Empowering the
Participant Voice

What if you knew what participants were thinking?

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Empowering the Participant Voice

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Empowering the
Participant Voice

Collaborative Infrastructure and Validated Tools for Collecting Participant Feedback to Improve the Clinical Research Enterprise

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Wake Forest
School of Medicine

Duke Clinical & Translational Science Institute

Empowering the Participant Voice

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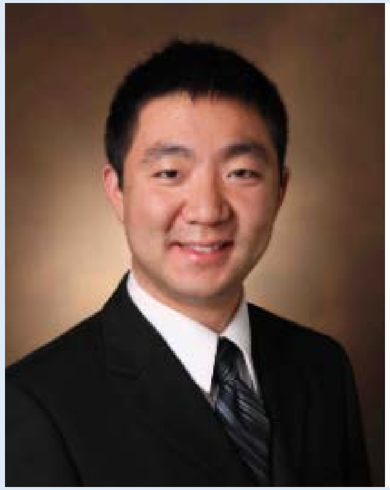

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Duke Clinical & Translational Science Institute

Empowering the Participant Voice

Overview

1. What is the Research Participant Perception Survey (RPPS)?
2. What is the *Empowering Participant Voice* project about?
3. Plans, Progress, What's Next…
4. How will the tools be shared beyond the EPV collaborators?
5. How might the EPV tools to test an innovation in a TIN trial?

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- What is the Research Participant Perception Survey (RPPS)?

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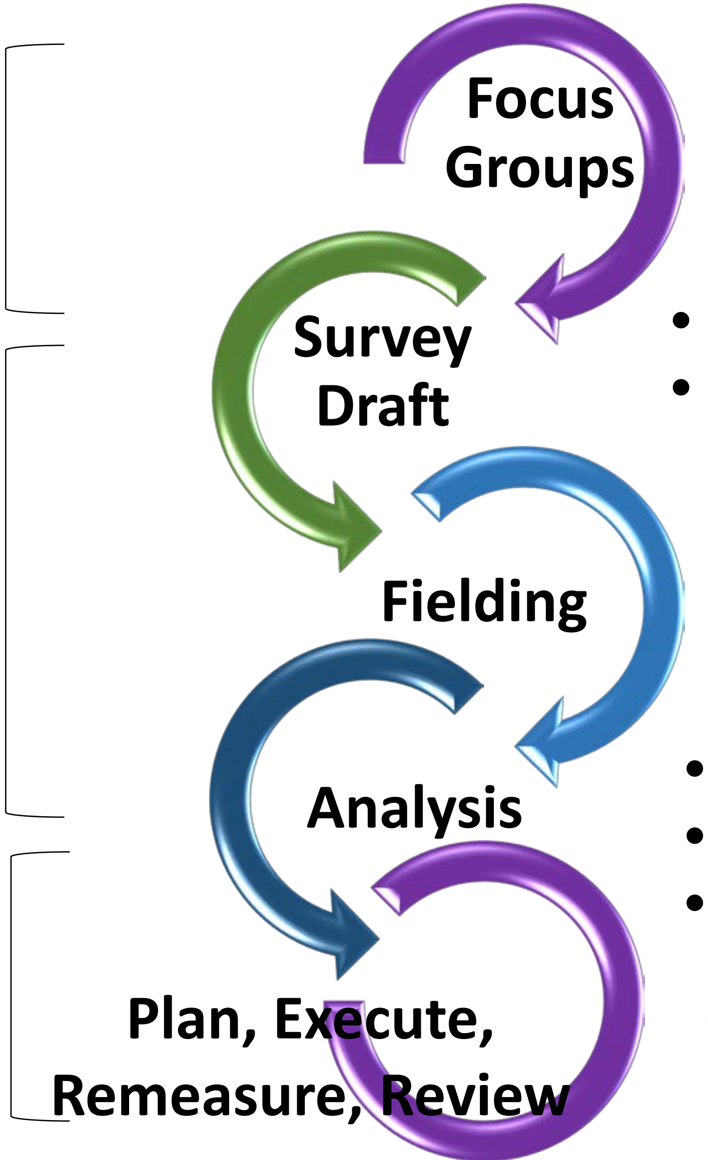
Research Participant Perception Survey – Validated Measures of the Research Participant Experience



Part I

Focus Groups

- **Participants & stakeholders (n=129) identify themes of positive and negative research experiences**

Part II

Survey Draft

- **“Actionable” question design**
- **Face/Content Validation – by participants and other stakeholders**

Fielding

- **Broad Sampling – representative of research population***

Analysis

- **Psychometric Analyses**
- **Instrument Reliability, validation**
- **Local & Aggregate Outcomes**

Part III

Plan, Execute, Remeasure, Review

- **Benchmarking, improvement cycles**

****CTSA grants: UL1TR000043; UL1 TR001866**

RPPS survey asks about…

- Motivations to join, stay, leave research
- Informed consent
- Listening/courtesy/respect
- Feeling valued
- Language/culture/privacy
- Communication with team
- Rate the Overall research experience
- Would you recommend to friends and family
- Demographics

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RPPS-Short-P

x. Motivation to join

1. Would you recommend joining a research study to your family and friends?
2. Did the study require that you already have a disease or condition in order to enroll?
3. Did the study involve taking a drug or a supplement or the use of a new medical device, or undergoing a new medical procedure?
4. Did the Informed consent form prepare you for what to expect during the study?

- ☐ Completely
- ☐ Mostly
- ☐ Somewhat
- ☐ Not at all
- ☐ No consent form

5. Did the information and discussions you had before participating in the research study prepare you for your experience in the study?
6. Did the research team members listen carefully to you?
7. Did the research team members treat you with courtesy and respect?

- ☐ Always
- ☐ Usually
- ☐ Sometimes
- ☐ Never
- ☐ No interaction with research team

8. During your discussion about the study, did you feel pressure from the research staff to join t
9. When you were not at the research site did you know how to reach the research team if you
10. When you were not at the research site and you needed to reach a member of the research team, were you able to reach him/her as soon as you wanted?
11. Did you feel you were a valued partner in the research process?
12. If you considered leaving the study, did you feel pressure from the Research Team to stay?
13. Did the research staff respect your cultural background (e.g. language, religion, ethnic group)?
14. Did the research staff do everything possible to provide assistance with any language difference you might have?
15. Did you have enough physical privacy while you were in the study?

x. Motivation to leave

x. Motivation to stay

15\. Which other things would be important to you in a future study:

16\. Please use the scale below to rate your overall experience in the research study, where 0 is the worst possible experience, and 10 is the best possible experience. Scale from (Worst)0……..9,10 (Best)

17\. How much did the study demand of you? (Pick the answer that most closely describes your experience)

x. Demographic questions

x. Is there anything else you would like to share about your experience in the study you most recently joined?

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Empowering the Participant Voice

RPPS Surveys

RPPS – Long survey, aggregate scores, from 15 CTSA centers (~5000 responses)

- 73% gave their overall experience the Top (9 or 10) rating (61-82% across sites)
- 66% Would Recommend research participation to friends and family completely (46-87% across sites)
- Overall rating correlated with feeling valued, respected, listened to (completely); understanding consent (completely), and being able to reach the research team (always) when needed.
- Participants who answered that they trusted the research team completely were the participants who felt they were always treated with courtesy and respect (99%) and always listened to (93%) (p<0.001)

Motivation insights:

- Participants stayed in research when they felt valued and perceive benefit.
- 85% said they would have liked to receive results of the study
- 72% said receiving results would be a factor in deciding about future participation

RPPS – Short and Ultrashort surveys

- Capture all the important drivers of overall research rating in a handful of questions (+ demographics)
- Increase response rates to 60-75%

Link to RPPS surveys and related publications

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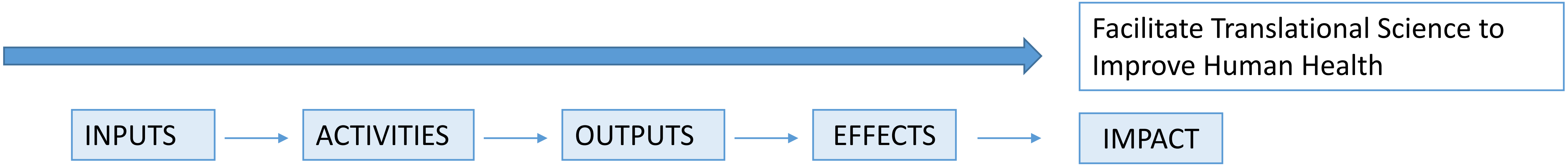
Evaluation - Causal Pathway



Facilitate Translational Science to Improve Human Health

INPUTS → ACTIVITIES → OUTPUTS → EFFECTS → IMPACT

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Evaluation - Causal Pathway

Facilitate Translational Science to Improve Human Health

INPUTS → ACTIVITIES → OUTPUTS → EFFECTS → IMPACT

Functionalized Knowledge

INPUTS

- **RPPS Surveys**
- Recruitment expertise
- Community engagement expertise
- Cultural competence
- Studios
- CABs
- Patient panels
- Research team expertise

ACTIVITIES

- **Assess participant experiences during research**
- Patient engagement
- Community engagement
- CEnR
- Recruitment outreach
- Aligning incentives

OUTPUTS

- **Participant experience data**
- Data-driven Patient-centered design
- Pragmatic /adaptive design
- Responsive design

EFFECTS

Better participant experiences

More…….

- Trust
- Sense of partnership
- Patient & Community-centeredness
- Communication
- Respect
- Felt listened to

→

Functionalized Knowledge

Faster study completion

Results applicable to affected populations

Best practices

→

IMPACT

Improve Human Health

Reduce Health Disparity

How to use the RPPS?

- Complementary to face-to-face initiatives
- Informed by stakeholder input before and after implementation
- Intentionally…
    - Take a pulse
    - Comparative
    - Pre/Post

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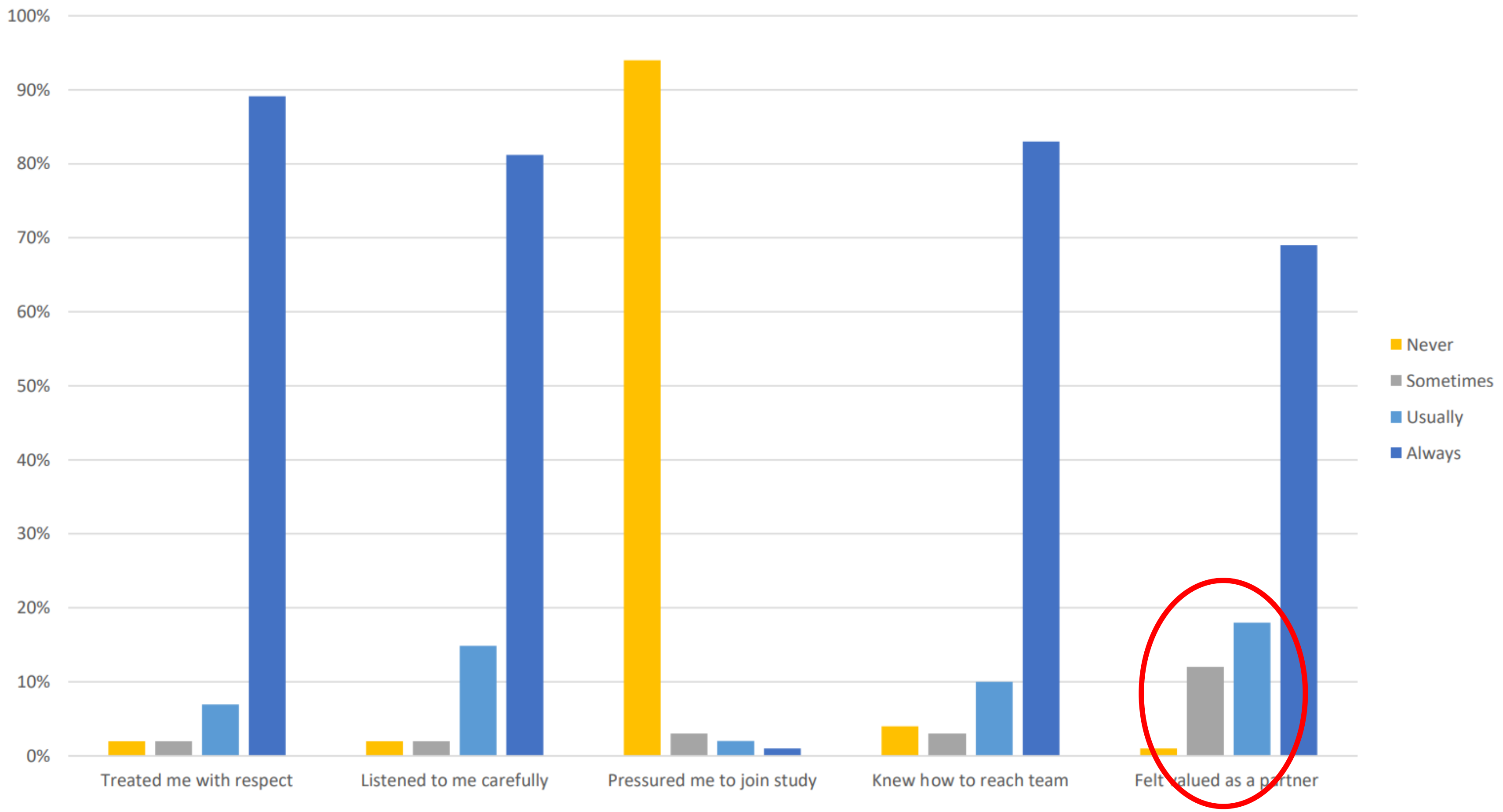
Empowering the Participant Voice

Cross Sectional - “Take a pulse”

Satisfaction with Research Team



https://ictr.johnshopkins.edu/programs_resources/research-participant-satisfaction-survey-results/

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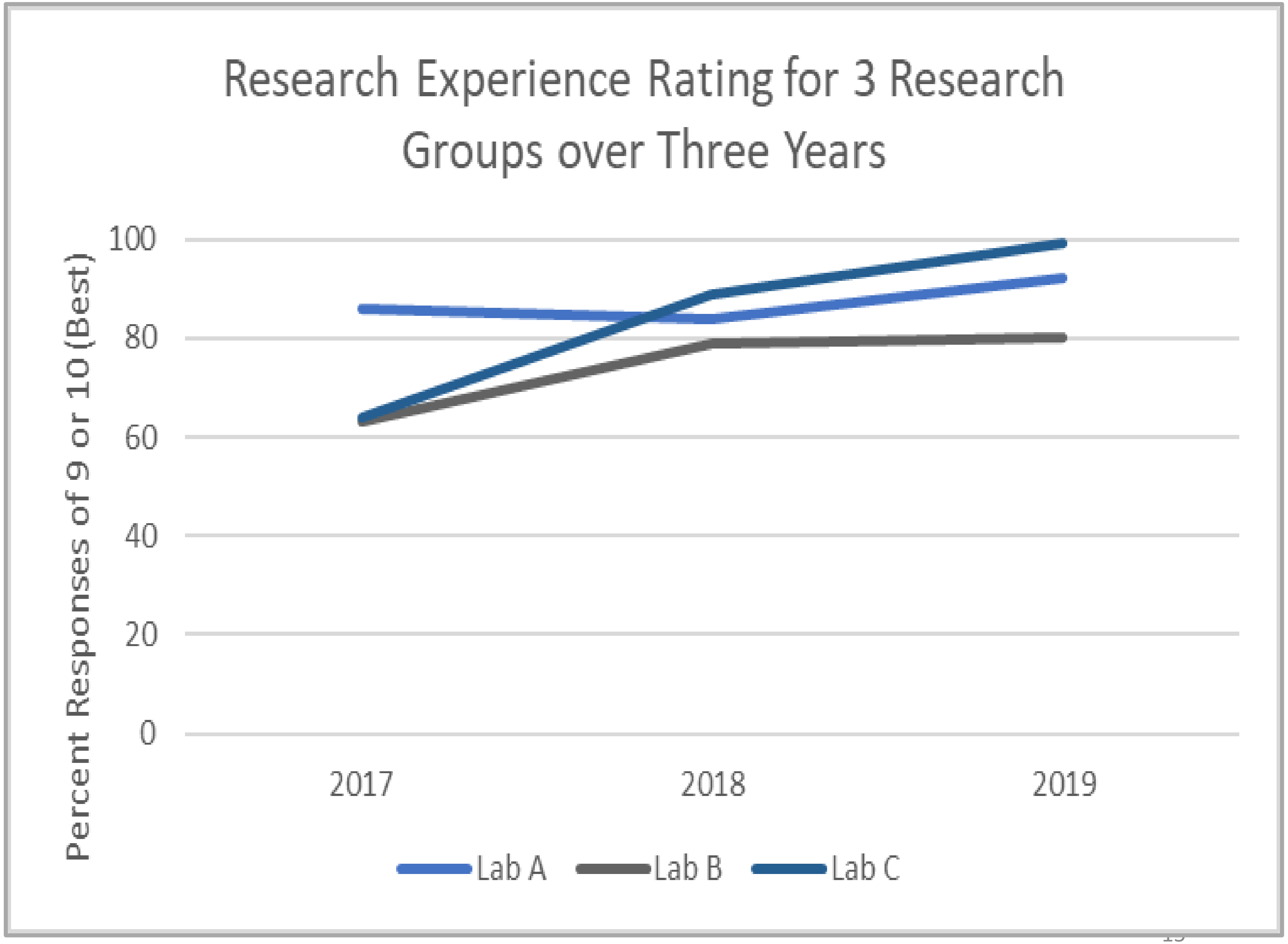
Comparative



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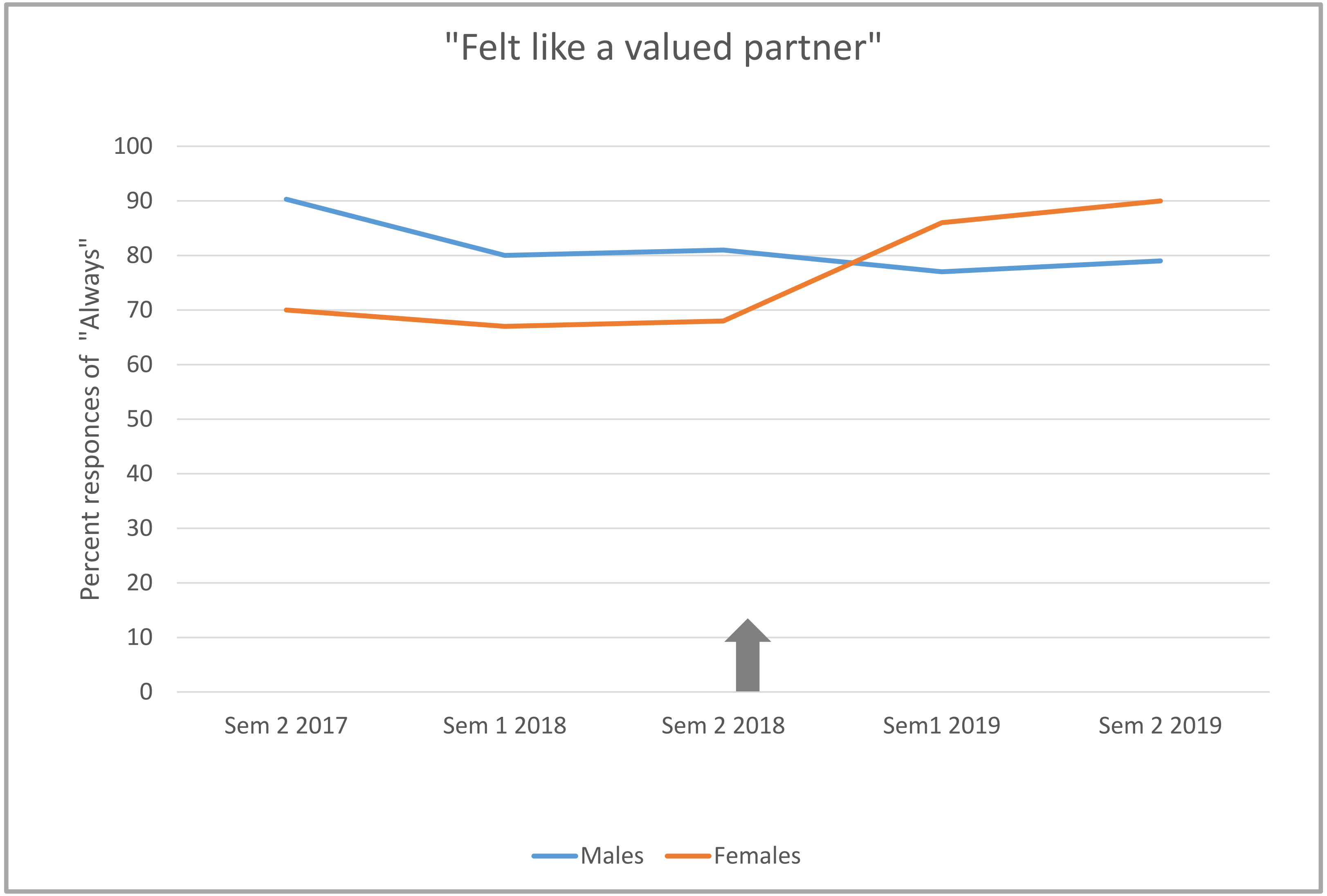
Comparative



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Pre/Post

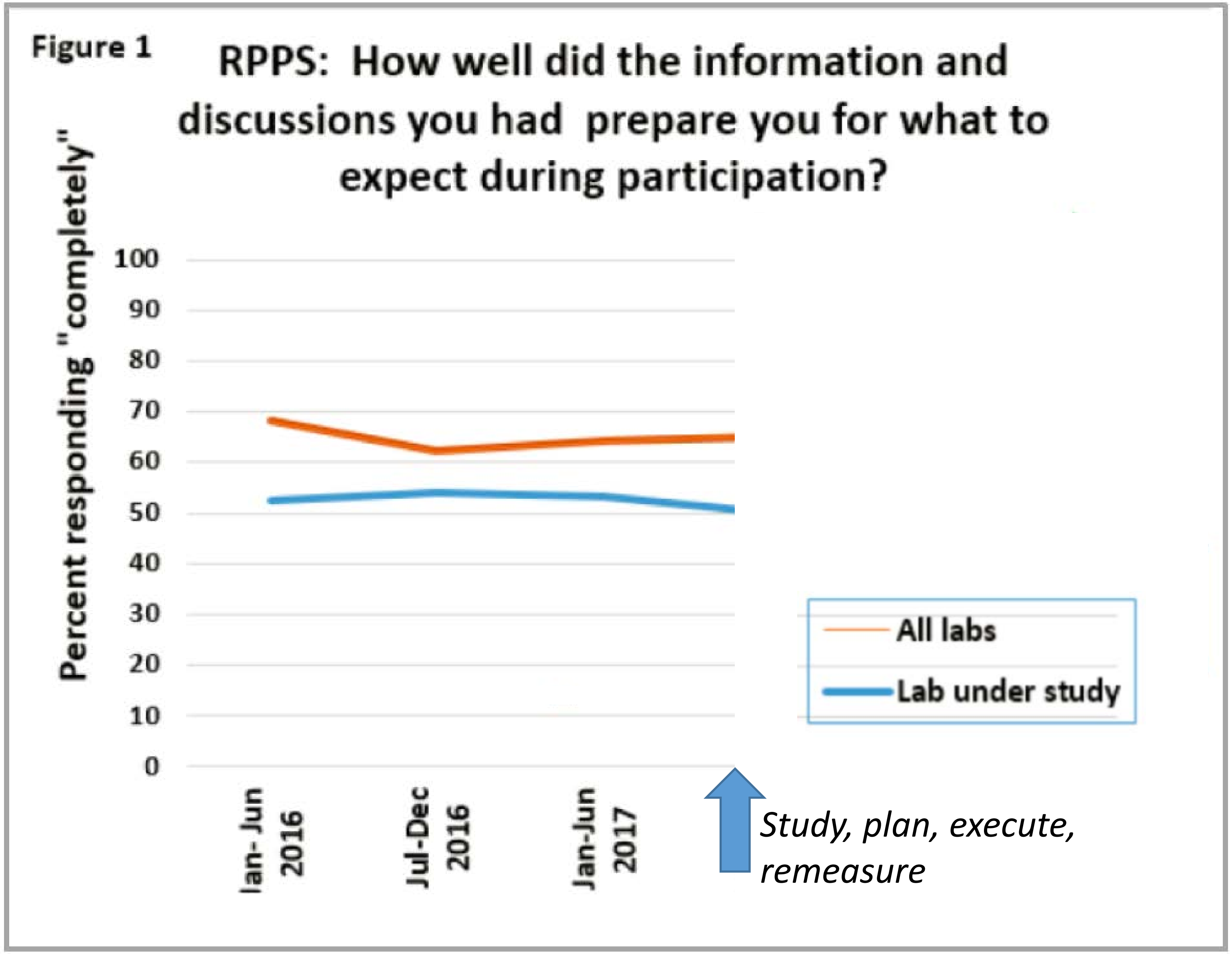
Figure 1

RPPS: How well did the information and discussions you had prepare you for what to expect during participation?

Study, plan, execute, remeasure

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Pre/Post

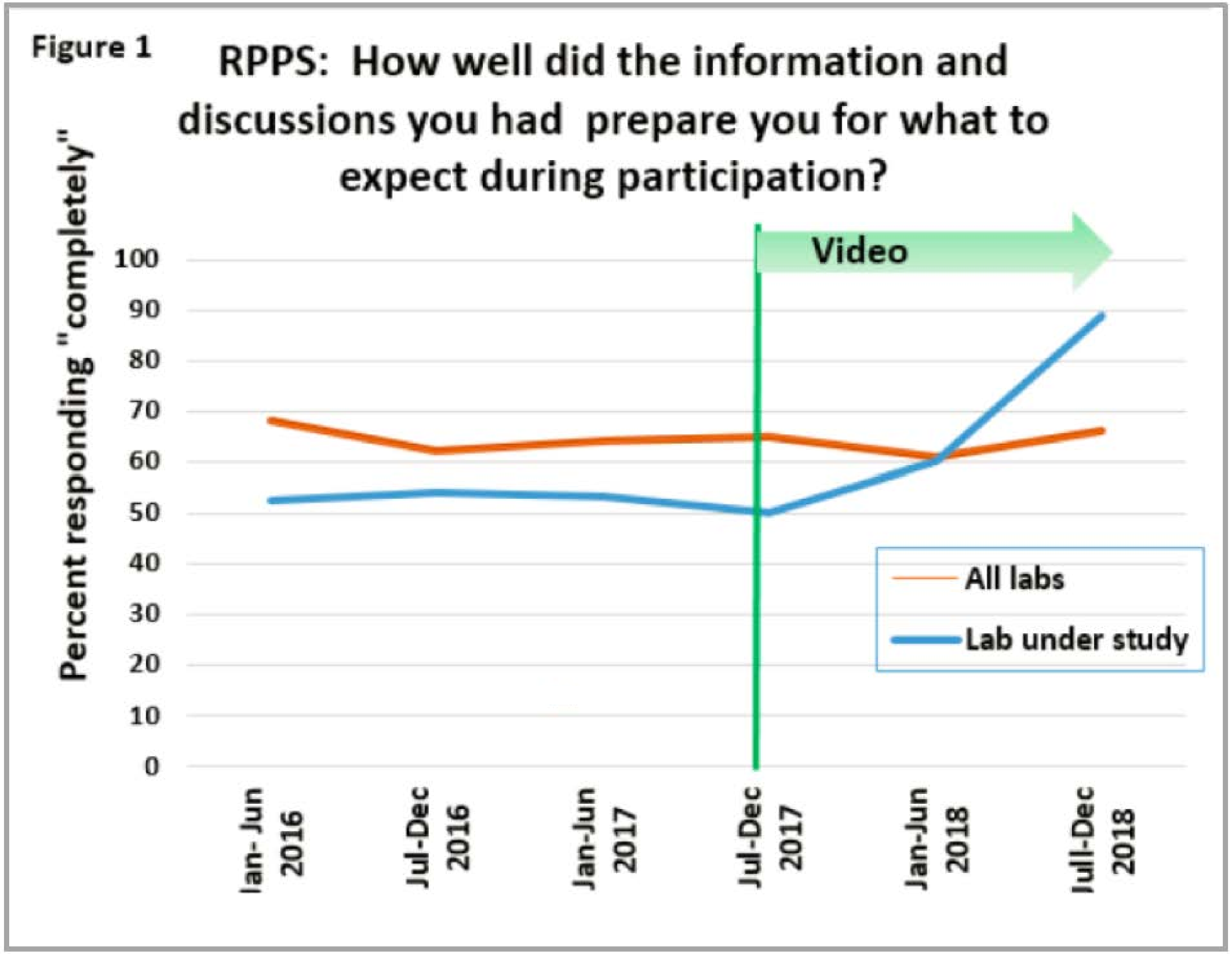

Figure 1

RPPS: How well did the information and discussions you had prepare you for what to expect during participation?

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If you could deploy the RPPS survey right now:

What would you want to learn from the survey?
Which participants would you send it to?
With whom would you share results?

Why isn’t the RPPS used more broadly

Common challenges…..

- Cost and logistics of sending surveys
- Managing data
- Analyzing data
- Visualizing data
- What does it mean?

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Empowering the Participant Voice

What is the *Empowering Participant Voice* project about?

Empowering the Participant Voice

Collaborative Infrastructure to streamline collection of participant feedback

Specific Aims:

1. **Develop** a novel Research Participant Perception Survey/REDCap (RPPS/REDCap) collaborative infrastructure and standard implementation models
2. **Demonstrate** that the collaborative RPPS/REDCap infrastructure and implementation model is an effective approach to collect institutional benchmarks and actionable data
3. **Disseminate** the infrastructure, catalyze research-on-research and transform evaluation by empowering the participant voice

www.Rockefeller.edu/research/epv

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Empowering the
Participant Voice

Study Timeline

Milestones	Year 1		Year 2		Year 3		Year 4	
	Sept	Mar	Sept	Mar	Sept	Mar	Sept	Mar
Convene RPPS/REDCap Stakeholder Collaborative	▨	▨	▨	▨	▨	▨	▨	▨
Develop Charter	🟧							
Develop RPPS/REDCap v1 Measures Consensus	🟧							
RPPS/REDCap v1 Implementation	▨	🟧						
Dashboard External Module v1	▨	🟧						
Implementation Framework (Standards) v1	▨	▨	🟧					
Use cases, Evaluation metrics, tools		▨	🟧					
Collaborating site surveys underway				🟩	▨	▨		
Site implementation metadata				▨	🟩	▨		
Investigator-level metadata				▨	▨	🟩		
Refine: RPPS/REDCap/Dashboard v2						▨	🟦	
Refine: Analytics External Modules v2						▨	🟦	
Dissemination/evaluation to REDCap network		▨	▨	▨	▨	▨	▨	▨
Analysis of impact/local use cases			▨		▨	▨	▨	🟦
Refinement of value proposition				▨	▨	▨	▨	🟦
Dissemination		▨		▨		▨		▨

▨ Program Development; 🟧 Milestones Aim 1; 🟩 Milestones Aim 2; 🟦 Milestones Aim 3

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Engaging stakeholders

- Institutional Leadership
- IRB/Privacy Officer
- Investigators
- Clinical Research Managers
- Research Coordinators/Research Nurses
- Community members/liaisons
- Patient/Participants
- Sponsor/NIH
- Other Consortium hubs

- Understand expectations, concerns
- Refine the value proposition
- Define the questions
- Input on implementation
- Reach hard-to-reach populations
- Plan how to share & analyze results, design interventions, measure impact, returning results to the community
- Foster trust, participation, impact

Empowering the Participant Voice

Standards, Data, Metadata

Survey Response Data

- Participant-provided, de-identified, RPPS-Short response data
- Demographics

Project Level Metadata - Survey project characteristics

- Timing (end of study, post-consent, other)
- Sampling approach (census, random, targeted, bias)

Study Level Metadata - Study characteristics

- Interventional /observational
- Domain (disease, trial design)- MeSH*
- Compensation yes/no
- Investigator, Coordinator
- Department, Unit

Evaluation Metadata

- Measures of ease of implementation and impact

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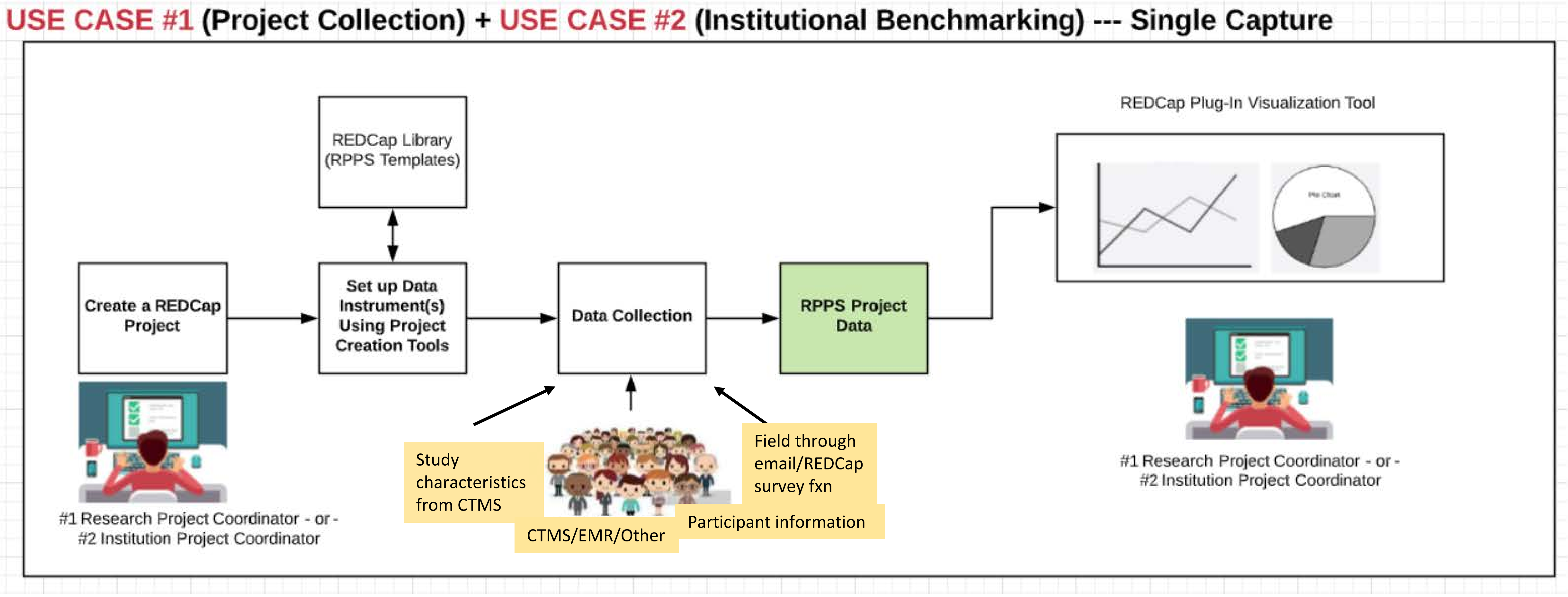
Data flow model: Use Cases 1 & 2



USE CASE #1 (Project Collection) + USE CASE #2 (Institutional Benchmarking) --- Single Capture

REDCap Library (RPPS Templates)

Create a REDCap Project

Set up Data Instrument(s) Using Project Creation Tools

Data Collection

RPPS Project Data

REDCap Plug-In Visualization Tool

Study characteristics from CTMS

CTMS/EMR/Other

Field through email/REDCap survey fxn

Participant information

#1 Research Project Coordinator - or -
#2 Institution Project Coordinator

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#2 Institution Project Coordinator

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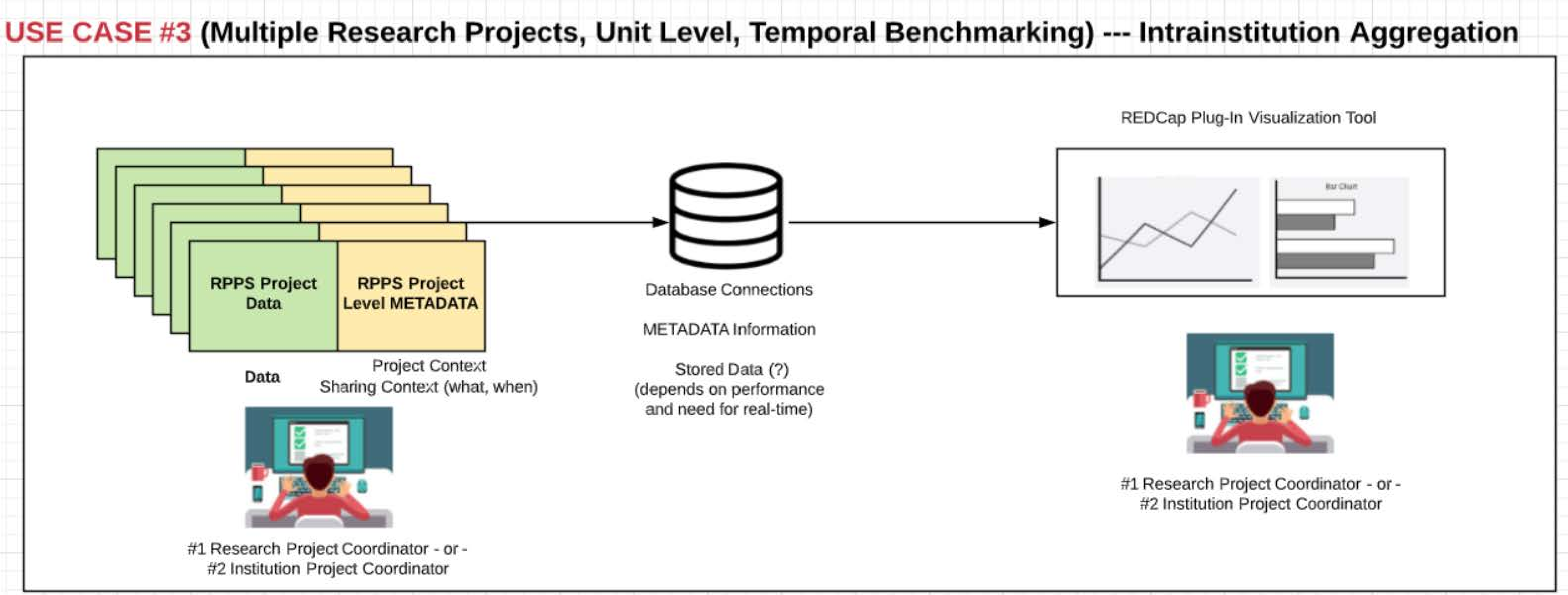
Data Flow Model: Use Cases 3 & 4



USE CASE #3 (Multiple Research Projects, Unit Level, Temporal Benchmarking) --- Intrainstitution Aggregation

RPPS Project Data

RPPS Project Level METADATA

Data

Project Context
Sharing Context (what, when)

#1 Research Project Coordinator - or -
#2 Institution Project Coordinator

Database Connections

METADATA Information

Stored Data (?)
(depends on performance
and need for real-time)

REDCap Plug-In Visualization Tool

#1 Research Project Coordinator - or -
#2 Institution Project Coordinator

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Study Timeline

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✓	Convene RPPS/REDCap Stakeholder Collaborative	▨	▨	▨	▨	▨	▨	▨	▨
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✓	Dashboard External Module v1	▨	🟧						
✓	Implementation Framework (Standards) v1	▨	▨	🟧					
✓	Use cases, Evaluation metrics, tools		▨	🟧					
	Collaborating site surveys underway				🟩	▨	▨		
	Site implementation metadata				▨	🟩	▨		
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	Refine: RPPS/REDCap/Dashboard v2						▨	🟦	
	Refine: Analytics External Modules v2						▨	🟦	
	Dissemination/evaluation to REDCap network		▨	▨	▨	▨	▨	▨	▨
	Analysis of impact/local use cases			▨		▨	▨	▨	🟦
	Refinement of value proposition				▨	▨	▨	▨	🟦
	Dissemination		▨		▨		▨		▨

▨ Program Development; 🟧 Milestones Aim 1; 🟩 Milestones Aim 2; 🟦 Milestones Aim 3

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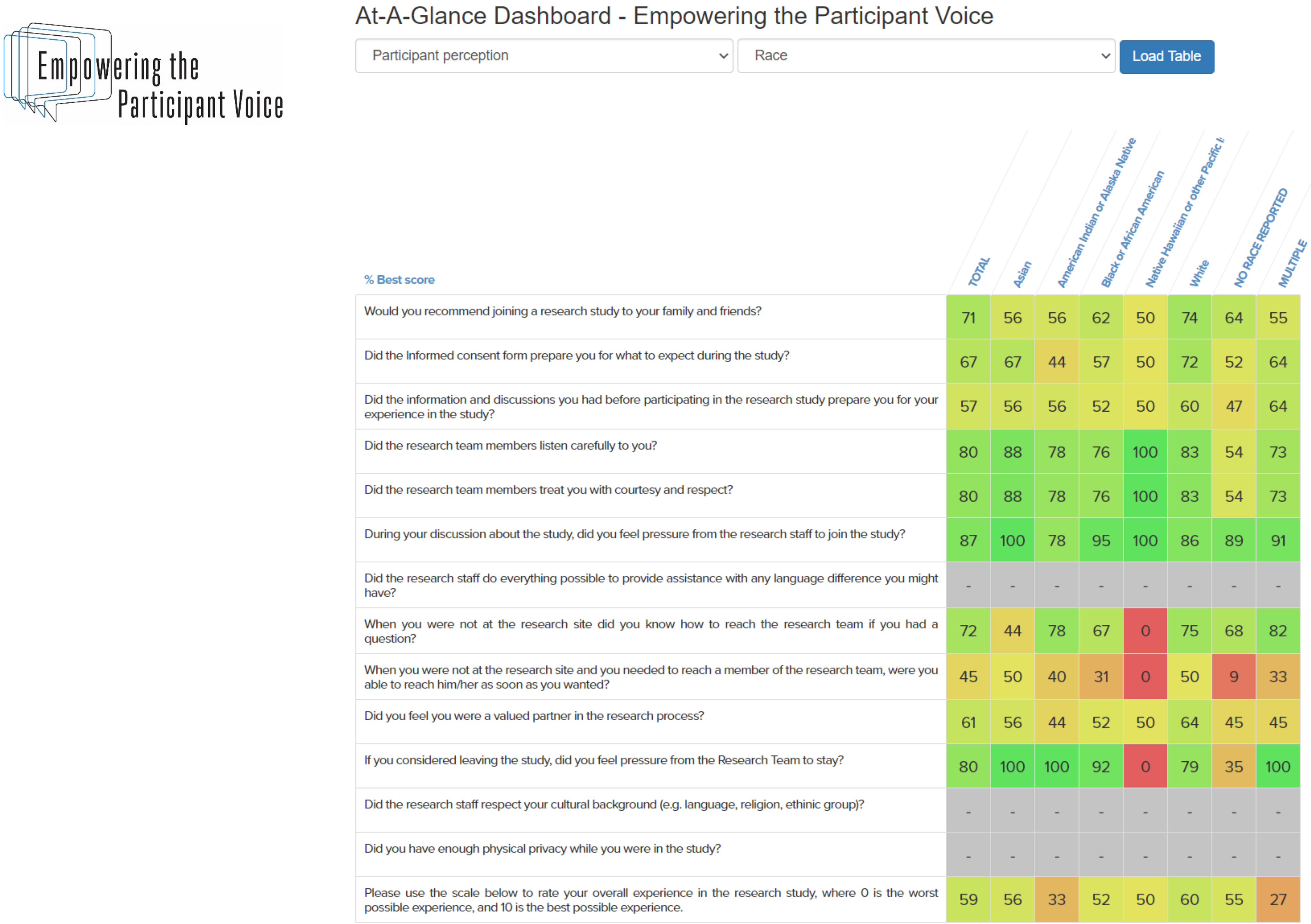
EPV At-a-Glance Dashboard



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At-A-Glance Dashboard - Empowering the Participant Voice

Participant perception
Race
Load Table

% Best score	TOTAL	Asian	American Indian or Alaska Native	Black or African American	Native Hawaiian or other Pacific I	White	NO RACE REPORTED	MULTIPLE
Would you recommend joining a research study to your family and friends?	71	56	56	62	50	74	64	55
Did the Informed consent form prepare you for what to expect during the study?	67	67	44	57	50	72	52	64
Did the information and discussions you had before participating in the research study prepare you for your experience in the study?	57	56	56	52	50	60	47	64
Did the research team members listen carefully to you?	80	88	78	76	100	83	54	73
Did the research team members treat you with courtesy and respect?	80	88	78	76	100	83	54	73
During your discussion about the study, did you feel pressure from the research staff to join the study?	87	100	78	95	100	86	89	91
Did the research staff do everything possible to provide assistance with any language difference you might have?	-	-	-	-	-	-	-	-
When you were not at the research site did you know how to reach the research team if you had a question?	72	44	78	67	0	75	68	82
When you were not at the research site and you needed to reach a member of the research team, were you able to reach him/her as soon as you wanted?	45	50	40	31	0	50	9	33
Did you feel you were a valued partner in the research process?	61	56	44	52	50	64	45	45
If you considered leaving the study, did you feel pressure from the Research Team to stay?	80	100	100	92	0	79	35	100
Did the research staff respect your cultural background (e.g. language, religion, ethinic group)?	-	-	-	-	-	-	-	-
Did you have enough physical privacy while you were in the study?	-	-	-	-	-	-	-	-
Please use the scale below to rate your overall experience in the research study, where 0 is the worst possible experience, and 10 is the best possible experience.	59	56	33	52	50	60	55	27

Empowering the
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Plans, Progress, What's next

- Alignment with institutional priorities and initiatives
- Priorities in Implementation
- Approach to analysis and using the results

1. RPPS Integration into Institutional Goals
   - Demonstrating our commitment to participant-centeredness in research;
   - As a mechanism for action to ensure alignment with participant expectations; and
   - Longitudinal measurement of success and evolving needs

2. Priorities
   1. Central Approach – reach as many research participants as possible
   2. Use tiered contact methods (EMR Portal; Text Messaging; Mail)

3. Acting on RPPS findings
   - Drill down to identify opportunities
   - Stakeholder committee; Research Community; and Leadership – meaningful solutions and reporting back

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- *How will RPPS be integrated into your Institutional initiative as a tool to measure progress toward institutional goals?*
  - Research Without Walls (Moving research out into the community)
    - RPPS - major evaluation component – assess/improve overall research infrastructure and the clinical research experience with greater use of new technologies and more remote operations
  - Increasing recruitment and retention into clinical research
    - Provide valuable data for Recruitment Innovation Unit and Office of Clinical Research
    - Strengthen engagement key stakeholders (especially community) to advise on paths forward to improve our processes

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- *Top priorities in Site Implementation*
  - Build into existing organizational structure (sustainability beyond funding period)
  - Increase survey response rates by research subjects (testing different strategies, i. e. Incentives)
- *Approach to acting on RPPR findings*
  - Systematically obtain feedback from our stakeholder groups on interpretation of findings and recommendations for modifications to survey methods
  - Conduct focus groups to brainstorm solutions/recommendations for changes to research processes

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Johns Hopkins has been conducting the Research Participant survey for almost 4 years on an institutional level . We randomly select a group of 500 participants who have signed consent to participate in a clinical trial in the last 6 months and send the survey by email.

Initially, we will continue to follow this plan to implement the EPV at JH so we may draw comparisons of the EPV implementation vs the local RPPS implementation.

Top 1-3 priorities in site Implementation at JH

- As little disruption to current surveying as possible
- Assure continued anonymity of participant responses
- Continued communication of findings to all partners

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JH will continue current approach to communicate findings with institutional officials, local site personnel and community partners via web posting of results, direct communication with institutional officers and HRRP leaders and dissemination via internal training and meeting opportunities. We also want to focus on racial ethnic disparities in results.

For example: From participant feedback in the past (from open response section) we have contracted with Greenphire to improve participant payments.

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Duke CTSI

Integration at our institution

- Multiple CRUs, some large, some small – lots of QI initiatives ongoing; need to socialize to raise interest and ensure buy-in
- Use-case #s 1 and 2: ID individual study teams willing to volunteer for the pilot as we continue to socialize the program across both the research enterprise and leadership.
- Demonstrate the **benefit** and **value** of surveying on a study-by-study basis and sharing the data on an institutional dashboard
  - Consider Use-Case #3 and central deployment of the survey across multiple studies

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Duke CTSI

Priorities in Implementation

- Ensure diversity of research teams and types using program
  - Non-traditional, community-based, one-touch studies
  - RCTs, Observational, University-based (non-clinical)
- Reach traditionally hard to engage populations with multiple survey delivery methods
- Continually engage with our stakeholders to ensure we are using appropriate and effective methods & socializing across the enterprise

Approach to acting on RPPS findings

- Identify 5-7 study teams willing to volunteer for pilot
- Years 3-4: Analyze collected data, define metrics for CRU scorecards, generate hypotheses and interventions to improve scores and/or processes
- Year 4: add metrics to monthly CRU scorecards

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The Rockefeller University
Center for Clinical and Translational Science

Integration at our Institution

- Rockefeller has been fielding the RPPS for more than 10 years
- Aligns with aim to use participant experience data to inform initiatives

Priorities in Implementation

- To reach every participant
- Improve response rates
- Work with stakeholders to integrate CE and RPPS efforts

Approach to Acting on RPPS Findings

- To identify opportunities and develop action plans with stakeholders
- To generate hypotheses and test the impact of specific innovations

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- How will the tools be disseminated beyond the EPV collaborators?

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Project Website www.Rockefeller.edu/research/epv/

- Links to the RPPS surveys in the REDCap Library for download
- Links to publications about RPPS
- In the future, links to External Modules for download
- Articles about how the tools are being used by Collaborating sites
- SIGN UP to receive periodic EPV project updates

Future: Aim 3 – Broad sharing, Learning Collaborative, Benchmarking

How might we insert EPV/REDCap tools into a TIN Trial to test an innovation?

- To evaluate the impact of initiatives on participants’ experiences
- To Compare approaches
- To Compare impact of an innovation across populations, sites, studies
- Compare +/- or pre/post innovation in the same study/population

Empowering the
Participant Voice

Q & A


program
future
treatment
another
drug
professional
please
find
problem
group
much
enjoyed
think
give
others
want
excellent
questions
medical
several
positive
xxxxx
life
team
told
apply
good
part
blood
done
doctor
first
time
one
follow
nurses
results
person
hospital
just
joined
involved
staff
way
last
people
participate
always
possible
research
really
nice
check
friendly
disease
years
like
dr
well
happy
also
felt
leave
thank
great
tests
answer
continue
patient
come
help
long
kind
wonderful
make
still
call
treated
extremely
visits
going
never
many
contact
care
hope
months
made
better
important
complete
back
condition
family
information
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coordinator
asked
cancer
interested