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Exploring the Multifaceted Roles of Patients and Caregivers in Health Preference Research (HPR) and Patient-Reported Outcomes (PRO) Research

Monday May 8, 2023 15.15PM – 16.15PM

Discussion Topics

	Topic	Presenters
1	The Multifaceted Roles of Patients and Caregivers in HPR and PRO research	Siu Hing Lo, PhD Acaster Lloyd Consulting
2	Preference Research: Case Studies Utilizing a Community Engaged Process	Holly Peay, PhD RTI International
3	Inclusion of Patients and Caregivers as Research Partners: An Example	Fraser Bocell, MEd, PhD US FDA
4	Patient Advocacy Groups Advancing the Science of Patient Input	Ryan Fischer, BA Foundation for Angelman Syndrome Therapeutics (FAST)

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Authors' Disclosures

Siu Hing Lo is an employee of Acaster Lloyd Consulting Ltd, United Kingdom.

Holly Peay is an employee of RTI International.

Fraser Bocell is an employee at the Center for Devices and Radiological Health at U.S. FDA.

Ryan Fischer, Foundation for Angelman Syndrome Therapeutics.

Mr. Fischer has no relevant financial or nonfinancial relationships to disclose.

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The Multifaceted Roles of Patients and Caregivers in Health Preference Research (HPR) and Patient-Reported Outcomes (PRO) Research

Patients as Research Participants and Partners

RESEARCH PARTICIPANTS

In HPR and PRO research, participants are the data source. Specifically, they are the source of patient experience data (PED):

“...intended to provide **information** about **patients’ experiences with a disease or condition**...that captures patients’ experiences, perspectives, needs, and priorities...”

Excerpt from FDA definition of PED

RESEARCH PARTNERS

Research partners are not subjects or data sources, but agents in the research process:

“The active, meaningful, and collaborative **interaction between patients and researchers** across **all stages of the research process**, where research **decision making** is **guided by patients’ contributions as partners**, recognizing their specific experiences, values, and expertise...”

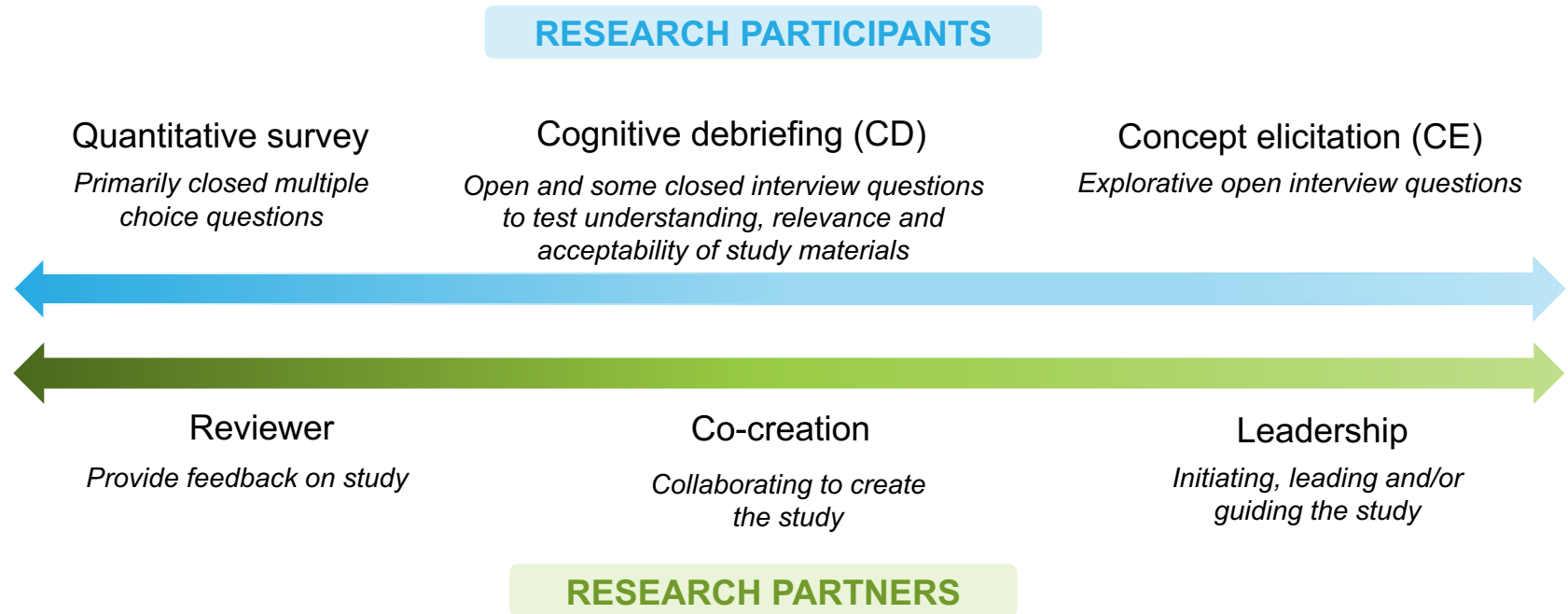
Definition of patient engagement in research from Harrington et al. 2020, VIH: Report of ISPOR Patient-Centered SIG

Polling Question #1

What do you believe are the biggest challenges in engaging patients in research?

If you are unsure, please respond 'don't know'

Range of Patient Roles in HPR and PRO Research as Participants and Partners



Patient Roles By Research Stages

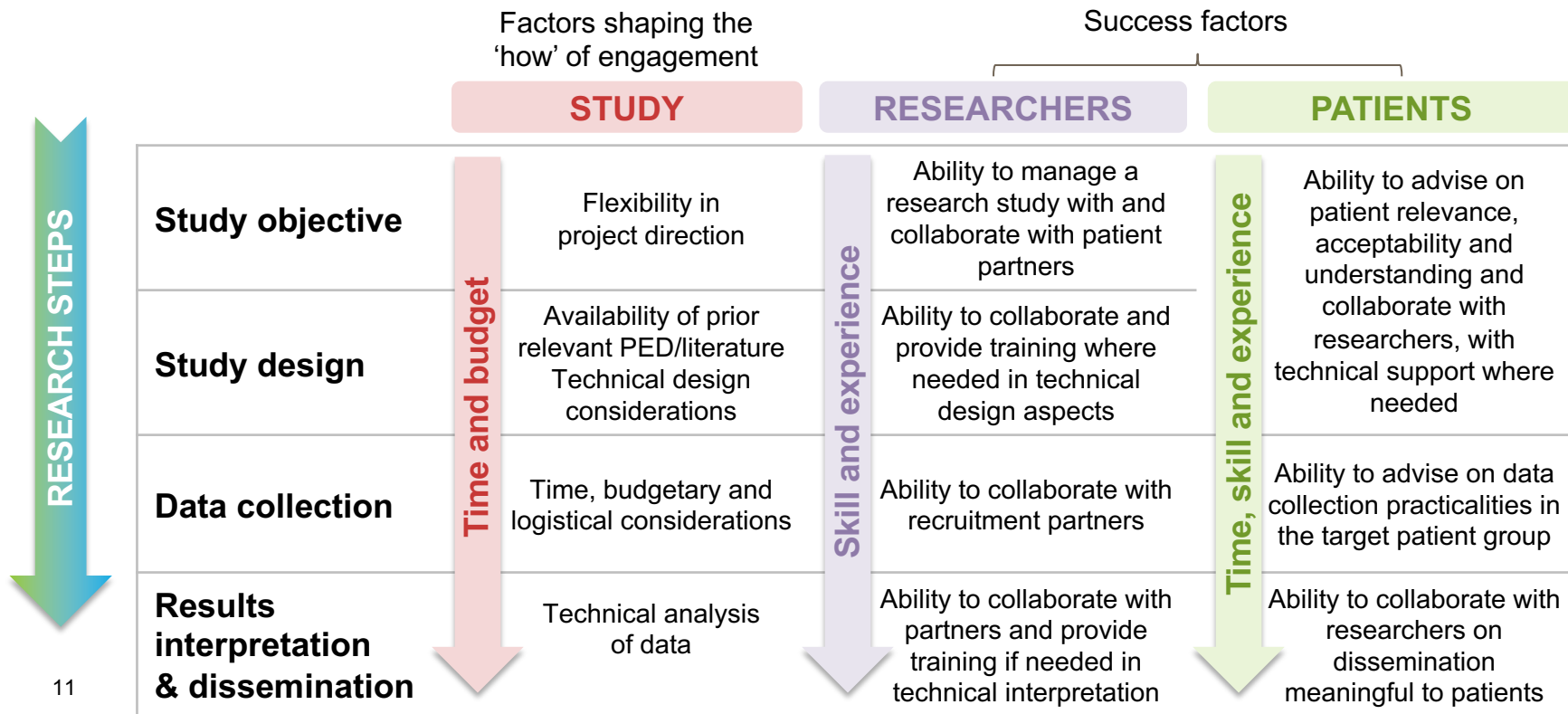
	RESEARCH PARTICIPANTS	RESEARCH PARTNERS
Study objective	<i>Not applicable</i>	Patient relevance of objectives
Study design	PED to inform study design	Patient relevance, acceptability and understanding of study materials used to collect PED
Data collection	PED for patient-centred development of medicines and other health technologies	Patient friendliness of study recruitment and data collection procedures
Results interpretation and dissemination	<i>Not applicable</i>	Patient relevance and understanding of results and dissemination

RESEARCH STEPS

Patient Input in PRO Development and HPR

	PRO DEVELOPMENT	PATIENT HPR	
RESEARCH STEPS ↓	Study objective	What aspect(s) of patient experience need to be measured?	What context of choice, and (treatment) choices are patient-relevant?
	Study design	What matters to patients? <i>Concepts of Interest</i>	What is relevant to patients within this context of choice? - <i>Attribute selection</i> - <i>Framing of choice scenario</i>
		Are study materials acceptable and understandable to patients?	
	Data collection	Are data collection procedures patient-friendly? <i>Maximise participation rates and data quality, and minimise participant burden</i>	
Results interpretation & dissemination	What is the relevance of the results to patients? Is dissemination intended for the patient community meaningful to patients?		

Patient Engagement By Study, Researcher and Patient Characteristics



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