Partnering for progress:

The Power of Patient Engagement

Steve Bourke CEO PersonalPulse MPhil. MSc. EUPATI Fellow
4th National Meeting on Clinical Research and Biomedical Innovation
May 14th 2025, Hospital de Braga, Portugal

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Imagine if ***every interaction*** *with clinical trials delivered* ***transparents mutual value*** *endpoints for* ***patients*** *and* ***health system*** *stakeholders.*

What would that look like?

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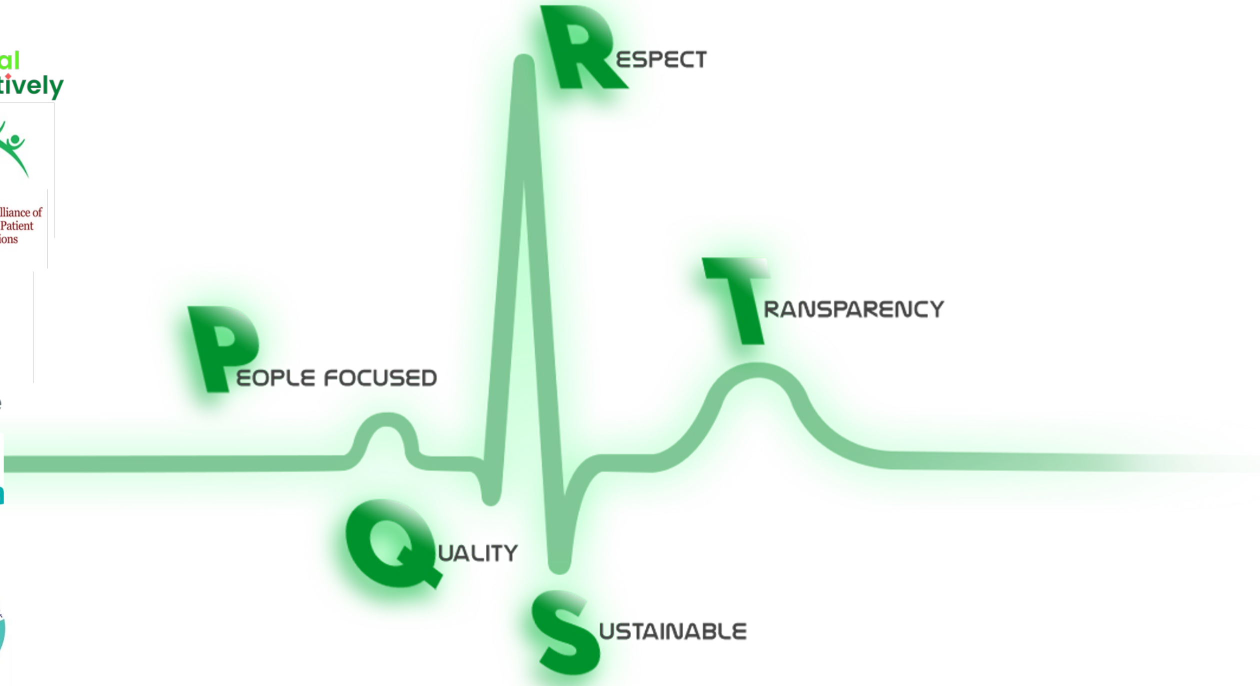
My Experience and my experience

CENTER FOR BIOETHICS
HARVARD MEDICAL SCHOOL
Innosuisse
Heal actively
UNIVERSITY OF MINNESOTA
ETH zürich
Zambon
EPF
n|w University of Applied Sciences and Arts Northwestern Switzerland
FDA
International Alliance of Dermatology Patient Organizations
GLOBALSKIN.ORG
FNIH
Foundation for the National Institutes of Health
IPPOSI
PharmaLedger
BLOCKCHAIN ENABLED HEALTHCARE
Roche
EUPATI
European Patients' Academy on Therapeutic Innovation
HKT Design:
Value Product Service
Innovation Booster
powered by Innosuisse
glimpse HEALTH
rheumacura
DAYONE
PFMD.org
Made WITH Patients
Helsana
SCTO
BIOMARIN
My Moves Matter
VPH Institute
Building the Virtual Physiological Human



RESPECT

PEOPLE FOCUSED

TRANSPARENCY

QUALITY

SUSTAINABLE

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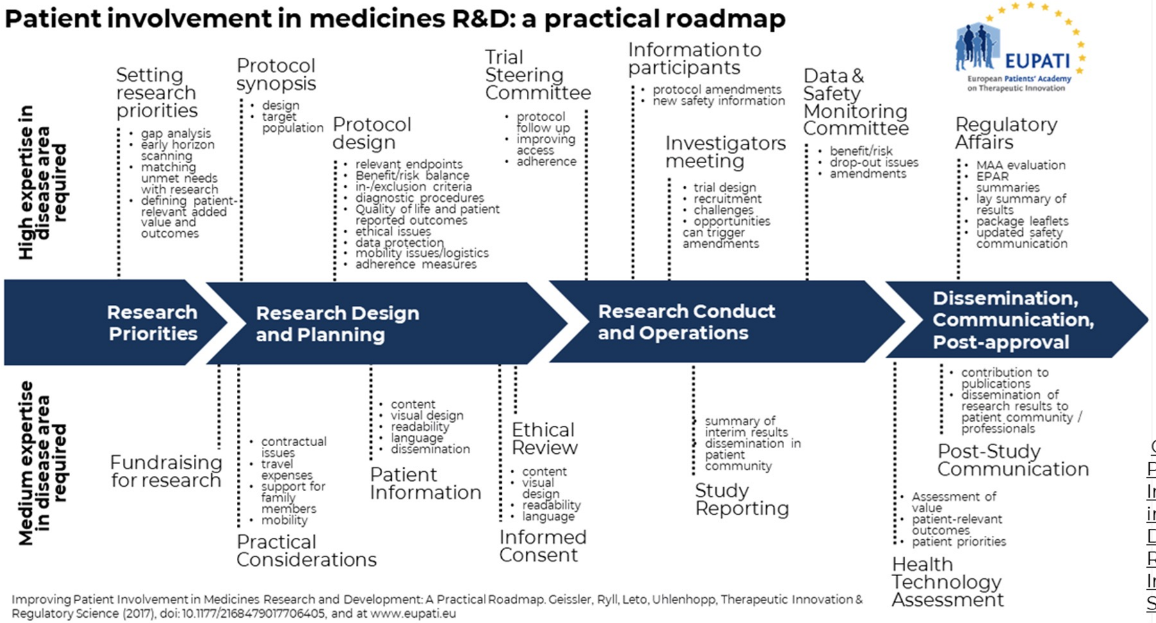
The Badge of Patient

https://hdsunflower.com/

When and where to include patients



Patient involvement in medicines R&D: a practical roadmap

High expertise in disease area required

Research Priorities

Setting research priorities
- gap analysis
- early horizon scanning
- matching unmet needs with research
- defining patient-relevant added value and outcomes

Research Design and Planning

Protocol synopsis
- design
- target population

Protocol design
- relevant endpoints
- Benefit/risk balance
- in-/exclusion criteria
- diagnostic procedures
- Quality of life and patient reported outcomes
- ethical issues
- data protection
- mobility issues/logistics
- adherence measures

Trial Steering Committee
- protocol follow up
- improving access
- adherence

Research Conduct and Operations

Information to participants
- protocol amendments
- new safety information

Investigators meeting
- trial design
- recruitment
- challenges
- opportunities

can trigger amendments

Data & Safety Monitoring Committee
- benefit/risk
- drop-out issues
- amendments

Dissemination, Communication, Post-approval

Regulatory Affairs
- MAA evaluation
- EPAR summaries
- lay summary of results
- package leaflets
- updated safety communication

Medium expertise in disease area required

Fundraising for research

Practical Considerations
- contractual issues
- travel expenses
- support for family members
- mobility

Patient Information
- content
- visual design
- readability
- language
- dissemination

Ethical Review

Informed Consent
- content
- visual design
- readability
- language

Study Reporting
- summary of interim results
- dissemination in patient community

Post-Study Communication
- contribution to publications
- dissemination of research results to patient community / professionals

Health Technology Assessment
- Assessment of value
- patient-relevant outcomes
- patient priorities

Improving Patient Involvement in Medicines Research and Development: A Practical Roadmap. Geissler, Ryll, Leto, Uhlenhopp, Therapeutic Innovation & Regulatory Science (2017), doi: 10.1177/2168479017706405, and at www.eupati.eu

Geissler, J., Ryll, B., Leto di Priolo, S., Uhlenhopp, M.: Improving Patient Involvement in Medicines Research and Development: A Practical Roadmap. Therapeutic Innovation & Regulatory Science 2017

Assumptions make a fool of you and I

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Informed consent

5 hrs infusion: arterial and venous

10 muscle biopsy

Keller, P., Penkowa, M., Keller, C., Steensberg, A., Fischer, C. P., Giralt, M., Hidalgo, J., & Pedersen, B. K. (2005). Interleukin-6 receptor expression in contracting human skeletal muscle: Regulating role of IL-6. The FASEB Journal, 19(9), 1181-1183. https://doi.org/10.1096/fj.04-3278fje

Understanding V's consent

- **5 hrs infusion: atrial and venous is beyond uncomfortable**
- **8/10 muscle biopsy are bearable**
- **Lifelong fear of needles**

"Creativity is thinking up new things. Innovation is doing new things."

Theodore Levitt

From tester to co-creator

JMIR Human Factors

Journal Information ▾ Browse Journal ▾

Published on 6.10.2022 in Vol 9, No 4 (2022): Oct-Dec

Preprints (earlier versions) of this paper are available at https://preprints.jmir.org/preprint/41481, first published August 03, 2022.

From Testers to Cocreators—the Value of and Approaches to Successful Patient Engagement in the Development of eHealth Solutions: Qualitative Expert Interview Study

Christine Jacob [1]; Steven Bourke [2]; Sabina Heuss [3]

The value and approaches to the successful development of eHealth solutions with people who are patients

Value


Identify unmet needs
Better usability and desirability
Fit into patient journey
Better adoption (stickiness)
Better health outcomes
Advoacacy and trust
Sense of purpose
Better health equity and access

Challenges

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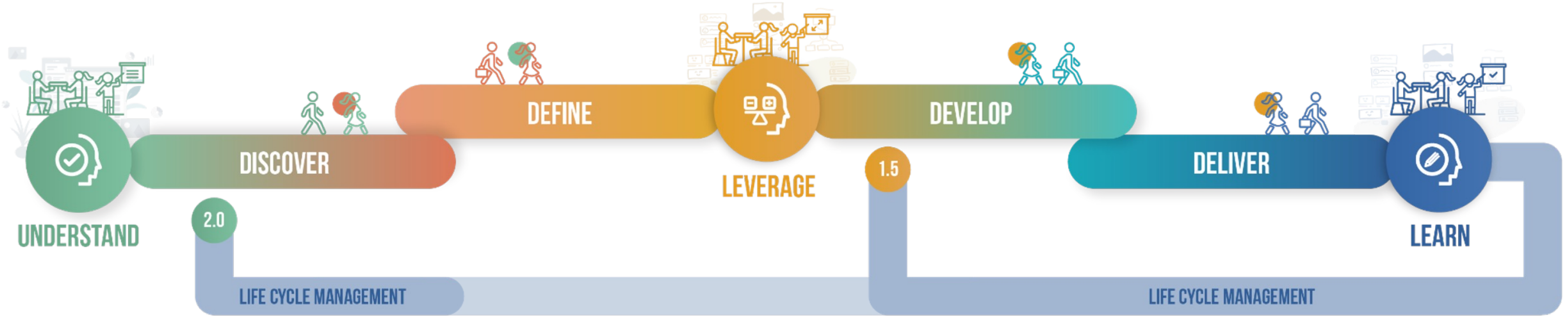
Innovation is not invention

PIDD



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Innovation patients included

LONG COVID SCHWEIZ SUISSE SVIZZERA SWITZERLAND

glimpse HEALTH

Measuring Fatigue with Precision.

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Glimpse Health : mutual value co-creation

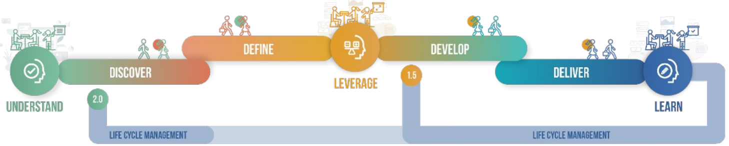
A startup out of ETH and University of Zurich Schools of Medicine

- Targeting fatigue management for MS and Long Covid patients
- Taking their basic research which is a digital therapeutic into second clinical trial
- Funded by a Innosuisse grant
- Proactively include patients' insights - patients as partners

Challenge

- Challenging trial for recruitment and 8 months retention of people living with MS or Long Covid
- Clinical staff having a lot going on besides the study

Workshop patient experts and nurse



Goals

- Presenting the purpose of the study to Patient Experts
- Discussing the clinical protocol to Patient Experts and nurses
- Evaluating the value propositions with Patient Experts and nurses

outcome

- Nurses and Patient Experts hear each others pain points and expectations
- Rating of the value propositions and introduction of the patient voice

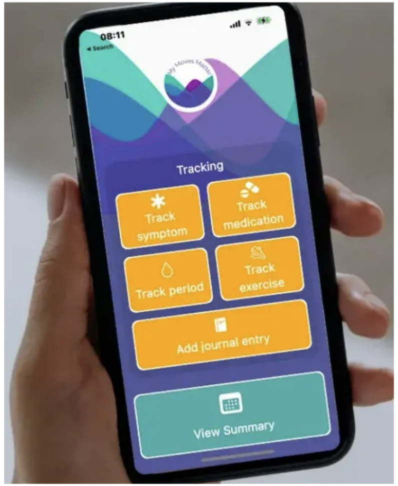
"Self-centered leaders manipulate when they move people for personal benefit. Mature leaders motivate by moving people for mutual benefit." *John C. Maxwell*

Mutual value data generation

UCC

My Moves Matter

Looking at the impact of different hormonal stages of life and their impact on Parkinson's symptoms.



Empowering people to live well with their Parkinson's

Mutual value through evidence-based research

"The power of public and patient involvement in healthcare innovation"

Gomes, V.P., May, M., Geissler, J. *et al.* The power of public and patient involvement in healthcare innovation. *Nat Rev Bioeng* (2025). https://doi.org/10.1038/s44222-025-00315-4


Publications > *RA Watch* >
RA Watch 8 – Experiences with 2021 changes to MD regulatory framework

Patient input into medical device development: A missed opportunity

nature > nature biomedical engineering > comment > article

Comment | Published: 18 March 2024

Towards on-skin analysis of sweat for managing disorders of substance abuse

Noe Brasier, Juliane R. Sempionatto, Steven Bourke, George Havenith, Dietmar Schaffarczyk, Jörg Goldhahn, Christian Lüscher & Wei Gao

Nature Biomedical Engineering **8**, 925–929 (2024) | Cite this article


Open Access

Short- and longer-term goals for change – A report from the 2nd workshops of the EHC Think Tank Workstreams on Access Equity and Future Care Pathways

Zita Gacser, Naja Skouw-Rasmussen, Steven Bourke, Renske ten Ham and Dalma Hosszú | Dec 29, 2023

Published on 6.10.2022 in Vol 9, No 4 (2022): Oct-Dec

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VOICES · Volume 1, Issue 1, 100014, February 25, 2025

The values driving development and investigation of innovative healthcare technology: Stakeholder voices

Noé Brasier · Wei Gao · Joseph Wang ... · Lindsay Kehoe · Steven Bourke · Jörg Goldhahn ... Show more

Volume 7, Issue 1
January – December 2023

OTHER TYPES | MAY 12 2023

Reverse Engineering of Digital Measures: Inviting Patients to the Conversation

Article Collection: High Impact Articles in Further Areas

Subject Area: Further Areas , General Medicine , Public Health

Ieuan Clay; Nele Peerenboom; Dana E Connors; Steven Bourke; Alison Keogh; Katarzyna Wac; Tova Gur-Arie; Justin Baker; Christopher Bull; Andrea Cereatti; Francesca Cormack; Damien Eggenspieler; Luca Foschini; Raluca Ganea; Peter MA Groenen; Nicole Gusset; Elena Izmailova; Christoph M Kanzler; Lada Leyens; Kate Lyden; Arne Mueller; Julian Nam; Wan-Fai Ng; David Nobbs; Foteini Orfaniotou; Thanneer Malai Perumal; Wojciech Piwko; Anja Ries; Alf Scotland; Nick Taptiklis; John Torous; Beatrix Vereijken; Shuai Xu; Laurenz Baltzer; Thorsten Vetter; Jörg Goldhahn; Steven C Hoffmann

Digit Biomark (2023) 7 (1): 28–44.
https://doi.org/10.1159/000530413 Article history
PubMed:37206894

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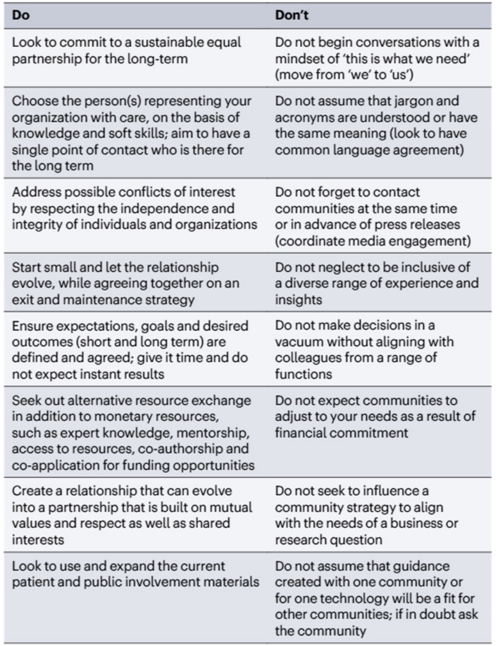
Mutual benefit by actionable insights



Do	Don't
Look to commit to a sustainable equal partnership for the long-term	Do not begin conversations with a mindset of 'this is what we need' (move from 'we' to 'us')
Choose the person(s) representing your organization with care, on the basis of knowledge and soft skills; aim to have a single point of contact who is there for the long term	Do not assume that jargon and acronyms are understood or have the same meaning (look to have common language agreement)
Address possible conflicts of interest by respecting the independence and integrity of individuals and organizations	Do not forget to contact communities at the same time or in advance of press releases (coordinate media engagement)
Start small and let the relationship evolve, while agreeing together on an exit and maintenance strategy	Do not neglect to be inclusive of a diverse range of experience and insights
Ensure expectations, goals and desired outcomes (short and long term) are defined and agreed; give it time and do not expect instant results	Do not make decisions in a vacuum without aligning with colleagues from a range of functions
Seek out alternative resource exchange in addition to monetary resources, such as expert knowledge, mentorship, access to resources, co-authorship and co-application for funding opportunities	Do not expect communities to adjust to your needs as a result of financial commitment
Create a relationship that can evolve into a partnership that is built on mutual values and respect as well as shared interests	Do not seek to influence a community strategy to align with the needs of a business or research question
Look to use and expand the current patient and public involvement materials	Do not assume that guidance created with one community or for one technology will be a fit for other communities; if in doubt ask the community

Patient Focused Medicines Development. Patient Engagement Quality Guidance v 2.0 [Internet]. PFMD; 2018 [cited 2024 Feb 1]. Available from: https://patientfocusedmedicine.org/peqg/patient-engagement-quality-guidance.pdf

Repurpose with community insight

PKU ADVOCATES MESSAGE GRID

It's time to have a different conversation about PKU

LET'S ADVOCATE TOGETHER FOR CHANGE!

Co-created with the 2024 PKU Patient Leaders Council

This resource has been funded and developed by BIOMARIN

EUCAN-MPRL-PKU-00005 May 24

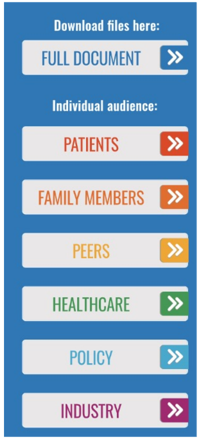
What is your stand on mental health and people living PKU?

What is your understanding of the challenges around mental health in PKU? We are looking for solutions.

What can you commit to in helping the PKU community to address the subject of mental health research and support in clinical trials?

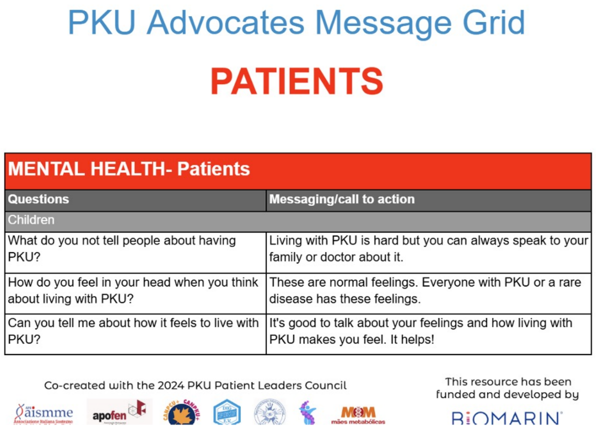
What support can you offer the community for non-responders in clinical trials?

We should work together to research and develop assessments for the impact of innovative therapies on mental health and quality of life as patient-relevant endpoints in their clinical studies. Let's advocate together for change.



Download files here:

Individual audience:



PKU Advocates Message Grid

PATIENTS

MENTAL HEALTH- Patients	
Questions	**Messaging/call to action**
Children	
What do you not tell people about having PKU?	Living with PKU is hard but you can always speak to your family or doctor about it.
How do you feel in your head when you think about living with PKU?	These are normal feelings. Everyone with PKU or a rare disease has these feelings.
Can you tell me about how it feels to live with PKU?	It's good to talk about your feelings and how living with PKU makes you feel. It helps!

Co-created with the 2024 PKU Patient Leaders Council

This resource has been funded and developed by BIOMARIN

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Actions

- Find the right patients - who will challenge and co-create
- Be mindful and active around assumptions, innovation, and mutual value
- Be bold, be brave, be brilliant in delivering impact through co-creation with patients and patient communities

Actions

By actively partnering with patients, you can Empower People who are Patients to partner in delivering better outcomes faster!

Bio Steve Bourke MPhil. MSc. EUPATI Fellow CEO Personal Pulse

Steven (Steve) Bourke is a dynamic advocate with a drive to Empower People who are Patients. A passion for effective, clear health communications combined with over ten years of expertise in biomedical research offers a distinctive advocate who excels in building bridges and delivering impactful outcomes. Founder and CEO of PersonalPulse: Empowering People who are Patients. Co-founder RheumaCura Foundation: Rheumatic and musculoskeletal diseases can be prevented and cured. EUPATI CH member and EUPATI fellow. He is involved in several multi stakeholder-level projects designed to co-create digital health projects to deliver a real impact on people who are patients. I have held global roles in patient engagement within the pharmaceutical industry. IHI projects include PharmaLedger and Combine CT. Co-founder and champion lead of DayOne Health Hack digital health innovation unmet needs challenge. Development of a strategic plan for Global Skin Europe developed and led the project for PKU message GRID advocate tool—peer review author in the area of DHTs and advisor and committee member of the FNIH Biomarker consortium. I also have lived experience of four chronic diseases. I have consulted in developing digital health technologies at all stages of development through to launch.

Email: steve@personalpulse.com
Phone: +41 79 961 13 36
LinkedIn: https://www.linkedin.com/in/personalpulsestevebourke/
Website: www.personalpulse.com

Thank you for your time.

Muito obrigado pela vossa atenção.

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