MULTI-REGIONAL CLINICAL TRIALS

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

JOINT TASK FORCE FOR CLINICAL TRIAL COMPETENCY

Joint Task Force for Clinical Trial Competency (JTF):
Strategic Global Meeting

Barbara E. Bierer, MD

Co-chair, JTF
Faculty Director, MRCT Center
Professor of Medicine, Harvard Medical School
bbierer@bwh.harvard.edu

Stephen Sonstein, PhD

Co-chair, JTF

Carmen Aldinger, PhD

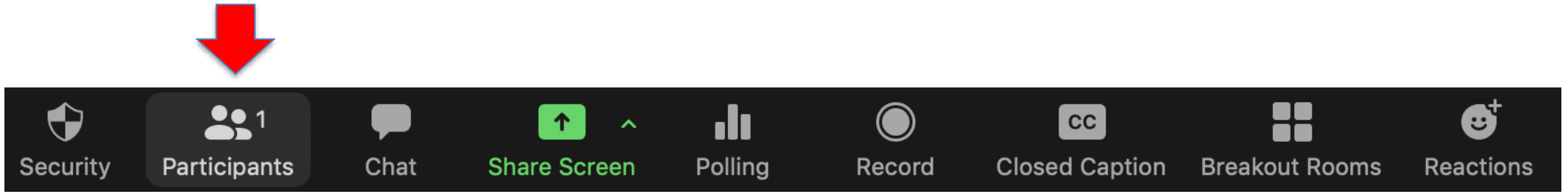
Senior Administrative and Training Manager,
MRCT Center

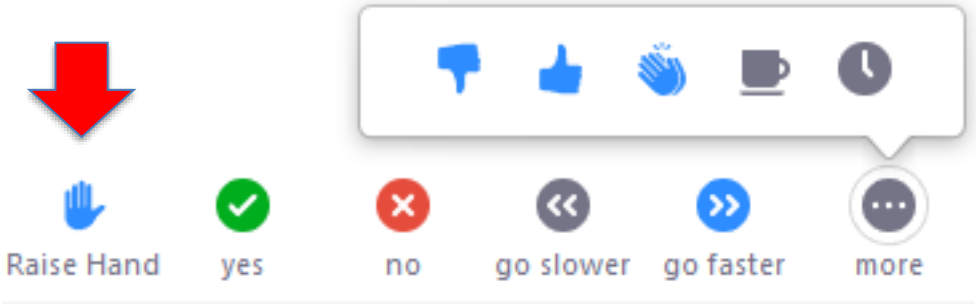
14 November 2022

https://mrctcenter.org/

Virtual Meeting

- Please keep video on
- Please mute yourself unless you are speaking
- If you would like to speak, please **unmute and speak** or '**raise your Zoom hand'** (and introduce yourself)





This meeting

- We are recording this meeting for internal purposes of note taking only.
- Recording will not be posted and will be deleted after the executive summary is finalized.

- We do wish to post slides and an executive summary of the meeting.
- We will follow up regarding permission to post the slides.

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—and its directors—retain responsibility and final control of the content of any products, results and deliverables.
- We have no personal financial conflicts of interests with the content of this presentation.
- Today's meeting will be recorded for internal purposes.

The Multi-Regional Clinical Trials Center (MRCT Center)

The MRCT Center is a research and policy center focused on addressing the conduct, oversight, ethics and regulatory environment for clinical trials.

Our Vision

Improve the integrity, safety, and rigor of global clinical trials.

Our Mission

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

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

HARVARD UNIVERSITY

Agenda

Time	Topic	Speaker / Facilitator
9:00-9:10	Introduction Overview	Barbara Bierer, MD Co-Chair, JTF Faculty Director, MRCT Center
9:10-9:50	**JTF Updates**: (3-5 min update each)	
	Integrating JTF Framework into Takeda's R&D's Knowledge Development Academy (KDA)	**Jesús Gómez-Navarro, M.D.** Distinguished R&D Fellow Scientific Advisor, Takeda Physician Scientist Accelerator Program Takeda Pharmaceuticals International, Co.
	Update on Translations	**Allan Wilsdorf, Engr., MSc** Head of the Training & Education Unit French Clinical Research Infrastructure Network (F-CRIN)
	JTF Competency survey in Low-and Middle Income Countries: Initial Analysis of Results	**Miwa Sonoda, RN, MPH**, GDip (Clinical Trial), GDip (Global Health) Medical Science Liaison Department of International Trials, Center for Clinical Sciences National Center for Global Health and Medicine (NCGM), Japan
	Clinical Research Core Competencies: an adaptation of the JTF Framework to Switzerland	**Melanie Glättli, PhD** Scientific Coordinator, Swiss Clinical Trial Organisation
	Update from CIOMS (Council for International Organizations of Medical Sciences) meeting	**Stephen Sonstein, PhD** Co-Chair,, JTF
	Discussion	**Barbara Bierer, MD**

Agenda cont.

Time	Topic	Speaker/Facilitator
9:50-10:15	**Data Management Task Force** 10-12 min presentation about proposed data management task force, e.g., • Motivation, mandate, structure and launch of task force	**Meredith Nahm Zozus, PhD** Professor, Div. Chief and Director of Clinical Research Informatics University of Texas Health Science Center San Antonio
	Discussion	**Barbara Bierer, MD**
10:15-10:45	**Assessment of competencies** 10-12 min presentation on the assessment of competencies, may include: • Need for objective assessment methods to measure competencies • Need for reliable and valid measures • Proposed process	**Elias Samuels, PhD** Program Director of Workforce and Evaluation Michigan Institute for Clinical & Health Research University of Michigan
	Discussion	**Stephen Sonstein, PhD**
10:45-11:00	**Wrap up and next steps** • Process for making changes to Framework going forward • Plan JTF meetings every 6 months	**Barbara Bierer, MD & Stephen Sonstein, PhD**

JTF Updates

Integrating the JTF Framework into Takeda R&D's Knowledge Development Academy (KDA)

JTF Global Strategy Meeting

Jesús Gómez-Navarro, MD

November 14th, 2022

Better Health, Brighter Future

Origins of Takeda R&D's Knowledge Development Academy

Distinguished R&D Fellows program launched in 2020

- Focused on contributing to shaping the future of R&D
- Appointment in late 2020 of two fellows (including Jesús Gomez-Navarro)
- Program housed within the Takeda *Data Science Institute*, led by Anne Heatherington

Takeda's corporate philosophy incorporates in 2020 lifelong learning and a growth mindset as a priority

- Takeda Learning Team formed with the purpose to defining, implementing and realizing an integrated global learning strategy and transformation plan at Takeda which enables critical business priorities, creates an exceptional people experience and builds a culture of continuous lifelong learning.

Topic **"Takeda R&D's Development Academy: upskilling the R&D organization to meet challenges and opportunities of the future"** proposed and endorsed by the R&D Management Committee in March 2022

Current vs. Future State of Learning

Scientific, clinical and technical knowledge and skills are mainly the territory of individual functions	Clinical Research & Development is an ***R&D-wide core capability*** supported cross-functionally
Lack of consistency regarding educational or experiential requirements & personnel certification in clinical research	A ***harmonized, leveled core competency framework*** guides training and accreditation and informs career ladders & trajectories, job descriptions, & performance evaluations
Available learning is focused on general competencies and processes (SOPs, etc.)	Learning encompasses ***all knowledge, skills and behaviors necessary for innovative and productive clinical R&D*** (as defined in a competency-based, leveled curriculum)
Knowledge is hidden, scattered, inaccessible, stale and available in few formats	Knowledge has ***unified access***, evolves constantly (users can annotate it) and is available always (on schedule and on demand) and in multiple formats (original documents, audio, video, dynamic visualizations, etc.)
There is limited ready-access to internally-generated knowledge	Knowledge is ***systematically*** generated, identified, captured, shared, applied and leveraged, enabling extracting optimal value from it
Non automatized	***AI-supported:*** right knowledge at the right time for the right employee
Focused on personal growth	Adds a focus on ***R&D and enterprise productivity and competitive advantage***, as well as risk management
Functional leaders support learning within their functions	***Everyone in R&D is accountable*** to contribute to learning and to the knowledge-base
Learning is mostly done individually at fixed timepoints	Learning is conducted as well as part of a ***Community of Learning,*** including small cohorts, peers, experiential learning, and ***"learning in the flow of work",*** when needed (including micro-formats)
Learning is focused on compliance	Learning journeys are ***individualized***, and tailored to the most needed knowledge, skills and behaviors (competencies)
Outputs and effectiveness of learning are assessed individually	***Feedback*** is systematically captured so that new learners benefit from the experience of prior learners and approach to learning is informed by results of prior learning offerings
Onboarding and exit processes do not systematically capture and transfer "clinical knowledge pearls"	"Clinical knowledge pearls" are ***systematically captured and transferred*** as part of the employee onboarding & exit processes
Reluctance to communicate lessons broadly, and time constraints, prevent full engagement in learning	***Effective incentives*** of knowledge management are embedded into time and performance management and career development processes (promotion requirements)

Bersin, J. "The Capability Academy: where corporate training is going." *Josh Bersin Academy*, 30 August 2022, https://joshbersin.com/2019/10/the-capability-academy-where-corporate-training-is-going/
Glaveski S. Where companies go wrong with Learning and Development. HBR, Oct 2019

Current vs. Future State of Learning

Scientific, clinical and technical knowledge and skills are mainly the territory of individual functions	Clinical Research & Development is an ***R&D-wide core capability*** supported cross-functionally
Lack of consistency regarding educational or experiential requirements & personnel certification in clinical research	A ***harmonized, leveled core competency framework*** guides training and accreditation and informs career ladders & trajectories, job descriptions, & performance evaluations
Available learning is focused on general competencies and processes (SOPs, etc.)	Learning encompasses ***all knowledge, skills and behaviors necessary for innovative and productive clinical R&D*** (as defined in a competency-based, leveled curriculum)
Knowledge is hidden, scattered, inaccessible, stale and available in few formats	Knowledge has ***unified access***, evolves constantly (users can annotate it) and is available always (on schedule and on demand) and in multiple formats (original documents, audio, video, dynamic visualizations, etc.)
There is limited ready-access to internally-generated knowledge	Knowledge is ***systematically*** generated, identified, captured, shared, applied and leveraged, enabling
Non automatized	***AI-supported:*** right knowledge at the right time for the right employee
Focused on personal growth	Adds a focus on *R&D and enterprise productivity and competitive advantage*, as well as risk management
Functional leaders support learning within their functions	***Everyone in R&D is accountable*** to contribute to learning and to the knowledge-base
Learning is mostly done individually at fixed timepoints	Learning is conducted as well as part of a *Community of Learning*, including small cohorts, peers, experiential learning, and *"learning in the flow of work"*, when needed (including micro-formats)
Learning is mostly about compliance	Learning journeys are ***individualized***, and tailored to the most needed knowledge, skills and behaviors (competencies)
Outputs and effectiveness of learning are assessed individually	*Feedback* is systematically captured so that new learners benefit from the experience of prior learners and approach to learning is informed by results of prior learning offerings
Onboarding and exit processes do not systematically capture and transfer "clinical knowledge pearls"	"Clinical knowledge pearls" are ***systematically captured and transferred*** as part of the employee onboarding & exit processes
Reluctance to communicate lessons broadly, and time constraints, prevent full engagement in learning	*Effective incentives* of knowledge management are embedded into time and performance management and career development processes (promotion requirements)

Bersin, J. "The Capability Academy: where corporate training is going." *Josh Bersin Academy*, 30 August 2022, https://joshbersin.com/2019/10/the-capability-academy-where-corporate-training-is-going/
Glaveski S. Where companies go wrong with Learning and Development. HBR, Oct 2019

Initial *R&D Knowledge Development Academy* Framework

Pillar 1

Core Clin Dev Curriculum:
Foundational curriculum to level-up competencies (knowledge, skills and behaviors) related to clinical development:

-leveled curricula based on (1) standard curriculum* + (2) items driven by Takeda's strategy (e.g., digital medicine, Elevate China, cell and gene therapy, etc.)

-self-assessment

-study guides

Pillar 2

Knowledge and learning sharing:

Manage knowledge life cycle

Generate, reflect, capture and exploit learning related to clinical development:

-structured at program, asset, study level, and business process (R&D Playbook)

-available on demand

-multiple formats, levering automation and AI

Pillar 3

Community of Learning:

Leverages our culture and leadership behaviors:

-leaders who model culture, serve as faculty, curate case studies

-supports growth/adapting mindsets

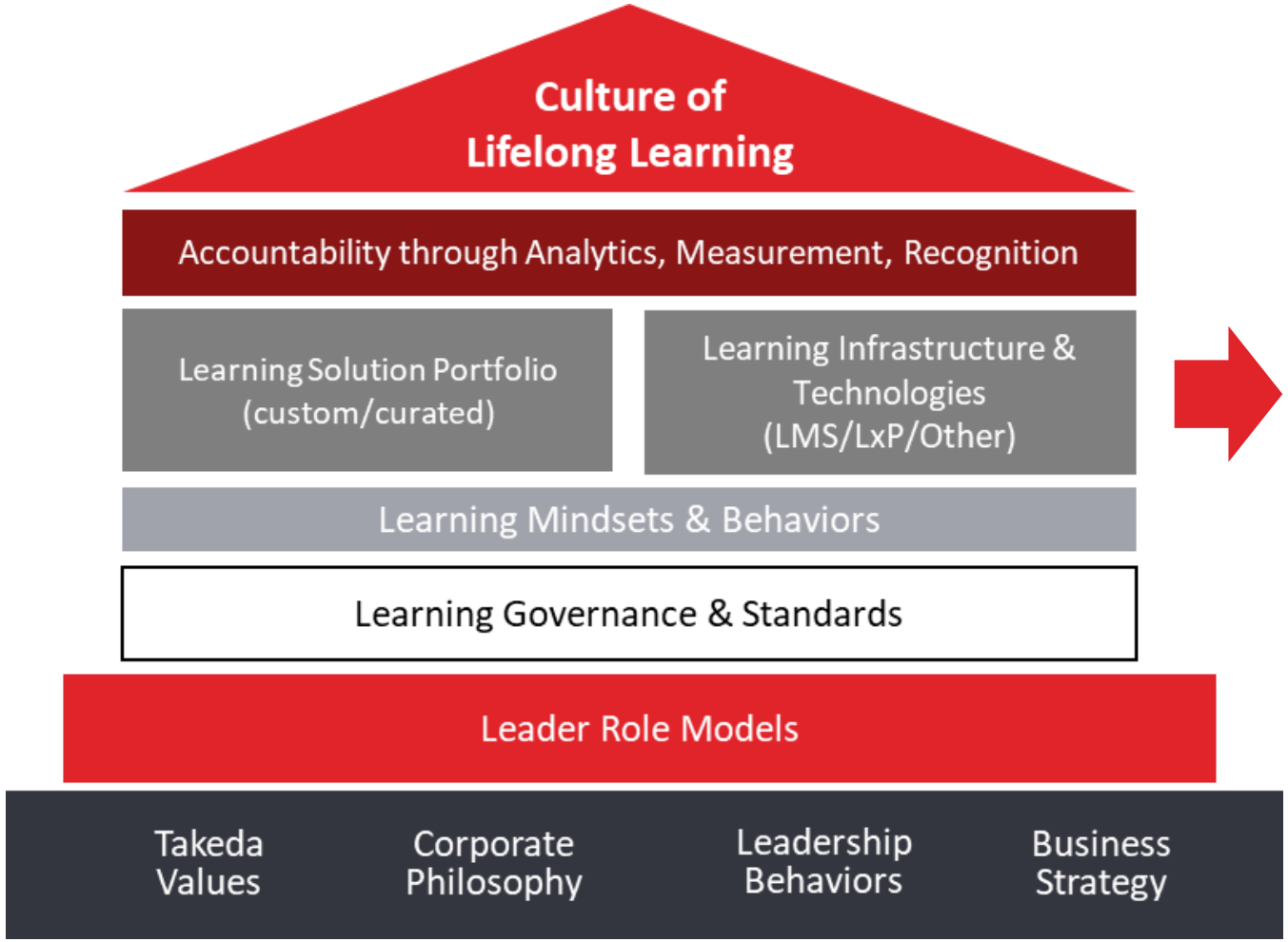
-sustains the learning organization

-ensures broad accountability

Scope: Scientific, Medical & Technical (as applied cross-functionally)
R&D-wide and Enterprise-enabled

* Multi-Regional Clinical Trial Center's Core Competency Framework for clinical research professionals

Enabling a culture of lifelong learning through learning technologies



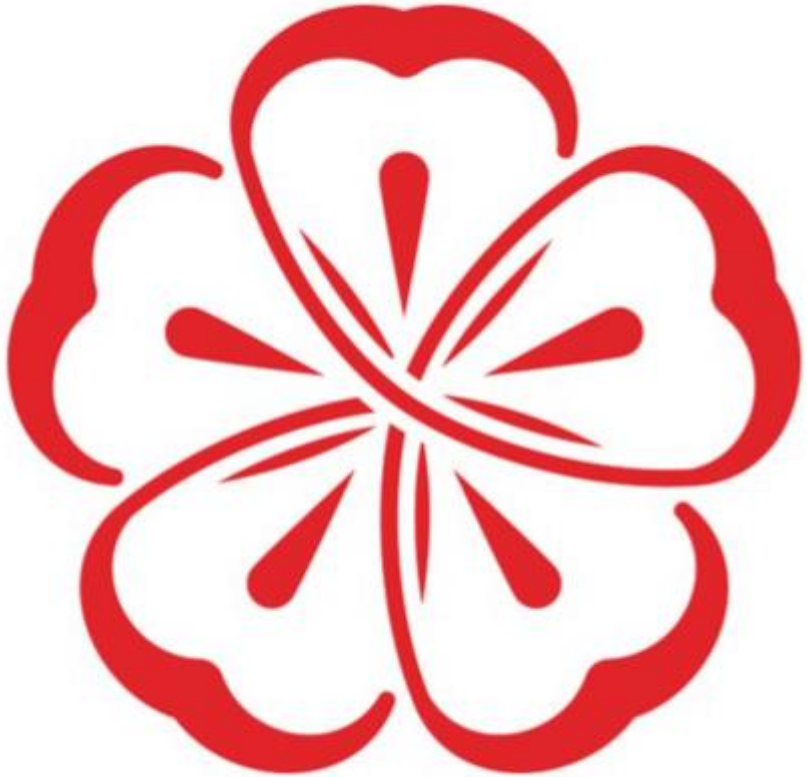
Integrated learning infrastructure and technology will enable the delivery of **relevant, personalized, continuous** learning solutions.

A **unified, learner-friendly interface** which can connect learning solutions and people systems/data is foundational to sparking one's interest and excitement about learning.

And we gave it a name

Bloom

学び花開く



Our Learning Experience Platform, Bloom, provides content for everyone

Strategic Learning Initiatives for All Employees: Learning Channels for All Employees based on key learning initiatives

Core Enterprise Learning for All Employees: Our Takeda, My Development & My Productivity

My BU/F: Learning Channels for Specific BU/F Learning Experiences

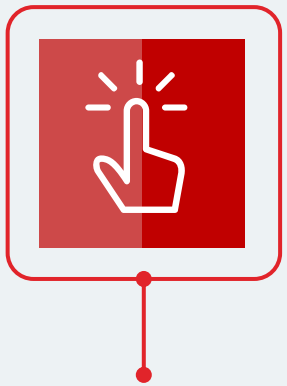
My Roles: Learning Channels for Specific Roles (i.e., People Managers, E&C Professionals, etc.)

Featured Content Providers: Enterprise Content Providers (for all Takeda employees)

Bloom's CONTENT ARCHITECTURE

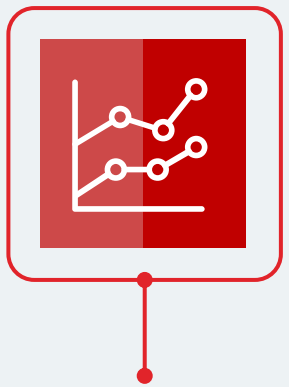
Overview

CONTENT ASSETS



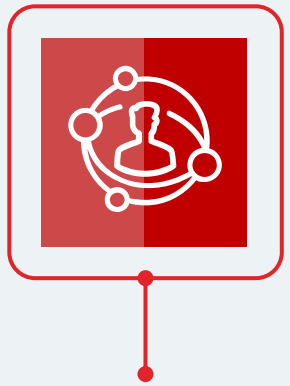
SMARTCARDS

It is the basic unit of content, such as video, link, article, etc.



PATHWAYS

It is a collection of Smartcards.



JOURNEYS

It is a structured collection of Pathways or SmartCards.

CONTENT CONTAINERS

CHANNELS

It is a collection of content from multiple sources related to a topic.

~Songs	~Albums	~Boxed Set		~Radio Station

CHANNEL:

R&D Knowledge Development Academy

JOURNEYS:

Foundational Clinical Development Curriculum

Core leveled competency framework (MRCT)

Digital Medicine Fundamentals for Pharma Course (*DiMe-Takeda*)

Takeda Physician Scientist Accelerator Program Curriculum

The Oncology Clinician Journey

Savo's ("the engineer & data scientist") Journey

The Learning Journey

Target audience:

Clinical research professionals and colleagues supporting clinical development

All R&D colleagues

Clinicians joining Takeda from Academia or government

Clinical Subteam members joining the oncology TAU with limited experience in pharma; all may benefit from AAADV workshop

Engineers, data scientists, and others without experience in biopharma

Anyone interested on effective learning

PATHWAYS:

Basic (Dev 101)

Introduction to Clinical Trials (ACRP)

The Drug Development Process: Improving Trial Feasibility and Exploring Your Growth Potential (ACRP)

FDA 101 (FDA)

Intermediate

Good Clinical Practice Simulation (ACRP)

Regulatory Education for Industry (FDA)

Advanced

CERSI Immersion Course in Drug Discovery, Development, and Regulation (UCSF-Stanford)

CDER Small Business and Industry Assistance Learn (FDA)

*Interpretation and Application of ICH E6 (R2) - **Good Clinical Practice** (MRCT)*

Education Clearinghouse (NIH CLIC)

Level 1 / Basic

Level 2 / Basic Plus

Level 3 / Pro

Curriculum for reference

Workshops

TPSAP Brochure

Oncology Clinical Development Physician/Scientist Training Program

AAADV Workshop (Duke Univ. and FDA)

After Action Reviews

Learning to Learn

AAADV: Accelerated Anticancer Agent Development & Validation
ACRP: Association of Clinical Research Professionals.
DiMe: Digital Medicine Society
MRCT: Multi-Regional Clinical Trials Center at Harvard

Next steps for Takeda R&D's Knowledge Development Academy

Enhance the digital medicine offering: a digital curriculum?

In addition to the foundational curriculum (JTF), we envisioned having a Takeda-specific component of the curriculum for clinical research professionals that aligns directly with Takeda's corporate philosophy and strategy. "Data, digital, and technology" is a new, central element of the strategy.

- We partnered with the Digital Medicine Society to develop and offer a Digital Medicine Fundamentals for Pharma course.
- Jenifer Goldsack, DiMe's CEO, recently announced its completion and availability.

There is a need and an opportunity to start building a curriculum for that specific aspect of the work of clinical research professionals at Takeda, given the anticipated scale-up within Takeda and across the ecosystem.

Build a knowledge management platform that links with the curriculum/competency framework

Engage the recently created Takeda *R&D Learning Community of Practice* to support the KDA (governance, employee participation, sustainability plan)

Deploying the JTF framework across the world – Translations and applications

Allan WILSDORF, F-CRIN/CRIGH

JTF – Strategic Global Meeting

November 14th 2022

CRIGH

Translations

14th November, 2022

CRIGH

JUNE 2022

Publication of the French Translation

Pays	Structure		Contributeur
Belgique	KCE	KCE TRIALS	Nelle Stocquart
France	F-CRIN (French Clinical Research Infrastructure Network)	F.CRIN	Allan Wilsdorf
Luxembourg	LIH (Luxembourg Institute of Health)	LUXEMBOURG INSTITUTE OF HEALTH	Jonathan Cimino
République démocratique du Congo	Université de Kinshasa (UNIKIN)		Yves Lula Ntamba
Sénégal	IRESSEF (Institut de Recherche en Santé de Surveillance Epidémiologique et Formation)	IRESSEF	Jean-Pierre Nguessan
Suisse	SCTO (Swiss Clinical Trial Organisation)	swiss clinical trial organisation	Melanie Glättli

To be proofread by the Canadian Cancer Clinical Trials Network (3CTN)

CRIGH

Finalisation of the Italian Translation

Currently being proofread by the CTU in Lugano (SCTO – Switzerland)

New Translations

- Assist the **Thaï**, **Indonesian** and **Vietnamese** translations within ARISE (ARO Alliance for ASEAN & East Asia) led by NCGM (Japan)
- Several on-going contacts for the setup of an **Arabic** translation group (Saudi Arabia and Dubai)
- On-going contact for the setup of a **Dutch** translation group

Work on original English version

Objectives of the critical reading of the original English version

- Wording homogeneisation
- Global meaningfulness
- Additional topics

- Mapping of the differences between the original framework and the Swiss adaptation (SCTO)

Shows what has been kept "untouched", what has been discarded and what has been added

- Wording analysis of the Swiss adaptation

Highlights the work which has been conducted by SCTO on the homogeneisation of the wording

CRIGH

Applications

CRIGH

Following the survey set up in France (297 answers collected between January and July 2021)

- Work with Tech4Health's Training Working Group (French Investigation Network specialised in medical devices)
- Identification of specific competency families for clinical research professionals working with medical devices (to be used for the second survey targeting clinical research professionals of the private sector)

Talks with Inserm (French National Institute of Health and Medical Research) for the use of the framework in the design of a training program specific to project managers

CRIGH

JTF Competency survey in Low-and Middle Income Countries: Initial Analysis of Results

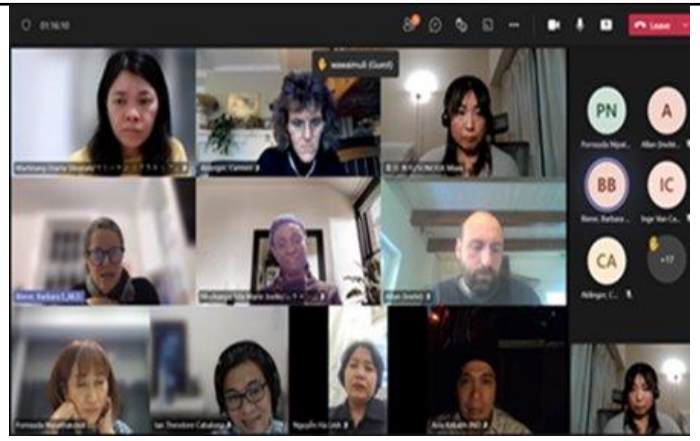
Miwa SONODA RN, MPH, GDip(Clinical Trial), GDip(Global Health)

Deputy Director General of ARISE Secretariat

Medical Science Liaison
Department of International Trials
Center for Clinical Sciences
National Center for Global Health and Medicine

Team Members

Name of Institute	Project Participants
National Center for Global Health and Medicine (NCGM)	Dr. Sifa Muchanga, Dr. Nattha Kerdsakundee, Dr. Umano Maria Ruriko, Ms. Marlinang Diarta Siburian, Dr. Tastuo Iiyama
Osaka Electro-Communication University	Dr. Masahiko Sakaguchi
University of Indonesia	Dr. Wawaimuli Arozal, Dr. Anggi Gayatri, Dr. Melva Louisa
Philippines University of Philippines Manila	Dr. Ian Cabulana, Dr. Edwin C Ruamero
Thailand, Mahidol University	Dr. Kulkanya Chokephaibulkit, Ms. Pornsuda Nipathakosol
Vietnam, Bach Mai Hospital	Ms. Ngueyn Thi Thu Ha, Ms. Phuong Doan, Ms. Huong Nguyen
DRC, The University of Kinshasa	Dr. Tona Lutete Gaston, Dr. Yve Lula Ntamba

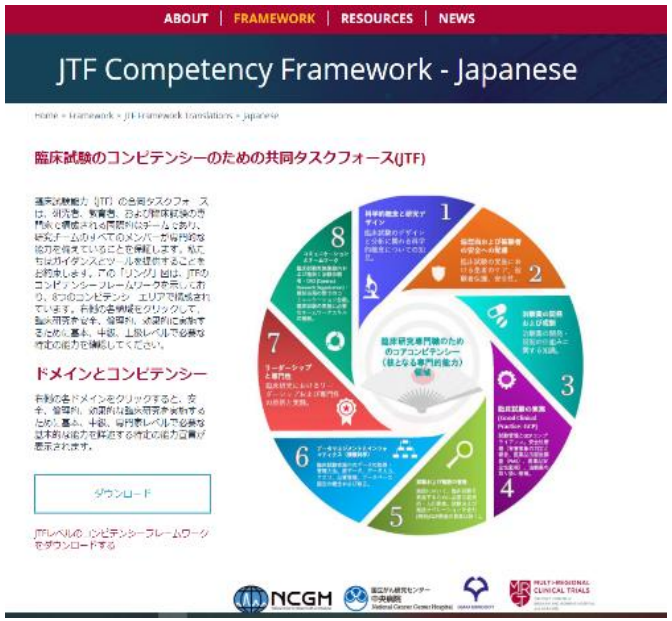


Competency Translation

Plan: Make available in 2022 on the website at each country, NCGM & the MRCT Center

Japanese

websitehttps://mrctcenter.org/clinical-trial-competency/framework/translations/japanese/



Thai (Done)

Indonesian

Vietnamese

Survey: Self-Assessment of Clinical Research Competence

- **Study objective:**

  To investigate
  - the competency level of clinical research professionals
  - the relationship between each competency and job function
  - the training needs of each competency.

- **Participating country;** Indonesia, DRC, Philippines, Thai, Vietnam

- **e-Survey:**

  The questionnaire developed by the MRCT center was applied and translated into the local languages.

- **Data collection Period;** From March to June 2022

- **Study Population**
  - The study population is a non-random, purposeful samples.
  - The minimum number of participants is 150 in each country

- **Respondents;** 843/1020 (Respondents rate 82.6%)

https://www.surveymonkey.com/r/FKUI?lang=id

SCTO PLATFORMS

Clinical Research Core Competencies (CRCC):
an adaptation of the JTF Framework to Switzerland

JTF Strategic Global Meeting, November 14, 2022

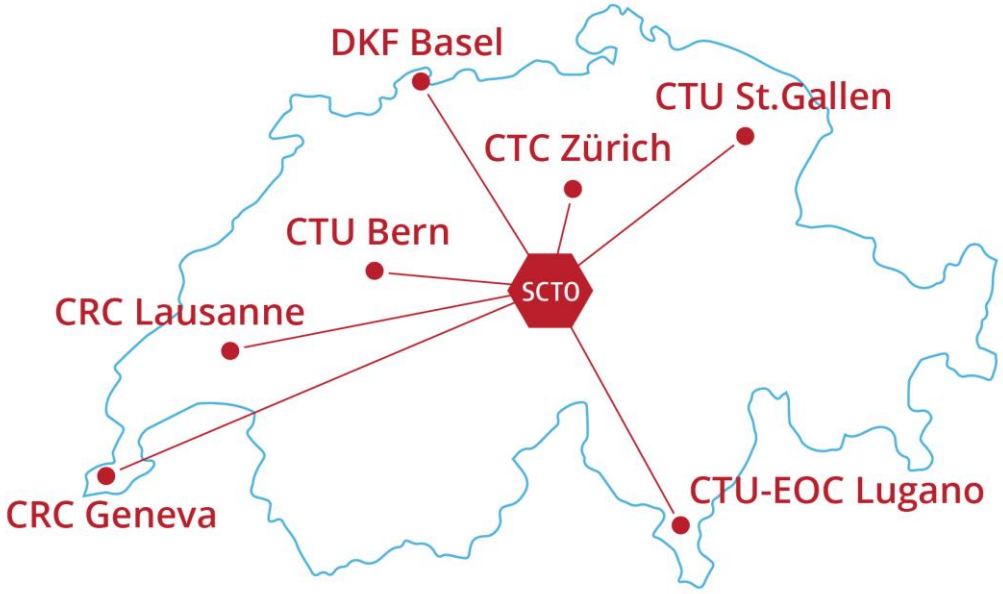
Melanie Glaettli, Swiss Clinical Trial Organisation (SCTO)

SCTO PLATFORMS

Swiss Clinical Trial Organisation

- National and decentralised clinical research infrastructure since 2009.
- Network of **7 CTUs**, including all 5 Swiss university hospitals
- Since 2017, setup of **8 thematic platforms**

swiss
clinical
trial
organisation



http://www.scto.ch/

SCTO PLATFORMS

SCTO Platforms

- Each thematic platform includes persons from each CTU
- We develop **freely available tools and resources**

Auditing

Data Management

Education

Monitoring

Project Management

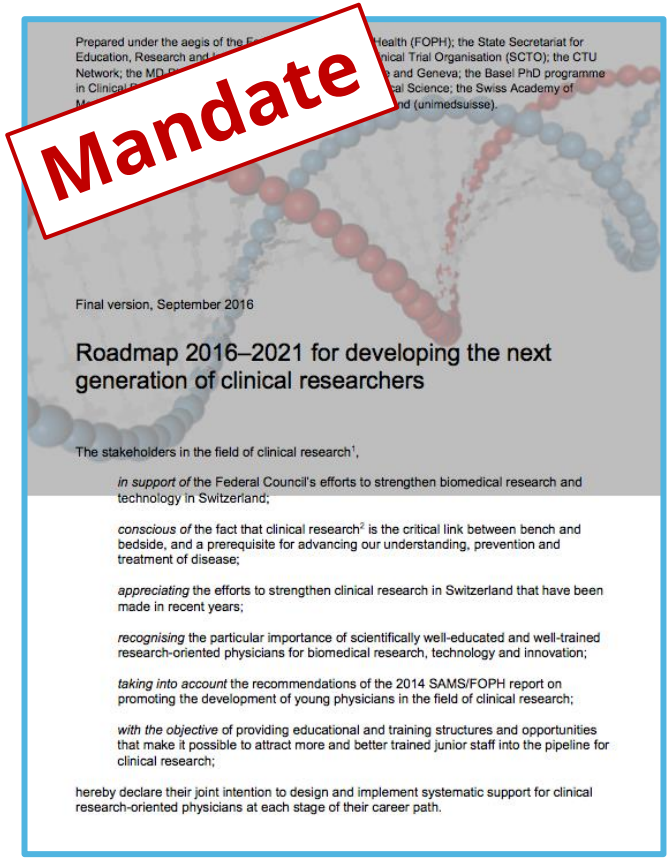
Regulatory Affairs

Safety

Statistic & Methodology

www.sctoplatforms.ch

Roadmap “next generation”



Federal Office of Public Health

Roadmap of national relevance

- support research-oriented physicians at each stage of their career path

- Two mandates for the SCTO Education Platform
  - Standards for clinical research skills
  - Clinical Research Education Centre

Clinical Research Competencies: what we did

Review of existing frameworks

Adaptation to Swiss context

Clinical Research Careers

Implementation on career development website

Glaettli et al. 2022. Swiss Medical Weekly

Clinical Research Competencies: what we did

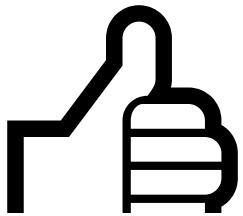
Review of existing frameworks

Adaptation to Swiss context

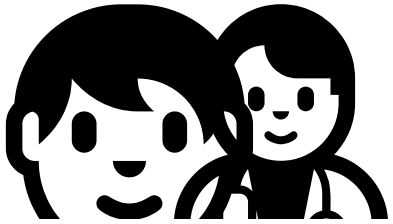
Clinical Research Careers

Implementation on career development website

Link to training opportunities of our CTU network



Acknowledgement of stakeholders



Consultation of physician-scientists running clinical trials

Glaettli et al. 2022. Swiss Medical Weekly

SCTO PLATFORMS

Clinical Research Careers website

Clinical
Research
Careers

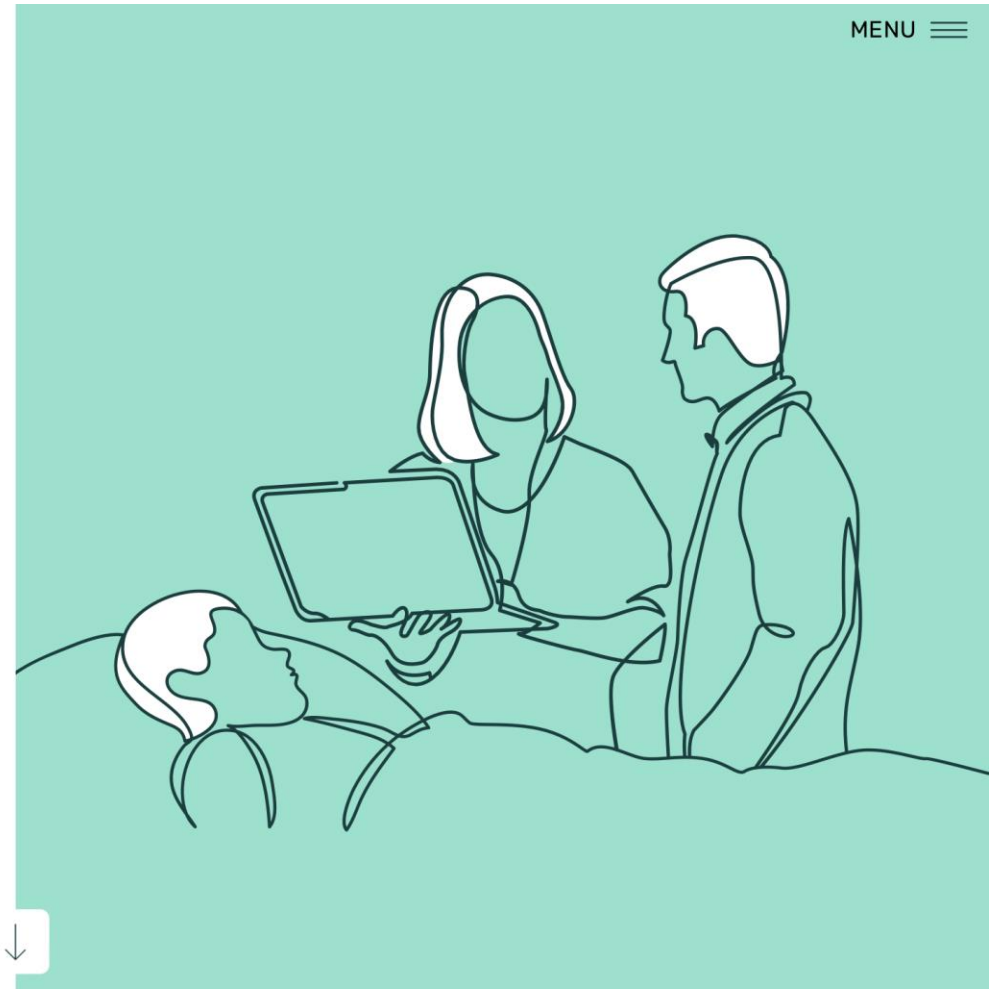
MENU

Become a clinical researcher

Are you a medical student or a resident interested in a clinical research career in Switzerland? Or a senior registrar aiming to run high-quality clinical research projects?

This website provides you a clear overview of career support and funding opportunities, available training options and mentoring programmes. Use it to explore typical career tracks and plan your academic career.

MORE ON CAREER TRACKS



http://www.cr-careers.ch/

Clinical Research Careers website

http://www.cr-careers.ch/

SCTO PLATFORMS

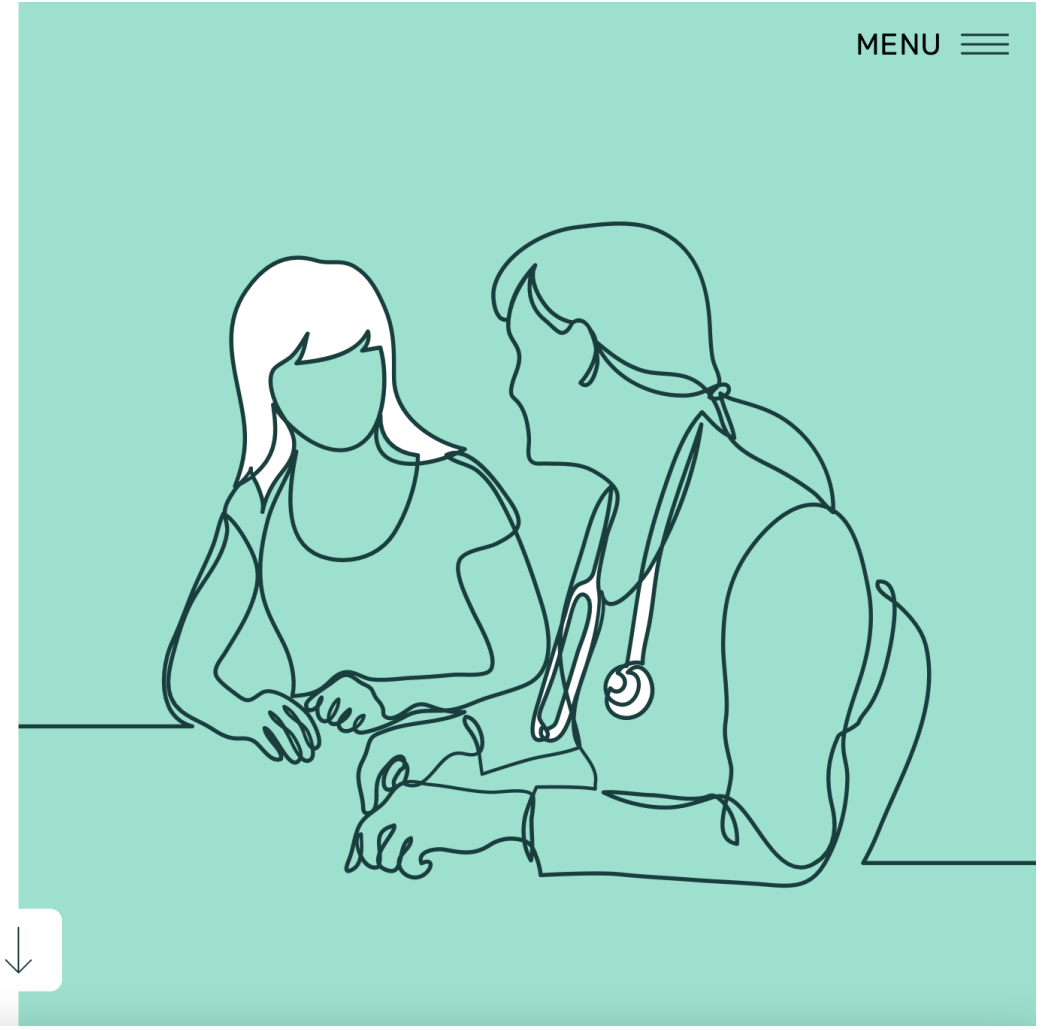
Core Competencies Framework

Clinical
Research
Careers

Core competencies

Explore each of the 8 competency domains below to identify the knowledge, skills, and attitudes necessary for the effective, ethical, and safe conduct of clinical trials. The domains are based on the internationally recognised Joint Task Force for Clinical Trial Competency (JTF) framework and have been adapted to Swiss legislation on human research.

Fundamental, skilled, and advanced levels correspond to sub-investigator, investigator and sponsor-investigator roles respectively, as defined by ICH-GCP guidelines and Swiss legislation on human research.



SCTO PLATFORMS

Core Competencies Framework

– 1 – Scientific concepts and research design	**– 2 –** Ethics and participant rights	**– 3 –** Healthcare intervention development and regulation	**– 4 –** Clinical research operations (Good Clinical Practice)
– 5 – Trial and site management	**– 6 –** Data management	**– 7 –** Leadership and professionalism	**– 8 –** Communication and teamwork

1 — Scientific concepts and research design

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

1.1 Have health-related knowledge and practical experience in the medical area

1.2 Apply scientific principles to the discovery and development of interventions

1.3 Identify scientific questions, clinical research hypotheses, and objectives of clinical trials

SCTO PLATFORMS

Core Competencies Framework

1.5

Identify the elements and explain the principles and processes of a clinical trial; understand clinical research methodology

Fundamental level

A1. Recognise the basic differences between the various types of clinical trials

A2. Identify the key elements of a clinical trial protocol

A3. Adhere to a clinical trial protocol to ensure validity of the trial

Example: When given a clinical trial protocol, researcher identifies the trial type and key elements of the protocol and can adhere to them.

Skilled level

B1. Review a clinical trial protocol to ensure all needed elements are included

B2. Understand (design) aspects of a clinical trial that are critical to answer the scientific question(s)

B3. Evaluate strengths and weaknesses of trial designs and explain these to others

B4. Understand the importance of and methods for accessing, critiquing and synthesising literature appropriately

Example: When given a clinical trial protocol, researcher identifies missing, incomplete, or inappropriate features and aspects that are of relevance for conducting the trial and are critical for the objectives.

Advanced level

C1. Evaluate the clinical trial design and communicate it to others

Example: When given a clinical trial protocol that has misalignment between the measures and objectives, researcher appropriately modifies the protocol.

VIEW TRAINING OPTIONS

Raising awareness and further work

Clinical Research Core Competencies Framework
for clinical trials

Making the framework more visible

SMW publication

Adapting the framework to “research projects” (not clinical trials: observational and/or further use of health data & samples)

in progress

- 80% of projects submitted to ECs
- Make it more accessible to young researchers

Thank you for your attention


Melanie Glaettli


Laura Di Petto


Aurélie Fayet


Caecilia Schmid


Andreja Vujicic Zagar


Verena Küppers


Claudia Fila


Simone Kälin


Antoine Poncet


Sven Trelle

MULTI-REGIONAL CLINICAL TRIALS

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

Update from CIOMS

CIOMS

- The Council for International Organizations of Medical Sciences (CIOMS) is an international, non-governmental, non-profit organization established jointly by WHO and UNESCO in 1949.

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

- April, 2021: Based on JTF leadership, Barbara and Stephen asked to join international group developing:

  "Recommended Standards of Education and Training for Health Professionals Participating in Medicines Development"

- Motivation for formation of workgroup was:
  - General lack of understanding by health professionals of the process of medicines development
    - Primarily due to lack of content on subject in educational programs
  - Controversies relating to medicines development and regulation during COVID pandemic
  - Increasing global medicines development activity and need for all levels of health professionals to understand process at varying levels

- Workgroup met online multiple times during 2021 and 2022 and developed Table of Contents, Background and Objectives

- Workgroup met face to face in Geneva, Switzerland on 9/6-7, 2022
  - Refined table of contents
  - Developed proposed text for Chapter 1: Background and Objectives
    - Much of proposed content designed around JTF Core Competency Framework, IFAPP Framework and PharmaTrain
  - Assigned subgroups to develop content for remaining chapters:
    - Principles of Working Group and Intended Benefits
    - Educational and Training Landscape
    - Syllabus Proposals
    - Good Education Practice Principles
- Workgroup planning another face to face meeting in February or March, 2023
  - Plan is to have final document by late Summer, 2023.

Discussion

Data Management Task Force

Discussion

Assessment of Competencies

Questions on Assessment of Competencies: Personal answers & examples

Presentation to the Joint Task Force for Clinical Trial Competency (JTF)

-

November 14, 2022

Elias M. Samuels

University Michigan

Michigan Institute for Clinical and Heath Research

Presentation Outline

Q1: Why should competency be assessed?
A: To evaluate & enable learning.

Q2: What competencies should be assessed?
A: Subjective & objective measures of comprehension or skill.

Q3: When should competency be assessed?
A: Pre- & post-program, or at every milestone.

Q4: Whose competency should be assessed?
A: All members of the workforce, including students, teachers, & staff.

Q5: How should competency be assessed?
A: Using rigorous evaluation plans & appropriate validation methods.

Why should competency be assessed?

Assessing competency is essential for measuring what & if;

- information is understood.
- capacities are possessed.
- competency changes over time.

Assessing competency is essential for enabling learning by;

- disseminating formative & summative evaluations.
- informing the content & design of new training programs.
- educating the next generation of teachers & investigators.

Why should competency be assessed?

Samuels, E., Ianni, P.A., Chung, H., Eakin, B., Martina, C., Murphy, S.L. and Jones, C., 2020. Guidelines for evaluating clinical research training using competency assessments. *MedEdPublish, 8*(202), p.202.

MedEdPublish

MedEdPublish 2020, 8:202 Last updated: 13 DEC 2021

RESEARCH ARTICLE

Guidelines for Evaluating Clinical Research Training using Competency Assessments [version 2]

Elias Samuels[1,5], Phillip Anton Ianni[1,5], Haejung Chung[2,6], Brenda Eakin[1,5], Camille Martina[3,7], Susan Lynn Murphy[1,5], Carolynn Jones[4,8]

[1]Michigan Institute for Clinical and Health Research
[2]Tufts Clinical and Translational Science Institute
[3]Clinical Translational Science Institute
[4]Center for Clinical and Translational Science
[5]Michigan Institute for Clinical and Health Research
[6]Tufts Clinical and Translational Science Institute
[7]Clinical Translational Science Institute
[8]Center for Clinical and Translational Science

What competencies should be assessed?

Subjective measures of comprehension & skill, including;

- learning outcomes: ‘As a result of this course I can…’
- self-efficacy: ‘How confident are you in your ability to…’
- expert ratings: ‘How well does _____ understand…’

Objective measures of comprehension & skill, including;

- knowledge checks & competency-based tests.
- ‘See One, Do One, Teach One’.
- programmatic benchmarks & milestones.

What competencies should be assessed?

Hornung, C.A., Ianni, P.A., Jones, C.T., Samuels, E.M., Ellingrod, V.L. and DIAMOND Investigators, 2019. Indices of clinical research coordinators' competence. *Journal of Clinical and Translational Science, 3*(2-3), pp.75-81.

Ianni, P.A., Eakin, B.L., Samuels, E.M., Champagne, E. and Ellingrod, V.L., 2021. The Research Objective Structured Clinical Exam (R-OSCE): an innovative tool to assess clinical and translational research competencies. *MedEdPublish, 10*(143), p.143.

Journal of Clinical and Translational Science

www.cambridge.org/cts

Education Research Article

Cite this article: Hornung CA, Ianni PA, Jones CT, Samuels EM, and Ellingrod VL for the DIAMOND Investigators (2019) Indices of clinical research coordinators' competence. *Journal of Clinical and Translational Science* **3**: 75–81. doi: 10.1017/cts.2019.381

Received: 13 February 2019
Revised: 16 April 2019
Accepted: 5 May 2019
First published online: 24 July 2019

Key words:
Core competency; clinical research professional; clinical research coordinator; assessment tool; exploratory factor analysis

Address for correspondence:
C. A. Hornung, PhD, MPH, Department of Medicine, University of Louisville, 18613 John Connor Rd., Cornelius, NC 28031, USA.
Email: CAHornung@Louisville.edu

Indices of clinical research coordinators' competence

Carlton A. Hornung[1,2], Phillip A. Ianni[3], Carolynn T. Jones[4], Elias M. Samuels[3] and Vicki L. Ellingrod[3,5] for the DIAMOND Investigators

[1]Consortium of Academic Programs in Clinical Research; [2]Department of Medicine, University of Louisville School of Medicine, Louisville, KY, USA; [3]Michigan Institute for Clinical and Health Research, University of Michigan, Ann Arbor, MI, USA; [4]College of Nursing, The Ohio State University, Columbus, OH, USA and [5]College of Pharmacy, University of Michigan, Ann Arbor, MI, USA

Abstract

Introduction: There is a clear need to educate and train the clinical research workforce to conduct scientifically sound clinical research. Meeting this need requires the creation of tools to assess both an individual's preparedness to function efficiently in the clinical research enterprise and tools to evaluate the quality and effectiveness of programs that are designed to educate and train clinical research professionals. Here we report the development and validation of a competency self-assessment entitled the Competency Index for Clinical Research Professionals, version II (CICRP-II). *Methods:* CICRP-II was developed using data collected from clinical research coordinators (CRCs) participating in the "Development, Implementation and Assessment of Novel Training In Domain-Based Competencies" (DIAMOND) project at four clinical and translational science award (CTSA) hubs and partnering institutions. *Results:* An exploratory factor analysis (EFA) identified a two-factor structure: the first factor measures self-reported competence to perform Routine clinical research functions (e.g., good clinical practice regulations (GCPs)), while the second factor measures competence to perform Advanced clinical functions (e.g., global regulatory affairs). We demonstrate the between groups validity by comparing CRCs working in different research settings. *Discussion:* The excellent psychometric properties of CICRP-II and its ability to distinguish between experienced CRCs at research-intensive CTSA hubs and CRCs working in less-intensive community-based sites coupled with the simplicity of alternative methods for scoring respondents make it a valuable tool for gauging an individual's perceived preparedness to function in the role of CRC as well as an equally valuable tool to evaluate the value and effectiveness of clinical research education and training programs.

Introduction

The timely and successful translation of pharmaceuticals and medical devices into clinical applications to improve human health requires a well-prepared and competent workforce of clinical research professionals that includes principal investigators, research coordinators, monitors, administrators, regulatory affairs experts, informaticians, data managers, statisticians, and others. Appropriate training and mastery of the competencies characterizing each role in the research process is essential for the efficient conduct of clinical and translational research [1–3]. Accordingly, there is a critical need for tools to assess an individual's preparedness to execute his or her role in the research process; tools to assess an individual's need for continuing education and training; and, tools to evaluate the quality of education and training programs that prepare individuals to work in the clinical research enterprise.

Several steps have been taken to identify the core competencies that define the clinical

MedEdPublish

MedEdPublish 2021, 10:143 Last updated: 13 DEC 2021

Check for updates

RESEARCH ARTICLE

The Research Objective Structured Clinical Exam (R-OSCE): An Innovative Tool to Assess Clinical and Translational Research Competencies [version 2]

Phillip A. Ianni[1,2], Brenda L. Eakin[1,2], Elias M. Samuels[1,2], Ellen Champagne[1,2], Vicki L. Ellingrod[1,2]

[1]University of Michigan
[2]University of Michigan

v2 **First published:** 24 May 2021, **10**:143
https://doi.org/10.15694/mep.2021.000143.1
Latest published: 03 Sep 2021, **10**:143
https://doi.org/10.15694/mep.2021.000143.2

Abstract

This article was migrated. The article was marked as recommended.

Introduction

The Research Objective Structured Clinical Exam (R-OSCE) described in this paper was designed as part of a comprehensive program to assess competency in specific domains of clinical and translational research (CTR) for students enrolled in a 12-week introductory summer research program.

Methods

The program curriculum was mapped to core competencies developed by the National Center for Translational Science (NCATS) and used to develop R-OSCE stations. Twelve stations were developed, with five administered during orientation as a practice test and seven

Open Peer Review

Migrated Content

"Migrated Content" refers to articles submitted to and published in the publication before moving to the current platform. These articles are static and cannot be updated.

Invited Reviewers

	1	2	3
version 2 03 Sep 2021	report		report
version 1 24 May 2021	report	report	

1. **BALAJI ARUMUGAM**, TAGORE MEDICAL COLLEGE AND HOSPITAL

2. **Trevor Gibbs**, AMEE

When should competency be assessed?

Pre- & post-program, including assessments conducted;

- at the point of application.
- when needed for formative evaluation.
- as need to measure long-term programmatic outcomes.

Established program milestones could include participants';

- matriculation & completion the program.
- demonstration of key competencies in practice.
- meeting programmatic benchmarks.
- advancing programmatically or professionally.

When should competency be assessed?

Samuels E, Ianni P, Eakin B, Champagne E, Perorazio T, Ellingrod V. (2022) Quasi-experimental approaches to evaluating clinical research training programs. *Performance Improvement Quarterly. 35*(3) (In press)

A QUASIEXPERIMENTAL EVALUATION OF A CLINICAL RESEARCH TRAINING PROGRAM

Elias Samuels | Phillip A. Ianni | Brenda Eakin | Ellen Champagne | Vicki Ellingrod

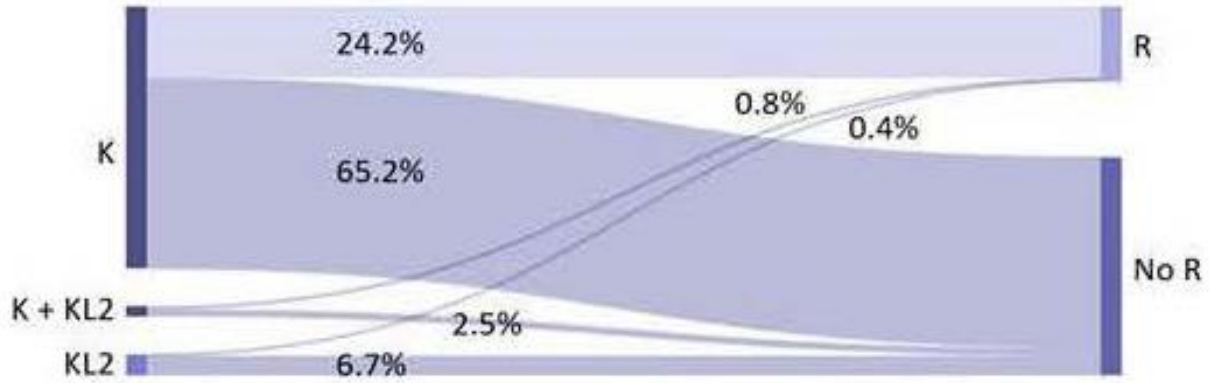


FIGURE 2. Sankey diagram of the paths U-M K awardees took to an R01 award (2005–2015).
Note: Diagram was created using SankeyMATIC

Whose competency should be assessed?

Assess those involved in training programs, including;

- faculty, investigators & program directors.
- scholars, trainees, fellows & students.
- staff, contractors, volunteers & mentors.

Assess professionals constituting the workforce, including;

- workers in all contributing roles, units and partnerships.
- workers advancing or onboarding into new roles.
- interns, apprentices & others in probationary statuses.

Whose competency should be assessed?

Sonstein, S.A., Samuels, E., Aldinger, C., White, S.A. and Bierer, B.E., 2022. Self-assessed Competencies of Clinical Research Professionals and Recommendations for Further Education and Training. *Therapeutic Innovation & Regulatory Science, 56*(4), pp.607-615.

Average Self-assessed Competency Rating by Role and by Domain	Number of respondents	Scientific Concepts & Research Design	Ethical and Safety Considerations	Investigational Product Development and Regulation	Clinical Study Operations	Study and Site Mgt	Data Mgt and Informatics	Leadership and Professionalism	Communications and Teamwork
Clinical Research Associate/Monitor	52	6.9	7.4	7.3	7.9	7.7	7.3	7.9	7.5
Clinical Research Coordinator/Nurse	183	6.4	7.5	6.1	7.6	6.9	7.1	7.4	6.7
Educator/Trainer	51	7.8	8.4	7.8	8.5	8.3	7.4	8.5	8.8
Principal Investigator/Co-Investigator	51	7.5	8.0	6.9	7.7	7.0	6.8	8.0	7.7
Project Manager/Research Manager	164	7.5	8.2	7.9	8.3	8.8	7.8	8.6	8.3
Regulatory Affairs Professional (49)	46	6.8	8.3	7.5	7.8	6.8	6.6	8.1	6.8
Average of All Roles	661	6.9	7.8	7.1	8.0	7.5	7.1	8.0	7.6

How should competency be assessed?

Competency assessments benefit from evaluations of;

- differences across domains of comprehensive frameworks.
- appropriate comparisons between & within groups.
- changes in competency over time.

Apply statistical techniques to validate assessments by;

- generalizing assessments to valid study populations.
- analyzing the factor structure of valid assessments.
- demonstrating assessments are predictive of outcomes.

How should competency be assessed?

Ianni, P.A., Samuels, E.M., Eakin, B.L., Perorazio, T.E. and Ellingrod, V.L., 2021. Assessments of research competencies for clinical investigators: a systematic review. *Evaluation & The Health Professions, 44*(3), pp.268-278.

Evaluation & the Health Professions
2021, Vol. 44(3) 268-278

DOI: 10.1177/0163278719896392
journals.sagepub.com/home/ehp
SAGE

Assessments of Research Competencies for Clinical Investigators: A Systematic Review

Phillip A. Ianni[1], Elias M. Samuels[1], Brenda L. Eakin[1], Thomas E. Perorazio[1], and Vicki L. Ellingrod[1,2]

Abstract

Although there is extensive research literature on clinical skill competencies and the use of competency-based frameworks for clinical research, the appropriate methods to assess these competencies are not as well understood. Our goal in this systematic literature review is to identify, compare, and critique assessments of clinical research competencies. Articles were included in this review if they examined clinical investigators or clinical investigators in training, focused on research-based skills, and included some form of assessment of research-based competencies. A total of 76 articles were identified as part of the initial search; 16 met the criteria for inclusion. Two types of assessments of clinical research competence were identified: subjective self-assessments ($n = 13$) and objective tests ($n = 6$). These assessments covered a wide range of competencies, but there were no competency domains common to all. Most assessments had limited validation. Training was consistently associated with self-assessed com-

Thank You

Co-authors
&
Joint Task Force
for Clinical Trial Competency (JTF)

Elias M. Samuels
University Michigan
Michigan Institute for Clinical and Heath Research

November 14, 2022

Discussion

Wrap Up and Next Steps

New JTF Initiatives

- Update of Data Management and Informatics (Domain 6) competencies
- Issues relating to Assessment of Competency

Wrap Up and Next Steps

- New initiatives
- Process for making changes to JTF Framework going forward
  - Issues related to future changes and modification of translations
- Next Meeting of JTF

Questions, Comments, Suggestions

Questions and discussion

Carmen Aldinger, PhD
caldinger@bwh.Harvard.edu

Barbara E. Bierer, MD
bbierer@bwh.Harvard.edu

Stephen Sonstein, PhD
ssonstein@gmail.com