Avicenna Alliance
Association for Predictive Medicine

Position Paper

Public & Patient Involvement for *in silico* medicine

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2. Executive summary

"*Nothing about us without us*" is a patient centric approach to medicine that has remained largely overlooked within the biomedical research and innovation domain. Activities are traditionally shaped by the scientists themselves across the entire project lifecycle, from focus prioritisation based on previous scientific literature to emphasising outputs (e.g., publications and devices) over impact (e.g., improving quality of life). Public and patient involvement (PPI) unlocks the potential for research activities to ensure patient relevance and benefit, foster technology adoption, lower risk of attrition and associated costs, and ultimately accelerate research translation into positive societal impact through collaborative co-creation.

The Avicenna Alliance (AA) policy development group PPI task force (TF) identified that PPI has gained considerable momentum in the wider biomedical community, with dedicated national and international efforts currently ongoing within AA member geographies including the UK, EU, and USA. However, **there has been no coordinated international PPI initiative with focus on *in silico* medicine prior to the AA PPI TF establishment**. Based on our recently conducted survey, there is currently low PPI awareness, mixed perceptions, and little internal support within AA member organisations (including both academia and industry), in contrast with a general consensus for PPI to be a worthwhile pursuit.[1] With the wider biomedical community already embracing PPI, including internal and external incentives such as access to funding, the *in silico* community is therefore at risk of finding itself left behind in a rapidly evolving environment that valorises on PPI-enabled comparative advantage.

The PPI TF therefore strives to address the above-identified challenges by providing a coordinated international PPI initiative with a focus on *in silico* medicine. Based on our analyses, we propose a 3-stage approach to promote PPI implementation within the digital health community based on 1. creating awareness, 2. supporting implementation, and 3. enabling the requisite culture change to accelerate research translation into positive societal impact. Collaborating with internationally leading PPI networks, we have instigated PPI momentum *via* the policy development group to generate a 'snowball effect' first through focus internally on the AA. Then, we shall amplify our learnings through the wider *in silico* medicine community to craft a strategic fit transcending the wider biomedical health community, to maximise positive societal impact together with patients and the public.

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3. Introduction

Public and patient involvement (PPI) in research and innovation signifies that activities are undertaken *with* or *by* members of the public/patients.[2] Involvement implies the proactive collaboration between experienced stakeholders, including people with a lived experience.

When conducting health research, it is therefore important to have patient representatives on the project team to be involved in activities such as design, operations, governance, monitoring, and results publication.[3] A prerequisite for successful PPI therefore entails relationship building with the very communities affected by the research & development (R&D) activities and/or associated outcomes. Therefore, representative individuals or associations must be identified well before project start to enable meaningful collaboration for shaping the prospective project. PPI has become an increasing topic of interest and is nowadays an essential need for scientists, regulatory agencies, and industries to get patient and public voices integrated into the decision-making process of product development and access to market.

Thus, co-creation through a dialogue-driven mutual partnership is central to PPI. Conversely, the sometimes confounded concepts of "*outreach*" and "*engagement*" describe predominantly unilateral relationships where research is undertaken *to*, *about*, or *for* patients/public. *Outreach* and *engagement* activities may play a role in PPI implementation, but they do not warrant PPI on their own. For example, initiating PPI may require *outreach* activities and associated communication & dissemination to translate technical concepts for a non-technical audience, yet outreach on its own is insufficient to establish effective dialogue because of its one-way communication. Similarly, *engagement* can mean the various ways in which research and its outcomes can be shared with the public in a two-way process by listening to and interacting with the public,[4] yet often the decision-making process remains unilateral, in which case the public and patients are participants rather than partners. Nevertheless, the term *engagement* is sometimes used synonymously with *involvement*, e.g., by the European Commission.[5] The persisting uncertainty in terminology is a symptom of the still early stages of PPI development and highlights the **need for a concerted, international effort for effective PPI implementation**.

Similarly, for life-sciences companies, *patient involvement* is often confused with clinical trial *participation*, with the patient being a passive actor. While PPI may currently have started finding some momentum, attempts at PPI remain isolated, fragmented, and inconsistent on a broader perspective.[6] If patients' specific needs and perspectives are not met, there is a high risk amounting to inappropriate research priorities and decisions, clinical trial failure due to inappropriate assumptions regarding patient-centric endpoints and outcomes, high burden of

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trial logistics (e.g., number and length of visits), and low participation and/or retention rates, in turn resulting in costly late-stage failure. Currently, in the digital health context, *in silico* clinical trials (ISCTs), for example, are at risk to be met with hesitation from a patient perspective due to a comparative lack of precedents in the healthcare system. Therefore, there is a real need for all stakeholders (including, e.g., physicians, nurses, patients) to be involved in the development of such new healthcare approaches. While helping to facilitate ISCTs with a patient-centric focus overall, there is also ample scope to adopt a more patient-centric approach in the development of the individual ISCT-constituting technologies, such as wearable devices for remote clinical trial participation, or the Internet of Medical Things (IoMT) for real-time data monitoring. Systematic involvement of patients, caregivers, relatives, and the public has generally been overlooked in clinical trials, thereby failing to unlock innovative thinking to make knowledge and therapeutic technologies safer and more promptly available to clinicians and patients.

PPI thereby presents an attractive opportunity to mitigate such risks. Implementing a PPI approach also requires a simultaneous culture shift from a traditionally top-down and passive to a participatory and iterative health science R&D environment. It is therefore important to carefully consider who specifically is representative of technology beneficiaries in a given context, including, e.g., individual patients, carers or caregivers, patient advocates, patient organisation representatives, and patient experts (*cf*. **Glossary**).[7] Such an end user-driven process holds the potential to accelerate the research outcome cycle into user-friendly technologies and reducing attrition risk throughout all stages of the project lifecycle. Enabling the co-creation of future technologies may also catalyse implementation of the research outcomes, such as policies or devices, through proactive and iterative minimisation of potential barriers of adoption through systematic stakeholder involvement. With PPI, research and innovation can be driven by real, relevant societal, rather than anticipated or assumed, needs, thereby creating a win-win scenario enhancing both economic and societal outcomes, i.e., maximise health *and* lower technology development costs.

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4. The current international PPI landscape in the *in silico* medicine context

There is currently no coordinated international PPI initiative specific to the field of digital health, as inferred from our review of the international PPI landscape at the time of writing. Relative to other health innovation communities (e.g., clinical trials), the *in silico* medicine community is therefore weakly positioned to effectively valorise on the increasingly evolving PPI opportunity for enhancing the generation of positive societal impact. Therefore, the community also faces the imminent threat of becoming left behind, such as by missing out on access to PPI public funding mechanisms which are increasingly demanding dedicated PPI provisions to be an eligible applicant.

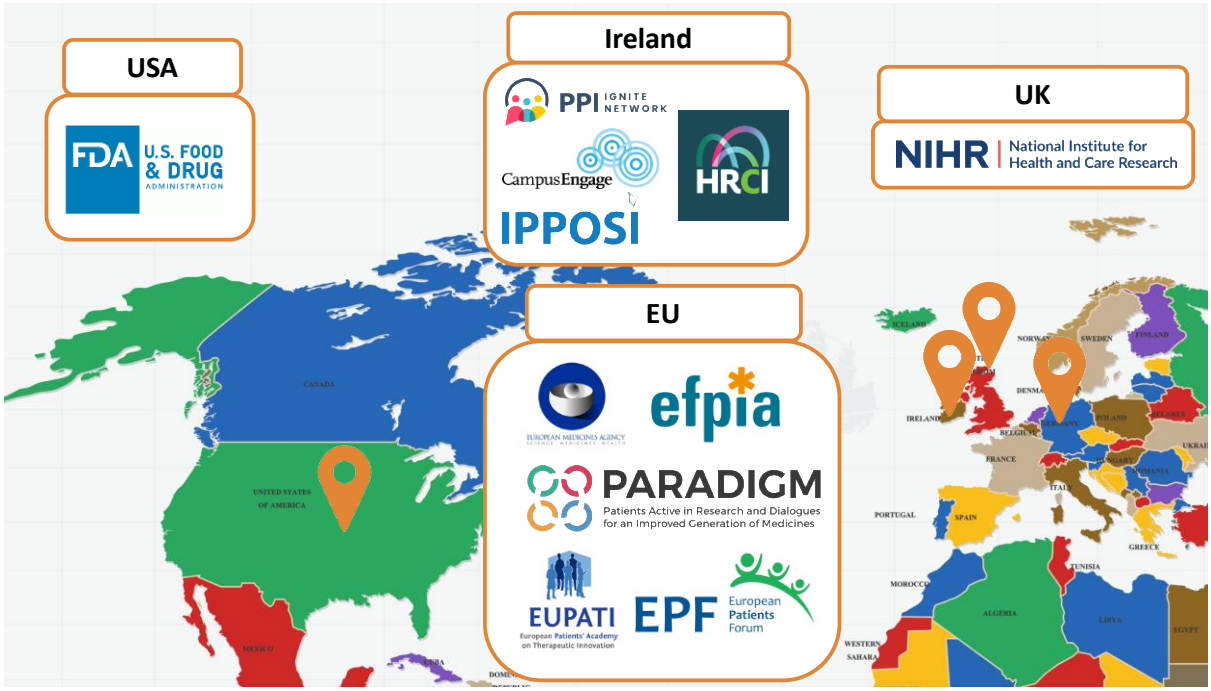

Figure 1: Examples of major players engaged in PPI-related activities within the networks of the Avicenna Alliance members.

Within the overall biomedical research field, PPI is continuously gaining international momentum through the establishment of coordinated PPI endeavours. At the European level for instance, the European Patients' Academy on Therapeutic Innovation (EUPATI) was funded by the Innovative Medicines Initiative (IMI) in 2017 and continues to be a major patient-driven organisation, which aims to empower patients in advocating for their own health and train stakeholders in patient engagement.[8] Notably, EUPATI composed an ensemble of guidelines on patient involvement for biomedical innovation.[9] Another example is Patients Active in Research and Dialogues for an Improved Generation of Medicines (PARADIGM),[10] a public-private partnership created by the European Patients Forum (EPF)[11] and the European Federation of Pharmaceutical Industries and Federations (EFPIA)[12] who have implemented a patient engagement toolbox to facilitate patient engagement across the planning, implementing, and reporting stages for medicines development.[13] In Ireland, the recently established PPI Ignite

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network[14] unites 7 universities as lead sites and 10 national partners to pioneer PPI implementation into health impact through a coordinated national effort, including key stakeholders with a focus on engaged research, such as Campus Engage[15] and the Irish Platform for Patient Organisations, Science, and Industry (IPPOSI).[16] In the UK, the National Institute of Health Research (NIHR) provides extensive PPI guidance and resources which were co-developed by charities and research institutions,[17] also including the UK national standards for public involvement.[18]

Research funders are also increasingly committed to supporting PPI through their funding mechanisms and mandating dedicated provisions on PPI implementation for proposals to be eligible (e.g., NIHR in the UK or the Health Research Board (HRB) in Ireland). The funders enable such PPI planning and implementation *via*, e.g., the establishment of public review (in addition to peer review by researchers), awards for PPI excellence,[19] and the establishment of co-funding schemes with relevant health charities, such as Health Research Charities Ireland (HRCI).[20] Notably, the European Commission considers Responsible Research and Innovation (RRI) as one of the bases of European partnerships. Any European partnership and preparation for joint calls should have RRI considerations. RRI involves advancing research and innovation while adhering to high ethical, legal and social standards by engaging the communities affected by said innovations.[5] Therefore, PPI is an attractive means to also align the expectations and needs of society, science, and innovation to ensure RRI.[21]

On the other side of the Atlantic, the U.S. Food and Drug Administration (FDA) frequently issues guidance and recommendations on patient engagement. Some are rather generic, such as *Patient Engagement in the Design and Conduct of Medical Device Clinical Investigations*,[22] while others are more specific: *Patient-Focused Drug Development: Collecting Comprehensive and Representative Input*.[23] The latter provides a methodology on how stakeholders (patients, researchers, medical product developers, and others) can collect and submit patient experience data and other relevant information from patients and caregivers for medical product development and regulatory decision making. Moreover, the FDA also publishes patient consultation reports on specific diseases, such as in *The Voice of the Patient* series,[24] including, e.g., for Huntington's disease or for chronic pain, in which the FDA reports patient consultations to hear their perspectives on the disease, about their daily life, and experience with available therapies. The European Medicines Agency (EMA) was an early proponent for involving patients in the discovery, development and evaluation of health technologies to ensure high quality in research, innovation, and decision making,[25] such as enabling the systematic inclusion of patient experience data in the development and regulation of medicines.[26] Considering that patient voices are essential in medicines regulation, based on the unique perspective and lived experience of somebody diagnosed with a specific disease, the FDA, together with the EMA, have set up a patient engagement cluster to provide a forum to share experiences and best practices for the involvement of patients in the development, evaluation, and post-authorisation activities related to medicines. Notably, the FDA Patient Engagement Collaborative (PEC) provides an attractive point of contact in the US for PPI alignment.[27] The PEC was modelled after the EMA Patients' and Consumers' Working Party and facilitated by federal law to foster patient participation and incorporate patient experiences in the regulatory process. Therefore, **patient involvement has now entered a new phase as regulatory authorities, health technology assessment (HTA) bodies, funders, and payers are also continuously shifting from expert-driven *output*, to a more diverse stakeholder-driven *outcome* focus**.

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In addition, *in silico* medicine may challenge some key principles such as transparency and fairness of data usage, data privacy and protection across platforms and systems (e.g., data integration and interoperability, data availability and quality, data sharing, intellectual property, equal accessibility for persons and populations).[28] The healthcare industry has become a prime target for data breaches despite the growing awareness and improvement in data security. In 2022, the cost of data breach in healthcare was 10.1 million USD, the highest among all US industries.[29] Security is therefore a prime concern, including for patients. The main reason why patients do not feel comfortable using technologies are security issues for 35% of surveyed patients.[30] Nowadays, patient data can be collected in various ways, from the classic and well-accepted channels such as doctor visits, patient calls, email, and connected or wearable devices. But the reality is that patient privacy as well as other regulatory requirements for managing patient health information (PHI), such as Europe's General Data Protection Regulation (GDPR)[31] and the California Consumer Privacy Act (CCPA)[32], or regulations for products classified as 'software as a medical device' (SaMD), may now have become limiting factors for the adoption of ISCTs. It is therefore important that the data security regulatory and legal landscapes, too, are involved such to mitigate potential risks of creating undue barriers in the processes for secure data sharing such to ensure effective implementation of digital health innovations for societal benefit.

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5. The PPI opportunity for digital health

The PPI TF establishment of the AA policy development working group is a coordinated effort to pioneer PPI implementation within the *in silico* medicine community, thereby directly addressing the identified lack of such an initiative in the digital health area until now. Access to, and reflection on, the emerging wealth and diversity of emerging PPI knowledge and experience presents a unique opportunity to craft a strategic fit for the PPI TF within the global PPI landscape by establishing a collaborative learning environment through strategic partnerships, creating a win-win scenario by valorising on already existing networks, and creating comparative advantage by co-creating novel opportunities specific to the Digital Health community. Informed by the current overall PPI landscape analysis (**Figure 1**) and the results from an internal survey on PPI perceptions within the AA,[1] we propose the following 3-stage approach for developing the *in silico* medicine PPI opportunity, i.e., **1. create awareness**, **2. support implementation**, and **3. enable a culture change** within the digital health community towards embracing PPI for accelerating positive societal impact (**Figure 2**).

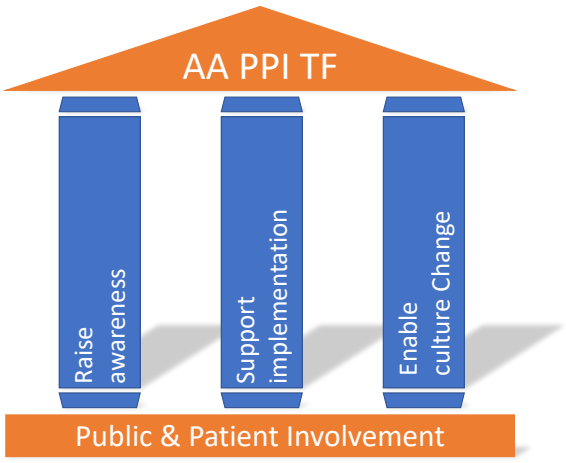

Figure 2: Depiction of the proposed approach by the PPI TF residing on the 3 pillars of 1. raising awareness, 2. supporting implementation, and 3. enabling a culture change to establish PPI within the *in silico* medicine community and ultimately catalyse positive societal impact through systematic stakeholder involvement.

The PPI TF shall **create awareness** of the PPI opportunity within the *in silico* medicine community and beyond through the AA. As inferred from the survey, PPI awareness is currently relatively low among AA members, with individual perceptions on PPI found to be very heterogeneous and subjective.[1] The PPI TF shall therefore contribute to the promotion of a clear and unified understanding of PPI across the digital health community by endorsing and developing good practice in alignment with leading PPI networks, as identified in Section 2. The PPI TF will facilitate a coherent and unified PPI language, values, and principles in dialogue with the AA and the wider *in silico* and PPI communities, to facilitate access (and remove potential barriers) to PPI, both general and specific to the *in silico* community, coherent with PPI in the wider biomedical environment. The PPI TF will foster a diverse media portfolio, including position papers, information leaflets, videos, and posters, to be disseminated *via* the relevant AA and individual members' institutional channels, including the AA website, conferences (e.g., the VPHi

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conference)[33], workshops, symposia (e.g., Avicenna Days), newsletters, and social media channels. Each of these outputs shall present a stakeholder engagement opportunity for continuous improvement by, e.g., providing tangible discussion points to stimulate critically reflective dialogue, guiding the identification and involvement of new stakeholders for nurturing a diverse PPI network, and generating effective pathways to impact through iteratively evolving innovative concepts for supporting PPI implementation specific to the Digital Health community.

The PPI TF will **support PPI implementation** within the *in silico* medicine community by providing functional, interpersonal, and operational guidance along the entire research lifecycle from pre-project conception throughout post-project valorisation. Such an R&D lifecycle approach shall include activities pertaining to, e.g., identifying & prioritising research themes, study design, grant proposal development, undertaking & managing projects, analysing & interpreting results, output dissemination, outcome implementation, and monitoring & evaluating processes. The PPI TF endorses a research lifecycle approach such to nurture the best possible impacts for patients, and society as a whole, *via* targeted PPI implementation especially within key project stages. Notably, there shall be no potential misconception for PPI to be a ubiquitous requirement for each and every project stage (just like each project partner would not be involved in each and every stage in traditional multidisciplinary consortia), i.e., one shall not be mistaken to adopt a tokenistic approach towards PPI, likely leading to inefficiencies. Particular care shall be taken during early project stages including, e.g., the identification of priorities and project design, to ensure the conceptualisation of R&D endeavours adopts a *patient first* approach. Project owners shall therefore consider pathways to impact (e.g., how to steer project outcomes to contribute to an increase in quality of life, such as by defining appropriate primary/secondary study outcomes) and operations (e.g., how to enable the best possible PPI contribution), including considerations on diversity & inclusion, both interpersonally (e.g., ensure all stakeholders feel welcome), as well as practically (e.g., provide appropriate budget allocation). The PPI TF shall therefore strive to support PPI implementation such to nurture impactful, effective, and efficient *in silico* research cycles. Potential avenues may take inspiration from already established PPI guides and toolkits in the wider biomedical research field,[34] as well as other domains with a *digital* focus, such as the software industry, e.g., by developing/implementing an “agile PPI approach”, including iterative improvement, frequent and systematic stakeholder contribution, and timely/responsive implementation. Such an iterative lifecycle approach shall not only catalyse the development of impactful technologies as such, but also contribute to the enhancement of mutual understanding between diverse stakeholders through collaborating on tangible outcomes, as well as lowering potential barriers for final technology adoption by empowering the end user (e.g., patients) to inform and make design thinking-enabled choices, in addition to offering opportunities to interact with different prototypes and thereby accelerate tacit learning, thereby promoting adoption by the relevant end user groups, as well as individuals. *In silico* medicine PPI therefore presents a tangible opportunity to promote precision health through the co-development of personalised digital approaches, in contrast to the currently still predominant ‘one-size-fits-all top-down’ approach within biomedical R&D environments.

The PPI TF is therefore committed to support an increasingly urgent **culture change** towards a participatory approach to tackle healthcare challenges in the best interest of the individual patient throughout key stages along the entire health technology development cycle. *In silico* approaches are particularly amenable to generate low-risk and high-impact case studies as state-of-the-art computational modelling enables mechanism-derived hypothesis generation, thereby providing informed guidance to accelerate successful research outcomes while lowering the risk

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of attrition throughout each stage of technology development, from pre-clinical exploration to *in silico* clinical trials. Involving individual stakeholders early and throughout the R&D cycle shall enable technology development tailored towards the specific needs of individual user groups and overcoming potential biases compared to a more traditional, one-size-fits-all approach, including, e.g., enabling access to bespoke technologies to otherwise underrepresented stakeholder segments. PPI is therefore a crucial high-value step towards systematic stakeholder involvement, including regulators, payers, and policy makers, towards **equitable access to the best possible health technologies, eventually paving the way towards the democratisation of health(care)**.

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6. Glossary

Involved research: "Refers to co-created and co-produced research with a focus on collaboration."[35]

Engaged research: "Describes a wide range of rigorous research approaches and methodologies that share a common interest in collaborative engagement with the community. It aims to improve, understand, or investigate an issue of public interest or concern, including societal challenges. Engaged research is advanced *with* community partners rather than *for* or *about* them. 'Community' refers to a range of public research stakeholders, including public or professional service and product users, policy makers, civil and civic society organisations (CSOs) and actors (Engaged Research: Society and Higher Education Working Together to Address Societal Challenges, Campus Engage, 2017)."[35, 36]

Science communication and outreach: "Science communication and outreach broadly describes the practice of communicating science-related topics to wider and non-expert audiences. This might include young people, politicians, journalists, education professionals and so on." Science outreach implies a primarily one-way mode of communication.[37]

Research participation: "The recruitment of study participants is participation of the public rather than involvement."[35]

Individual patients: "Persons with personal experience of living with a disease. They may or may not have technical knowledge in R&D or regulatory processes, but their main role is to contribute with their subjective disease and treatment experience".[7]

Carers or caregivers: "Persons supporting individual patients such as family members as well as paid or volunteer helpers".[7]

Patient advocates: "Persons who have the insight and experience in supporting a larger population of patients living with a specific disease. They may or may not be affiliated with an organisation".[7]

Patient organisation representatives: "Persons who are mandated to represent and express the collective views of a patient organisation on a specific issue or disease area".[7]

Patient experts: "In addition to disease-specific expertise, persons who have the technical knowledge in R&D and/or regulatory affairs through training or experience, for example EUPATI Fellows who have been trained by EUPATI on the full spectrum of medicines R&D".[7]

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