



# ***Putting real-time participant feedback into the hands of investigators***

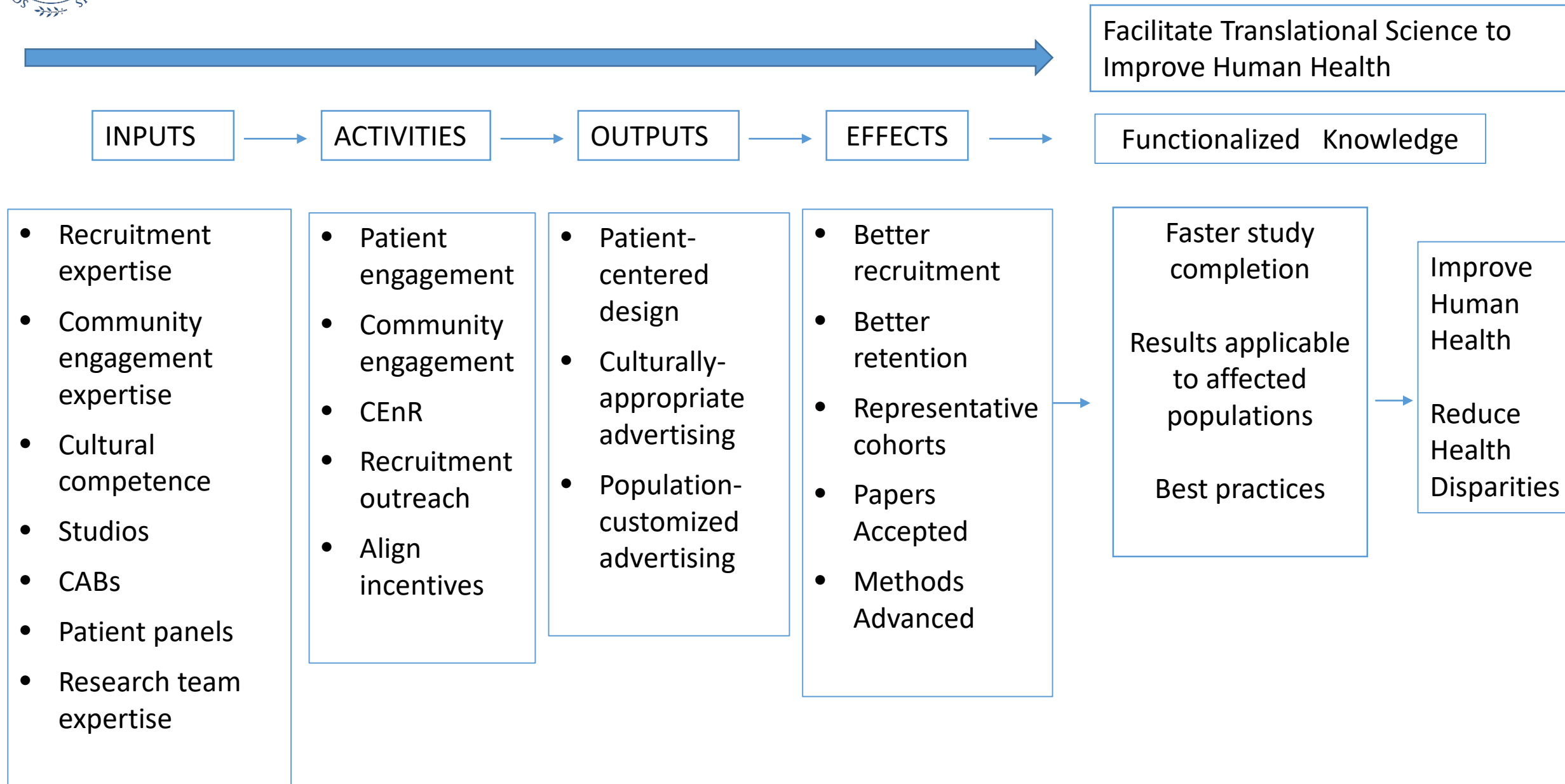
Rhonda G. Kost MD  
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Associate Professor, Center for Clinical Translational Science  
The Rockefeller University



First, the landscape.....



# What we do now.....



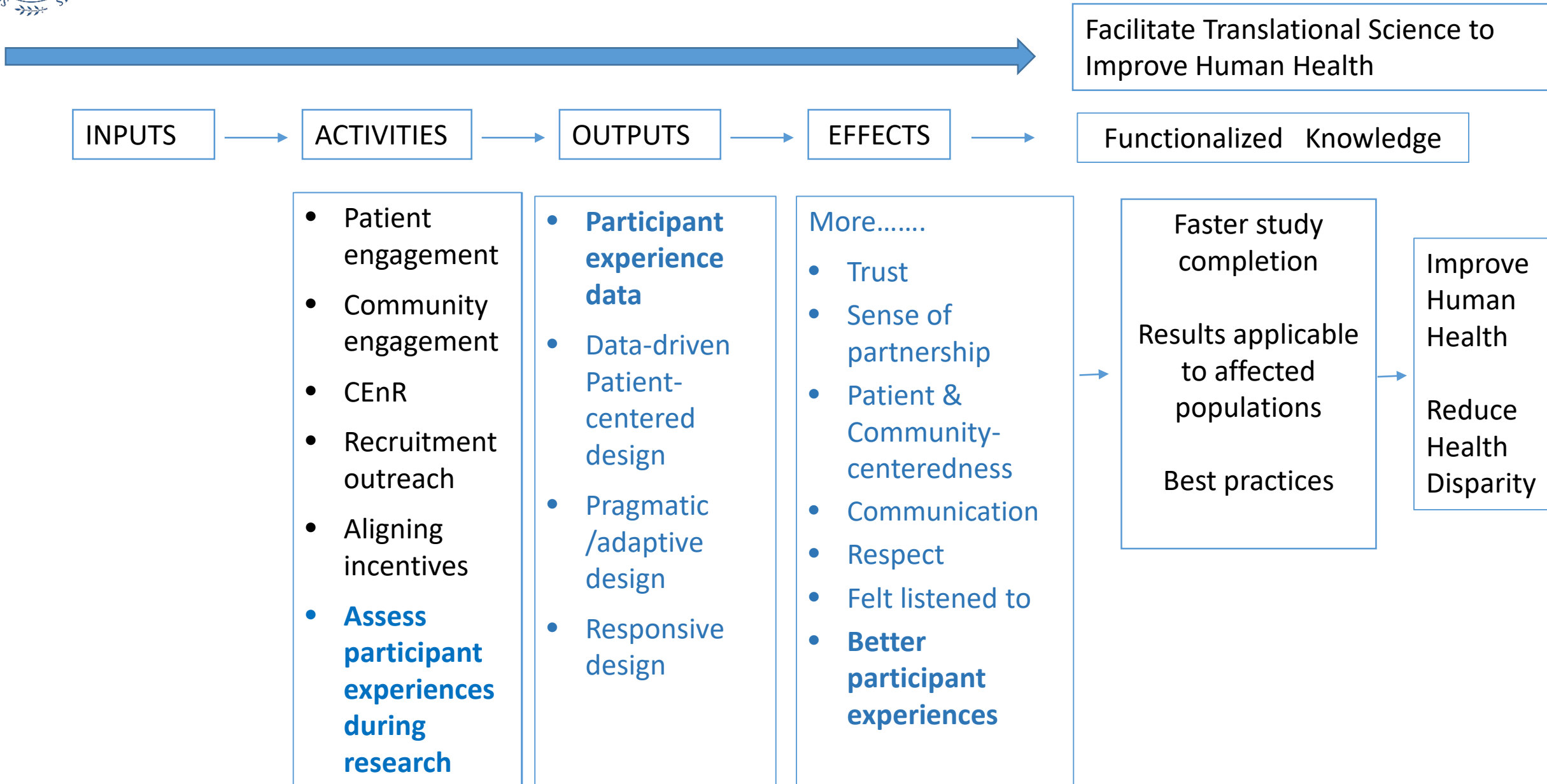
#1 – Do you/investigators at your institution collect participants' feedback about their research experiences?

Select all that apply:

- ☐ Yes --Generally investigators DO collect feedback
- ☐ No – Generally investigators DO NOT collect feedback
- ☐ Yes --We have an institutional program to collect participant feedback
- ☐ No - No institutional program to collect participant feedback
- ☐ I don't know whether participant feedback is collected



# Evaluation - Causal Pathway



- #2 – Would it be valuable to investigators to have real-time feedback from participants (and when)?

Select all that apply:

- ☐ Around/after recruitment
- ☐ Around/after Informed consent
- ☐ During conduct/at specific milestones (e.g. crossover, withdrawal)
- ☐ At the end of the study
- ☐ No, I don't think this information would be valuable

### #3 – Do you have standard tools to collect feedback

Select all that apply:

- ☐ Email / mail survey
- ☐ Mobile app survey
- ☐ Survey through patient portal
- ☐ Research Participant Perception Survey, or derivative
- ☐ Other



# Development of the Research Participant Perception Survey

## Vision

To develop validated measure(s) of the human subjects protections such as the informed consent process, and obtain actionable data about participant's experiences in order to improve the experience and enhance research recruitment, retention, and integrity.





# Research Participant Survey Acknowledgements

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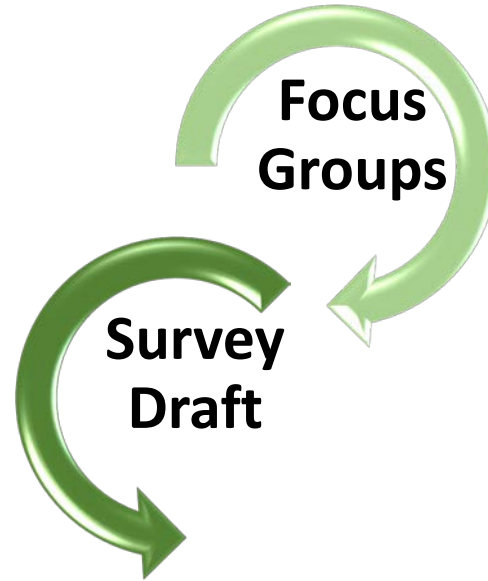
Jean Larson  
Sandra Alfano

## **Feinstein Medical Institute, LIJH**

Cynthia Hahn

# Research Participant Perception Survey Project - Methods

Part I



- Participants & stakeholders identify themes that move forward

- NIH Clinical Center
- Public/private partnership – NRC-Picker
- 34 CTSA/GCRCs provided early design input
- 8 CTSA/GCRC collaborated for the first study
- Rockefeller CTSA grant: UL1RR024143
- NIH/NCRR SO7 Award: S07 RR018141

# Research Participant Perception Survey Project - I



## Participants

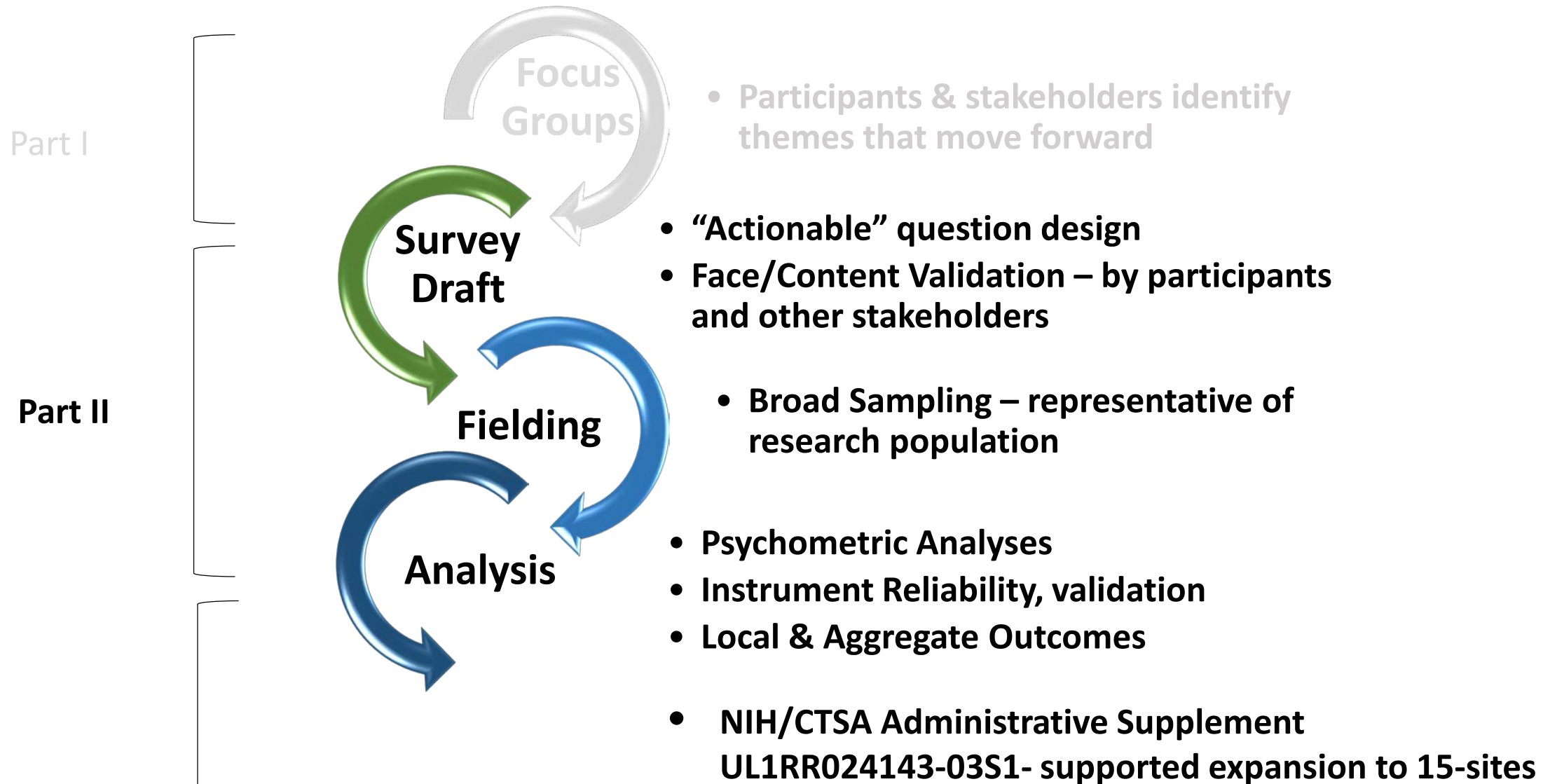
45% male  
50 yrs old (19-86)

58% white  
28% African American  
2% Asian  
2% Native American  
9% Not reported

13% ≤ high school  
28% some college  
31% college graduate  
26% graduate education

1-20 protocols  
experience

# Research Participant Perception Survey Project - Methods





# Design of the survey - scope

- Demographics – usual, plus research characteristics
- Recruitment experience
- Motivation to join
- Informed Consent
- Experience during study – actual vs. expectations, unanticipated pain, side effects, burdens, pressures, benefits, feeling of partnership, being listened to, courtesy, respect, trust
- Motivation to leave/stay
- Sharing of research results, test results
- Likelihood to participate again
- Overall Rating & Would recommend to family and friends
- Top Box Scores

# Survey Validation - Cohort characteristics

- 15 NIH-supported research centers
- Mailed to over 18,890 research participants
- Received 4,961 responses (29%)
  - 57% female
  - 63% “disease-affected”
  - 37% healthy volunteer
  - 50% in studies with test drug/device/procedure
  - 7% Hispanic / 85% White / 9% Black / 3% Asian

# Research Participant Experience Outcomes -National

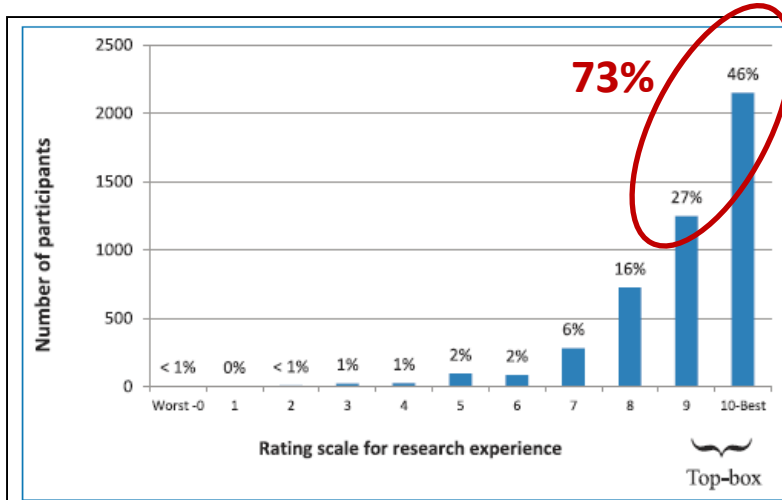


Figure 1. Participants' ratings of their overall research experience (N = 4,961)

Overall Rating of the research experience

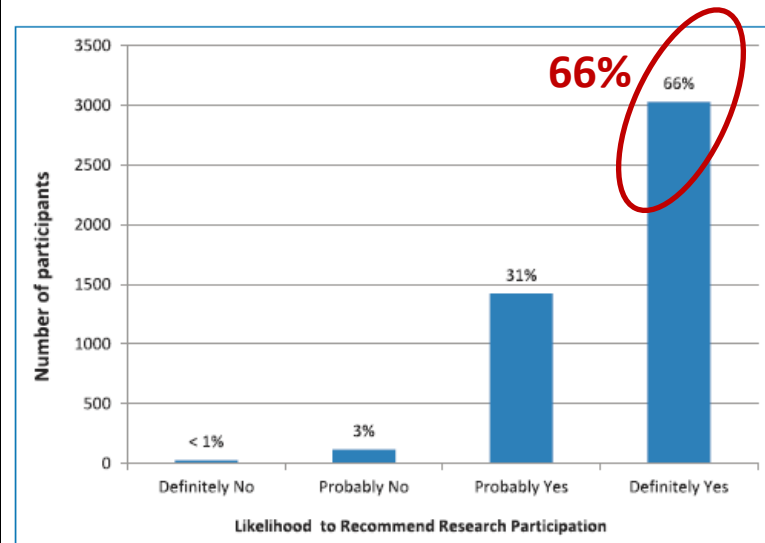


Figure 2. Participants' ratings of their likelihood to recommend research participation to family or friends (N = 4,961).

Would recommend research participation to a friend or family member

# Creation of Research-Specific Dimensions

Dimensions and individual items within each dimension	Item Numbers	Cronbach's Alpha Coefficient			
		All	Drug	Disease	African American
<b>All items</b>	1–44	.96	.93	.93	.92
<b>Informed consent</b>	1–13	.86	.87	.86	.84
1. Overall study explained understandably	1–12	.84	.85	.85	.83
2. Someone took the time to answer questions about the study					
3. Study details explained understandably					
4. Risks/benefits of joining study explained					
5. Study details included in informed consent docs					
6. Informed consent document understandable					
7. Prepared for what to expect by informed consent document					
8. Something happened that you were not prepared for					
9. Prepared by info/discussions before participation					
10. Felt pressure from research staff to join study					
11. Had enough time before signing informed consent					
12. Felt pressure from research team to stay in study					
13. Understood which tests/visits were for research*					



# Motivations to Join a Research Study

Factors influencing decision	Relative importance in decision to join a study			
	Healthy volunteer	Disease-affected volunteer	Subgroups	
			Study involves drug, device, procedure	
			No	Yes
To help others	1	1	1	1
Concern about the topic	2	2	2	2
Because of center's reputation	3	6	4	5
To obtain education/learning	4	5	3	6
To find out more about my disease	7	3	5	4
To gain access to new treatment	8	4	6	3
Because no other options available	11	7	11	7
To obtain free healthcare	9	10	10	9
Because of prior positive experience	5	8	7	8
To earn money/payment	6	12	8	12
Because of family influence	10	11	9	11
Because of caregiver encouragement	12	9	12	10
Because of relationship with the team	-	-	-	-
Because of improved health	-	-	-	-
Because of feeling valued	-	-	-	-

# Motivations to Remain in a Research Study

Factors influencing decision	Relative importance in decision to remain in a study			
	Subgroups			
	Healthy volunteer	Disease-affected volunteer	Study involves drug, device, procedure	
			No	Yes
To help others	1	2	1	1
Concern about the topic	2	3	2	2
Because of center's reputation	4	7	4	7
To obtain education/learning	5	5	3	6
To find out more about my disease	8	1	6	4
To gain access to new treatment	10	6	8	5
Because no other options available	13	10	12	10
To obtain free healthcare	12	12	13	12
Because of prior positive experience	7	11	9	11
To earn money/payment	9	15	11	15
Because of family influence	14	14	14	14
Because of caregiver encouragement	15	13	15	13
Because of relationship with the team	11	9	10	9
Because of improved health	6	4	7	3
Because of feeling valued	3	8	5	8

# Top Actionable Lessons from Survey Results

- 85% said they would have liked to receive results of the study
  - Only 23% reported receiving aggregate research results
- 72% said receiving results would be a factor in deciding about future participation
- Participants who trusted the research team completely (86%) felt they were treated with courtesy and respect (99%) and listened to (93%) ( $p < 0.001$ )
- Participants stayed when they felt valued and perceive benefit.

# Research Participant Perception Survey Project I & II

## Assessing Research Participants' Perceptions of their Clinical Research Experiences

*Clin Transl Sci* 2011

Rhonda G. Kost, M.D.<sup>1</sup>, Laura M. Lee, R.N., B.S.N.<sup>3</sup>, Jennifer Yessis, Ph.D.<sup>2</sup>, Barry S. Collier, M.D.<sup>1</sup>, and David K. Henderson, M.D.<sup>3</sup>, and The Research Participant Perception Survey Focus Group Subcommittee<sup>4</sup>

## Development of a Research Participants' Perception Survey to Improve Clinical Research

*Clin Transl Sci* 2012

Jennifer L. Yessis, Ph.D.

## Research Participant-Centered Outcomes at NIH-Supported Clinical Research Centers

*Clin Transl Sci* 2014

Rhonda G. Kost, M.D.<sup>1</sup>, Laura N. Lee, B.S.N., M.S.<sup>2</sup>, Jennifer L. Yessis, Ph.D.<sup>3</sup>, Robert Wesley, Ph.D.<sup>2</sup>, Sandra Alfano, Pharm.D.<sup>4</sup>, Steven R. Alexander, M.D.<sup>5</sup>, Sylvia Baedorf Kassis, M.P.H.<sup>6</sup>, Philip Cola, M.A.<sup>7</sup>, Ann Dozier, R.N., Ph.D.<sup>8</sup>, Dan E. Ford, M.D., M.P.H.<sup>9</sup>, Paul A. Harris, Ph.D.<sup>10</sup>, Emmelyn Kim, M.A., M.P.H.<sup>11</sup>, Simon Craddock Lee, Ph.D., M.P.H.<sup>12</sup>, Gerri O'Riordan, R.N.<sup>5</sup>, Mary-Tara Roth, R.N., M.S.N., M.P.H.<sup>6</sup>, Kathryn Schuff, M.D.<sup>13</sup>, June Wasser, M.A.<sup>14</sup>, David K. Henderson, M.D.<sup>2</sup>, and Barry S. Collier, M.D.<sup>1</sup>

PERSPECTIVE

ASSESSING PARTICIPANT-CENTERED OUTCOMES

*NEJM* 2013

## Assessing Participant-Centered Outcomes to Improve Clinical Research

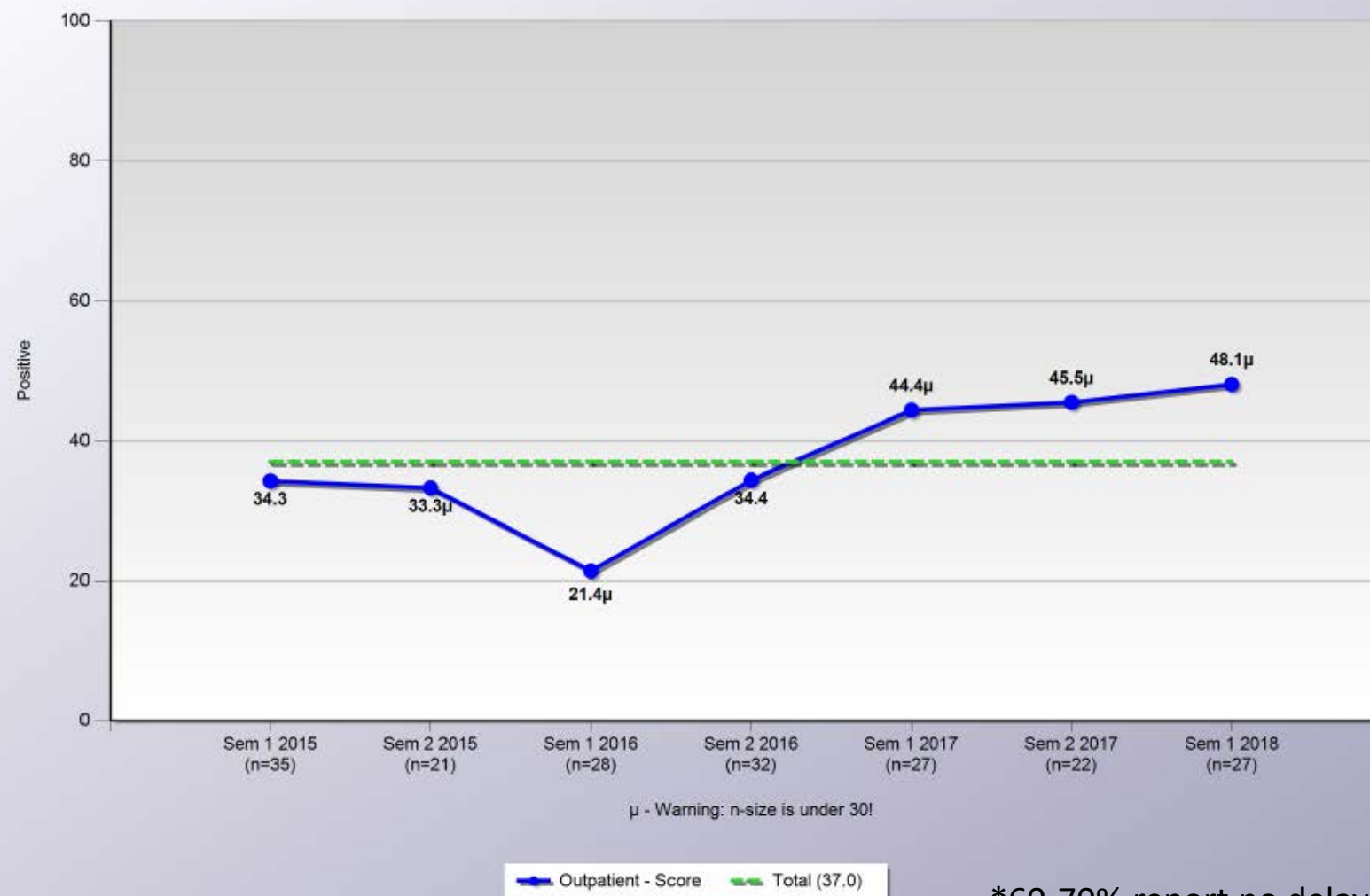
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# Research Participant Perception Survey Project - Methods



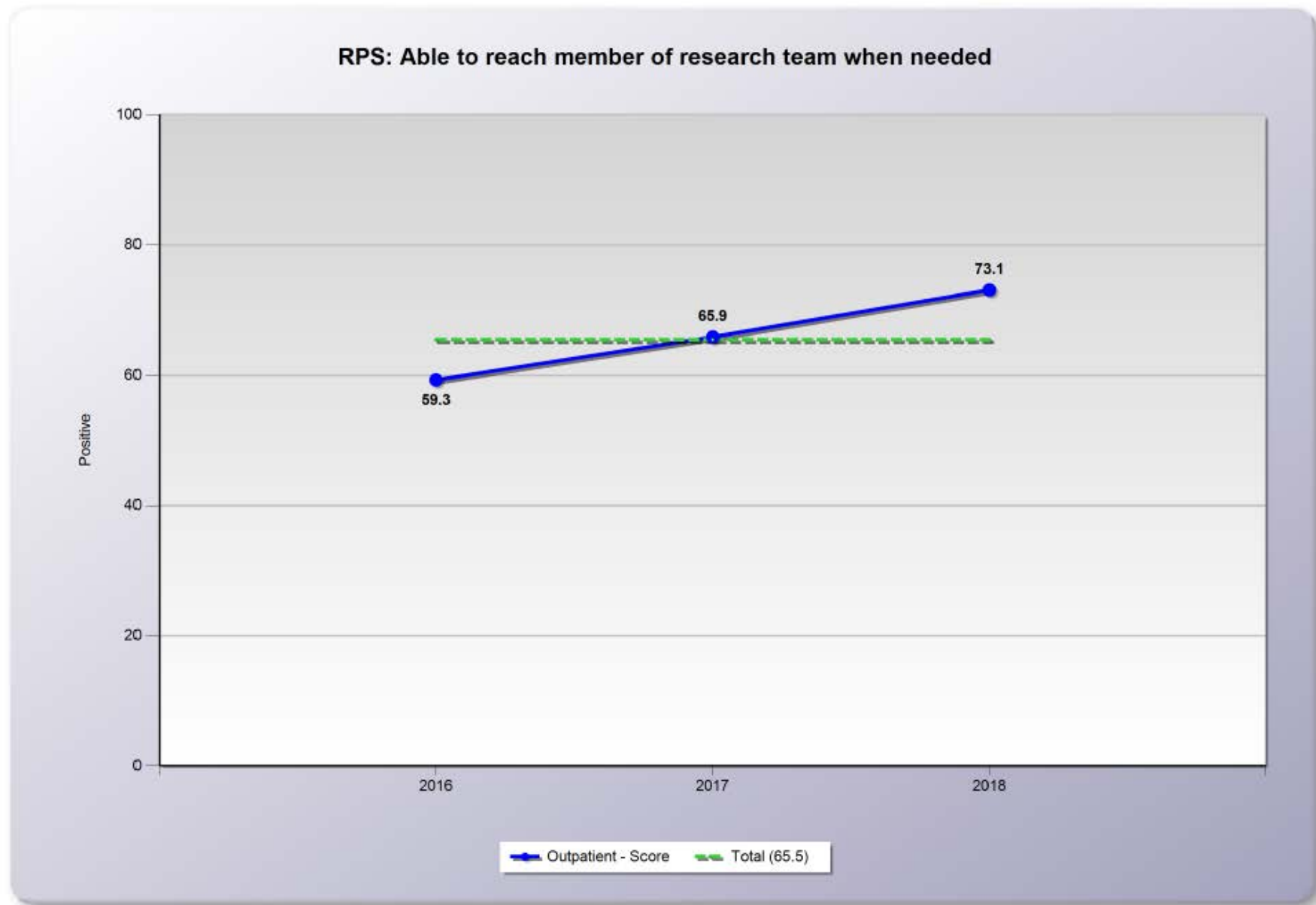
# Internal Benchmarks - Unit

RPS: Reasons for delays were explained \*

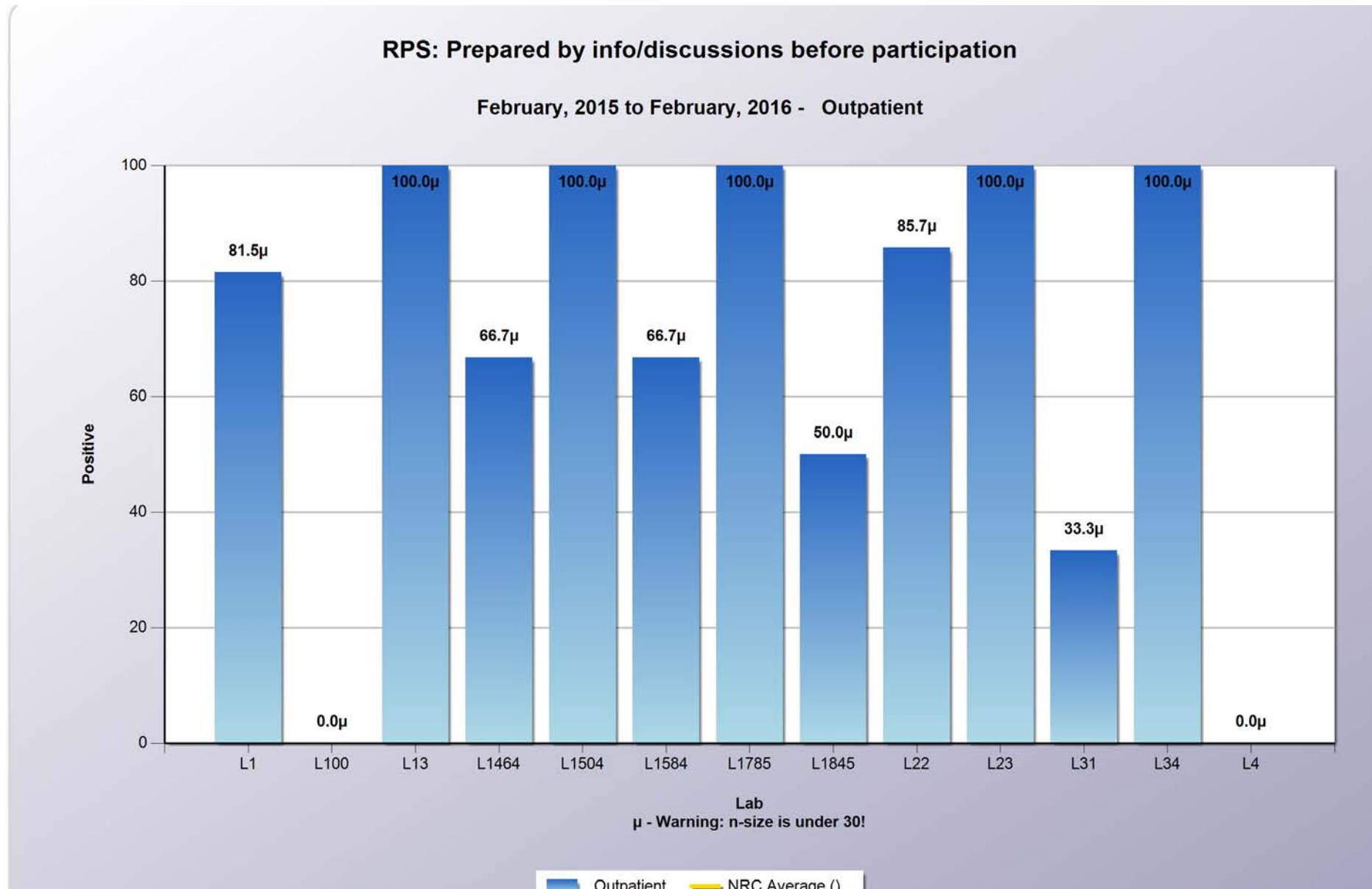


\*60-70% report no delays

# Internal Benchmarks - Unit

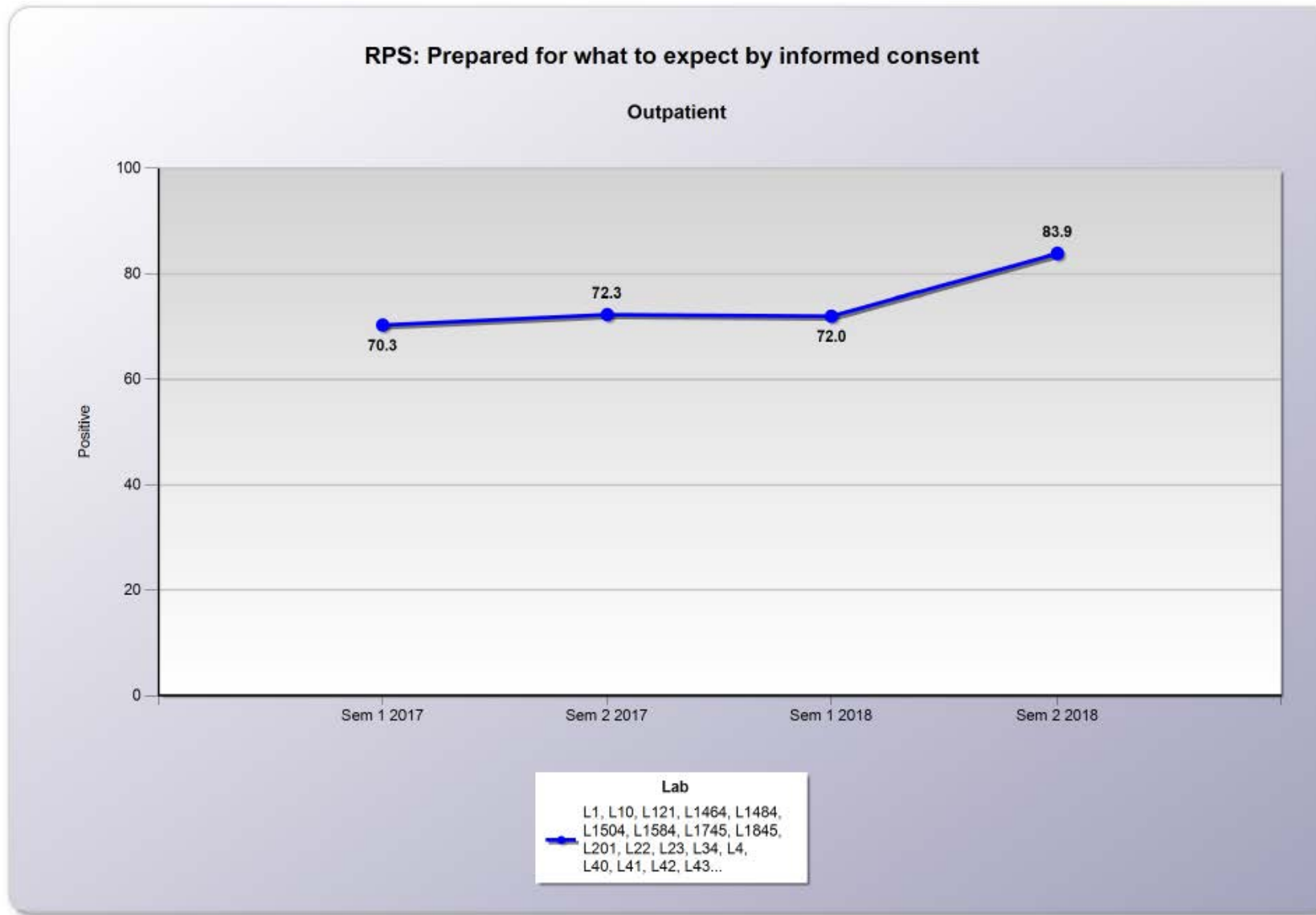


# Internal Benchmarks – Across Teams

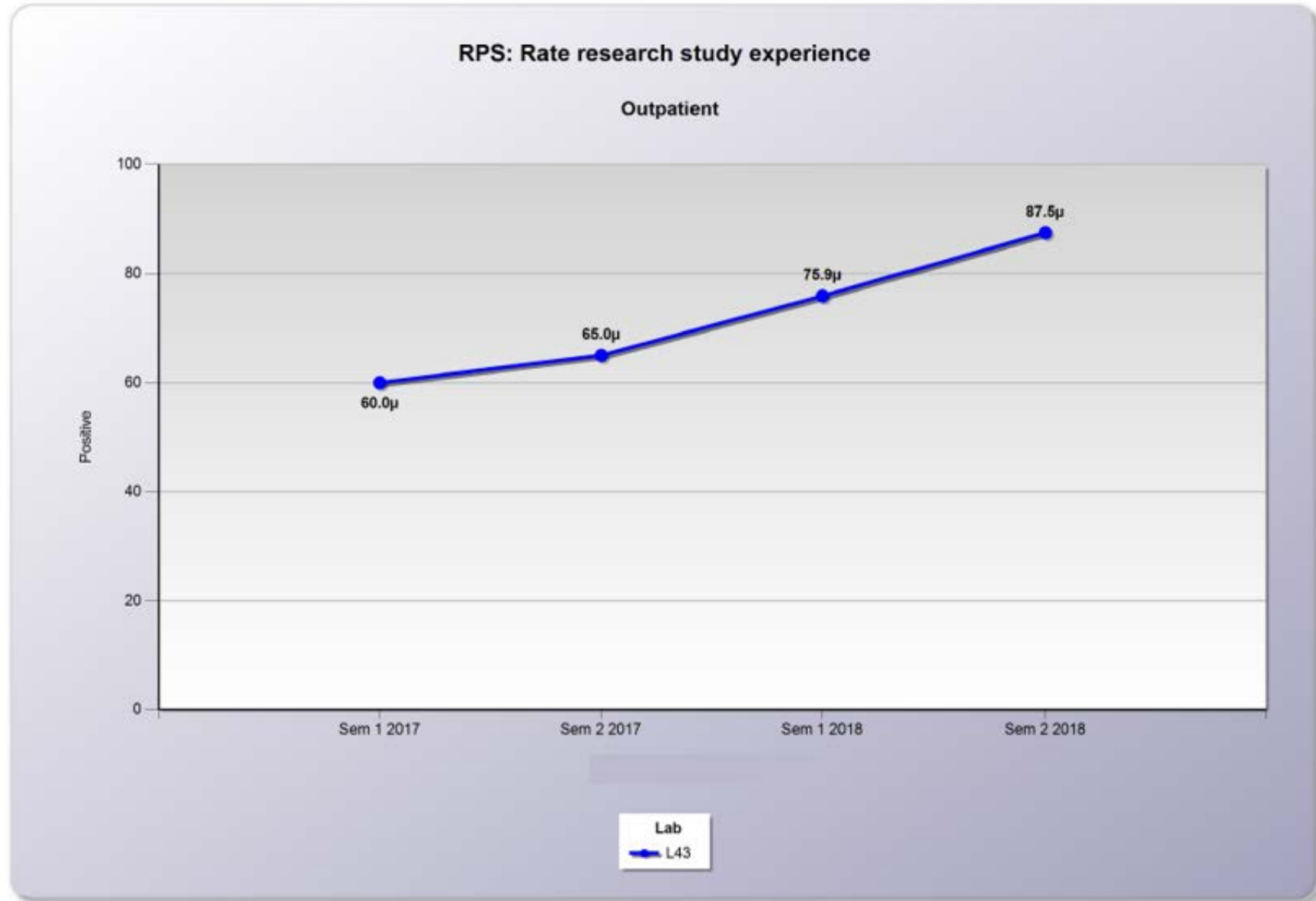




# Internal Benchmarks – Performance Improvement



# Internal Benchmarks – Individual Research Team



## #4

What are the barriers to collecting timely feedback from participants?

Select all that apply:

- ☐ No barriers
- ☐ Finding the right survey (questions, length, language)
- ☐ Level of effort/cost to collect/analyze the data
- ☐ Response too low/slow to be relevant
- ☐ Something else

**#5**

What would facilitate collecting timely feedback from participants?

Select all that apply:

- ☐ Short validated surveys
- ☐ Making my own survey
- ☐ Integrated survey/collection/analysis tools
- ☐ Mobile friendly platform
- ☐ Low cost/free

# Making the survey shorter.....

Multiple Regression: Rating score captured in 6 questions

Items included in model*	$R^2$	Adjusted $R^2$ for each additional question in the model**
Treated with courtesy and respect by the investigator or research doctor	0.816	0.809
Prepared for what happened by information and discussions provided before participation	0.896	0.888
Research doctor or investigator listened carefully	0.939	0.932
Prepared for what to expect by informed consent documents	0.950	0.942
Knew how to reach research team	0.961	0.953
Able to reach member of research team when needed	0.968	0.959

# Validated Suite of tools

Research Participant Experience Survey - U

13 questions

Enter the Survey

Research Participant Perception Survey - S

25 questions

Enter the Survey

Research Participant Perception Survey - L

72 questions

Enter the Survey

Please answer the questions below regarding the research study you enrolled in within the past two years. (If you

*ResearchMatch®* registry  
4,000 responses  
2,500 interested  
1,875 eligible/sent  
997 completed

---

Overall: 53% response

Survey	Cronbach's alpha (95% C.I.)	Cohen's Kappa (95% C.I.)
RPPS-Ultrashort	0.81	0.84
RPPS-Short	0.83	0.85
RPPS-Long	0.87	0.81

# Impact of length and compensation

## Response and Completion Rates

Survey version	RPPS-U	RPPS-S	RPPS-L
Sent	481	494	617
Started survey	312	314	316
Completed	301	267	227
Response Rate	65%*	64%*	51%*
Completion Rate	63% <sup>t</sup>	54% <sup>t</sup>	37% <sup>t</sup>

P=0.001

- Compensated respondents were younger ( $p < 0.001$ ) and more often persons of color ( $p = 0.03$ ) than were uncompensated respondents

# Uptake...

- RPPS
  - Johns Hopkins University: fielding RPPS-S, post results every 6 months since 2016
  - Wake Forest University: 1) RPPS-U in NHLBI cohort; 2) via patient portal (JCTS 2018)
  - University of Rochester: RPPS-S at large & adapting for Deaf Community
  - NIH Clinical Center: RPPS derivative
  - ? Duke, UCSF, University of Florida, Children's Hospital Connecticut



## #6

When you collect participant feedback, how do you/investigators use it?

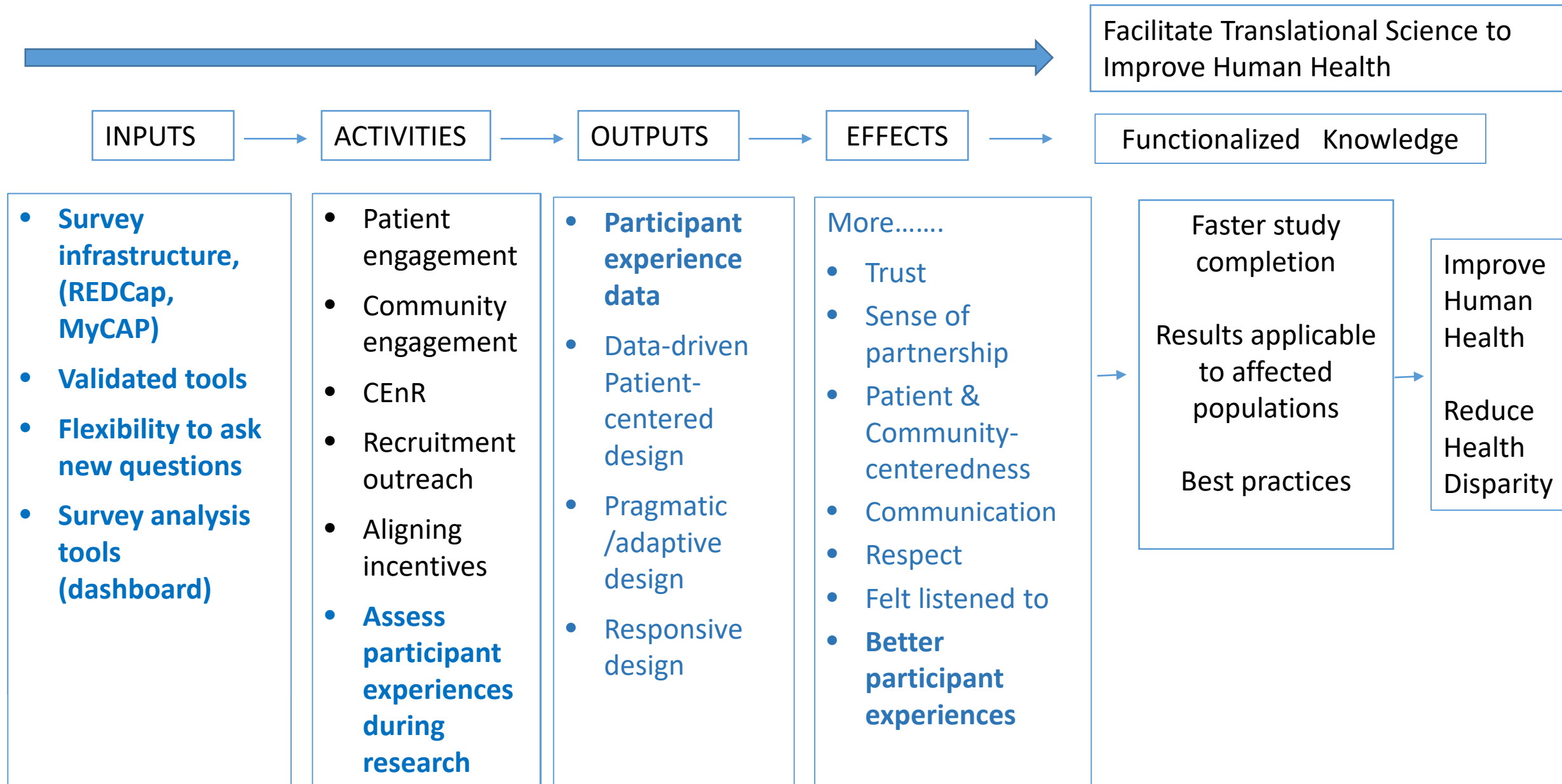
- ☐ We don't collect participant feedback
- ☐ We collect data, but have not yet been able to use it
- ☐ We use data to revise current practices (recruitment, consent)
- ☐ We use data to design the *next study*
- ☐ We share participant feedback with leadership/teams

# Time for a paradigm shift.....

- Previously, top down, institutional use with dissemination to teams
  - Survey free, but fielding and analysis required resources
- 

- Flip, to put surveys and results into the hands of teams
- Contribute results “up” to the institution, if they want to
- Design to overcome barriers to use and to facilitate benchmarking

# Evaluation - Causal Pathway



# REDCap platform for new RPPS infrastructure

- Free, Easy, Robust - REDCap, MyCap
  - Core survey – RPPS-Ultrashort – benchmark
  - Research team ‘brand’ likely to boost response rate
  - Team determines best timing
- 
- Build specific dashboard features
  - Provide the ability to pair with team’s own questions, scales.....
  - Create infrastructure to contribute team-level data to institution



# Blue sky.....

- If you could easily push out short validated surveys to participants, what would you want to see on your dashboard?
- What would you want to see?
- How would you use it?
- What would you be worried about?



# Contact

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