

PATIENT CENTRICITY in Medical Affairs: Identifying and Overcoming Barriers

Presented by the MAPS Patient Centricity Focus Area Working Group

Presenters



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Conflict of Interest and Disclosures

- Betsy Williams is employed by IQVIA
- Jessica Santos is employed by Oracle
- Rebecca Vermeulen is employed by Genentech, a Member Company of Roche

The opinions expressed herein are the presenters' own and do not reflect the opinions or interest of the companies who employ them.

Educational Objectives

This session will provide a learning opportunity for our audience by:

- Sharing insights from the recent MAPS Patient Centricity Survey on industry perspectives
- Providing guidance and potential solutions on addressing major barriers for Patient Centricity Initiatives identified through the survey

MAPS conducted a survey to better understand Patient Centricity (PC) in practice, followed by individual interviews


Goal:

Gain a deeper understanding on how patient centricity lives in different organizations, including best practices, current trends, specifics about barriers, and opportunities to overcome those

Approach:

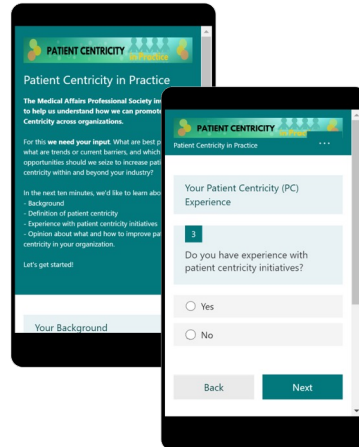
Survey Medical Affairs professionals and industry members November 2022 (n=133)

Follow up interviews with experienced Medical Affairs professionals March - May 2023 (n=11)

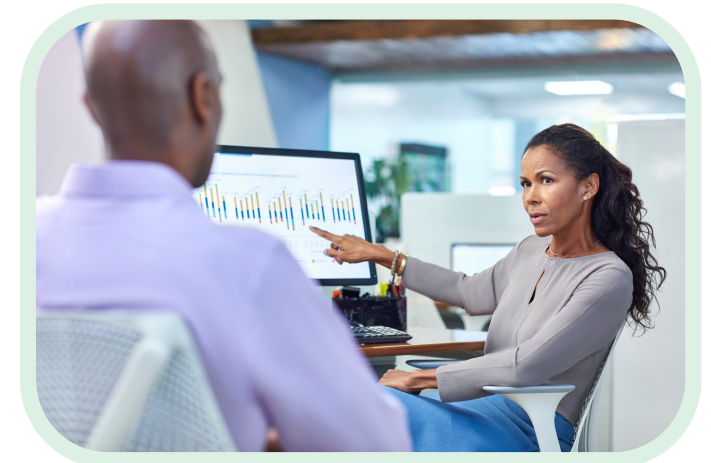
Direct outreach  to MAPS members



LinkedIn



In-person and remote, single and panel interviews



Perspective on the meaning of Patient Centricity in organizations varied widely



- What it is (Definition)
- Who is responsible
- What initiatives are in scope without overstepping boundaries
- What is its impact/return
- How does it transfer to day-to-day routines for individual roles

Patient Centricity in organizations

“Everything we do is around patients”.

"If we can't track down in some ways what [our product] means for the patient at the end, then we probably shouldn't be doing [the work we do] or don't need to be doing it".

"In very small emerging company, there's a **not a lot of familiarity with the concept** of Patient Centricity. (...). Pretty much it's Medical Affairs only talking about it”.

“I **haven't heard the term** patient centricity (...) We see our end user as the prescriber and the person that applies the product and not necessarily the patient”.

High

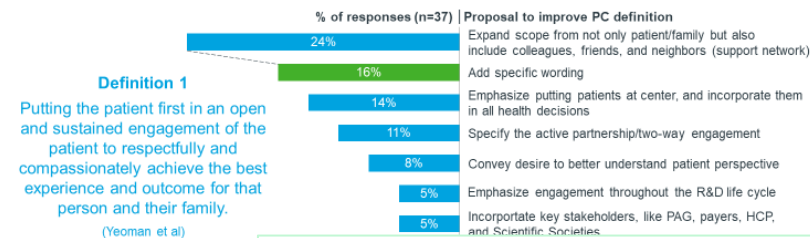
Low

Based on feedback from the survey, the FAWG developed a definition of Patient Centricity in Medical Affairs

1. Received feedback on 2 current definitions for Patient Centricity

2. Developed Definition for Patient Centricity

The first Patient Centricity definition may benefit from including patient's support network and mutual, active engagement

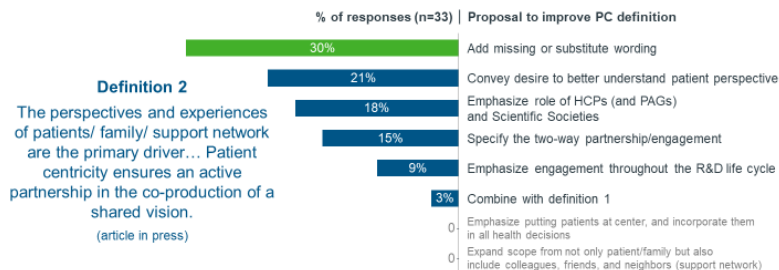


Proposals to add specific wording

- ... and deliver and provide in convenient manner
- ... without financial cost
- ... best and safest evidence

PC: Patient Centricity, HCP: Health Care Provider, Multiple proposals per response possible
IQWiM-MAPS Survey

Per the responses, definition 2 needs word smithing and more emphasis on patients' perspective and HCP support



Proposals to add missing or substitute wording

- ... to give more confidence for their life.
- ... needs. (perspective and experiences...)
- ... and access to affordable, cost-effective care that ensure optimal outcomes
- It is people centricity, where ...
- ... of a shared vision *resources and learnings.*
- ... in the co-production *co-construction of...* (2x)
- ... in the co-production *achievement of...*
- ... in the co-production of a *co-creation of solutions based on the shared vision.*

PC: Patient Centricity, HCP: Health Care Provider, Multiple proposals per response possible - % does not add up to 100%
IQWiM-MAPS Survey

What is Patient Centricity in Medical Affairs?

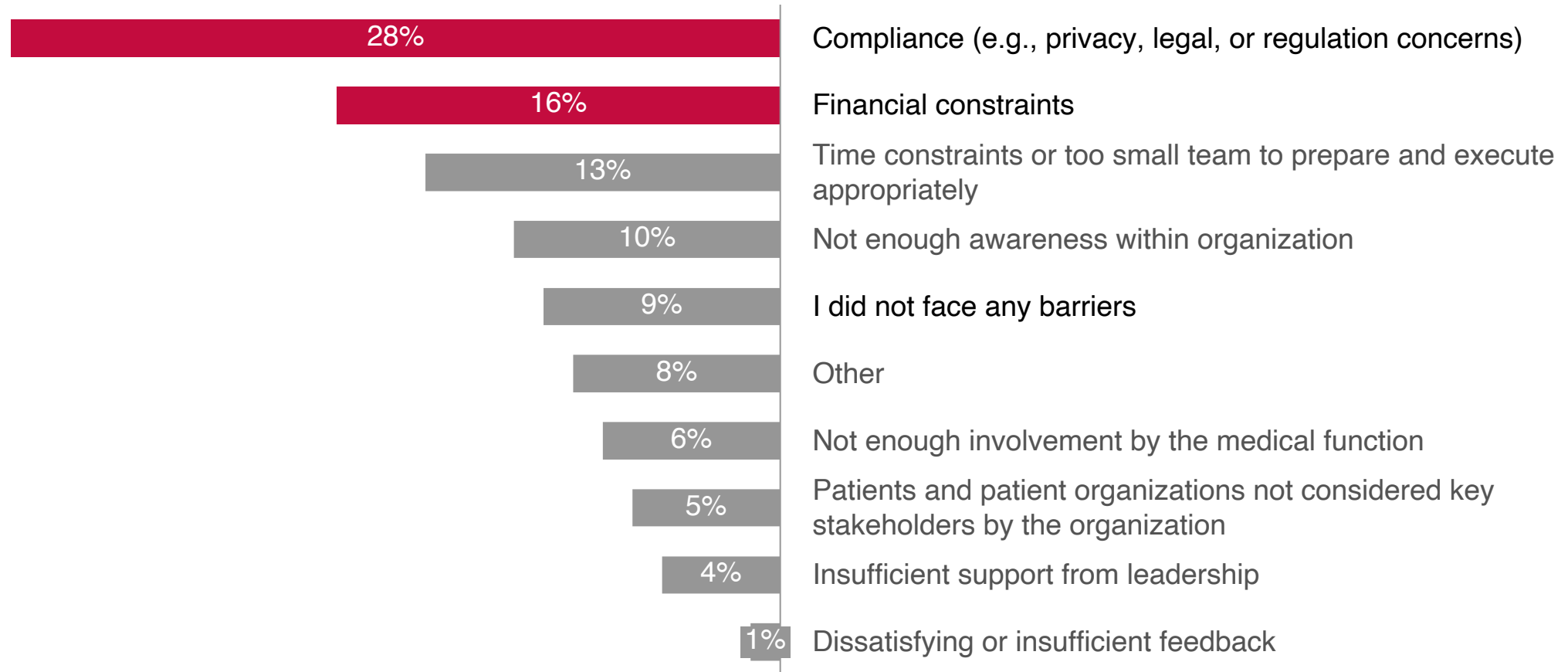
Patient centricity in Medical Affairs puts the patient in the center of ethical considerations and decision making across the product development lifecycle.

It is prioritizing the patient and their support network to foster active engagement and transparent partnership and integrating their perspectives in Medical Affairs activities.

It supports the goals of optimizing outcomes and quality of life for patients, promotes accessibility and inclusion, improves patient experiences, and places patient needs at the forefront of healthcare innovation.

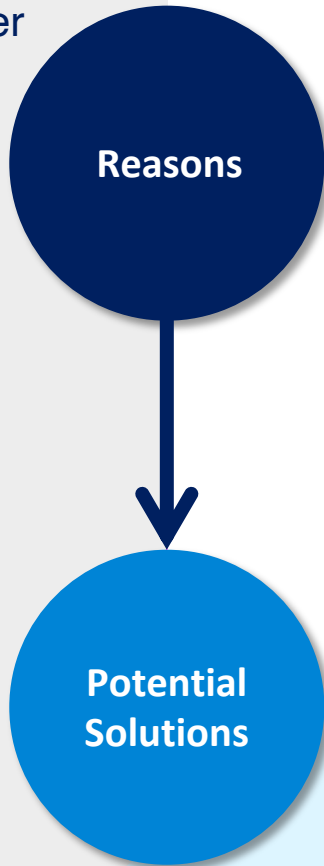
Based on survey responses, compliance and financial constraints were identified as major barriers

% of responses (n=93) | Major barrier for Patient Centricity



Interviewees provided potential solutions to overcoming **compliance** - increased education, collaboration, and advocacy

COMPLIANCE
as major barrier
for Patient
Centricity
Initiatives



Unclear boundaries of Patient Centricity vs advertisement

Risk averse company compliance guidance

Guidelines/policies lag global trends (e.g., patients increasingly using social media or YouTube)

Regional differences

Insufficient mutual understanding with compliance team

1 Educate organization on compliance issues, show opportunities and boundaries, and processes

2 Increased and earlier collaboration with compliance teams

3 Advocacy for updating guidelines and policy

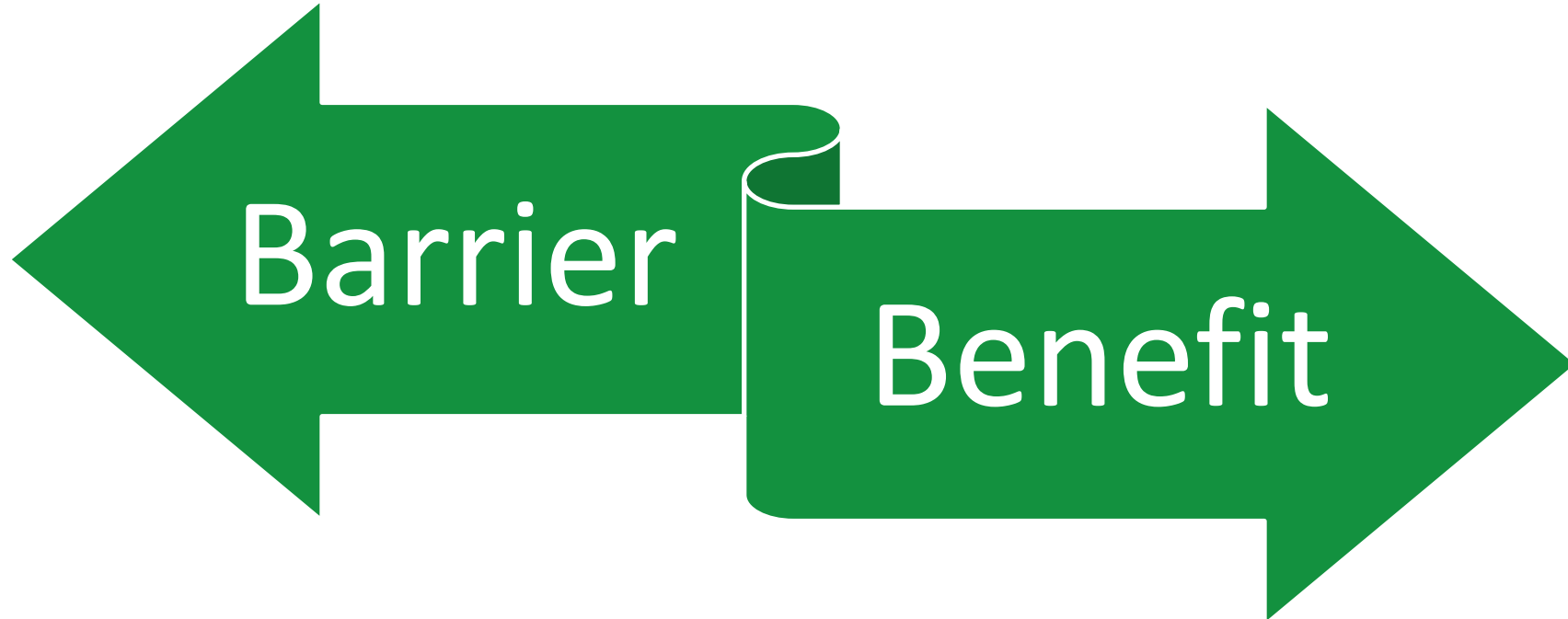
Polling Question 1 – “Is compliance a partner?”

Question: Are you proactively reaching out to your compliance team when you plan patient centricity initiatives?

Responses:

- Yes - I include my compliance team during the planning process
- Getting there - I start out on my own but involve compliance later
- No - I do not involve my compliance team in patient centricity initiatives
- I do not plan patient centricity initiatives

Compliance is



Some Compliance Considerations



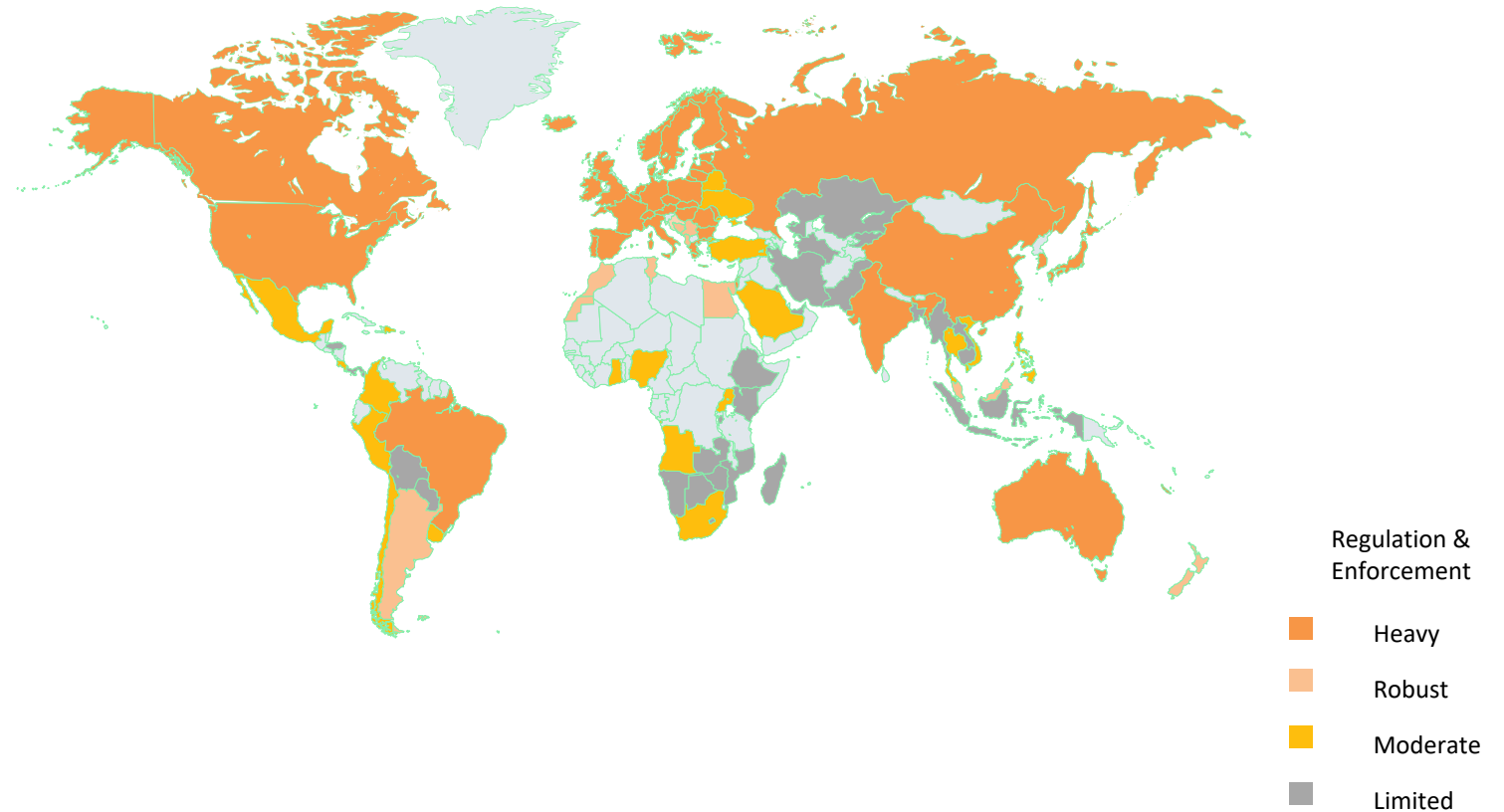
Privacy



GDPR, CPRA, HIPAA

Sensitive data /
personal data /
pseudonymised data
/ anonymised data

Data Controller
/Data Processor
/Data Subject



More details: <https://www.dlapiperdataprotection.com/#handbook/world-map-section>

Direct to Patient Engagement



Advertising?

Communication?

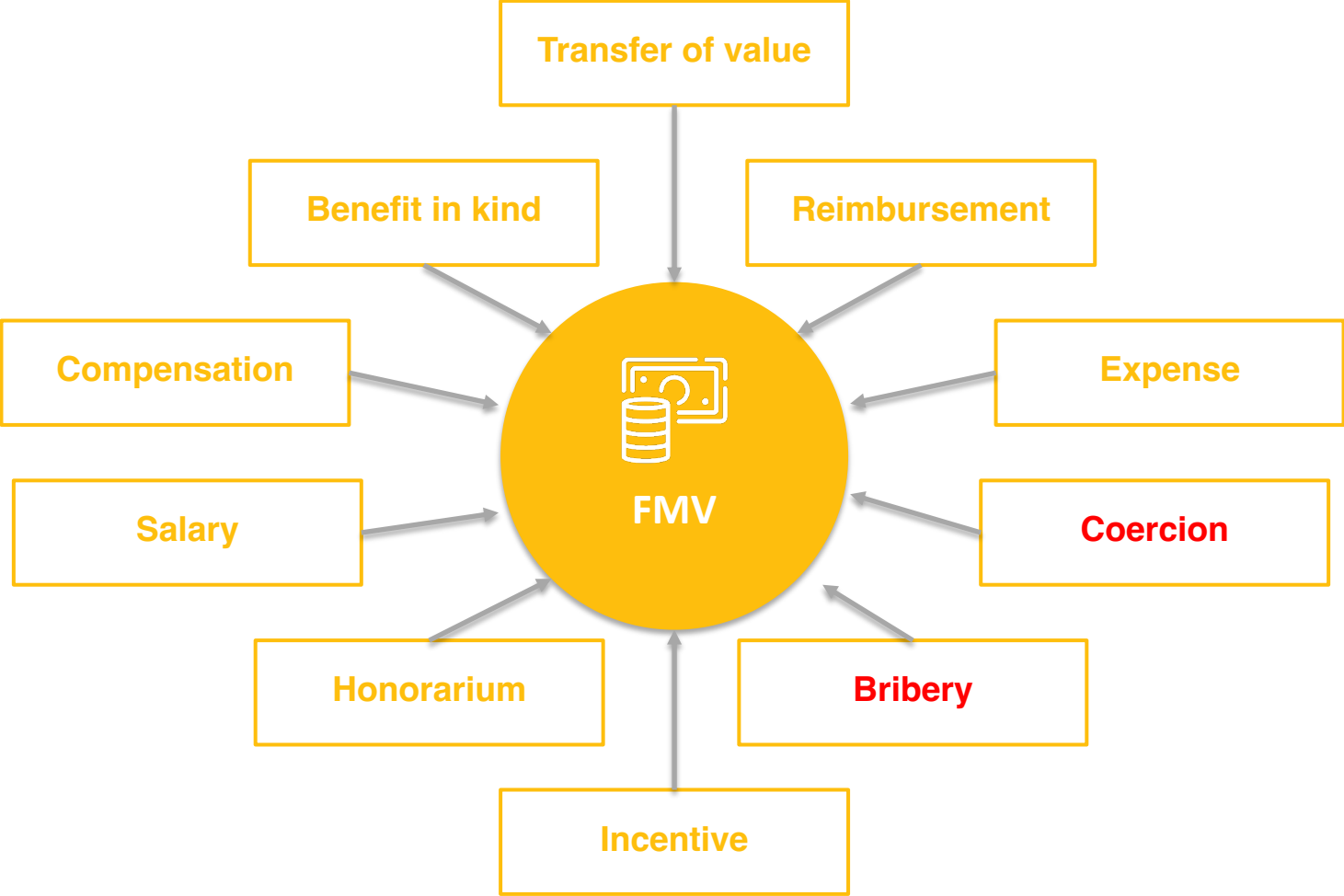
Participation?

Advisory Board

Social Media



Let's talk about money \$€£



Ref: <https://nationalhealthcouncil.org/fair-market-value-calculator/>



Contract / Agreement / Consent

Liability

Indemnity

Confidentiality

Risk assessment





**Principles - Beneficence,
nonmaleficence, autonomy & justice**

Practitioner vs Subject

**IRB (Independent Review Board) / EC
(Ethics Committee)**

Risk vs Benefit to Patients

Code of conduct / Guidance

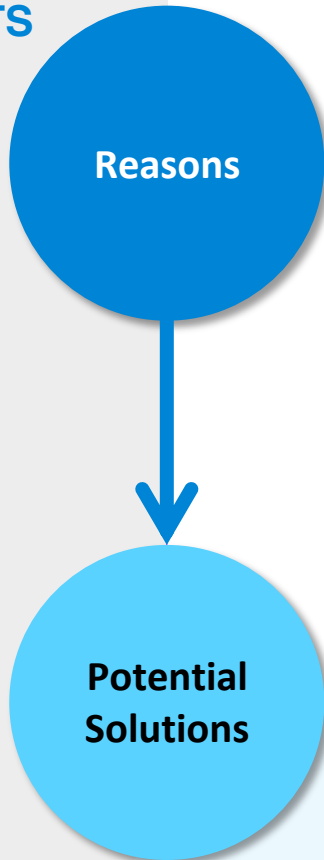


Ref: <https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html>

Underappreciation of the cost benefit of Patient Centricity initiatives and poor planning lead to financial constraints

FINANCIAL CONSTRAINTS

as major barrier for Patient Centricity Initiatives



Organizational priorities: Budgets purely based and prioritized on ROI

Poor planning: Initiative owners, mostly the executing function, do not account for PCIs in annual budgeting process. Ad-hoc budget unlikely

Patient Centricity not reflected in organizational goals

Digital initiatives are very expensive

1 Showcase competitive advantage to C-suite and shareholders to increase appreciation for potential cost benefit from including the patient

2 Focus on timely and proper budget planning

"Once it starts to become clear that the [organizations] who do this [patient centricity] well are becoming more successful, enrolling patients faster, getting drugs to the market faster, having better engagement....."
[Interview participant]

Polling Question 2 – “Guesstimate”

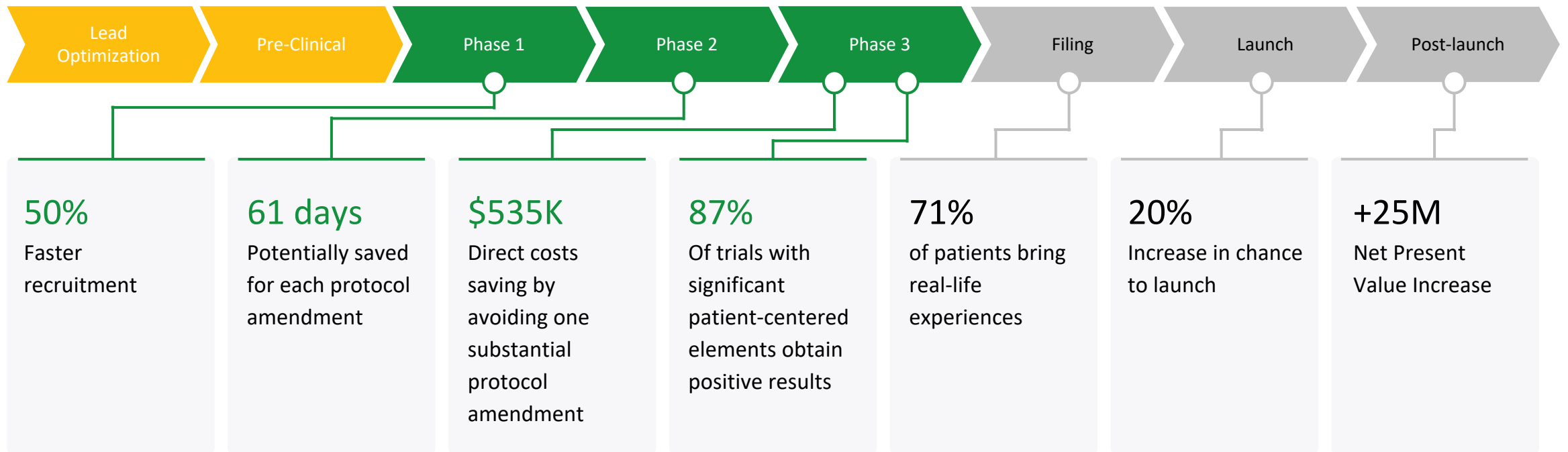
Question: For a pre-phase 2 project, the cumulative impact of a patient engagement activity that avoids one protocol amendment and improves enrollment, adherence, and retention **is an increase in net present value (NPV) of how much?**

Responses:

- \$7.5 million USD
- \$22 million USD
- \$45 million USD
- \$62 million USD

The Added Value When Patient Engagement is Done Right

Positive impacts felt across the full lifecycle of the medicine

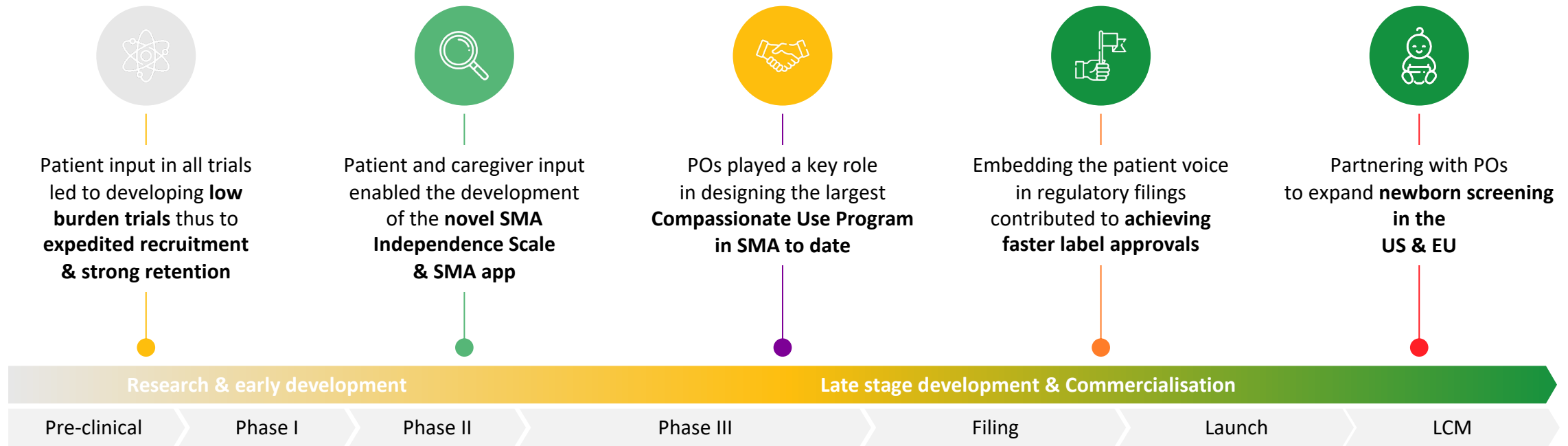


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***Patient Partnership Team

Case Study: Partnerships with the SMA Patient Community

Ensured our strategy and programme addressed patient needs



SMA Europe:

“We are proud of our long-established partnership with Roche. Our close collaboration has ensured that the community's expectations and unmet needs are at the centre of decision-making.”

***Patient Partnership Team

To Summarize

- According to the MAPS Patient Centricity FAWG survey and additional interviews, compliance and financial considerations were the major barriers to implementing patient centricity initiatives in Medical Affairs.
- We developed a specific definition for Patient Centricity in Medical Affairs based on input from the survey
- Jessica provided considerations to keep in mind when working with your compliance team, including starting as early as possible and considering compliance as a partner
- Rebecca provided considerations for financial implications of both engaging and *not* engaging in patient centricity activities

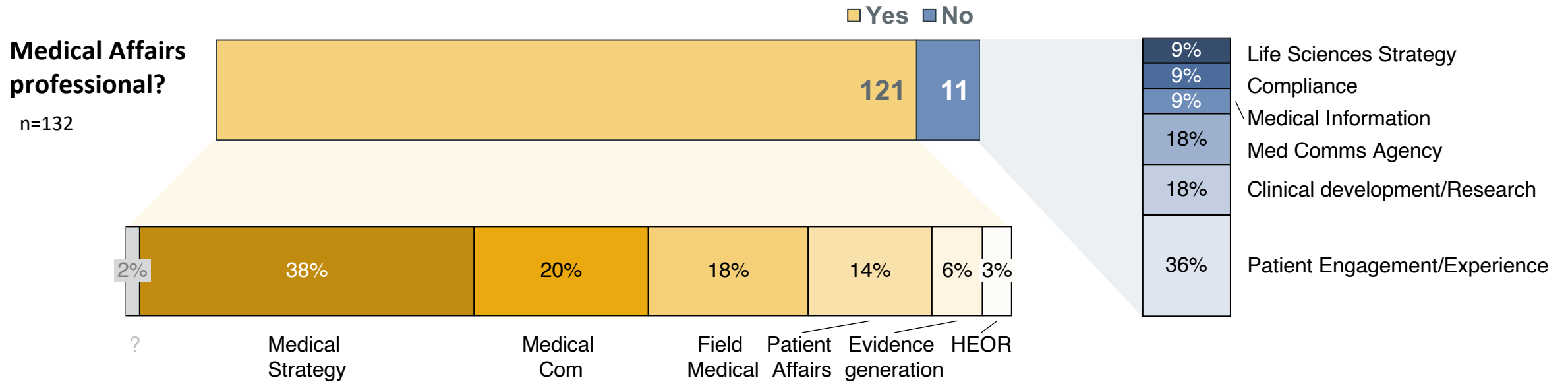


Q&A



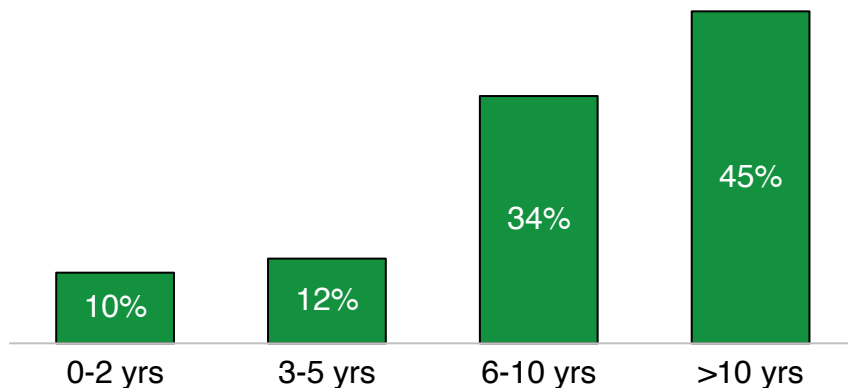
Additional Information

Most of the 133 survey respondents are well experienced Medical Affairs professionals



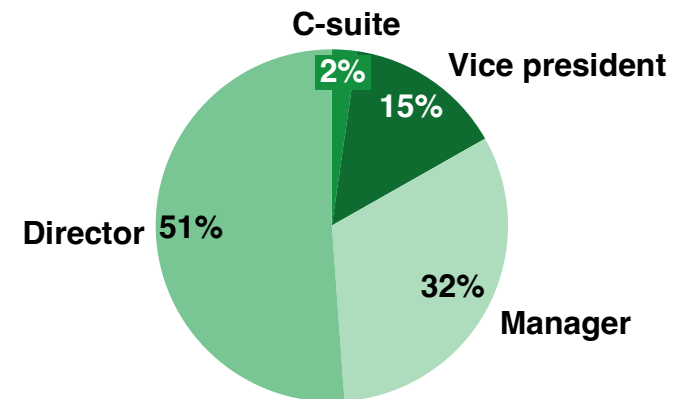
Years of experience

n=104



Job level

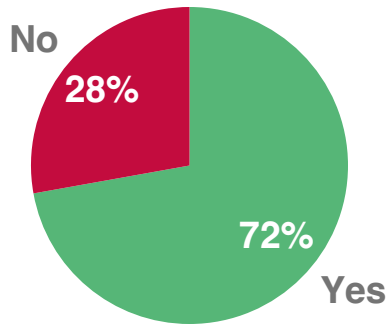
n=132



Most respondents had experience with PC, whereas MA often budgets and leads initiatives – but KPIs not systematically implemented

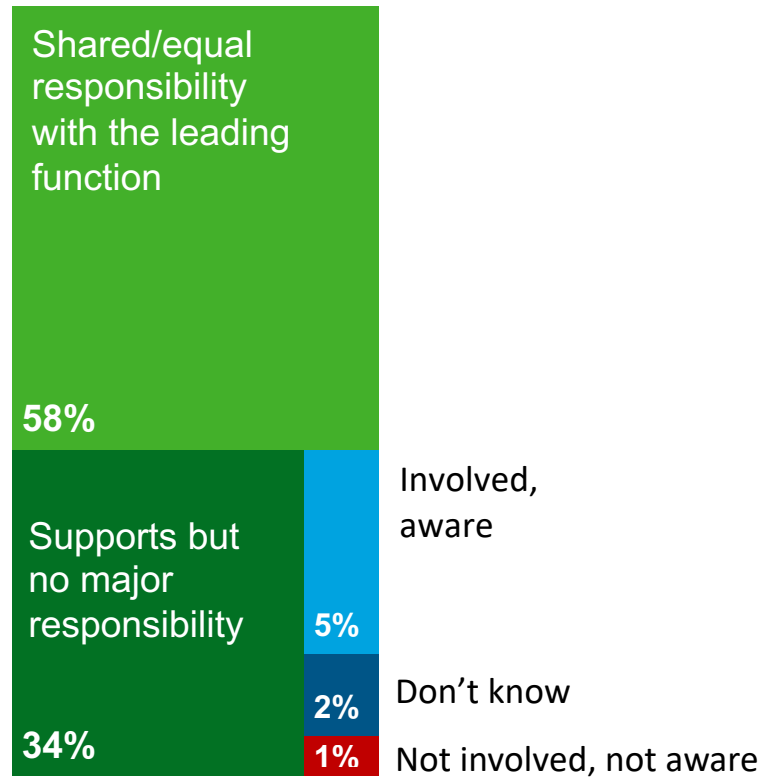
Experience with patient centricity initiatives

n=133



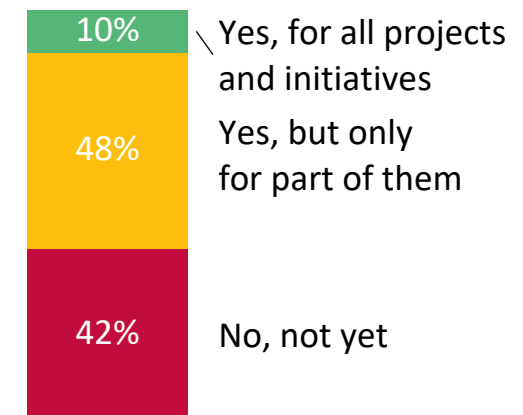
Role of MA in PC initiatives

n=92



Organization implemented success measurement for PC initiatives

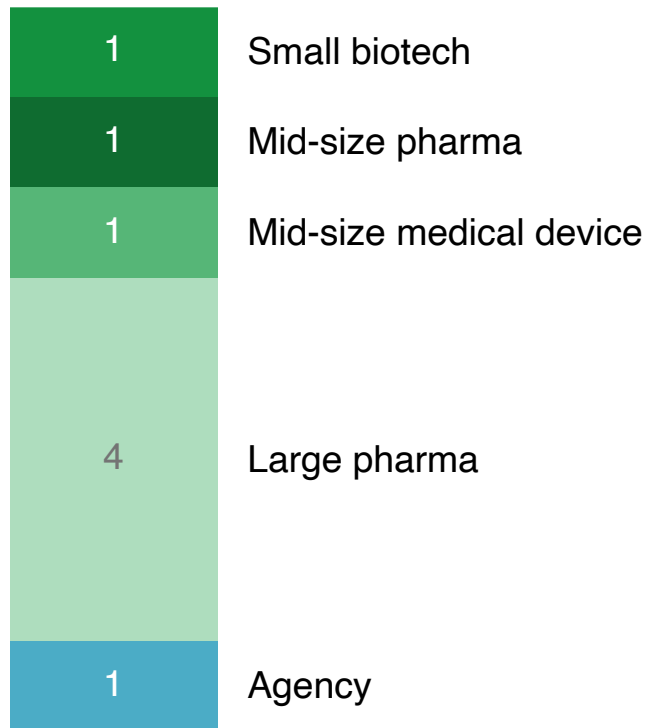
n=96



All 11 interviewees are well experienced Medical Affairs professionals, and half of them were from large pharma

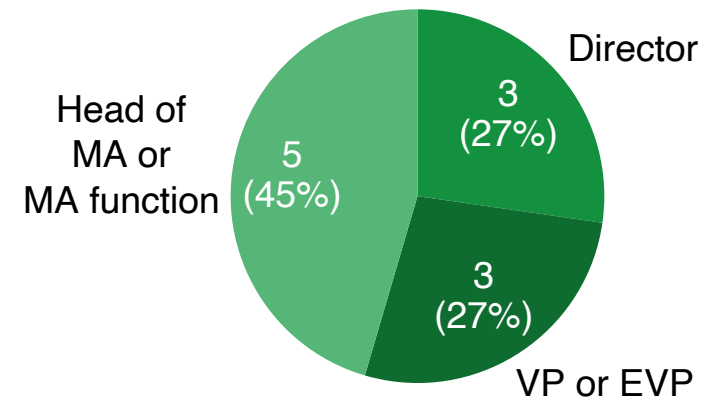
Half of interviews were conducted with experts from large pharma

n=8



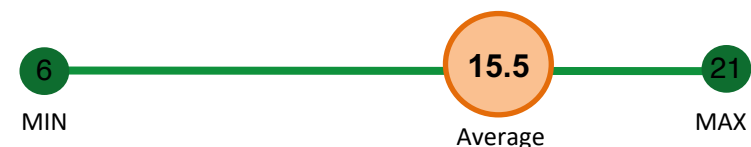
Most are Head or Vice president of Medical Affairs...

n=11



... with many years of MA experience

n=11



The need to shift the organizational mindset to truly live Patient Centricity was reported as one of the biggest challenges

Major barrier mentioned | n=20 (%)



“Organizational mindset - budget and compliance barriers are the results of the mindset”. [Large Pharma]

“Do you believe in Patient Centricity? How do you define it? What are company imperatives and how to execute that into a workstream within each role?”. [Large Pharma]

“Patient centered - but it's very nebulous. So how do you tackle this? What do you actually do?”. [Large Pharma]

“Sometimes the barrier is that patients themselves are not organized in an easy fashion to seek (...) A lack of community organization hinders a good cross section of patient input (...) not representing a community viewpoint“. [Small Biotech]

“As organizational priorities shift, so does funding (...) Because you've built relationships and you wanna be a consistent and trusted partner, that creates challenges“. [Large Pharma]

Legend

Barrier from survey

Newly identified barrier