Welcome!

Overcoming Compliance Concerns and Barriers to Patient Engagement
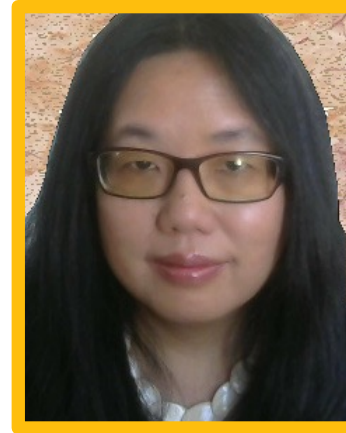
Presenters

Laura Perry

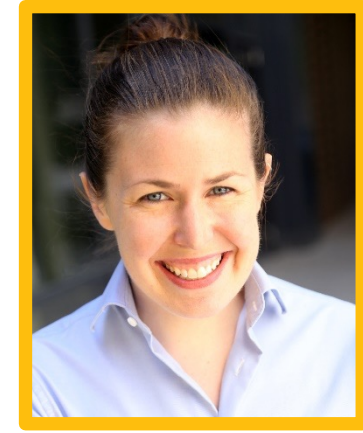Vice President
Cactus Life Sciences

Maarten Beekman, MD

Managing Director
Medical Impact+

Lily Chu, MD, MSHS

Vice President

The International Association for Chronic Fatigue Syndrome/ Myalgic Encephalomyelitis

Katie MacTurk, MS

Executive Research Director Health Union

Today's Learning Objectives

Identify assets for guidance to relevant information related to patient engagement

Apply solutions for inclusion of the patient perspective in Medical Affairs deliverables and development of clinical trial protocols

Recognize best practices/key insights on how to work with patients in a compliant manner

Provide guidance in developing your patient engagement strategy at your organization

2022 Workshop and Benchmark of Key Findings

Transforming Patient Centricity to Patient Inclusive within Medical Affairs

1. 25% of participants polled strongly agree and 75% agreed that their organization should do more than they are currently doing to become patient inclusive

2. The majority of participants reported that they do not work on any co-creation of education materials with patients, but would like to in the future

3. Compliance was the major hurdle in becoming a true patient centric company

Good Patient Engagement Practices®:

How to Start or Enrich Your Patient Engagement Strategy & Organization

Maarten Beekman, MD

Polling Question #1

Patient Engagement in my Company

A. Is well-established, we have a clear organizational structure and standard operating procedures in place and involve patients/caregivers in all what we do

B. Is reasonably established, we have a clear organizational structure in place, some standard operating procedures and involve patients/caregivers in most of what we do

C. Is somewhat established, we have some individuals working with patients/caregivers, some standard operating procedures in place and sometimes involve patients in what we do

D. Is not established, we don't have an organizational structure in place, no standard operating procedures and we don't involve patients in what we do

Conflict of Interest and Disclosures

- I don't have a conflict of interest

- "Collaborative Patient Engagement: Mapping the Global Landscape" by PFMD is licensed under CC BY-NC-SA 4.0. I have selected relevant material from the PFMD website, did not change any of the content and would like to thank and give credit to the authors and contributors of the relevant documents of PFMD in the hand-out.

- I have selected relevant material from the EUPATI website, did not change any of the content and would like to thank and give credit to the authors and contributors of the relevant documents from EUPATI in the hand-out.

- I have selected relevant material from the PARADIGM website, did not change any of the content and would like to thank and give credit to the authors and contributors of the relevant documents from PARADIGM in the hand-out.

Introduction

The main reason for being for Medical Affairs is to catalyze a change in clinical practice and/or policy based on robust science and real-world experience with the ultimate goal to provide better lives to people living with a disease (and to their caregivers)

Therefore, it is of utmost importance that Pharma and Biotech companies engage with patients (and their caregivers) to ensure these better outcomes

The reality is that there are still many Pharma and Biotech companies without a strong Patient Engagement strategy fully implemented, often as a result of perceived compliance risks

But not engaging with patients (and their caregivers) may become a bigger risk than engaging with them. With the information in this presentation, you will find useful information, standards, documents and tools to compliantly start or enrich your Patient Engagement strategy and organization

For this presentation, I have consulted the websites of three organizations, all active in Patient Engagement:

PFMD: **P**atient **F**ocused **M**edicine **D**evelopment

PARADIGM: **P**atients **A**ctive in **R**esearch **A**nd **D**ialogues for an **I**mproved **G**eneration of **M**edicines


EUPATI: **EU**ropean **P**atients' **A**cademy in **T**herapeutic **I**nnovation

Please consult the **downloadable hand-out** which contains links to all relevant documents

RESOURCE GUIDE
MARCH 2023

Good Patient Engagement Practices®

HOW TO START OR ENRICH YOUR PATIENT ENGAGEMENT STRATEGY & ORGANIZATION

Maarten Beekman, MD

How do I start?

- **Building trust** with the patient and caregiver's community **is a critical success factor in Patient Engagement.** Pharma and Biotech companies should develop a transparant framework with a clear description of roles and responsibilities, quality measures and ways of working.

- The following resources are recommended to use as a foundation on which to build your Patient Engagement strategy and operations:
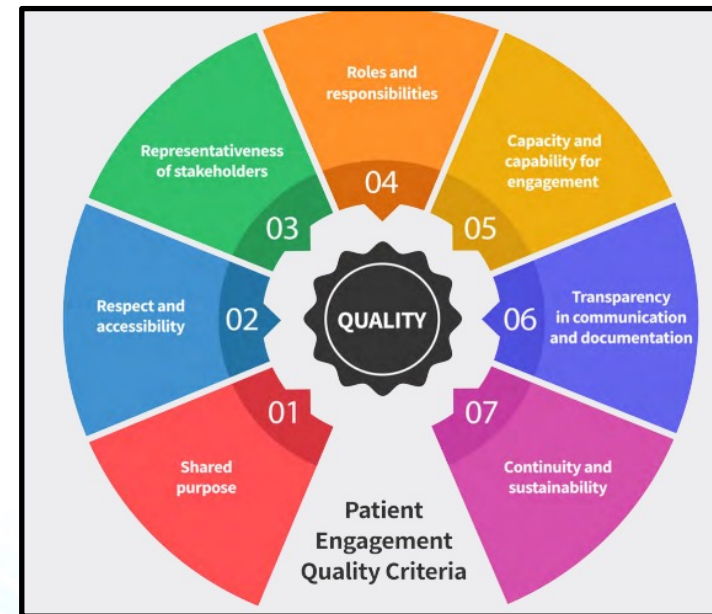
How do I know we have the right capabilities to engage with patients?

- **Understanding the capabilities needed** to ensure quality and effective engagement with patients and caregivers **is also a critical success factor in Patient Engagement**.

- Pharma and Biotech companies should perform a thorough assessment of the available capabilities within the companies as well as a proper gap analysis. Training and/or acquisition of talent may be needed to ensure the right capabilities for Patient Engagement.

The following resource is recommended:
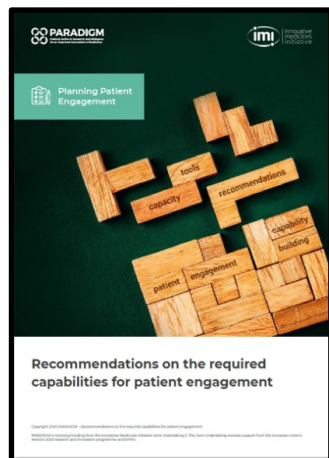
This tool provides recommendations on the competencies (understood as knowledge, skills and behaviours) and resources that each stakeholder organisation should aspire to have in place in order to plan, implement and evaluate meaningful and sustainable Patient Engagement activities across the medicines lifecycle.

Are their practical guidance's available that will help me to accelerate my Patient Engagement activities?

POLICY AND PRACTICE REVIEWS
published: 09 October 2018
doi: 10.3389/fmed.2018.00270

frontiers in Medicine

Check for updates

EUPATI Guidance for Patient Involvement in Medicines Research and Development (R&D); Guidance for Pharmaceutical Industry-Led Medicines R&D

OPEN ACCESS

Kay Warner[1*†], Wolf See[2†], David Haerry[3†], Ingrid Klingmann[4†], Amy Hunter[5†] and Matthew May[6†]
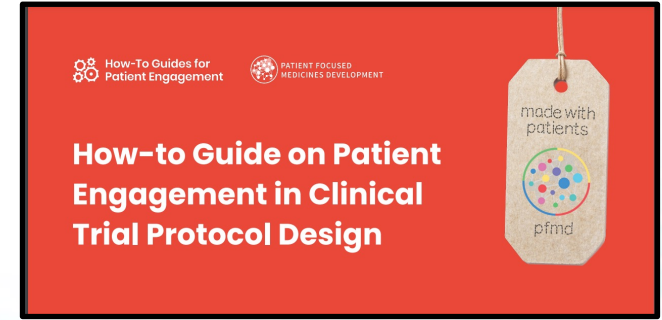
The EUPATI Guidance Document in this article aims at providing recommendations for ground rules and proposals for the integration of patient involvement across the entire process of medicines R&D in the pharmaceutical industry

And outlines specific activities where patients can be involved and influence future medicines research and development

Are their practical guidances available that will help me to accelerate my Patient Engagement activities?

PFMD developed a number of practical **"How To Guides" for Patient Engagement** that aim to provide specific support in Patient Engagement efforts, on key activities across the medicine development lifecycle

How-To Guides for Patient Engagement · PATIENT FOCUSED MEDICINES DEVELOPMENT

How-to guide for patient engagement in the early discovery and preclinical phases

This How-To guide is part of a series of PFMD How-To guides that have been co-created in a multi-stakeholder environment built with the Patient Engagement Quality Guidance as a starting point. All How-To's are connected and provide a full set of instructions on how to involve patients across the research, development, and delivery of medicines

made with patients · pfmd

How-To Guides for Patient Engagement · PATIENT FOCUSED MEDICINES DEVELOPMENT

Plain language summaries (PLS) of peer-reviewed publications and conference presentations: practical 'How-To' Guide for multi-stakeholder co-creation

This How-To guide is part of a series of PFMD How-To guides that have been co-created in a multi-stakeholder environment built with the Patient Engagement Quality Guidance as a starting point. All How-To's are connected and provide a full set of instructions on how to involve patients across the research, development, and delivery of medicines.

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How-To Guides for Patient Engagement · PATIENT FOCUSED MEDICINES DEVELOPMENT

'How-To' Guide on patient engagement in the development of a Clinical Outcome Assessment (COA) strategy

made with patients · pfmd

How-To Guides for Patient Engagement · PATIENT FOCUSED MEDICINES DEVELOPMENT

How-to Guide on Patient Engagement in Clinical Trial Protocol Design

made with patients · pfmd

Are there examples of Best Practices in Patient Engagement?

PFMD published three "**Books of Good Practices**".

If you are a starter in Patient Engagement, this book can offer you guidance and ideas on how to get it right. This tool can also be used **to reach a common agreement about what is "good practice" in Patient Engagement**.

The examples in the books demonstrate the quality and impact of the Patient Engagement activities:
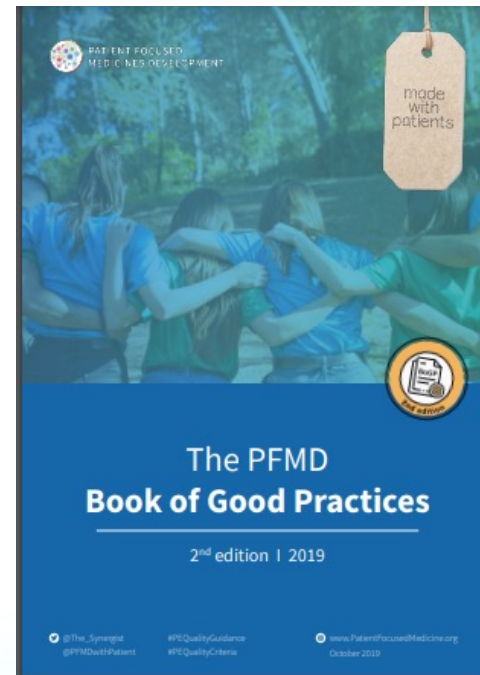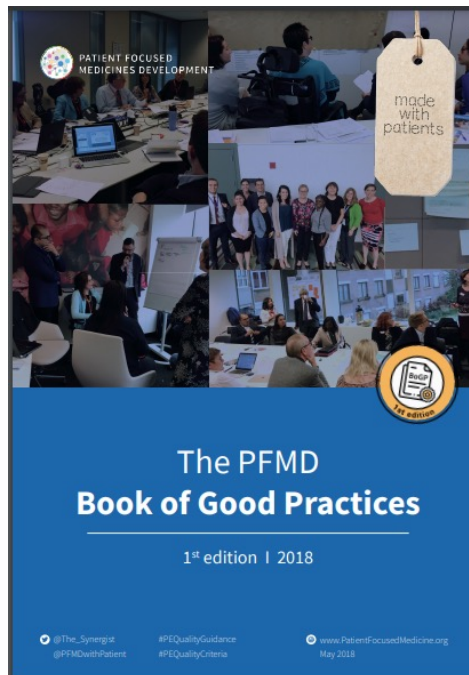
Are there examples of Best Practices in Patient Engagement?

The **Patient Engagement Synapse** is an online tool to capture and map key information from Patient Engagement initiatives across the globe. The below screenshot of the countries allows you on the website to discover some of the most active organizations, people, initiatives and resources in Patient Engagement:
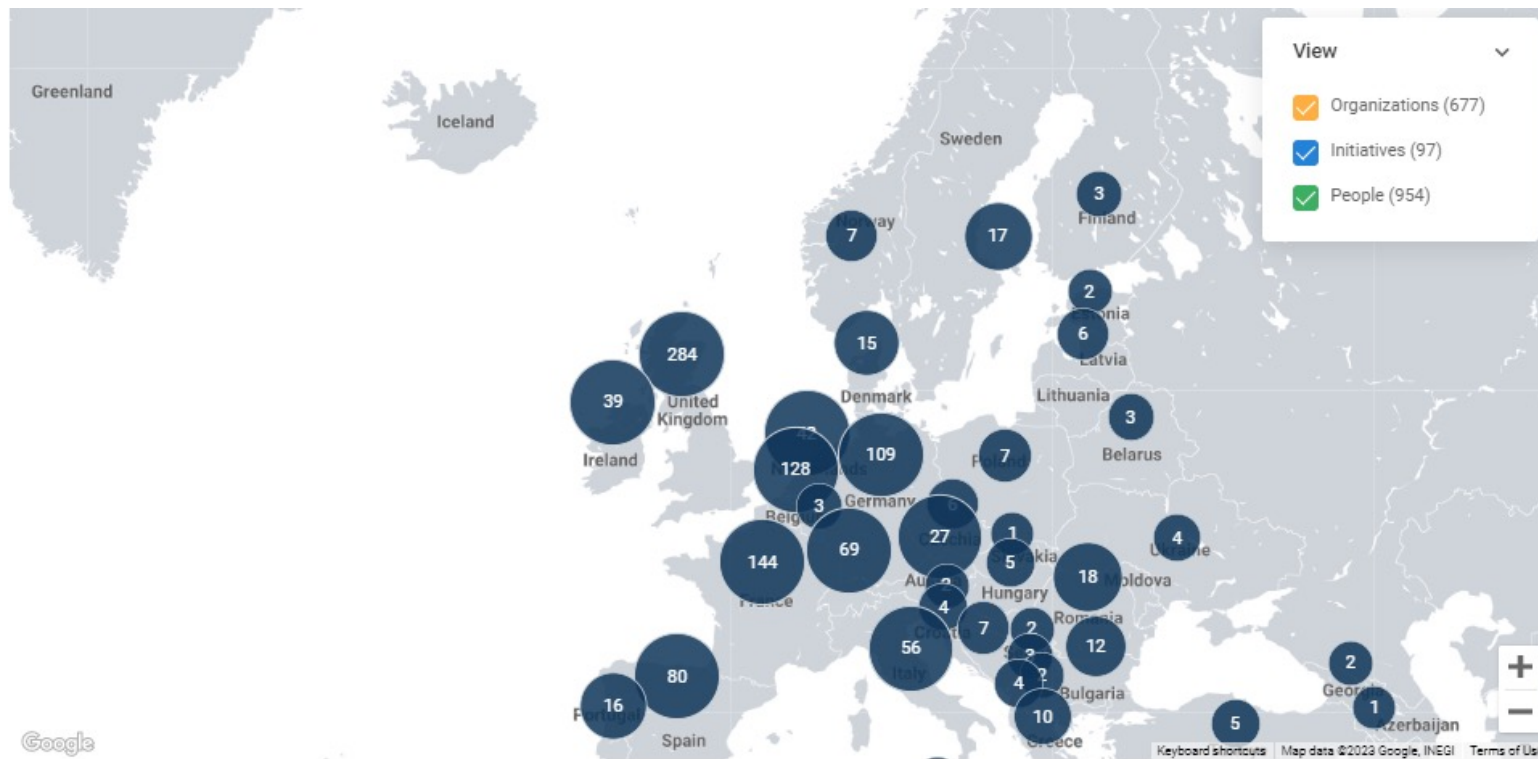
Conclusions and Recommendations

There is a wealth of information and guidance available on how to engage with patients in a compliant way, so **no need to re-invent the wheel**, just steal shamelessly!

Collaborate with your cross-functional colleagues, like Compliance and Legal, to develop your own standards and procedures and integrate Good Patient Engagement Practice (GPEP) as part of your GxP management system

Please **download the hand-out** where you can find all the relevant links to the documents I discussed (and many more!)

Helpful Guide with Resources Discussed

RESOURCE GUIDE
MARCH 2023

Good Patient Engagement Practices®

HOW TO START OR ENRICH YOUR PATIENT ENGAGEMENT STRATEGY & ORGANIZATION
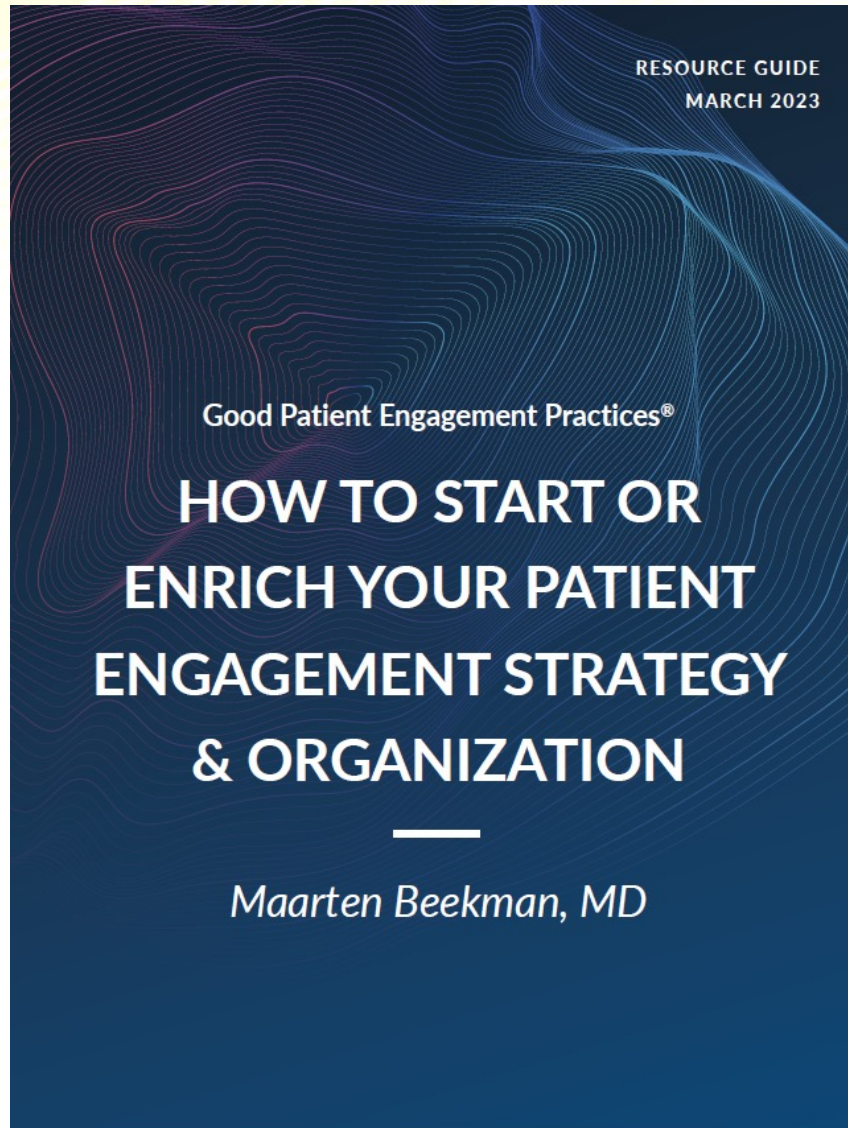
Maarten Beekman, MD

This link will be available on MAPS website by Monday.

For questions and/or feedback, please email: maartenjbeekman@gmail.com

Overcoming Barriers to Patient / Caregiver-Engaged Research

Lily Chu, MD, MSHS

Conflict of Interest and Disclosures

NO financial conflicts of interest to disclose

Contents of this talk are solely my own thoughts and opinions. They do not necessarily represent the official views of the International Association for Chronic Fatigue Syndrome/ Myalgic Encephalomyelitis (IACFS/ME).

What is patient/ caregiver (PC)-engaged research?

Photo by Kampus Production, Pexels

PC
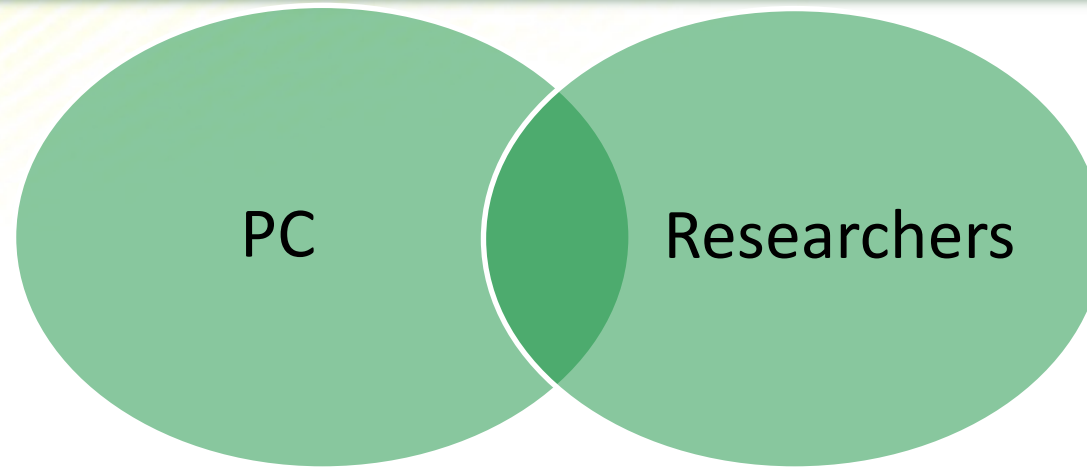
Researchers

Photo by National Cancer Institute on Unsplash

"Research conducted **by/ with** PCs not only **to/ for** them"

Why?

Lead to effective, practical, acceptable treatments

Generate new ideas

Improve patient recruitment/ retention

Meet public, regulatory, funder requirements

Survey responders : ME/CFS and long COVID

- Community dismissed, ignored
- UK PACE: $6 million/ time wasted; FOIA lawsuit
- Private PC e-group; personal contacts
- Active in clinical care, research, advocacy
- 80% involved in research before

Which group do you identify with most?

PC = patient/caregivers
PC - L = PCs leaders/ advocates
PC - P = PC & work in science/health field

N = 23

- 26.1% PC-P
- 34.8% PC
- 30.4% PC-L
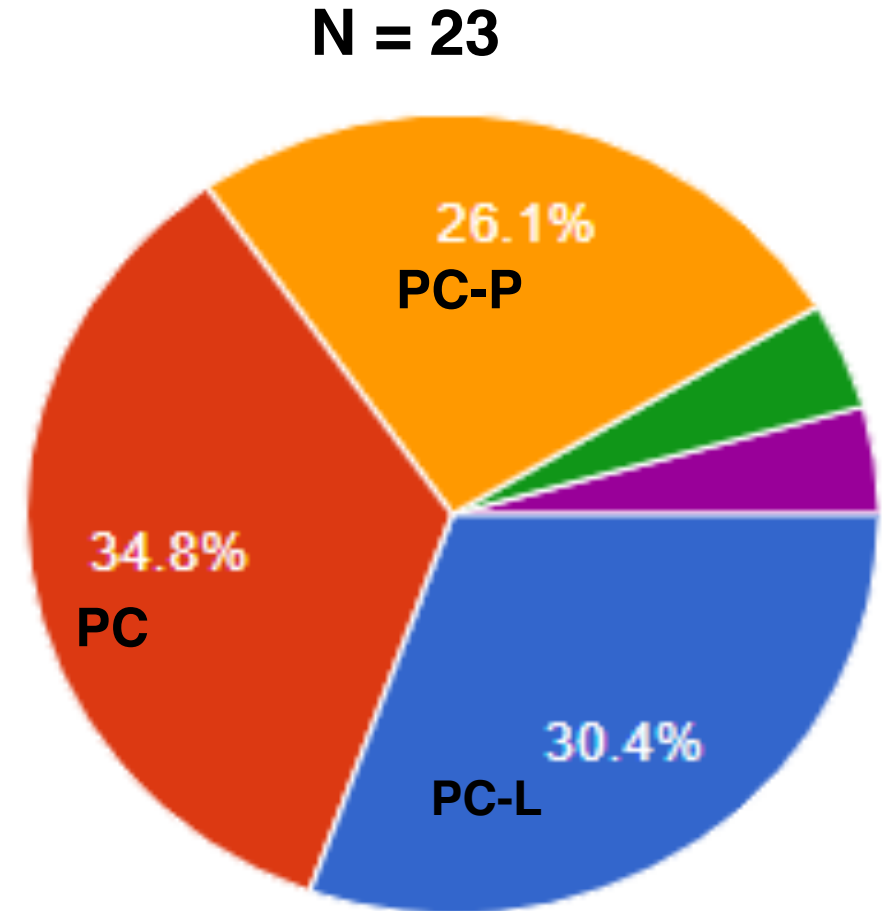
Polling Question #2:

What do PCs believe to be barriers to engagement?

What discourages you/ others from engaging?

Reasons (y-axis)

- LACK OF INCENTIVES — 5
- OTHER OBLIGATIONS (WORK, SCHOOL) — 10
- LACK OT TIME — 6
- HEALTH CHALLENGES — 18 — 82%
- DOUBT STUDY VALUE — 9
- DOUBT INVOLVEMENT IMPACT — 16 — 73%
- LACK OF TRUST IN ORGANIZERS — 15 — 68%
- UNCLEAR INFORMATION — 13 — 59%
- NOT "RIGHT" PERSON — 3
- CONCERNS ABOUT LACK — 5
- LACK OF MED/ SCI KNOWLEDGE — 7
- NOT ASKED FOR INPUT — 18 — 82%

Number of Answers (x-axis: 0 2 4 6 8 10 12 14 16 18 20)
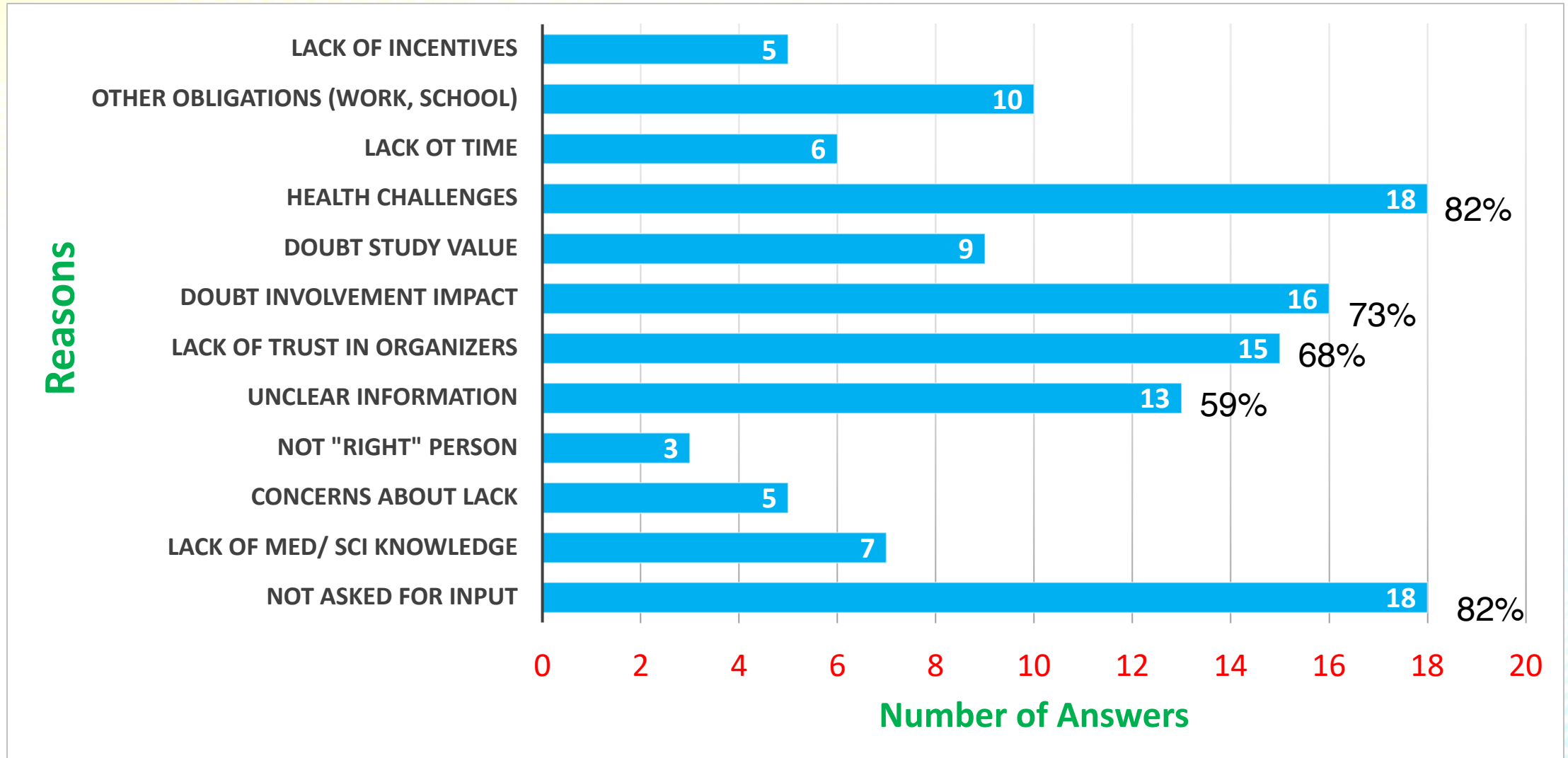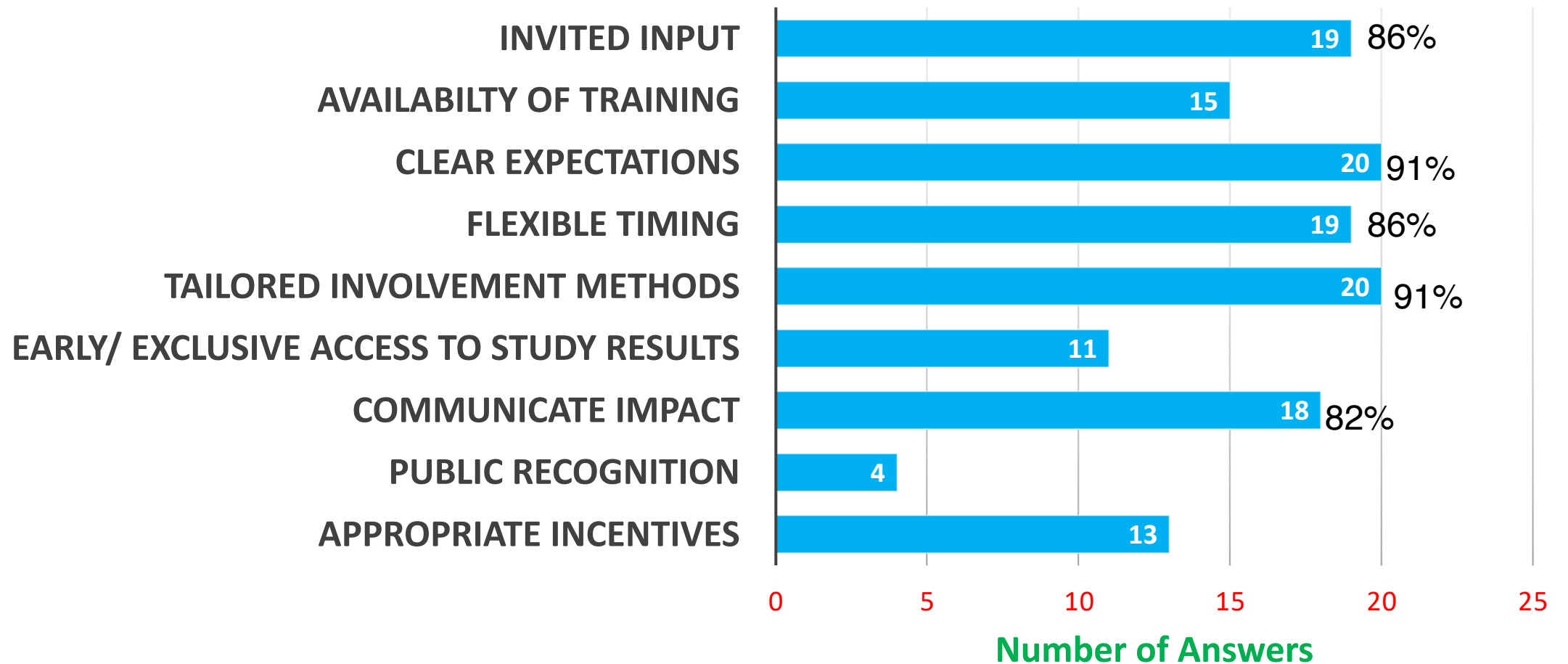
Facilitating PC engagement

Ask! Consider what you want to know, who to ask.
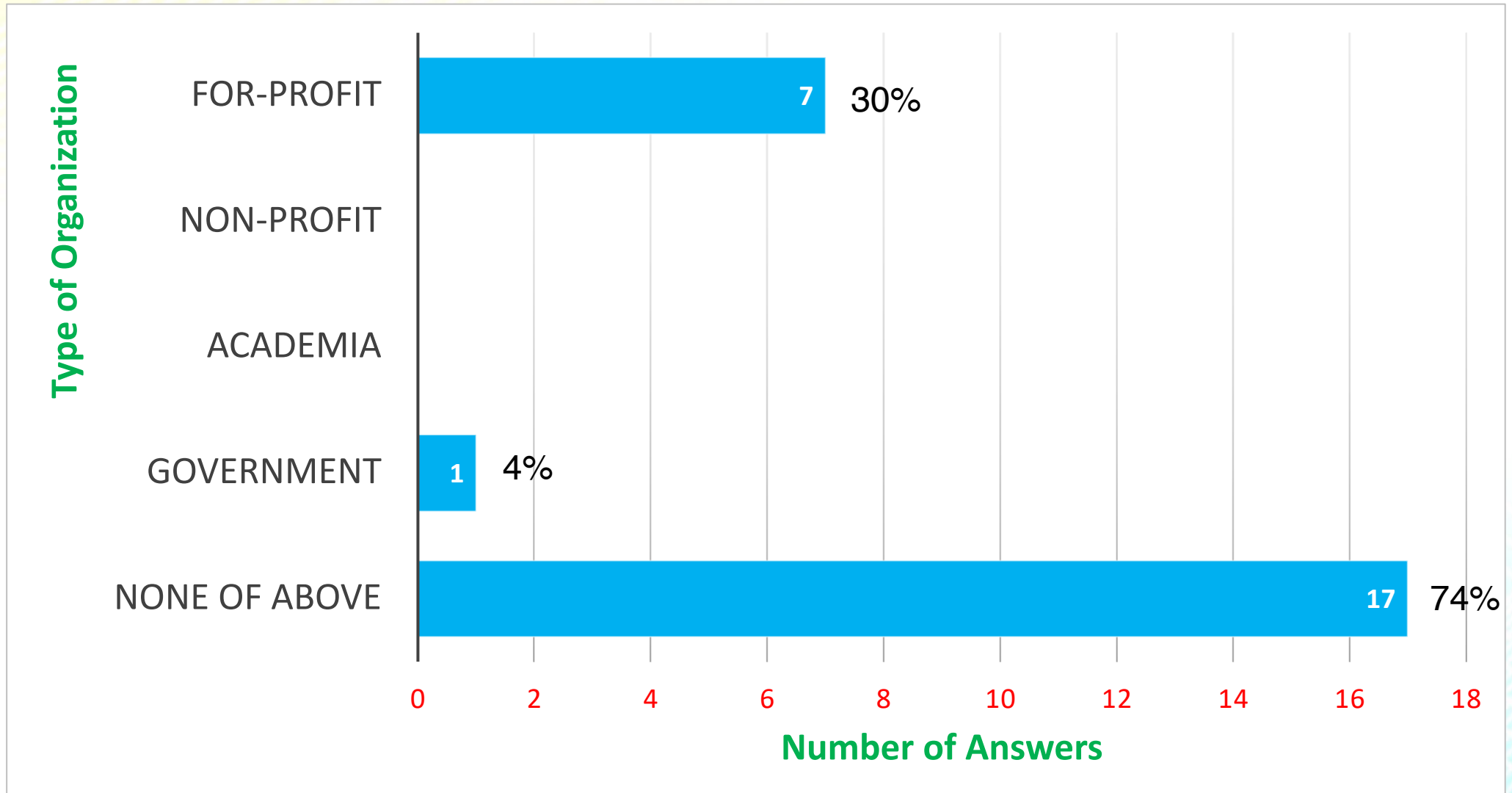
Outline expectations and involvement

Offer appropriate medical/ scientific training

Tailor participation methods and timing

Communicate impact. How did PC input affect study?

Which are you concerned about engaging with?

What are your concerns?

1. Profit Motive:

"What is the pharmaceutical company giving me?, They're motivated by profit, so I'm hesitant to trust their motivations."

"[C]ritical drugs [are not] readily available for people….. they do not care about the well being of people….. only care about profit and exploiting patients."

2. Lack of objectivity/ transparency:

"….concern that my name would be associated with a study which might involve the spinning of data…. by a for profit organization."

"My data would be used to support something I ethically disagree with and I would have no power or options to prevent it."

3. Data safety/ confidentiality:

"concerns about the objectivity of for-profit organizations and data-safety/confidentiality in studies involving for-profit groups."

Developing and building trust

Lessons from community-based participatory research (CPBR) → MA

"Collaborative approach; equitably involves all partners; recognizes strengths each brings."

1. Learn about history of community & research
2. Designate specific person(s) – including leaders - for PCs to contact
3. Use plain language, understandable terms
4. Ask PCs what they need to participate meaningfully
5. Conduct relationship "check-ups"

Summary

PCs are eager to participate as research partners.

Top barriers: not being asked for input, health challenges, doubts about involvement impact, lack of trust, unclear information.

There are many ways to overcome these barriers and build trust.

Conflict of Interest and Disclosures

No financial conflicts of interest to disclose

Health Union is a company that, among other services and products, provides research / engagement services that can be used to obtain patient / caregiver input

You think you need patient input. Now what?

This part of the discussion will focus on key information you need to know and keep in mind at all phases of engagement

Before Engagement → **During Engagement** → **After Engagement**

Most of discussion will focus here!

Key items to know prior to engagement

1 **What** — Key question / objective you need information about

2 **When / How Long** — Scope of engagement / time period

3 **Who / How Many** — Respondent pool

4 **How** — Avenue / path for engagement

Establishing Objective and Identifying Scope

1

Establish Key Question / Objective	**What do you want to hear from patients / caregivers about?** **What decision(s) will this inform?**	1. I want to understand how to increase clinical trial enrollment and adherence in metastatic lung cancer 2. I need to make sure that my development program for ASSET in psoriasis takes into account patient perspectives, needs, and preferences

2

Identify Scope	**How many times do you need to talk with a patient/caregiver?** **Over what time period?**	1. Talk with patients/caregivers once at outset of trial / finalization of protocol 2. Talk with patients at multiple time points throughout development program

Who do you want to talk with?

3

Identify Respondent Pool

What characteristics do the patients / caregivers need to have?

How many individuals do you want to talk with?

What level of knowledge or expertise is required to answer questions?

Do patients / caregivers need to speak for just themselves – or speak to the experiences of many?

Everyday Patient

- Can speak only on behalf of self (/loved one)
- Little (known) expertise beyond experience with condition
- More representative of "real world" patients
- Typically need more respondents (depending on number of key subgroups)

1. Patients living with metastatic lung cancer (and/or their caregivers) with similar characteristics as trial population (e.g., # of lines of therapy, necessary mutation status, etc.)
   - ~15 respondents (for qualitative discussions)

Expert / Trained Patient

- Can speak on behalf of other patients ("patient leader/advocate")
- Can know more about a specific topic and provide more informed opinions (e.g., knows how clinical trials work, familiar with drug development process, etc.)
- Typically need fewer respondents

2. Patients living with psoriasis who know the psoriasis treatment landscape, experiences & emotions of other patients; some knowledge of drug development a plus
   - ~2-5 respondents (for qualitative discussions)

2 Paths to engagement

4

Determine Path of Engagement

How will you find the patients / caregivers?

How will you handle logistics of conversations, contracting, etc.?

What type of interaction will you have? (e.g., qualitative discussion, online survey, etc. – *not discussed here*)

Pharma engages via 3rd party	Pharma engages directly
• 3rd party can: find patients, handle patient personal information and data, coordinate logistics, draft of materials to be used (screening form to qualify patients, questions to ask, etc.) • Can be especially helpful when first starting out – 3rd parties are experienced at 'translating' pharma questions into methodology, questioning for patients	• Pharma identifies/finds patients (can also be with help of outside partner, like advocacy organizations) • Contracts directly with patients for their time (& compensates appropriately) • Members of company speak directly back & forth with patient(s)
1. Pharma contracts with 3rd party, who will draft screening & discussion materials, recruit metastatic lung cancer patients & lead discussions about clinical trials, provide report of findings *(Pharma reviews, provides input, and approves all materials)*	2. Pharma identifies 3 psoriasis patient advocates and contracts with each for an hourly consulting rate; company individuals talk with them ~every 3 months (either individually or as a group) to get input on various topics

Practices to ensure quality & compliance

Pharma Legal / Compliance Review

Standard practice for materials to be reviewed by medical / legal / compliance team to ensure proper disclosures, adherence to required guidelines, etc.

IRB Approval / Exemption
(optional)

Can help those less familiar with patient engagement research feel comfortable that research is compliant with guidelines, industry-standard practices

Recommended if you intend to publish results

Health Literacy Review
(optional)

Team inside pharma company (or outside entity) can review all respondent-facing materials to ensure communication is at the appropriate level

I'm about to talk with patients. Now what?

Make It Easy
Schedule discussions around patient schedules, conduct via web to further facilitate participation

Share Rationale
Tell patients the impact of their participation: how will this help them? How will this help others?

Set Expectations
Be clear about how long engagement will last, what topics will be covered, what patient will need to do/bring/share

Be Upfront, Transparent
Tell patient in clear, straightforward terms: who will handle personal information, what will be shared with whom (data safety, confidentiality)

Emphasize openness, neutrality
Share that pharma representative is neutral – not there to change patient thoughts, just to hear *all* their thoughts / perspectives (even if negative or critical)

Keep in mind the key concerns about pharma from patients:

Profit motivation for actions   *Lack of transparency*   *Data security/confidentiality*

What to do now? Follow through!

With Patient Respondents

Compensate as established at engagement initiation

Be clear about any next steps / follow up

Continue to establish company as trustworthy

With Patients Broadly

Take learnings from engagement and apply them!

Improving patient experiences is the reason for engaging!

With Your Organization

Document process and assess what worked, what didn't, & what could be done better to improve future engagements

Have record of findings & share within organization

Make future patient engagements better

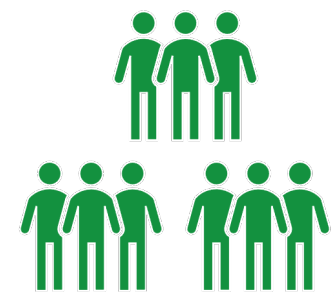# What is the impact of patient discussions?

Engaging with patients directly can be beneficial on multiple levels

Patients spoken with during engagement can feel heard, like pharma cares

Patients have improved experiences with pharma (e.g., better clinical trial experience [apart from experience with treatment itself])

More patients have access to new treatment given successful clinical trial

Barriers/ facilitators to clinical trial enrollment

Category	Examples
About the Study	general attitude towards research, study procedures
About the Participant	age, gender, health issues
About Information	confusing information, misconceptions
About Others	altruism, media influence
About Costs & Benefits	financial compensation

Rodríguez-Torres E, González-Pérez MM, Díaz-Pérez C. Barriers and facilitators to the participation of subjects in clinical trials: An overview of reviews. 2021.

Polling Question #3

Based on today's webinar, please rate from 1-5 if you feel this information made you more prepared to act on the following:

1. Identify assets for guidance to relevant information related to patient engagement

2. Recognize best practices/key insights on how to work with patients in a compliant manner

3. Apply solution to inclusion of the patient perspective in Medical Affairs deliverables and development of clinical trial protocols

4. Provide guidance in developing your patient engagement strategy at your organization

Panel Discussion and Q&A

Thank you to the attendees and our panelists: Maarten Beekman, MD, Lily Chu, MD, MSHS, Katie MacTurk, MS and Laura Perry.

We hope the attendees have found this webinar instructional. This webinar recording and corresponding PowerPoint deck will be uploaded to the MAPS website Content Hub by next week. Questions that we did not have time to respond to will be posted later to LinkedIn with responses. This concludes the webinar.