



PATIENT FOCUSED
MEDICINES DEVELOPMENT

Patient Focused Medicines Development

2018 report

Message from the Programme Director

We are now witnessing a paradigm shift in patient engagement. Instead of contemplating the risk of doing patient engagement, growing numbers of decision-makers in medicines development are speaking of the risks of not doing patient engagement.

Behavioral science, patient engagement capacity, and real-world evidence support the evolution towards a new model that integrates patient engagement at all levels. With FDA building expectations of patient input and how to generate it, we are approaching a tipping point where co-creation with patients is on the verge of becoming the default option throughout the system.

Momentum is behind the patient engagement community and we are now getting into the nuts and bolts of making patient engagement work. Whether it's the WECAN initiative on reasonable legal agreements between patient advocates and drug companies; forthcoming initiatives to determine the Fair Market Value of patient input; the EU-backed PARADIGM partnership; or the patient-centric focus of The Economist Intelligence Unit's new report on the future of drug development, it is clear that patient engagement is becoming internalised by the medicines development system.

PFMD has been playing its part in driving change in the patient engagement community. 2018 was a pivotal year for our collaborative initiative, preparing the way for a new phase in our shared history - where we can build on the Patient Engagement Quality Guidance as the robust foundation to develop more specific 'How-to' material, training modules, contract templates and fair market value assessment, plain language summaries, and more.

Nicholas Brooke,
Chief Executive Officer,
The Synergist

Achievements

PFMD membership

PFMD saw its membership grow by 5 organisations in 2018.

The membership is now 30 strong, welcoming Servier, Arthritis Foundation, Sant Juan de Deu Research Foundation, American Migraine Foundation, and Sheffield Biomedical Research Centre. This has increased the project's geographic and stakeholder group reach.



The Patient Engagement Quality Guidance

The framework-building work stream produced Patient Engagement Quality Guidance that has been shared within and beyond organisations, referred to in conferences and used as a tool to plan patient engagement projects and assess the quality of ongoing and completed projects.

The co-developed Patient Engagement Quality Guidance has been embraced by the patient engagement community which has shared it internally and beyond and utilised it for patient engagement projects. These initiatives spanned the full medicines-development continuum, the lifecycle of medicines, and care continuum in both health and social research. Member organisations have adopted it for various purposes, on a project basis or as a tool to design, assess and manage all their patient engagement activities. Other non-member companies have simply downloaded the document and worked through it step by step.

Currently, the Patient Engagement Quality Guidance is in the piloting phase with 5 projects in Europe and the United States by 2 organisations with diverse expertise including patient advocacy, medical affairs, pharmaceuticals, research and charity, healthcare services and consultancy. The outcomes of these projects will help us understand and explore the impact Patient Engagement Quality Guidance can bring to users. It can also improve its usability and help us incorporate it into Synapse, allowing you to manage all your patient engagement projects in one place.

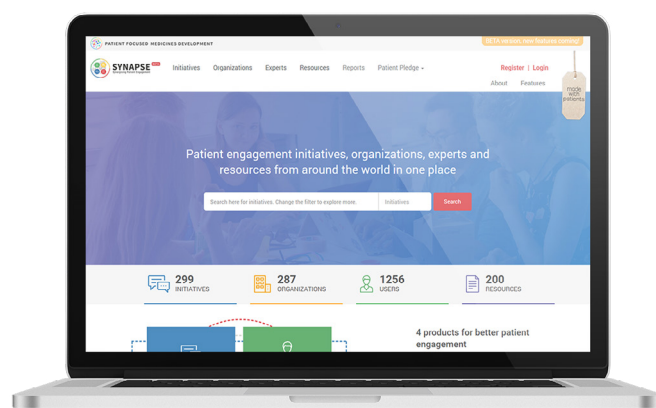


To continue building the patient engagement Metaframework, the public consultation that was conducted over the summer of 2018 gave us valuable information on how and which of the 150 patient engagement activities identified in the literature review phase should be prioritised. The consultation received 133 responses from 26 countries (taking us beyond the Europe and US) with all stakeholder groups represented.

Another relevant output of 2018 was the Book of Good Practices, which offers a set of 8 cases that exemplify one or more of the 7 Patient Engagement Quality Criteria introduced in the Patient Engagement Quality Guidance. We will continue to feed it as a source of best practices and case studies for ongoing and new patient engagement projects.

SYNaPsE

The SYNaPsE platform has evolved from mapping patient engagement initiatives to also connecting the whole patient engagement ecosystem of experts and their organisations to initiatives and related resources. The platform has grown 18% from 2017 in initiatives and 30% in organisations, further adding to the diversity of the tool.

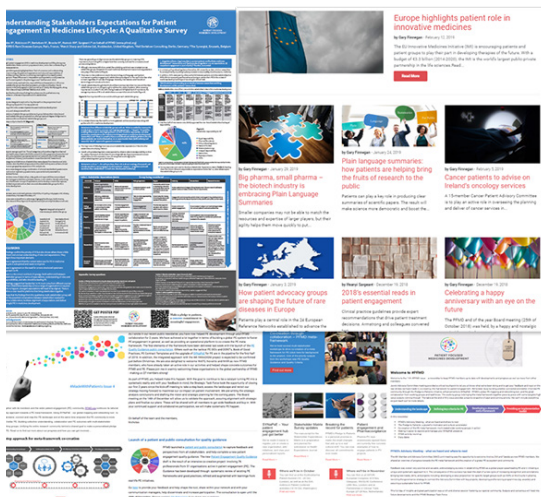


This kind of growth tells us the impact Synapse has for those working in patient engagement - it can bring efficiency and productivity to companies and organisations by enabling users to share their patient engagement projects, knowledge and reports in one coordinated place, available 24/7. A new relationship management function is piloted to allow any user to map, connect and now operate patient engagement. This allows them to shape, plan and assess patient engagement projects with partners, to keep tracks of relationship with partners and who they have been in touch with within your organization, and finally to aggregate the bigger picture of your organization's activities and its performance.

Reach and impact

In terms of reach and impact, PFMD Communication in 2018 has focused on reaching not only the patient engagement enthusiasts, but also the early majority that might not yet have fully embraced patient engagement.

In order to advance a more systematic, high quality and meaningful patient engagement, we need to create a mindset shift on a larger scale and not talk only to the “converted”. PFMD's relevance and reputation continues to grow with a milestone publication on understanding stakeholders' expectations of patient engagement across the medicines lifecycle. PFMD also published 45



insightful blogs, of which 22 were guest posts from members and collaborators receiving over 7,000 views by the patient engagement community. Constant communication with members and other interested groups has always been one of the focal points for PFMD and this continued in 2018 with 7 internal and external newsletters sent out reaching more than 4,000 patient engagement enthusiasts. Moreover, PFMD participated in 18 external conferences all over the globe, of which 12 included speaking opportunities.

2018 was a pivotal year for our collaborative initiative, preparing the way for a new phase in our

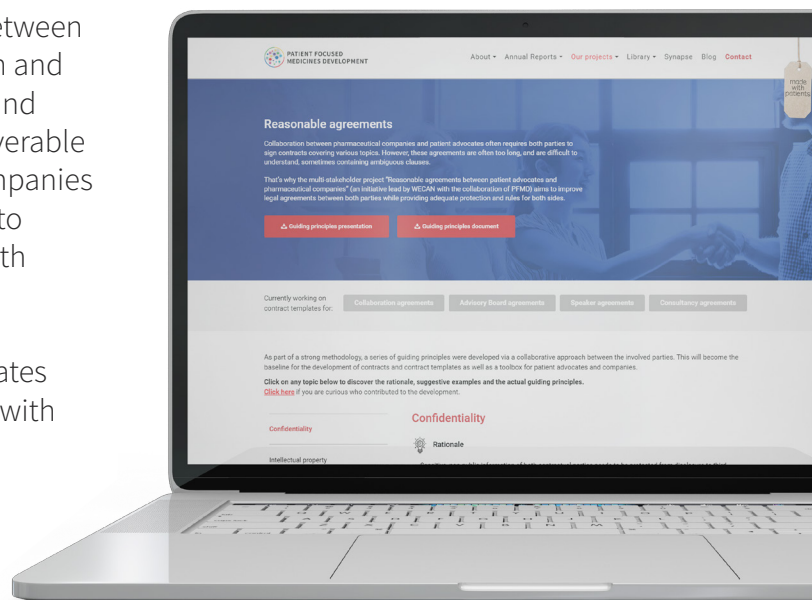
shared history - where patient engagement goes mainstream. Various initiatives within the patient engagement landscape have begun aligning with PFMD, joining efforts to maximise the global impact. This collective approach will be both a cause and a consequence of patient engagement going mainstream.

Reasonable agreements project

To ensure adoption and viable partnership between pharmaceutical companies and patient advocates, WECAN with the support of PFMD, initiated the multi-stakeholder project “reasonable agreements between patient advocates and pharmaceutical companies” (RAPP).

The project aims to improve legal agreements between both parties while providing adequate protection and rules for all sides. Collaboration between PFMD and WECAN on RAPP has produced the very first deliverable - “The Guiding Principles” - that aims to help companies working with patients and patient organisations to formulate agreements that are reasonable for both parties.

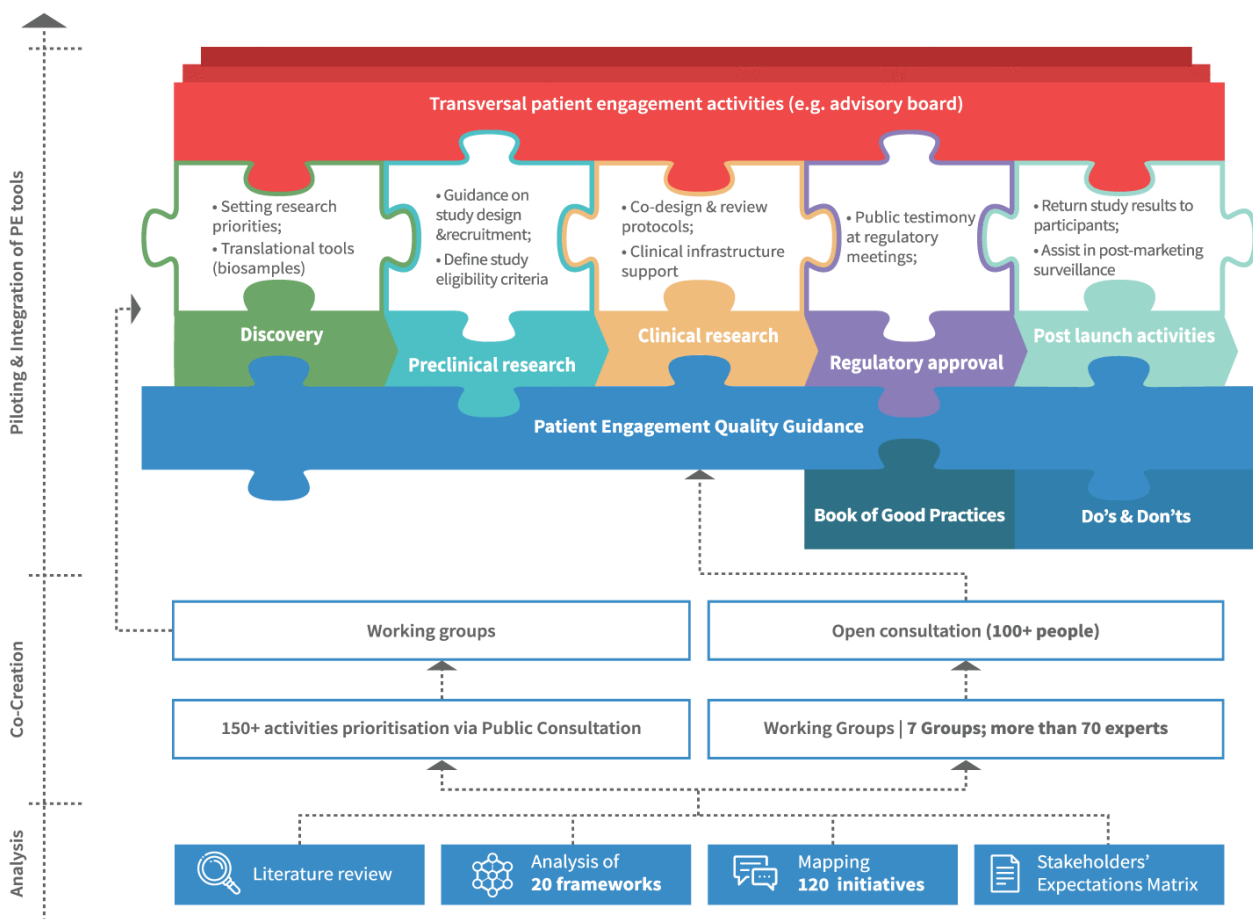
The work continues with drafting contract templates that can be adopted by all stakeholders, starting with contract templates for Patient Advisory Boards and then collaboration, consulting and speaking agreement.



2019 Approach

The need for PFMD remains present and is even increasing.

Since the beginning, PFMD has developed a systematic approach that ensures co-creation upon existing knowledge and balanced collaboration with all relevant stakeholders. Not only does this approach allow us to work in iterations and involve many collaborators in the co-creation process, it also prevents us from deviating from agreed objectives as checkpoints are frequent in each iteration.



And finally, it allows us to move away from the isolated and fragmented practices to bring all good practices into a unified coherent framework. The next step in making patient engagement happen systematically sees PFMD building on existing working groups to deliver “How-to Modules” for patient engagement activities, skills and development phases. We are taking a collaborative leadership role in defining and co-creating a patient engagement training programme for the pharmaceutical industry.

The planned training will be developed to take into account the complexities in big and small companies as well as the differing needs of patient engagement capacity-building in every company. The content and delivery method of the training will be created to match user and company needs. Interested people and organizations have the opportunity to join this work in 2019.

PFMD will focus on expanding the patient engagement ecosystem through strategic collaborations with other stakeholders who are working towards the same goal. This translates into continued positive discussions with the FDA on potential synergies, in particular about the system changing work on Patient Focused Drug Development (PFDD) in increasing the demand and creating the conditions for all stakeholders to adopt PE systematically. Specifically, the opportunities to support the ongoing Clinical Outcomes Assessment (COA) project will be the starting point in 2019.

One of the most exciting projects in 2019 will be the collaboration with European and US-based groups to develop a calculator for fair market value (FMV) compensation for patient input and expertise. PFMD will be the international connection to the regional work groups - the National Health Council (NHC), EFPIA Think Tank, and WECAN - and will act as the platform to globalise the FMV solutions created. First outcomes are expected in the summer.

The PFMD Team

Board members and PFMD team

The PFMD Board consists of:



Nicola Bedlington
Secretary General,
European Patients
Forum



Veronica Todaro
Vice President,
National Programs,
Parkinson's Disease
Foundation



Graeme Johnston
Patient Advocate,
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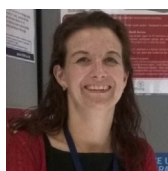
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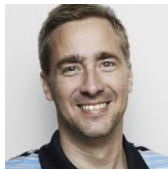


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The PFMD Team consists of:



Nicholas Brooke
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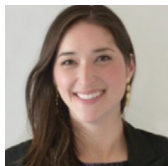
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Helena Harnik
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Editor In Chief



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Head Of IT



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Web Developer

Our partners

They made all this possible

A total of **30 partners** have decided to join forces to support and push forward our initiatives. This represents a major change in philosophy that has already started generating significant output on all projects.



2018



Overall Impact

Introduction

We believe collective action is the most untapped source of progress on societal issues. We believe in mutual collaboration and community, in joining forces and in building synergies to deliver on the challenges we face.

Investing in collaboration and collective action today means succeeding tomorrow. Maintaining a fragmented approach will continue to deliver a fragmented, inefficient or suboptimal impact.

2018 has been another important milestone in combining new skills, experiences, methodologies and tools. Neverbefore have we had such a well-balanced ecosystem for tackling complex societal issues. At the Synergist, we have developed Synapse - a mapping and collaborative suite dedicated to empowering collective platforms and their ecosystem. It is a key asset that, combined with offline collaborative best practices, blurs traditional boundaries and creates new opportunities.

We are still learning, we are still building capacity, and in 2019 we will continue this journey. However, armed with our combined experience, a growing team, and the power to develop tools together with 71 partners, we have never been so close to a scalable model that could be quickly applied to any societal issue.

We, The Synergist team and all involved partners, contributors, individuals and organizations, are working to make it happen.

The Synergist Team

Chi, Roxana, Eric, Jean-Christophe, Helena, Leticia, Danielle, Gulwish, Daniela, Laila, Geoffroy, Loic, Bernadette, France, Anne-Marie, Danielle, Gary, Marie-Neith, Lise and Nicholas

Context

Since its inception, The Synergist has aimed to achieve maximum impact for all its initiatives, delivering benefits to as many stakeholder groups and individuals as possible.

This can be seen in The Synergist's choice of focus areas and in the high-impact co-creation methods used. Yet, assessing the results of (new) methods and the outputs of (eco)system-wide initiatives is not an easy task. We have therefore decided to apply the Social Return on Investment (SROI) methodology to our projects, in order to create a strong foundation for any impact-related analysis or result we achieve.

Not sure what The Synergist is all about?

Check out www.thesynergist.org/about for more information.



Methodology

The SROI methodology has a strong track record and is increasingly being applied to all activities and businesses that want to accurately monitor and improve their social impact.

In short, it aims to measure impact at the level of the people whose lives are changed by the activity to be monitored, and to assess the extent to which resources correctly used to generate their maximum positive impact. The powerful effect of this methodology is that it fosters an iterative process: from the beginning of an initiative to its end, impact has to be measured and resources have to be (re-)allocated to improve positive impact.

At the Synergist, we have started applying this methodology to all our projects. Its iterative pattern matches our agile structure very well and guides our decision-making.

From Theory To Reality

The Synergist's Impact

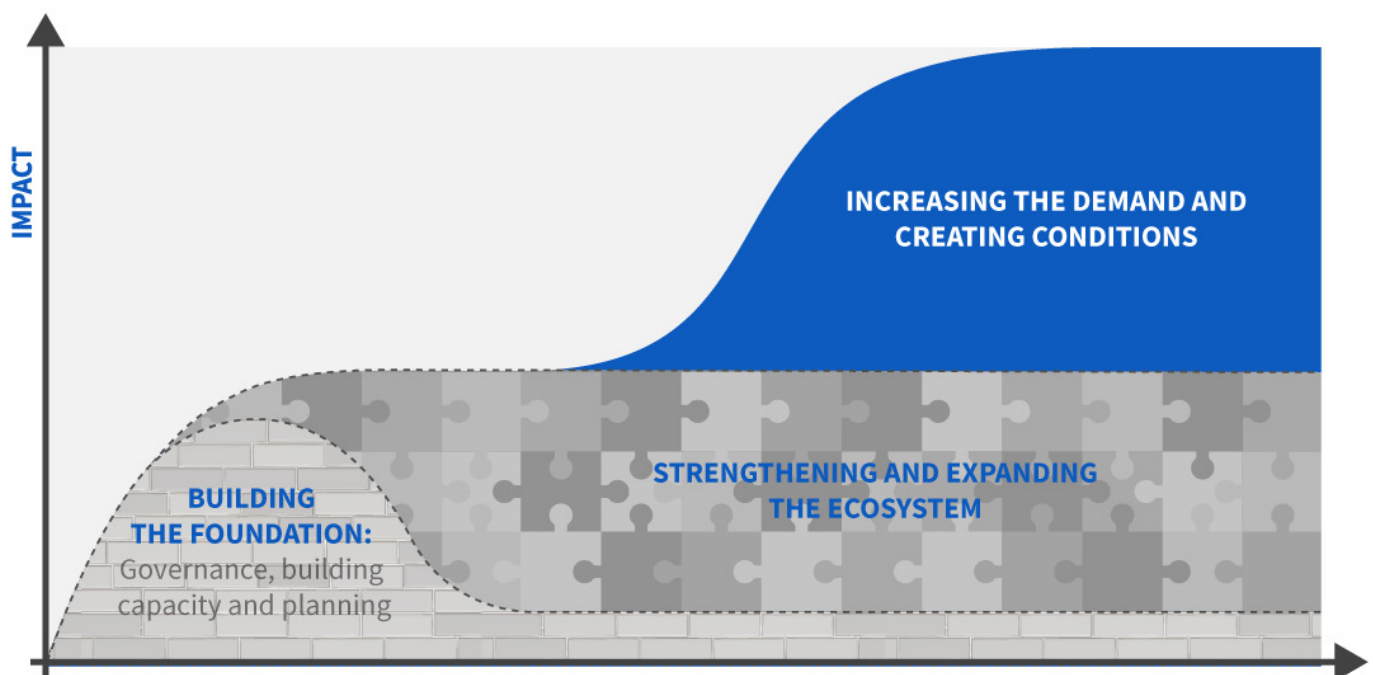
We have streamlined the above project structure across all our projects. The first step is to establish the backbone of the project, including the tools, processes and governance the project team will use.

Once this initial phase has been completed, ongoing project activities embed impact measurement making sure day-to-day activities and overall strategy remain aligned, while generating maximum impact.

On top of this, we strive to synergise other initiatives, filling the gaps coming from a fragmented approach, and delivering impact and outputs far beyond what any isolated initiative could reach.

In 2018, we have initiated impact measurement surveys for new initiatives for Break Dengue and PFMD. We have created a structure to encompass feedback from end-users/beneficiaries into our pilot projects as a commitment to deliver maximum positive impact. In the PFMD project we have started measuring the amazing powerful impact that synergizing with other stakeholders' initiatives can generate.

We are proud that PFMD has been acknowledged as one of the major Patient Engagement initiatives globally, enabling the program to advance the global patient engagement ecosystem. This convergence of various initiatives and efforts, leadership and energy generates very powerful results. The change is happening !



Highlights

Meaningful numbers

2

new projects

7

new partners, bringing
us to a total of **71**

43

total partners
(owned projects)

1.252

experts in patient
engagement ecosystem

1.206

experts in dengue
ecosystem

154

experts in maternal
health ecosystem

706.601

total visits on our project
websites

2.725.560

social media reach (total)

239.574

social media engagement
(total)

5

new team members

22

team members in
total

Financial Report

	Project Turnover (€)	Project Expenses (€)	In-kind hours	In-kind contribution (€)
Break Dengue	150.000	233.642	700	45.500
Motherhood Collective Impact Programme (MCIP)	145.000	126.332	50	3.250
PatientFocused Medicines Development (PFMD)	995.000	934.301	1.229	79.885
PARADIGM	181.276	150.909		
Share4Rare	80.750	101.588		
European Projects	262.026	252.497		

Partners

They made all this possible

A total of **71 partners** have decided to join forces to support and push forward our initiatives. This represents a major change in philosophy that has already started generating significant output on all projects.



www.PatientFocusedMedicine.org