



Session 3#

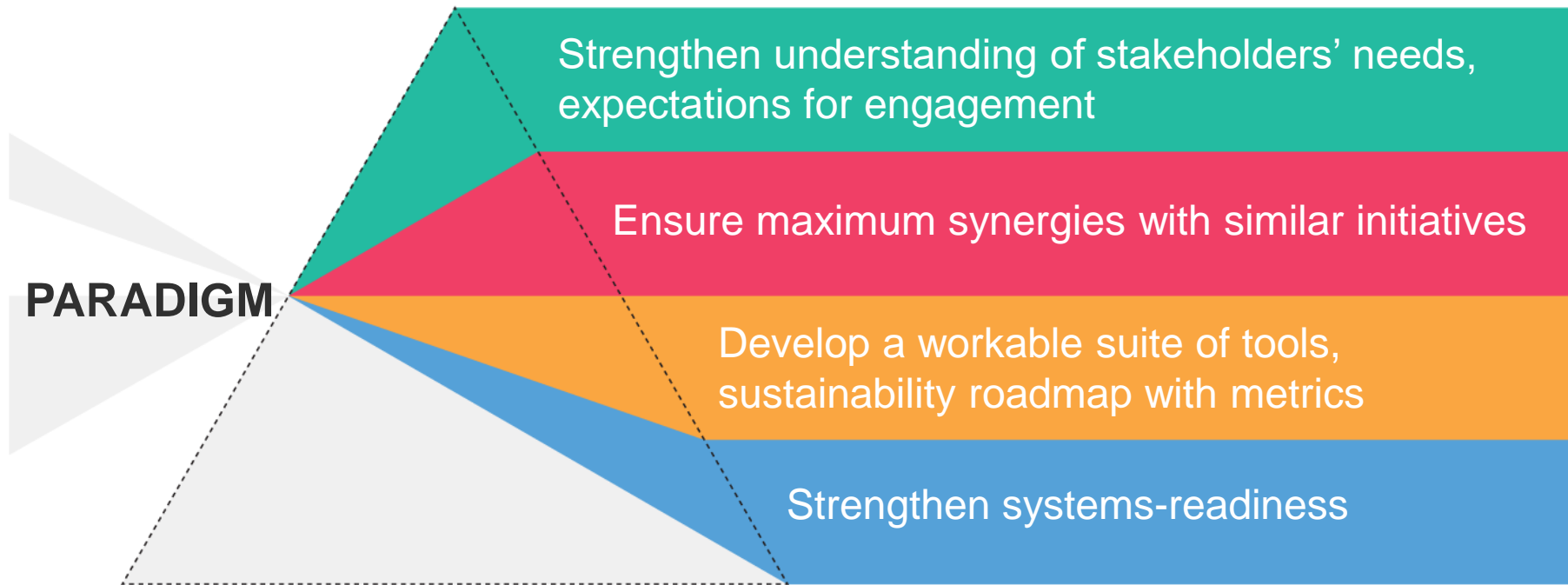
WP2 - Identifying and understanding gaps in practice and process of patient engagement

Stuart Faulkner

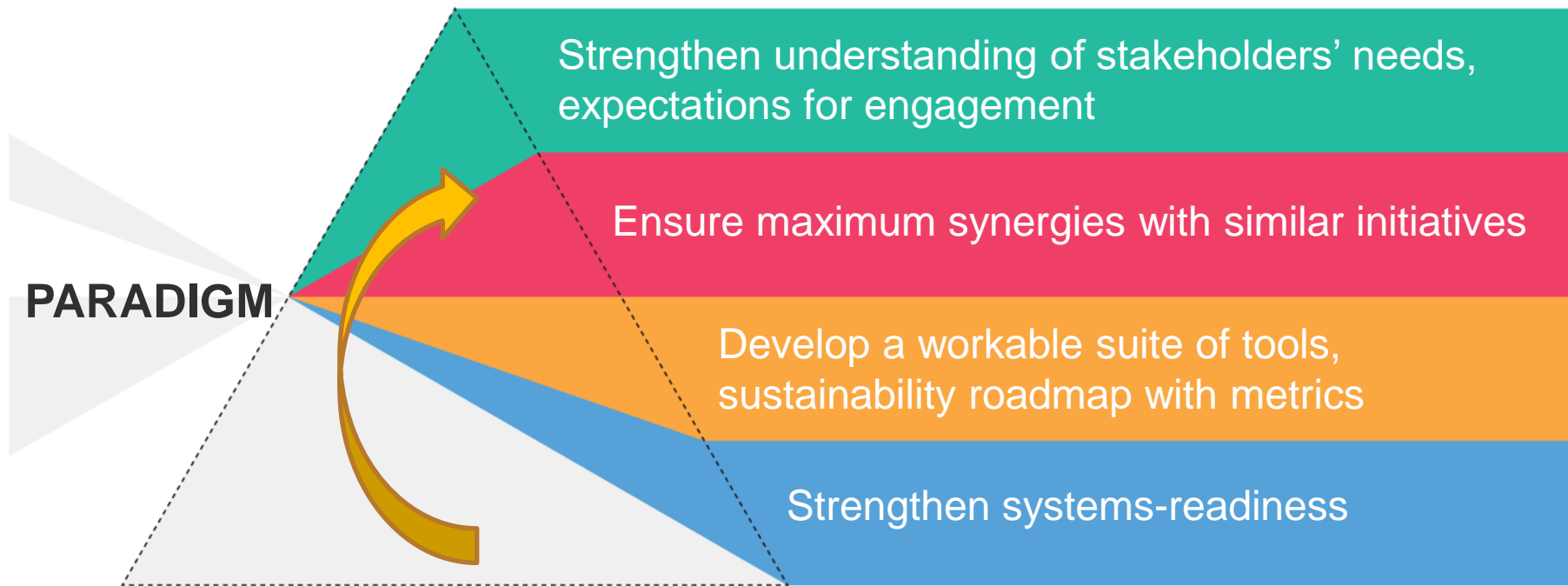
Oxford University

Sept 18th 2019

Intended Outcomes of PARADIGM



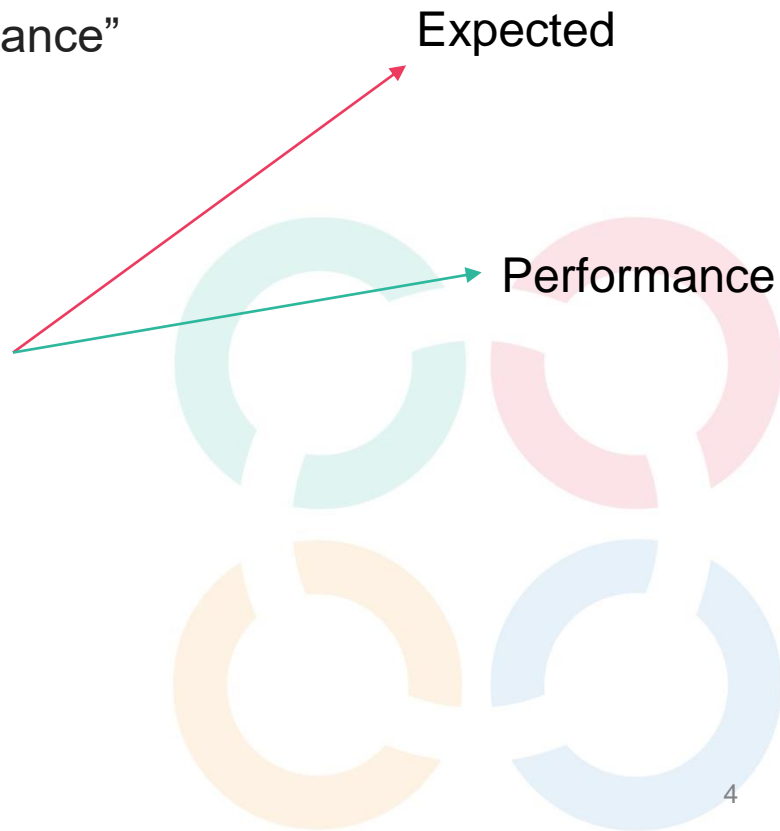
Intended Outcomes of PARADIGM – Need a common thread



The need for gap analysis

Gap analysis:..."the comparison of actual performance with potential or desired performance"

[Wikipedia](#)



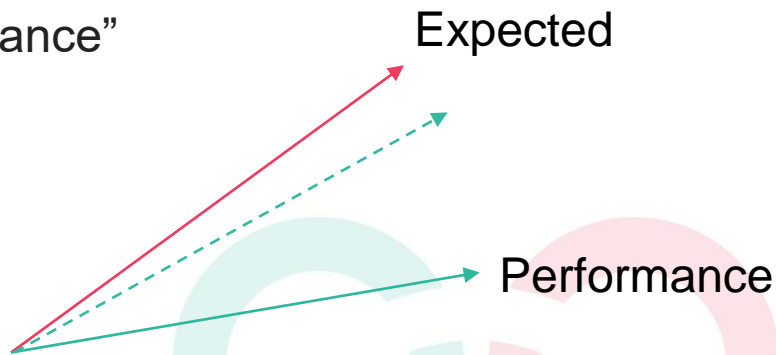
The need for gap analysis

Gap analysis:... "the comparison of actual performance with potential or desired performance"

[Wikipedia](#)

- >What is expected
- >>What is actually being done
- >>>What to do better and how to do it better

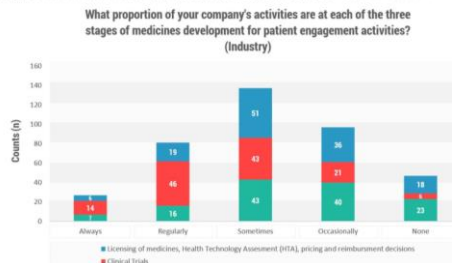
.....Providing a strong, methodological, co-created, validated and valuable narrative as to how and why some of PARADIGM outputs are being created



How did we get here?

A dedicated PE function within the organization

The majority of (n=99/130) industry respondents reported a dedicated function in their organisation



WP2 - Gap analysis tool

Process/guidance/framework

[Click here for the glossary](#)



The following questions are about how participants are selected and whether the selection is an adequate representation

* 17. Is there an attention for including relevant diversity of the target population (included but not limited to cultural background, socio-economic status, gender, age, ethnicity, educational level, disease, disability, vulnerability, etc.) and their range of perspectives?

- ☐ Yes, there is attention for relevant diversity of population.
- ☐ No, there is no attention for relevant diversity of population.
- ☐ It is not possible to assess based on the available information.
- ☐ This question is not relevant to this initiative.

Created a framework (gap tool) to accept the outputs and inputs

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CRITERIA	WEIGHT
Aims and objectives	14
Patient engagement impact	14
Target participants involved	12
Legal and ethical consideration	11
Involvement and participation	11
Resources	10
Capacity building	10
Evaluation of the PE practice in the Design of Clinical Trials	10
Sustainability	8
	100

50+

Translated all outputs from WP1 and inputs from WP 3 and 4 onto framework

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[Click here for the glossary](#)

Initiative name	Initiative link	Organization	Country
2. Expert Patient and Researcher EUORIS Summer School	https://involvement-mapping.patientfocusedmedicine.org/initiative/EUORIS-Summer-School	EUORIS	Rare Diseases
1. Involvement in the development of the patient focused medicine	https://involvement-mapping.patientfocusedmedicine.org/initiative/Involvement-in-the-development-of-the-patient-focused-medicine	EUORIS	Rare Diseases
2. Expert Patient and Researcher EUORIS Summer School	https://involvement-mapping.patientfocusedmedicine.org/initiative/EUORIS-Summer-School	EUORIS	Rare Diseases
3. Patient Input Forums	https://involvement-mapping.patientfocusedmedicine.org/initiative/Patient-Input-Forums	Merck Sharp & Dohme	US
4. Health Literate Product Labeling	https://involvement-mapping.patientfocusedmedicine.org/initiative/Health-Literate-Product-Labeling	Merck Sharp & Dohme	US
5. NPS's CSD Patient Registry	https://involvement-mapping.patientfocusedmedicine.org/initiative/NPSs-CSD-Patient-Registry	National Kidney Foundation	US
6. M-CRDS Conference on Patient-Focused Drug Development	https://involvement-mapping.patientfocusedmedicine.org/initiative/M-CRDS-Conference-on-Patient-Focused-Drug-Development	University of Maryland	US
7. Clinical Trial Access and Protocol Optimisation	https://involvement-mapping.patientfocusedmedicine.org/initiative/Clinical-Trial-Access-and-Protocol-Optimisation	Patients Like Me	US
8. TrialMark: The Patient Experience Measurement Standard	https://involvement-mapping.patientfocusedmedicine.org/initiative/TrialMark-The-Patient-Experience-Measurement-Standard	Patients Like Me	US
9. PRO Development	https://involvement-mapping.patientfocusedmedicine.org/initiative/PRO-Development	Patients Like Me	US
10. (TAIN) Treatment of Adrenal Insufficiency in Neonates	https://involvement-mapping.patientfocusedmedicine.org/initiative/TAIN-Treatment-of-Adrenal-Insufficiency-in-Neonates	UK Genetics Alliance	UK
11. NICE Technology Appraisals	https://involvement-mapping.patientfocusedmedicine.org/initiative/NICE-Technology-Appraisals	NICE	UK
12. Generation II	https://involvement-mapping.patientfocusedmedicine.org/initiative/Generation-II	UK	UK
13. Navigate Melanoma	https://involvement-mapping.patientfocusedmedicine.org/initiative/Navigate-Melanoma	Melanoma International	US
14. Post-trial responsibility	https://involvement-mapping.patientfocusedmedicine.org/initiative/Post-trial-responsibility	Multi Regional Clinical	US
15. Partnering with Patients	https://involvement-mapping.patientfocusedmedicine.org/initiative/Partnering-with-Patients	BMJ (British Medical Journal)	UK
16. Patient Engagement Portal	https://involvement-mapping.patientfocusedmedicine.org/initiative/Patient-Engagement-Portal	Cure PSP - Patient En	US
17. CANCER ID	https://involvement-mapping.patientfocusedmedicine.org/initiative/CANCER-ID	CANCER ID (BMC)	US
18. Polypharmacy Kidney Disease Outcome Consortium	https://involvement-mapping.patientfocusedmedicine.org/initiative/Polypharmacy-Kidney-Disease-Outcome-Consortium	Critical Path (C-Path)	US
19. FDA Patient Representative Program	https://involvement-mapping.patientfocusedmedicine.org/initiative/FDA-Patient-Representative-Program	FDA (US Food and Drug Administration)	US
20. Patients4C Road Map to Treatment	https://involvement-mapping.patientfocusedmedicine.org/initiative/Patients4C-Road-Map-to-Treatment	European Forum for G	US
21. Patient Reported Outcome Consortium	https://involvement-mapping.patientfocusedmedicine.org/initiative/Patient-Reported-Outcome-Consortium	Critical Path (C-Path)	US

Used gap tool to ask questions of many existing practices and processes

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WP2 - Gap analysis tool

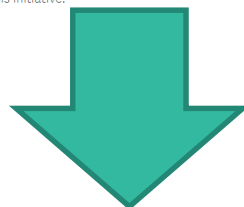
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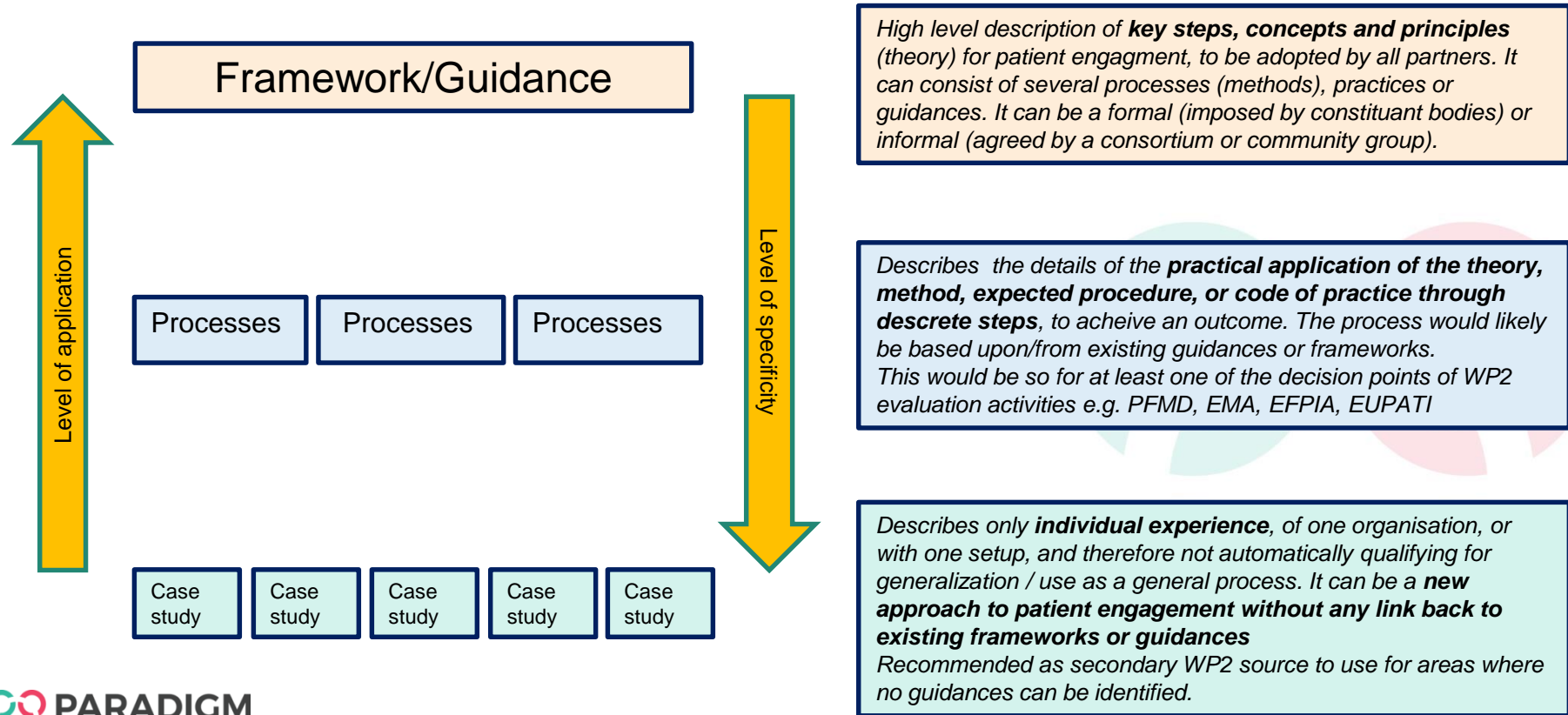
Inventory of practices and processes

Inform or nudge WPs what gaps could be incorporated into tools being developed within PARADIGM

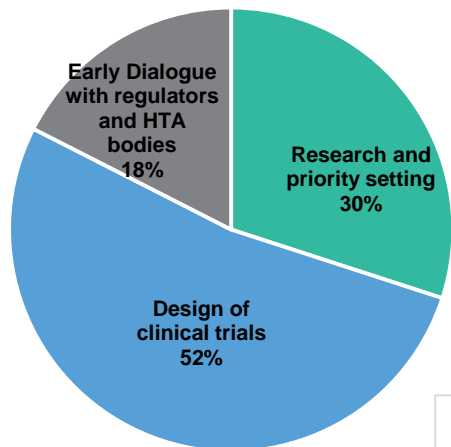
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2. Patient Input Forums	https://involvement-mapping.patientfocusedmedicine.org/initiative/Merck-Sharp-Dohme	Merck Sharp & Dohme
3. Health Literate Product Labeling	https://involvement-mapping.patientfocusedmedicine.org/initiative/National-Kidney-Foundation	National Kidney Foundation
4. IMCERS Conference on Patient-Focused Drug Development	https://involvement-mapping.patientfocusedmedicine.org/initiative/University-of-Maryland	University of Maryland
5. Clinical Trial Access and Protocol Optimisation	https://involvement-mapping.patientfocusedmedicine.org/initiative/Patients-Like-Me	Patients Like Me
6. TrialMark: The Patient Experience Measurement Standard	https://involvement-mapping.patientfocusedmedicine.org/initiative/Patients-Like-Me	Patients Like Me
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8. (TAIN) Treatment of Adrenal Insufficiency in Neonates	https://involvement-mapping.patientfocusedmedicine.org/UK-Genetics-Alliance	UK Genetics Alliance
9. NICE Technology Appraisals	https://involvement-mapping.patientfocusedmedicine.org/NICE-Platinum-Initiative	NICE Platinum Initiative
10. Generation II	https://involvement-mapping.patientfocusedmedicine.org/Medical-Research-Council	Medical Research Council
11. Navigate Metastoma	https://involvement-mapping.patientfocusedmedicine.org/Melanoma-International	Melanoma International
12. Post-trial responsibility	https://involvement-mapping.patientfocusedmedicine.org/MAJ-Breast-Medical-J	MAJ Breast Medical J
13. Partnering with Patients	https://involvement-mapping.patientfocusedmedicine.org/Cure-PSP-Patient-Engagement	Cure PSP - Patient Engagement
14. Patient Engagement Portal	https://involvement-mapping.patientfocusedmedicine.org/CAICER-OB-OB-OB-OB	CAICER OB OB OB
15. Polypharmacy Kidney Disease Outcome Consortium	https://involvement-mapping.patientfocusedmedicine.org/Critical-Path-C-PATH	Critical Path (C-PATH)
16. FDA Patient Representative Program	https://involvement-mapping.patientfocusedmedicine.org/FDA-US-Food-and-Drugs	FDA US Food and Drugs
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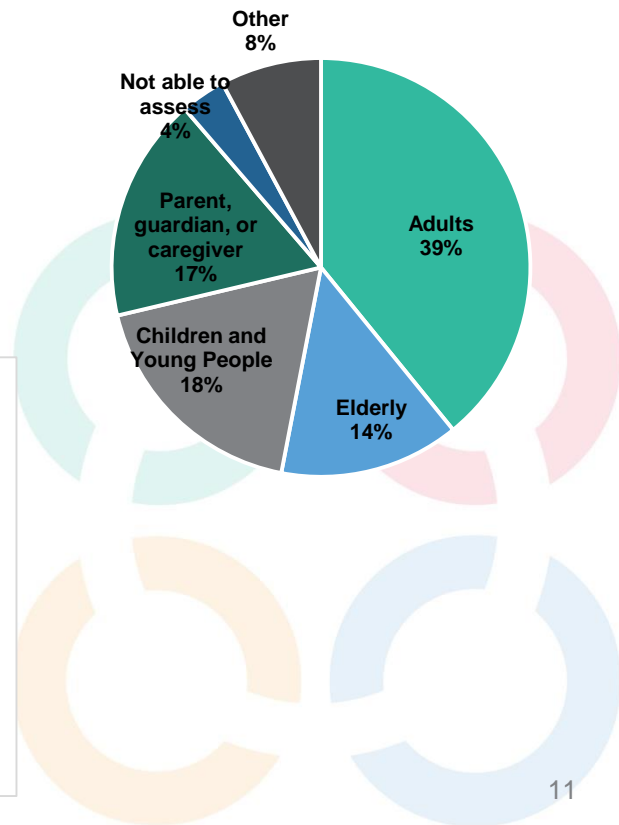
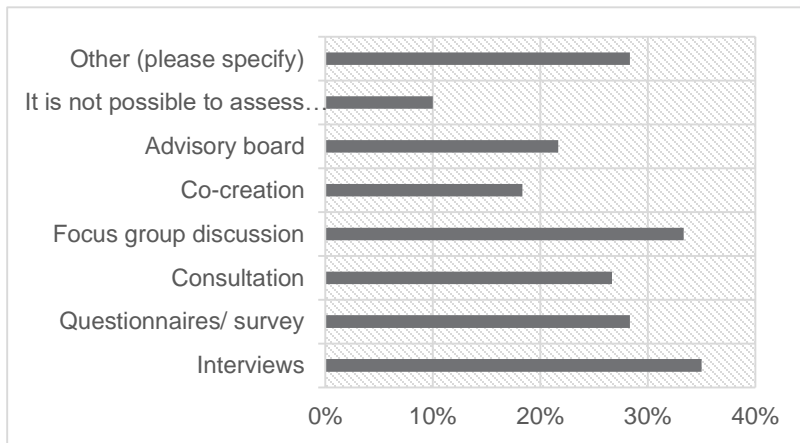
How did we get here? – what is a practice or process?



Preliminary data analysis of gaps - Initiative characteristics



60 initiatives
(57%) **individual case studies**
(23%) **framework or guidance**
(20%) **processes**



Gaps applicable to most categories and/or criteria

1) Gap in reporting standard and dissemination of PE [activities]

(what, who, when, how and outcomes)

Qualitative responses often confirmed:

- Lack of granularity in reporting
- Practise/process did occur to some extent but was not formally documented (time, effort, resource)

2) Gap in translation between 'what to do' and 'how to do it'

(Attention to criteria in framework/guidance but occurred less often in cases)

Qualitative responses often confirmed:

- Lack of detail in guidance
- Something being developed but not implemented or systemic as yet

Preliminary gaps

Category (Theme)	Criteria (Was there attention to.....)
Selection of participants and adequate representation	clear description of the criteria followed to identify patient representatives needed
Empowerment of stakeholders	training for their roles and responsibilities with training material accessible to all participants taking into consideration of languages, impairments, literacy levels, cultural background and the circumstances of (vulnerable) patients involved?
Transparency of roles, scope of involvement, and decision-making structure	communicating any changes that could occur during the PE initiative up-front
Communication and feedback	legal agreements written in a clear and accessible way and adapted to the target population
	include a dissemination and communication plan sharing the process and outcomes
Sustainability	ensure the formation and maintenance of a partnership between all stakeholders to ensure continuity

Preliminary gaps

Category (Theme)	Criteria (Was there attention to.....)
Legal and ethical considerations	<p>code of conduct, which clearly states the (ethical) principles, governance requirement, rules and procedure of participation for all stakeholders involved</p> <p>privacy policy that describes policy to maintain data privacy of engaged patients in the engagement</p> <p>identification and addressment of potential discriminatory, coercive, intimidating, and unethical behaviours, towards all stakeholders, before, during and after their participation?</p> <p>management of potential conflicts of interest (up to avoidance)? disclosure, transparency and accountability</p> <p>presentation of the terms and conditions of all policies and confidentiality agreements, in a clear and accessible way to the stakeholders involved</p>
Supportive resources	clear, transparent and equitable (fair) financial compensation framework to be in place and made available for patient representatives who participate
Impact for R&D	propose metrics to measure impact of PE

WP2 – How are identified gaps useful to other WP's?

- Gap: 'Lack of reporting standards and dissemination of PE practises and processes'

Outline

- [1. Introduction](#)
- [2. Scope](#)
- [3. Purpose](#)
- [4. Guiding Principles](#)
- [5. Values](#)
- [6. Conflict of Interest, Competing Interests and Conflict Management](#)
- [7. Contractual Framework](#)
- [8. Privacy, Data Protection and Intellectual Property](#)
- [9. Universal Accessibility to Information](#)
- [10. Access to Patient Engagement Opportunities](#)
- [11. Representativeness](#)
- [12. Competencies and Capacity Building](#)
- [13. Rights and Obligations](#)
- [14. Accountability and Responsibility](#)
- [15. Adherence to the Code of Conduct](#)
- [16. Efficiency](#)
- [17. Willingness and Readiness](#)
- [18. Appropriateness of Communication and Feedback](#)
- [19. Concluding Remarks](#)



Option:

Add theme 'Dissemination and communication practices' into WP4 Codes of conduct

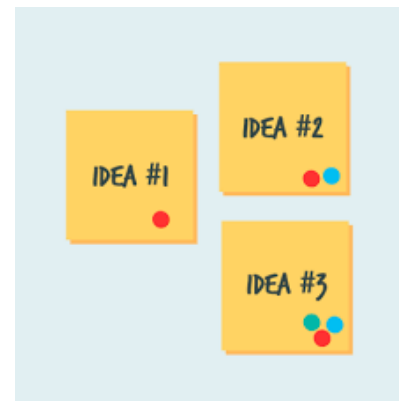
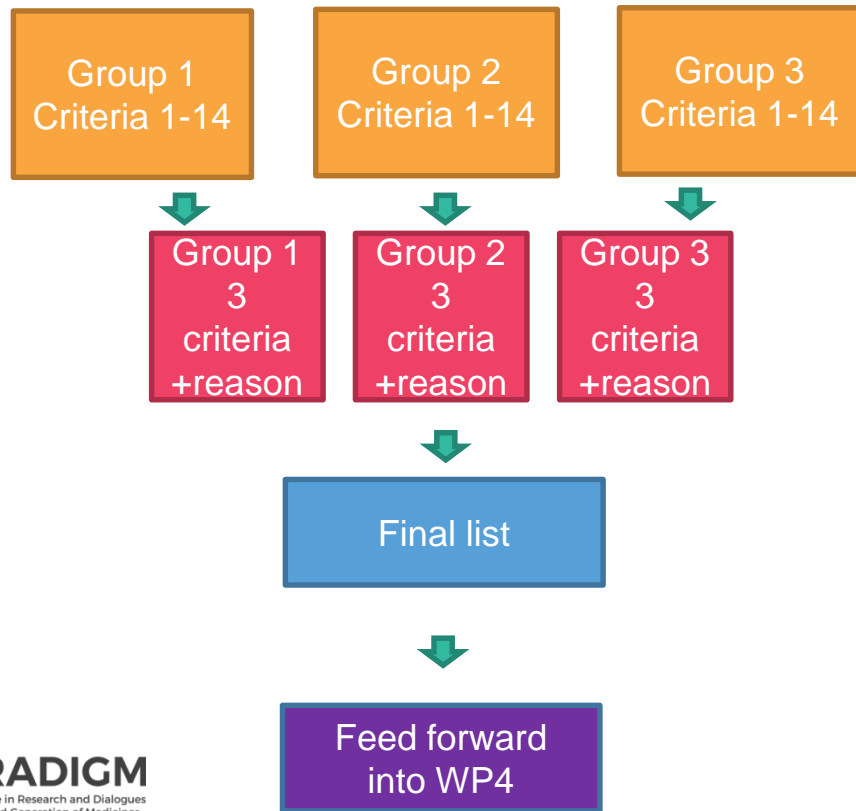
Aims and outcomes for today's interactive session

1) Contextualise identified gaps within PARADIGM - **Prioritisation**

2) Allocation of efficiencies - **Reality check**



Co-creation session and expectations – 60 mins



Why this choice of gap?

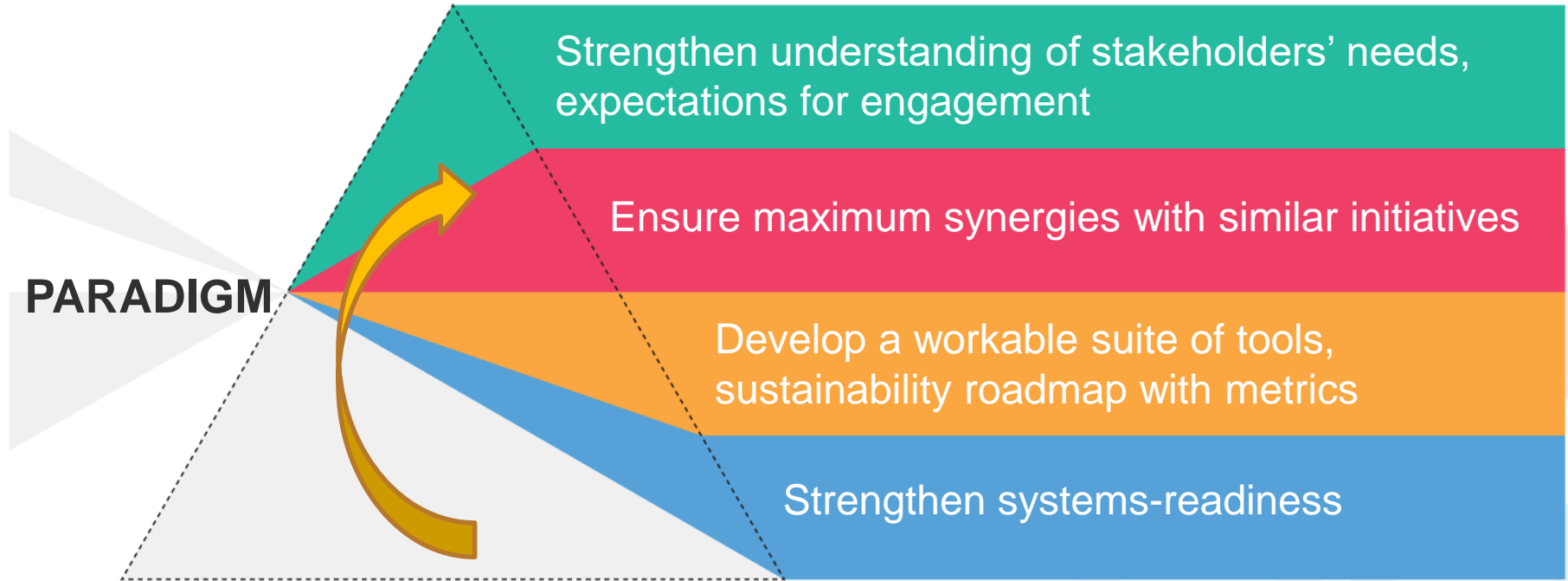
Is this gap already being covered by another initiatives?

Outcomes from YOUR prioritization

Thanks so much, this is precisely what we were looking for and hoping for.....



Intended Outcomes – Feed forward and looking back



What can we do with the results from today practically?

- **Results from today fed forward into content creation for WP4 tools, and others**

Please go to Session 7# - WP4 tomorrow to discuss this and more!

- **Further analysis to improve knowledge and identify gaps at; Research priority setting, Clinical trial design, and Early dialogues**
- **The gaps identified here can be valuable for other initiatives to run with or to build off**
- **Delphi outcomes and gap tool could be used in combination with other tools to repeat a gap analysis by others and organisations**

What can we do with this practically?

**Please go to session
7# WP4 tomorrow to discuss this and more!**