# CONFERENCE

# "Clinical Trials: Research that gives hope to patients and brings better life to all"

## May 17, 2024

# WORKSHOP

## Integrated vision on how to build an informed and active patient community


**Compilation of the perspectives and recommendations of the various stakeholders in the clinical trials ecosystem in Portugal, resulting from the workshop "Integrated vision on how to build an informed and active patient community" promoted by EUPATI within the scope of the Conference "Clinical Trials: Research that gives hope to patients and brings better life to all" organized by Apifarma on May 17, 2024.**

## INTRODUCTION

Research and the development of new medicines require comprehensive collaboration among various entities, including the National Health Service, regulatory authorities, public and private research centres, academia, patient associations, professional healthcare bodies, and the pharmaceutical industry. An integrated vision and global cooperation are essential to improving health, the quality of life for patients, scientific leadership, and economic growth in Portugal.

The active involvement of people affected by a disease, encouraged by EU Regulation No. 536/2014, enhances the effectiveness and credibility of clinical trials, reinforcing important societal principles such as justice, autonomy, and equity. It is crucial to value the diversity of perspectives, knowledge, and contributions from all stakeholders, promoting mutually beneficial relationships, active listening, openness, and flexibility.

## 1. HEALTH LITERACY AND ACCESS TO INFORMATION

Patients and their informal caregivers/family members need appropriate, transparent, and understandable access to information about clinical trials relevant to their medical conditions. This includes not only the availability of information but also education about what are the clinical trials, how they work, and what are their potential benefits and risks. By empowering them with knowledge and tools to access reliable information, patients can make informed decisions about whether to participate in clinical trials and can become ambassadors for clinical research.

At the same time, it is crucial to improve and anticipate appropriate access to quality health information, promoting health literacy programmes from an early age, in the first cycles of education in schools, transforming and empowering teachers/educators as active public health agents so that children and young people are well-informed today and become responsible adults in the future. Health literacy programmes should be extended to all age groups, being tailored to the specific target audience.

The public profile of the Clinical Trials Information System (CTIS) will be crucial for citizens' access to information about clinical research and clinical trials (lay summary). Thus, a public presentation session in Portuguese about this European platform would be useful, where the type of information available is presented.

It is important to include patient associations in the literacy process. AADIC (Associação de Apoio a Doentes com Insuficiência Cardíaca) can serve as an example, and its strategies can be adapted to other contexts. Regarding schools, the ACES (Health Centre Clusters) and, specifically, School Health programs, play a fundamental role in any adopted educational strategy. More important than the involvement of healthcare or educational professionals, it is crucial that the Ministry of Education and the authorities recognise the importance of including specific subjects about Clinical Trials in school curricula throughout the entire education process, and not just at the academic level.

It is not only important for teachers to act as public health agents, but also to involve

all citizens in the process of becoming public health agents themselves. It is imperative that this information is covered in high-viewership television programmes. It would be interesting for soap operas and other popular TV shows to depict characters participating in clinical trials, as this type of content has a large audience and significantly contributes to spreading the message and information. Additionally, morning or afternoon talk shows should also be considered to promote discussion and raise awareness about the topic.

## 2. CAPACITY BUILDING AND TRAINING

To empower people living with illness, it is essential for healthcare professionals to explain to patients and their caregivers how the research process is carried out, address their questions (and have the time to do so), and instill confidence in the process. Primary healthcare services are key in this area. Another crucial aspect key aspect is to build capacity among researchers to deal with the new reality of the "expert patient," promoting communication and bridging the gap in language, which is essential for more effective and meaningful connections between various stakeholders, such as academia, sponsors, healthcare units, and society.

It is also important for Sponsors and Contract Research Organizations (CROs) to engage with patient associations in Portugal, making them part of the research process and enabling them to gain experience in this field. Undoubtedly, ongoing training is important for those working in clinical trials. The Portuguese Order of Nurses, in partnership with Apifarma, has developed specific clinical trials training for nurses. However, professionalization is essential for achieving results and objectives. There must be full-time professionals dedicated to this area, not just part-time or as required by each institution.

Once again, it is important to involve the authorities/government in the need to create a specific career path in this area of research, particularly in clinical trials. Most research teams dedicated to working on clinical trials do so in addition to other responsibilities, often using their personal, family, or social time, rather than their working hours to perform these tasks. The creation of Clinical Research Departments within Hospital Centres/Local Health Units (ULS), in partnership with academia, partially addresses this need; however, without a dedicated career path for the various graduates in these Departments, the issue remains. The involvement of clinical trial participants already occurs in several medical/nursing conferences and congresses in certain areas of intervention.

## 3. INVOLVEMENT OF PEOPLE WITH A DISEASE AND FAMILIES IN RESEARCH

People living with illness and their families (informal caregivers) should be considered active partners in clinical research, not merely passive subjects. This approach involves engaging them in all phases of the research, from the early stages to study design and

result analysis, including participation in advisory boards for patients and caregivers.

It is crucial that patients and their representatives (Associations) participate in Ethics Committees, collaborating more closely with sponsors and researchers. To ensure effective participation and deep engagement of patients with various interest groups, the creation of a code of good practice for their involvement is suggested, based on universal values of relevance, justice, transparency, trust, equity, diversity, and empowerment.

It is essential to involve families and caregivers in all areas of clinical research, as their perspective and support are vital to the effectiveness and relevance of studies. Their involvement contributes to a more comprehensive understanding of patients' needs and to the adaptation of interventions to the real contexts of their lives. The participation of family members/caregivers is already seen in paediatric pathologies, and encouraging this involvement in all contexts is always an added value. Partnerships with groups that promote this reality are important.

Both in the context of pediatric and adult studies, the involvement of families in all stages of the development and research of diagnostic or therapeutic interventions is essential. This involvement should be substantial and continuous, not merely symbolic or transactional, recognising them as true experts.

There are structured and proven methodologies to facilitate this involvement, along with appropriate training and empowerment tools (e.g., through EUPATI). It is vital to acknowledge the needs and particularities of the paediatric context, considering the ethical aspects and practices of involving children and families, which should be respected without using them as justification for excluding them from the research process.

Groups and initiatives such as EUPATI, EURORDIS, eYPAGNet, along with the conect4children network, among others, have extensive experience in promoting the involvement and empowerment of adults, children, and families. These organisations develop tools to train and equip these groups to actively participate, such as YPAG (Young Persons Advisory Group), which advises researchers and teams on clinical research projects.

It is a priority to identify and promote training tools and approaches already developed and tested internationally by these groups, as well as to highlight high-quality materials produced nationally, such as those developed by EUPATI and STAND4Kids, which is committed to identifying national resources aimed at adults, children, and families.

The idea of including patient representatives in Ethics Committees is interesting, but it always raises the issue of training in different areas. At a time when the new European directive on clinical trials is still being discussed, this could be an appropriate moment to implement such representation. The discussion on European health data sharing has already included patient involvement and may help implement this idea.

It is important that research institutions develop transparent mechanisms, integrated

into their regular research practices, to allow collaboration with “patient experts” and to consider or integrate, as early as possible, the real unmet needs of these populations into the research flow. Besides bringing science closer to society, proactive and systematic involvement can help promote a sense of belonging to this sector, which is crucial for health promotion and disease prevention.

## 4. COMMUNICATION AND DISSEMINATION OF CLINICAL TRIALS

Communication is key to the dissemination, recruitment, and retention of participants in clinical trials. Currently, the lack of a clearly defined process to establish the role of all involved parties, such as the Pharmaceutical Industry, hospitals/health centres/local health units, and patient associations, complicates this task and limits the potential for participatory research.

For more effective and systematic communication, it is suggested to create and implement a strategic communication plan that includes the use of social media, collaboration among stakeholders, synergies, and leveraging existing platforms (e.g., Portugal Clinical Trials), increasing literacy about clinical trials, mitigating stigma, and distributing informative materials via social media.

A digital platform that can be used to engage patients and the general public in clinical trials, providing clear information and opportunities for participation, seems indispensable. This digital approach can make the participation process more accessible and transparent, promoting awareness and active community involvement in clinical research, making it more up-to-date and inclusive.

Given the low recruitment/planned participation rates of patients in clinical trials in Portugal, and as Portugal is a small country, it would also be important to develop an effective patient referral strategy. This measure would enhance the number of citizens with access to innovative treatments.

It would be interesting to use each institution's internal network to promote and disseminate the clinical trials available at that institution. Patients spend a lot of time waiting for appointments or exams in waiting rooms, and the institution's intranet system could be used to share this information. Many patients also access the institution's official website via the internet, where they can book exams or view their results. This could also serve as a useful tool for disseminating such information.

The creation of a strategic communication plan is important and should cover social media, podcasts on various platforms, as well as social communication channels. In this regard, it is essential to involve the government in this strategic communication plan and combat illiteracy in clinical trials.

An example of a digital platform that can serve as inspiration is the EVITA Platform, developed by the EVITA-Hereditary Cancer Association as a "Citizen to Citizen" initiative. The EVITA Platform was created to fill gaps in the area of hereditary cancer, which are also observed in other diseases, providing a virtual space to share news,

events, educational materials, and clinical trials. The features developed and implemented in the EVITA Platform demonstrate how the process of engaging people affected by a disease can be made more agile and efficient

## 5. COLLABORATION AND PARTNERSHIPS

Patient associations play a vital role in developing campaigns that raise awareness of the value of clinical research. Such initiatives can promote greater engagement and active participation of citizens (both with and without illnesses) in clinical research.

It is also essential to continue investing in and promoting awareness campaigns among professionals and the public about the importance of reporting adverse events related to the use of medicines, contributing to the ongoing evaluation of the safety and efficacy of medicines. The involvement of the wider community, including citizens without illness, is also crucial to fostering a culture of information, transparency, and trust in clinical research.

In addition to patient associations, partnerships with the pharmaceutical industry, hospitals, research institutes, and other entities can also significantly contribute to increasing literacy about clinical trials.

Patient associations are important, and there should be greater involvement in creating partnerships with professional healthcare bodies in different fields, including training. Partnerships should be established with those responsible for creating high-audience television content, with a proposal for a programme about clinical trials on health-dedicated channels, such as Canal Saúde Mais. Collaborations with academia should be fostered to promote more training in clinical trials, and the inclusion of AICIB/Apifarma/industry in educational and dissemination partnerships, whether through these institutions or by participating in congresses/scientific meetings of healthcare professionals from different functional areas and various healthcare institutions.

## CONCLUSION

The integration of citizens, both with and without illness, as active partners in clinical research is not only beneficial but necessary and fundamental for the advancement of medical science in Portugal and worldwide. By fostering an environment of trust and cooperation among the various stakeholders and leveraging the unique perspective and motivation of patients and their families, the country can enhance the quality, relevance, and impact of its clinical research.

Moreover, empowering patients through better and easier access to information and greater involvement in research projects and activities promotes a more inclusive, effective, and sustainable healthcare system. Patient associations should be recognised as key players in the social economy, with their roles and contributions supported through innovative funding strategies and enhanced collaboration with research

centres and the pharmaceutical industry, among other stakeholders. Furthermore, the active participation of patients in Ethics Committees and Advisory Boards ensures that their voices are heard at every stage of the research process.

Finally, the adoption of a code of conduct, best practices, and ethical standards based on the best available evidence for patient engagement will ensure that Portugal remains a leader in medical research and healthcare delivery.

This collective and participatory effort will not only advance scientific research but also ensure that it aligns with the real needs of patients, thereby improving health outcomes across the country.

During the workshop, the various stakeholders in the clinical trials ecosystem in Portugal presented different perspectives and recommendations aimed at building an informed patient community actively engaged in clinical research activities.

Attached, you will find an infographic and the list of participants.

Report prepared with the support of *medical writer* Ana Sofia Correia, in May 2024.

# ANNEX 1

Compilation of the perspectives and recommendations of the various stakeholders in the clinical trials ecosystem in Portugal, resulting from the workshop "Integrated vision on how to build an informed and active patient community" promoted by EUPATI as part of the Conference "Clinical Trials: Research that gives hope to patients and brings a better life to all" organized by Apifarma on May 17, 2024. The aim is to build a community of people with illness who are informed and actively involved in clinical research activities.

| | PRE-DEVELOPMENT | DEVELOPMENT | DISSEMINATION | EXECUTION |
|---|---|---|---|---|
| **HEALTH LITERACYAND ACCESS TO INFORMATION** | • Promote health literacy programs from an early age, in the first cycles of education in schools.<br>• Transforming and training teachers/educators into active public health agents.<br>• Adapt health literacy programs to all age groups, depending on the target audience. | • Include associations of people with the disease in the literacy process.<br>• Involve the Agrupamentos de Centros de Saúde (ACES) and School Health in teaching strategies.<br>• Include subjects on Clinical Trials in school curricula throughout education. | • Organize public sessions to present CTIS (Clinical Trials Information System) in Portuguese, to explain the type of information available.<br>• Improve access to information on clinical trials by empowering people with diseases and their caregivers with knowledge and access tools. | • Include the participation of characters in clinical trials in soap operas and other popular television programs to increase the audience and the dissemination of information.<br>• Use morning or evening debate programs to promote discussion and awareness of clinical trials. |
| **CAPACITY BUILDING AND TRAINING** | • To enable researchers to deal with the reality of the "specialist patient", promoting communication and the approximation of language between academia, promoters, health units and society.<br>• Promoting lifelong learning for professionals working in clinical trials. | • Promote contact between Promoters and Contract Research Organizations (CRO) with associations of people with the disease in Portugal, making them part of the research process.<br>• Develop specific training in clinical trials for nurses and other health professionals, as the Order of Nurses has done with Apifarma. | • Explaining the research process to people with the disease and their caregivers, clarifying doubts and conveying confidence, especially in primary health care.<br>• Dedicate full-time professionals to the area of clinical trials, rather than part-time or according to the needs of each institution. | • Include the tutelage/government in the creation of a specific career in clinical trials.<br>• Create Clinical Research Departments in Hospital Centres/Local Health Units (ULS), in partnership with academia, to respond to the need for professionalization and exclusive dedication of professionals to the research area. |
| **INVOLVEMENT IN RESEARCH** | • Involve people with the disease and their caregivers from the earliest stages of the research.<br>• Create advisory councils for people with the disease and their carers.<br>• Develop a code of good practice for the involvement of people with illness, based on values of relevance, fairness, transparency, trust, equity, diversity and empowerment. | • Ensure the participation of people with the disease and their associations in Ethics Commissions.<br>• Collaborate closely with promoters and researchers.<br>• Include families and caregivers in all areas of clinical research, both in pediatric and adult studies.<br>• Promote partnerships with groups that encourage the involvement of family members and caregivers. | • Implement structured and proven methodologies to facilitate the involvement of people with the disease, families and caregivers.<br>• Use training and capacity-building tools, such as those developed by EUPATI and other organizations.<br>• Include representatives of people with illnesses on the Ethics Commissions, guaranteeing the necessary training. | • Identify and promote training tools and approaches that have already been developed (e.g. EUPATI, EURORDIS, eYPAGNet and connect4children).<br>• Valuing high-quality materials produced nationally (e.g. EUPATI and STAND4Kids).<br>• Develop transparent mechanisms in research institutions for collaboration with "expert patients". |
| **COMMUNICATION AND DISSEMINATION** | • Create and implement a strategic communication plan that includes social media, collaboration between stakeholders and the use of existing platforms (e.g. Portugal Clinical Trials).<br>• Develop a digital platform to engage people with the disease and the general public, providing clear information and opportunities for participation. | • Increase literacy about clinical trials, mitigate stigmas and distribute information materials.<br>• Use each institution's internal network to promote and publicize clinical trials.<br>• Involving the government in the strategic plan to communicate and combat illiteracy in clinical trials. | • Work on an effective referral strategy for people with the disease to increase the number of participants in clinical trials.<br>• Use digital platforms (e.g. EVITA Platform) to make the process of engaging people with illness more agile and efficient. | • Use social networks, podcasts on various platforms and social media channels to publicize clinical trials.<br>• Promote the dissemination of clinical trials on the official websites of the institutions and through the intranet circuit, including the scheduling of tests and access to results. |
| **COLLABORATION AND PARTNERSHIPS** | • Develop awareness campaigns on the value of clinical research, promoted by associations of people with the disease.<br>• Create partnerships with the pharmaceutical industry, hospitals, research institutes and other entities to increase literacy about clinical trials.<br>• Involving citizens/people without disease to promote a culture of information, transparency and trust in clinical research. | • Invest in awareness campaigns on the importance of reporting adverse events related to medicines.<br>• Establish partnerships with health professional associations for greater involvement and training.<br>• Create partnerships with those responsible for creating television content for large audiences and with channels dedicated to health (e.g. Canal Saúde Mais). | • Proposing and developing programs on clinical trials for health television channels.<br>• Promote partnerships with academia to promote more training in clinical trials. <br> - Include AICIB, Apifarma and the pharmaceutical industry in training and dissemination partnerships, participating in congresses and scientific meetings of health professionals. | • Continue to promote awareness campaigns among professionals and citizens about the importance of reporting adverse events and clinical research.<br>• Use established partnerships to disseminate results and promote the safety and efficacy of medicines. |

**ANNEX 2**

**PARTICIPANTS (alphabetical order):**

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| **Ana Vieira**<br>Sjögren's Syndrome Center of the Portuguese League against Rheumatic Diseases | **João Rodrigues**<br>National Association of Bone Dysplasias (ANDO Portugal) |
| **Angela Papa**<br>PPD / EUPATI PORTUGAL | **Laetitia**<br>Treatment Activist Group (GAT) |
| **Arsisete Saraiva**<br>National Association of Patients with Rheumatoid Arthritis (A.N.D.A.R.) | **Manuel Belo Costa**<br>Order of Nurses |
| **Beatriz Lima**<br>Faculty of Pharmacy of the University of Lisbon | **Manuel Gonçalves**<br>Gonçalves & Partners |
| **Bruno Gago**<br>Association for Vocational Training and Research of the University of Aveiro (UNAVE) | **Maria João Salgado**<br>Johnson & Johnson Innovative Medicine |
| **Carolina Garcez**<br>*Patient Advocate* | **Patrícia Adegas**<br>Novartis |
| **Cristina Lopes**<br>Portuguese Association of the Pharmaceutical Industry Portuguese Association of the Pharmaceutical Industry (Apifarma) / EUPATI PORTUGAL | **Pedro Faleiro**<br>INFARMED I.P.\| Include |
| **Elsa Mateus**<br>Portuguese League against Rheumatic Diseases / EUPATI PORTUGAL | **Ricardo Fernandes**<br>Stand4Kids – Portuguese Hub |
| **Guilherme Luz**<br>Sanofi | **Ricardo Santos**<br>Order of Pharmacists |
| **Helena Beaumont**<br>Agency for Clinical Research and Biomedical Innovation (AICIB) | **Sofia Alaiz**<br>Abbvie |
| **Jaime Watermelon**<br>Portuguese Psoriasis Association | **Tatiana Vassilevskaya**<br>EVITA Association - Hereditary Cancer |

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| (PSOPortugal) | |
| **Joana Camilo**<br>Atopic Dermatitis Association Portugal (ADERMAP) | **Vera Gomes**<br>Crohn's Colite United Kingdom |
| **Moderation:**<br>**Nadim Habib**, Nova School of Business and Economics Professor and International Consultant | |