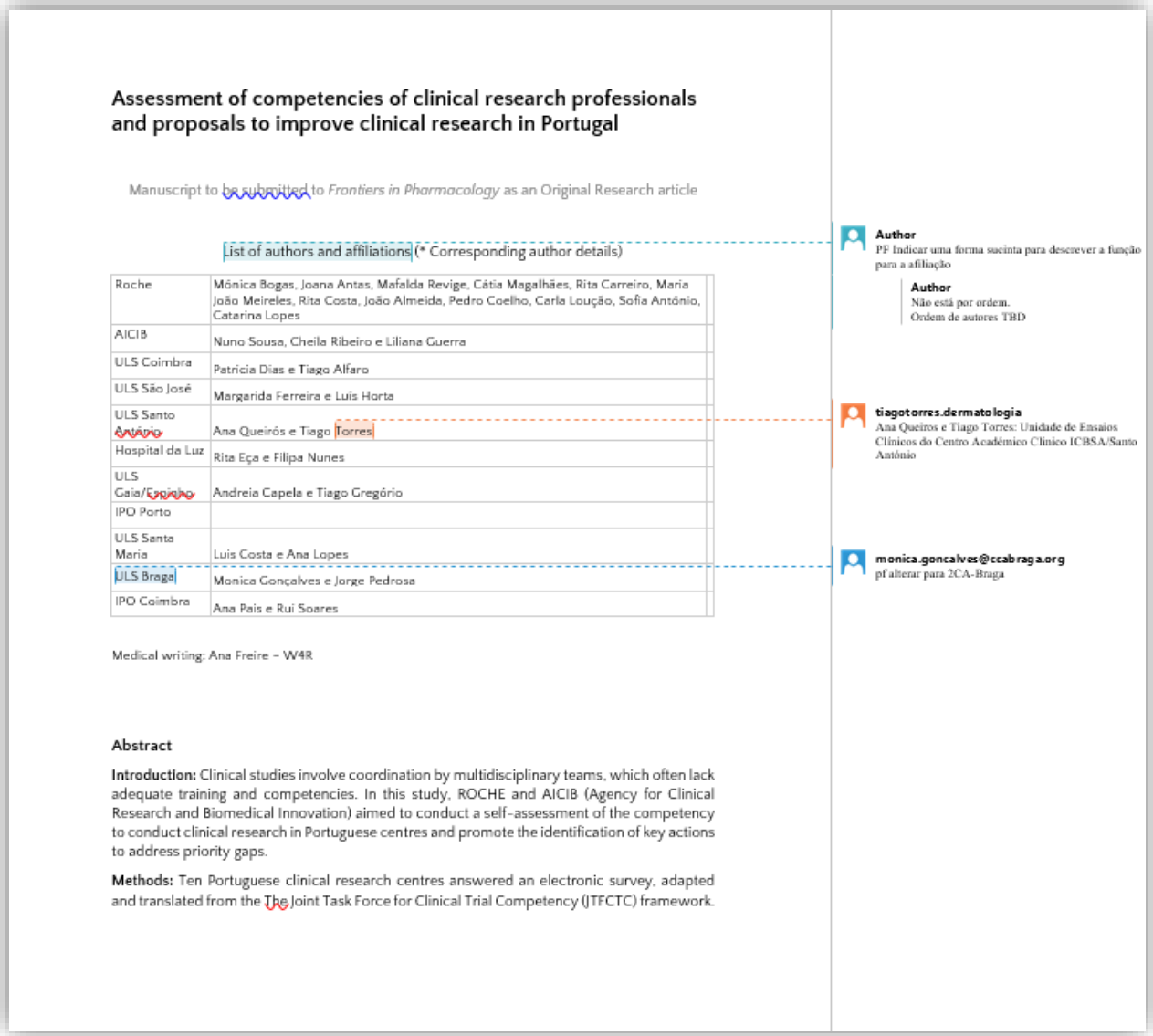
4 groups, each discussing 2 domains

AICIB president interview at the end, focus on discussing the importance of Clinical Trials

Conclusions

- This **study is pioneer in Portugal** and **one of few in Europe** to conduct a national survey to assess competency to conduct clinical studies
- It registered an impressive **participation rate** and provided a good representation of the knowledge and competencies in the Portuguese clinical research context
- It provided a **Portuguese translation of the survey** that can be applied not only in other Portuguese clinical research centres but can also serve as a guideline for other Portuguese speaking countries
- The **list of suggested actions** in this study can serve as a reference to national or international centres that may identify similar gaps
- We are heading for the next steps **aiming at enhancing national competencies** for conducting clinical studies working together with all relevant stakeholders - regulatory authorities, national agencies, investigators and clinical research centres, academia and patient organizations

Next steps
Publish results



Assessment of competencies of clinical research professionals and proposals to improve clinical research in Portugal

Manuscript to be submitted to *Frontiers in Pharmacology* as an Original Research article

List of authors and affiliations (* Corresponding author details)

Roche	Mônica Bogas, Joana Antas, Mafalda Revige, Cátia Magalhães, Rita Carreiro, Maria João Meireles, Rita Costa, João Almeida, Pedro Coelho, Carla Loução, Sofia António, Catarina Lopes
AICIB	Nuno Sousa, Cheila Ribeiro e Liliana Guerra
ULS Coimbra	Patrícia Dias e Tiago Alfaro
ULS São José	Margarida Ferreira e Luís Horta
ULS Santo António	Ana Queirós e Tiago Torres
Hospital da Luz	Rita Eça e Filipa Nunes
ULS Gaia/Espinho	Andreia Capela e Tiago Gregório
IPO Porto	
ULS Santa Maria	Luís Costa e Ana Lopes
ULS Braga	Monica Gonçalves e Jorge Pedrosa
IPO Coimbra	Ana Pais e Rui Soares

Medical writing: Ana Freire – W4R

Author
PF indicar uma forma sucinta para descrever a função para a afiliação

Author
Não está por ordem.
Ordem de autores TBD

tiagotorres.dermatologia
Ana Queirós e Tiago Torres: Unidade de Ensaios Clínicos do Centro Académico Clínico ICBSA/Santo António

monica.goncalves@ccabraga.org
pf alterar para 2CA-Braga

Abstract

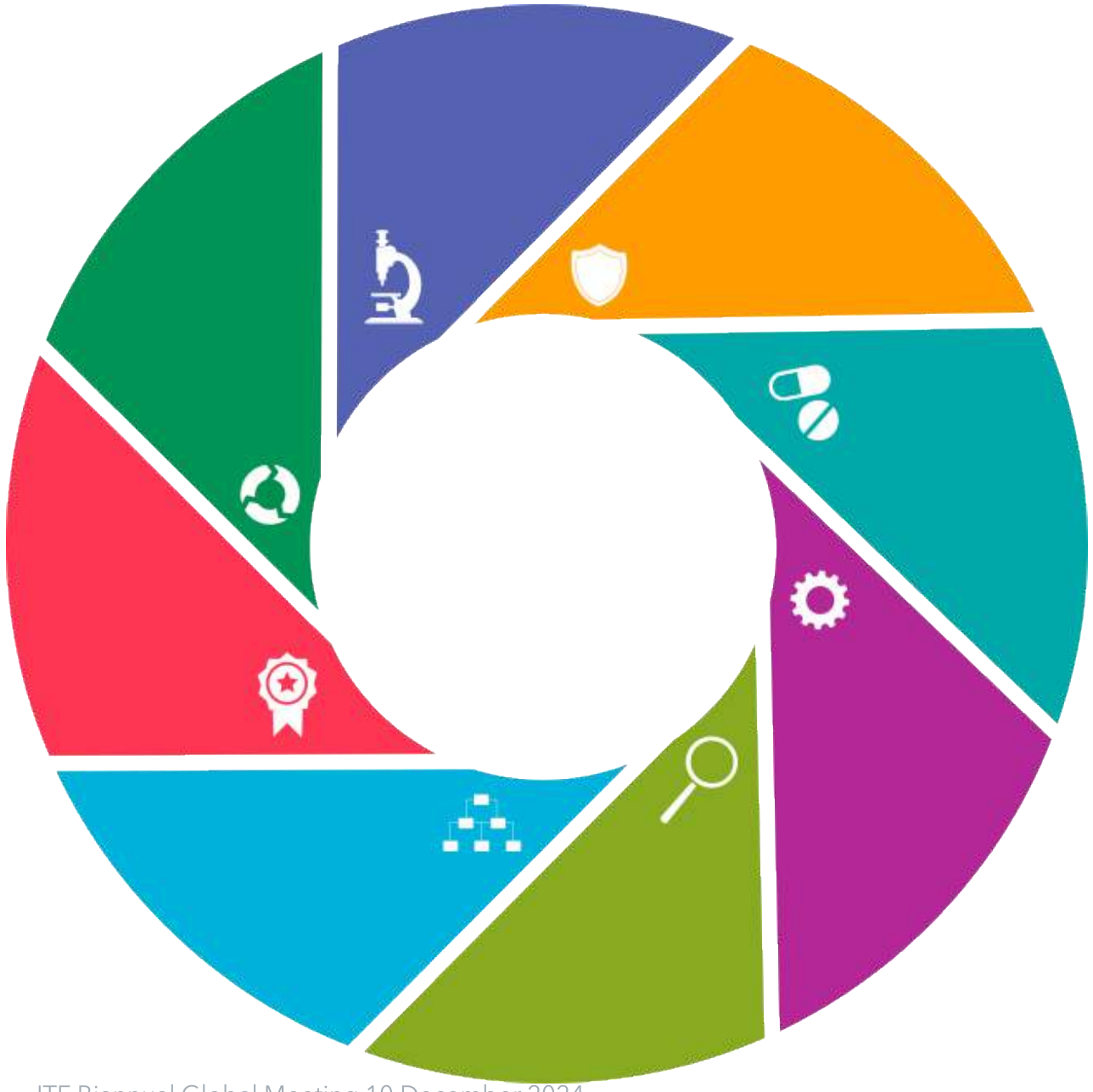
Introduction: Clinical studies involve coordination by multidisciplinary teams, which often lack adequate training and competencies. In this study, ROCHE and AICIB (Agency for Clinical Research and Biomedical Innovation) aimed to conduct a self-assessment of the competency to conduct clinical research in Portuguese centres and promote the identification of key actions to address priority gaps.

Methods: Ten Portuguese clinical research centres answered an electronic survey, adapted and translated from the The Joint Task Force for Clinical Trial Competency (JTFCTC) framework.

- Collaborate in **training modules** and in the certification for clinical research professionals
- Support **onsite events** to facilitate knowledge sharing among professionals with diverse roles, along with fostering collaboration and networking
- Support coordination between clinical **research centres** to streamline their training programs
- Develop **specialized training for GCP, inspection readiness** and **safety reporting** information

Doing now what patients need next

BackUp slides, if needed



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

Training Community Health Workers (CHWs) for the Vital Jobs in Clinical Research and Expanding the Workforce Directly into Communities

Amin Yakubov, MPH, MBA, ACRP-CP

Associate Director- Research Operations

Clinical & Translational Science Institute (CTSI)

NYU Langone Health Brooklyn

Emily Drum, MPH

Program Manager, Research Education and Strategic Initiatives

Clinical & Translational Science Institute (CTSI)

NYU Langone Health Brooklyn

NYU Langone Health

NYU CTSI CLINICAL & TRANSLATIONAL SCIENCE INSTITUTE
NYU LANGONE HEALTH • NYC HEALTH+HOSPITALS • NEW YORK UNIVERSITY

NYU Langone Health Brooklyn

Training Community Health Workers for the Vital Jobs in Clinical Research and Expanding the Workforce Directly into Communities

Amin Yakubov, MPH, MBA, ACRP-CP

Emily Drum, MPH

JTF Biannual Global Meeting

Tuesday, December 10, 2024

Current Challenges in the Clinical and Translational Research (CTR) Workforce

CRITICAL NEED TO MEET INDUSTRY GROWTH AND INCREASE DIVERSITY IN THE CTR WORKFORCE

- Staffing challenges slow down our ability to run trials.
- Projected job growth of ~10% by 2026
  - Currently 7 jobs available for every CRC seeking work
  - ~1,000 open positions in NYC
- 24% of the U.S. STEM workforce comprises underrepresented minorities
  - Black and Latine workers = 23% of NYC's scientific workforce
- The CTR workforce should reflect the languages, cultures, and lived experiences of the communities we serve.

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Diversity in clinical trial participation is a social justice issue.

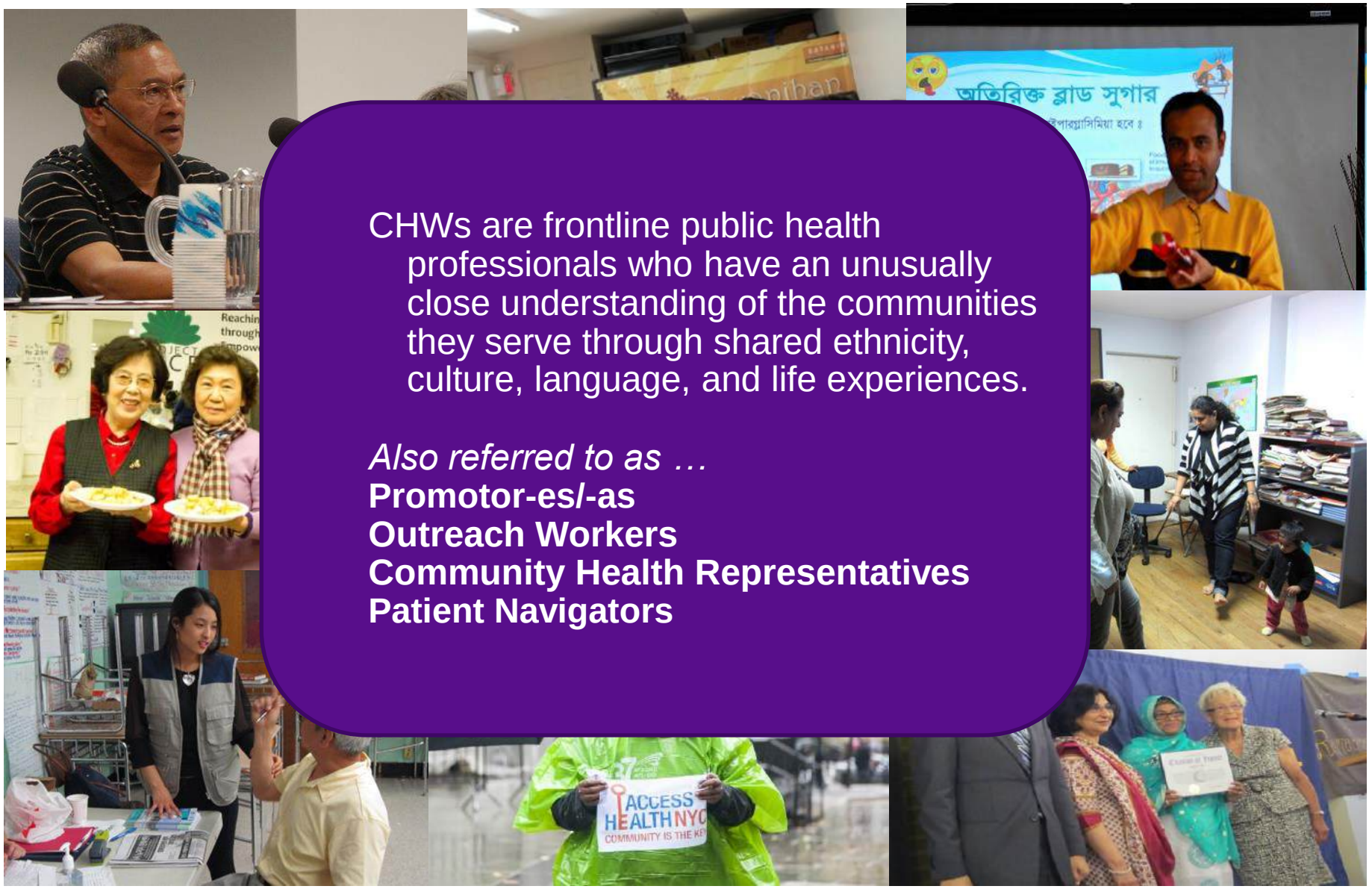
- In 2001, NIH mandated inclusion of women and minoritized individuals in all funded clinical trials yet enrollment remains suboptimal.

- FDA's 2023 guidance encourages decentralized clinical trials:
  - Increase community engagement
  - Recruit and retain diverse participant populations
  - Meet people where they live and work

A DIVERSE WORKFORCE IS AN IMPORTANT PART OF THE SOLUTION.

Who Are Community Health Workers (CHWs)?

Emily



CHWs are frontline public health professionals who have an unusually close understanding of the communities they serve through shared ethnicity, culture, language, and life experiences.

Also referred to as …

Promotor-es/-as
Outreach Workers
Community Health Representatives
Patient Navigators

Literature on CHWs in Research

Emily

The literature shows that CHWs:

- Are key players in increasing awareness about cancer clinical trials
- Express a strong interest in learning about clinical trials to better inform and guide community members
- Have low levels of knowledge about clinical trials, which limits their ability to effectively educate their communities
- Help reduce disparities in clinical trial participation by reaching out to minoritized communities
- Face challenges with integration into research teams due to factors such as lack of formal recognition, training disparities, and systemic barriers

Who are CHWs in the Research Context?

- Create links between researchers and communities
- Recruit participants
- Help researchers understand communities' interests, perceptions, concerns, and needs
- Share the importance of research with communities and understand what community members know and want to know
- Deliver interventions (eg, health education)
- Schedule participants for study appointments
- Follow up with participants
- Conduct baseline and follow-up data collection
- Keep participants motivated and engaged with studies (ie, retention)
- Provide counseling, support, and resources to participants
- Assist with development of study materials
- Translate study materials
- Participate in learning exchanges and trainings
- Keep organized study logs and data files
- Collaborate on writing manuscripts and abstracts
- Share study results back to the community
- Become a clinical research coordinator
- ...and more!

TL;DR - CHWs can and should work alongside CRCs on research teams!

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Emily

COMMUNITY HEALTH WORKER RESEARCH TRAINING

WHO WE ARE

A collaborative partnership between researchers and community health workers at the NYU Clinical & Translational Science Institute (CTSI), NYU Community Health Worker Research & Resource Center (CHW-RRC) and the Beatrice W. Welters Breast Health Outreach & Navigation Program at NYU Langone Health.

WHAT WE DO

Provide a free, on-demand training for all community health workers and patient navigators to enhance health literacy about clinical research.

HOW WE DO IT

This innovative research training provides community health workers with a basic level of competency in clinical research to better advocate for their communities' health needs and enhance the quality and effectiveness of their work.

WHY WE DO IT

A well-trained community workforce promotes deeper integration of community stakeholders into the research team and connects underserved populations with clinical research opportunities to enhance quality of care.

CHW Clinical Research Training Aims

Aim 1: Enhance the knowledge and skills of CHWs to help promote understanding of clinical research

Aim 2: Create a community and research linkage between researchers and the community

Aim 3: Develop a community centered and experienced research workforce

CHW Research Training Overview

- Based on the JTF Clinical Trial Competencies
  - Utilizes a “basic” level of competency for each of the 8 domains
- Seminar 1: Clinical Research 101 (Modules 0-19)
  - Fundamentals of clinical trials, study design, drug development process, protocols, biostats, participant safety, and dissemination
- Seminar 2: Research History & Research Diversity (Modules 1-8)
  - History of research and research ethics, enrollment barriers, recruitment, importance of diversity, myths/misconceptions

Applying the JTF Framework

JTF Competency Domain	CHW Training Modules
Scientific Concepts and Research Design	S1,M1-5, 7-8, 14: Basics of clinical trials, phases/lifespan, and study design
Ethical and Participant Safety Considerations	S1,M11, 16: Inclusion/exclusion criteria, informed consent
Investigational Products Development and Regulation	S1,M6: Drug and vaccine development process
Clinical Study Operations (GCP)	S1,M9-10, 13, 15, 17: Basics of protocols and protocol design, placebo and blinding, risks/benefits, safety

JTF Competency Domain	CHW Training Modules
Study and Site Management	S1,M18: Patient enrollment timeline
Data Management and Informatics	S1,M12: Power statistics
Leadership and Professionalism	
Communications and Teamwork	S1,M19: End of study

Applying the JTF Framework

Emily

- Health equity lens:
  - Expands on the JTF competencies to include new, CHW-specific competencies
    - History and ethics of clinical research in diverse populations
    - Recruitment/retention of diverse participant populations

How do we apply the health equity lens to all domains in the framework?

Applying the JTF Framework

Emily

Health Equity Domains	CHW Training Modules
History of Clinical Research Ethics	S2,M1: History of clinical research, barriers to participation
Minority and Immigrant Participation in Research	S2,M2: Medical mistrust and willingness to participate
Recruitment and Retention	S2,M3-5: Barriers to participation, recruitment, importance of diversity
Myths & Misconceptions	S2, M7: Myths and misconceptions
Access to Clinical Research	S2,M6, 8: Finding research, talking with your doctor

Applying a Health Equity Lens to the JTF Framework

Emily

- Scientific concepts and research design
  - How do we engage diverse communities in development of research questions and study design?
  - How do we develop trainings that will improve access of underrepresented individuals to the research workforce?
  - How do we think about access to tech/tech literacy when we incorporate new technologies to facilitate study conduct?
- Ethical and participant safety considerations
  - Are current definitions of vulnerable populations sufficient?
  - How do we incorporate underrepresented populations into assessment of risks and benefits?
  - What biases are present in selection of eligibility criteria?
- Investigational products development/regulation
- Clinical study operations (GCP)
  - What roles exist for community members on the research team?
- Study and site management
  - When we select sites, how do we consider relevance of the study to the sites' communities and their capacity to engage their communities?
- Data management and informatics
  - How do we engage communities in the questions we ask and how we analyze data (eg, disaggregation of AAPI populations)?
- Leadership and professionalism
  - What biases exist in how we define professionalism?
  - Who is in charge?
- Communication and teamwork
  - How are we engaging communities in dissemination of results?

Development Timeline

Amin

Phase 1: Exploration & Research
(Months 1-3; 6/22-9/22)

Exploration & Research
- Faculty and CHW requests for research training
- Research on available trainings internally
- Research on available (open platform) trainings externally
- CEPHR proposal (Meeting 1)
- Interviews with CHWs and Departments (OSR, PCC, FHC, Neurology, CHW-RRC)
- Information collected to develop modules based on needs of NYULH CHWs
- 2-seminars (CRC foundations & CRC history)

Phase 2: Module Development
(Months 3-9; 10/22-4/23)

Module Development
- Development of modules
- Presentation to CEPHR (Meeting 2)
- Development of CHW Research Training workgroup
- Presentation to CEPHR (Meeting 3)
- Presentation to Center to Community Health Alignment and University of South Carolina

Phase 3: Technology
(Months 10-12; 5/23-7/23)

Technology
- Explore internal/external platforms from CTSI/OSR
- Recruit CHWs and coordinators to write scripts
- Recruit CHWs to provide voiceovers
- Upload into FOCUS, RISE, and Diamond
- Launch with CHW research reception (6/23)
- Dissemination (CHW-RRC, local NYC CBOs, CHW conference, publication)

Phase 4: Scalability & Sustainability
(Months 13+; 8/23-current)

Scalability & Sustainability
- Improve UX
- Identify gaps
- Translate modules
- Streamline evaluation
- Partner with other orgs/institutions to create new modules/versions
- Reconvene collaborative partners for strategic planning

CHW Research Training Feedback

- >600 people have completed or are in progress with the training
- Post survey results (n=376):
  - 76% CHWs, 10% patient navigators, 13% other
  - 44% reported that it was their first time taking a research training
  - 98% reported that this training provides practical tips and guidelines for CHWs that will be used in their day-to-day roles
  - 71% responded with a 4 or 5 rating in response to the following question: "After taking this training, how confident are you in applying the knowledge gained to your work?" (1-5 scale, where 1=not at all confident and 5=very confident)
  - 98% said they would recommend the training to others

CHW Research Training Feedback

"I have been inundated with inquiries by more than 380 CHWs in our network across a few states. Online trainings like yours shall revolutionize the CHWs' policies, practices and services by equipping CHWs more appropriately for better health service delivery." –Bob David, Rural Community Health Worker Network (RCHWN)

"The training was awesome and encouraging. This is the first time I feel that I am in the right profession. Thanks a million."

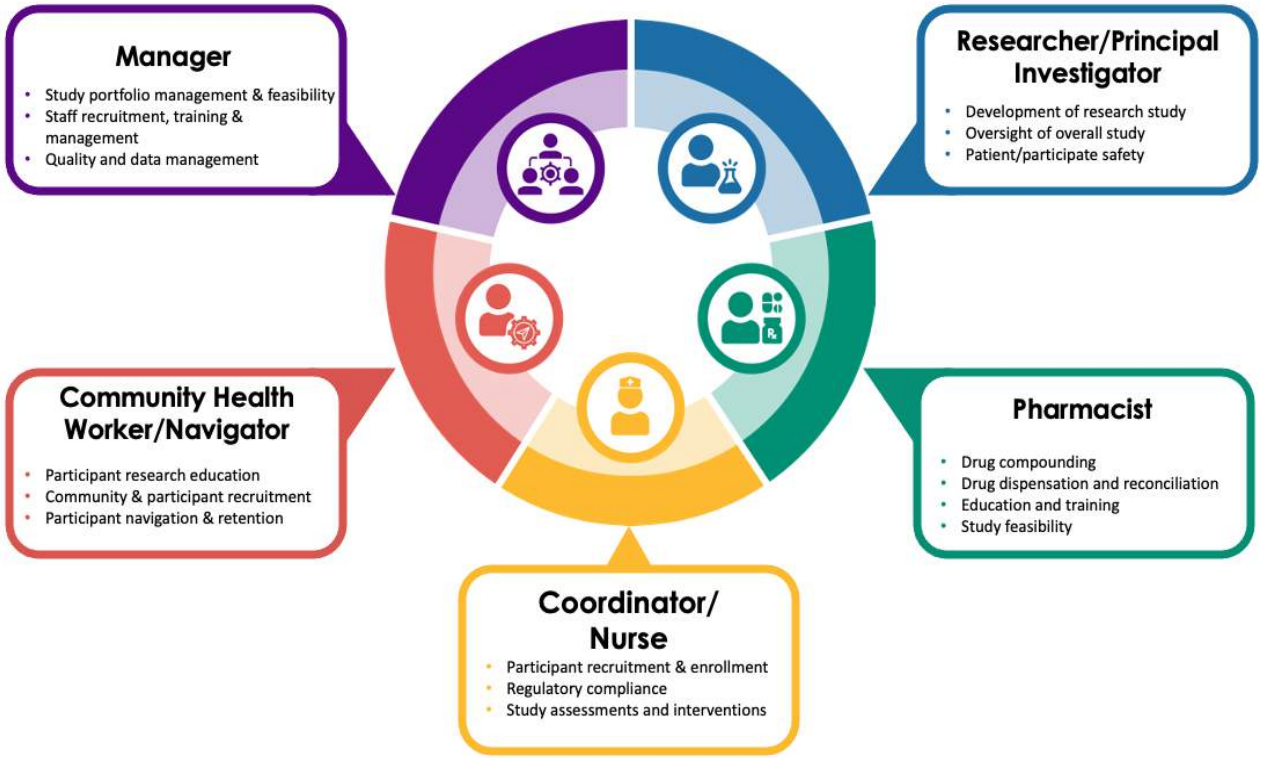
"Really refreshing training. Thanks to you guys. The word is being spread all over my professional network."

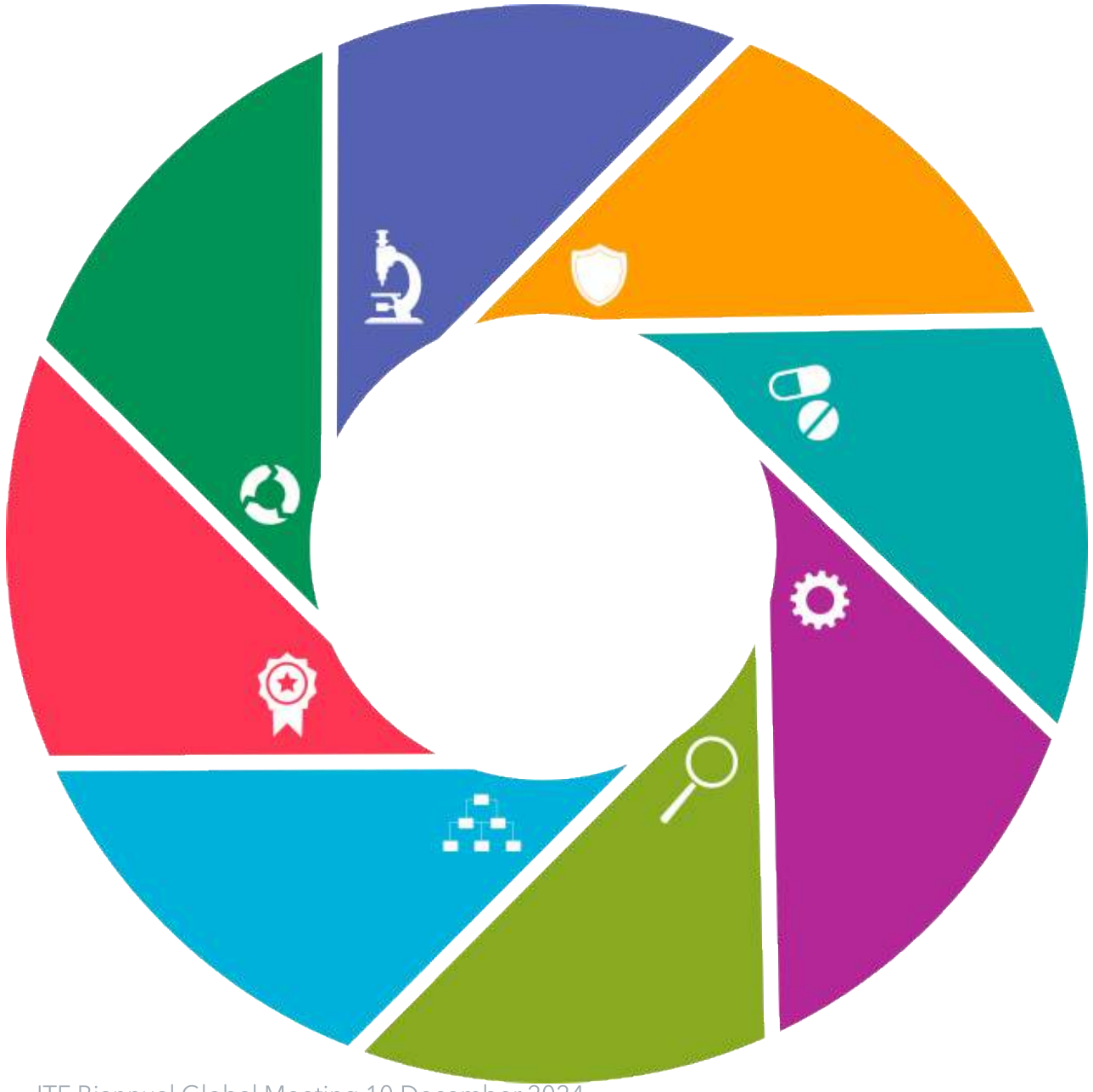
"The training has revived my professional zeal."

The Future of the Research Team

- **Future research teams will involve a variety of experts**

- **CHWs have a unique and vital role to play on the research team:**
  - Do the work of clinical research coordinators (CRCs) *IN* the community
  - Bring skills and experience that CRCs cannot replace or duplicate





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

Data Management Update: Results from Delphi

Meredith Zozus, PhD

Professor, Division Chief, Clinical Research Informatics

University of Texas (UT) Health San Antonio, Long School of Medicine, Department of Population Health Sciences

Draft Competencies for Domain 6: Data Management, Informatics and Statistics

Joint Task Force for Clinical Trial Competency (JTF)

Round 3 Results

For questions, please contact:
Manju Bikkanuri, MBBS bikkanuri@uthscsa.edu
Clinical Research Informaticist
Joe R. and Teresa Lozano Long School of Medicine
University of Texas Health Science Center San Antonio

Working Framework (JTF 6)

Data Management, Informatics and Statistics

Encompasses how data are generated, collected, managed, and used during a clinical study and prepared for sharing following a study.

6.1 Data Definition and Generation	6.2 Data Collection and Processing	6.3 Data Use	6.4 Statistical Analysis	6.5 Data Re-use

6.6 Information System Selection, Application, Use and Evaluation

Round 3 Results

Each competency statement at each level was rated on a three point Likert scale (too easy, no change, too hard).

6.1 Data definition, generation, and collection

-1	-2	1
-2	0	1
-1	0	-1

6.2 Data processing

-2	-3	0
1	-1	3
0	-1	-2

6.3 Use data to manage a study

2	-1	1
0	1	0
4	2	1
2	2	1

6.4 Statistics

1	1	0
3	1	2
1	2	1
0	0	1

6.5 Data sharing

0	0	0
0	0	0

6.6 Information systems

1	2	-3
2	1	2
0	1	-1
0	-1	0

-4	-3	-2	-1	0	1	2	3	4

Updates

No updates

Updates

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

Patient Participants Task Force

Sylvia Baedorf Kassis, MPH

Program Director

Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard

Opportunity

Patient Partners are experts in their own lived experience and personal history of disease.

Patient Partners are increasingly being engaged to advise on more technical aspects of clinical research studies.

Patient Partners may not have all the necessary competencies to advise on clinical trials, and the existing Joint Task Force (JTF) Clinical Trial Competency Framework may not sufficiently address this audience.

Users of the JTF recommended the creation of an addendum of Patient Partner oriented competencies.

Collaborative Leadership

The groups that are co-leading this effort are:

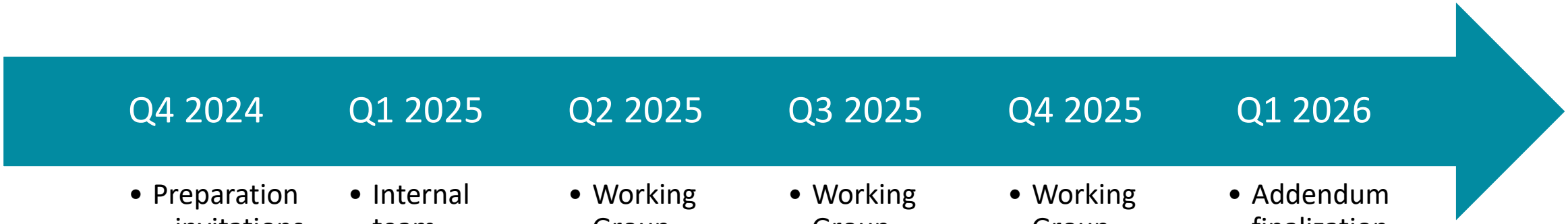
- the CANadian Consortium of Clinical Trial TRAINing (CANTRAIN)
- the European Patient's Academy on Therapeutic Innovation (EUPATI), and
- the Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard (MRCT Center)

Goal

The main goal of this effort is to create a set of clinical research competencies that augment the existing JTF to ensure that:

- **patient partners** have a set of competencies that undergirds their roles as leaders, advisors, and reviewers in the context of clinical research, and
- **clinical research team members** have the competencies necessary to engage intentionally and effectively with patient partners in the context of their roles as leaders, advisors, and reviewers in the clinical research context.

High Level Timeline – approximately 15 months



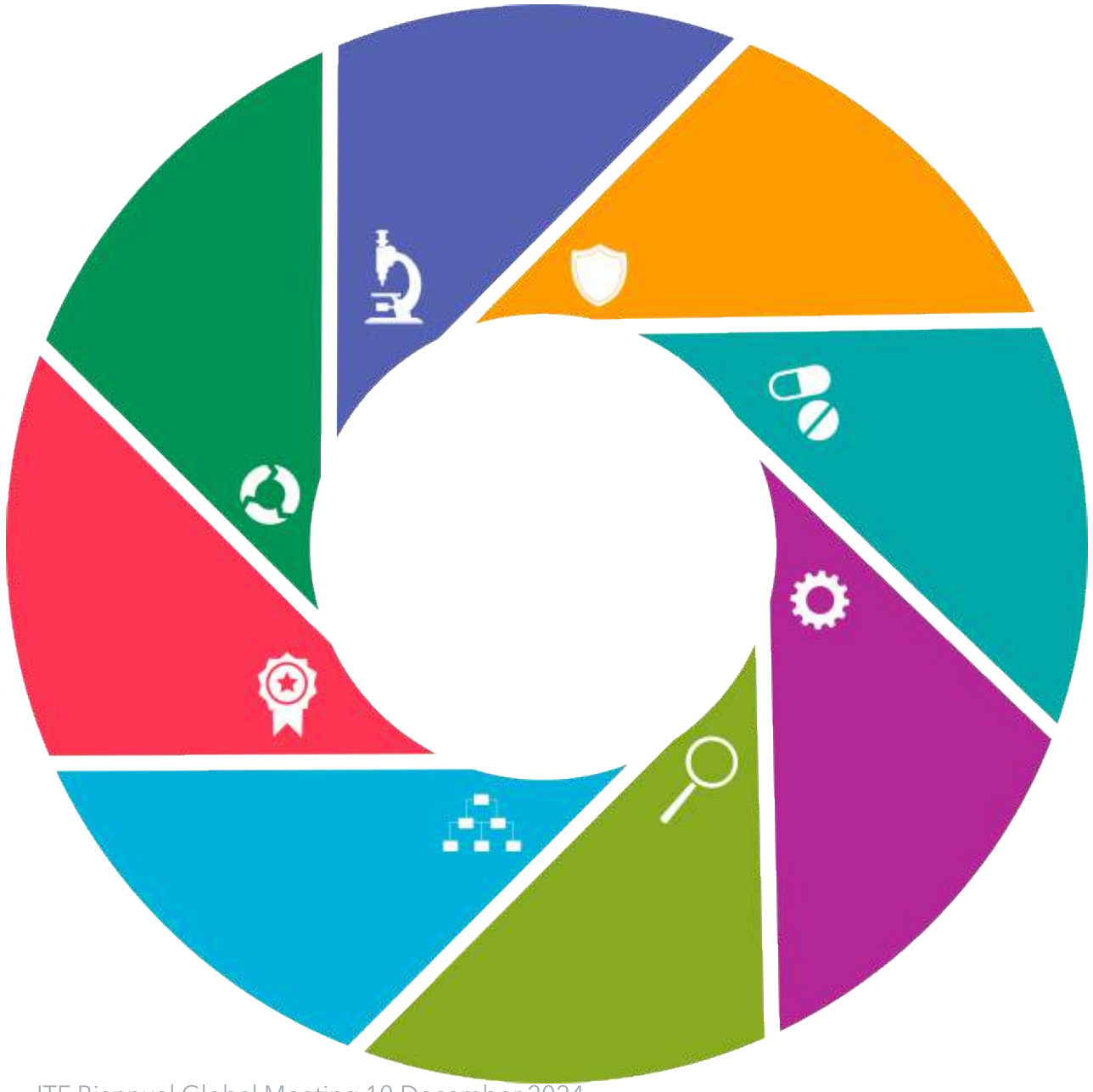
Q4 2024	Q1 2025	Q2 2025	Q3 2025	Q4 2025	Q1 2026
• Preparation – invitations out (Dec) • Internal team building	• Internal team building cont'd • Launch Working Group (Jan-Feb) • Workgroup Activities - start	• Working Group Activities • Review Team engaged	• Working Group Activities • Strategic Review Team involvement • Intro Webinar?	• Working Group Wraps Up • Review Team Final Input	• Addendum finalization • Release (with joint webinar) • Draft paper and prep for submission

e.g. scoping, gap analysis, competency additions/updates

Next Steps

- Potential working group and review team members are currently being identified; invitations will be sent out in the coming weeks and months (respectively)
    - Working group activities should commence in the January-February
    - Review Team activities will commence shortly thereafter.

- Please let us know if you or an individual or organization that you would recommend are interested in getting involved in this effort.



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

Team Science Competencies for Clinical Research Professionals

Carolynn Thomas Jones, DNP, MSPH, RN, CRN-BC, FAAN

Clinical Professor, College of Nursing

Director, Master of Clinical Research, College of Nursing

Co-Director of Workforce Development, OSU Clinical Translational Science Institute

The Ohio State University

JTF Biannual Global Meeting 10 December 2024

CRP- Team Science Competencies and Learning Needs Assessment (Domains 7&8)

Carolynn Thomas Jones, DNP, MSPH, CRN-BC, FAAN
Clinical Professor, OSU College of Nursing
Director, Master of Clinical Research,
Co-Director of Workforce Development- OSU

Objectives

- Describe new Team Science Competencies for CRPs to enhance JTF Domains 7&8
  - Methods: Two initiatives
  - Results
  - Next Steps

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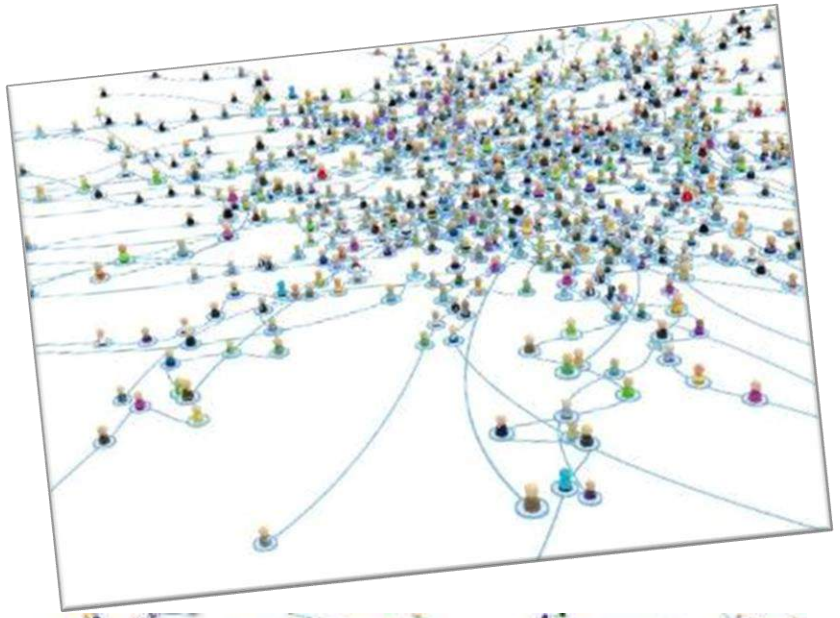
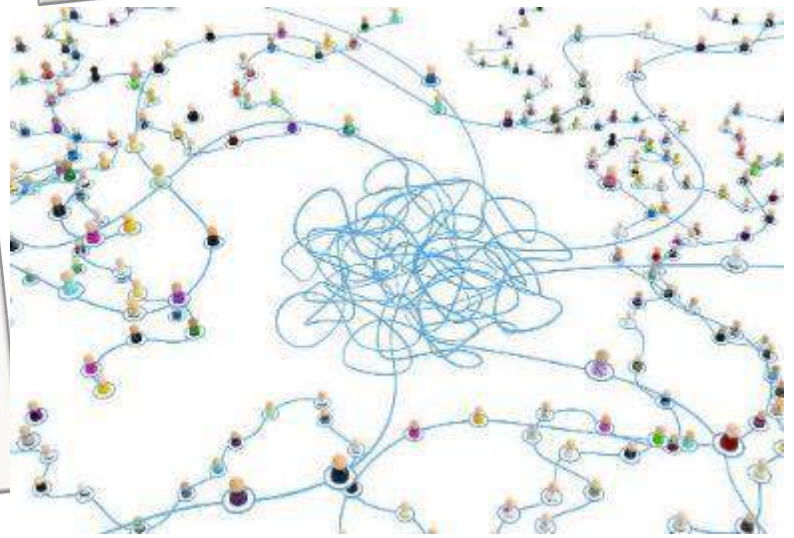
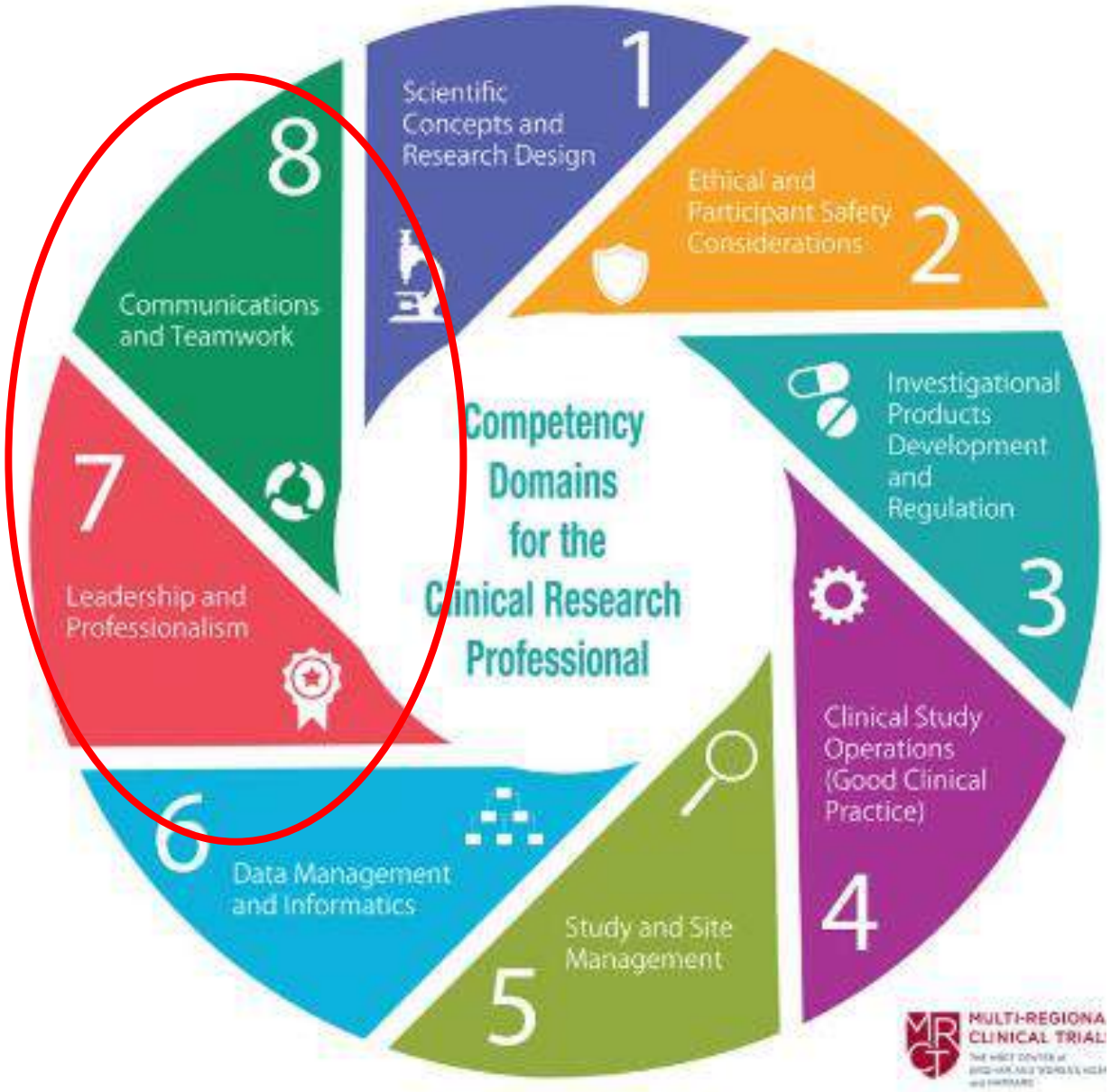




Matrix of Individual and Team Interactions in Clinical Research

Joint Task Force for Clinical Trial Competency

- What should CRPs, CRNs, PIs know (KSAs, Leveled Competencies)
- How can we best operationalize clinical research? (narrowing clinical translational science gaps)
- What should be in CR Curricula?
- Where should we expand?
- What is new?



CRPs are essential members of interdisciplinary clinical research teams.

Interdisciplinary teams rely on domain 7 & 8 to collaborate across research roles and disciplines.

Background: Team Science for CRPs

CLINICAL RESEARCH PROFESSIONALS (CRPS/CRNS) = ESSENTIAL MEMBERS OF TRANSLATIONAL SCIENCE TEAMS

TS COMPETENCIES FOR CRPS/CRNS WERE LACKING IN THE LITERATURE

TRAINING REMAINS “ON THE JOB” FOR MOST

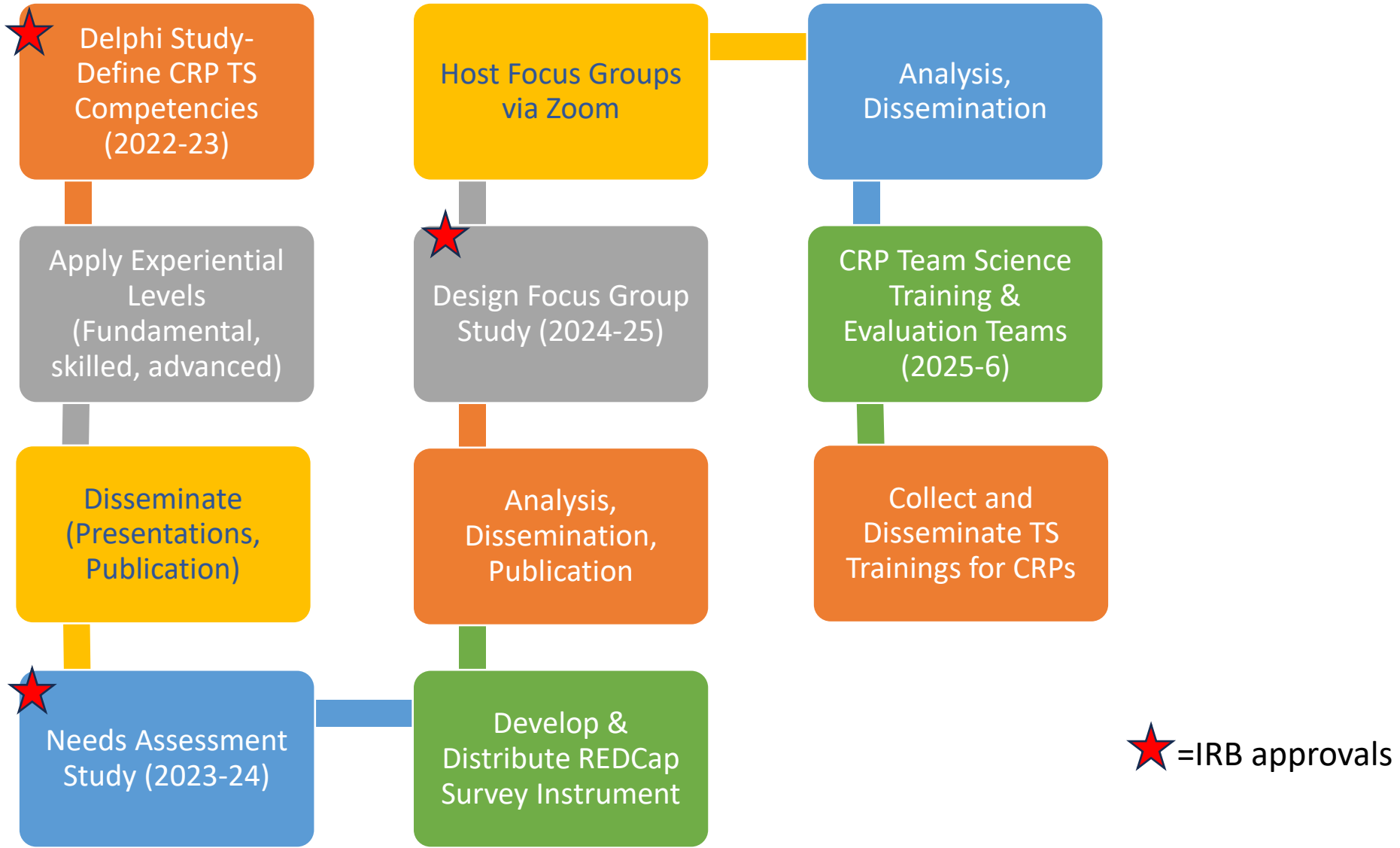
TRAINING/CERTIFICATION FOCUS (ACRP/SOCRA): JTF DOMAINS 1-6

TEAM SCIENCE FOR CRP WORKING GROUP WAS FORMED (2022)

POPULATION:

ACADEMIC MEDICAL CENTER CRNS AND CRPS COMBINED

Team Science Working Group – Strategic Plan



CRP TSWG: Delphi Study 2022-2023

- Applied the team science Framework (Lotrecchiano, et. al, 2021) to identify CRP team science competencies (5 Individual-based and 8 team-based).

Team Science Competencies (n=13) (Lotrechianno et al, 2021)	
Individual Competencies (n=5)	Team Competencies (n=8)
• Facilitating Awareness & Exchange • Cognitive Openness & Intersubjectivity • Self-Awareness • Interdisciplinary Research Management • Passion & Perseverance	• Team Roles • Team-Based Communication • Shared Visioning • Understanding Complexity • Team Learning and Adaptive Behaviors • Meeting Management • Interdisciplinary Collaboration • Building Trust

- Identified 59 smart skills and 177 leveled examples (fundamental, skilled, advanced)
- Contribute to the science: expand the literature, provide a platform for future research and training in CRP Team Science competencies.

Lotrecchiano et al (2021). Individual and team competencies in translational teams. *Journal of Clinical and Translational Science, 5*(1), E72.

Example: CRP Leveled Team Science Competencies

Competency 1: Facilitating Awareness and Exchange

Defined as: Sharing information and perspectives, active listening and probing, reframing skills			
SMART SKILLS:	**FUNDAMENTAL LEVEL**	**SKILLED LEVEL**	**ADVANCED LEVEL**
Active listening	**Identify** examples of active listening during training sessions	**Demonstrate** active listening to gain clarity of exchanged messages.	**Integrate** active listening into staff training and meetings
Relational openness	**Recognize** the importance of relational openness as a team member	**Exhibit** relational openness by welcoming and introducing team members	**Create** a welcoming, inclusive and positive environment.
Open sharing	**Explain** benefits of openness in sharing	**Practice** openness in sharing skills with others	**Mentor** openness and cross-team sharing

The published supplement is provided.

CRP TSWG- Needs Assessment (2023-24)

CRP UNDERLYING KNOWLEDGE

CRP LEARNING NEEDS

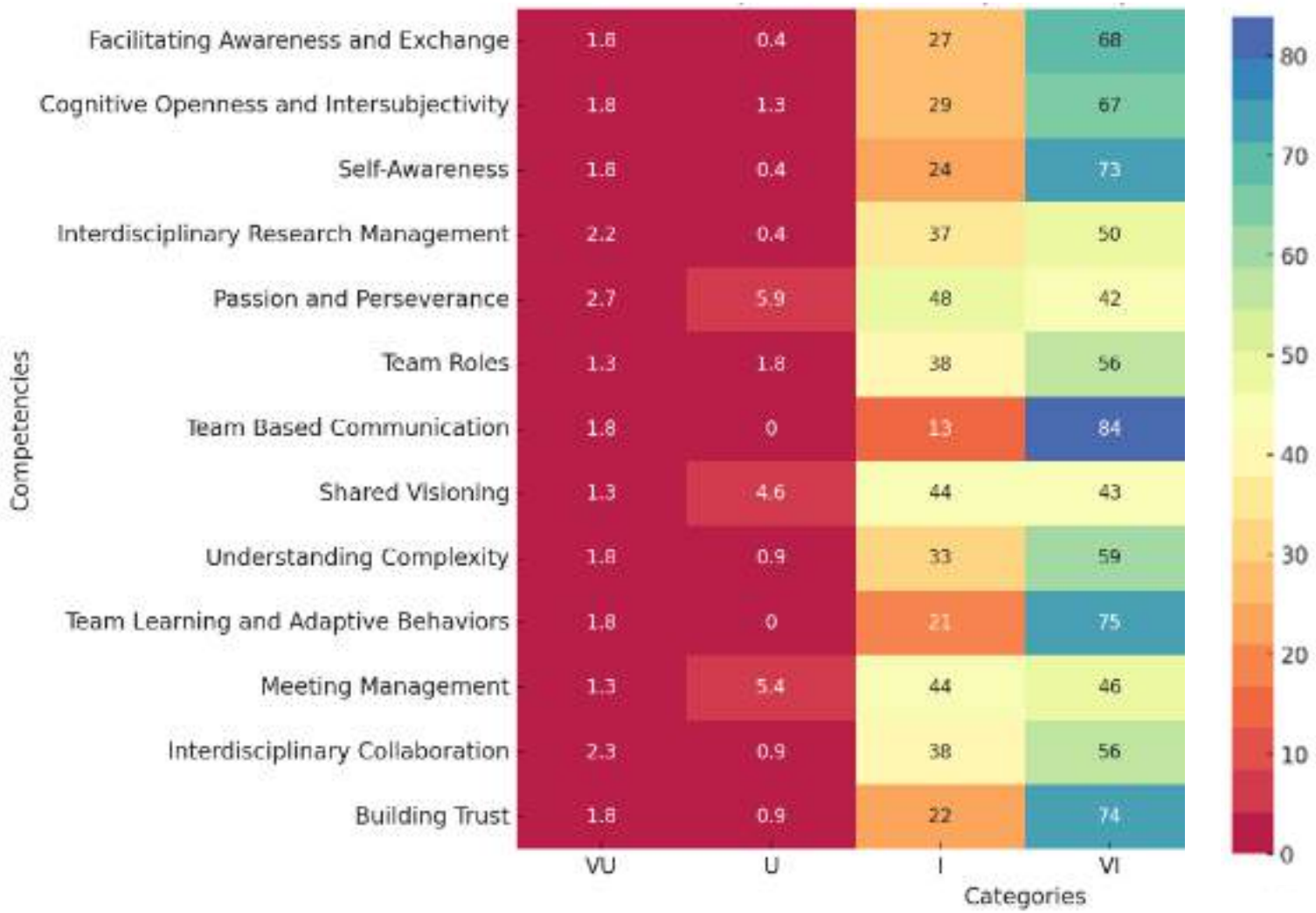
CRP KNOWLEDGE DELIVERY PREFERENCES OF TARGET LEARNERS.

FOCUS GROUP DISCUSSIONS

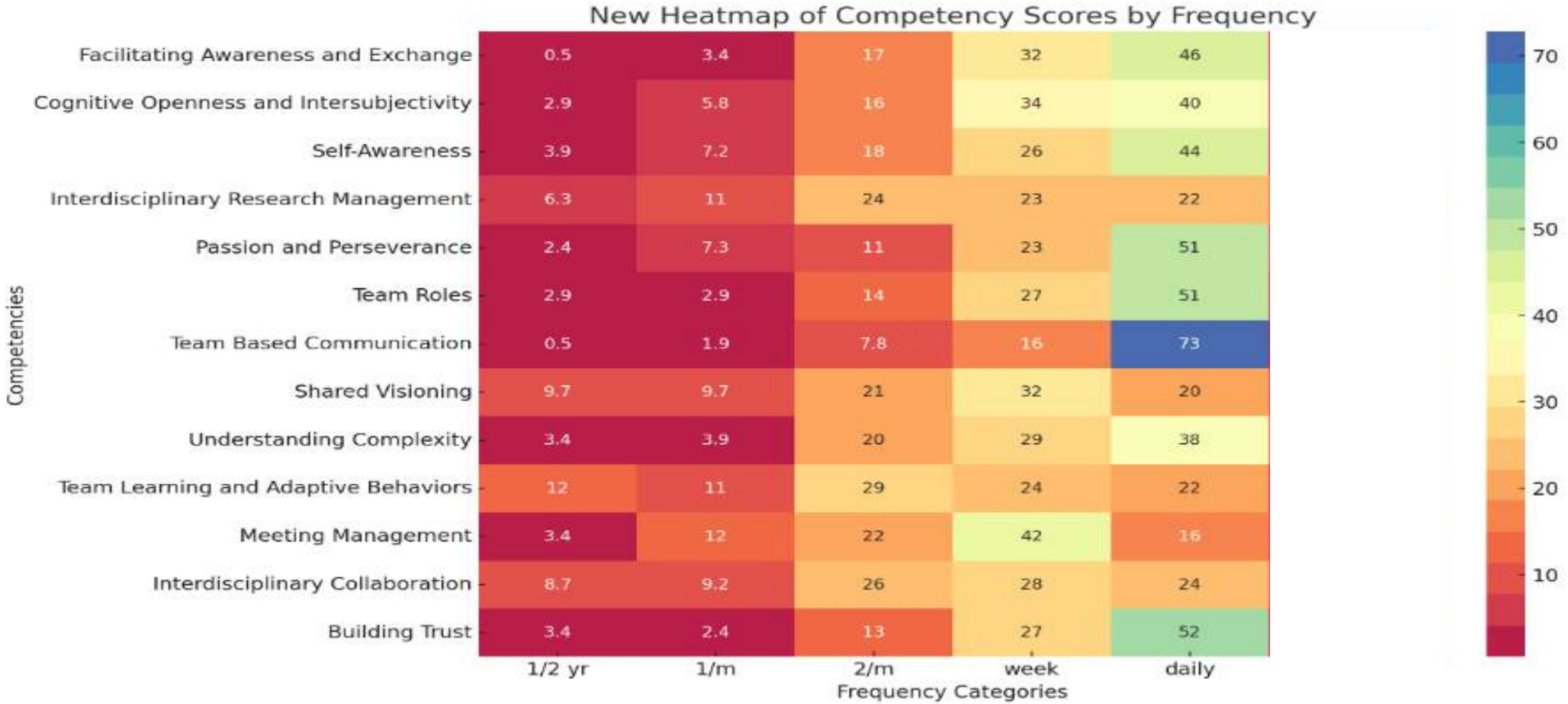
NEEDS ASSESSMENT METHODS

- Population: CRPs in US Academic Health Centers recruited by the study team and the ACTS CRP SIG via an IRB approved survey invitation URL.
- Survey Instrument: Using an anonymous REDCap survey we assess current TS competency skills, identify training gaps, and explore preferred learning methods and topics.
- Survey Opened: February – March 2024

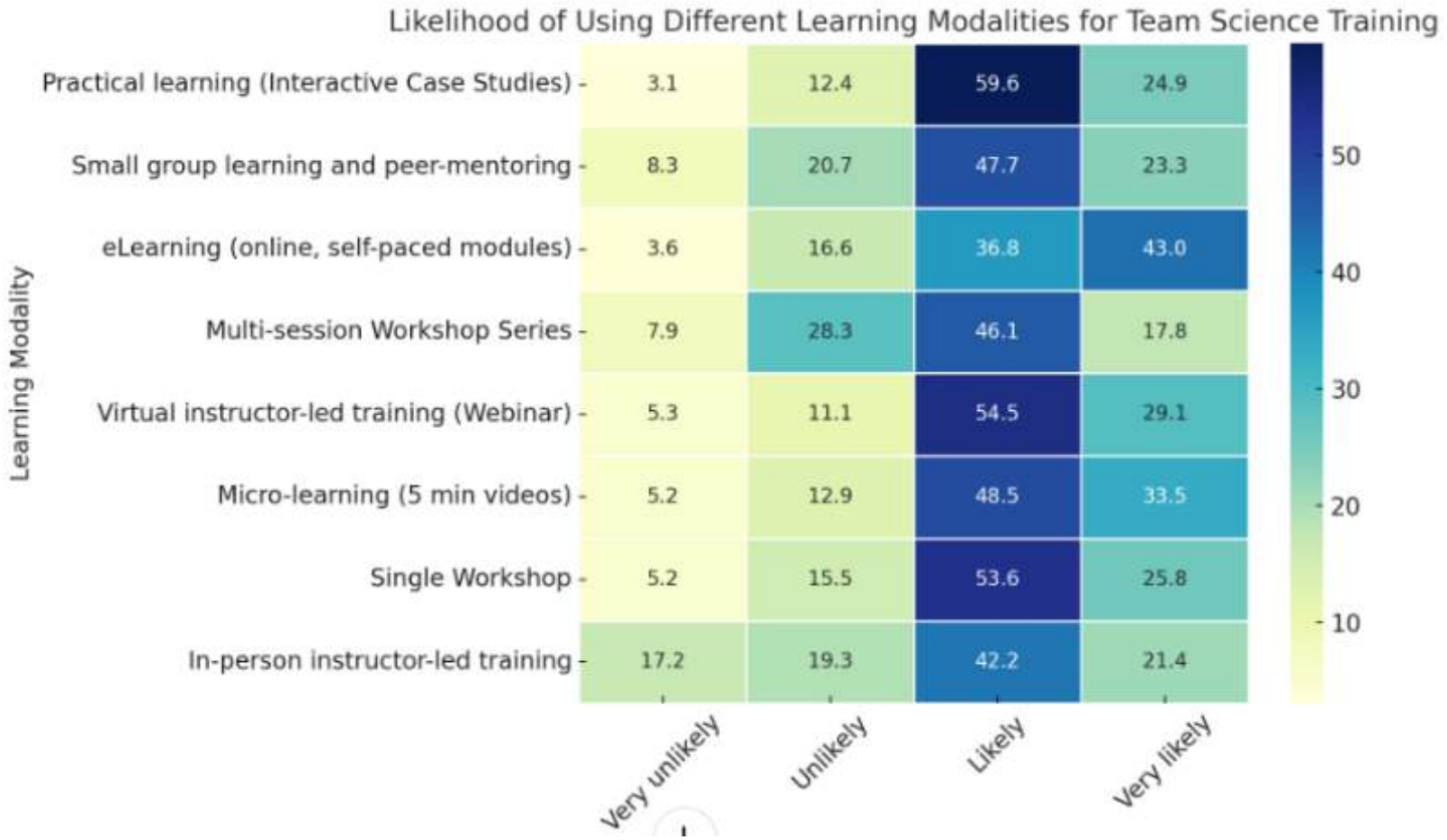
How important is it for you to apply these competencies in your role (n=223) Heat Map



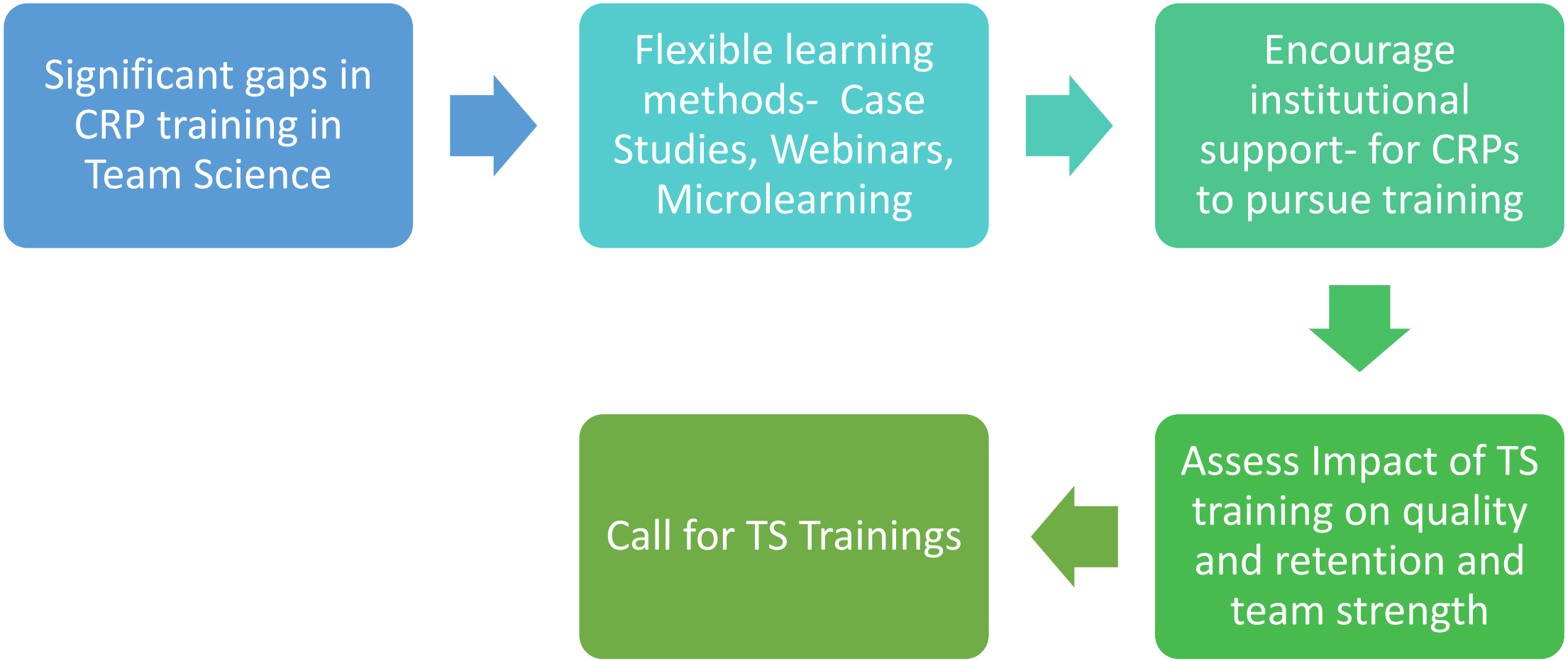
How often TS Competencies used in your Role? (N=207)



How would you like to learn about Team Science Competencies for CRP/CRN Roles (%) (n=143)?



Recommendations



Focus Group Study Qualitative Analysis

Bringing clarity on results.

Discovering other issues.

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ACKNOWEDGING OUR TEAMS!

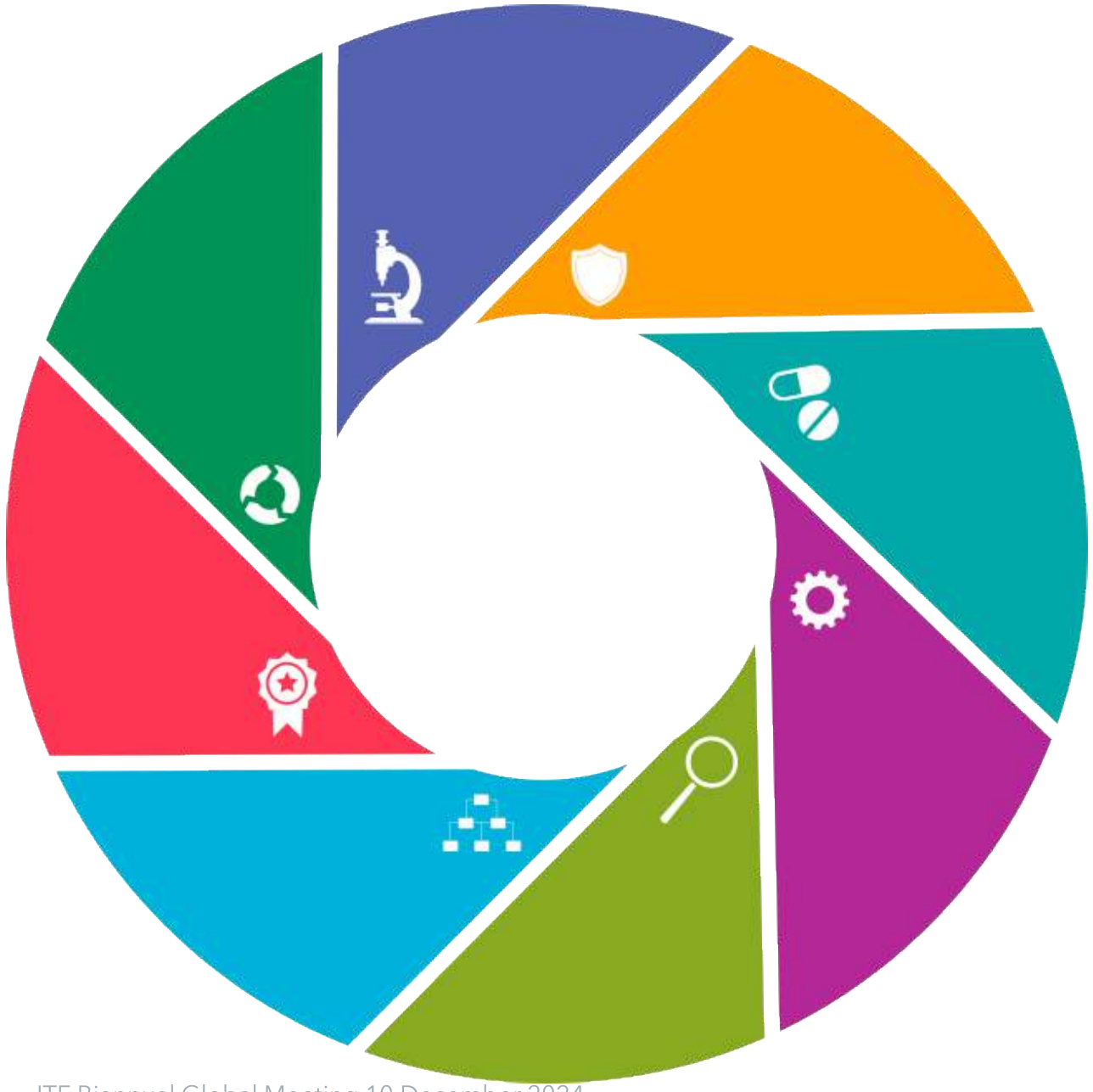
CRP Team Science Competencies (14 Members, 7 CTSA Hubs)

Angela Mendell (U Cincinnati) Carolynn Jones (OSU),Bob Kolb (UFL), Elizabeth Kopras (U Cincinnati), Laura Hildreth (U Cincinnati), Karen Carter (OSU), Jessica Fritter (OSU), Ty Salana (OSU), David Aslaner (OSU), Nicole Exe (U Michigan), Jen Sprecher (U Washington), Nicole Summerside (U Washington), Bernadette Capili (Rockefeller U), Shirley Helm (VCU)

CRP TS Needs Assessment Study Team (11 Members, 6 CTSA Hubs)

Carolynn T. Jones (OSU), Bernadette Capili (Rockefeller U) Jessica Fritter (OSU), Shirley Helm (VCU), Jackie Knapke (U Cincinnati), Elizabeth Kopras (U Cincinnati) Jill McCabe (Rockefeller U), Nicole Exe (U Michigan), John Kues (U Cincinnati), Meredith Fitz-Gerald, (UAB), Angela Mendell (U Cincinnati)

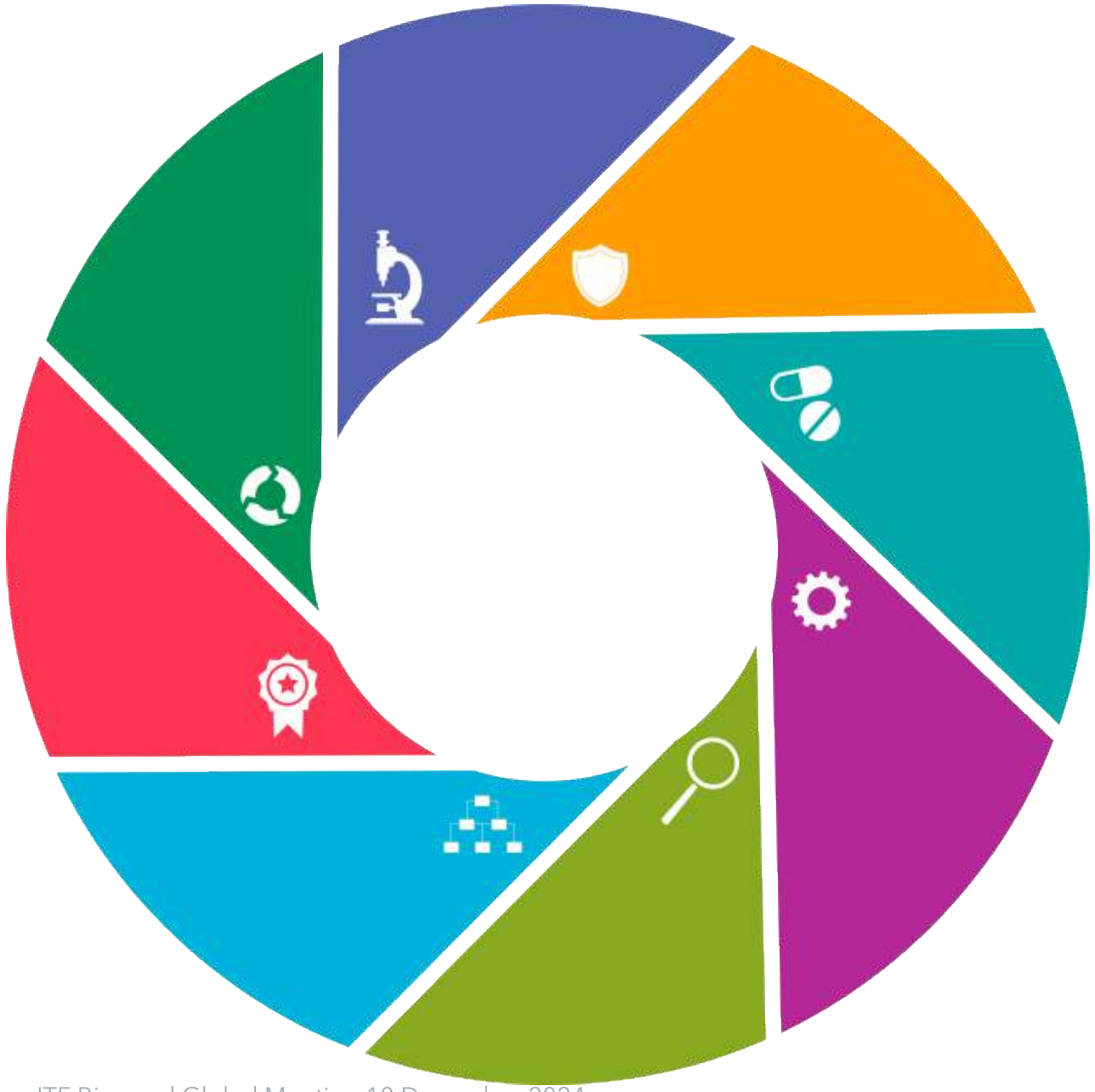
Questions?



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



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Thank you!

Barbara Bierer, MD
bbierer@bwh.Harvard.edu
Stephen Sonstein, PhD
ssonstein@gmail.com
Carmen Aldinger, PhD
caldinger@bwh.Harvard.edu