

IMPROVING CLINICAL TRIALS AWARENESS AND ACCESS

*Insights from Rheumatic Disease
Patient Advocates*



On 2 June, 2022, in a meeting held during the EULAR Congress, the European Alliance for Patient Access hosted a meeting of representatives from international rheumatic and musculoskeletal disease patient associations. Together they explored clinical trials awareness and access challenges, which are fundamental patient access issues.

Presenters & Topics



Brian Kennedy

Executive Director, Global Alliance for Patient Access, highlighted positive developments in terms of clinical trials. There are about 416,555 studies underway worldwide, Mr Kennedy noted, with an annual investment of \$160 billion.

Yet challenges remain, specifically: low enrolment, clinical trial delays and high costs. Mr Kennedy mentioned that 55% of studies terminate due to low enrolment and 80% of studies fail to meet enrolment timeline goals, adding millions to already high costs.

Several barriers impede patient access to clinical trials, Mr Kennedy noted. These include: lack of awareness, failure of providers to participate in trials, failure to recruit participants from minority communities, related costs to patients, the perception of personal risks and fears, and the time and bureaucracy involved to qualify for a clinical trial.

Mr Kennedy identified four main stakeholders in improving clinical trial awareness:

- **Investors**, as 90% of investments is done by life science companies
- **Patients**, who are calling for patient-centred research
- **Health care providers**, tens of thousands of whom engage in medical research
- **Policymakers**.

Policymakers specifically could support clinical trials awareness in several ways, Mr Kennedy noted:

- **Supporting patients** in navigating the clinical trials landscape
- **Empowering health care providers** to talk about clinical trials with patients
- **Prioritising diversity** in trial enrolment
- Making clinical trials participation a **public health priority**.

He concluded by calling on public health authorities in Europe, as well as European patient associations, to collaborate on improving clinical trials awareness and access.



Dr Elena Nikiphorou

from the Rheumatology Department at the King's College Hospital and Centre for Rheumatic Diseases in the United Kingdom, spoke about clinical trials and registries from a population health perspective.

She explained that clinical trials and registries advance the medical and scientific knowledge of a disease and its treatment, leading to better health and potentially disease-free generations.

Dr Nikiphorou outlined both individual and societal benefits of clinical trials.



INDIVIDUAL BENEFITS:

- Having an active role in one's health care
- Contributing to available knowledge about the disease and the clinical decision making
- Getting insights into one's disease and health
- Receiving access to new treatments
- More frequent input and check-ups
- Easier access to relevant information, support groups and resources.



SOCIETAL BENEFITS:

- Increasing available information about disease risk factors, trends, treatment and outcomes
- Providing insights for the development of new therapies
- Generating information about health care use, costs and public health interventions.

These benefits, Dr Nikiphorou explained, can lead to improved health care and public health, increased longevity, and greater productivity, which in turn boost national economies.

Dr Nikiphorou also identified several challenges, including public engagement and the lack of representation of racial and ethnic minorities. Greater inclusivity is important, she noted, as are better education, increased awareness, and greater trust and acceptance of clinical trials.



Ana Vieira

from the Portuguese League against Rheumatic Diseases (Liga Portuguesa Contra as Doenças Reumáticas) shared the patient perspective on clinical trials.

Ms Vieira participated in a Phase II clinical trial on a treatment for primary Sjögren's syndrome. By participating, she hoped to improve her quality of life and gain access to an innovative therapy. She also hoped to allow for other patients to access the treatment in the future.

She did have some reservations, however. Ms Vieira worried that the treatment being tested might interfere with her usual treatment and might cause side effects that could impact her daily life. She also considered the travel time, emotional distress, number of unscheduled visits and the impact of COVID-19.

Reflecting on her experience, Ms Vieira praised the institutional support she received but lamented the trial's lack of patient centricity.

Having the opportunity to talk to other patients involved in trials, or to patient organisations, Ms Vieira noted, can be motivating and reassuring. She emphasised that patient organisations should be invited to partner on clinical trial design to ensure the use of accessible language and appropriate timing for access to information, and to incorporate patient preferences, expectations, experiences and rights.

Patient organisations should be partners on clinical trial design.

She concluded that better clinical trial designs, approaches and care focused on patients' needs and preferences would improve patients' clinical status and health outcomes. These changes might also encourage more patients to participate, Ms Vieira explained, advancing the development of new drugs and medical devices.



Linda Stone

Secretary of Sjörögen Europe and Chairman of the British Sjörögen Syndrome Association, reflected on the societal benefits of participating in clinical trials.

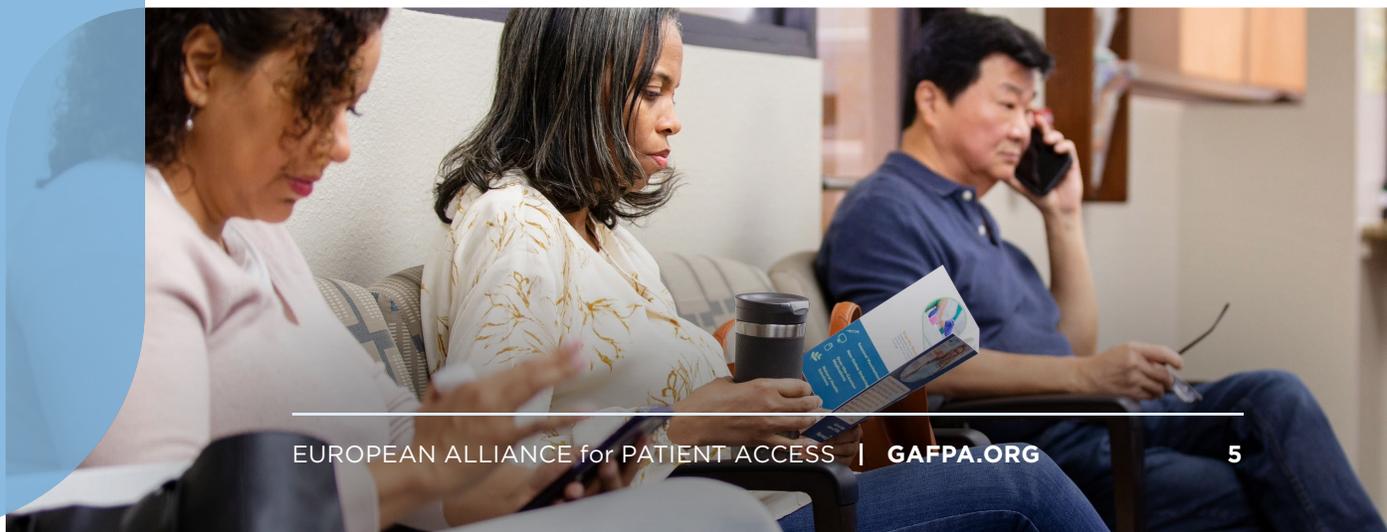
Patients are very conscious of the burden of their disease, Ms Stone observed, and alleviating that burden will provide significant benefit. The main challenges for clinical trial awareness, she explained, fall largely into one of two areas: how patients can be encouraged to participate in clinical trials and how researchers can enrol sufficient patients.

Ms Stone also examined the role of pharmaceutical companies in clinical trials, breaking down which practices help and which do not.

Some pharmaceutical companies invest time and effort in building relationships and in maintaining them over time, Ms Stone noted. They also invest significant resources and involve patients right from the beginning of a project. When using these best practices, pharmaceutical companies can support patients to play an active role in the bench-to-market process, recognising patients as experts on their own disease.

Plain-language materials can make clinical trials participation easier for patients.

If researchers adopt similar practices, Ms Stone conjectured, recruiting trial participants might become easier. She also emphasised the importance of simplifying the language used in clinical trials, highlighting simple solutions such as offering a reader-friendly summary or an addendum.





DISCUSSION

The presentations prompted a discussion, which was moderated by Neil Betteridge, Director of the European Alliance for Patient Access.



Nadia Malliou from the Hellenic League Against Rheumatism said that clinical trials and registries go alongside validated patient-reported outcome measures, which need to be part of the equation. She urged effort to bring on patients to develop such measures.



Prof Anthony Woolf from the Global Alliance for Musculoskeletal Health emphasised the importance of working with patients and patient organisations to improve clinical trials recruitment. He also acknowledged the role of relevant authorities who are deciding on the outcomes measures. These outcome measures are usually quantitative, Prof Woolf noted, and soft measures such as how the patient feels are rarely considered. Patient-relevant outcome measures are therefore important, Prof Woolf explained, as there is not enough data on them.



Dr Elena Nikiphorou agreed that patients should be involved in research from the start and all the way to when the results are disseminated. Patients should play an important role in each stage of the clinical trial, she noted.



Andri Phoka from the Cyprus League of People with Rheumatism raised the point that patients need to be educated to participate in the development of clinical trials. Otherwise, Ms Phoka noted, they will struggle to engage.



Claire Jacklin from the National Rheumatoid Arthritis Society explained that the whole medical community should commit to including racial and ethnical minorities in the discussion. This should start in regular health care, Ms Jacklin explained, so that people from these groups will be introduced into research, thereby making them feel listened to and included in the process.



Corinna Elling-Auders from the German Rheumatism League (Deutscher Rheuma-Liga Bundesverband) noted that education is important but argued that patients should also be able to understand clinical trials without prior medical education. The responsibility of making trials straightforward and accessible should lie with pharmaceutical companies, Ms Elling-Auders emphasised.

Mr Betteridge concluded the discussion by reiterating that expert patients are needed to design protocols and ensure that the information provided to patients is written in a friendly and accessible way. Trial participation should nevertheless be fully inclusive, Mr Betteridge noted. He thanked participants for their insights.



About the European Alliance for Patient Access

The European Alliance for Patient Access is a division of the Global Alliance for Patient Access, an international platform for health care providers and patient advocates to inform policy dialogue about patient-centered care.

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