Clinical Research Professional Development through Inter-institutional, Peer-led, Competency-based Workshops

Mary-Tara Roth, RN, MSN, MPH Director, Clinical Research Resources Office, Assistant Director Human Research Protection Program, BU Medical Campus/Boston Medical Center

Kimberly Luebbers, MSHS, RN, BSN, OCN® Assistant Dean for Clinical Research; Director - Office of Clinical Trials Research; Larner College of Medicine at the University of Vermont

H. Robert Kolb RN, MS, CCRC Director, Clinical Research Professionals' Programing; Clinical Translational Science Institute - Workforce Directorate; University of Florida

Diana Lee-Chavarria, MA Assistant Director for Operations, Translational Science Education and Workforce Development; South Carolina Clinical & Translational Research (SCTR) Institute; Medical University of South Carolina

H. Robert Kolb RN, MS, CCRC

Director, Clinical Research Professionals Programing

UF | Clinical and Translational Science Institute

Translational Workforce Development

UNIVERSITY of FLORIDA

We will …

…describe creation of a novel workforce development program:

The Research Professionals Network (RPN) Workshops

- Multi-institutional
- Peer-led
- Joint Task Force for Clinical Trial Competency
- Enable participants to practice with the material
- Engage with others across institutions

Learning Objectives

1) Describe a novel workforce development program for research professionals: workshops which are peer led, competency based, and multi-institutional.

2) Discuss multi-year data presented highlighting the role of the workshops in professional development.

3) Utilize the essential elements, lessons learned and best practices as a model for attendees to develop similar educational programs.

"We envision a need for a <u>clinical research workforce organized in several dimensions</u> that reflect the broad missions of the Clinical Trial Enterprise, the specific disciplines involved, and the level of desirable expertise" (p. 161).

Bonham, A., Califf, R., Gallin, E.(2012). Developing a robust clinical trial workforce. In: *Envisioning a Transformed Clinical Trials Enterprise in the United States: Establishing an Agenda for 2020.* National Academies Press: Washington DC.
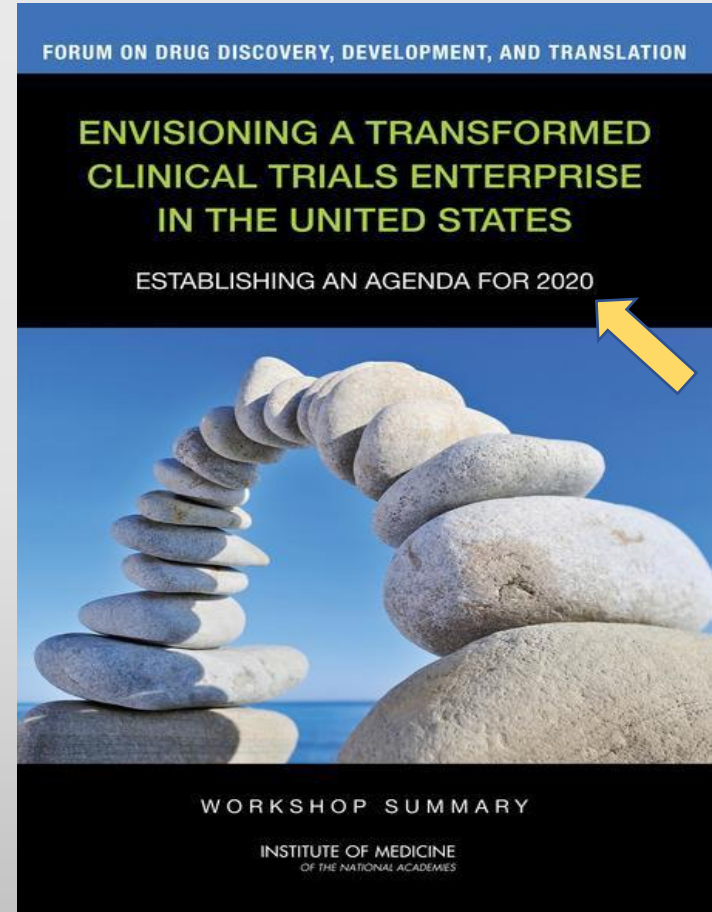
Timeline

Original CTSA Regulatory Knowledge KFC– Research Coordinator Taskforce

Publication Critical Needs for Clinical Research Coordinator Training Support & Career Development Requirements of Clinical Research Coordinators: Recommendations

Enhancing Clinical Research Professionals Training and Qualifications (ECRPTQ)

Addition of 3rd collaborating site University of Florida

Addition of collaborating sites' affiliates: Maine Medical Center and Florida State University

2010 **2011** **2012** **2014** **2016** **2017** **2019** **2020** **2021** **2022→2030**

A CTSA-Sponsored Program for Clinical Research Coordination: Networking, Education, and Mentoring*

Joint Task Force Clinical Trial Competencies (JTF)

RPN Workshops Started Boston University University of Vermont

Addition of 4th collaborating site Medical University of South Carolina

IOMs 2030 agenda

Critical Needs: Programs <u>Advancing CRP Training</u> Leadership and Certification in Academic Medical Centers

Key priority challenges and opportunities framing the 2030 agenda:

- Diversity and inclusion of clinical trial participants
- Convergence of clinical research and clinical practice
- Clinical trial data sharing
- Incorporation of new technologies into drug research and development
- **Workforce and career development**
- Public engagement and partnership
- Regulatory Environment
- Cultural and Financial Incentives
- Practical short- and long-term goals for improving the efficiency, effectiveness, person-centeredness, inclusivity, and integration with healthcare of the clinical trials enterprise.

Community of Practice

Diverse and broad group of CTSI/CTR clinical research professionals who promote cross-functional collaboration for research initiatives at across CTSA Hubs and other research networks.

==Goal to help CRPs grow professionally== and to achieve success by championing professional development.

It's about Connections ...

Kimberly Luebbers, MSHS, RN, BSN, OCN®
Assistant Dean for Clinical Research
Director - Office of Clinical Trials Research
Administrative Director - UVM Clinical Research Center
Co-Chair of the NNE-CTR Professional Development Core

The Larner College of Medicine at the University of Vermont
The University of Vermont Medical Center
Burlington, Vermont

Research Professionals Network Workshops: Inter-institutional Collaborating Teams

- Boston University/ Boston Medical Center

- University of Vermont/ UVM Medical Center
  - Affiliates at Maine Medical Center

- University of Florida
  - Affiliates at Florida State University

- Medical University of South Carolina
  - Affiliates at Clemson University & South Carolina State University
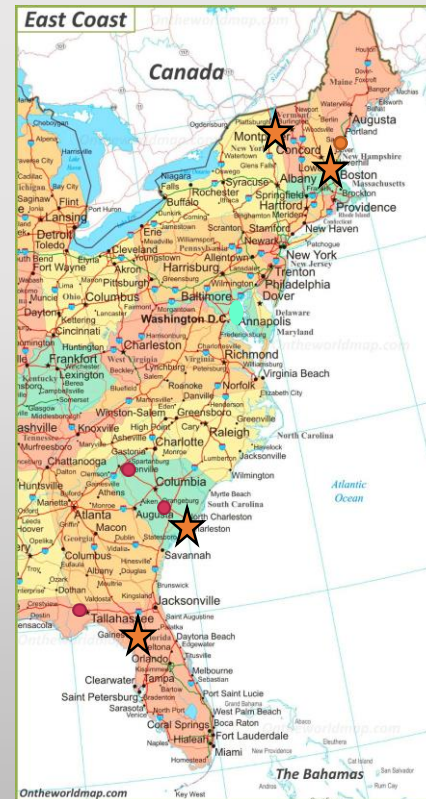
Workshop Presentation Format

- Peer-led
- Collaborative
  - 2-4 presenters
  - Inter-institutional
- Monthly presentation/workshops – academic year
  - Zoom platform (pre-registration is required)
  - Breakout rooms (small group work: cases, activities, problem solving, etc.)
  - Polling (Zoom polling, Poll Everywhere, Slido, etc.)
  - Ancillary web-based tools (wordle, Jam board, etc.)
- Competency-based
  - JTF Core Competency Framework for Clinical Research Professionals
  - Fundamental/ Advanced training levels

- Sonstein et al, Moving from Compliance to Competency…., Clinical Researcher, June 2014, 17-23

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

Workshop Logistics

- Presenters for Workshops
  - Professional Development Opportunity
  - Presenter Resource Guide
  - Mentoring
- Facilitators for Breakout Rooms
  - Professional Development Opportunity
  - Facilitator Resource Guide
  - Facilitator Training
- Follow up Surveys/Evaluations
  - Attendees
  - Presenters
- Contact Hours
  - Ongoing professional development for our ACRP and SOCRA certified research professionals
- Enduring Materials
  - Presentation
  - Workshop/Activities
  - Video

Presenters
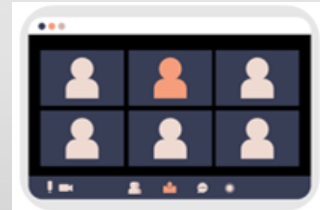
Facilitators

Evaluation

RPN Planning Leadership Team

- Year-round planning team meetings
  - Weekly meetings
  - Academic year workshop planning
    - Topics
    - Presenters
      - Identification
      - Individual presenter outreach
      - Connecting the individual presenters to each other
  - Meetings with presenters (multiple)
    - Presenter Resources
    - Activity development
    - Institutional specific resources
  - Workshop announcements to our participant audiences
  - Pre-registration/participant management
  - Facilitator engagement
  - Contact hours application

idea   planning   strategy   success
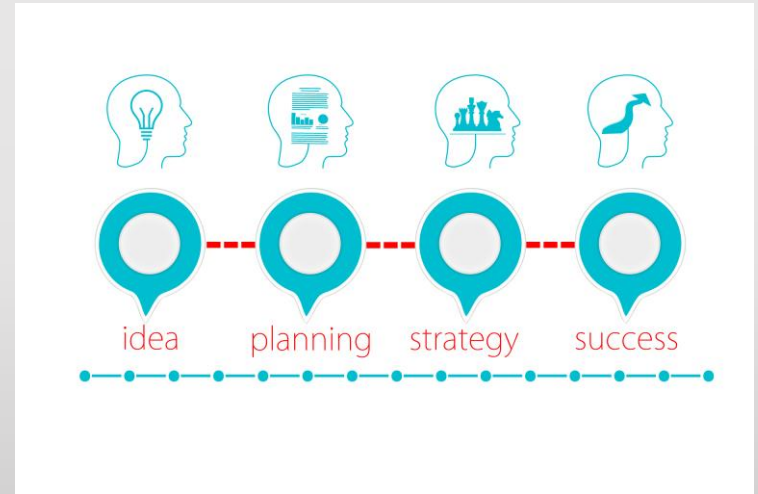
Inter-institutional Collaborations

- Leadership team

- Presenter teams

- Mentoring

- Workshop activities
  - Peer to peer networking
  - Sharing of best practices
  - New approaches – other institutions doing things differently
  - Affirming current approaches – other institutions doing things the same
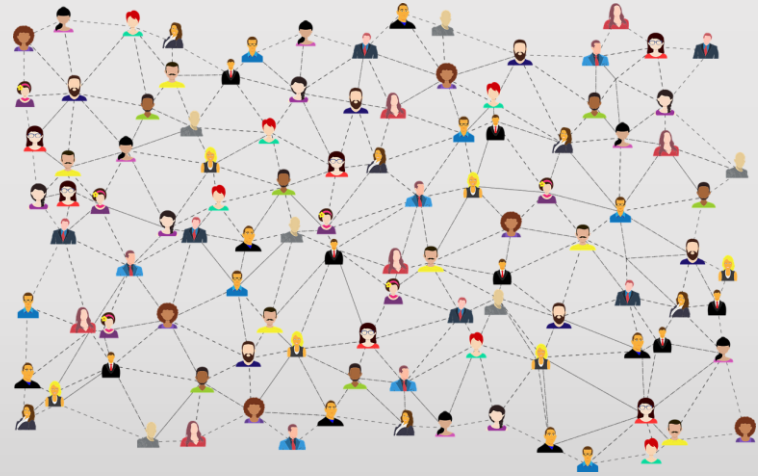
Types of Training and Educational Materials

Workshop Topics	JTF Competency Domains	Level
How We Can Improve Scientific Communication in Clinical Research Using Cultural Competence: Lessons from the TED Stage	2, 7, 8	Advanced
Qualitative Research Design and Analysis	1, 6	Advanced
Time Management Best Practices for Clinical Research Staff	5, 7, 8	Fundamental
Remote and E-Consent – Lightening Talks and Group Discussions	2, 4, 5	Advanced
Conducting Remote Research Study Visits	4, 5, 8	Advanced
Developing a Budget for Clinical Research	5	Fundamental
GCP Overview and Jeopardy!	4	Fundamental
Team Science	8	Fundamental
Lead Site Responsibilities: Monitoring, Oversight, Communications	4, 5, 8	Advanced
Creating a Culture of Quality Assurance	4	Fundamental
When Novel turns Normal: Social media recruitment in an ever-evolving research landscape	2, 5, 8	Fundamental
Cede Review: Navigating the World of Single IRB	2, 4, 5	Fundamental
Basics on Developing Source Data Collection tools and Case Report Forms for Clinical Research Studies	2, 6	Fundamental
Basics on REDCap: A Tool for Data Collection and Management in Clinical Research	6	Fundamental
REDCap Advanced Features	5, 6	Advanced

Why we are doing what we are doing

- Elements of RFA/ IOM to why we chose this model
- Addresses adult learning principles - learn by doing, practice, self-directing, etc.
- "Tailored, practical, interactive"
- Competency-based
- Applicable to a variety of levels of expertise
- Accessibility: easy to access
- Available in various options and formats
  - In-person/Zoom: allows for engaging and learning from others
  - On-line modules: allows for reaching many learners as well as providing information *when* it is needed
- Streamline resources by collaborating with other hubs

Diana Lee-Chavarria, MA

Assistant Director for Operations, Translational
Science Education and Workforce Development
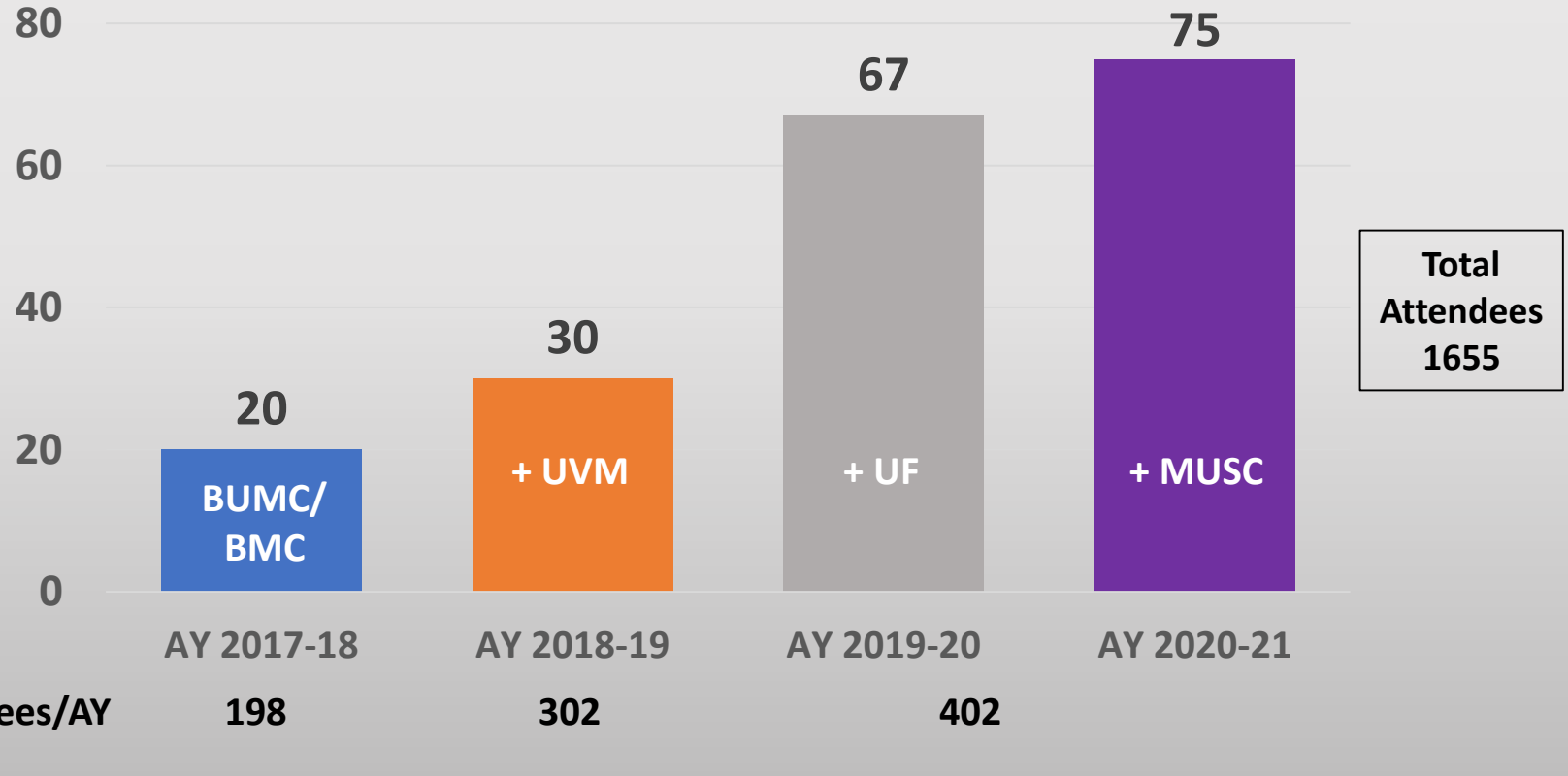
South Carolina Clinical & Translational Research
Institute

RPN Workshop by AY (17/18 – 20/21)
Mean and Total Attendance

Total Attendees 1655

	BUMC/BMC	+ UVM	+ UF	+ MUSC
	20	30	67	75
	AY 2017-18	AY 2018-19	AY 2019-20	AY 2020-21

Attendees/AY 753 — 198 — 302 — 402

% Role from Evaluation Surveys
AYs 2017/18 – 2020/21

% Role
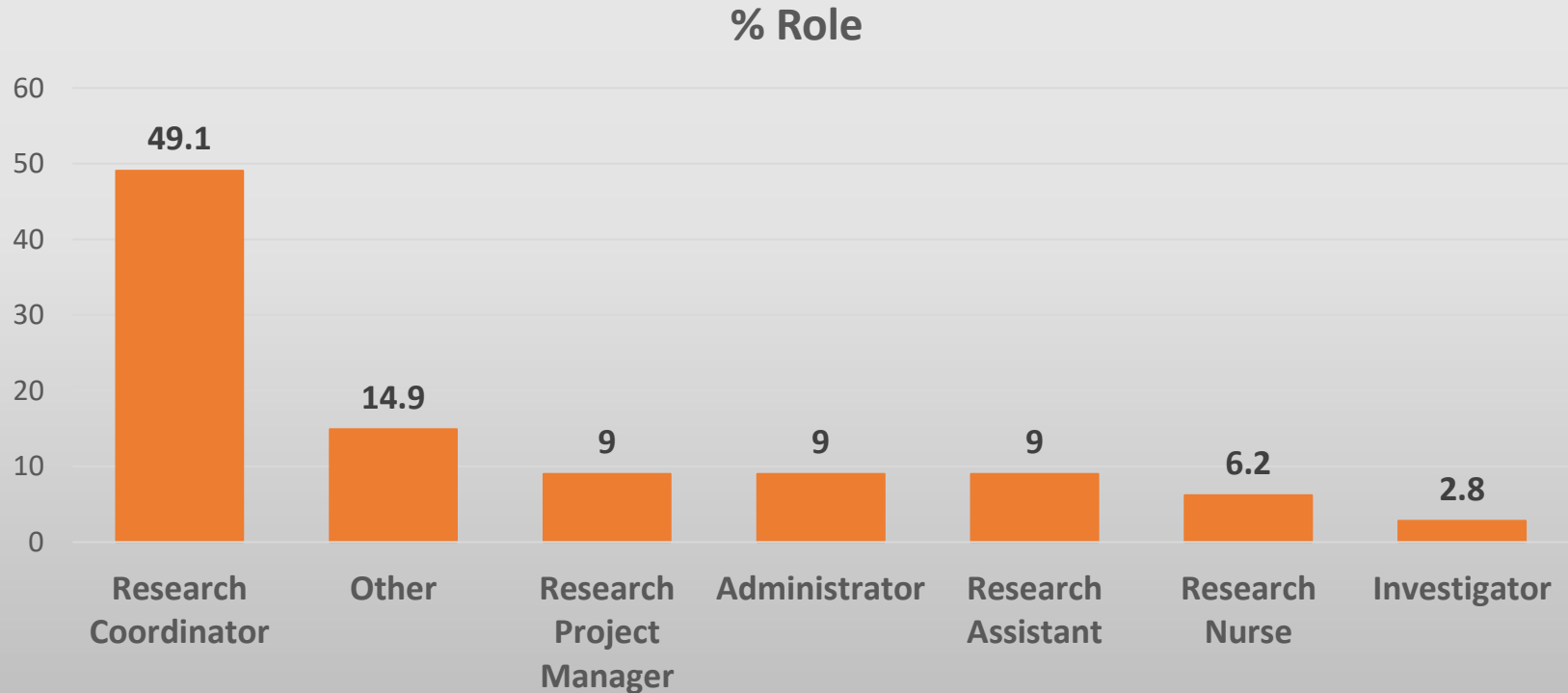
Evaluation of RPN Workshops Sept 2017 – June 2021

BMC/BUMC IRB Determination Exempt, Category 2

- Evaluation of learners directly after the workshop (Immediate)
  - Quality of workshop, workshop activities, teaching strategies/effectiveness
  - Collaboration: Value collaboration? Technology used to enable collaboration?

- Evaluation of learners after 6 weeks (6-week follow-up)
  - Implementation of learnings, motivation, incentive and enabling factors and barriers

- Evaluation of Workshop Presenters (peer leaders)

▪ Prior experience leading training/workshop?	▪ Inter-institutional collaboration
▪ Increase in topic knowledge?	▪ Usefulness of Evaluation summary feedback
▪ Satisfaction with mentorship and process	▪ How useful for professional development?

- Other Data
  - Registration/attendee data (job title, academic degrees, department, institution, etc.), # minutes attended
  - # workshops attended per individual; % repeat attendees

Evaluation of RPN Workshops, *Cont'd.*

- Descriptive statistics
  - Frequency distribution of all responses
  - Categorical variables – cross tab/contingency tables
  - Continuous variables – mean, sd, median, range
- Stratification of results by
  - Institutions (BMC/BUMC, UVM/affiliates, UF/affiliates, MUSC/affiliates); Academic years (AY17-18, AY18-19, AY19-20, AY20-21); Change before and after March 2020
- Statistical tests
  - Categorical variables – chi square and fisher exact tests
  - Continuous variables – ANOVA, T tests
- Statistical Software NCSS version 9
  - Statistical significance set at $p<0.05$
- Qualitative analysis of open-ended responses (on-going)

| Sample Sizes of <u>Attendee</u> Surveys by Type, Institution, AY	Immediate Evaluation Survey	6-week Follow-up Survey	Subtotal RPN Surveys
Institutional CTSA Hub/Date start			
BUMC/BMC	355	171	526
UVM and affiliates	365	118	483
UFL and affiliates	230	74	304
MUSC and affiliates	36	14	50
Other	13	1	14
Academic Year (AY)			
AY 2017-18	155	56	211
AY 2018-19	193	106	299
AY 2019-20	261	89	350
AY 2020-21	390	127	517
Pre/Post COVID changes			
Pre March 2020	495	221	716
Post March 2020	504	157	661
Total RPN Workshop Surveys	**999**	**378**	**1377**

Percent Distributions of Responses from RPN Immediate Evaluation Survey, Quantitative

Survey Questions	Responses (n)	Excellent (%)	Good (%)	Fair (%)	Poor (%)
Overall workshop quality	(999)	61.0 **95.2 %** 34.2		4.6	0.2
Quality of hands-on activities	(985)	52.6 **90.7 %** 38.1		8.9	0.4
Presenter teaching strategies	(992)	58.2 **92.7 %** 34.5		6.9	0.5
Presenter teaching effectiveness	(991)	59.1 **93.3 %** 34.2		6.1	0.6
		Definitely	Probably	Maybe/ Unsure	Probably/ Definitely not
Plan to apply skills to work setting	(997)	58.8 **84.3 %** 25.5		12.7	3.0
		Excellent	Good	Fair	Poor
Collaboration technology	(587)	55.4 **92.5 %** 37.1		7.0	0.5
		Very much	Somewhat	Not at all	
Valued inter-institutional collaboration	(584)	85.1 **99.0 %** 13.9		1.0	

Inter-institutional Collaboration Technology and Value
Immediate Evaluation survey, before/after March 2020
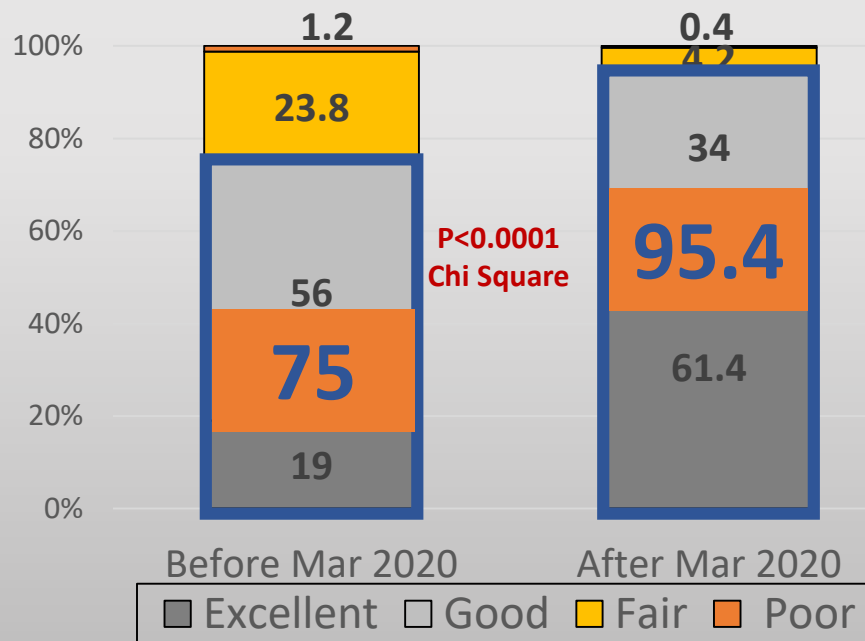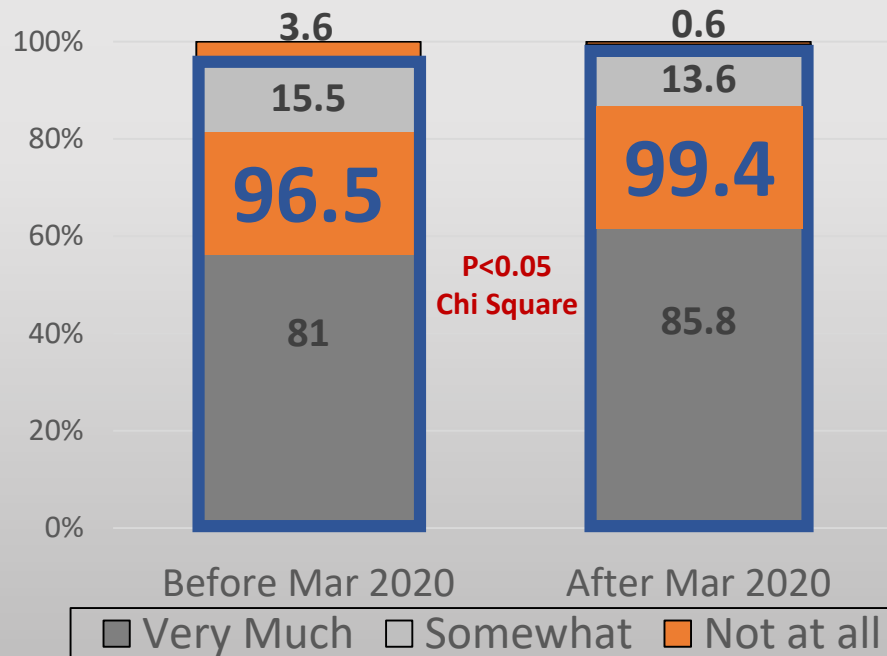
Although the topics that RPN workshops address are interesting, I would say **what is more important and valuable for me is the inter-institutional collaboration. I think this is an incredible opportunity and platform to develop the field of resear**ch, **with multiple organizations working together** and learning strategies other institutions are using …

It's great to have a larger pool of presenters and viewpoints. It was also nice to hear that BU and UF have similar challenges to UVM in this area. **This is an important collaboration and allows attendees to hear from experts at various institutions for the important research topics covered**.

Tremendous experience by having colleagues from other institutions share their experiences on the same topic/challenge.

Expanding the RPN workshops have vastly increased expertise, points of view, and resources…

I am **glad I am not the only one** who has issues.

I think it was massively **beneficial to be able to connect with other experienced coordinators across the country** and gain valuable insight and knowledge related to our roles.

Immediate Evaluation survey:
Provide further feedback in regards to how you value the inter-institutional collaboration.

Percent Distributions of Responses from RPN 6-week Follow-up Survey, Quantitative

Survey Questions In last 6 weeks....	Responses (n)	Strongly agree (%)	Agree (%)	Neither (%)	Disagree (%)	Strongly disagree (%)
Applied workshop content to job	(376)	29.0 73.9 % 44.9		17.0	6.9	2.1
Motivated to practice skills	(377)	37.1 88.6 % 51.5		8.2	1.9	1.3
Incentives to apply skills to work	(376)	36.2 83.0 % 46.8		12.5	3.2	1.3
Continued learning beyond workshop	(374)	26.2 60.7 % 34.5		24.6	12.8	1.9

SOPs
I am currently developing an MOP for the clinical trial I work on, so **have been writing SOPs non-stop for the past few weeks using the skills I learned in this workshop**.

Multisite
I was just starting to work on setting up a study at another site …At the time, my plan and guidance was fairly bare, so the **recommendations offered at the workshop served as a good reference…**

Budget
Tips on things to consider when building budgets helped me in creating a budget for our next year of grant funding.

Recruitment
During the group activity our group explored factors that make recruitment harder for studies. **After this session, I explored with our PI how our trial could improve any issues with recruitment, by finding where we introduce constraints that are not scientifically impactful**.

Informed Consent
- Learning the teach back method was super beneficial to me and **I was able to review this skill with the study clinician who does informed consent** with our participants.
- **Changed the way I assess capacity** to provide informed consent.

E-Consent
At the time of the presentation, I was in the beginning phases of implementing e-consenting. I have now fully implemented this approach for one of my studies and **I used the skills learned and discussed to develop my workflow.**
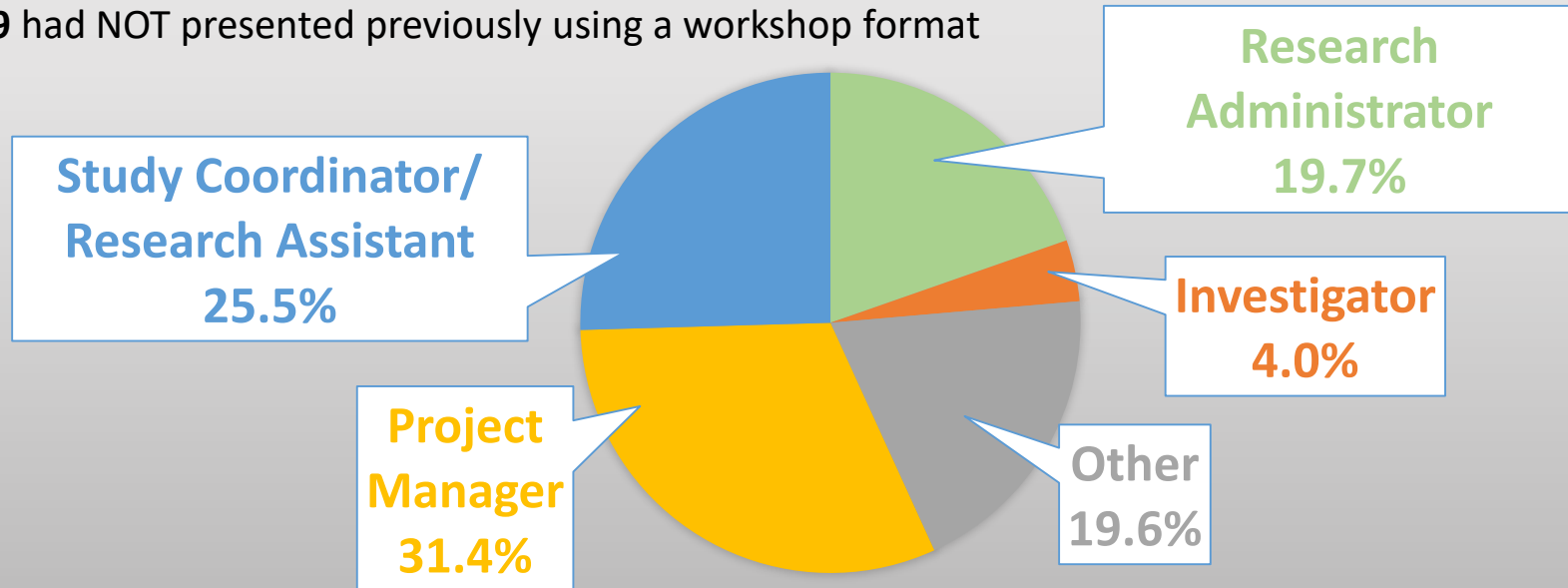
6 week Follow-up survey:
- What are examples of how you have implemented the learnings into your work?

% Distribution of Presenter Research Roles Distribution of Presenter surveys 2018-21

- **86** presenters total
- **79%** response rate; 55/70 presenters who were sent survey
- **76.4**% had prior experience presenting on a clinical research topic
- **51.9%** had NOT presented previously on the workshop topic
- **50.9** had NOT presented previously using a workshop format

Research Administrator
19.7%

Study Coordinator/
Research Assistant
25.5%

Investigator
4.0%

Project Manager
31.4%

Other
19.6%

Distribution of Presenter Ratings for Preparing and Teaching
Range of Ratings from 1 (lowest) to 10 (highest)
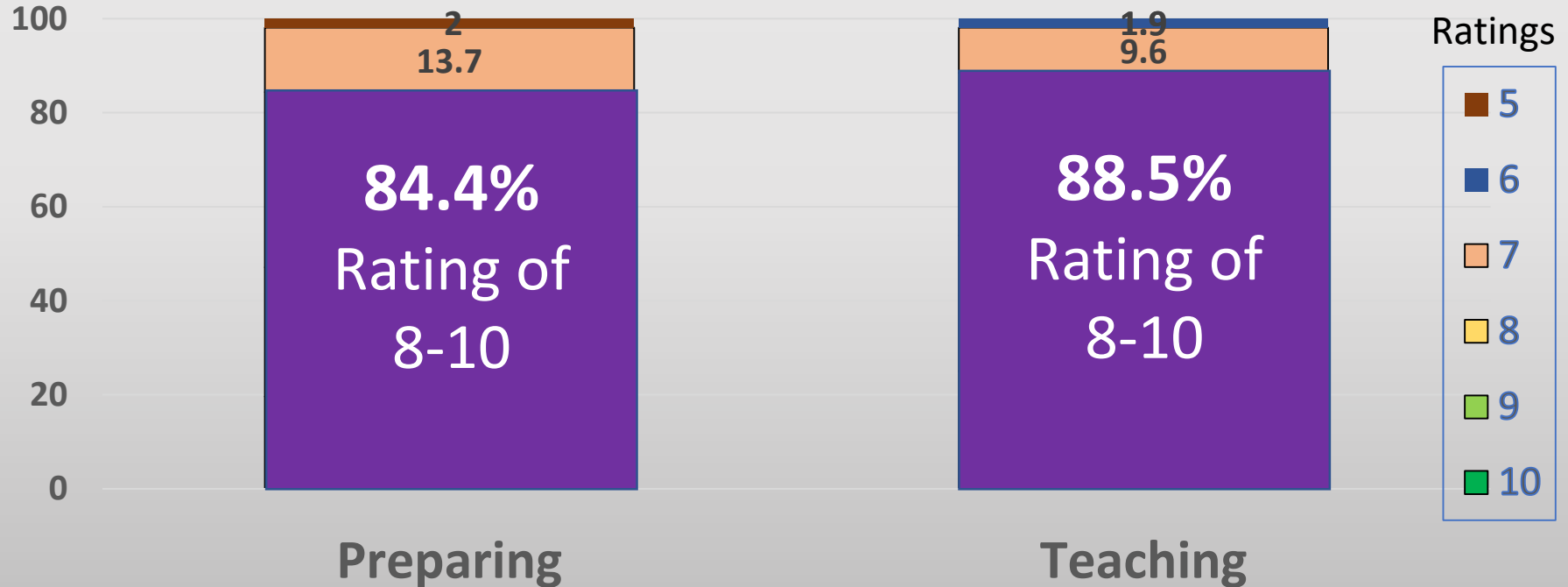
Presenter Ratings on Professional Development and Inter-institutional Collaboration

- **98%** strongly agreed/agreed that **teaching the workshop is a useful professional development activity.**

- **100%** strongly agreed/agreed that **attendee evaluation summary will enhance their own professional development**.

- **100%** strongly agreed/agreed that **collaborating with their co-presenter(s) positively impacted their experience leading the workshop.**

Teaching a workshop is a **great professional development opportunity** because most of the time you learn a lot about your topic as you prepare for a presentation, **you get mentoring from experienced professionals, and you increase your comfort and confidence with presenting to others** which is something everyone can benefit from.

Absolutely! I think teaching a workshop is a tremendous professional development opportunity, especially for those who plan to grow in this field…. public speaking in front of large masses is a must skill.

Had a truly wonderful experience. Would definitely do this again. The co-presenter was delightful to work with and the RPN leadership provided great ideas and gentle prodding.

It allows each presenter to spend time curating relevant training for their peers. It also gives them insight on current information they may not know on chosen topic. Also, it **gives each presenter the chance to practice their public speaking skills**.

Yes, this is an **excellent opportunity to practice our capacity to convey knowledge** to colleagues who may be facing similar challenges.

… **can further strengthen the knowledge of one's areas of expertise** by requiring the presenter/teacher to know their topic well to be able to teach it.

Presenters:
- Do you think teaching a workshop is a useful professional development opportunity?

I think it's great to work with other professionals from other institutions as research foci and policies may differ **so it can contribute to cross disciplinary presentation tools and strategies.**

I enjoyed the inter-institutional collaboration through this workshop. **I got to know colleagues from different institutions and different view points. We learned some common challenges and new ones.** It was also a great opportunity to learn about resources offered at different institutions.

The collaboration between institutions was the high point ... I gained knowledge and ideas by listening to my co-presenters. Overall, this was a positive experience.

Working with Ashley was not only incredibly fun but really eye-opening as well. We are all at our individual universities essentially doing the same thing, **so sharing knowledge and tips were super helpful. It really made me feel a sense of community and comradery.**

The **inter-institutional aspect provided wider perspectives on the topic.**

I enjoyed the inter-institutional collaboration through this workshop. **I got to know colleagues from different institutions and different view points. We learned some common challenges and new ones. It was also a great opportunity to learn about resources offered at different institutions.**

Presenters:
- What worked well re: inter-institutional collaboration?

Major Lessons Learned from the Inter-institutional RPN Workshop Initiative

1) Multiple groups benefit
2) People like the inter-institutional collaboration
3) Importance of Facilitator role
4) Workshop format: More work/rewards
5) Role-based guidance documents are essential
6) Baby bear
7) Time warp is real

Multiple groups benefit from RPN Workshop professional development opportunities

Lessons Learned

1

- **Presenters**
  - Opportunity to take on a leadership role
  - Presentation skills – important opportunity to hone skills needed for higher level roles
  - Mentorship
  - Teamwork (presenters working together)
- **Attendees**
  - Opportunity to learn new or delve further into topics essential to role of coordinator/study team member
  - Earn ACRP or SoCRA CE credits
- **Breakout Room Facilitators**
  - Opportunity to take on leadership and education role
  - Opportunity to hone communication skills: getting people to engage/work with each other; teach
  - Sometimes "entry-level" to presenting

People like the inter-institutional collaboration – A LOT

Lessons Learned

2

- Diversity of perspectives, from….
  - Presenters
  - Attendees
  - Breakout room facilitators
  - Collaborator team
- Increased pool of research professionals with expertise in topics of interest

Facilitator role is essential for workshop activities in Zoom breakout rooms

Lessons Learned

3

- Help to get breakout rooms started: quick intros, review of activity, guiding participants

- Maintain group of individuals trained in the facilitator role

- Provide training on:
  - being a facilitator
  - specific workshop activity

Workshop format:
More work … *but also* … more rewards

Lessons Learned

4

- Enabling learners to practice and engage with the content
  - Adult-learning model
- Enabling presenters to engage with each other in brainstorming/developing content and activities

Role-based guidance documents are essential

Lessons Learned

5

- Presenter and Facilitator roles

- Lay out responsibilities, recommendations, timelines, expectations, best practice guidance

Workshop activities
Getting to "Baby Bear": What's "Just right"

Lessons Learned

6

- Takes some practice
- Not too simple and not too complicated
- Promote engaging with the material
- Promote engaging with other learners
- Ensure sufficient time budgeted
  - Interactions take time – allot the time
- Have faith in the breakout room process

Workshop "Time-warp" – It's a real thing

Lessons Learned

7

- Insufficient time → disappointment
  - Reduces opportunity to engage further with those from other institutions
  - Minimizes potential for positive impacts of the inter-institutional collaboration
- Recommend devoting approx. half of workshop time to activities
  - At least one interactive activity; 3 <u>at most</u>; be careful! "Pad" the time estimates.
- Make sure to account for:
  - Instruction time, before activity begins
  - Transition time, if using breakout rooms
  - "Summing up" time, after any group activity, including polling; what were the learning points?

Summing up Evaluation and Lessons Learned

- Workforce development initiative:
  - Workshop format + Inter-institutional collaboration
- Evaluation data clearly supports value of these important components
- Synergy in relation to professional development of research professionals
- Our experience provides lessons learned to enhance feasibility and quality and overall impact on professional development

Breakout rooms

- Please join one of two breakout rooms, facilitated by members of the RPN Collaborating team. We want to know your opinions! ☺
- We will introduce questions in Jamboard. We'd love to talk about your ideas for RPN Workshops moving forward.
  - We will use Jamboard and Zoom Chat to capture ideas.
- Once you arrive to the breakout room we will put a link to the Jamboard in Zoom Chat. Click the link.
- Use sticky note option in the left menu (4th icon down) or text (7th down). If you use Jamboard, have fun with colors and size!
- After about 20-25 minutes we'll come back to the full workshop group and share our ideas.

Looking Ahead

Continued development of the RPN Workshops

A CTSA Priority (PAR-21-293)

CTSA Program Goals

NCATS amended the CTSA Program goals in response to the recent feedback and the maturation of the existing CTSA Program and will use a variety of mechanisms to achieve these goals, including this UM1 FOA and other training and research opportunities.

1. Advance CTS: develop, demonstrate, and disseminate scientific and operational innovations that improve the efficiency and effectiveness of clinical translation from identification to first-in-human studies to medical practice implementation to community health dissemination
2. Promote partnerships and collaborations to facilitate and accelerate translational research projects locally, regionally, and nationally
3. Create, provide, and disseminate innovative research programs and partnerships across institutions and communities to address health disparities and deliver the benefits of translational science to all
4. Create and implement scientific and operational innovations that increase the quality, safety, efficiency, effectiveness, and informativeness
5. Provide a national resource for the rapid response to urgent public health needs
6. Create, provide, and disseminate CTS training programs for clinical research professionals of all disciplines on the research team
7. Create, provide, and disseminate CTS training and career support programs for translational scientists
8. Foster the development of the emerging field of translational science

6) *Create, provide, and disseminate CTS training for **clinical research professionals** of all disciplines on the research team*

Element C: Training & Outreach

CRPs should…

- …be provided **foundational education and training**

- …learn the **collaborative nature** of CTS

- …receive **training, education, and mentoring** as part of professional development

- …participate in educational activities, including **workshops**

Operational Enhancement

Timeline

- Topics/potential presenters >6 months out
- Check-ins at regular intervals
- Cut the time warp!

Evaluation

- Evidence-based quality improvement
- Interest in presenter participation
- Focus groups

Activity & Technology Database

- "One-stop-shop"
- Tools to promote interactivity and collaboration
- New strategies for engagement

Innovation Expansion

- Standardized and scalable model
- Dissemination across hubs
- Support evaluation project and educational technologist
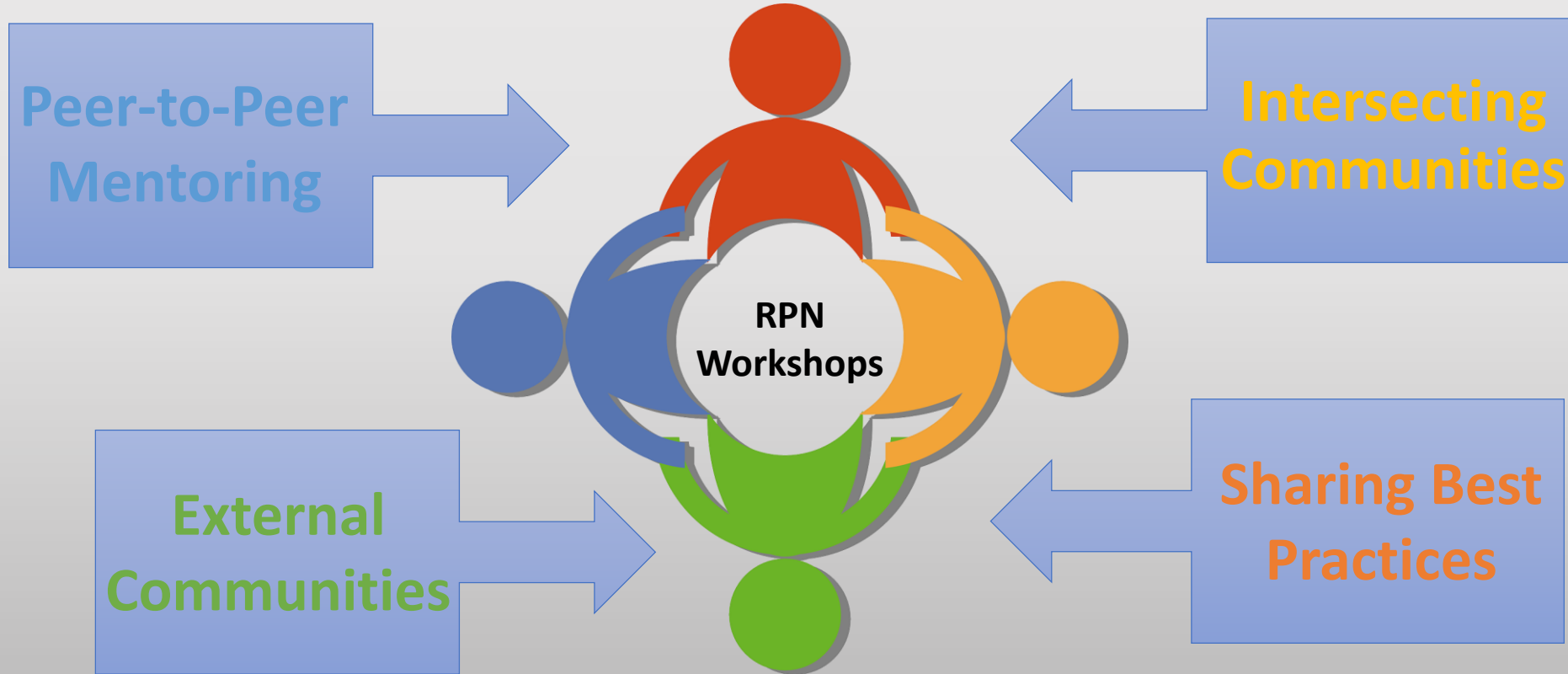
Content Evolution

Assess our **content**

Meet **learners** where they are

Pathways to **competency**

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Thank you!

Please stay in touch:

- **Mary-Tara Roth, RN, MSN, MPH -** Boston University mtroth@bu.edu

- **Kimberly Luebbers, MSHS, RN, BSN, OCN® -** University of Vermont Kimberly.luebbers@med.uvm.edu

- **H. Robert Kolb RN, MS, CCRC -** University of Florida kolbhr@ufl.edu

- **Diana Lee-Chavarria, MA -** Medical University of South Carolina leeachar@musc.edu