ADVISORY PANEL ON PATIENT ENGAGEMENT MEETING

Via GoToWebinar

Spring 2020 Meeting

Day Two, June 5, 2020
11:30am-3:15pm EDT

pcori®
PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Welcome

Kristin L. Carman
Director, Public and Patient Engagement

Thomas Scheid
Chair, Advisory Panel on Patient Engagement

Day Two

Part I (EDT):

- 11:30 AM – Welcome
- 11:40 AM – PCORI Reauthorization Activities: Update on National Priorities & Research Agenda
- 12:10 PM – PEAPs in Action: Current Advances in Patient-focused Drug Development Building Awareness and Encouraging Use of PCORI's Engagement Learnings
- 12:50 AM – Panel Discussion
- 12:50 PM – Panel Discussion
- 1:15 PM – Break

Part 2 (EDT):

- 1:45 PM – Virtual Engagement: Lessons from a Cystic Fibrosis Community
- 2:25 PM – Appreciation and Farewells
- 2:55 PM – Wrap-up
- 3:10 PM – Adjourn (complete post-event survey)

Housekeeping

- Meeting is available to the public and is being recorded
- Members of the public are invited to listen to this teleconference and view the webinar
- Anyone may submit a comment through the chat function, although no public comment period is scheduled
- A meeting summary and materials will be made available on PCORI’s website following the meeting
- Visit www.pcori.org/events for more information on future activities

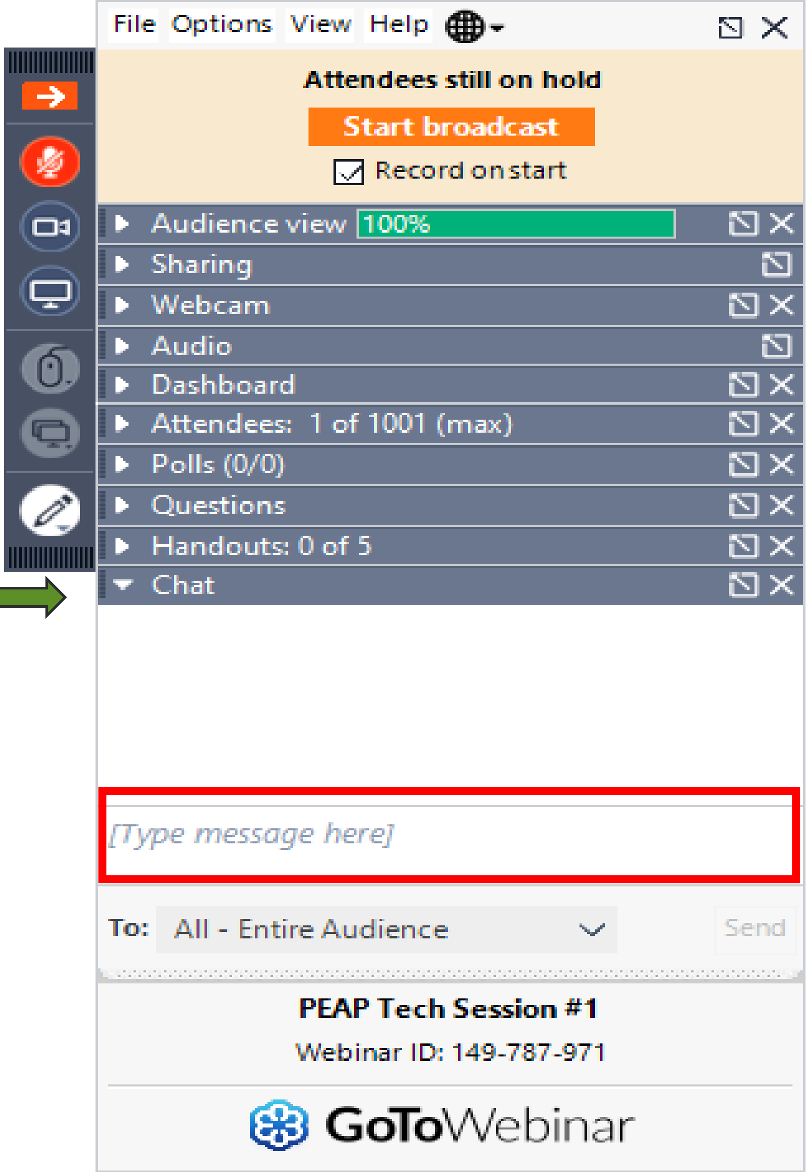
GoToWebinar Housekeeping

- Attendees are in listen-only mode
- Panelists (PCORI PEAP) can mute/unmute themselves
    - Please keep yourself on mute when not talking
- Submitting questions/comments (PCORI PEAP)
    - Type “I have a question/comment”
- If you need to leave the meeting early, please send Lisa a note so we aren’t concerned that you are having connectivity issues

How to Ask Questions – Panelist Instructions

You are muted

Type “I have a comment” in the chat box

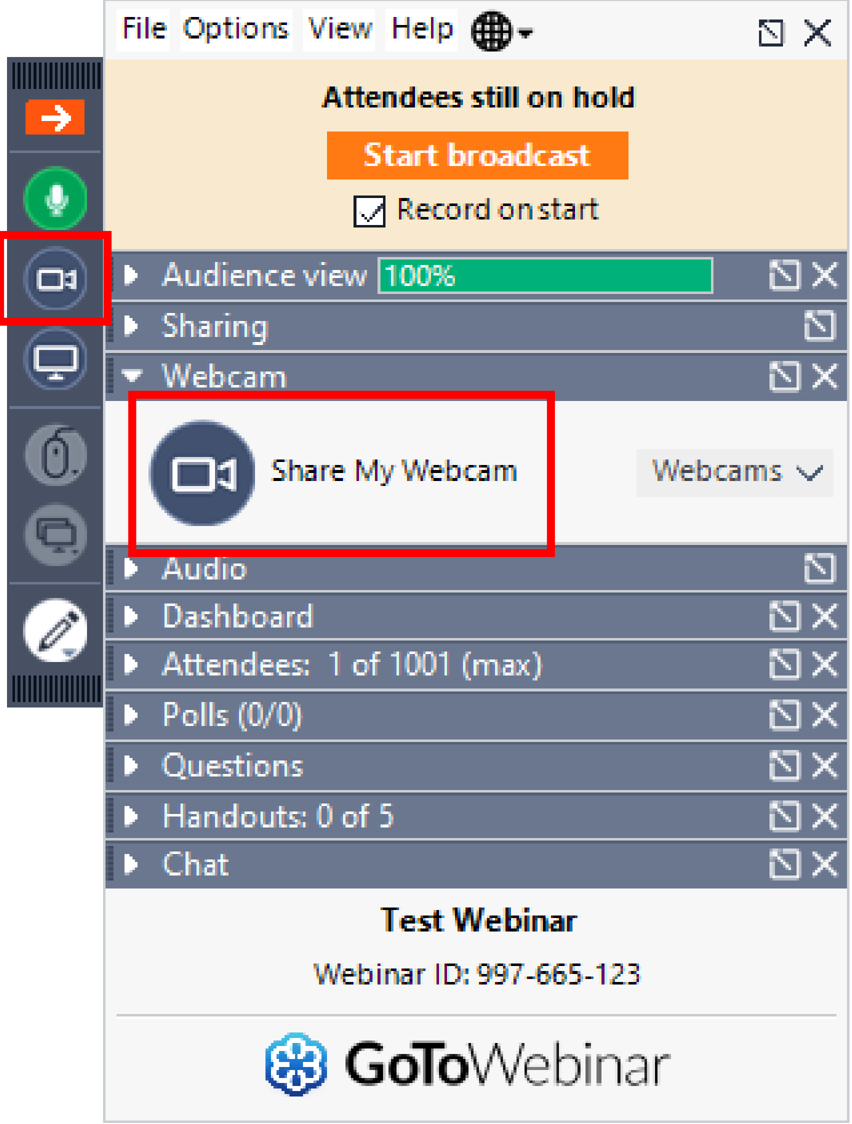


PEAP Tech Session #1

Webinar ID: 149-787-971

How to Turn on Your Webcam – Panelist Instructions

Click to turn webcam on/off. Icon is green when on.



Advisory Panel Members

Sonya Ballentine
Patients, Caregivers, and Advocacy Organizations

Jennifer Canvasser
Patients, Caregivers, and Advocacy Organizations

Katherine Capperella
Industry

Beth Careyva
Researchers

Tracy Carney
Patients, Caregivers, and Advocacy Organizations

Gwen Darien
Patients, Caregivers, and Advocacy Organizations

Sarah Donelson
Industry

Maureen Fagan
Clinicians

Marilyn Geller
Patients, Caregivers, and Advocacy Organizations

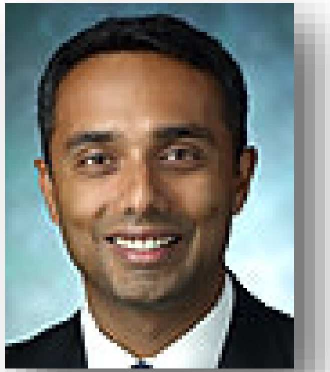
Crispin Goytia
Patients, Caregivers, and Advocacy Organizations

James Harrison
Researchers

Jill Harrison
Patients, Caregivers, and Advocacy Organizations

Advisory Panel Members


Matthew Hudson
Patients, Caregivers, and Advocacy Organizations


Simon Mathews
Clinicians


Anita Roach
Patients, Caregivers, and Advocacy Organizations


Brendaly Rodriguez
Patients, Caregivers, and Advocacy Organizations


Beverly Rogers
Patients, Caregivers, and Advocacy Organizations


Thomas Scheid
Patients, Caregivers, and Advocacy Organizations


Norah Schwartz
Researchers


Umair Shah
Policy Makers


Sandy Sufian
Patients, Caregivers, and Advocacy Organizations


Danny van Leeuwen
Patients, Caregivers, and Advocacy Organizations


Freddie White-Johnson
Patients, Caregivers, and Advocacy Organizations


Neely Williams
Patients, Caregivers, and Advocacy Organizations

New Staff Introduction

Tasha Parker
PCORI's New Director of Communications

- Prior to joining PCORI, she served as the Chief Marketing Officer at the American College of Obstetricians and Gynecologists (ACOG)
- Brings extensive experience developing strategy and managing teams to deliver sophisticated communications, digital, and integrated marketing efforts

PCORI Reauthorization Activities

Update on National Priorities and Research Agenda

Michele Orza
Chief of Staff

Greg Martin
Deputy Chief Engagement and Dissemination Officer

Jean Slutsky
Chief Engagement and Dissemination Officer

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Looking Forward: Refreshing PCORI's National Priorities

Michele Orza
Chief of Staff

Greg Martin
Deputy Chief Engagement and Dissemination Officer

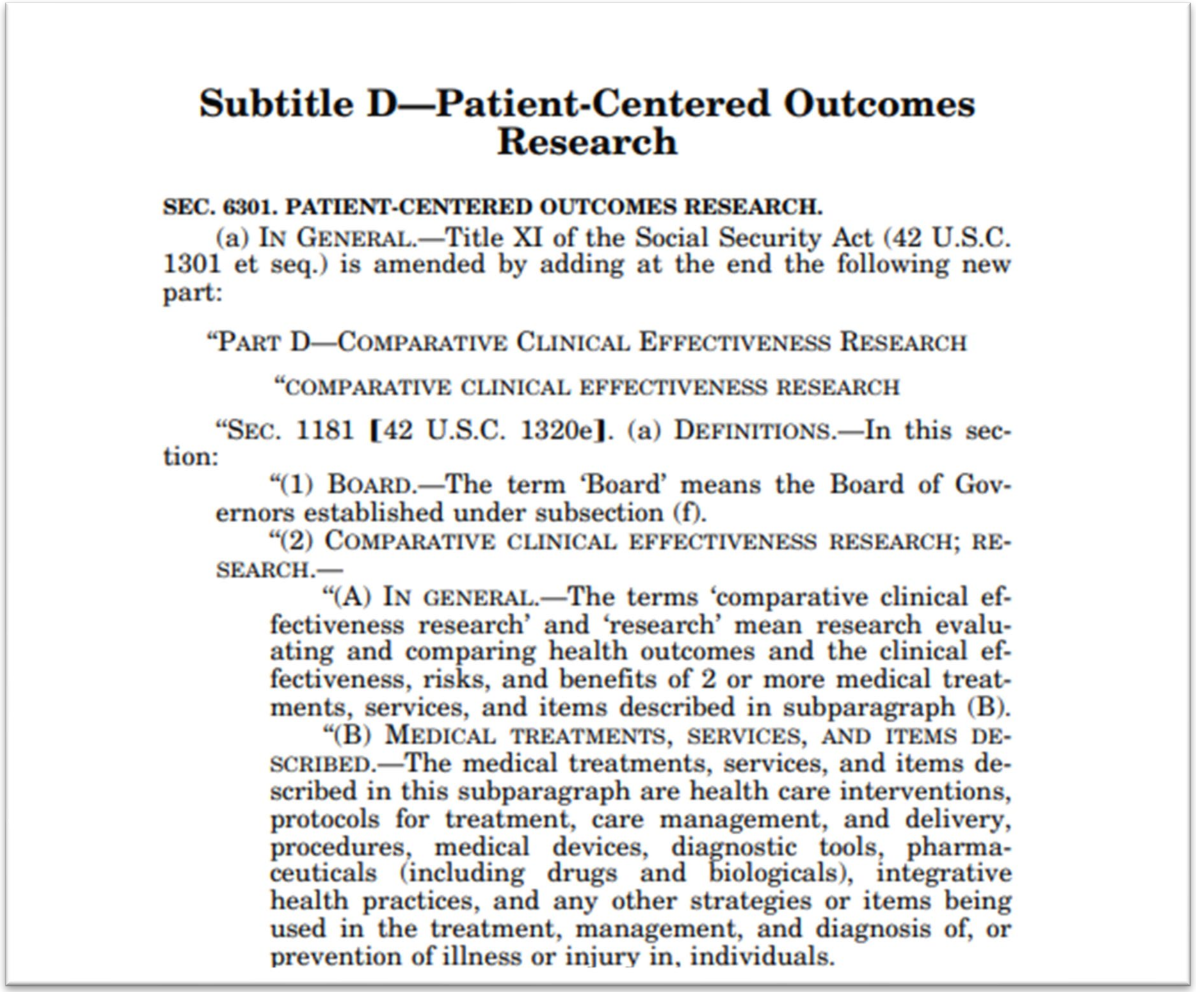
Agenda

1. Statutory Mandates
2. Current National Priorities
3. Looking Forward: Panelists' Perspectives on a Refresh

Statutory Mandate

National Priorities

- Required under PCORI's authorizing law.
- Identification is a core duty—the first enumerated duty—of the Institute
- Intended to guide PCORI and provide transparency to the public on the Institute's investment strategy in patient-centered comparative clinical effectiveness research



Subtitle D—Patient-Centered Outcomes Research

SEC. 6301. PATIENT-CENTERED OUTCOMES RESEARCH.

(a) In General.—Title XI of the Social Security Act (42 U.S.C. 1301 et seq.) is amended by adding at the end the following new part:

"Part D—Comparative Clinical Effectiveness Research

"COMPARATIVE CLINICAL EFFECTIVENESS RESEARCH

"Sec. 1181 [42 U.S.C. 1320e]. (a) Definitions.—In this section:

"(1) Board.—The term 'Board' means the Board of Governors established under subsection (f).

"(2) Comparative clinical effectiveness research; research.—

"(A) In general.—The terms 'comparative clinical effectiveness research' and 'research' mean research evaluating and comparing health outcomes and the clinical effectiveness, risks, and benefits of 2 or more medical treatments, services, and items described in subparagraph (B).

"(B) Medical treatments, services, and items described.—The medical treatments, services, and items described in this subparagraph are health care interventions, protocols for treatment, care management, and delivery, procedures, medical devices, diagnostic tools, pharmaceuticals (including drugs and biologicals), integrative health practices, and any other strategies or items being used in the treatment, management, and diagnosis of, or prevention of illness or injury in, individuals.

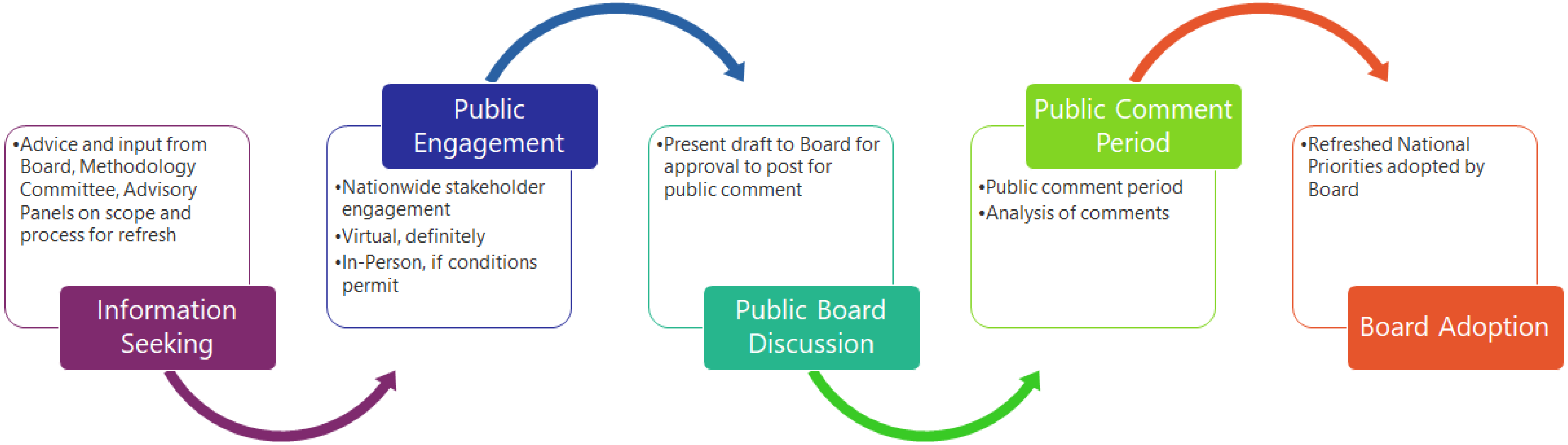
National Priorities

- The Institute shall identify national priorities for research, taking into account **factors of disease** incidence, prevalence, and burden in the United States (with emphasis on chronic conditions), **gaps in evidence** in terms of clinical outcomes, **practice variations** and **health disparities** in terms of delivery and outcomes of care, the **potential for new evidence** to improve patient health, well-being, and the quality of care, the effect on national expenditures associated with a health care treatment, strategy, or health conditions, as well as patient needs, outcomes, and preferences, the relevance to patients and clinicians in making informed health decisions…

**emphasis added*

Mandated Process

- Formal Public Comment is required
  - Minimum: 45 days
  - Maximum: 60 days
- Final approval/adoption rests with PCORI Board of Governors



Information Seeking

- Advice and input from Board, Methodology Committee, Advisory Panels on scope and process for refresh

Public Engagement

- Nationwide stakeholder engagement
- Virtual, definitely
- In-Person, if conditions permit

Public Board Discussion

- Present draft to Board for approval to post for public comment

Public Comment Period

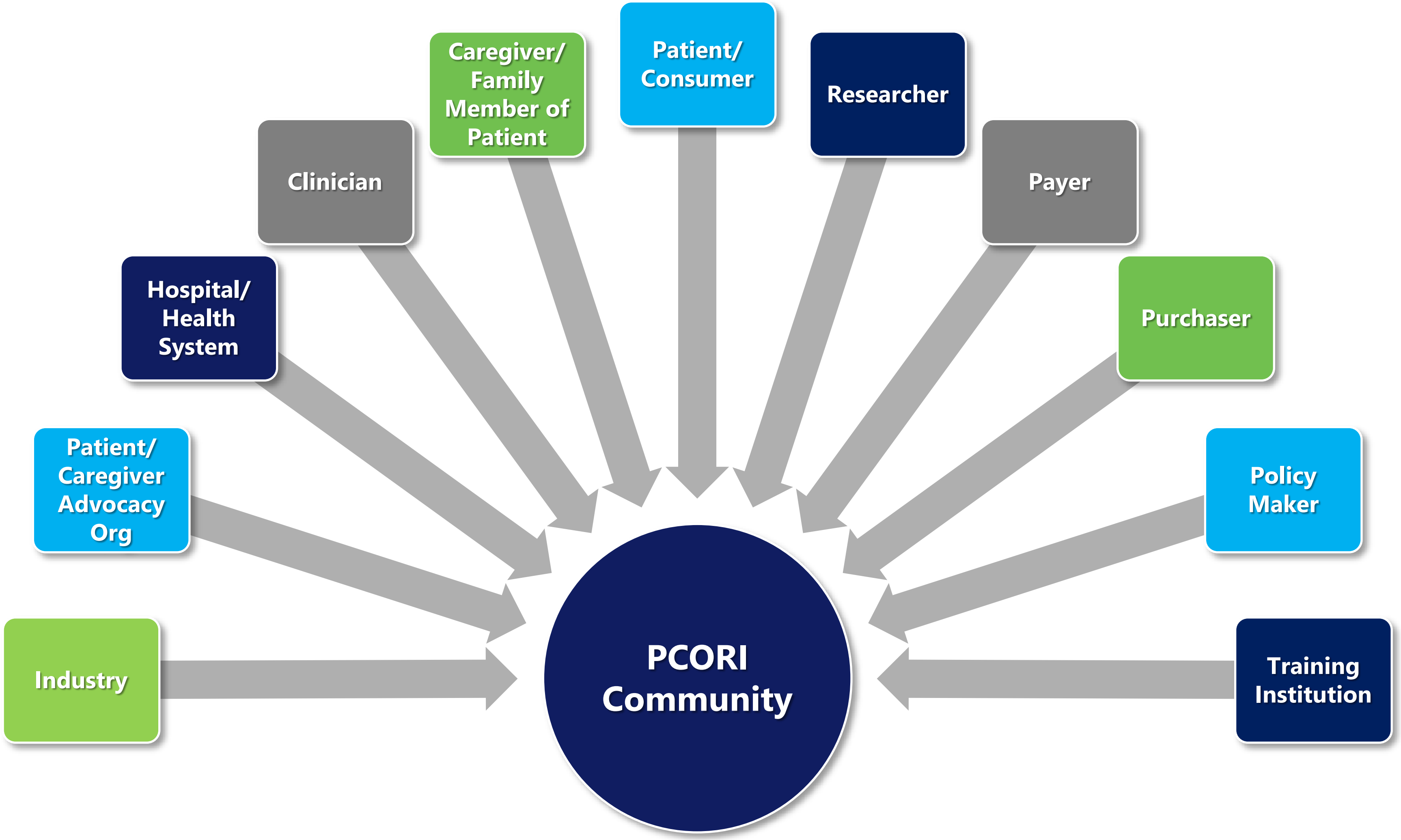
- Public comment period
- Analysis of comments

Board Adoption

- Refreshed National Priorities adopted by Board

Who We Will Engage

- PCORI
  - Board of Governors
  - Methodology Committee
  - Advisory Panels
- Our Stakeholders across the Nation



Current
National Priorities

Our Current National Priorities

Our prior approach:

- Broad national priorities
- Articulation of criteria to inform the *process* for establishing a research agenda

Assessment of Prevention, Diagnosis, and Treatment Options

- Comparing the effectiveness and safety of alternative prevention, diagnosis, and treatment options to see which ones work best for different people with a particular health problem.

Improving Healthcare Systems

- Comparing health system-level approaches to improving access, supporting patient self-care, innovative use of health information technology, coordinating care for complex conditions, and deploying workforce effectively.

Communication and Dissemination Research

- Comparing approaches to providing comparative effectiveness research information, empowering people to ask for and use the information, and supporting shared decision-making between patients and their providers.

Addressing Disparities

- Identifying potential differences in prevention, diagnosis or treatment effectiveness, or preferred clinical outcomes across patient populations and the healthcare required to achieve best outcomes in each population.

Accelerating Patient-Centered Outcomes Research and Methodological Research

- Improving the nation's capacity to conduct patient-centered outcomes research, by building data infrastructure, improving analytic methods, and training researchers, patients and other stakeholders to participate in this research.

Looking Forward: Perspectives on a Refresh

We Want to Hear from You

- Questions and Discussion

Today's Discussion

1. Full Range of Outcomes Data
2. Maternal Morbidity and Mortality
3. Intellectual and Developmental Disability
4. Next Steps

Consideration of Full Range of Outcomes Data

Consideration of Full Range of Outcomes Data

Where appropriate, PCORI-funded studies may capture data on the **potential burdens and economic impacts** of the utilization of medical treatments, items, and services for all stakeholders. This data includes:

- Medical out-of-pocket costs, including:
    - Health plan benefit
    - Formulary design
- Healthcare utilization
- Nonmedical costs to patients and family, including:
    - Caregiving
    - Effects on future costs of care
    - Workplace productivity
    - Absenteeism

This compromise language **does not** remove statutory prohibitions on PCORI establishing cost-per quality adjusted life year (QALY) thresholds or allow PCORI to conduct cost-effectiveness analyses

Consideration of Full Range of Outcomes Congressional and Stakeholder Intent

- Congressional leaders and stakeholders across the healthcare community weighed in on whether to include provisions directing PCORI to capture additional economic/cost-related data

- The goals of this provision is to direct PCORI-funded research to better inform healthcare decisions based on the clinical effectiveness, impact on patient-reported outcomes, **and** potential economic and cost burden

- The provision is a compromise between stakeholders to ensure PCORI-funded research capture both population-level (i.e., utilization, ROI, etc.) and patient-centric (i.e., caregiver burden, impact on medical out-of-pocket costs, etc.) data

- This compromise language **does not** remove statutory prohibitions on PCORI establishing cost-per quality adjusted life year (QALY) thresholds or allow PCORI to conduct cost-effectiveness analyses

Consideration of Full Range of Outcomes Early Stakeholder Input on Implementation

Summary of the key take-aways for implementation include:

- Ensure **transparency**, notably patient engagement, throughout implementation
- Identify the **long-term goals** of capturing this data to inform implementation efforts
- Consider the **full range of treatment options** and the **investment costs** for payers and health systems to implement practice change
- Need to **develop standards** around identifying and capturing patient-centric cost data
- **Concerns around the use/misuse** of cost data that could lead to cost-effectiveness or inappropriate value assessment
- Hope to **expand beyond traditional health economic perspectives** on cost/value

Maternal Mortality (and Morbidity)

The Evolution of PCORI's Focus on Maternal Mortality (and Morbidity)

1

Existing PCORI Investments

Approximately $65m in investments on maternal health related topics

2

Congressional Recognition

Maternal mortality named one of two newly specified research priorities for PCORI

3

Evolving Efforts

Hearing from stakeholders informs future investments and research related products

Background

- Included in PCORI's reauthorization legislation as a priority area
- PCORI continues to engage Congress and stakeholder organizations
    - Multi-stakeholder salon on maternal mortality in Fall 2019
    - Listening Session with the Black Maternal Health Caucus in early 2020
    - Intended multi-stakeholder meeting in March 2020, cancelled due to the pandemic

Objectives for Recent and Ongoing Stakeholder Input on Maternal Mortality (and Morbidity)

Hearing from subject matter experts and key voices

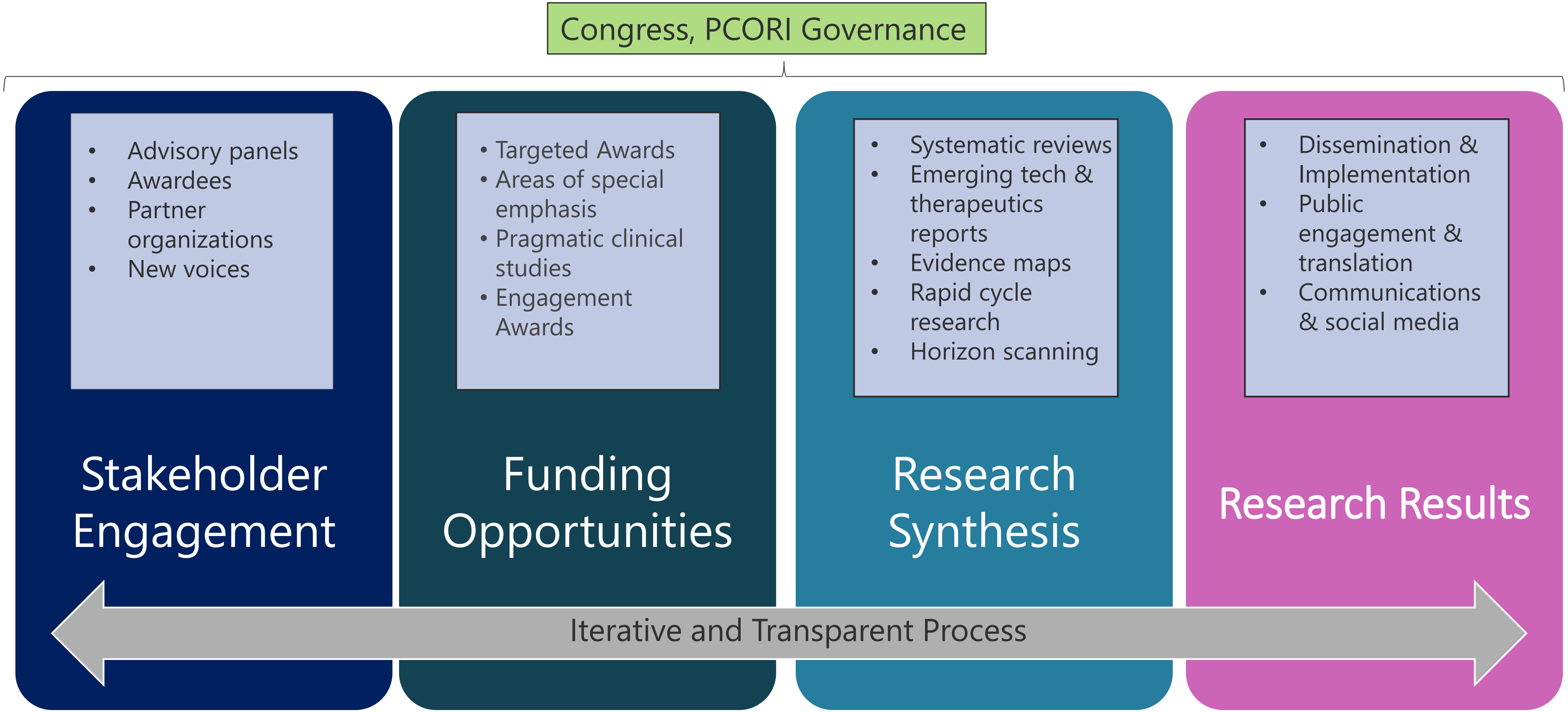
Creating opportunities for stakeholders to share and refine ideas

Supporting PCORI's understanding of the current landscape

- e.g., impact of COVID-19

Building stakeholder relationships and identifying new and vital voices

PCORI Approach to Funding Impactful Work and Supporting Stakeholder Priorities



Congress, PCORI Governance

- Advisory panels
- Awardees
- Partner organizations
- New voices

Stakeholder Engagement

- Targeted Awards
- Areas of special emphasis
- Pragmatic clinical studies
- Engagement Awards

Funding Opportunities

- Systematic reviews
- Emerging tech & therapeutics reports
- Evidence maps
- Rapid cycle research
- Horizon scanning

Research Synthesis

- Dissemination & Implementation
- Public engagement & translation
- Communications & social media

Research Results

Iterative and Transparent Process

Intellectual and Developmental Disability (IDD)

Background

- IDD still early in topic development phase, compared to other new topic areas
    - Language regarding IDD was a relatively late addition to reauthorization legislation
- PCORI topic development began in January 2020
- A few stakeholder meetings early in 2020 to express enthusiasm for this new priority area

Overview of IDD Portfolio

PCORI HAS AWARDED

$39 MILLION TO FUND 40 awards that focus on IDD

This investment includes:
- $28.4M for **12 Research Awards**
- $6.2M for **5 Infrastructure Awards**
- $3.9M for **23 Engagement Awards**

Categories for Engagement

Broad/multi-condition groups

- e.g., Association of University Centers on Disability (AUCD)

Clinicians, researchers and funders

- e.g., American Occupational Therapy Association (AOTA)

Condition-specific & co-occurring condition groups

- e.g., National Down Syndrome Society (NDSS)

Topic-specific engagement

- e.g., transition from pediatric to adult care

Objectives of Engagement

1. Engage stakeholder groups with **broad constituencies** to ensure PCORI has a solid understanding of the field globally.
2. Engage **clinicians, researchers and funders** to identify research gaps and maximize PCORI's contribution to the field.
3. Engage **condition-specific organizations** to gain deeper understanding of individual and co-occurring conditions.
4. Engage on **key topics** that may structure and inform PCORI's funding approach as implementation of this national priority progresses.

Next Steps

- PCORI will continue to engage stakeholders on these important topics in a virtual context amid the COVID-19 pandemic
- Engagement will inform funding opportunity development framing of other evidence products like systematic reviews, and implementation plans for data collection
- PCORI understands the importance of long-term engagement on these new priority areas over the next decade
- What is important to you and your communities as PCORI addresses maternal morbidity and mortality and intellectual and developmental disability?

PEAPS IN ACTION

Katherine Capperella

PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

CURRENT ADVANCES IN PATIENT FOCUSED DRUG DEVELOPMENT

PCORI Engagement Advisory Panel
June 5, 2020

Katherine Capperella
VP, Global Patient Engagement Leader
Janssen Pharmaceutical Companies of Johnson & Johnson

Patient Focused Drug Development (PFDD)

“A systematic approach to help ensure that **patients**' experiences, perspectives, needs, and priorities are captured and meaningfully incorporated into **drug development** and evaluation” (U.S. FDA)

PFDD Evolution:
Milestones and Stakeholders – Partial List

1980's
AIDs
Movement

2006
DIA
Patient
Fellowship

2009
PRO
Guidance

2012
FDA
PFDD
Initiative

2014
Industry
Chief
Patient
Officers

2015
PATIENT FOCUSED
MEDICINES DEVELOPMENT

2016


2018
FDA
PDUFA VI
- Guidance 1

2019
FDA
Guidance 2

PARADIGM
Patients Active in Research and Dialogues
for an Improved Generation of Medicines

pcori
2011 Engagement
2014 Engagement Rubric

CLINICAL TRIALS TRANSFORMATION INITIATIVE

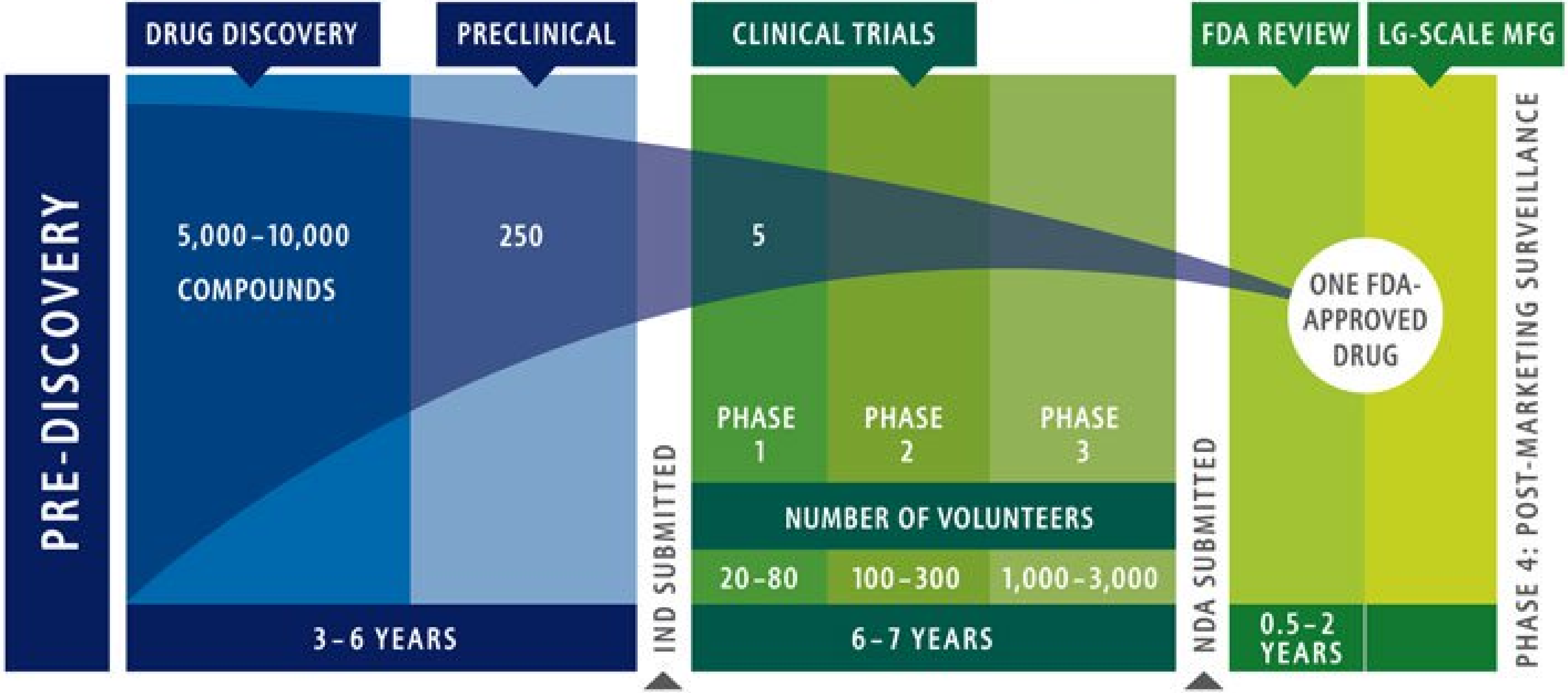
CISCRP
THE CENTER FOR INFORMATION & STUDY ON CLINICAL RESEARCH PARTICIPATION

PUTTING PATIENTS FIRST
NATIONAL HEALTH COUNCIL

EPF
European Patients Forum

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Drug Discovery and Development: A LONG, RISKY ROAD



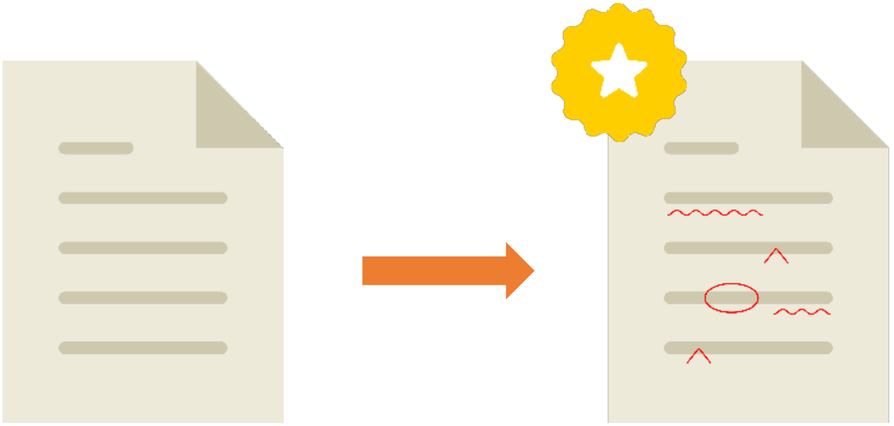
Source: Pharmaceutical Research and Manufacturers of America

How is PFDD implemented and how is patient engagement placed/viewed in industry?

- There is a strong commitment to PFDD in the pharmaceutical industry
  - Individual companies
  - Trade organizations: BIO, PhRMA, EfPIA
  - Collaboration across companies for the benefit of patients
- There are a variety of different approaches to Structure: Engagement Responsibility
  - Chief Patient Officers
  - Embedded in all departments
  - Marketing/Commercial
  - Government Affairs
  - Communications
  - Market Access
- And varying degrees of implementation
  - Tools, process, expectations, senior leader support, budget may influence success

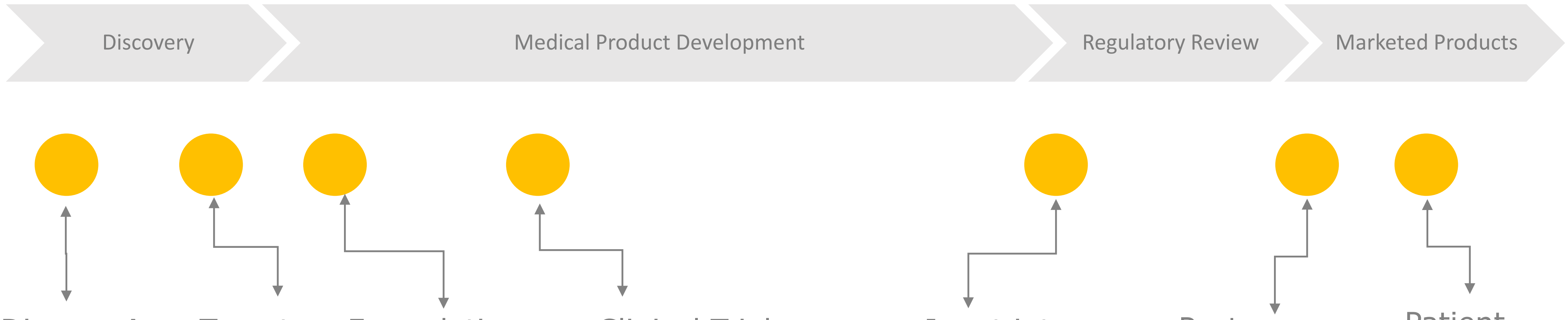
Patients are involved early and shaping solutions

Modifications to a Clinical Trial
Outcome: No dropouts



Updated Target Product Profile
Outcome: Pursuing ways to know sooner whether a treatment will work

Patient insights are proactively incorporated early and throughout product lifecycle



Disease Area Strategies

Target Product Profiles

Formulation Decisions, use instructions

- Clinical Trial Design
- Patient Reported Outcomes

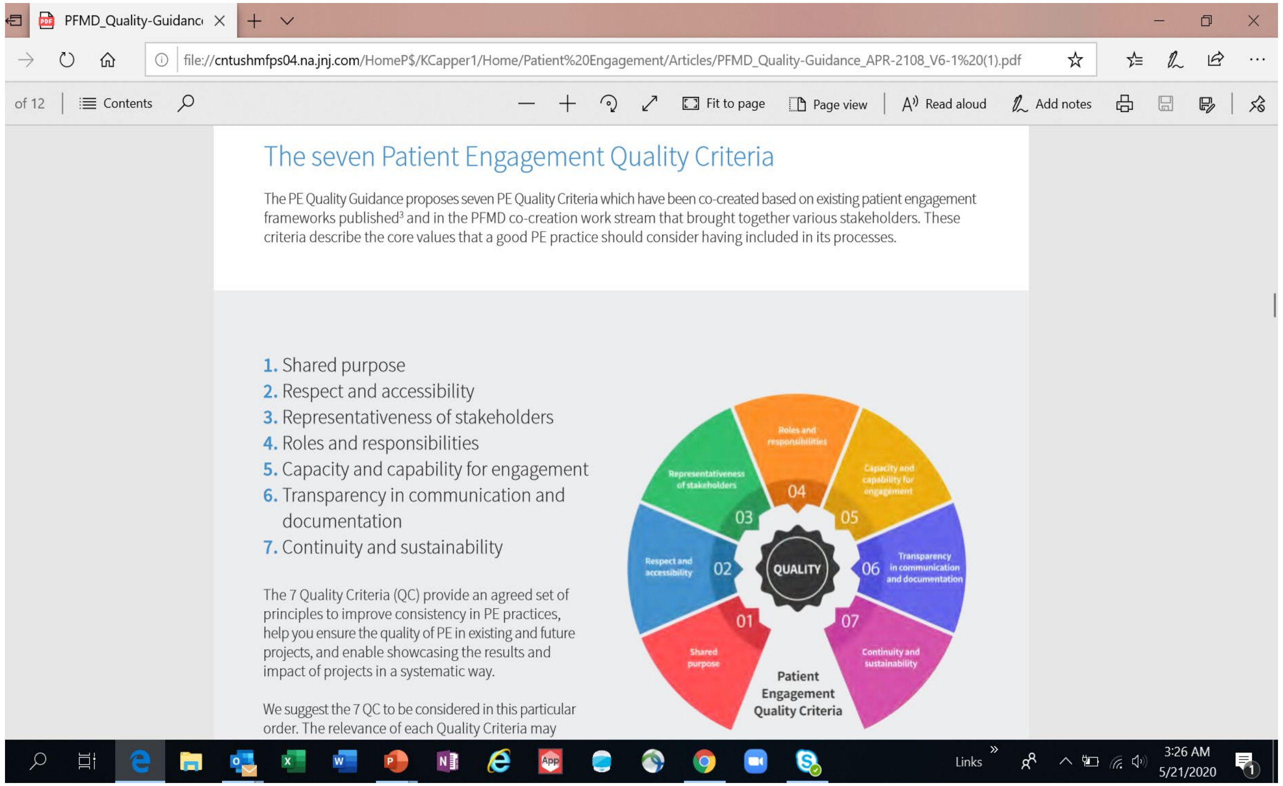
Input into regulatory and access

Post Marketing Clinical Studies/RWE

Patient Educational Materials

Examples of Engagements and Sources of Patient Voice

- Patient Advisory Boards
  - In person
  - Global (virtual)
  - Single event or ongoing/standing ad boards
  - Industry or Community : CABs
  - Interaction with a single patient group or individuals
- Market Research
  - Facilitated discussion
  - Ethnography
- Social Listening
- Online Patient Communities
- Etc
  - FDA Guidance Document on Methods



The seven Patient Engagement Quality Criteria

The PE Quality Guidance proposes seven PE Quality Criteria which have been co-created based on existing patient engagement frameworks published[3] and in the PFMD co-creation work stream that brought together various stakeholders. These criteria describe the core values that a good PE practice should consider having included in its processes.

1. Shared purpose
2. Respect and accessibility
3. Representativeness of stakeholders
4. Roles and responsibilities
5. Capacity and capability for engagement
6. Transparency in communication and documentation
7. Continuity and sustainability

The 7 Quality Criteria (QC) provide an agreed set of principles to improve consistency in PE practices, help you ensure the quality of PE in existing and future projects, and enable showcasing the results and impact of projects in a systematic way.

We suggest the 7 QC to be considered in this particular order. The relevance of each Quality Criteria may

Tools and processes to incorporate patient perspectives throughout development

Patient Insights & Integrated Patient Journey Template: Document and ensure shared understanding of patient journey to better meet needs

Target Product Profiles: Patients shape blueprints for solution design

Customer Centered Design (CCD): Incorporating patient insights into formulation decisions

Patient Voice in Clinical Trials: Improving clinical trial design and implementation based on patient feedback

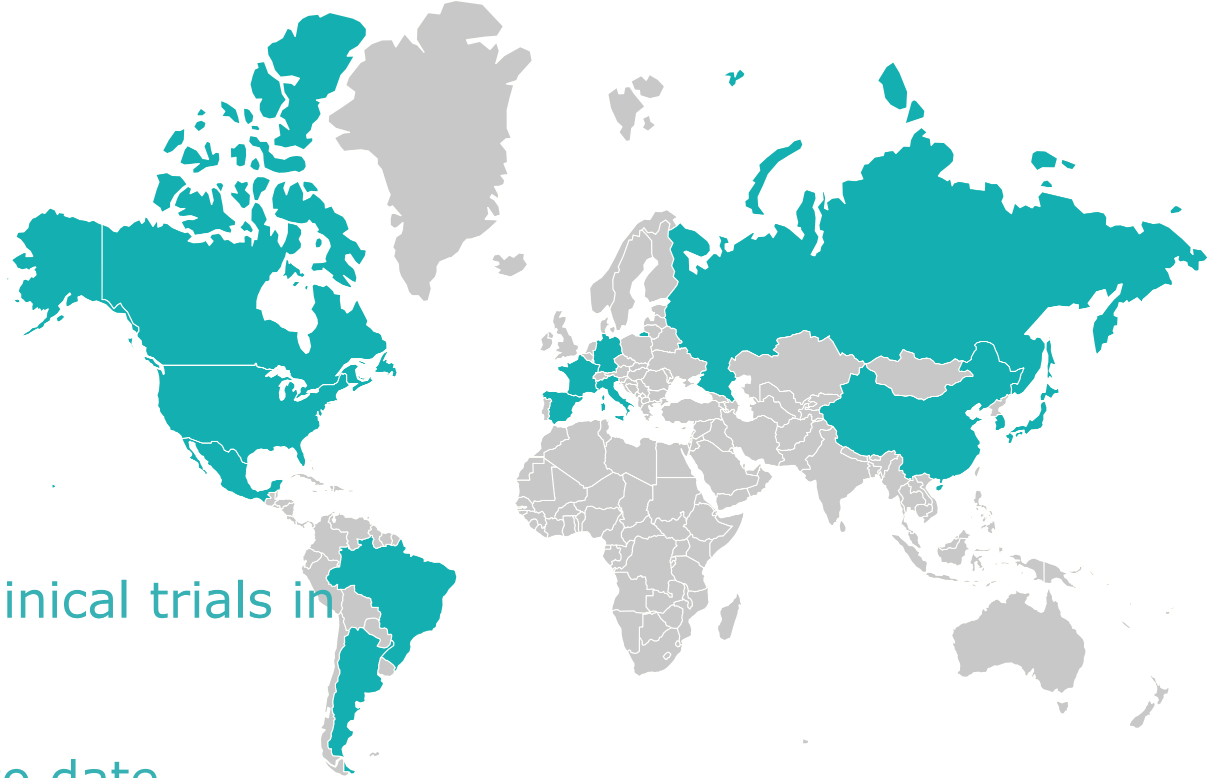
BEST PRACTICE SHARING TO ACCELERATE ADOPTION

Patient Involvement in Clinical Trial Design
One Approach for Broad Implementation

1,950 patients & caregivers

30 countries

All Disease Area Strongholds



- Operational changes made to **100%** of clinical trials in PVCT program
- Protocol changes made to **40%** of trials to date
- Engagement Reports posted for any employee to read

Clinical
Insights &
Experience
CIE

How Patients are Shaping Clinical Trials

Clinical Trial Simulation

- Reversed task order and provided rest periods in between, to increase likelihood of completing assessments
- *Trial is progressing per plan*

Global **C**ommunity **A**d **B**oard (Virtual, standing)

- Reduced number of invasive tests

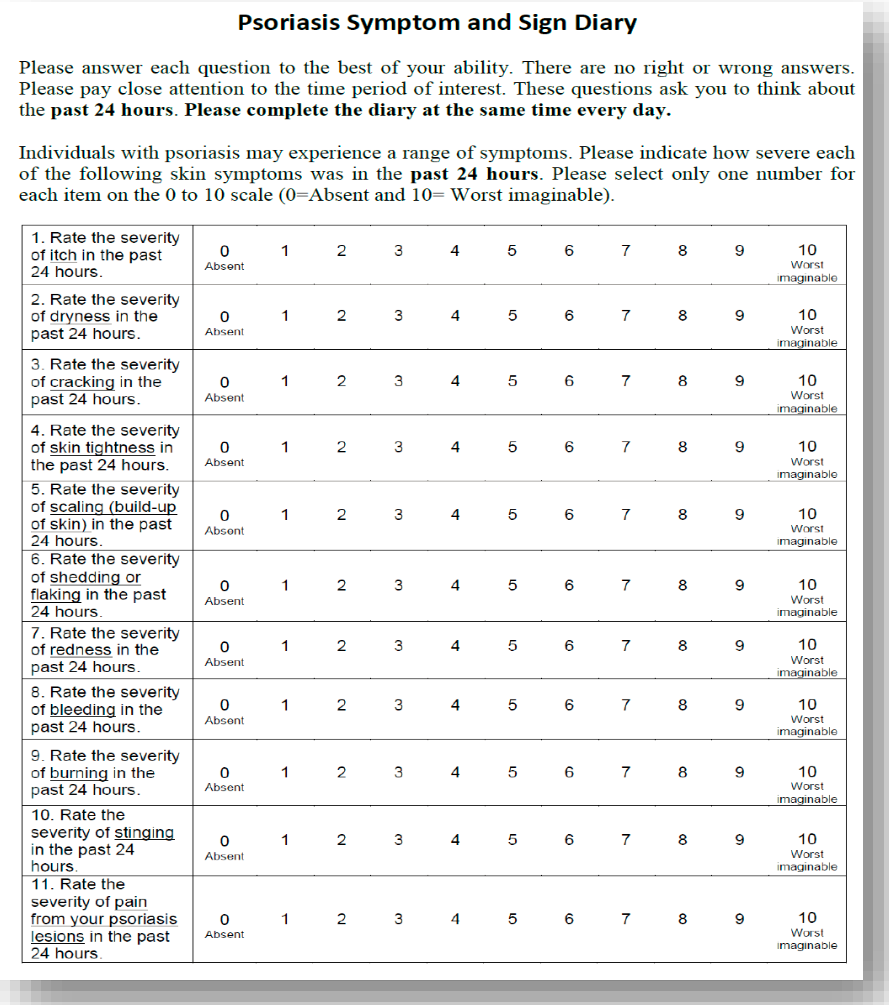
Patient interviews, ad boards (Global)

- Business Case for providing travel assistance
- Patient Video at investigator meeting
- DICT Clinical Enrollment manager
- *Exceeded enrollment goals, including diversity patient enrollment*

Patient Reported Outcomes (PROs) are systematically incorporated into development. PRO Teams develop new instruments when needed.

Psoriasis Symptoms & Signs Diary (PSSD)

- New PRO measurement tool developed in collaboration with patients, clinicians and Janssen with input from regulators
- Available publicly for anyone to use



Psoriasis Symptom and Sign Diary

Please answer each question to the best of your ability. There are no right or wrong answers. Please pay close attention to the time period of interest. These questions ask you to think about the **past 24 hours**. **Please complete the diary at the same time every day.**

Individuals with psoriasis may experience a range of symptoms. Please indicate how severe each of the following skin symptoms was in the **past 24 hours**. Please select only one number for each item on the 0 to 10 scale (0=Absent and 10= Worst imaginable).

1. Rate the severity of itch in the past 24 hours.	0 Absent	1	2	3	4	5	6	7	8	9	10 Worst imaginable
2. Rate the severity of dryness in the past 24 hours.	0 Absent	1	2	3	4	5	6	7	8	9	10 Worst imaginable
3. Rate the severity of cracking in the past 24 hours.	0 Absent	1	2	3	4	5	6	7	8	9	10 Worst imaginable
4. Rate the severity of skin tightness in the past 24 hours.	0 Absent	1	2	3	4	5	6	7	8	9	10 Worst imaginable
5. Rate the severity of scaling (build-up of skin) in the past 24 hours.	0 Absent	1	2	3	4	5	6	7	8	9	10 Worst imaginable
6. Rate the severity of shedding or flaking in the past 24 hours.	0 Absent	1	2	3	4	5	6	7	8	9	10 Worst imaginable
7. Rate the severity of redness in the past 24 hours.	0 Absent	1	2	3	4	5	6	7	8	9	10 Worst imaginable
8. Rate the severity of bleeding in the past 24 hours.	0 Absent	1	2	3	4	5	6	7	8	9	10 Worst imaginable
9. Rate the severity of burning in the past 24 hours.	0 Absent	1	2	3	4	5	6	7	8	9	10 Worst imaginable
10. Rate the severity of stinging in the past 24 hours.	0 Absent	1	2	3	4	5	6	7	8	9	10 Worst imaginable
11. Rate the severity of pain from your psoriasis lesions in the past 24 hours.	0 Absent	1	2	3	4	5	6	7	8	9	10 Worst imaginable

Measuring Progress Drives Change

OBJECTIVES:

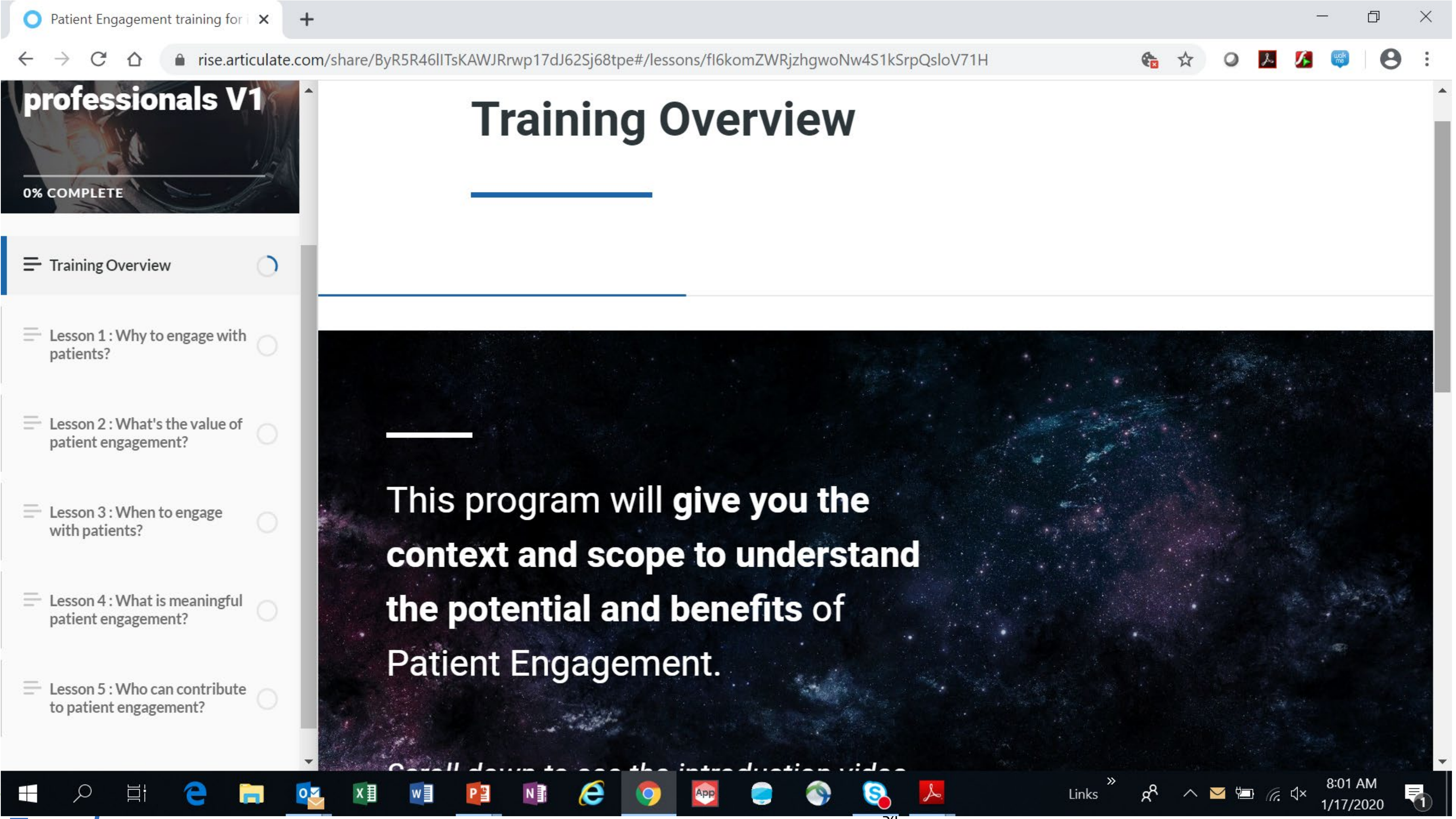
- Drive behavior to incorporate direct patient voice early
- Understand barriers

MEASUREMENT:

- A targeted list of high priority compounds

PATIENT ENGAGEMENT DASHBOARD	
Disease Area Strategy	Integrated patient journey
	Disease area strategy
Compound Strategy	Target Product Profile (TPP)
	Indication(s) and end points
	Product formulation and delivery
	Need for pre-approval access
Clinical Development Plan	Patient insight prior to pivotal
	Protocol designs and operational strategies
	Patient Reported Outcomes

Patient Engagement 15-minute training for Industry: Co-created and available publicly



professionals V1

0% COMPLETE

- Training Overview
- Lesson 1 : Why to engage with patients?
- Lesson 2 : What's the value of patient engagement?
- Lesson 3 : When to engage with patients?
- Lesson 4 : What is meaningful patient engagement?
- Lesson 5 : Who can contribute to patient engagement?

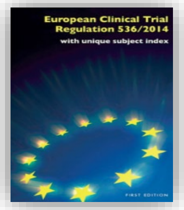
Training Overview

This program will **give you the context and scope to understand the potential and benefits** of Patient Engagement.

Scroll down to see the introduction video

Better
Made Together.

Plain Language Summaries of Clinical Trial Results


European Clinical Trial Regulation 536/2014
with unique subject index

- **EU Clinical Trial Regulation mandates PLS provision**
  - EU Clinical Trial Regulation 536/2014 requires public access to clinical trial results
  - Portal is not live yet
- **Dutch Law**
  - Adopts EU CTR requirements
- **Not Required by FDA, however Industry is providing voluntarily**

Additional Patient Centered Initiatives

- Diversity and Inclusion in Clinical Trials
- Patient Voice in Safety and Benefit/Risk
- Patient Voice in product formulation and Design

Ways to get involved

- Patient Organizations
- Market Research Organizations
- Agencies
- Nonprofits
- Direct Industry Connections

Thank you

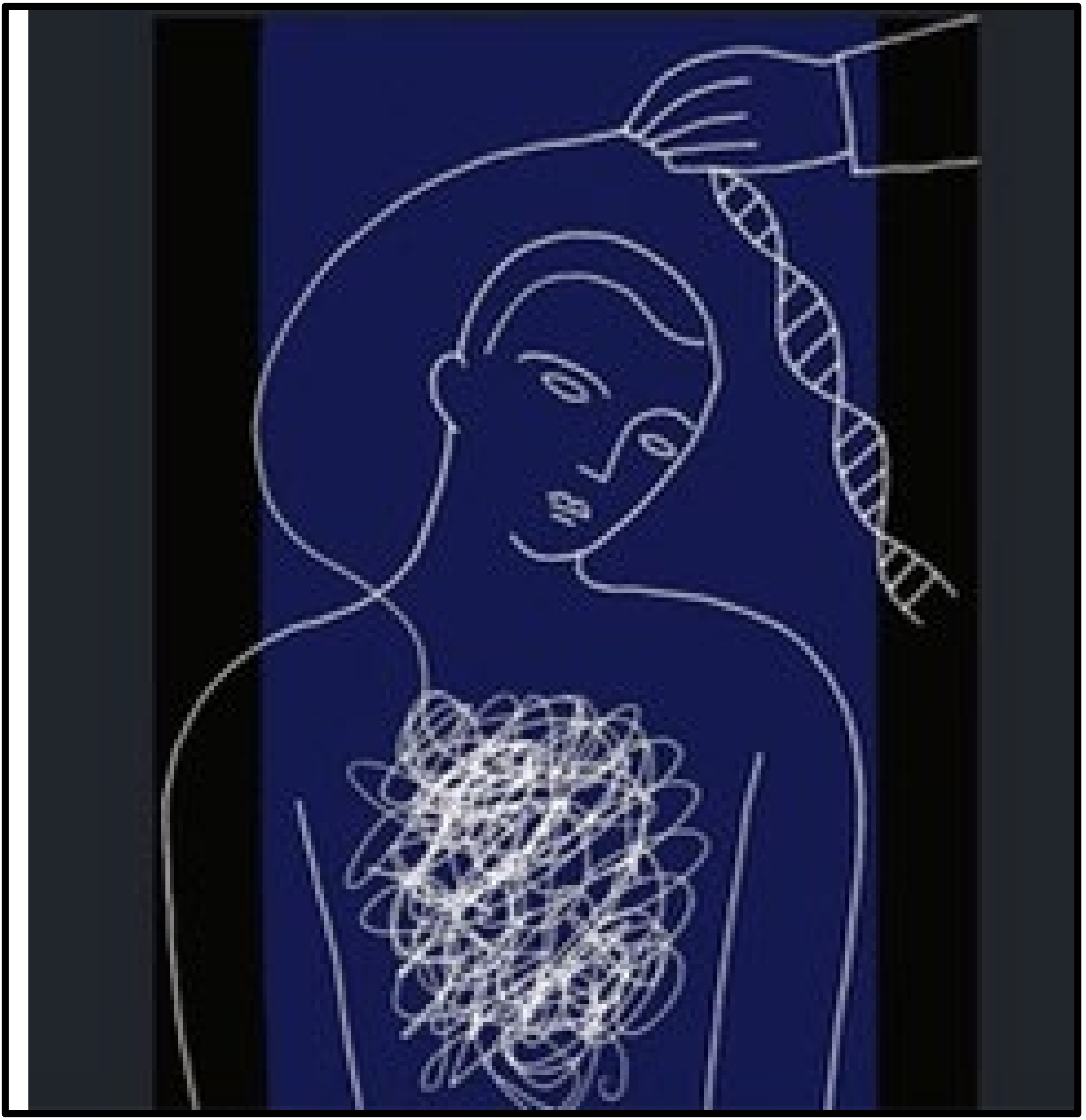
Panel Discussion

Break

1:15 – 1:45 EDT

PEAPS IN ACTION

Sandy Sufian



Virtual Patient Engagement: Lessons from the Cystic Fibrosis Community

Sandy Sufian, PhD, MPH
Associate Professor,
Health Humanities, History and Disability Studies
University of Illinois at Chicago
PI: CFF CFReSHC Impact Award
sandy.sufian@cfreshc.org

- Cystic Fibrosis & Social Distancing
- CFReSHC: PCORI P2P & CFF Impact Grant
- Virtual Patient Engagement Infrastructure: Team & Processes
- Patient Engagement Format
- Facilitation Training
- Example: CF-SRH Resource Guide Project
- Virtual Engagement Challenges

Cystic Fibrosis

- Rare, life-shortening genetic disorder
- Multi-system disease-- primarily affects lungs and pancreas
- ∾ 30,000 people in US
- median age of survival: 47 years (due to improved therapies)
- >½ patients= past 18 years of age

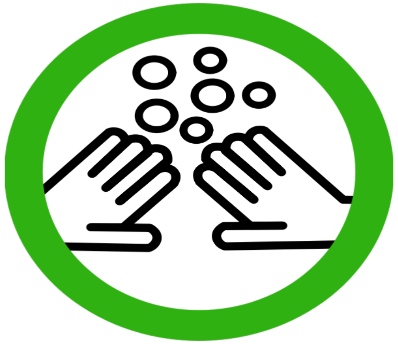
Cystic Fibrosis Foundation Patient Registry,
Annual data report. 2016, Bethesda

Michael Boyle: President of Cystic Fibrosis Foundation

"While millions of Americans make sense of this new reality [of COVID], there are thousands who live this way every day…."

--PwCF are *at much greater risk* for getting and spreading dangerous germs to one another.

--Infection Prevention & Control guidelines: strikingly similar to CDC's COVID guidelines:



Michael Boyle "For some, social distancing is the norm" *Medium* 3.31.20
https://medium.com/@MichaelBoyleMD/for-some-social-distancing-is-the-norm

"Here's what people… can learn from the CF community's experience: ..."

- *Creating a vibrant online culture is possible*

"...Communities can grow and thrive even without physical contact. Individuals with CF maintain a vibrant social community despite being unable to spend time together....Over the last decade there has been an explosion of creative ideas for virtual socializing. These digital interactions require planning and commitment, and intentionally making the time and space for them is essential to building virtual community."

Boyle, *Medium* 3.31.20

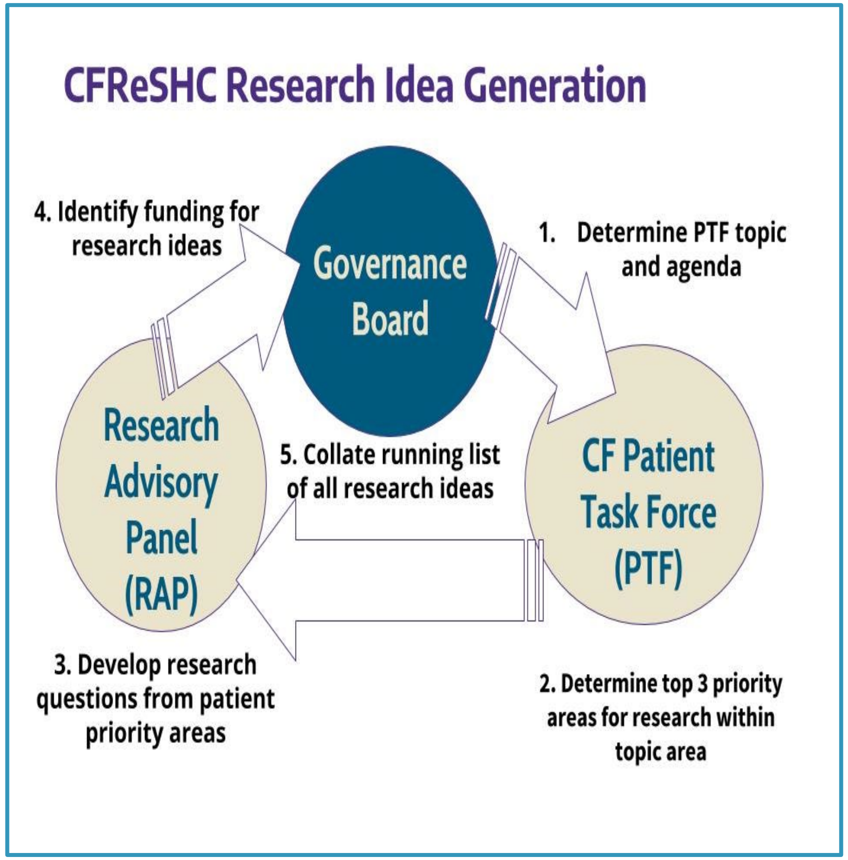
- *Social distancing: can be reimagined as facilitator, not a barrier*

Allows movement and relationships without jeopardizing health. Makes life *more* accessible in face of risk (ie. immunocompromised can participate, those lower income) rather than less.

CFReSHC

Cystic Fibrosis Reproductive and Sexual Health Collaborative

Mission



CFReSHC Research Idea Generation

Governance Board

1. Determine PTF topic and agenda

CF Patient Task Force (PTF)

2. Determine top 3 priority areas for research within topic area

Research Advisory Panel (RAP)

3. Develop research questions from patient priority areas

4. Identify funding for research ideas

5. Collate running list of all research ideas

CFReSHC is committed to patient-engaged research (PCOR) through partnerships with people with CF, researchers, and clinicians.

Our research responds to the healthcare needs of the CF community and provides data for healthcare professionals, paving the way for improved sexual/reproductive health (SRH) resources, care, and knowledge for people with CF

Funding: PCORI P2P Tiers I and II and CFF Impact Awards

CFReSHC: Virtual Patient-Facing Activities

Methods

- Almost 4 years experience in virtual patient engagement
- Patients meet once a month: share experiences in supportive environment and brainstorm ideas on focus topic for research and improving provision of care.
- Communication Platforms: Google Team Drive (Project Materials), Slack (Team Communication), and Zoom (All Meetings Virtual)

Results

- 60 patient-generated research questions
- CF-SRH Resource Guide by patients for providers and patients
- 2016= 25 women with CF part of PTF; 2020= over 200 women with CF

Norms Document

- Team Norms
- Operations
- Team Roles and Responsibilities
- Meeting Format
- Compensation
- Flow of Operations

Master Task List

- Project Management Platform with Deadlines

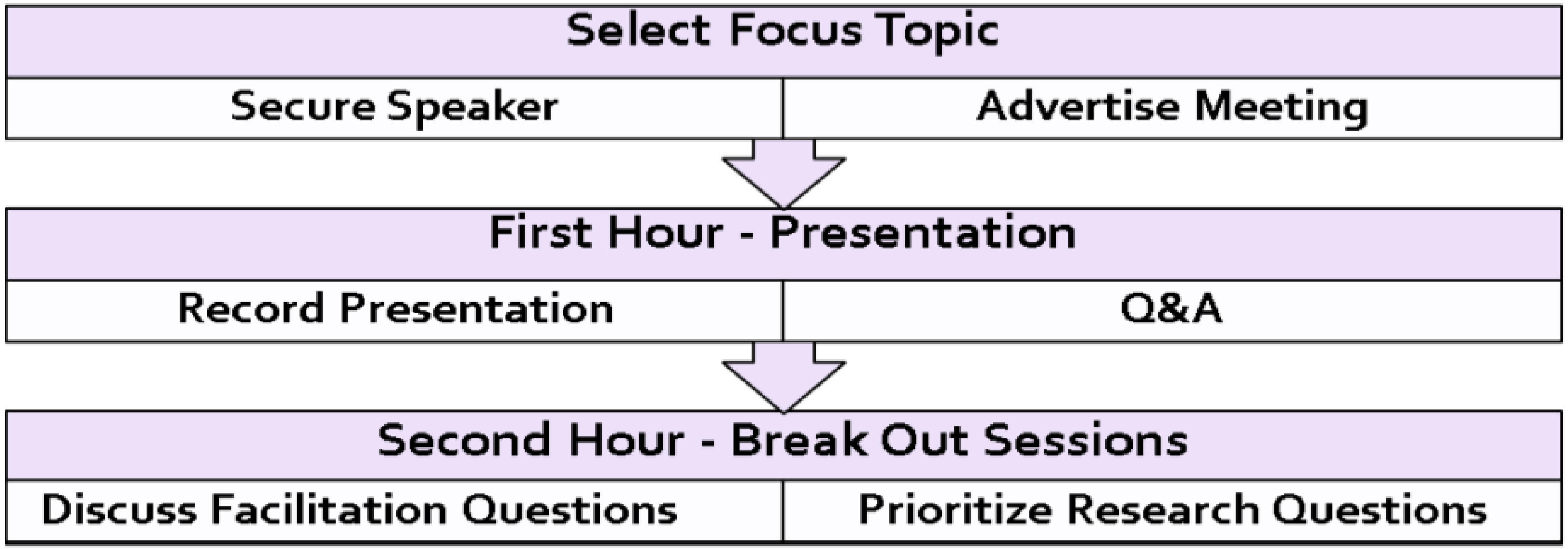
Email and Team Agenda Templates

- Speaker Invitation Email
- Patient Facilitator/Notetaker Email
- Meeting Forms

Team Rotation Schedule for Patient Meeting Roles

- Facilitator
- Notetaker & Attendance Taker
- Timekeeper
- Training program for Breakouts

Process for Effective Virtual Patient Engagement



Select Focus Topic

Secure Speaker | Advertise Meeting

First Hour - Presentation

Record Presentation | Q&A

Second Hour - Break Out Sessions

Discuss Facilitation Questions | Prioritize Research Questions

Women with CF: Join us to learn more

May 14, 2020

1:30-3:30 p ET

RSVP: info@CFReSHC.org for login details and password

Dr. Jeanne Sheffield (MFM at Hopkins) will discuss her experiences treating pregnant women with CF. We also plan to discuss: preparing to get pregnant, experiencing pregnancy, labor/delivery, postpartum, and pregnancy loss.

Pregnancy in CF

CFReSHC

Cystic Fibrosis Reproductive and Sexual Health Collaborative

- ★ *Can be used for any kind of project, question or priority*
- ★ *Side effect: support group because patients share experiences*

Virtual Patient Engagement
Meeting Format (*Zoom*) Sent to Presenter, Breakout Facilitators, Notetakers

Time	**Forum**	**Purpose**
5 minutes	Overview of Project and Name/Location in chat box	Framing and Relationship building
30 minutes	Large Group: Invited presenter speaks on predetermined SRH topic; Recorded w/permission	To educate women on existing data and practices about a specific CF-SRH topic.
15	Q/A about presentation	To allow engagement from the PTF on the speaker's research.
5	Break	Presenter leaves session.
25 minutes	Breakout session 1: After being divided into separate virtual rooms with a patient-facilitator, women discuss *focus topic-related questions* in an informal and confidential format.	Explore CF-SRH focus topic together. Share experiences and articulate needs and priorities. Engage women's voices
25 minutes	Breakout session 2: After having rotated to another virtual room, women discuss another set of questions related to the same topic.	Explore additional facets of CF-SRH topic together. Share experiences and articulate needs.
10 minutes	Large group: Facilitators report to the group participants' attitudes, preferences, and recommendations. Session facilitator wraps up meeting.	Create consensus and define priorities for research and care. Poll to rank top patient-generated questions put in chat and results reported.

**Depending upon the number of participants, patients may not divide up into two breakout rooms and proceed with topic-related questions as one group.

Facilitator/Notetaker Breakout Training

- Template Email to Patient Breakout Facilitators and Notetakers (w/pre-circulated docs)
- Facilitation/Notetaking Guide Document
- Breakout Facilitation Training Session
  30 min before Patient Topic Meeting

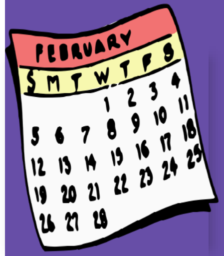
During Meeting:

- ❑ Collect Potential Research Questions from Breakout Discussions
- ❑ Conduct Poll via Chat
- ❑ Show and Discuss Preliminary Results

Dissemination: Post-Meeting Email, FB post, & newsletter to all PTF Members:

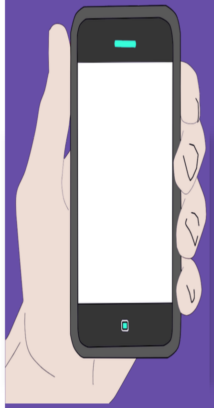
- ❑ Provide Recording of Speaker Presentation
- ❑ Provide Poll for Those Unable to Attend
- ❑ Announce Next Scheduled PTF Meeting

Virtual Patient Engagement: Team Committees



Meeting Planning Committee

Selects and books guest speakers on Focus Topic
Communicates with Speaker
Schedules Patient Meetings on Zoom
Creates Patient Meeting Agenda
Devises Facilitation questions for focus topic
Creates Poll so Patients can Rank top three questions



Communications Committee

Creates and Distributes Patient Meeting Announcement Flyers
Sends out Polls to those who cannot attend
Creates and Distributes Newsletter to Mailing Lists (Patients, Researchers, and Clinicians)
Posts Material on Social Media
Facilitates private FB page discussions about relevant issues

Outreach and Announcements

- Website: http://cfreshc.org @CFReSHC1 @CFReSHC
- Newsletter: April 2020 @cfreshc

  https://mailchi.mp/cab2a9d61005/cfreshc-feb2020-newsletter-2612334?e=f229ffda54
- More Meeting Flyers:

WOMEN WITH CF:
JOIN OUR PATIENT TASK FORCE MEETING

EMAIL: INFO@CFRESHC.ORG FOR LOGIN DETAILS

BODY IMAGE

CFReSHC

MARCH 13, 2020
TIME HERE

CFReSHC

Women with CF: Join our Patient Task Force Meeting

HORMONES

Apr 29, 2020
3-5p EST

Email info@CFReSHC.org for login details

WOMEN WITH CF:

MENOPAUSE IN CF
JOIN US TO LEARN MORE

July 12, 2020
7-9pm EDT

CFReSHC

Email: Info@CFReSHC.org for details

Leveraging Patient Expertise to Advance CF Sexual & Reproductive Health Research

Sandy Sufian, PhD, MPH[1]; Georgia Brown, MLA[2]; Laura Mentch[2]; Molly Pam[2]; Melissa Shiffman, MSW[2];
Emily Godfrey, MD, MPH[3]; Lily Zheng[1]
[1]University of Illinois-Chicago; [2]CFReSHC; [3]University of Washington

INTRODUCTION

Our patient-engagement project, the Cystic Fibrosis Reproductive and Sexual Health Collaborative (CFReSHC): Promoting Sexual and Reproductive Health for Women with CF, empowered women with Cystic Fibrosis (CF) to identify sexual and reproductive health (SRH) research questions to remedy gaps in scientific knowledge and improve standards of care.

OBJECTIVES

- To provide a forum that leverages the experiential expertise of adult women with CF to advance CF-SRH research and care.
- To enable other chronic disease communities to adopt our programmatic structure to identify SRH research areas specific to their needs.

METHODS

- Disseminated a survey to 150 women with CF to prioritize the focus topics for the project.
- Held 9 monthly, two-hour virtual sessions to prevent cross-infection among women. Each patient-run session covered one CF-SRH topic, with an average of 14 members per meeting.
- Invited experts presented existing research in the first hour. Confidential breakout sessions in the second hour allowed attendees to share their experiences, discuss preset facilitation questions, identify research gaps, and formulate research questions.
- Attendees ranked their top three, patient-generated research questions to share with researcher-partners for translation into viable studies (n = 27).
- Participants received compensation for their time and expertise.

SELECT PRIORITY QUESTIONS

- Do CF patients enter menopause earlier than the general population? If so, why?
- What is the prevalence of vaginitis in CF patients?
- How do women with CF and their partners feel about going through the prenatal testing process?
- What are the barriers to discussing concerns about sexual infections in clinic?
- What is considered a healthy diet for people with CF now that new medicines dramatically affect weight gain?
- How do we inform primary care and women's health providers about patients' CF-SRH concerns?

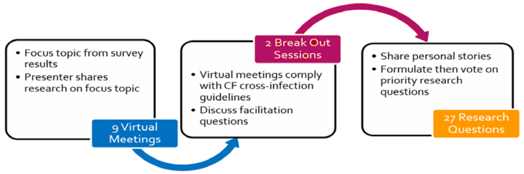
Women with Cystic Fibrosis propose highly innovative and relevant research questions *precisely* because of their proximity to, and *expertise* about, their illness experience.

★★★★

Our project structure provides a model for other chronic and rare disease communities interested in pursuing patient-driven research; in particular, for those that cannot safely or easily meet in person.

To learn more about this project,
please use this QR code
or visit www.cfreshc.org.

PROJECT STRUCTURE



- Focus topic from survey results
- Presenter shares research on focus topic

9 Virtual Meetings

- Virtual meetings comply with CF cross-infection guidelines
- Discuss facilitation questions

2 Break Out Sessions

- Share personal stories
- Formulate then vote on priority research questions

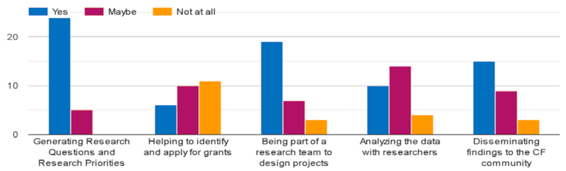
27 Research Questions

DISSEMINATION

We use our newsletter and social media outlets to announce meetings and to disseminate survey results.

POST-PROJECT SURVEY

What parts of patient-driven research are you most interested in?



TESTIMONIALS

- *"CFReSHC is an empowering community that brings much-needed attention to issues that affect all women with CF. As people with CF, we are experts in our own lives, and it means a lot to me to be able to speak openly and contribute my perspective."*
- (CFReSHC is) *"addressing issues that are so important and are not talked about enough and providing education that is invaluable."*
- (CFReSHC provides) *"a sense of community… regular meetings,* (with) *good facilitating,* (and) *clear goals."*

ACKNOWLEDGEMENTS

Cystic Fibrosis Reproductive and Sexual Health Collaborative
info@cfreshc.org | www.cfreshc.or | @cfre c | @cfreshc1

Funded by the Cystic Fibrosis Foundation Impact Award &
PCORI Eugene Washington Award
This is not a research project

By patients for providers and patients

- ➢ Chapter Writing Teams by Focus Topic (patients)
- ➢ Writing teams present draft during PTF meetings for feedback and brainstorming of questions re:
  - provider to patient questions
  - peer to peer advice
  - patient to provider questions
  - resources

Sample chapter:
https://docs.google.com/document/d/1Ean6zw6TSgm0yFwxRGprClgFeU8riW_svLHDZlB87sI/edit?usp=sharing

Chapter Team Patient Leader Packet:
https://drive.google.com/open?id=1ZQwKFKZkbbsHLYBn03VnhnMZlglQZqhw

Navigating Meetings Across Multiple Time Zones

Funding

Internet Access

Sustaining Interest

Scheduling Conflicts

Managing Technical Difficulties

Effective Virtual Patient Engagement requires:

- Team structure and protocols
- Processes for facilitating engagement
- Need to think about, plan for, and overcome common challenges
  - Think of as responsive, iterative process
- Persistence and multiple layers of consistent communication and marketing

Results:

- Relationality: Virtual engagement methods can engender trust
- Ensures safety and health; shows respect for these priorities
- Robust results and ideas for research and provision of care using PCOR principles

Thank You!

to PCORI &
PEAP

Appreciation and Farewells

Kristin Carman
Director, Public and Patient Engagement

Lisa Stewart
Senior Engagement Officer, Public and Patient Engagement

- **Thank you to:**
  - Sonya Ballentine
  - Katherine Capperella
  - Beverly Rogers
  - Brendaly Rodríguez
  - Norah Schwartz
  - Thomas Scheid
  - Freddie White-Johnson
- Photo Montage
- Farewell Padlet

Thank you, Sonya!

What they say…

Sonya Ballentine is a patient co-investigator on a Eugene Washington PCORI Engagement Award for a training and development project that engages African-American patients with serious mental illness to become research leaders. Her CBPR experience began in 2012 with her work on an NIMHD-funded peer navigator project in which she designed a peer navigator training manual for homeless African-Americans with serious mental illness in Chicago's Edgewater-Uptown neighborhood. **Representing: Patients, Caregivers, Patient Advocates**

What we know…

Generous beyond measure. Captivating public speaker. A vital force.

Thank you, Katherine!

What they say …

Katherine Capperella leads a global, cross-functional patient engagement leadership team responsible for developing and driving Janssen patient engagement strategy and measuring progress over time. She and her team are focused on incorporating direct patient voice into core processes, including disease area strategies, product development, clinical plans, pre-approval access, supply chain decisions and commercial strategies. She has over 20 years of experience at Johnson & Johnson in sales, marketing, and business development roles. **Representing: Industry**

What we know:

Global change agent. Bridge Builder. Creative. On a mission.

Thank you, Brendaly!

What they say….

Brendaly Rodriguez, manages the Community Engagement and Cultural Diversity Program of the Clinical and Translational Science Institute at the University of Miami (UM). At UM, Rodriguez managed the community outreach, research, and training activities of the South Florida Center for Cancer Disparities, where she first tested the community health worker (CHW)/promotora model as a culturally and linguistically appropriate intervention for women in South Florida. Rodriguez participated in the PCORI Latina Roundtable and joined the PCORI Ambassador program in 2014.

Representing: Patients, Caregivers, Patient Advocates

What we know…

Boundless energy. Visionary. Committed. Infectious goodwill.

Thank you, Beverly!

What they say…

When **Beverly Rogers**' husband was diagnosed with Alzheimer's disease, she made good use of many of the management skills she acquired as Director of two personal memberships at the American Hospital Association and Director of Chapter Services at Y-ME National Breast Cancer Organization. Those skills helped her through 12 challenging years of diverse healthcare relationships. Her passion is to empower and support family caregivers as they navigate healthcare and support systems for their loved ones while encouraging them to remember to take care of themselves. **Representing: Patients, Caregivers, and Patient Advocates**

What we know…

Wise. Believer in the power of community. Truth-teller. No mountain is too high.

Thank you, Norah!

What they say …

Norah Schwartz, is a Medical Anthropologist who has conducted ethnographic research with Mexican immigrant communities for the past 30 years. Her research centers around child health and breast cancer and aims to explore the lived experiences of patients and their families. Through interviews and photography, she helps patients explore issues that are of most importance to them, including the use of traditional medicine and seeking cross-border health care. As a breast cancer survivor, Dr. Schwartz understands the importance of maintaining affordable, accessible health care. **Representing: Researchers**

What we know…

Passionate advocate. Respect for all. Skilled researcher. Perseverance.

Thank you, Freddie!

What they say …

Freddie White-Johnson is the Program Director for the Mississippi Network for Cancer Control and Prevention at the University of Southern Mississippi. She founded the Fannie Lou Hamer Cancer Foundation in 2004, which is a 501(c)3 nonprofit community-based organization. In July 2014, she made history when she created and launched the first civil rights historic license plate in the state of Mississippi in commemoration of a civil rights leader, Fannie Lou Hamer, who died from untreated breast cancer. **Representing: Patients, Caregivers, and Patient Advocates**

What we know…

Justice. Grace and steel. Moral force. Strategic. The Legacy of Fannie Lou Hamer.

Thank you, Tom!

What they say….

Thomas Scheid, has extensive experience in shaping public policy and programs through engaging families and communities, and incorporating their perspectives into improvements of public programs. He had direct responsibility for community outreach and engagement as Ohio moved to providing health care through Medicaid managed care organizations. Tom is the Founding Director of the Welcome Home For Life Network which works to successfully re-integrate formerly incarcerated men into the community by providing them with support and connections to community resources. **Representing: Patients, Caregivers, and Patient Advocates**

What we know…

Flowing generosity. Statesmanship. Kind. Gifted Leader.

What’s Ahead

Events, Work Groups and Special Projects
Lisa Stewart, Michelle Johnston-Fleece, Krista Woodward, Christine Broderick, Denese Neu

Closing Remarks
Kristin Carman, Thomas Scheid, Gwen Darien

PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

What's Ahead

Upcoming Events

Lisa Stewart

Senior Engagement Officer, Public & Patient Engagement

What's Ahead: PEAP

New cohort of advisory panelists

  - Summer "lunches"
  - Approval by PCORI Board of Governors – August 2020
  - Orientation – PEAP Mentors needed

Fall Events – Save the Date

- 2020 PCORI Annual Meeting (A Virtual Event), September 16-17

  "Accelerating Impact on Care and Patient Outcomes"
- PCORI Ambassador Workshop (TBD)
- PEAP Meeting – October 22-23, 2020 (A Virtual Event)

What's Ahead

Resources for Multi-stakeholder Teams

Michelle Johnston-Fleece

Senior Program Officer, Public & Patient Engagement

Upcoming Resources for Engagement Practice

1. Provide **foundational knowledge in PCOR/CER to non-scientist participants** on research and other projects, and to patient and stakeholder merit reviewers, peer reviewers, and PCORI Ambassadors.
2. Provide **training and resources to support multi-stakeholder teams** in both the engagement of patient and stakeholder partners and effectively working together (i.e., team science).

Self-paced and focused on **just-in-time needs** throughout the PCOR process.

WELCOME

Research Fundamentals Learning Package

start

Research Fundamentals Structure

Learning Need Navigation Tool


The PCORI
Approach to
**Patient-Centered
Outcomes
Research**

pcori
Patient-Centered Outcomes Research Institute

Interactive PDF


Engaging in Stakeholder-Driven Research

Video-Based Module

Developing Research Questions

Designing the Research Study

Planning Patient-Centered Consent and Study Protocols

Sampling, Recruiting, and Retaining Study Participants

Understanding and Sharing Research Findings

Five Interactive Learning Modules

Updates due to COVID-19 Context:
Completion & Launch of Research Fundamentals

- **Research Fundamentals**
  - Exact launch date TBD, but anticipate mid-July
    - This represents a shift, and decoupling launch from the Annual Meeting session
  - As launch activities take shape, we will keep you apprised so you can share with your networks

What's Ahead: Learning Packages

Survey

- You will receive a survey for your input on:
  - Sources where you get information on research
  - Influencers that may promote the tools
  - New title for Working as a Team learning package

Contingency planning if Annual Meeting goes virtual

- Will need to alter the format of the Working As a Team breakout session and find different ways to collect recordings for podcasts and videos to be included in the learning package
  - May contact the PEAP for ideas on how to reformat to virtual session
  - May invite you to audio or video record research-related experiences that illustrate specific themes for use within the learning package

What's Ahead

Studying PCORI's Patient-Centered Approach (PCA) Workgroup

Michelle Johnston-Fleece

Senior Program Officer, Public & Patient Engagement

What's Ahead: Studying PCORI's Patient-Centered Approach (PCA) Work Group

Work Group Objective

- To advise on 1) PCORI's evaluation agenda, 2) projects to build evidence about promising practices for patient-centered research, and 3) projects to assess effectiveness of PCORI's approach to patient-centered research

Recent and Ongoing Activities

- Early March: Kick-off meeting
- Mid-March: Group provided input on a new project to conduct a landscape review and analysis of measures of engagement
- Ongoing: 1 PCA member is serving on the Project Advisory Group for the engagement measures project

Upcoming Activities

- Next meeting has been delayed while staff respond to COVID-related priorities, but we anticipate meeting again to advise on another project in the next 1-2 months

What’s Ahead

Ambassador Workshop

Krista Woodward

Program Officer,
Public & Patient Engagement

What's Ahead: Ambassador Workshop Planning

Workgroup Objective

- The Ambassador Work Group will advise and consult on the upcoming Ambassador workshop session topics, format, and engagement activities.
  - There will be an emphasis on DE&I and how to continue the PEAP's work and share with the broader PCOR community.

Ongoing & Future Activities

- The Ambassador Workgroup last met in April but will resume monthly meetings.
  - Contact Krista Woodward (kwoodward@pcori.org) if you would like to join this workgroup.
- Workgroup members will help create a vision for an Ambassador panel discussion and an interactive session related to DE&I.
- More to come!

What’s Ahead

Knowledge Translation and Uptake

Christine Broderick
Engagement Officer,
Public & Patient Engagement

What's Ahead:
Knowledge Translation and Uptake

Objectives

- To advise on (1) Translating and motivating uptake of key learnings about engagement in PCORI-funded research (2) Audiences, messages, strategies and approaches (3) Informing future research and practice

Upcoming Activities

- Prioritization by PCORI staff
- Form smaller working groups based on content or format
- Iterative process of workshopping ideas and strategies for packaging, promoting and encouraging use

What’s Ahead

DE&I

Denese Neu

Engagement Officer,
Public & Patient Engagement

What's Ahead: DE&I – PCOR Engagement Principles, Recommendations for PCORI

The fast road to writing draft recommendations …

When	Activity
6/12	Padlet will close for comments and input
6/15-6/26	Review, synthesis, integration of workshop comments
6/29-7/3	Agenda and content planning for next DEI workgroup meeting
7/10 (tentative date)	DEI workgroup session meeting
7/13-8/14	Collect personal experience for case studies/principles in practice
8/17-8/28	Draft recommendations for PCORI
8/31	Workgroup co-chairs submit recommendations

Closing Remarks

Kristin Carman and Tom Scheid

Thank You!

Adjourn

Please take this time to complete the [post-meeting survey]()