WEBINAR

Clinical Research Competencies to Support Effective Patient Partner Engagement

SESSION OPTION 01

May 7, 2026

9AM EDT (Boston)
3PM CEST/SAST (Brussels/Cape Town)
6:30 PM IST (New Delhi)

SESSION OPTION 02

May 7, 2026

8 PM EDT (Boston)

May 8, 2026

9 AM JST (Tokyo)
10 AM AEST (Melbourne)

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

EUPATI

CANTRAIN

Disclaimer

The views and findings expressed today are ours, serving in our individual capacity, and do not imply endorsement or reflect the views or policies of Mass General Brigham, Harvard Medical School, or any affiliated organization or entity.

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Before we get started…

- **This webinar is being recorded.** The recording, slides and other resources will be made available on the MRCT Center website next week.

- **Please use the Q&A to ask questions**. We will do our best to respond live – but will provide written responses to the questions we were unable to answer.

- **Please introduce yourself in the chat**, and tell us where you're joining from.

Today's Agenda

- **Introductory Remarks**
  - Barbara Bierer & Stephen Sonstein, JTF Co-Chairs
  - Maria Dutarte, EUPATI
- **Process and Outcome of JTF Patient Partner Project**
  - Sylvia Baedorf Kassis, MRCT Center
  - Linda Hunter, CANTRAIN
- **Reflections by Workgroup and Review Team members**
- **Closing**

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

JOINT TASK FORCE FOR CLINICAL TRIAL COMPETENCY

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 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 other 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 Dutarte

CANTRAIN

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 :

CIHR IRSC

EUROPEAN PATIENTS' ACADEMY ON THERAPEUTIC INNOVATION (EUPATI)

Enhancing patient involvement through education

EUPATI

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


European Patients' Academy on
Therapeutic Innovation - EUPATI
EUPATI
Maria Dutarte (EUPATI)

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
Jacquie 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

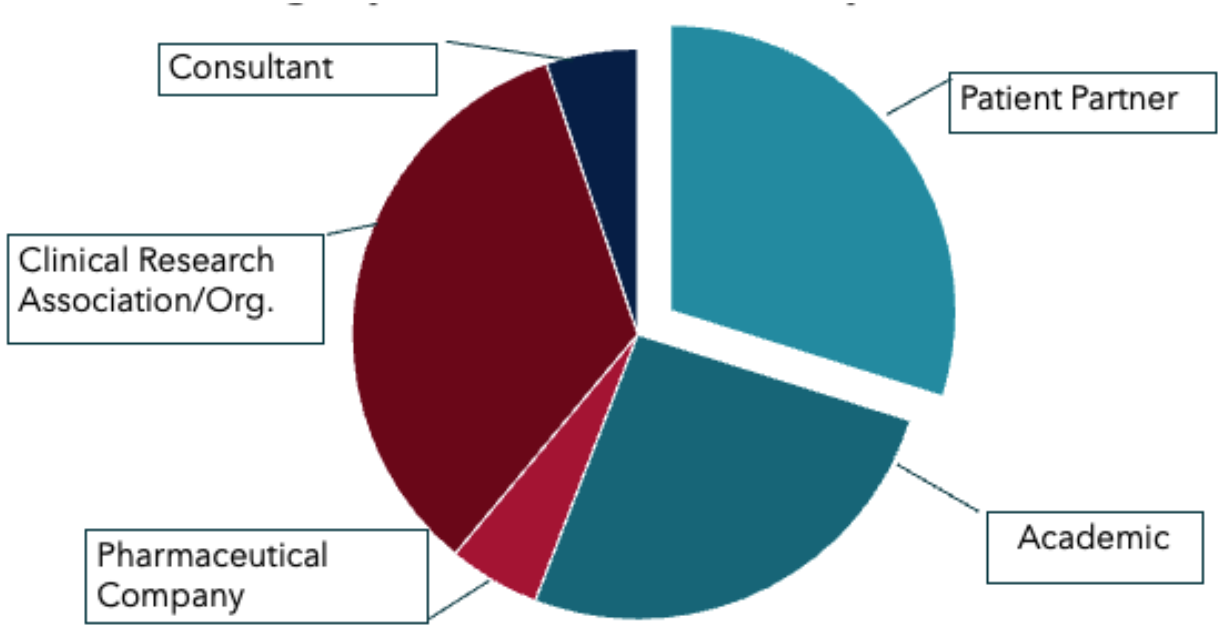
JTF-P3 Review Team

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
Kendra Orjada	Merck	USA/Global
Leanne West	iCAN (International Children's Advisory Network)	USA/Global
Malcolm & Alexandra King	University of Saskatchewan	Canada
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	Consultant	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:

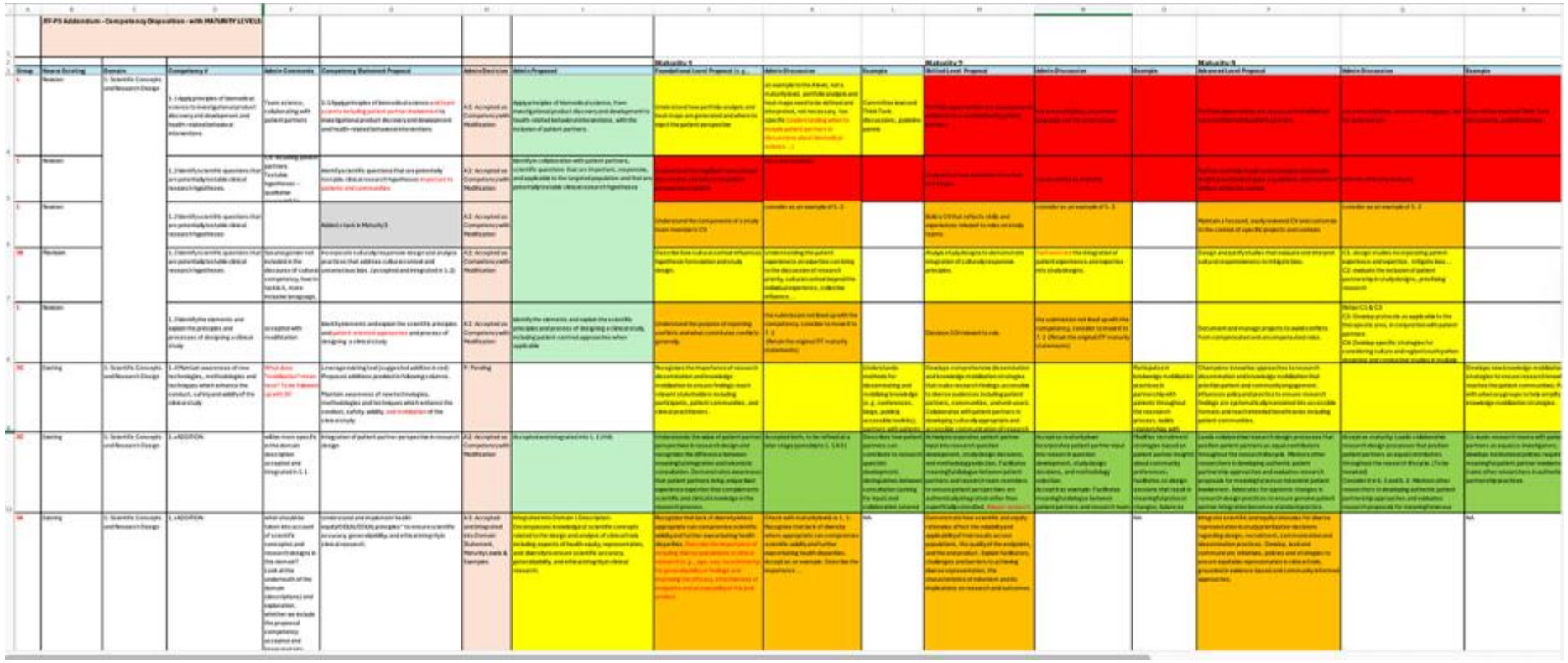
Work Group, March-September 2025

- Separate work streams, meeting monthly
- Iterative development of key prioritized proposals.

Feedback Review, October-December 2025

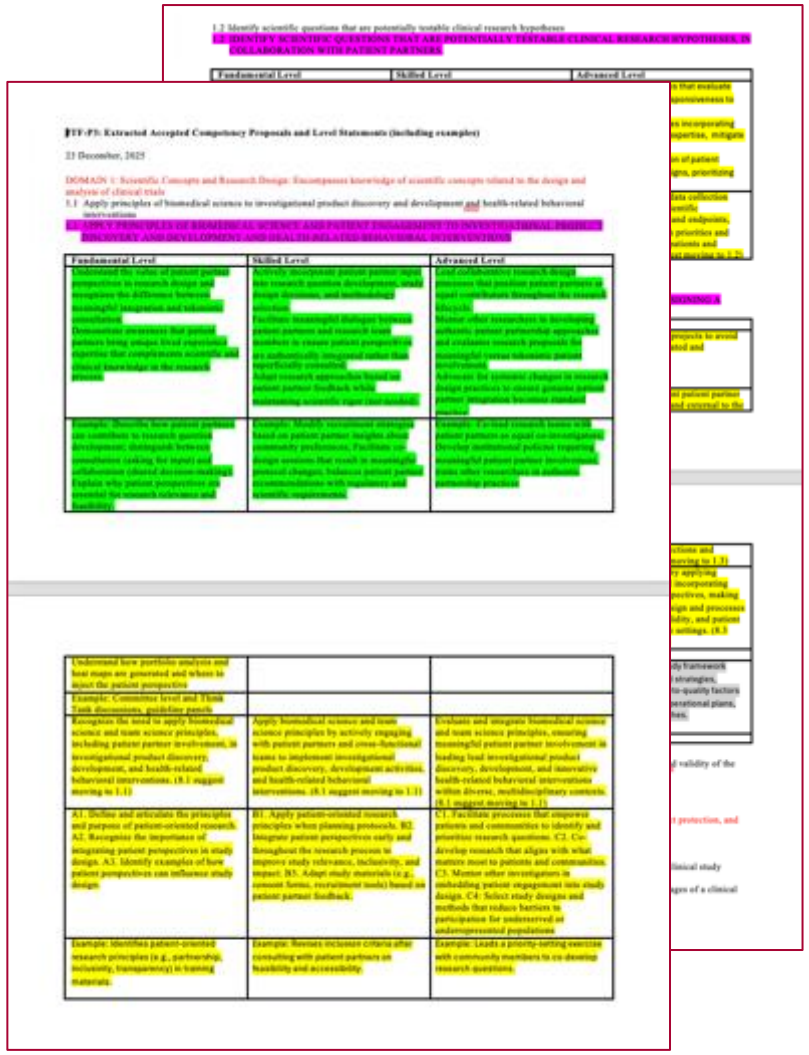
- Submitted high-level comments and overview, by domain:
  - Revision of or addition of new competency statements - ~**101** unique entries
  - Revision of or addition of new maturity level statements and examples - ~**303** unique entries
- Row-by-row review and assessment of each **competency statement entry** by 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:

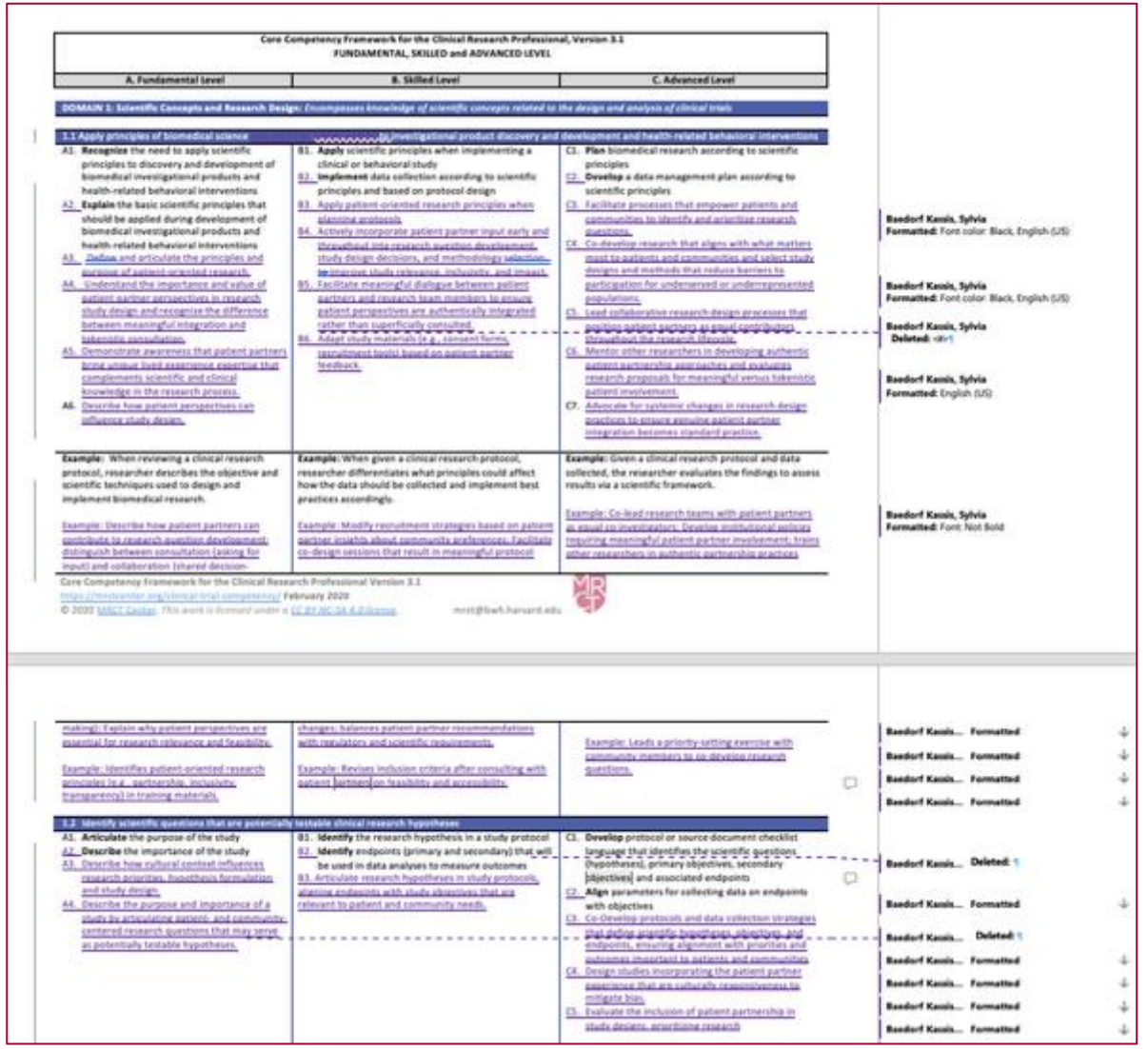


…and onward to Row 111…

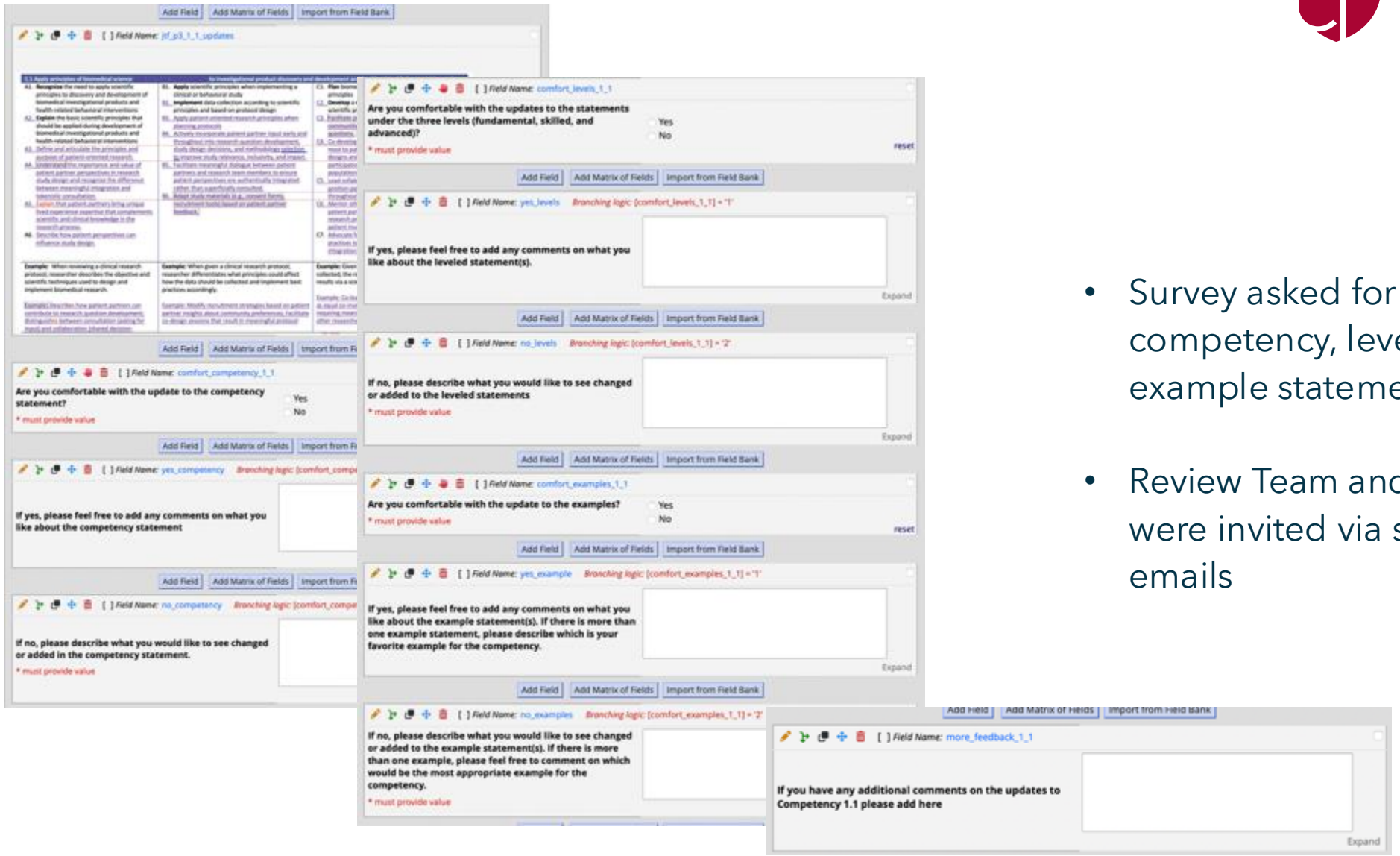
Proposals Summarized



Proposals Added



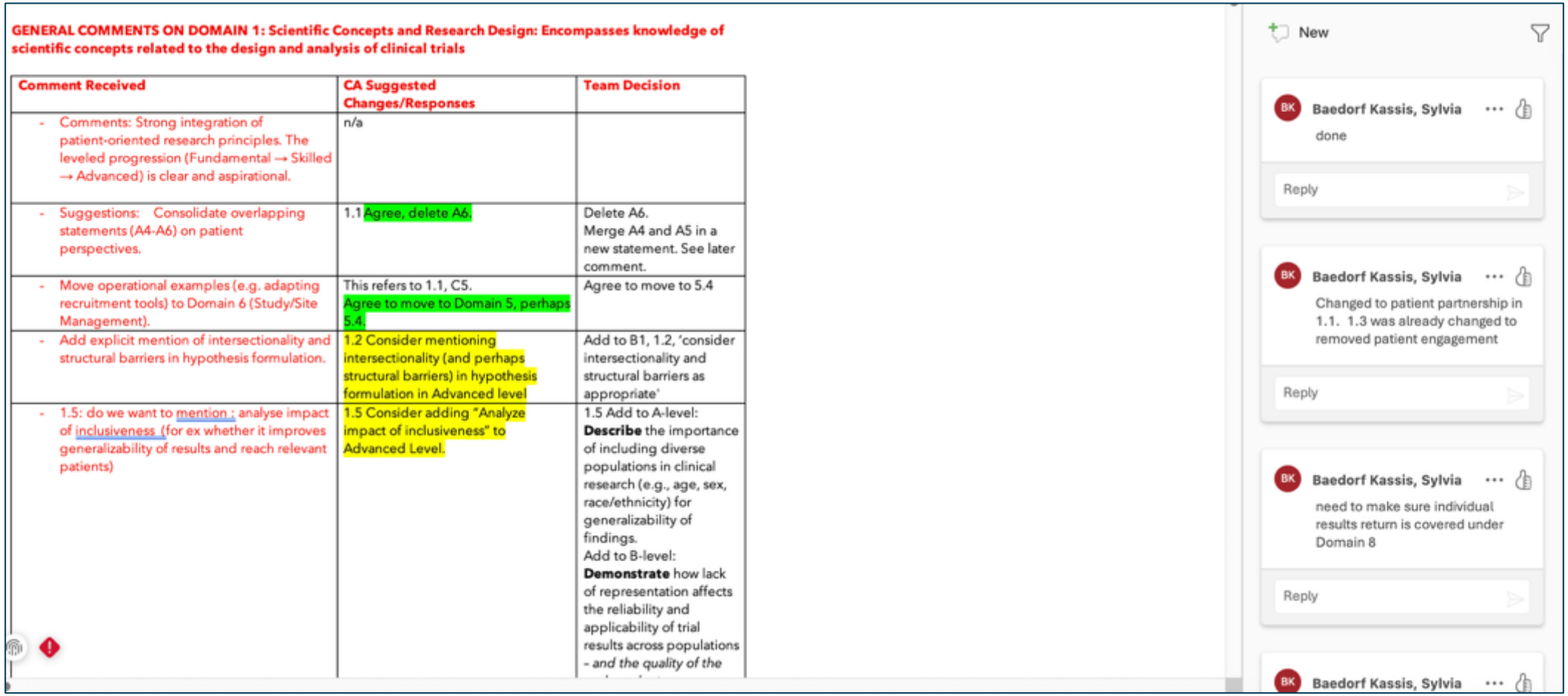
JTF-P3 Review Team Feedback Collection Survey



- 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

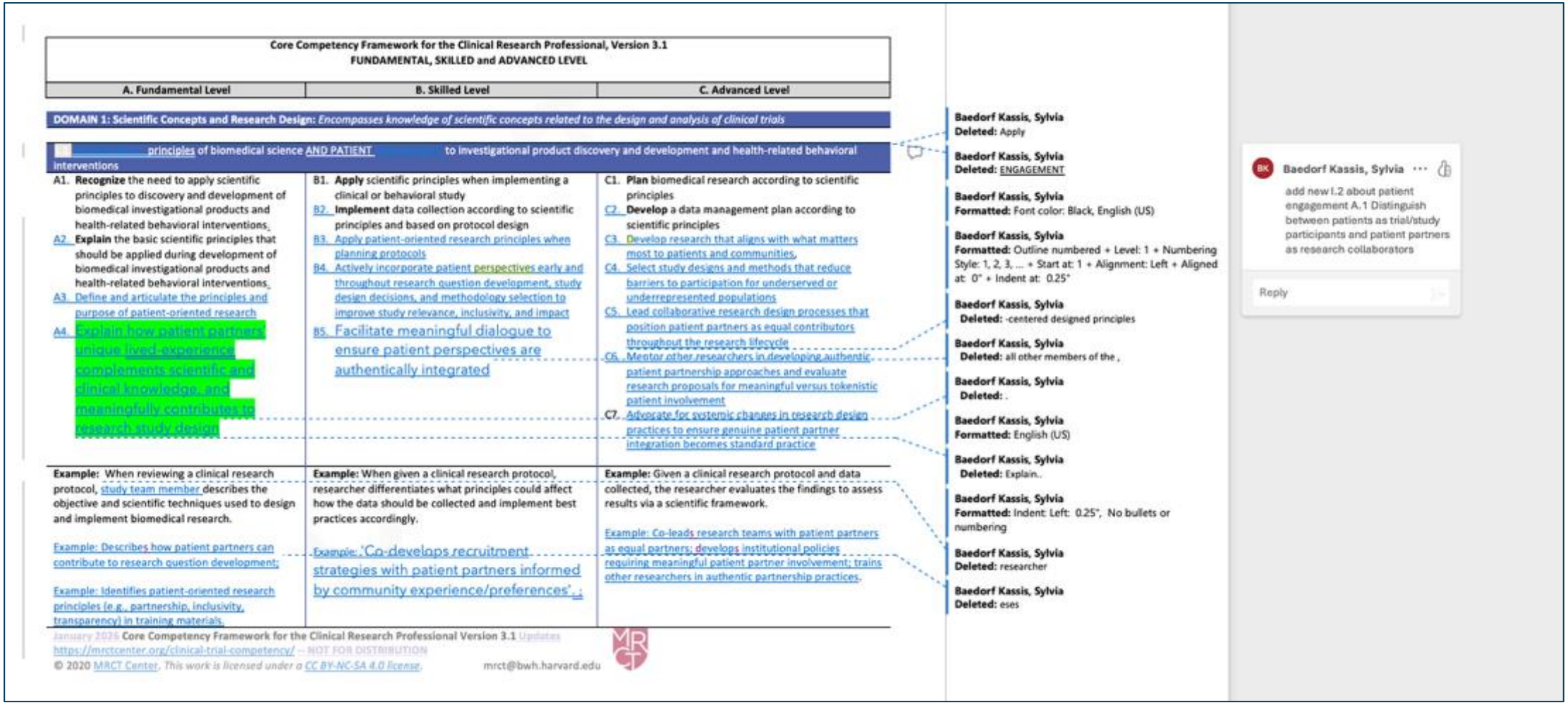
Baedorf Kassis, Sylvia
done
Reply

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

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

Baedorf Kassis, Sylvia

JTF-P3 Feedback Integration (Mar 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*		
principles of biomedical science AND PATIENT to investigational product discovery and development and health-related behavioral interventions		
A1. **Recognize** the need to apply scientific principles to discovery and development of biomedical investigational products and health-related behavioral interventions. A2. **Explain** the basic scientific principles that should be applied during development of biomedical investigational products and health-related behavioral interventions. A3. Define and articulate the principles and purpose of patient-oriented research A4. Explain how patient partners' unique lived-experience complements scientific and clinical knowledge, and meaningfully contributes to research study design	B1. **Apply** scientific principles when implementing a clinical or behavioral study B2. **Implement** data collection according to scientific principles and based on protocol design B3. Apply patient-oriented research principles when planning protocols B4. Actively incorporate patient perspectives early and throughout research question development, study design decisions, and methodology selection to improve study relevance, inclusivity, and impact B5. Facilitate meaningful dialogue to ensure patient perspectives are authentically integrated	C1. **Plan** biomedical research according to scientific principles C2. **Develop** a data management plan according to scientific principles C3. Develop research that aligns with what matters most to patients and communities. C4. Select study designs and methods that reduce barriers to participation for underserved or underrepresented populations C5. Lead collaborative research design processes that position patient partners as equal contributors throughout the research lifecycle C6. Mentor other researchers in developing authentic patient partnership approaches and evaluate research proposals for meaningful versus tokenistic patient involvement C7. Advocate for systemic changes in research design practices to ensure genuine patient partner integration becomes standard practice
Example: When reviewing a clinical research protocol, study team member describes the objective and scientific techniques used to design and implement biomedical research. Example: Describes how patient partners can contribute to research question development; Example: Identifies patient-oriented research principles (e.g., partnership, inclusivity, transparency) in training materials.	**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: 'Co-develops recruitment strategies with patient partners informed by community experience/preferences'.;	**Example:** Given a clinical research protocol and data collected, the researcher evaluates the findings to assess results via a scientific framework. 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.

January 2026 Core Competency Framework for the Clinical Research Professional Version 3.1 Updates
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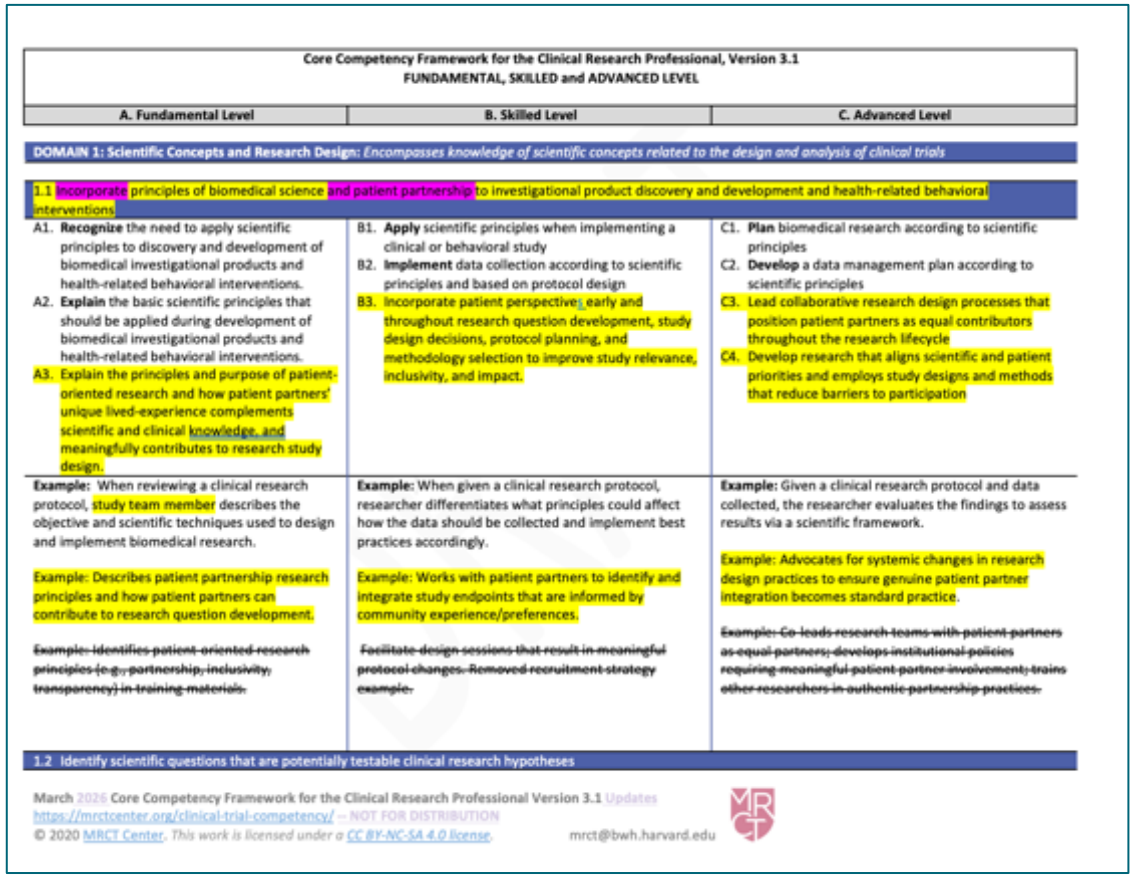
Baedorf Kassis, Sylvia
add new I.2 about patient engagement A.1 Distinguish between patients as trial/study participants and patient partners as research collaborators

Reply

JTF-P3 Feedback Integration (April 2026)



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1.1 Incorporate principles of biomedical science and patient partnership to investigational product discovery and development and health-related behavioral interventions		
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Example: When reviewing a clinical research protocol, study team member describes the objective and scientific techniques used to design and implement biomedical research. Example: Describes patient partnership research principles and how patient partners can contribute to research question development. ~~**Example:** Identifies patient-oriented research principles (e.g., partnership, inclusivity, transparency) in training materials.~~	**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: Works with patient partners to identify and integrate study endpoints that are informed by community experience/preferences. ~~Facilitate design sessions that result in meaningful protocol changes. Removed recruitment strategy example.~~	**Example:** Given a clinical research protocol and data collected, the researcher evaluates the findings to assess results via a scientific framework. Example: Advocates for systemic changes in research design practices to ensure genuine patient partner integration becomes standard practice. ~~**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.~~
1.2 Identify scientific questions that are potentially testable clinical research hypotheses		

March 2026 Core Competency Framework for the Clinical Research Professional Version 3.1 Updates
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JTF-P3 Final version, May 2026

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		
A1. **Recognize** the need to apply scientific principles to discovery and development of biomedical investigational products and health-related behavioral interventions A2. **Explain** the basic scientific principles that should be applied during development of biomedical investigational products and health-related behavioral interventions A3. Explain how patient partners contribute to research study design	B1. **Apply** scientific principles when implementing a clinical or behavioral study B2. **Implement** data collection according to scientific principles and based on protocol design B3. Incorporate patient perspectives throughout research question development, study design, protocol planning, and methodology selection	C1. **Plan** biomedical research according to scientific principles C2. **Develop** a data management plan according to scientific principles C3. Develop research that aligns scientific and patient priorities and employs study designs and methods that reduce barriers to participation
Example: When reviewing a clinical research protocol, study team member describes the objective and scientific techniques used to design and implement biomedical research. **Example:** Describes patient partnership research principles and how patient partners can contribute to research question development	**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:** Works with patient partners to identify and integrate study endpoints that are informed by community experience/preferences.	**Example:** Given a clinical research protocol and data collected, the researcher evaluates the findings to assess results via a scientific framework. **Example:** Advocates for research design practices that ensure patient partner integration.
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	• **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	• 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	• **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)	• **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	• **Co-lead initiatives to design, test, and evaluate recruitment strategies**
DOMAIN 6: Data Management and Informatics	• *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)*
DOMAIN 7: Leadership and Professionalism	• 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	• **Recognize and respect the unique lived experience and expertise that patient partners bring to transdisciplinary research teams**
JTF-P3 Supplement	• **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 →

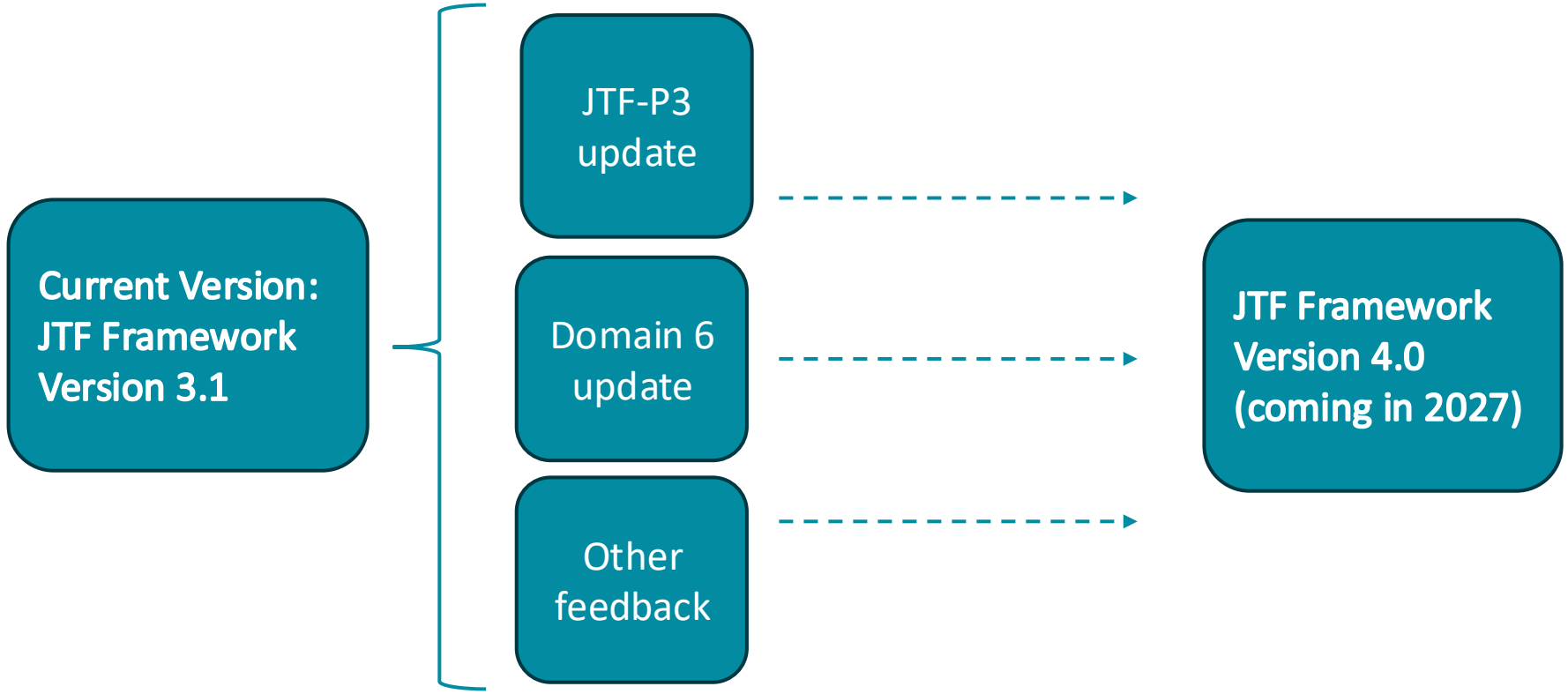
JTF-P3 Term Examples	Definition	Source(s)/ Adapted From
Patient Partnership	Meaningful and active collaboration between patients (or caregivers) and researchers, where patients are involved in decision-making and governance across the entire clinical research and development continuum.	CIHR SPOR; BC 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

Next steps

- The JTF-P3 Framework will be publicly available once published.
- Manuscripts on both the output and the process are in progress.
    - Journal submissions are expected later this month.
- A QI evaluation of patient partnership throughout this project is in progress.

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

The JTF-P3 in the context of other JTF efforts



A Warm Welcome to our Panelists

Session 1:

- **Monica Bogas**, Country Head of Clinical Operations, Roche Portugal
- **Kaushal Shah**, Program Director, Arizona State University
- **Leanne Hays**, Researcher PPIE Lead & Program Manager, University College Dublin
- **R. Bernard Coley**, Patient Partner Enable Your Vision

Session 2:

- **Janelle Bowden**, Founder and Consultant, AccessCR
- **Kyoko Imamura**, President, Japanese Institute for Public Engagement
- **Allison Bulat,** Patient Partner, ALS ONE

Register: https://mrctcenter.org/tribe-events/joint-task-force-for-clinical-trial-competency-jtf-global-biannual-meeting-4/

Miigwetch!

Shukran!

Merci!

Toda!

Grazie!

Gracias!

Mamnun!

THANK YOU!!

Tak!

Dhanyawad!

Arigato!

Obrigado!

Xièxie!

Do jeh!

Danke!

Gamsahamnida!

Wado!