



The challenge, the vision and the value

Meaningful patient involvement in
collaborative research projects

*Jan Geissler, Patvocates // LeukaNET // CML Advocates Network
IMI impact on patient involvement, 7 Oct 2021*

Why should academic researchers, industry and regulators involve patient advocates?

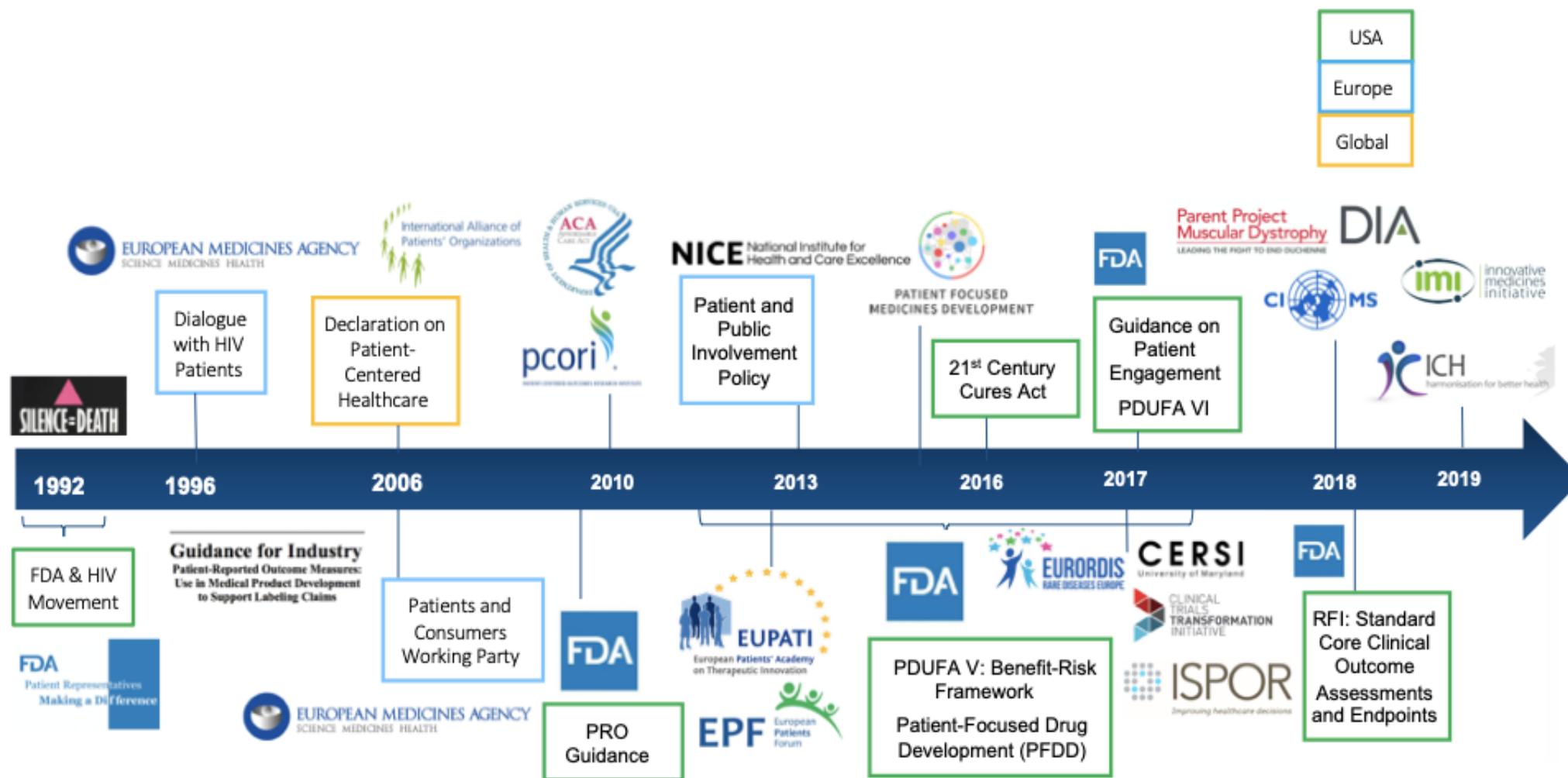


Move away from glossy statements on „patient centricity“ towards real involvement of patients in plans, actions, and outcomes

- Gather insights into the day-to-day reality of patients
- Understand „patients’ unmet need”, “patient preferences”, positive “benefit/risk” and „real value“ to patients
- Design better clinical trials, services and info resources, leading to wiser investment of limited resources and more meaningful data

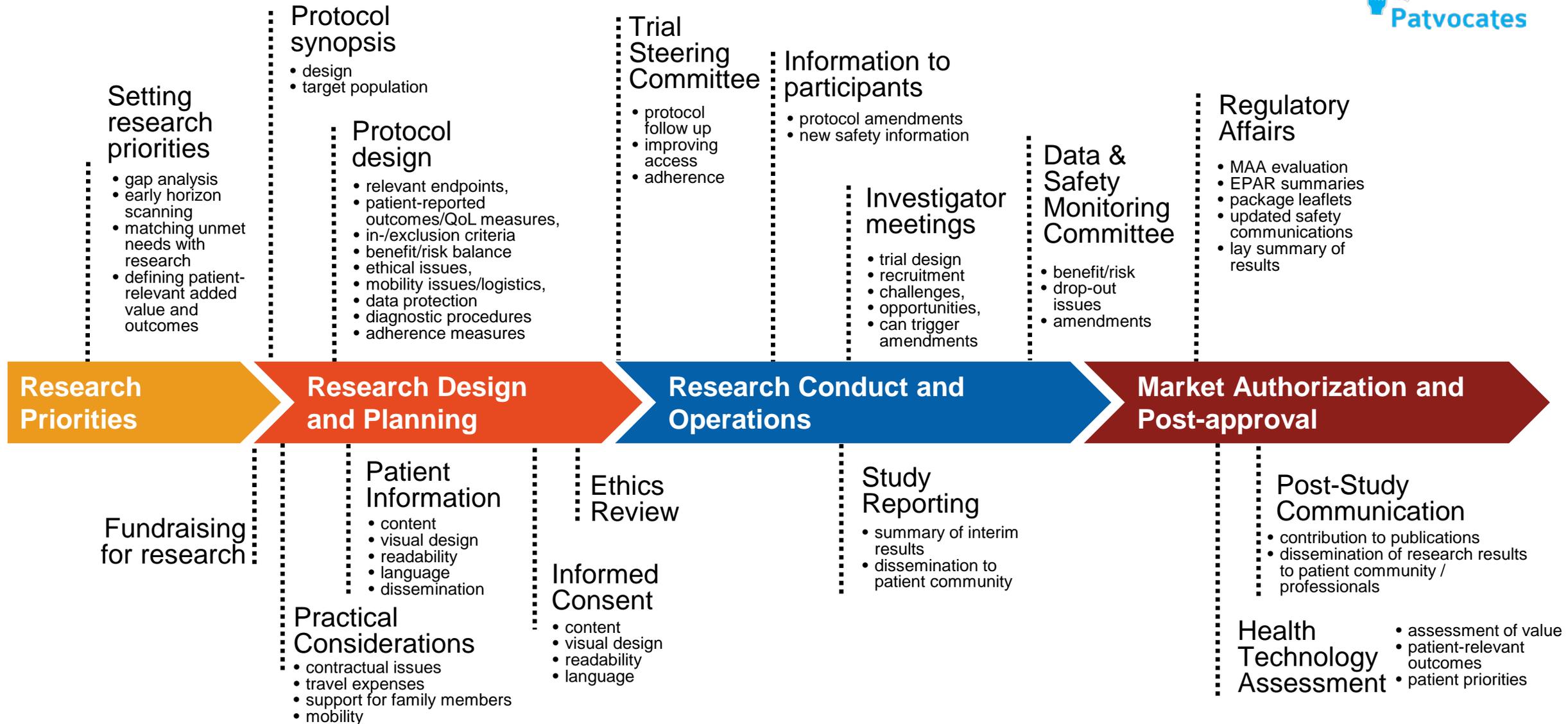
Patient involvement in R&D is not a new fashion!

Evolution from 1990s to strong maturity today



Source: PFMD / NHC (2020)

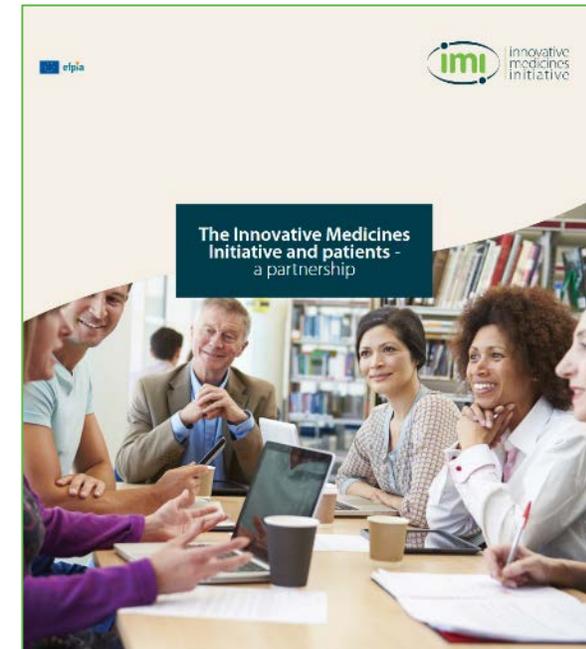
Patient involvement in clinical development in practice



20% of 135 IMI projects had patient organisations in the consortium, 30% in patient advisory boards (60% by 2021)



<p>Risk – Benefit Appraisal: PROTECT</p> <p>International Alliance of Patients' Organizations</p> 	<p>Dementia: EPAD</p> <ul style="list-style-type: none"> Alzheimer Europ 	<p>Incorporating Real World data: GetReal</p> <ul style="list-style-type: none"> International Alliance of Patients' Organizations 	<p>Big data in Hematological Malignancies</p> <ul style="list-style-type: none"> LeukaNET + Myeloma Patients Europe + MDS Alliance + Acute Leukemia Advocates Network + Childhood Cancer International + Lymphoma Coalition + CLL Advocates Network 
<p>Dementia: PHARMA-COG</p> <ul style="list-style-type: none"> Alzheimer Europe Greek Association of Alzheimer's Disease and Related Disorders: 	<p>Chronic Obstructive Pulmonary Disease (COPD): PRO-Active</p> <ul style="list-style-type: none"> Astma Fonds Longstichting British Lung Foundation 	<p>Neurodegenerative diseases: AETIONOMY</p> <ul style="list-style-type: none"> Alzheimer Europe 	<p>Big data in HM</p> <ul style="list-style-type: none"> LeukaNET + Myeloma Patients Europe + MDS Alliance + Acute Leukemia Advocates Network + Childhood Cancer International + Lymphoma Coalition + CLL Advocates Network CML Advocats Network + MPN Advocates Network 
<p>Alzheimer's disease: EMIF</p> <ul style="list-style-type: none"> Alzheimer Europe 	<p>Autism spectrum disorders: EU-AIMS</p> <ul style="list-style-type: none"> Autism Speaks Inc. 	<p>Recognising adverse drug reactions: WEB-RADR</p> <ul style="list-style-type: none"> European Organisation for Rare Diseases 	
<p>Asthma: U-BIOPRED</p> <ul style="list-style-type: none"> European Lung Foundation Netherlands Asthma Foundation Asthma UK European Federation of Allergy and Asthma Lega Italiana Anti Fumo 	<p>European Patients' Academy on Therapeutic Innovation: EUPATI</p> <ul style="list-style-type: none"> European Patients Forum European Organisation for Rare Diseases European AIDS Treatment Group Irish Platform for Patients' Organisations, Science and Industry European Genetic Alliances Network Vereniging Samenwerkende Ouder - en Patiëntenorganisaties Genetic Alliance UK 	<p>Patient engagement in R&D PARADIGM</p> <ul style="list-style-type: none"> European Patients Forum EURORDIS Alzheimer Europe European AIDS Treatment Group 	



Patient engagement ecosystem has evolved: Trainings and tools



Training for industry

- EUPATI Essentials
- EUPATI Fundamentals
- PFMD PE Training

Training for patient advocates

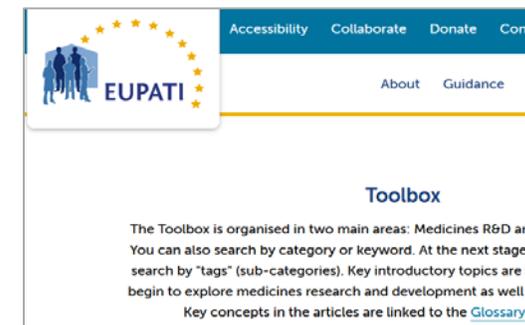
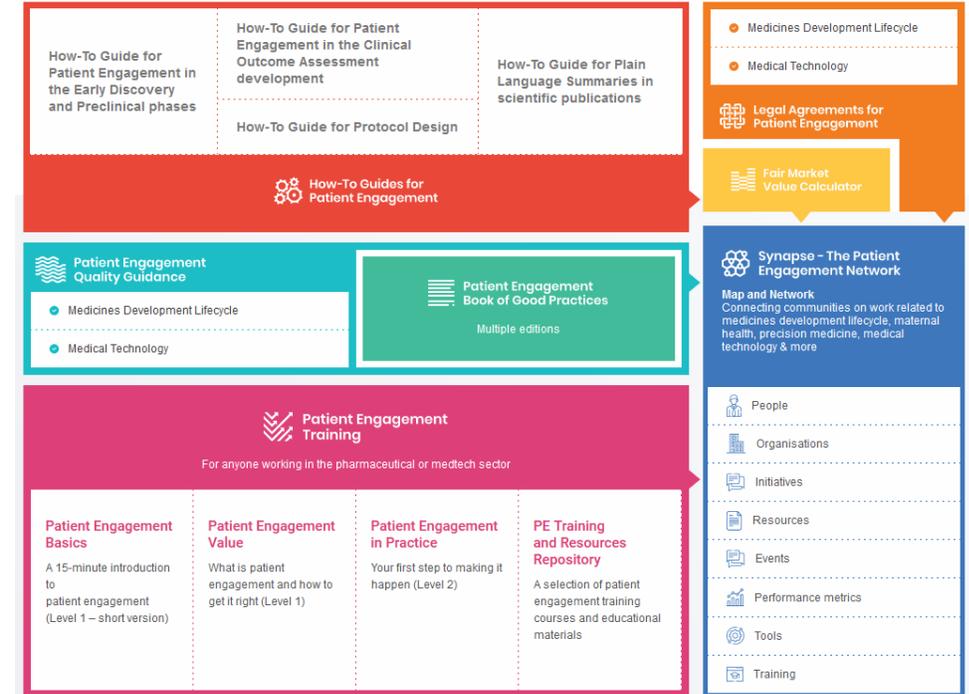
- EUPATI Patient Expert Training Course
- EUPATI Toolbox
- EUPATI National Platforms

Guidance, Frameworks and tools for patient engagement

- 4 EUPATI Guidances on Patient Engagement
- PARADIGM frameworks
- PFMD how-to-guides

Matchmaking & Best Practice Sharing

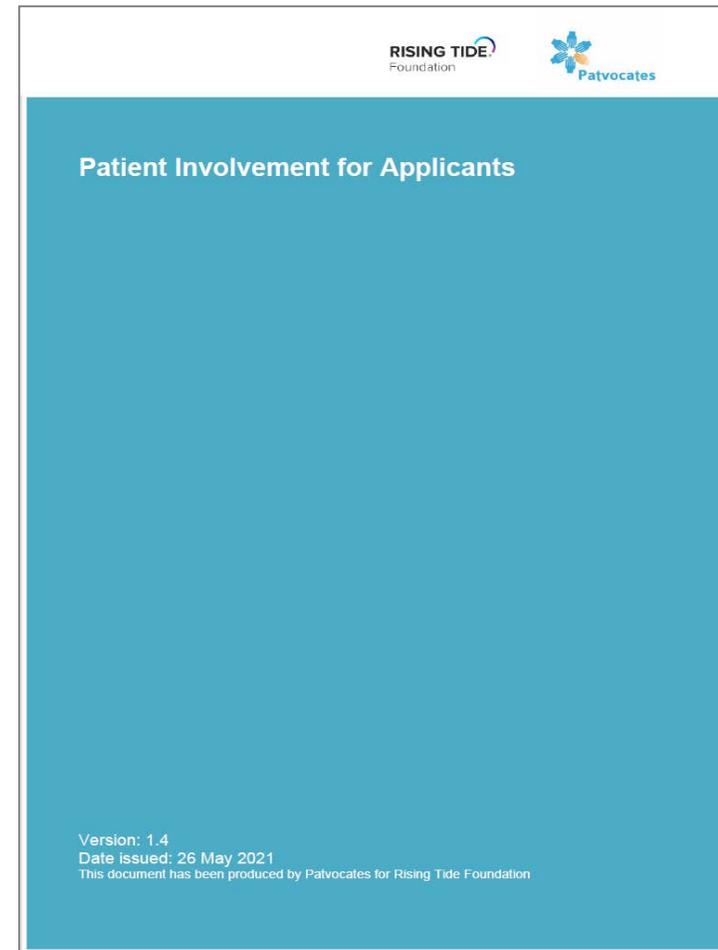
- PFMD Synapse



Practical guidance on patient involvement in collaborative research projects



- Checklist when planning patient engagement
- Examples of potential contributions of patients
- Organisational models of patient engagement in research projects
- Identification of the right patient organisation/patient advocates and resourcing the contributions
- Patient involvement plans
- Preparing the patient community for their contribution in the post-application, pre-launch phase



Involvement models for collaborative research projects



Engagement model	Patient organization's / patient expert's role	Impact
Project coordinator, chair or co-chair	Leads and coordinates the research project	Very high
Steering committee member	Member of the governance board of the research project	Very high
Work package leader	Coordinates a specific work package in the project	High
Research project member	Full member of the research teams	Medium
Patient involvement hub	Full project member, coordinating all contributions from the wider patient community	High
Associated project partner	Partnership agreement with the research project (but usually no funding)	Small
Advisor / advisory board member	Providing advice in ethics committee, scientific/project advisory board, data safety monitoring board, but no governance or leadership role	Small



The first and largest Public-Private Partnership for Big Data in Hematology

14 key targeted blood cancers



Patient input into HARMONY Core Outcome Sets, HARMONY Delphi Surveys, HARMONY Research proposals

HARMONY Patient Organisations Masterclass, HARMONY Communications about Big Data in Blood Cancer and about project results to patients and general audience

HARMONY Ethical Framework, De-identification Mechanisms

Patient input into core HARMONY tasks:

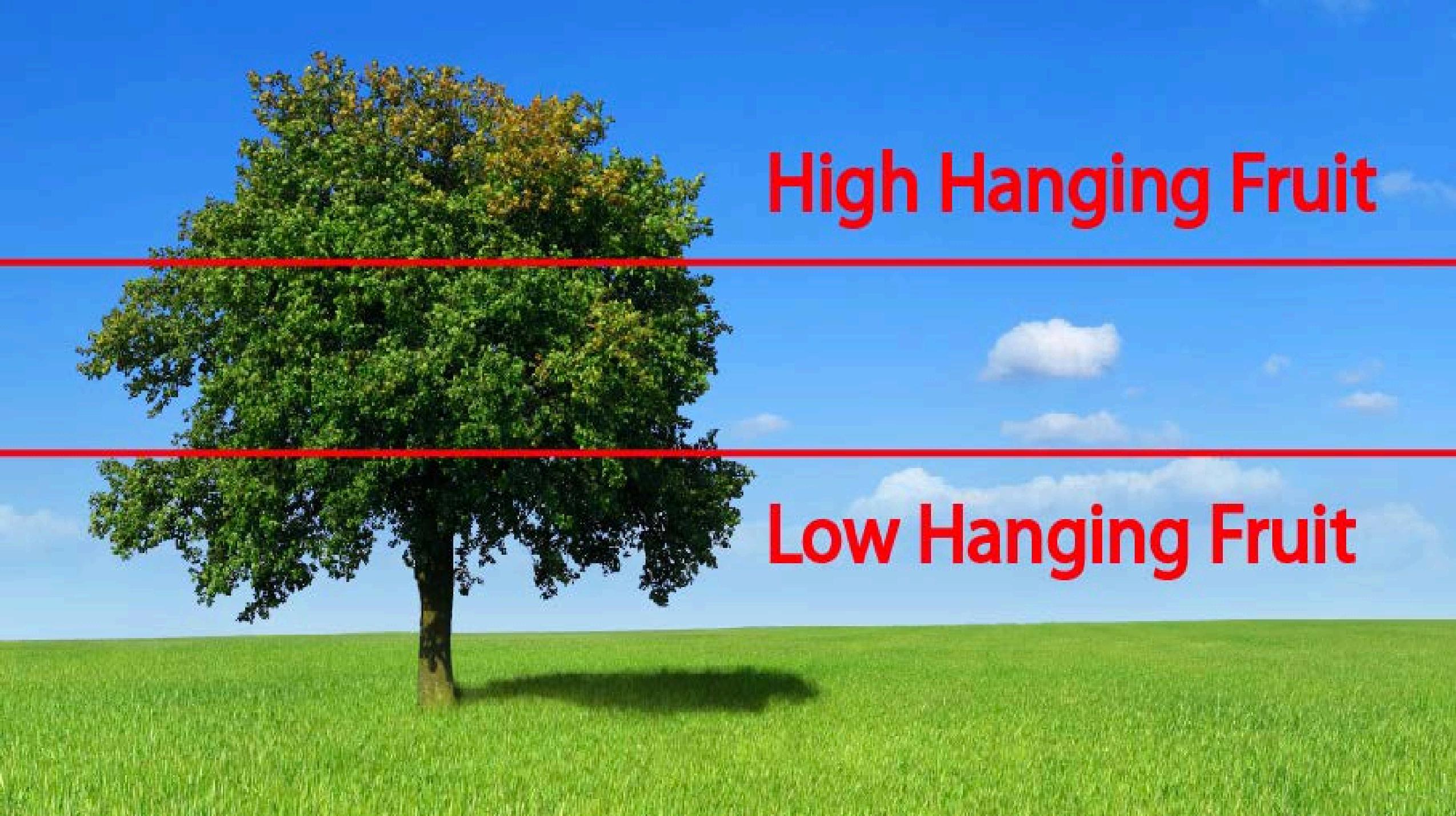
- Stakeholder Forum
- Clinical Value Framework
- Access Evidence Framework



All essential ingredients for patient engagement for more inclusiveness are here

- Shared purpose and **collaborative spirit**
- **Political and institutional will**
- Engagement **frameworks**
- **Capacity** to engage
e.g. by patient organisations,
companies and institutions



A large, leafy tree stands in a vast green field under a blue sky with scattered white clouds. Two horizontal red lines are drawn across the image. The upper line is positioned near the top of the tree's canopy, and the lower line is positioned near the bottom of the canopy. The text 'High Hanging Fruit' is written in red to the right of the upper line, and 'Low Hanging Fruit' is written in red to the right of the lower line.

High Hanging Fruit

Low Hanging Fruit

All essential ingredients are here. Let's engage!

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