



Mens-gebonden klinisch onderzoek: vitaal of finaal ?

DCRF jaarcongress 2019

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**EEN INTERNATIONALE
PHARMACEUTISCHE GROEP,
BESTUURD DOOR EEN STICHTING
ZONDER WINSTOOGMERK**

- Franse origine/hoofdzetel; 93% verkoop buiten Frankrijk; 62% buiten de EU
- 22.000 werknemers, waarvan 2900 in R&D en 4200 in productie; 50/50 vrouw/man
- Onderzoek in kanker, hart/ vaatziekten, immunologie, neuro-psiatrie, diabetes
- 2/3 merkgeneesmiddelen en 1/3 generische geneesmiddelen



Mens-gebonden ?

Vitaal of finaal ?

De patiënt centraal ?

vitaal of finaal

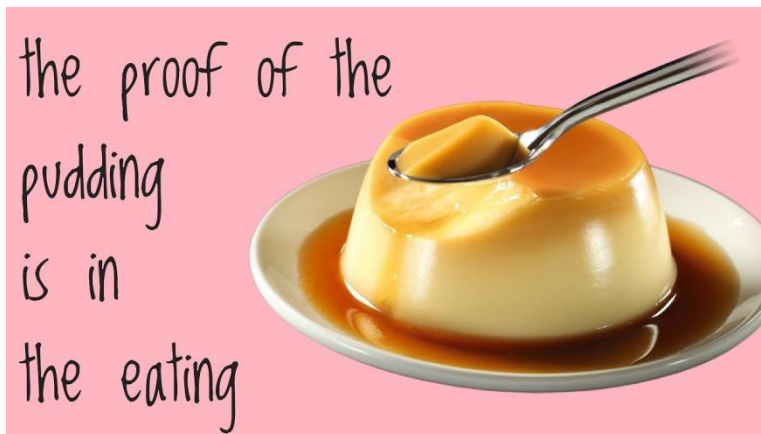
vitaal

- Vol van leven (= vita)
- Essentieel voor (goede) werking (incl leven)

finaal

- Uiteindelijk, laatste, definitieve
- Helemaal

Always Start with the WHY



Thank the customer who complains:
the other 9 went to another garage



Your most unhappy customers are
your greatest source of learning.

— Bill Gates —

AZ QUOTES

Patient In WITH and FOR patients



The future of Health is Collaboration



Collaboration is harder than innovation.



Our most consequential human problems will be resolved, not through competition, but collaboration... what we need in education is a learning climate in which students work together. In such an atmosphere, truth emerges as authentic insights are conscientiously exchanged.

— Ernest L. Boyer —

*Collaboration is harder
than innovation
because you **release control***

**I CAN DO THINGS YOU
CANNOT, YOU CAN DO
THINGS I CANNOT;
TOGETHER WE CAN DO
GREAT THINGS.**

MOTHER TERESA

Bureaucracy

is a disease

masquarading as its own treatment





100% PURE ESSENTIAL OIL

HOPE

Synergy
Blend

4 fl oz (118 ml)

PFMD in a nutshell

Projects and partners - 2019



PFMD Membership August 2019

made
with
patients

 NATIONAL HEALTH COUNCIL	 Parkinson's Foundation	 EPF European Patients Forum	 EUPATI European Patients' Academy on Therapeutic Innovation	 C101 CANCER101 EMPOWER. ORGANIZE. INFORM.	 Society for Participatory Medicine	 National Kidney Foundation™
 FasterCures A CENTER OF THE MILKEN INSTITUTE	 EURORDIS RARE DISEASES EUROPE	 LEUKEMIA PATIENT ADVOCATES FOUNDATION	 NIHR INVOLVE	 DIA	 PARKINSON'S ^{UK} CHANGE ATTITUDES. FIND A CURE. JOIN US.	 gsk GlaxoSmithKline
 Lilly	 HTAi™	 Roche	 NHS Health Research Authority	 ucb	 MSD	 World Alliance of Palliative Organizations
 Janssen PHARMACEUTICAL COMPANIES a Johnson & Johnson company	 NOVARTIS	 Pfizer	 Takeda	 SERVIER	 Arthritis Foundation®	 AMERICAN MIGRAINE FOUNDATION
 Saint Joan de Dieu Research Foundation	 NIHR Sheffield Biomedical Research Centre	 astellas				

Key projects

made
with
patients

Framework building workstream

Development of a practical PE meta-framework with tools that help all stakeholders to do more qualitative PE.

- PE Quality Guidance
- Book of Good Practices
- PE activities and Do's and Don'ts
- How-to modules



SYNaPsE Networking & Mapping Tool

An interconnected platform of PE actors, initiatives, organisations and resources. SYNaPsE is evolving from landscape mapping to offering a full range of integrated PE management tools



Fair Market Value

There is no agreed system in place for financial compensation that reflects the level of individual contribution and expertise of patient partners.



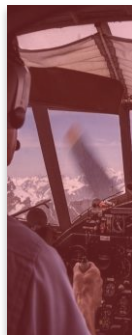
Reasonable legal agreements

This initiative aims to improve legal agreements between patient advocates and pharmaceutical companies while providing adequate protection and rules for both sides.



PE Industry Training

Co-designed with 13+ organisations from around the world. Twofold objective: an e-learning program about PE, as well as an awareness tool for culture change for reaching the early and late majority within the pharma industry.



Plain Language Summaries for Publications

Co-creation of a practical guidance for writing plain language summaries in a coherent way that brings value to the patient community.



Pledge to Patients

Committing to more meaningful patient engagement in medicines development by listening, co-creating or communicating with patients and sharing it with the world.



Strategic communication activities with PFMD members and collaborators

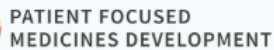


Guiding Principles on Reasonable Agreements between Patient Advocates and Pharmaceutical Companies

WE CAN – Final Consensus Document, 16 October 2018, V6.1

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Please note that in order to start using the platform you need to create a new account. You cannot log in using the same credentials as for your [Synapse](#) account.

1. Select "The Patient Engagement Industry Training" and "Add to training plan"
2. Click on "Start course"

1. At the end of every screen, continue by clicking "Complete and continue" at the bottom of the page. Only then your progress will be saved.
2. It is not possible to skip lessons.
3. Click on the + signs in the interactive visuals to get the additional information and/or examples. The course will resume where you left off.
4. At the end of the quiz, you will be able to download your training certificate.

WORKING TOGETHER WITH PATIENTS

PRINCIPLES FOR REMUNERATING PATIENTS, PATIENT ORGANISATION
REPRESENTATIVES & CARERS FOR WORK UNDERTAKEN WITH
THE PHARMACEUTICAL INDUSTRY

June 2019

Developed by the EFPIA Patient Think Tank



The principles are:

1. THE RIGHT TO REMUNERATION
2. LEVEL SHOULD BE FAIR
3. NON-DISCRIMINATION
4. RESPECT
5. NON-PROMOTIONAL
6. TRANSPARENCY
7. APPROPRIATE PAYMENTS
8. CONSISTENCY
9. RIGHT TO REFUSE

PFMD Contributors' Network initiated in Feb/ 2019 - Sep/ 2019

made
with
patients

52 Participants, representing
38 Organisations, in
* 6 Working Groups

15 Industry representatives
10 Patient/ patient organisation representatives
6 Consultancy representatives
6 Patient experts/ advocates
3 Independent experts with various related expertise
2 Publishers
2 Academic researchers

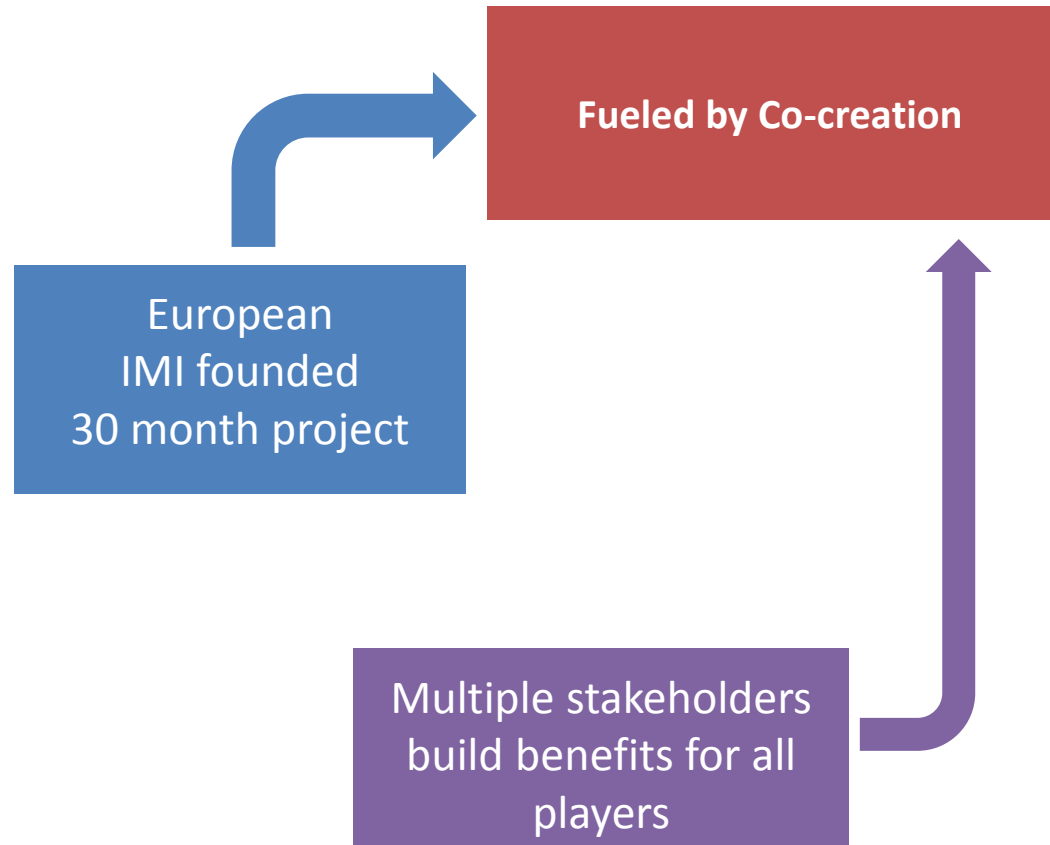
2 Medical Communications Agency
2 CRO/ Service providers to pharma industry-representatives
1 Research Hospital representative
1 National public and patient involvement organisation
1 Research Institute
1 Young Patients Advisory Network representative



PARADIGM: A collaboration for enhanced patient engagement

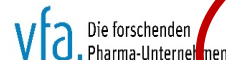
Advancing meaningful patient engagement (PE) in the life cycle of medicines for better health outcomes

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



Multi-stakeholder collaboration

- to drive meaningful and systematic patient engagement



PARADIGM

Mission

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



Research
and priority
setting

- Patients' perspective largely untapped for this in research priority setting
- Input on unmet medical needs critical for prioritization
- Patients' perspective required for determination of value proposition



Design of
clinical trials

- Building block of development necessitates routine patient input
- Voice of vulnerable and unaffiliated patients not yet integrated
- New insights to support generation of standard processes



Early dialogues
with regulators
and HTA bodies

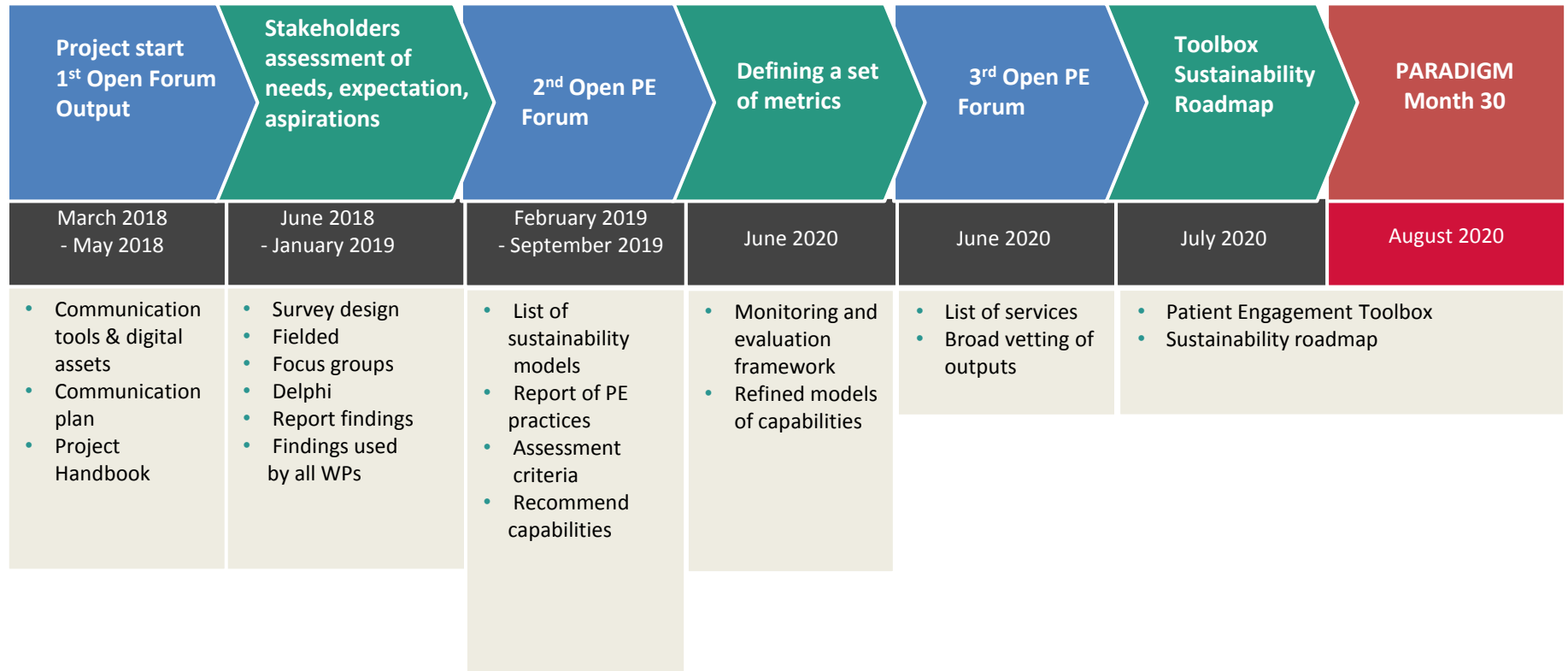
- Patients' input not regularly sought
- Patient perspectives critical to inform access decisions
- Guide generation of standardized processes

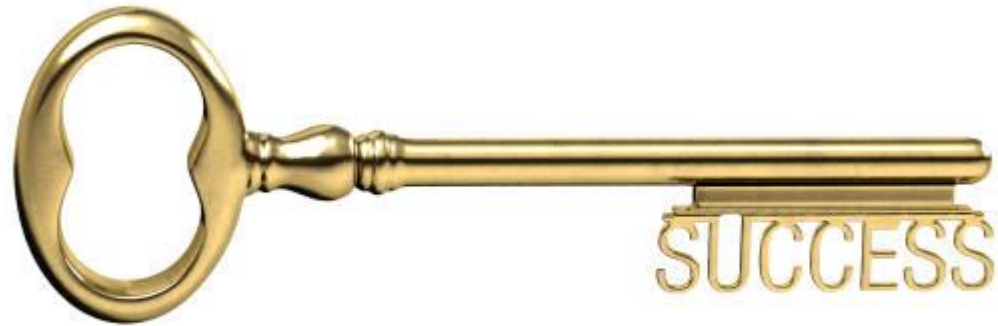


Objectives

Develop processes and tools for these three points in the medicine lifecycle
Develop a sustainability roadmap for patient engagement

High-level Deliverables





Cost divides

Value unites

The best time to plant a
tree was 20 years ago.
The second best time is now.

~ Chinese Proverb



PATIENT IN: WERKEN *MET* EN VOOR PATIENTEN



ONZE BESTAANSREDEN

- Toegewijd aan therapeutische vooruitgang om de behoeften van de patiënt te dienen

ONZE 10-JAARSVISIE

- De patiënt betrekken in al onze activiteiten
- Focus op het scheppen van waarde

IN DE PRAKTIJK

- Beginnen met direct te luisteren en te kijken
- Steeds feedback vragen en impact meten

vitaal of finaal

vitaal

- Vol van leven (= vita)
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finaal

- Uiteindelijk, laatste, definitieve
- Helemaal

of

- Typisch voor duaal denken



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KEEP
CALM
AND
WORK
TOGETHER