



Il coinvolgimento del paziente/cittadino nella ricerca clinica: presente e futuro

L'Italia e gli altri Paesi Europei: l'esperienza Paradigm

Pietro Erba

12 giugno 2019, Roma

Dichiarazione di trasparenza/interessi*

Le opinioni espresse in questa presentazione sono personali e non impegnano in alcun modo l'AIFA

| Interessi nell'industria farmaceutica | NO | Attualmente | Da 0 a 3 anni precedenti | oltre 3 anni precedenti |
|---|----|--------------------------|--------------------------|---------------------------------------|
| <i>INTERESSI DIRETTI:</i> | | | | |
| 1.1 Impiego per una società: Ruolo esecutivo in una società farmaceutica | X | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> obbligatorio |
| 1.2 Impiego per una società: Ruolo guida nello sviluppo di un prodotto farmaceutico | X | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> obbligatorio |
| 1.3 Impiego per una società: altre attività | X | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> facoltativo |
| 2. Consulenza per una società | X | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> facoltativo |
| 3. Consulente strategico per una società | X | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> facoltativo |
| 4. Interessi finanziari | X | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> facoltativo |
| 5. Titolarità di un brevetto | X | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> facoltativo |
| <i>INTERESSI INDIRETTI:</i> | | | | |
| 6. Sperimentatore principale | X | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> facoltativo |
| 7. Sperimentatore | X | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> facoltativo |
| 8. Sovvenzioni o altri fondi finanziari | X | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> facoltativo |
| 9. Interessi Familiari | X | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> facoltativo |

N.B. Per questo intervento non ricevo alcun compenso

* **Pietro Erba**, secondo il regolamento sul Conflitto di Interessi approvato dal CdA AIFA in data 25.03.2015 e pubblicato sulla Gazzetta Ufficiale del 15.05.2015 in accordo con la policy EMA /626261/2014 sulla gestione del conflitto di interessi dei membri dei Comitati Scientifici e degli esperti.

PARADIGM

ADVANCING PATIENT ENGAGEMENT





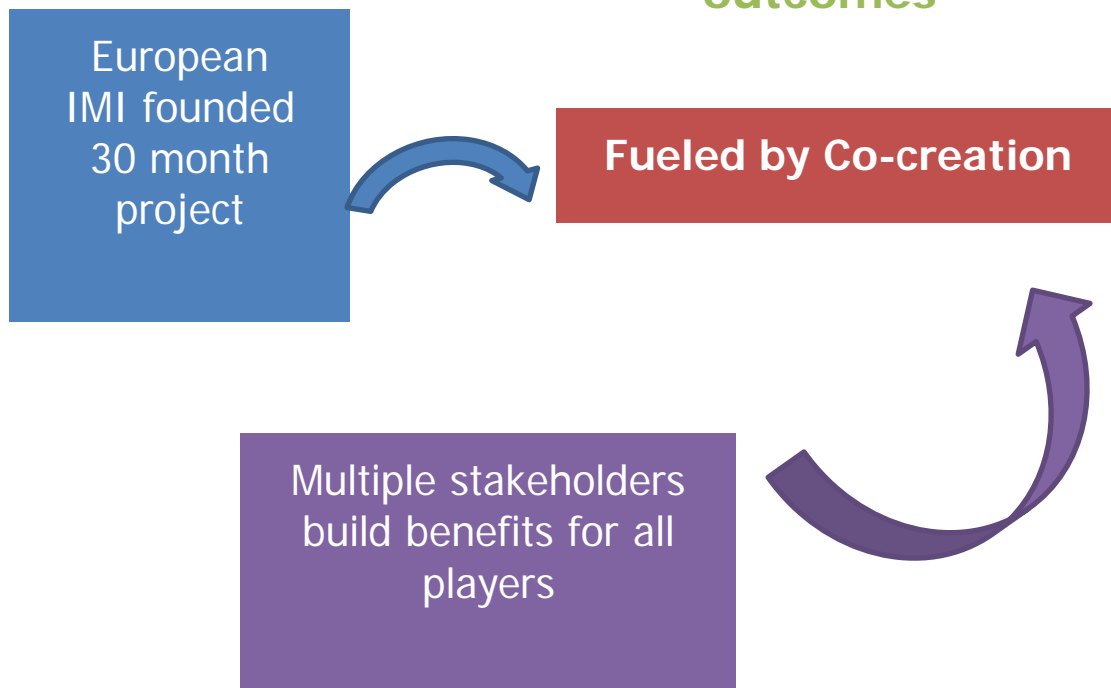
Key Focus

WHAT AND WHY

A collaboration for enhanced patient engagement

Patients
Active in
Research
And
Dialogues for
An
Improved
Generation of
Medicines

Advancing meaningful patient engagement in the life cycle of medicines for better health outcomes



A distinct voice in the Patient Engagement landscape

Mission

Contribute to a sustainable framework that enables meaningful patient engagement and demonstrates 'return on engagement' for all players



Research and
priority setting



Design of
clinical trials



Early dialogues with
regulators and HTA bodies



Objectives

Develop processes and tools for these three points in the medicine lifecycle
Develop a sustainability roadmap for Patient Engagement

Three core concepts, a single aspiration



**Patient
education
and training**



**Guidance
on engagement**



Sustainability
*concept,
resources
and processes*

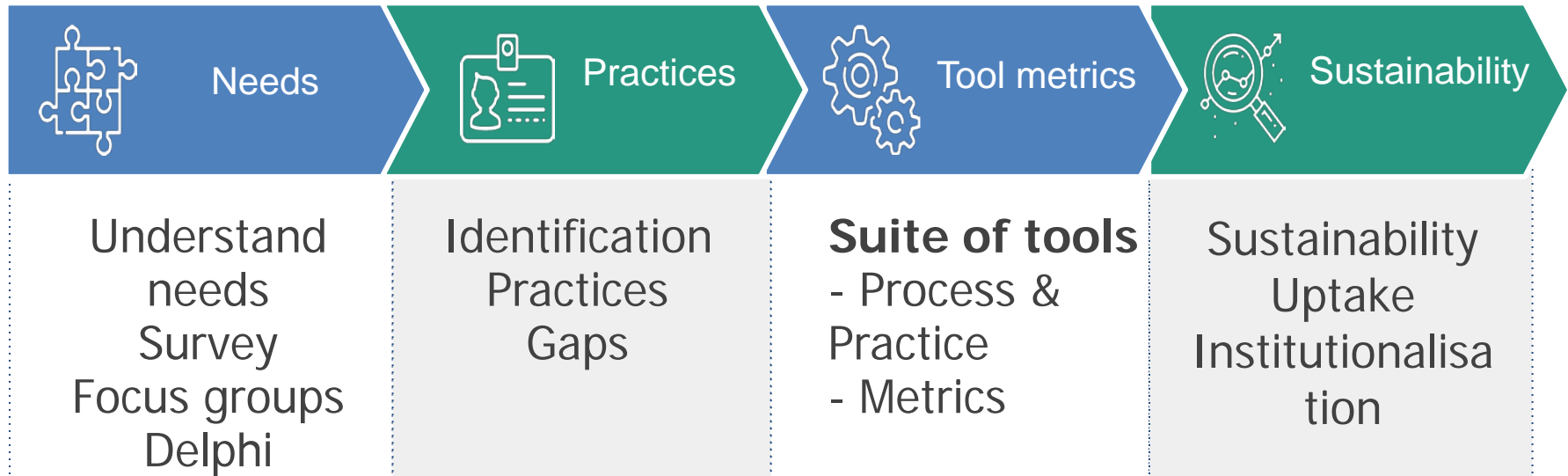
Structured, Meaningful, Sustainable & Ethical Patient Engagement

Collaborative initiatives dedicated to Patient Engagement

| |  PATIENT FOCUSED MEDICINES DEVELOPMENT |  PARADIGM <small>Patients Active in Research and Dialogues for an Improved Generation of Medicines</small> |  EUPATI |
|--|---|--|---|
|  | Global Focus | European Focus | European Focus |
|  | Patient Engagement Guidance & Tools | Patient Engagement Guidance & Tools | Patient Capability Building |
|  | Full Medicine Lifecycle | Time Points: Research Prioritization; Clinical Trials; Early Dialogue Regulatory & HTA Bodies | Full Medicine Lifecycle |
|  | No Time Boundary | 30 Months Duration | No Time Boundary |

PARADIGM advances the patient engagement agenda
Integrated approach with initiatives like EUPATI and PFMD

A virtuous development process



Communication

Project Management



Co-creation at the heart of everything we do

Joint Value Proposition

- Value must be inherent for all stakeholders
- Value is subjective and may vary amongst stakeholders

Terms of Engagement

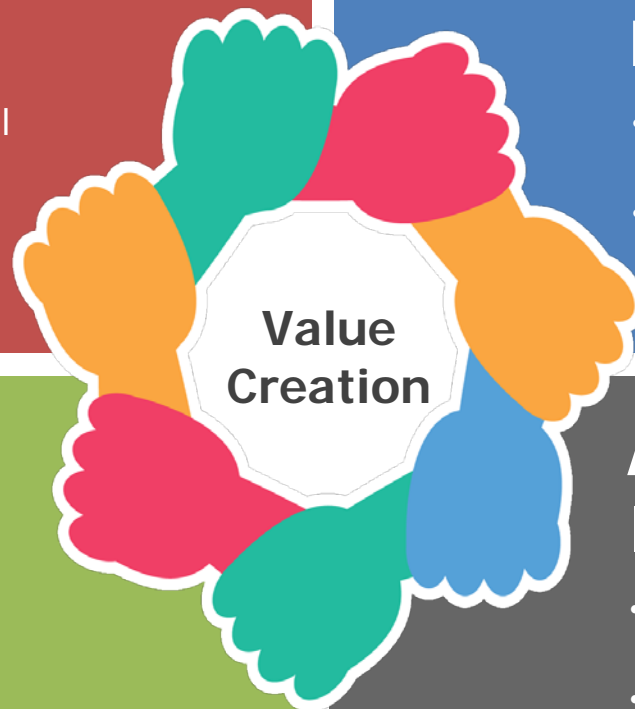
- Invest in getting to know partners
- Define terms of agreement upfront

Human Experience Essential

- Core focus on stakeholders and patient experience
- Flexibility core requisite, it's a dynamic interface

A Real Investment

- A time commitment required to build trust
- Longer-term partnership, not a transactional relationship



Enabling factors

Output Requirements

Articulation of requirements across disease states and patient populations

Rules of engagement by phases of the medicines lifecycle and needs of selected vulnerable populations

Ensuring strategic and extensive outreach to a broad set of stakeholders

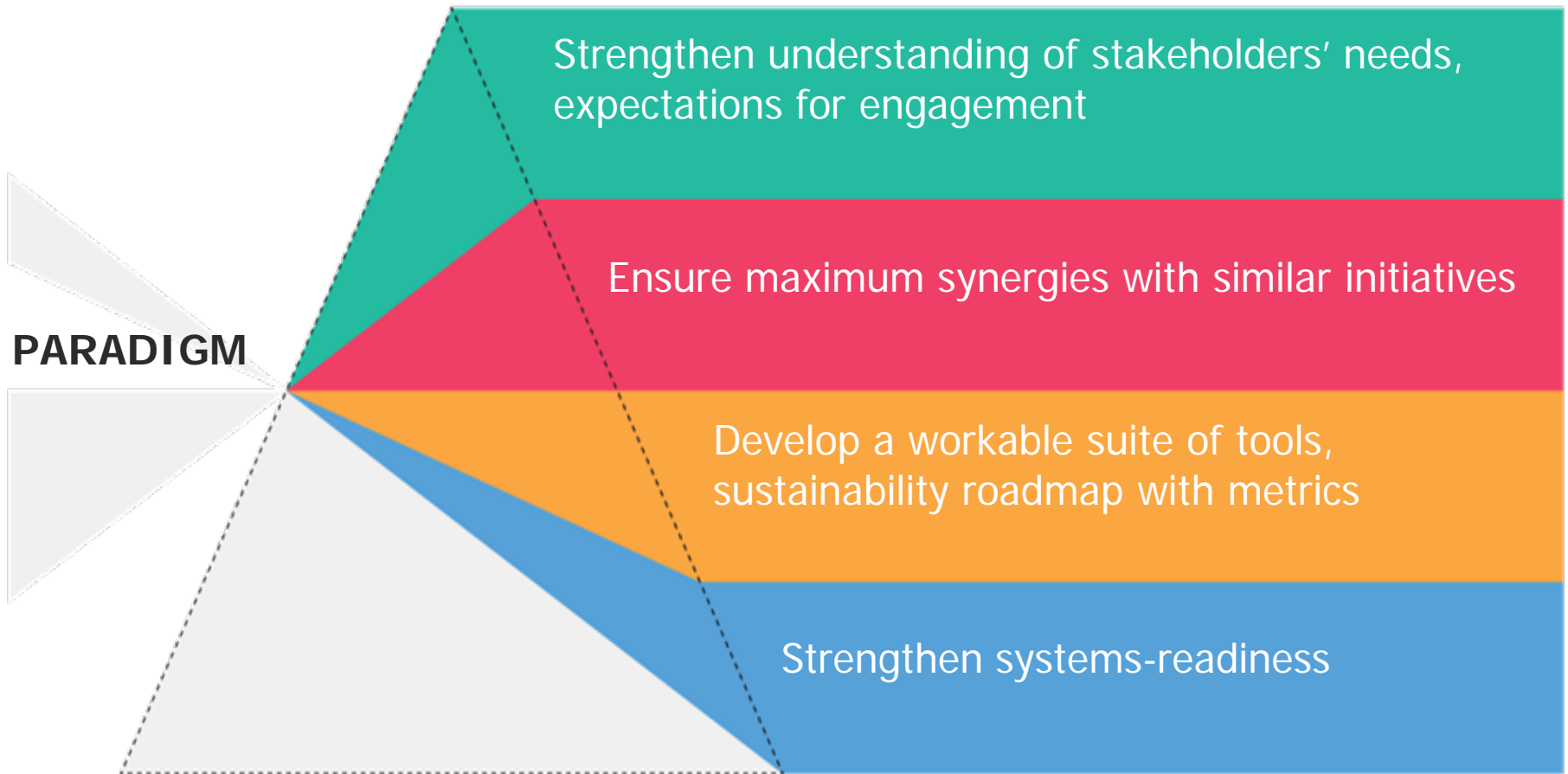
Uptake Requirements

Adoption of practices by stakeholder groups

A 'lowest common denominator' of expectations to engender effective engagement

Resource and mobilisation specifications for sustainability

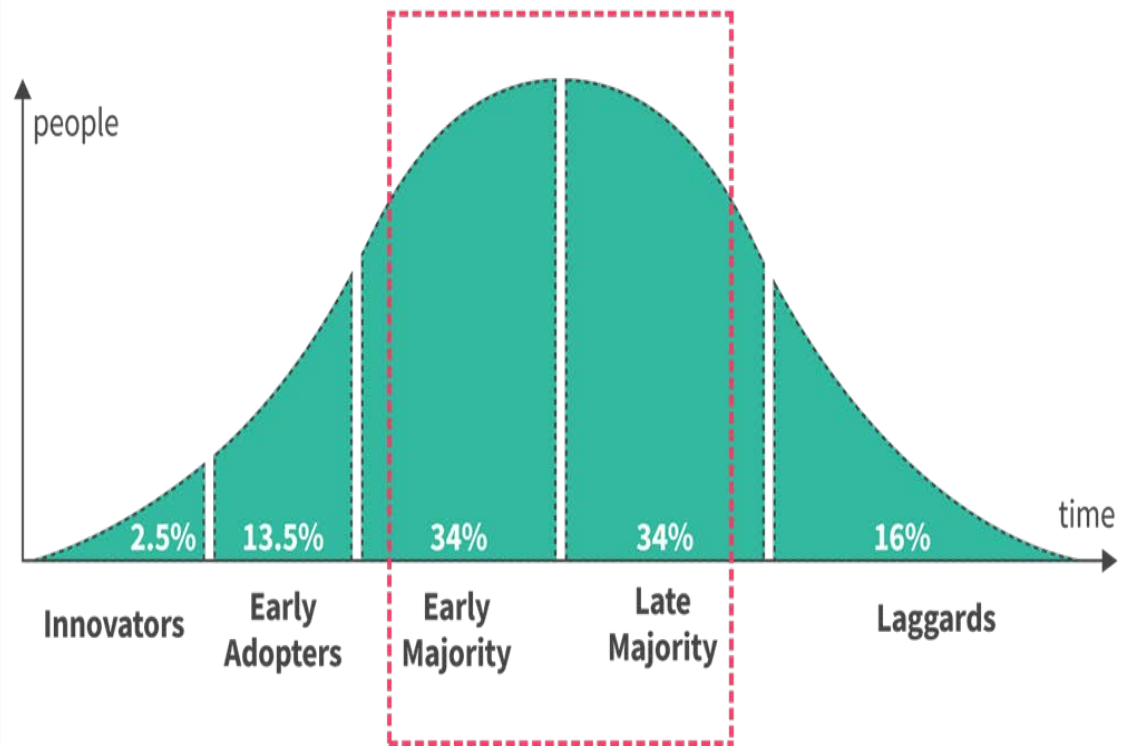
Intended outcomes



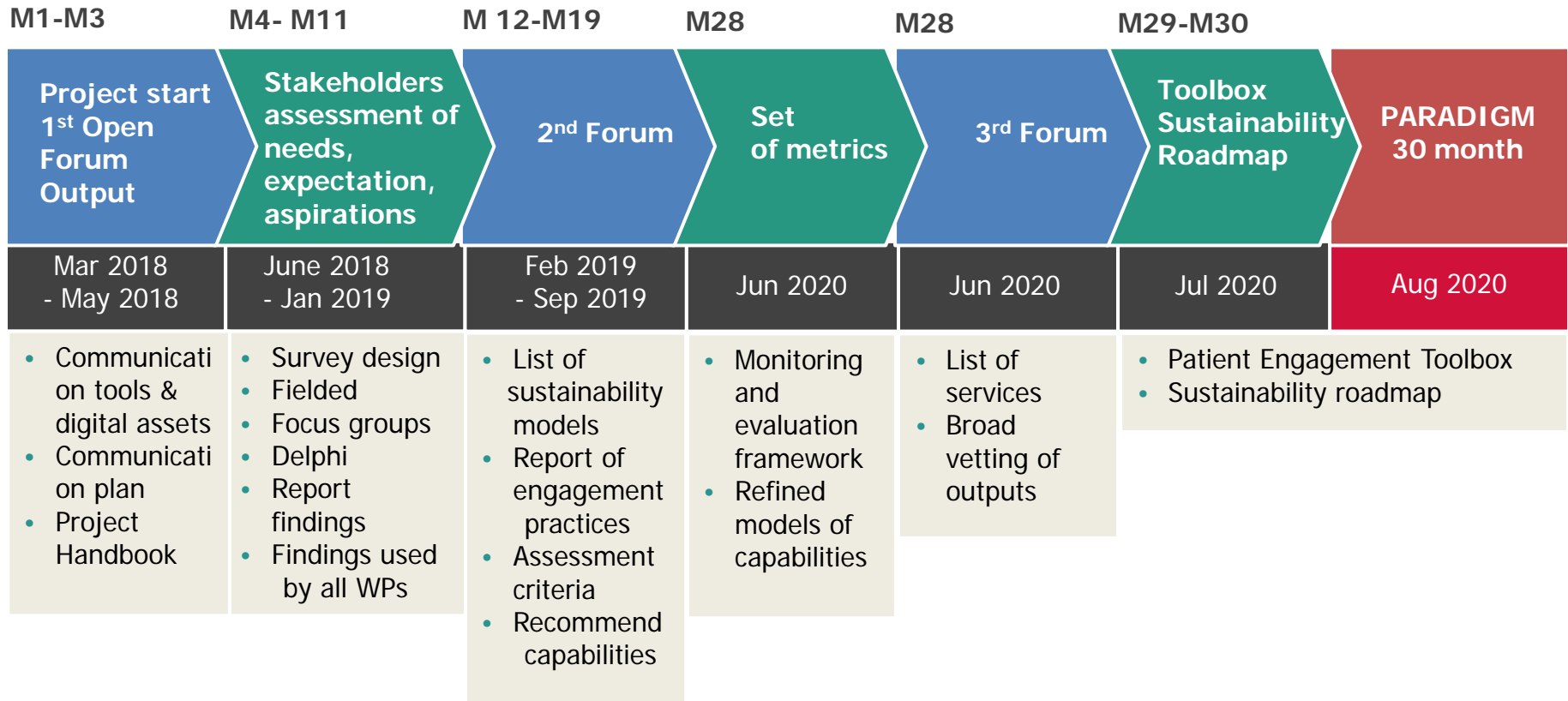
Normalizing Patient Engagement it's a step change

Normalizing Patient Engagement

- Incremental progress made to date
- Inclusion of the willing and the converted
- Key success factor will be the ability to expand to win the hearts and minds of the majority
- PARADIGM will aim to also include vulnerable groups (like dementia, or paediatric patients)
- PARADIGM will aim to gain a greater mass of acceptance within each stakeholder group



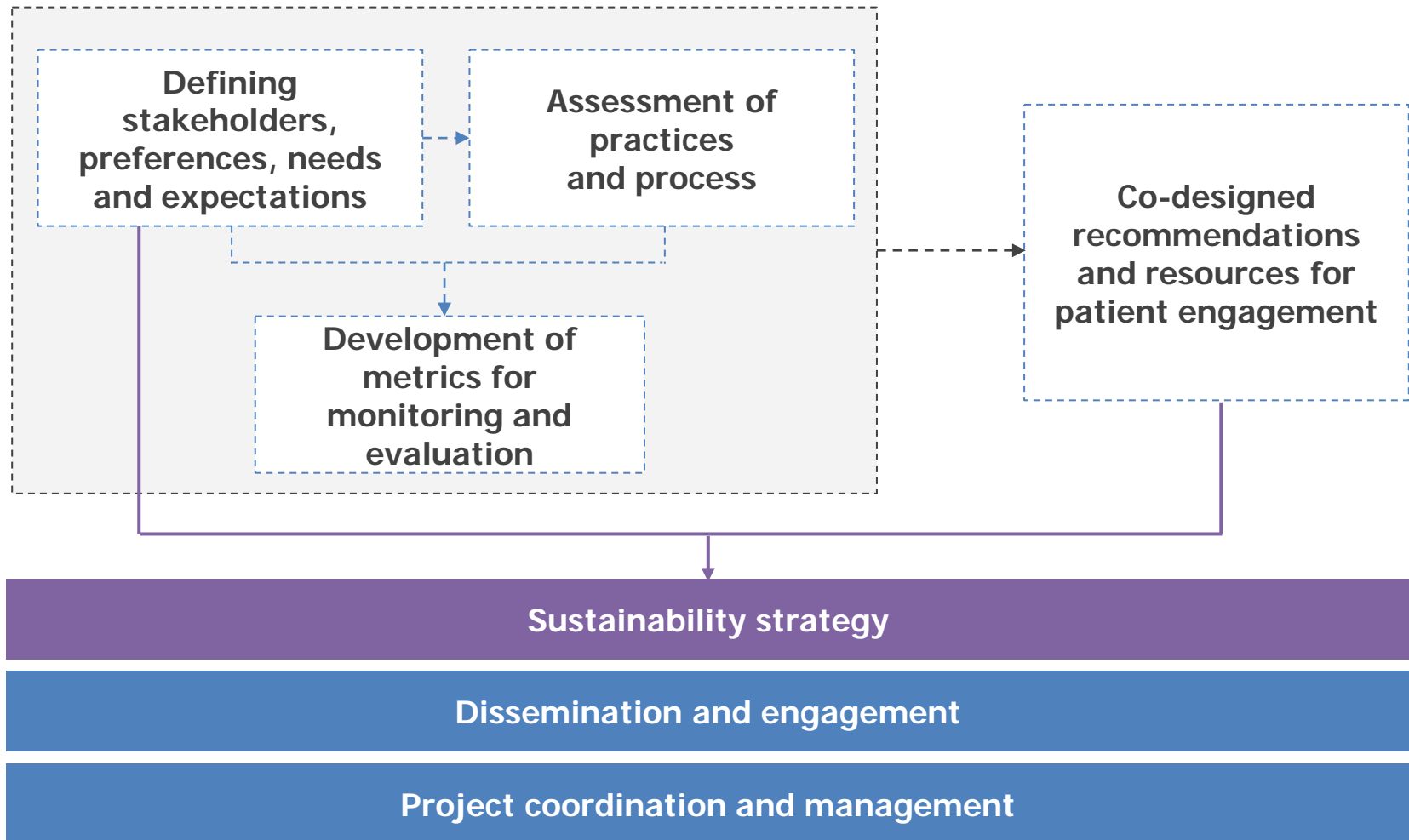
High-level deliverables



1 Consortium with the voice of 34 Partners



Seven distinct Work Packages deliver specific outputs



Governance

**REVIEW, STRATEGY,
 DECISION AND
 ADVISORY LEVEL**

GENERAL ASSEMBLY (GA)

Ultimate decision making responsibility on project strategy, consortium composition and budget.

PARADIGM INTERNATIONAL LIAISON GROUP (PILG)

Advisory and engagement role. Engages with key IMI and international PE initiatives. External guidance on the relevance of PARADIGM

STEERING COMMITTEE (SC)

Defines overall strategy and oversees the project.

ETHICS EXPERTS PANEL

Infrastructure and access to the required intelligence and

PROJECT TEAM (PT)

Project organisation and coordination, building synergies, implementation and monitorisation of activities.

COORDINATION LEVEL



Storytelling Team

Objectives

- Relevant communication materials that showcase project evolution and outputs
- Identification of potential avenues for varied types of communication
- Ensure communications are consistent with established brand and tone
- Comprised of a editor and representatives from each line of work
- Editor in chief guides the process and outputs

| | |
|--|---|
| Editor in chief: Danielle Barron - Synergist | Practices/Processes assessment (WP2): Pooja Merchant - Bayer |
| Communication (WP5): Roxana Radu - Synergist, Chi Pakarinen - Synergist, Maarten Kraaijenhagen, - Pfizer, Paula DeCola – Pfizer | Regulators/HTA: Chiara Panci - AIFA |
| Metrics (WP3): Lidewij Vat - VU-Athena | Stakeholder assessment (WP1): Barbara Haake - VFA |
| Project Coordination: Mathieu Boudes - EPF | Sustainability (WP6): Roz Schneider - Pfizer |
| Project Management (WP7): Eva Molero – Synapse | Tools and templates (WP4): Kay Warner - GSK |

Membership PARADIGM International Liaison Group (PILG)

| | |
|---|---|
| DO-IT (IMI) | International Society For Pharmacoeconomics and Outcomes Research (ISPOR) |
| Drug Information Association (DIA) | Medicines and Healthcare products Regulatory Agency (MHRA) |
| European Patient Academy (EUPATI) | National Health Council (NHC) |
| External experts - staff from NL regulator (MEB) and former staff of DE regulator (BfArM) | Other initiatives considering joining |
| FasterCures | Patient Focused Medicines Development |
| International Children's Advisory Network (iCAN) | PREFER (IMI) |
| International Consortium for Health Outcomes Measurement (ICHOM) | TransCelerate BioPharma Inc |

PARADIGM International Liaison Group (PILG) Linkage Point and Resource

Linkage & Alignment

- Share an international perspective on patient engagement
- Expand relationships with key international players
- Align initiatives across the entire Liaison Group membership

Advice & Insights

- Guidance to create well-defined roadmap & operational documents and tools
- Advise on relevance of outputs and results on a global basis
- Support to overcome obstacles and barriers

Dissemination & Reach

- Support for global implementation of outcomes
- Share PARADIGM outputs with other initiatives
- Support to improve dissemination, implementation and uptake

Ethics Expert Panel

| | | |
|---|---|---|
| Ingrid Klingmann , Chair – EFGCP | Prof. Bob Wilffert - University of Groningen | Bernadette Hendrickx - The Synergist |
| Ariella Kelman - Roche/Genentech | Maia Gonzales Hinjos - Instituto Aragonés de Ciencias de la Salud (IACS) | Fredebrik Kibsgaard – Novo Nordisk |
| Anne-Sophie Lapointe - EURORDIS | Uta Baddack-Werncke - EU Commission Contact Point, Germany | Isabelle Huys - UZ Leuven |

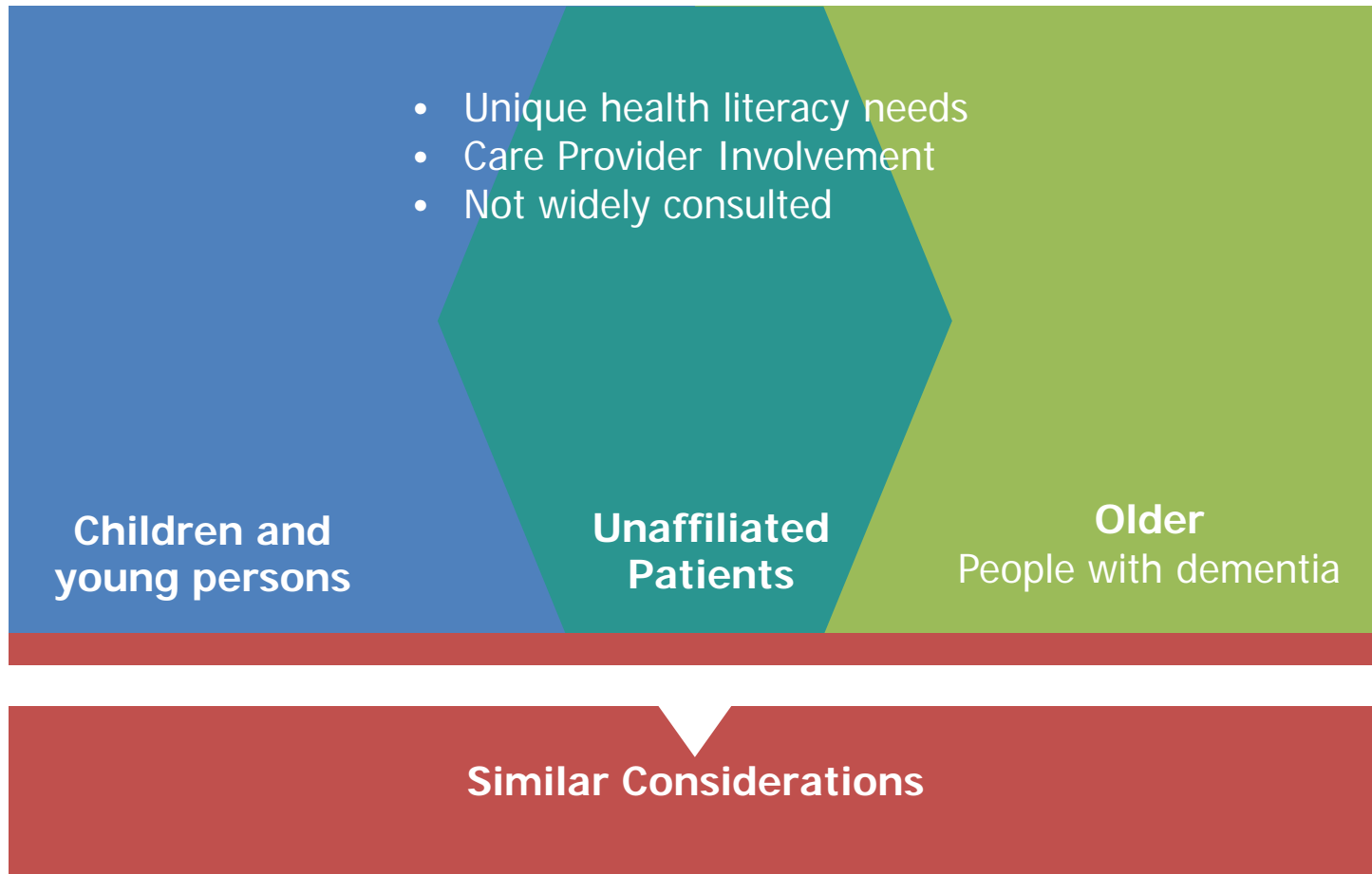
Embed a pragmatic, critical and transparent ethics dimension to project outcomes

Implement applied ethics to relevant tasks and ad hoc ethical expertise and support

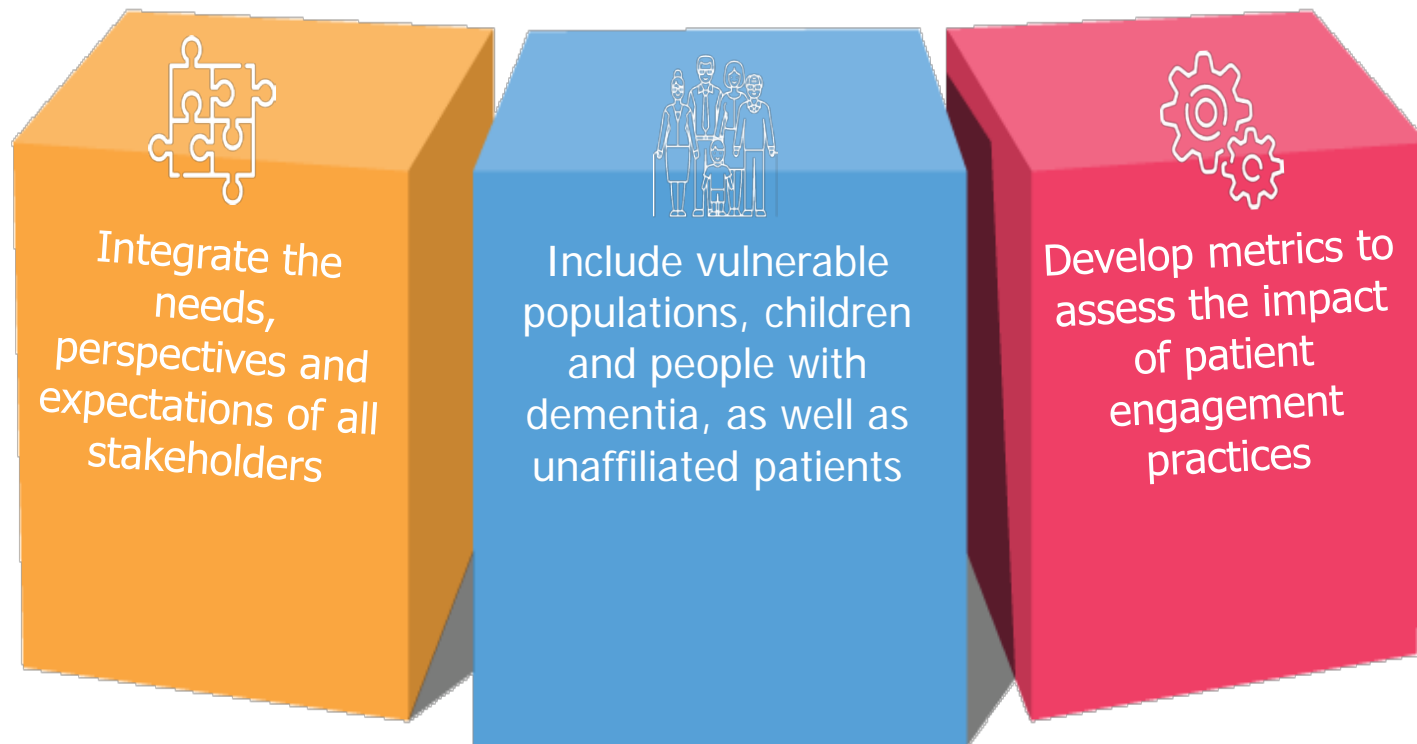
Outputs include

- An ethical framework
- Brief mid-term report
- Final report

Involvement of vulnerable and unaffiliated patients distinguishing attributes



Our building blocks



Learn more at

<http://imi-paradigm.eu/>



@imi-paradigm

www.aifa.gov.it



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