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Joint Task Force for Clinical Trial Competency (JTF)

Biannual Global Meeting

June 22 , 2026

9:00 AM - 11:00 AM ET



**MULTI-REGIONAL
CLINICAL TRIALS**

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

This Meeting



We are recording this meeting for note-taking purposes and to potentially make some or all of the recording available for on-demand viewing.

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.

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

Agenda



Time EDT	Topic	Speaker
9:00-9:10 AM	Welcome and Introduction	<p>Barbara Bierer, MD Co-Chair, JTF Faculty Director, MRCT Center</p> <p>Stephen Sonstein, PhD Co-Chair, JTF Consultant, MRCT Center</p>
9:10-9:35 AM	Process and Output of JTF Patient Partner Project (P3)	<p>Sylvia Baedorf Kassis, MPH Program Director, MRCT Center</p> <p>Linda Hunter, BScN, MScN, PhD (C) Patient Engagement Lead Consultant, Bruyere Health Research Institute Former National Manager of the Patient and Community Partner Stream, Grant Co-Applicant, CANTRAIN</p>
9:35-10:00 AM	Process and Output of JTF Domain 6 Revision	<p>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</p> <p>Richard Ittenbach, PhD Professor, Pediatrics Director, Clinical Data Science Program Associate Director for Planning and Evaluation Division of Biostatistics and Epidemiology, University of Cincinnati College of Medicine</p>

Agenda



Time EDT	Topic	Speaker
10:00-10:55 AM	<p>Discussion:</p> <p>What are the issues and processes for incorporating JTF-P3 and Domain 6 revision into the JTF Framework?</p> <p>What other changes are needed to the JTF Framework for Version 4.0?</p>	<p>Facilitators:</p> <p>Barbara Bierer, MD Co-Chair, JTF Faculty Director, MRCT Center</p> <p>Stephen Sonstein, PhD Co-Chair, JTF Consultant, MRCT Center</p> <p>Discussants include:</p> <p>Elizabeth Edwards Parexel</p> <p>Stephanie Freel, PhD, PMP Duke University</p> <p>Jessica Fritter, DHSc, MACPR, ACRP-CP, FACRP The Ohio State University</p> <p>Debra Pritchett, MBA, ACRP-CP Merck</p> <p>David Vulcano, MSW, MBA, CIP, RAC, FACRP Association of Clinical Research Professionals (ACRP)</p> <p>& any of the meeting participants</p>
10:55-11:00	Wrap-up	<p>Stephen Sonstein, PhD Co-Chair, JTF Consultant, MRCT Center</p> <p>Barbara Bierer, MD Co-Chair, JTF Faculty Director, MRCT Center</p>



Introduction

Barbara Bierer, MD

Faculty Director, MRCT Center
Co-Chair, JTF

Stephen Sonstein, PhD

Co-Chair, JTF

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.



www.mrctcenter.org

Introductory Remarks



Clinical trial competencies: one of the earliest projects of the MRCT Center

Focused on competencies, not roles or titles, job descriptions or degrees

It takes a team

Clinical research is ever evolving:

- Study trial design and complexity

- Data at scale: Accumulation and interoperability

- Technology and analytic advances

- Patient and community engagement and partnership



JTF: identifying the knowledge and skills required for **safe, ethical, and high-quality clinical research** wherever trials are conducted in the world

www.mrctcenter.org/clinical-trial-competency



Each domain has specific competency statements



FOR EXAMPLE:

Domain 1: Scientific Concepts and Research Design

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

- 1.1 Apply principles of biomedical science to investigational product discovery and development and health-related behavioral interventions
- 1.2 Identify scientific questions that are potentially testable clinical research hypotheses
- 1.3 Identify the elements and explain the principles and processes of designing a clinical study
- 1.4 Maintain awareness of new technologies, methodologies, and techniques that enhance the conduct, safety, and validity of the clinical study
- 1.5 Critically analyze clinical study results

Evolution:

- Data management and governance
- Patient, family, and community importance and partnership

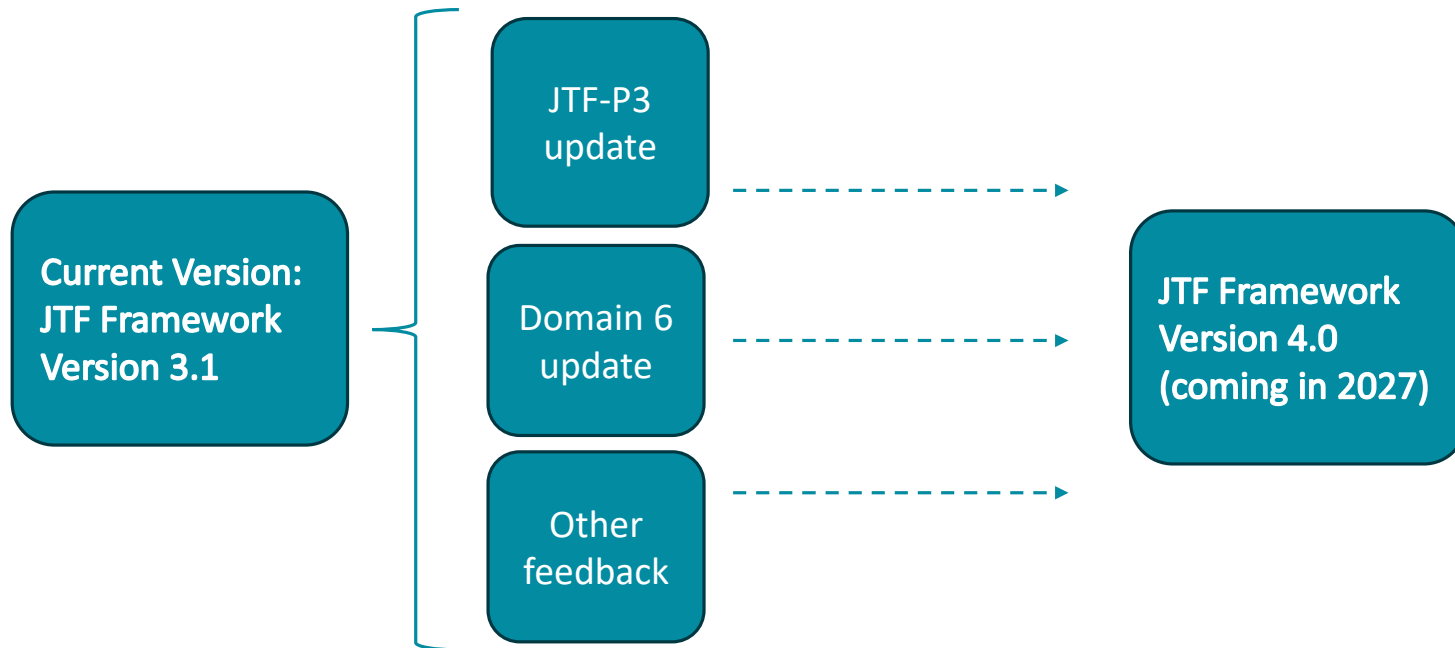


Fundamental, Skilled, and Advanced Level Competencies

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

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

The context of the JTF efforts





The Joint Task Force Patient Partner Project (JTF-P3)

Sylvia Baedorf Kassis, MPH
Program Director, MRCT Center
Linda Hunter, BScN, MScN, PhD (C)
Former National Manager of the Patient and Community Partner Stream, Grant Co-Applicant, CANTRAIN

Joint Task Force for Clinical Trial Competency

Co-Creating Clinical Research Competencies to
Support Effective Patient Partner Engagement
Activities

JTF Biannual Meeting - June 22, 2026



Today's Agenda



- **The Joint Task Force-Patient Partner Project (JTF-P3) North Star**
- **The JTF-P3 Process and Outcome**
- **JTF-P3 Practical Applications**
- **Closing**

The Joint Task Force: Patient Partner Project (JTF-P3)



A central focus of the JTF -P3 update is the inclusion of patient partners as active and integral collaborators and contributors.

The leveled competencies have specific elements that highlight where the inclusion of patient partner input is especially important, accompanied by practical examples.

Reciprocally, **engagement with patient partners is a critical competency for all clinical research professionals**, including establishing processes for and supporting patient partners from an institutional and study-specific perspective.

The JTF-P3, includes a Supplement focused explicitly on the integration of patient partners into the study team, to support more skilled, inclusive, and equitable study activities.

The JTF-P3 North Star



Co-Creating Clinical Research Competencies to Support Effective Patient Partner Engagement Activities

An initiative to unite a representative group of patient and caregiver partners, academic researchers and study staff, industry representatives, and others, to enhance the original JTF Framework.

Goal to co-create a resource that:

- (1) **supports patient partners** as active collaborators who have the competencies necessary to contribute as leaders, designers, advisors, and reviewers of clinical research, and
- (2) **ensures all members of the clinical research team** involved in the design, conduct, and reporting of clinical research **have the competencies needed to engage effectively with patient partners.**

Both are necessary for patient partners to be included as active and valued members of the research team.

JTF-P3 Leadership and Admin Team



MRCT Center/JTF

- Barbara Bierer
- Stephen Sonstein
- Jane Perlmutter
- Carmen Aldinger
- Sylvia Baedorf Kassis

CANTRAIN

- Jean Bourbeau
- Lisa Goos
- Julie Dessureault
- Sarah Ibrahim
- Linda Hunter
- Mei Li

EUPATI

- Ingrid Klingmann
- Maria Duterte



CANadian Consortium of Clinical Trial TRAINing Platform



OUR HIGHER PURPOSE

Improve health and wellbeing through clinical trial research for the Canadian population and beyond.



**BETTER PREPARED.
BETTER CARE.**

**MIEUX PRÉPARER.
MIEUX TRAITER.**

Funded by: | Financé par :



JTF Biannual Meeting - June 22,

EUROPEAN PATIENTS' ACADEMY ON THERAPEUTIC INNOVATION (EUPATI)

Enhancing patient
involvement
through education



Mission: To provide education and resources that enable patients and researchers to collaborate, co-create and innovate, inspiring collective global change across the health innovation ecosystem

JTF-P3 Work Group



Name	Role / Org.	Country
Alan Hamilton	Consultant	Canada
Allison Dalton	GWU	USA
Annie Leblanc	SPOR	Canada
Begonya Nafria Escalera	SJD Pediatrics	Spain
Bernard Coley	Patient Partner	USA
C. Daniel Mullins	University of Maryland	USA
Christine Mungoshi	Patient Partner / Zimbabwe Brain Tumor Association	UK/ Zimbabwe
Deborah Collyar	Patient Partner, Patient Advocates in Research	USA
Jacque van Ierssel	University of Ottawa	Canada
James Holahan	NYU Langone/CTSA	USA
Jana Popova	Patient Partner	Bulgaria
Jane Perlmutter	Patient Partner, Gemini	USA
Janice Tufte	Patient Partner	USA
Jennifer Monaghan	Patient Partner	Canada

Name	Role / Org.	Country
Katie Bainbridge	CANTRAIN	Canada
Kaushal Shah	Arizona State University	USA
Kay Warner	GSK	UK
Kyoko Imamura	Japanese Institute for Public Engagement	Japan
Leanne Marie Hays	UCD	Ireland
Mabel Crescioni	PCORI	USA
Mandy Daly	Patient Partner	Ireland
Mitchell Silva	Patient Partner	Belgium
Monica Bógas	Roche	Portugal
Rick Bangs	Patient Partner	USA
Sandra Karabatic	Healthcare Provider	Croatia
Sara Riggare	Patient Partner	Sweden
Trudy Flynn	Patient Partner	Canada

JTF-P3 Review Team

Name	Role / Org.	Country
Ana Maria Rodriguez	IQVIA/Mc Gill University	Canada/ Europe
Angela Kyalo	KEMRI Wellcome	Kenya
Alistair Nichol	University College Dublin	Ireland
Allison Bulat	Patient Partner	USA
Ambar Shrivastava	Patient Partner	India
Atsushi Kitamura	Pfizer	Japan
Barry Stein	Colorectal Cancer Canada	Canada
Cara Philpott	EUPATI Fellow	Australia
Caroline Jose	Université de Sherbrooke and Université de Moncton	Canada
Carolynn Jones	The Ohio State University	USA
Carrielynn Lund	Patient Partner/University of Saskatchewan	Canada
Catherine Hanson	University of Miami	USA
Christine Kubiak	ECRIN	France
Christine Samara	Patient Partner/Sunnybrook Research Inst.	Canada
Daniel Seifu	University of Global Health Equity	Rwanda
Fuzhen Guo	Capital Medical University	China
Ika Washington	Patient Partner	Canada
Janelle Bowden	AccessCR Pty Ltd	Australia
Jennifer Gallagher	Sunnybrook Research Inst.	Canada
Kara Neil	King Faisal Hospital & Research Center	Rwanda

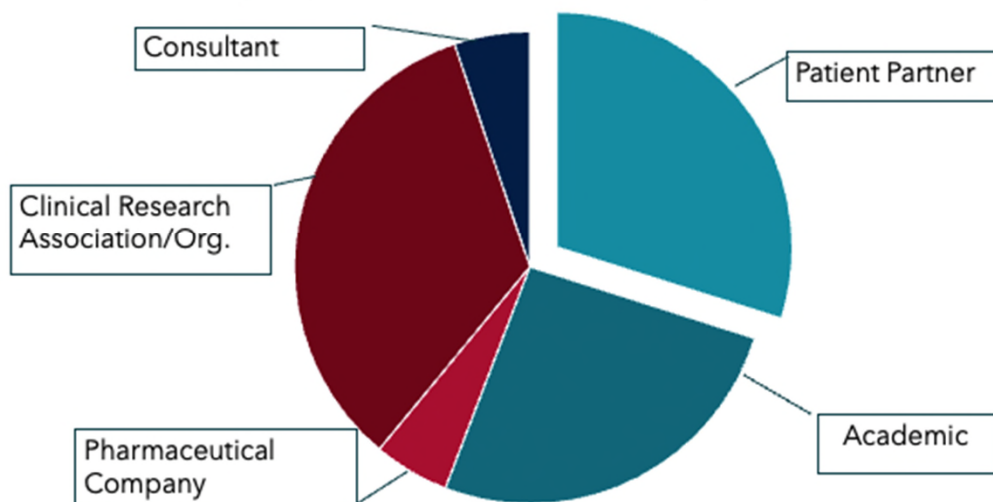
Name	Role / Org.	Country
Kendra Orjada	Merck	USA/Global
Leanne West	iCAN (International Children's Advisory Network)	USA/Global
Marian Valia	ACRP	USA
Marissa Bielecki	Patient Partner/IQVIA	USA
Martie Carnie	Patient Partner/Brigham and Women's	USA
Maxine Janis	Pacific Northwest University	USA
Midori Senoo	Myotonic Dystrophy Patients' Group	Japan
Munaza Jamil	CANTRAIN	Canada
Peery White	Strengthening Native Connections	USA
Richie Kahn	Canary Advisors	USA
Roberta Albany	Patient Partner	USA
Sally Armstrong	PRAXIS Australia	Australia
Sanjeev Sharma	Patient Partner	India
Sharareh Hosseinzadeh	Executive Clinical Director & Independent Researcher, University of Toronto	Canada
Sierra Portillo	Biostatistician & Patient Advocate	USA
Stephanie Chisholm & Patricia Rios	Bladder Cancer Network	USA
Stuart Nicholls	Ottawa Hospital Research Institute	Canada
Thobekile Mthethwa-Pitt	Alfred Health	Australia
Thomas Nyirenda	European & Developing Countries Clinical Trials Partnership	South Africa
Tony Keyes	Johns Hopkins University	USA
Urvashi Prasad	Patient Partner	India
Yaqing Yu	Fortrea	China

JTF-P3 Global Collaboration



- us USA – **22**
- ca Canada – **11**
- in India – **3**
- au Australia – **3**
- ie Ireland – **3**
- jp Japan – **3**
- cn China – **2**
- rw Rwanda – **2**
- fr France – **1**
- es Spain – **1**
- pt Portugal – **1**
- be Belgium – **1**
- hr Croatia – **1**
- bg Bulgaria – **1**
- zw Zimbabwe – **1**
- ke Kenya – **1**
- za South Africa – **1**

Workgroup and Review Team Self-Reported Roles



Process:



Work Group, Mar-Sept 2025



- Patient engagement articles, frameworks, tools, etc. identified to frame and guide workgroup conversations
- Separate work streams, meeting monthly
 - Work stream #1** - existing/current JTF domains and related competencies
 - Work stream #2** - already co-created Patient Partner competency domains (from CANTRAIN's initial work)
 - Work stream #3** - new JTF themes and competency domains
 - 3A - Diversity and Representation
 - 3B - Cultural Responsiveness
 - 3C - Knowledge, Skills, and Attitudes
 - 3D - Evaluation
- Iterative development of key prioritized proposals.

Feedback Review, Oct-Dec 2025

- Submitted high-level comments and overview, by domain:
 - Revision of or addition of new competency statements - ~**101** unique entries
 - Revision of or addition of new maturity level statements and examples - ~**303** unique entries
- Row-by-row review and assessment of each **competency statement entry** by the core team
- Line-by-line review and assignment:
 - **Green** - relevant; should be included as written
 - **Yellow** - relevant; needs to be tweaked and added to appropriate section
 - **Orange** - relevant; duplicate or already integrated
 - **Red** - not a level statement or relevant; covered elsewhere.
- Many rounds of review, discussion, and analysis

Field-by-field review and evaluation:



JTF PA Attribution - Competency Objectives with MATURITY LEVELS										
1	2	3	4	5	6	7	8	9	10	11
1	2	3	4	5	6	7	8	9	10	11
1	2	3	4	5	6	7	8	9	10	11
1	1	1	1	1	1	1	1	1	1	1
2	2	2	2	2	2	2	2	2	2	2
3	3	3	3	3	3	3	3	3	3	3
4	4	4	4	4	4	4	4	4	4	4
5	5	5	5	5	5	5	5	5	5	5
6	6	6	6	6	6	6	6	6	6	6
7	7	7	7	7	7	7	7	7	7	7
8	8	8	8	8	8	8	8	8	8	8
9	9	9	9	9	9	9	9	9	9	9
10	10	10	10	10	10	10	10	10	10	10
11	11	11	11	11	11	11	11	11	11	11

↓ ...and onward to Row 111...

Proposals Summarized

Proposals Added



1.2 Identify scientific questions that are potentially socially clinical research hypotheses

REQUIREMENT FOR NON-RESEARCH QUESTIONS THAT ARE IDENTIFIED AS RESEARCH QUESTIONS: EXPLAINATION WITH PATIENT PARTNERS

Fundamental Level	Skilled Level	Advanced Level
<p>1.1 Apply principles of biomedical science to investigational product discovery and development and health-related behavioral interventions.</p> <p>1.2 Identify scientific questions that are potentially socially clinical research hypotheses</p> <p>1.3 Apply principles of biomedical science to investigational product discovery and development and health-related behavioral interventions.</p>		

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

Fundamental Level	Skilled Level	Advanced Level
<p>Recognize the need to apply biomedical science and basic science principles including patient partner involvement in development product discovery, development, and health-related behavioral interventions. (A.1 suggest meeting to 1.1)</p>	<p>Apply biomedical science and basic science principles to actively engaging with patient partners and cross-functional teams to implement investigational product discovery, development activities, and health-related behavioral interventions. (B.1 suggest meeting to 1.1)</p>	<p>Explain and integrate biomedical science and basic science principles, ensuring meaningful patient partner involvement in leading level investigational product discovery, development and associated health-related behavioral interventions within diverse, multi-disciplinary contexts. (B.1 suggest meeting to 1.1)</p>

1.2 Identify scientific questions that are potentially socially clinical research hypotheses

Fundamental Level	Skilled Level	Advanced Level
<p>Identify and articulate the strengths and purposes of patient-oriented research. (A.1 Recognize the importance of integrating patient perspectives in study design. A.1 Identify examples of how patient perspectives can influence study design.)</p>	<p>Apply patient-oriented research principles when planning research. (B.1 Integrate patient perspectives early and throughout the research process to improve study relevance, feasibility, and impact. (B.1) Adapt study research to fit current teams, recruitment needs based on patient partner feedback.)</p>	<p>Facilitate processes that engaged patients and communities to identify and prioritize research questions. (C.1 Co-develop research that aligns with what matters most to patients and communities. (C.2) Co-develop research that aligns with what matters most to patients and communities and select study design and methods that reduce barriers to participation for underserved or underrepresented populations.)</p>

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

Fundamental Level	Skilled Level	Advanced Level
<p>Identify, describe patient-oriented research principles (e.g., partnerships, reciprocity, transparency) in training materials.</p>	<p>Develop, Review relevant criteria after consulting with patient partners on feasibility and accessibility.</p>	<p>Develop, Leads actively seeking research with community members to co-design research questions.</p>

Core Competency Framework for the Clinical Research Professional, Version 3.1

FUNDAMENTAL, SKILLED AND ADVANCED LEVEL

A. Fundamental Level	B. Skilled Level	C. Advanced Level
<p>DOMAIN 3. Scientific Concepts and Research Design: Encompasses knowledge of scientific concepts related to the design and analysis of clinical trials</p> <p>3.1 Apply principles of biomedical science</p> <p>A1. Recognize the need to apply scientific principles to discovery and development of biomedical investigational products and health-related behavioral interventions</p> <p>A2. Explain the basic scientific principles that should be applied during development of biomedical investigational products and health-related behavioral interventions</p> <p>A3. Define and articulate the principles and purpose of action-oriented research</p> <p>A4. Understand the importance and value of patient partner perspectives in research study design and recognize the difference between meaningful integration and tokenistic participation</p> <p>A5. Demonstrate awareness that patient partners have unique lived experiences relative to complex scientific and clinical knowledge in the research process</p> <p>A6. Describe how patient perspectives can influence study design</p>		
<p>B1. Apply scientific principles when implementing a clinical or behavioral study</p> <p>B2. Implement data collection according to scientific principles and based on protocol design</p> <p>B3. Apply patient-oriented research principles when planning research</p> <p>B4. Actively incorporate patient partner input early and throughout the research process (development, study design decisions, and methodology selection)</p> <p>B5. Integrate diverse perspectives, including and across, to improve study relevance, feasibility, and impact</p> <p>B6. Facilitate meaningful dialogue between patient partners and research team members to ensure patient perspectives are authentically integrated into the research process</p> <p>B7. Adapt study methods to fit current teams and recruitment needs based on patient partner feedback</p>	<p>C1. Plan biomedical research according to scientific principles</p> <p>C2. Develop a data management plan according to scientific principles</p> <p>C3. Facilitate processes that empower patients and communities to identify and articulate research questions</p> <p>C4. Co-develop research that aligns with what matters most to patients and communities and select study design and methods that reduce barriers to participation for underserved or underrepresented populations</p> <p>C5. Lead collaborative research design processes that align with what matters most to patients and communities and select study design and methods that reduce barriers to participation for underserved or underrepresented populations</p> <p>C6. Mentor other researchers in developing authentic research approaches and systems research processes for meaningful versus tokenistic patient involvement</p> <p>C7. Advocate for systemic changes in research design practices to ensure genuine patient partner integration becomes standard practice</p>	<p>Example: When reviewing a clinical research protocol, researcher describes the objective and scientific techniques used to design and implement biomedical research.</p> <p>Example: Describe how patient partners can contribute to research question development throughout the research process leading for shared and collaborative clinical decision-making.</p> <p>https://www.mrctcenter.org/clinical-research-professional-care-competency-framework/ February 2020</p> <p>© 2020 MRCT Center. This work is licensed under a CC BY-NC-SA 4.0 license.</p> <p>mrct@bwh.harvard.edu</p>
<p>Example: Explain why patient perspectives are essential for research relevance and feasibility.</p> <p>Example: Identify patient-oriented research approaches (e.g., partnerships, reciprocity, transparency) in training materials.</p>	<p>Example: Review inclusion criteria after consulting with experts (based on feasibility and accessibility).</p>	<p>Example: Leads a priority setting exercise with community members to co-develop research questions.</p>
<p>2.2 Identify scientific questions that are potentially socially clinical research hypotheses</p> <p>A1. Articulate the purpose of the study</p> <p>A2. Describe the importance of the study</p> <p>A3. Describe how cultural context influences research research hypotheses in study protocols</p> <p>A4. Describe the purpose and importance of a study in addressing patient- and community-centered research questions that may serve as potentially testable hypotheses</p>		
<p>B1. Identify endpoints (primary and secondary) that will be used in data analyses to measure outcomes</p> <p>B2. Identify research hypotheses in study protocols</p> <p>B3. Identify endpoints with study objectives that are relevant to patient and community needs</p>	<p>C1. Develop protocol or source document checklist language that identifies the scientific questions (hypotheses), primary objectives, secondary objectives and associated endpoints</p> <p>C2. Align parameters for collecting data on endpoints with objectives</p> <p>C3. Co-develop protocols and data collection strategies that define scientific hypotheses, objectives, and endpoints, ensuring alignment with priorities and outcomes important to patients and communities</p> <p>C4. Develop studies incorporating the patient partner perspective that are relevant to underserved or marginalized populations</p> <p>C5. Evaluate the inclusion of patient partnership in study design, selection, and analysis</p>	<p>Example: Leads a priority setting exercise with community members to co-develop research questions.</p>

JTF-P3 Review Team Feedback Collection Survey



The screenshot shows a survey form with several sections:

- Section 1:** A table with three columns of text, likely containing statements or examples for review.
- Section 2:** A question: "Are you comfortable with the updates to the statements under the three levels (fundamental, skilled, and advanced)?" with Yes/No radio buttons and a "reset" button.
- Section 3:** A question: "If yes, please feel free to add any comments on what you like about the leveled statements(s)." with a text input field and an "Expand" button.
- Section 4:** A question: "If no, please describe what you would like to see changed or added to the leveled statements" with a text input field and an "Expand" button.
- Section 5:** A question: "Are you comfortable with the update to the competency statement?" with Yes/No radio buttons and a "reset" button.
- Section 6:** A question: "If yes, please feel free to add any comments on what you like about the competency statement" with a text input field and an "Expand" button.
- Section 7:** A question: "Are you comfortable with the update to the examples?" with Yes/No radio buttons and a "reset" button.
- Section 8:** A question: "If yes, please feel free to add any comments on what you like about the example statement(s). If there is more than one example statement, please describe which is your favorite example for the competency." with a text input field and an "Expand" button.
- Section 9:** A question: "If no, please describe what you would like to see changed or added to the example statement(s). If there is more than one example, please feel free to comment on which would be the most appropriate example for the competency." with a text input field and an "Expand" button.
- Section 10:** A question: "If you have any additional comments on the updates to Competency 1.1 please add here" with a text input field and an "Expand" button.

- Survey asked for comfort with competency, level, and example statements (yes/no)
- Review Team and Work Group were invited via separate emails

JTF-P3 Feedback Disposition (Jan-Mar 2026)

~ 100 pages that looked like this:



GENERAL COMMENTS ON DOMAIN 1: Scientific Concepts and Research Design: Encompasses knowledge of scientific concepts related to the design and analysis of clinical trials

Comment Received	CA Suggested Changes/Responses	Team Decision
- Comments: Strong integration of patient-oriented research principles. The leveled progression (Fundamental → Skilled → Advanced) is clear and aspirational.	n/a	
- Suggestions: Consolidate overlapping statements (A4-A6) on patient perspectives.	1.1 Agree, delete A6.	Delete A6. Merge A4 and A5 in a new statement. See later comment.
- Move operational examples (e.g. adapting recruitment tools) to Domain 6 (Study/Site Management).	This refers to 1.1, C5. Agree to move to Domain 5, perhaps 5.4	Agree to move to 5.4
- Add explicit mention of intersectionality and structural barriers in hypothesis formulation.	1.2 Consider mentioning intersectionality (and perhaps structural barriers) in hypothesis formulation in Advanced level.	Add to B1, 1.2, 'consider intersectionality and structural barriers as appropriate'
- 1.5: do we want to mention : analyse impact of inclusiveness (for ex whether it improves generalizability of results and reach relevant patients)	1.5 Consider adding "Analyze impact of inclusiveness" to Advanced Level.	1.5 Add to A-level: Describe the importance of including diverse populations in clinical research (e.g., age, sex, race/ethnicity) for generalizability of findings. Add to B-level: Demonstrate how lack of representation affects the reliability and applicability of trial results across populations - and the quality of the

New

BK Baedorf Kassis, Sylvia ... done

Reply

BK Baedorf Kassis, Sylvia ... Changed to patient partnership in 1.1. 1.3 was already changed to removed patient engagement

Reply

BK Baedorf Kassis, Sylvia ... need to make sure individual results return is covered under Domain 8


Reply

BK Baedorf Kassis, Sylvia ...

JTF-P3 Feedback Integration (April 2026)



JTF-P3 Final version, May 2026

Core Competency Framework for the Clinical Research Professional, Version 3.1 FUNDAMENTAL, SKILLED and ADVANCED LEVEL		
A. Fundamental Level	B. Skilled Level	C. Advanced Level
DOMAIN 1: Scientific Concepts and Research Design: Encompasses knowledge of scientific concepts related to the design and analysis of clinical trials		
1.1 Incorporate principles of biomedical science and patient partnership to investigational product discovery and development and health-related behavioral interventions		
<p>A1. Recognize the need to apply scientific principles to discovery and development of biomedical investigational products and health-related behavioral interventions.</p> <p>A2. Explain the basic scientific principles that should be applied during development of biomedical investigational products and health-related behavioral interventions.</p> <p>A3. Explain the principles and purpose of patient-oriented research and how patient partners' unique lived-experience complements scientific and clinical knowledge, and meaningfully contributes to research study design.</p> <p>Example: When reviewing a clinical research protocol, study team member describes the objective and scientific techniques used to design and implement biomedical research.</p> <p>Example: Describes patient partnership research principles and how patient partners can contribute to research question development.</p> <p>Example: Identifies patient-oriented research principles (e.g., partnership, inclusivity, transparency) in training materials.</p>	<p>B1. Apply scientific principles when implementing a clinical or behavioral study</p> <p>B2. Implement data collection according to scientific principles and based on protocol design</p> <p>B3. Incorporate patient perspective, early and throughout research question development, study design decisions, protocol planning, and methodology selection to improve study relevance, inclusivity, and impact.</p> <p>Example: When given a clinical research protocol, researcher differentiates what principles could affect how the data should be collected and implement best practices accordingly.</p> <p>Example: Works with patient partners to identify and integrate study endpoints that are informed by community experience/preferences.</p> <p>Facilitate design sessions that result in meaningful protocol changes. Removed recruitment strategy example.</p>	<p>C1. Plan biomedical research according to scientific principles</p> <p>C2. Develop a data management plan according to scientific principles</p> <p>C3. Lead collaborative research design processes that position patient partners as equal contributors throughout the research lifecycle</p> <p>C4. Develop research that aligns scientific and patient priorities and employs study designs and methods that reduce barriers to participation</p> <p>Example: Given a clinical research protocol and data collected, the researcher evaluates the findings to assess results via a scientific framework.</p> <p>Example: Advocates for systemic changes in research design practices to ensure genuine patient partner integration becomes standard practice.</p> <p>Example: Co-leads research teams with patient partners as equal partners; develops institutional policies requiring meaningful patient partner involvement; trains other researchers in authentic partnership practices.</p>
1.2 Identify scientific questions that are potentially testable clinical research hypotheses		
<p>March 2018 Core Competency Framework for the Clinical Research Professional Version 3.1 Updates https://mrctcenter.org/clinical-trial-competency/ – NOT FOR DISTRIBUTION © 2020 MRCT Center. This work is licensed under a CC BY-NC-SA 4.0 license  mrct@wh.harvard.edu</p>		

Core Competency Framework for the Clinical Research Professional, Version 3.1 – JTF-P3 Updates FUNDAMENTAL, SKILLED and ADVANCED LEVEL		
A. Fundamental Level	B. Skilled Level	C. Advanced Level
DOMAIN 1: Scientific Concepts and Research Design: Encompasses knowledge of scientific concepts related to the design and analysis of clinical trials		
1.1 Incorporate principles of biomedical science and patient partnership to investigational product discovery and development and health-related behavioral interventions		
<p>A1. Recognize the need to apply scientific principles to discovery and development of biomedical investigational products and health-related behavioral interventions</p> <p>A2. Explain the basic scientific principles that should be applied during development of biomedical investigational products and health-related behavioral interventions</p> <p>A3. Explain how patient partners contribute to research study design</p> <p>Example: When reviewing a clinical research protocol, study team member describes the objective and scientific techniques used to design and implement biomedical research.</p> <p>Example: Describes patient partnership research principles and how patient partners can contribute to research question development</p>	<p>B1. Apply scientific principles when implementing a clinical or behavioral study</p> <p>B2. Implement data collection according to scientific principles and based on protocol design</p> <p>B3. Incorporate patient perspectives throughout research question development, study design, protocol planning, and methodology selection</p> <p>Example: When given a clinical research protocol, researcher differentiates what principles could affect how the data should be collected and implement best practices accordingly.</p> <p>Example: Works with patient partners to identify and integrate study endpoints that are informed by community experience/preferences.</p>	<p>C1. Plan biomedical research according to scientific principles</p> <p>C2. Develop a data management plan according to scientific principles</p> <p>C3. Develop research that aligns scientific and patient priorities and employs study designs and methods that reduce barriers to participation</p> <p>Example: Given a clinical research protocol and data collected, the researcher evaluates the findings to assess results via a scientific framework.</p> <p>Example: Advocates for research design practices that ensure patient partner integration.</p>
1.2 Identify scientific questions that are potentially testable clinical research hypotheses		

Exemplar Patient Partnership Additions



DOMAIN	JTF-P3 ADDITIONS
DOMAIN 1: Scientific Concepts and Research Design	<ul style="list-style-type: none"> • Incorporate patient perspectives throughout research question development, study design, protocol planning, and methodology selection • Develop research that aligns scientific and patient priorities and employs study designs and methods that reduce barriers to participation
DOMAIN 2: Ethical and Participant Safety Considerations	<ul style="list-style-type: none"> • Identify the clinical study activities and distinguish them from the standard of care • Apply best practices in informed consent processes by incorporating plain language, cultural adaptations, and decentralized methods, ensuring alignment with regulatory guidance and individual, group, and community partners
DOMAIN 3: Investigational Products Development and Regulation	<ul style="list-style-type: none"> • Recognize that cultural and socioeconomic factors influence which products get developed, how they are tested, and who ultimately benefits from them
DOMAIN 4: Clinical Study Operations (Good Clinical Practice)	<ul style="list-style-type: none"> • Collaborate to determine and agree upon patient partners' responsibilities on the study team and reassess and recalibrate during the project • Include patient partners in safety monitoring committees to ensure lived experience informs adverse event identification, management, and reporting

Exemplar Patient Partnership Additions



DOMAIN	JTF-P3 ADDITIONS
DOMAIN 5: Study and Site Management	<ul style="list-style-type: none"> • Co-lead initiatives to design, test, and evaluate recruitment strategies
DOMAIN 6: Data Management and Informatics	<ul style="list-style-type: none"> • <i>No changes (This domain was being updated by a separate team at the time of the JTF-P3. Patient partnership will be incorporated into this domain in a future iteration)</i>
DOMAIN 7: Leadership and Professionalism	<ul style="list-style-type: none"> • Demonstrate awareness that one’s own background and experience may influence perspectives on research priorities and processes • Engage in ongoing critical reflection about own assumptions, privileges, and biases that may impact the research and the study team
DOMAIN 8: Communication and Teamwork	<ul style="list-style-type: none"> • Recognize and respect the unique lived experience and expertise that patient partners bring to transdisciplinary research teams
JTF-P3 Supplement	<ul style="list-style-type: none"> • Support the active engagement of patient partners to ensure their perspectives, needs, and priorities are integrated throughout the clinical research life cycle. • Explain the meaning of patient and community partnership in clinical research and how best practices incorporating the perspectives of those with lived experience can support and inform meaningful study design, recruitment, retention, and reporting

JTF-P3 Glossary



- Three Categories of Terminology

- JTF Framework Terms
e.g., domain
- JTF Framework Study Team Members
e.g., CRP, PI, patient partner
- JTF-P3 Concepts →

JTF-P3 Term Examples	Definition	Source(s)/ Adapted From
Patient Partnership	Meaningful and active collaboration between patients (or caregivers) and researchers, where patients are involved in decision-making and governance across the entire clinical research and development continuum.	CIHR SPOR; BC SUPPORT Unit; EUPATI
Patient Engagement	An active and continuous process of involving patients and caregivers in meaningfully co-creating across the life cycle of research projects, from priority setting, study planning and conduct, to results dissemination and knowledge translation, ensuring that research reflects the needs and preferences of patients and communities.	CIHR SPOR; Alberta SPOR SUPPORT Unit; PCORI, FDA, EUPATI, PFMD

Applying the JTF-P3



The JTF-P3 offers a new way of integrating patient partners throughout the trial life cycle:

- Train on the JTF-P3 more generally - what it is, why it matters, how to use it...
- Adopt the JTF-P3 to add new competencies to update existing trainings.
- Include JTF-P3 in introductory courses for PIs and other study team members.
- Use the JTF-P3 in onboarding, orientation, and continuing education for current and new teams.
- Adapt JTF-P3 concepts in grant applications and proposals.
- Apply the JTF-P3 across the clinical trial life cycle in protocol development, implementation, dissemination, and beyond.

Next steps



- The JTF-P3 Framework output and process will be publicly available once published.

Sign up here to be notified when the JTF-P3 framework is published:



- A QI evaluation of patient partnership throughout this project is also in progress, with a manuscript to follow.



Miigwetch!

Shukran!

Toda!

Merci!

Grazie!

Gracias!

Mamnun!

THANK YOU!!

Dhanyawad!

Tak!

Obrigado!

Arigato!

Xièxie!

Do jeh!

Danke!

Gamsahamnida!

Wado!

The Joint Task Force Domain 6 Revision



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

Joint Task Force for Clinical Trial Competency (JTF)

Project Report

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Goal: to update the Data Management and Informatics JTF Competencies

6

Domain 6: Data Management and Informatics

Encompasses how data are acquired and managed during a clinical trial, including source data, data entry, queries, quality control, and correction and the concept of a locked database

- + 6.1 Describe the role and importance of statistics and informatics in clinical studies
- + 6.2 Describe the origin, flow, and management of data through a clinical study
- + 6.3 Describe best practices and resources required for standardizing data collection, capture, management, analysis, and reporting
- + 6.4 Describe, develop, and implement processes for data quality assurance



AKA:

What every Clinical Research Professional should know about Informatics, Data Management, and now Statistics

Methods:

- Panel of experts

 - In Clinical Research + Data Management, Informatics or Statistics

 - Representation from industry (drug, bio, device), academia, funders and regulators

 - Representation from around the world

- **Four-round Delphi Process**

 - **Round One:** Open-ended, what should be there, what shouldn't be *at each JTF level*

 - After round one

 - responses were deconstructed and inductively sorted to identify main topics

 - gaps were deductively filled for coverage within the main topic areas

 - **Round Two:** Panel rated whether the proficiency statement was too hard, about right or too easy

 - **Round Three:** Panel received their rating along with the aggregate and could change their ratings

 - After round three only outliers were updated

 - **Round Four:** Member checking results in written report form

- **Updates at twice-yearly JTF calls during the process**

- **Independent peer-review following Round Four**

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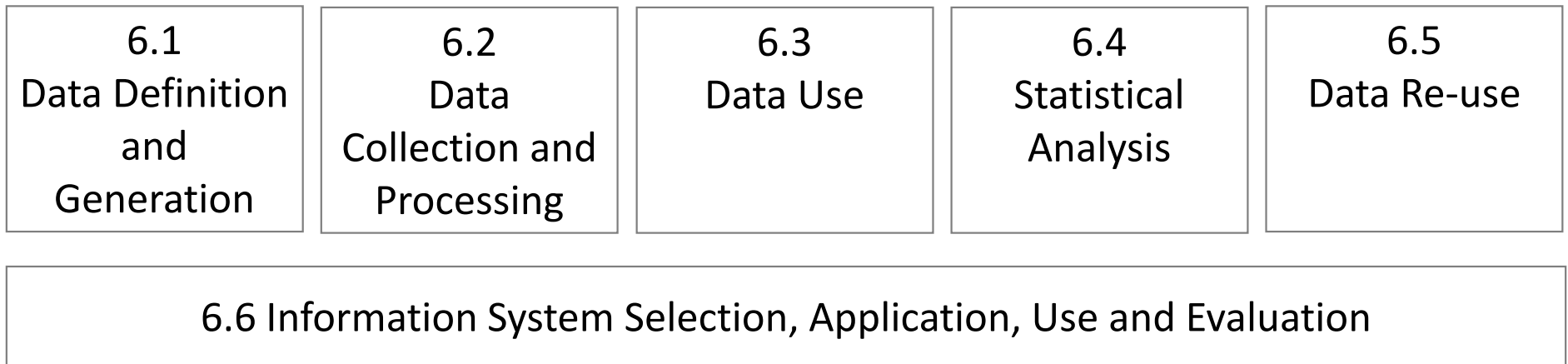
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Round One: Open Ended Questions

Appendix: 1
1. Competencies in Data Management
1.a. What competencies in Data Management are important for clinical research professionals such as PI's, study coordinators, Monitors, and Statisticians at the JTF Basic level? (Please list from 3 to 6 exhaustive and mutually exclusive competencies)
1.b. What competencies in Data Management are important for clinical research professionals such as PI's, study coordinators, Monitors, and Statisticians at the JTF Skilled level? (Please list from 3 to 6 exhaustive and mutually exclusive competencies)
1.c. What competencies in Data Management are important for clinical research professionals such as PI's, study coordinators, Monitors, and Statisticians at the JTF Advanced level? (Please list from 3 to 6 exhaustive and mutually exclusive competencies)
Comments:
2. Competencies in Informatics
2.a. What competencies in informatics are important for clinical research professionals such as PI's, study coordinators, Monitors, and Statisticians at the JTF Basic level? (Please list from 3 to 6 exhaustive and mutually exclusive competencies)
2.b. What competencies in Informatics are important for clinical research professionals such as PI's, study coordinators, Monitors, and Statisticians at the JTF Skilled level? (Please list from 3 to 6 exhaustive and mutually exclusive competencies)
2.c. What competencies in Informatics are important for clinical research professionals such as PI's, study coordinators, Monitors, and Statisticians at the JTF Advanced level? (Please list from 3 to 6 exhaustive and mutually exclusive competencies)
Comments:
3. Competencies in Statistics
3.a. What competencies in statistics (beyond those already articulated in JTF Framework Domain 1: Scientific Concepts and Research Design) are important for clinical research professionals such as PI's, study coordinators, Monitors, and Data Managers at the JTF Basic level? (Please list from 3 to 6 exhaustive and mutually exclusive competencies)
3.b. What competencies in Statistics (beyond those already articulated in JTF Framework Domain 1: Scientific Concepts and Research Design) are important for clinical research professionals such as PI's, study coordinators, Monitors, and Data Managers at the JTF Skilled level? (Please list from 3 to 6 exhaustive and mutually exclusive competencies)
3.c. What competencies in Statistics (beyond those already articulated in JTF Framework Domain 1: Scientific Concepts and Research Design) are important for clinical research professionals such as PI's, study coordinators, Monitors, and Data Managers at the JTF Advanced level? (Please list from 3 to 6 exhaustive and mutually exclusive competencies)
Comments:
General Questions
4. Please provide your thoughts about current JTF Framework definition of Data Management and Informatics as: "encompasses how data are acquired and managed during a clinical trial, including source data, data entry, queries, quality control, and correction and the concept of a locked database."
5. What else should be considered in revising the Data Management and Informatics domain of the JTF Framework?
Comments:

Framework Developing

Data Management, Informatics, and Statistics



Round 2 Rating

Data Definition and Generation:
Ensure consistent and appropriate data definition and generation

	Fundamental	Skilled	Advanced
Data definition	A.1 Identify data to be collected from a clinical study protocol <i>Too easy No change Too Hard</i>	B.1 Distinguish between similar and equivalent data elements <i>Too easy No change Too Hard</i>	C.1 Select data standards; Define and maintain data element definitions for clinical studies <i>Too easy No change Too Hard</i>
Data generation	A.2 Adhere to and recognize deviation from procedures for observation, measurement, and recording of data <i>Too easy No change Too Hard</i>	B.2 Recognize and report reportable deviations from data observation, measurement, and recording procedures <i>Too easy No change Too Hard</i>	C.2 Establish and maintain systematic detection and classification of reportable deviations from procedures for observation, measurement, and recording of data <i>Too easy No change Too Hard</i>
Data quality	A.3 Explain the importance of precision, reliability, and calibration in data generated by humans and devices <i>Too easy No change Too Hard</i>	B.3 Perform instrument calibration and participate in reliability assessment <i>Too easy No change Too Hard</i>	C.3 Establish and maintain procedures to ensure that data are generated within pre-determined tolerance limits <i>Too easy No change Too Hard</i>
Source data	A.4 Identify the source for study data <i>Too easy No change Too Hard</i>	B.4 Generate and maintain accurate source data and documents <i>Too easy No change Too Hard</i>	C.4 Establish and maintain traceability of data values from analysis datasets to the source <i>Too easy No change Too Hard</i>
Form design	A.5 Adhere to data collection guidelines, and form completion guidelines <i>Too easy No change Too Hard</i>	B.5 Identify and report problems with data collection forms and guidelines <i>Too easy No change Too Hard</i>	C.5 Draft and maintain data collection forms, data collection guidelines, and form completion guidelines <i>Too easy No change Too Hard</i>
Metadata definition	A.6 Describe the role of metadata in procedures and information systems <i>Too easy No change Too Hard</i>	B.6 Identify metadata established by procedures and generated in information systems <i>Too easy No change Too Hard</i>	C.6 Identify, specify, and implement metadata needed for process control, study management, and reproducibility <i>Too easy No change Too Hard</i>

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

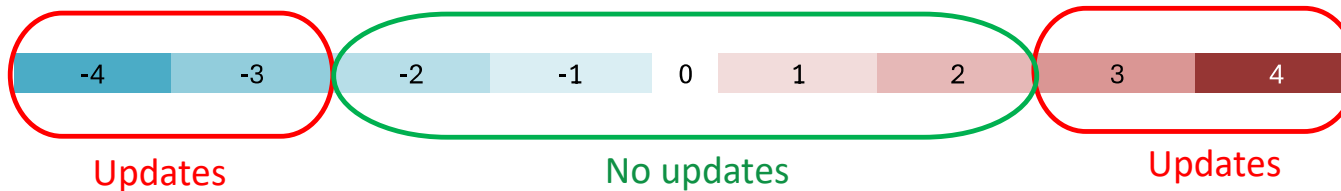
1	1	0
3	1	2
1	2	1
0	0	1

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



Round 4 comments

- Nine responses for the Round four.
- Nine comments re wording of the competencies
- 3 editorial comments
- A lot of help bringing more detail to the report

Peer Review Comments (10 peer reviewers)

- Eighty-eight comments were received from nine peer reviewers.
 - 13 were supportive of one or more aspects of the draft competencies,
 - 21 directly impacted a change in the competencies,
 - 13 caused a change to the competencies other than that recommended by the reviewer, and
 - 41 did not result in a change to the competencies.
- By far the most prevalent change suggested and made was adjusting the competency verbs to better reflect the cognitive level, or shifting leveled proficiency statements to a higher or lower level.
- Eight additional concepts were added to the competencies as a result of peer review comments.
- No concepts were removed based on peer review comments.

Largest changes based on Comments

- The Domain 6 revision means that some members of the clinical research study team, including the principal investigator in many cases, will be functioning at the Fundamental level in Domain 6 while other professional members of the research team practice at higher levels of proficiency. This is particularly significant for investigators.
- CRP roles that do not perform data management or statistical analysis will likely use the fundamental level of many Domain 6 competencies, while CRP roles requiring data handling or analysis might use the skilled or advanced level.
 - Rich statements of professional competencies for clinical research data managers, informaticists, and biostatisticians exist in discipline-specific competency sets.
 - The expansion of the Domain 6 competencies stretches current data literacy and computational fluency expectations of many CRP roles.

Expertise and Responses of Expert Panel

Expert	CI	Site	DM	Inf.	Stat.	Adm.	ARO	CRO	Fed.	Ind.	Edu.	Country	Round
1	X					X	X					Africa	--, --, --, --
2			X		X		X		X	P, T		US	R, R, R, R
3			X					X		C		US	--, --, --, --
4		C		X								US, ME	R, R, R, R
5			X					X		P, C		EU	R, R, R, R
6					X		X				X	US	R, R, R, R
7				X							X	US	R, R, R, R
8					X				X			US	--, --, --, --
9			X					X		P, C		EU	R, R, R, R
10			X							P, B		US	--, R, R, R
11**		A										US	--, --, R, R
12**					X		X					US	--, --, --, R
13**		A	X									US	--, --, R, --
Total*	1	3	6	2	4	1	4	3	2	5	2	–	6, 7, 9, 9

You now have
the resulting
competency
set

Draft Manuscript Updated from Co-Author Review (June 12, 2026)

Revision of JTF Competencies Domain 6 – Data Management, Informatics, and Statistics

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Abstract

Prompted by significant advances in data and computational sciences and the recent third revision of the Good Clinical Practice (GCP) guidelines and methodological advances, Domain 6 of the Joint Task Force

6.1 Data Definition and Generation

Table 1:

6.1 Ensure consistent and appropriate data definition, generation, and collection for a clinical study

Fundamental	Skilled	Advanced
A.1 Describe the role of data definition, data standards, and metadata in clinical studies	B.1 Identify data for evaluating study outcomes for a clinical study protocol, data critical to participant safety and research results. Draft and maintain data element definitions for clinical studies, including selection of applicable standards, and metadata needed for interpretation and quality management	C.1 Assess the appropriateness of data sources for a clinical study, including sources of Real-World Data (RWD), taking into consideration validity and completeness of information, feasibility of obtaining the data, and available metadata
A.2 Follow protocol-specified procedures for observation, measurement, and recording of data	B.2 Recognize, report, and suggest remediation for deviations from data observation, measurement, and recording procedures	C.2 Select appropriate quality data generation methods and procedures; Establish and maintain systematic quality control and reporting for data generation and collection procedures
A.3 Identify the source for study data and adhere to data collection and form completion guidelines	B.3 Recognize, report, and suggest remediation for problems with data collection forms, guidelines and processes	C.3 Apply risk-based principles to draft and maintain data collection processes and tools such as forms, data collection guidelines, form completion guidelines, and quality control
Example: Documents the source at the clinical investigational site for data collected in a clinical study	Example: Suggests needed data in the design of a clinical study data collection form. Assesses whether data are consistent with accepted data integrity characteristics such as Attributable, Legible, Contemporaneous, Original, Accurate (ALCOA), Complete, Consistent, Enduring, Available (ALCOA+), and Traceable (ALCOA++)	Example: Establishes appropriate quality control procedures for critical data. Selects appropriate controlled terminologies for common types of clinical data such as lab tests, medications, and adverse events

6.2 Data Collection and Processing

Table 2: 6.2 Apply best practices for processing clinical study data

Fundamental	Skilled	Advanced
A.1 Adhere to and report deviations from procedures for data processing such as recording, transcription, abstraction, coding, classification, entry, and resolving discrepancies	B.1 Analyze local site data processes and planned study data procedures; identify and resolve conflicts between them	C.1 Establish, maintain, and optimize data flow, workflow, and related procedures for data collection, processing, and privacy across the data lifecycle. Identify potential failure points
A.2 Describe basic types of data collected in clinical studies	B.2 Identify potential data problems when working with data; use reports and information systems to identify and resolve instances of late, missing, discrepant data, and root causes; carry-out procedures for the testing and quality control of manual and computer-aided data processing tasks	C.2 Decide when to use manual vs automated methods for data collection and processing activities such as conversions, calculations, data standardization, mapping, coding, classification and flagging, formatting, restructuring, record linkage, and data cleaning
A.3 Explain the role of change control in data collection and processing	B.3 Identify changes that require IRB approval and adhere to change control procedures	C.3 Assess the need for changes in data collection and processing; design, implement and evaluate changes
<p>Example: Follows data processing guidelines for clinical study data.</p> <p>Explains the basic differences between structured and unstructured data and their impact on data use</p>	<p>Example: Identifies and documents data flow and workflow at study sites that need to be adjusted to accommodate study-specific procedures</p>	<p>Example: Drafts study-specific data processing procedures and ensures that documentation, whether system- or human-generated, ensures traceability of all operations performed on data</p>

6.3 Data Use

Table 3: 6.3 Interpret and use study data to manage a clinical study

Fundamental	Skilled	Advanced
A.1 Interpret basic data structures and displays such as data listings, tables, and graphical representations including to detect problems and signals	B.1 Formulate and execute queries using basic logic (AND, OR, =, IN, NOT) on research databases using form-based query applications and Structured Query Language (SQL) or equivalent; Generate simple reports for study teams using structured and unstructured data	C.1 Design, implement and evaluate use-specific information displays; Extract data contained within relational and other database systems using Structured Query Language (SQL) or equivalent
A.2 List dimensions of data quality important for a clinical study; explain the ways in which poor data quality can impact data use	B.2 Recognize instances where data problems are adversely impacting data use within a clinical study; suggest and carry-out remediation and prevention steps	C.2 Assess the impact of potential or real data quality problems on data use and analysis; design, implement and evaluate procedures and technology to prevent or detect them
A.3 Recognize and report discrepant, aberrant, and implausible data on displays and in reports	B.3 Identify and report unexpected output or performance in system automation and decision support	C.3 Analyze study processes to suggest those that need or would benefit from automation or decision support. Design, configure, test, implement, maintain, and evaluate information system-based automation and decision support in clinical studies
A.4 Describe the basic concepts in Artificial Intelligence (AI), data mining and machine learning	B.4 Use Artificial Intelligence (AI), data mining and machine learning output and identify potential problems in the output	C.4 Apply, implement and evaluate Artificial Intelligence (AI), data mining and machine learning based tools such as text coding, natural language processing, and AI in clinical studies. Suggest areas where they may be useful in a clinical study
Example: Identifies study processes where alerts or reports are needed to ensure quality or optimize efficiency	Example: Writes simple database queries to investigate data problems or trends	Example: Designs data reports and visualizations to aid study conduct such as status reports and figures to monitor developing trends such as attrition or late visits

6.4 Statistical Analysis

Table 4: 6.4 Apply statistical methods and tools in clinical study conduct and analysis

Fundamental	Skilled	Advanced
A.1 Discuss the importance of basic descriptive statistics including measures of central tendency, variability, and association	B.1 Calculate and communicate specific descriptive statistics for a given data set based on its distributional properties	C.1 Interpret more advanced descriptive statistics reflecting combinations of variables such as contingency tables, scatter plots, and regression models
A.2 Explain basic inferential tests and their role in the scientific process	B.2 Differentiate inferential tests based on the level of data, including comparative as well as correlational tests	C.2 Interpret key features of inferential tests such as alpha, <i>p</i> -values, confidence intervals, and unique as compared with shared variance
A.3 Describe the role and importance of a Statistical Analysis Plan to the integrity of a clinical trial	B.3 Apply relevant parts of a Statistical Analysis Plan to operational aspects of a clinical trial	C.3 Reconcile elements of the Statistical Analysis Plan to identify critical inconsistencies such as those in population definitions, sample selection, and sequencing of analyses
A.4 Explain the importance of statistical methods and techniques to the integrity of a clinical trial	B.4 Recognize common threats to the validity of clinical trials such as recruiting inconsistencies, incomplete data, and insufficient power/sample size estimates that may be addressable using statistical methods and techniques	C.4 Collaborate effectively with a clinical trial team to respond to risks and problems occurring during a clinical research study
A.5 Describe the purpose, role, and scope of a Data Safety Monitoring Board in a clinical trial	B.5 Map Data Safety Monitoring Board report recommendations to data base or operational modifications	C.5 Compose responses to comments and questions generated by a Data Safety Monitoring Board
A.6. Identify literature search criteria and types of studies needed to access evidence-based practice in the professional literature	B.6. Recognize articles in the professional literature capable of informing evidence-based practice for a specific clinical trial	C.6. Interpret a systematic review of the literature using PICO (Problem, Intervention, Comparison, Outcomes) or other professional guidelines to frame questions relevant to evidence-based practice
A.7 Describe the importance of a Study Design to the overall integrity of a clinical trial	B.7 Discuss the advantages and disadvantages of adaptive study designs	C.7 Articulate key features of Innovative study designs that allow for a more efficient use resources or more informative results, including but not limited to stepped wedge designs, pragmatic clinical trials, and master protocols
A.8 Explain the importance to clinical research of obtaining valid and reliable information from a clinical trial	B.8 Distinguish between study design descriptions that do and do not meet the Design, Analyze, and Communicate (DAC) Assessment Tool (DAT) criteria	C.8 Demonstrate facility with the Design, Analyze, and Communicate (DAC) Assessment Tool (DAT) when evaluating the potential for obtaining high quality information from a clinical trial
Example 1A. Provides examples of descriptive statistics and what they represent in a typical data set	Example 1B. Distinguishes between inferential and descriptive study results and explains how they inform or complement each other	Example 1C. Describes what information <i>p</i> -values and confidence intervals in study results convey and how they are different from one another

6.5 Data Re-use

Table 5: 6.5 Follow best practices for study registration and data sharing

Fundamental	Skilled	Advanced
A.1 Describe the role of study registration, such as in Clinicaltrials.gov, in clinical research	B.1 Update and maintain records for registered studies	C.1 Use existing data to support the design and planning of future studies
A.2 Explain how the Findable, Accessible, Interoperable, and Reusable (FAIR) principles apply to sharing data from clinical studies	B.2 Locate and follow repository-specific specifications to curate and submit data for sharing	C.2 Draft data sharing plans for clinical studies that ensure that data and documentation will support re-use
Example: Points out identifiers and other metadata used to connect studies with their output such as shared data, shared resources and publications	Example: Maintains a ClinicalTrials.gov record for a study	Example: Chooses an appropriate repository for sharing data from a publicly funded clinical study

6.6 Information System Selection, Application, Use and Evaluation

Table 6:

+ 6.6 Leverage information systems to optimize clinical study processes

Fundamental	Skilled	Advanced
A.1 Describe information systems such as Clinical Trial Management Systems (CTMSs) or Electronic Data Capture (EDC) systems in the conduct of clinical studies and report unexpected systems behavior	B.1 Use and monitor information systems used in clinical studies to identify and report unexpected events	C.1 Establish procedures and controls for information system use in clinical studies
A.2 Describe the steps in the software development lifecycle and the importance of change control	B.2 Participate in testing and change control of information systems used in clinical studies	C.2 Design, configure, test, implement, maintain, and evaluate information systems used in clinical studies
A.3 Describe the purpose of and adhere to information system security procedures such as encryption and access control	B.3 Apply or oversee application of local implementation of information system security procedures	C.3 Ensure that information system security procedures are appropriate
A.4 Identify instances and explain the role of system interfaces, data exchange and interoperability	B.4 Identify and report areas where interfaces, data exchange and interoperability are needed; recognize and report unexpected problems with system interfaces	C.4 Establish, implement and maintain interfaces, data exchange and interoperability for clinical studies
A.5 Describe risk-based management concepts such as Critical To Quality Factors (CTQs), Key Risk Indicators (KRIs), Quality Tolerance Limits (QTLs), and Quality by Design (QBD) Identify risks to study CTQ factors and the systems or tools in place to track and mitigate them	B.5 Carry out risk-based study plans such as risk-based monitoring and risk-based data cleaning including managing risk.	C.5 Participate in the definition of CTQs, KRIs, QTLs . Establish and implement risk-based study plans including risk control measures.
Example: Identifies data from one information system, such as an external central lab, that are needed to ensure data completeness in the study database.	Example: Works with a study team to implement a protocol amendment that requires a change in the study data collection, i.e., a change in the data entry screens.	Example: Identifies and writes specifications for needed system interfaces for a clinical study. Implements risk-based data cleaning and monitoring.

Many Thanks to the expert panel,
peer reviewers, JTF and the JTF
Leadership !

Agenda



Time EDT	Topic	Speaker
10:00-10:55 AM	<p>Discussion:</p> <p>What are the issues and processes for incorporating JTF-P3 and Domain 6 revision into the JTF Framework?</p> <p>What other changes are needed to the JTF Framework for Version 4.0?</p>	<p>Facilitators:</p> <p>Barbara Bierer, MD Co-Chair, JTF Faculty Director, MRCT Center</p> <p>Stephen Sonstein, PhD Co-Chair, JTF Consultant, MRCT Center</p> <p>Discussants include:</p> <p>Elizabeth Edwards Parexel</p> <p>Stephanie Freel, PhD, PMP Duke University</p> <p>Jessica Fritter, DHSc, MACPR, ACRP-CP, FACRP The Ohio State University</p> <p>Debra Pritchett, MBA, ACRP-CP Merck</p> <p>David Vulcano, MSW, MBA, CIP, RAC, FACRP Association of Clinical Research Professionals (ACRP)</p> <p>& any of the meeting participants</p>
10:55-11:00	Wrap-up	<p>Stephen Sonstein, PhD Co-Chair, JTF Consultant, MRCT Center</p> <p>Barbara Bierer, MD Co-Chair, JTF Faculty Director, MRCT Center</p>

Next JTF Biannual Global Meeting



Tuesday, 1 December 2026, 1:00-3:00 PM EST

A circular graphic composed of ten colored segments (green, purple, orange, teal, red, blue, light green, purple, red, blue) arranged in a spiral pattern. Each segment contains a white icon representing a different aspect of clinical trials: a microscope, a shield, a pill, a gear, a magnifying glass, a cluster of dots, a ribbon, a recycling symbol, a person, and a shield.

Joint Task Force for Clinical Trial Competency (JTF)

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Thank you!

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