Myeloma Patients Europe report finds huge inequalities in access to myeloma clinical trials in Central and Eastern Europe

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Myeloma Patients Europe (MPE) has today launched a first-of-its-kind advocacy report on *Addressing access barriers to myeloma clinical trials in Central and Eastern Europe (CEE).*

The report, led by the MPE CEE Workgroup on Access, found huge inequalities for patients, confirming reports from MPE CEE members about a lack of clinical trials opening in the region and difficulties in patient participation.

Biba Dodeva, MPE Board Member and Chair of the MPE CEE Workgroup on Access commented:

"This is an important report which for the first time shines a light on the differences in myeloma trial access between countries and explores potential reasons for this. In my country, North Macedonia, we do not have access to many clinical trials, and this is a situation replicated across the Balkans. I very much hope this report and recommendations lead to discussion, best practice sharing and identified action on improving the situation for patients across CEE."

The MPE report presents clinical trial analytics, looking at the number of clinical trials held in CEE countries between 1 January 2001 and 28 September 2020. The analytics found:

- Only 6% of the 3,229 worldwide myeloma trials included patients from CEE countries
- Of the 17 CEE countries that ran at least one myeloma clinical trial, 11 were EU members
- Czech Republic (128 trials), Poland (95 trials) and the Russian Federation (79 trials) were involved in the largest number of trials
- In relative terms to myeloma prevalence, Czech Republic, Hungary (66 trials) and Bulgaria (24 trials) were the CEE countries most efficient in conducting research
- Seven countries had no access to myeloma clinical trials and 12 countries had fewer than five myeloma clinical trials

To explore the analytics further, MPE conducted a literature review exploring the barriers and facilitators to clinical trial access in Europe, alongside qualitative interviews with haematologists, researchers and regulators in three selected CEE countries (Poland, Croatia and Macedonia). Key findings include:

- Population size (and subsequent patient population) is an important, but not the only, determinant in where clinical trials launch
- Trial access in CEE countries is strongly correlated to EU membership
- Most myeloma clinical trials in CEE are run by the pharmaceutical industry (around 80%) given their ability to invest in and finance such research

- Lack of reimbursement and access to “standard of care” treatment in myeloma (e.g. ESMO-EHA myeloma guidelines) make it difficult for trials to run in some countries. For example, impacting on the trial eligibility of patients and the comparator arm of trials
- For “innovative” immunotherapies and cancer drugs, such as CAR-T and bispecifics, additional resources, monitoring and diagnostics tools need to be in place to run trials, which some countries do not have
- A lack of adequate staffing and workforce planning was identified as a barrier to trial set-up in countries. The situation has worsened with the increasing number of physicians and nurses leaving some CEE countries to work in Western Europe (the “brain drain”)
- Too much bureaucracy and administration for setting up trials (e.g. registration, ethics) impacts on access. This has the biggest impact on access to academic trials which are less well resourced
- Even where trials are available within CEE countries, patients face access barriers related to factors including geography and socio-economic aspects

The report subsequently makes a series of 27 recommendations for key stakeholders (including researchers, industry, policymakers and advocates) designed to promote discussion on potential solutions for improving clinical trial access across CEE.

The recommendations relate to the following topics: promoting regional and international collaboration on clinical trials and research; facilitating international peer-to-peer support and knowledge sharing on clinical trials; minimum staffing requirements or guidelines; creating a supportive policy environment for research and R&D; improved information and communication on clinical trials for patients; and, improving the wider access environment including medicines access and diagnostics.

For the full list of findings and recommendations, you can see the Executive Summary and Full Report here.

Next steps

The report has been launched today during an MPE online event. During the event, the report and recommendations were presented, alongside case studies from North Macedonia, Czech Republic and Poland. The event recording will be available soon on our website.

You can see a pre-recorded video from speaker Prof Oliver Karanfilski on the challenges running clinical trials in North Macedonia here.

In 2023, MPE plans to hold a multi-stakeholder, roundtable discussion on the issues and recommendations included in the report to further analyse the access barriers and facilitators to clinical trials in CEE. If you are interested in this work, please email access@mpeurope.org

Finally, this work was developed and steered by the MPE CEE workgroup on access. Again, if you are interested in joining this workgroup, please email access@mpeurope.org