Biomedical Alliance in Europe

FEAM
Federation of European Academies of Medicine

WORKING TOGETHER FOR THE FUTURE OF EUROPEAN HEALTH RESEARCH

Summary Report

31 January 2020, EU Parliament, Brussels

About the Federation of European Academies of Medicine (www.feam.eu)

The Federation of European Academies of Medicine (FEAM) is the European umbrella group of national Academies of Medicine, Medical Sections of Academies of Sciences, Academies of Veterinary Sciences, and Academies of Pharmaceutical Sciences. It brings together 21 national Academies representing over 5000 among the best biomedical scientists in Europe.

FEAM's mission is to promote cooperation between national Academies of Medicine and Medical Sections of Academies of Sciences in Europe; to provide them with a platform to formulate their collective voice on matters concerning human and animal medicine, biomedical research, education, and health with a European dimension; and to extend to the European authorities the advisory role that they exercise in their own countries on these matters.

About the Biomedical Alliance in Europe (www.biomedeurope.org)

The Biomedical Alliance in Europe (BioMed Alliance) is a non-profit organisation representing 33 leading European research and medical societies uniting more than 400,000 researchers and healthcare professionals.

The BioMed Alliance is committed to promoting excellence and innovation in the European healthcare field with the goal of improving the health and well-being of all European citizens. It promotes the interests of researchers and healthcare professionals organised in not-for-profit scientific medical associations and organisations, across all medical disciplines.

Acknowledgements

FEAM and the BioMed Alliance would like to thank all speakers, panellists and participants of this event and in particular MEPs Prof Maria da Graça Carvalho, Dr Cristian Bușoi and Prof Petra De Sutter for kindly hosting the discussions. Thanks as well to Dr Rosa Castro from FEAM, Marieke Meijer and Loredana Simulescu from the BioMed Alliance for drafting this report.

Disclaimer

Opinions expressed in this report do not necessarily represent the views of all participants at the event, the Federation of European Academies of Medicine (FEAM) or the BioMed Alliance.

All web references were accessed in February 2020.

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Key messages

Health research is key to address health challenges across the EU

The EU is facing an increasing burden of diseases, multi-morbidities linked to an ageing population, and financial pressures on healthcare systems. At the same time, there are new advances in health research and emerging technologies offering potential benefits, but there are also potential risks associated with their use. An integrated approach to health research (one encompassing the whole process, from basic to applied, and to implementation research), is needed to face current challenges and benefiting citizens and patients.

More multi-sectoral and multi-country collaboration needed

Complex challenges call for broad collaborative approaches. Health research is often complex, long and costly. It spans from basic research to understand the mechanism of diseases, to applied research and to the implementation of a wide set of interventions. The facilitation of collaborative research across countries (within and outside the EU), including with the UK post-Brexit, is needed to ensure that patients and citizens continue to benefit from research. Effective partnerships between the private and the public sectors with academia and patient participation are also needed. Patient's involvement needs to occur early and be meaningful to ensure that health research matches societal needs.

Public funding for health research is needed for key specific areas

The contribution of the pharmaceutical sector is very significant for the development of new therapies and vaccines. Nonetheless, these efforts should be complemented by publicly funded health research, including publicly funded clinical trials, in areas that are not sufficiently addressed by the private sector. This is for instance the case in clinical trials for the comparative effectiveness of treatments, including combinations of drugs, or for areas where the market is small such as rare diseases and paediatric indications, or for surgical techniques, screening or lifestyle interventions.

Complex health challenges call for supporting ecosystems

There are certain areas of health research that have not progressed as much as needed. Examples include research about sepsis, neurodegenerative diseases and some types of cancer. For sepsis, this is also due to the complex and heterogeneous character of this disease. For these complex areas of research, a supportive ecosystem needs to combine support for broad research happening at all levels (e.g. basic, translational, applied, and implementation research) with long timelines to allow for iterative learning. In addition to this, broad collaboration between sectors, and the innovative and joint use of multiple existing technologies (such as artificial intelligence, big data and molecular technologies) is needed.

Harnessing the power of EU health data

The EU has made important progress in facilitating the exchange of health data through its work on eHealth. There is still enormous potential for health data to be shared across the EU for the benefit of citizens and patients. However, data exchange is a complex issue affected by many technical hurdles as well as ethical and regulatory constraints. With its EU Health Data Space work, the new EU Commission envisions a more ambitious plan to pool and use data for the benefit of healthcare systems and health research.

Summary of presentations

Welcome message

Maria da Graça Carvalho, MEP

Prof. Maria da Graça Carvalho welcomed the audience, the co-organisers of the event, FEAM and the BioMed Alliance, and the co-hosting MEPs, Dr. Petra De Sutter and Dr. Cristian Bușoi. As a scientist with an engineering background, she welcomed the opportunity to discuss research, innovation and education with different stakeholders and policymakers. Prof. Carvalho opened the event by mentioning key policy challenges in this area:

- Institutions, including hospitals, often lack a multi-disciplinary approach, which is key to tackle the growing burden of multiple diseases;
- Flexibility is often needed to respond and adapt to emerging situations where society needs innovative and fast paced solutions;
- Sharing data among countries and institutions is another key challenge for health research. One successful example in Europe is the exchange of data for rare diseases;
- Another important challenge is the high administrative costs of carrying out clinical trials in multiple countries. Maintaining the ethical values of the European project while lowering costs is key to keep clinical trials in Europe;
- Inequalities are affecting research and need to be addressed as they often translate into health inequalities;
- Last but not least, it is important to merge clinical and research careers; closer cooperation between research and clinical practice is needed. In some countries, such as Portugal, it is difficult for a health professional to combine clinical practice with a research career. Oftentimes, a research career is not sufficiently rewarded, and this needs to be addressed.

Welcome message

Cristian Bușoi, MEP

Dr. Cristian Bușoi welcomed the audience and thanked the co-organisers of the event via a recorded message sent from Romania. Healthcare is at a crossroads with many challenges on multiple fronts, including the increasing disease burden and European healthcare systems being forced to cope with financial issues. Non-communicable diseases take an immense toll on patients, their families and the economy. Europe's ageing population means that today more than one-third of EU citizens suffer from a chronic disease; this includes about 23% of the working population.

Against this background, health research is more important than ever. It has a transformative impact on the lives of patients and provides a return on investment to society. Nonetheless, bottlenecks persist, including fragmentations in the health research funding system, and limitations to the sustainability of funding. Health research is constantly evolving, and policymakers and researchers

should work together to ensure that researchers have access to new developments, concepts, and technologies needed to develop innovative ideas.

At the same time, efforts should focus on effectively scaling-up and implementing these innovations, so they quickly reach patients. Cross-sectoral and cross-border cooperation are key in ensuring health research meets societal needs. Therefore, Dr. Bușoi welcomed again that the BioMed Alliance and FEAM joined forces to organise this workshop and to provide a forum to discuss opportunities and challenges for maximizing the impact of European Health Research in the forthcoming years.

As rapporteur of the Horizon programme in the past, Dr. Bușoi worked together with many colleagues to incorporate health research in the new Horizon programme. This programme will strengthen medical research and aims to build synergies with the proposed missions. Dr. Bușoi finished his message by saying that he looks forward to hearing about the outcomes of the discussion and to joining forces with all stakeholders to improve both the impact of Europe's next research programme and of health research in general.

Added value of publicly-funded clinical trials: opportunities and challenges

Petra De Sutter, MEP

Prof. Petra De Sutter started her presentation by stressing the importance of research collaboration. Given the significance of this workshop taking place on 31 January 2020 (deadline for Brexit), she stressed the importance of joining forces to ensure smooth collaboration between the EU and the UK post Brexit.

Prof. De Sutter drew from her medical expertise and presented her vision on the added value of publicly-funded clinical trials. It is important to acknowledge the key role played by the pharmaceutical industry in our health system but there are certain important research questions that will never be fully answered by a market-driven industry. Public funds for clinical trials are key to ensure qualitative, evidence-based medicine, which reflects the needs of European citizens. They also have important benefits from an economic perspective, as they can help ensure the sustainability of our European healthcare systems.

As listed in a report from KCE[1], there are several areas where publicly funded clinical trials could play a key role, including:

- Research on the comparative effectiveness of different pharmaceutical treatment options and to assess the real impact of innovative therapies;
- Repurposing trials with old off-patent medical products. While repurposing is common practice in current pharmaceutical R&D, it is often limited to patented drugs. Old and often

[1] Neyt, M., Christiaens,T., Demotes, J. & Hulstaert, F. (2015). Publicly-funded pratice-oriented clinical trials. KCE Report 246. Belgian Health Care Knowledge Center.
https://kce.fgov.be/sites/default/files/atoms/files/KCE_246_Public_funded_clinical_trials_Report.pdf

relatively affordable off-patent drugs can offer many possibilities for therapeutic progress, but sometimes these specific repurposing studies are not conducted by the pharmaceutical industry as they do not offer sufficient incentives;

- Paediatric and orphan medicinal products are another important area due to the small number of patients involved and because of the low profitability of the treatments for pharmaceutical companies. Hence, governments should support trials in paediatric and orphan diseases to facilitate the development of new treatments;
- With the increasing uptake of personalised medicine and the arrival of new technologies, the role of academic research is going to be even more important to help select appropriate treatments. Academic research will be essential to assess innovative and immunological therapies for NCDs, and especially for cancer in order to identify the best treatment option for targeted patients;
- There might also be opportunities for trials with medical devices. For example by using a trial to compare the effectiveness of two medical devices or to compare the effectiveness of a medical device intervention versus a surgical or pharmaceutical intervention;
- More broadly, publicly funded trials are needed to advance research in specific areas that are traditionally not sufficiently addressed by industry, for example in studying surgical techniques, screening or lifestyle interventions.

The EU should therefore play an important role in supporting European collaboration and providing funding for these trials. European collaboration has advantages, offers opportunities, avoids duplication, delivers faster and facilitates the involvement of a larger number of patients.

The European Clinical Trials Regulation[2] will hopefully soon enter into force and it is expected to facilitate cross-border collaboration for clinical trials and improve transparency in line with the recent ruling by the European Court of Justice with regard to data from clinical trials[3]. However, legislation is not enough. Trials are complex, costly and often require expertise from different medical fields. Despite their huge importance, these trials are generally underfunded. There are some very good national programs, such as the NIHR in UK and the KCE in Belgium, but more money is needed. Being so crucial for patients, citizens and for our healthcare systems, it is therefore important to ensure that non-commercial trials receive enough attention in the next European framework programme for research and innovation (Horizon Europe) and other European efforts in this area. There should be enough funding going to health research projects, and in particular to those areas of research where the unmet health needs are the most pertinent, not just the areas that are most commercially profitable. R&D for which the need is biggest, and not only where most profit can be expected. Health investments give great return on investment and should be given priority.

[2] Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC.

Re-engineering clinical research: a focus on converging research ideas into solutions for patients

Mihai Netea

Prof. Mihai Netea started his presentation by explaining that he would use the particular example of sepsis to illustrate some of the challenges of clinical research. Similar challenges are also present in other complex disease areas, including Alzheimer's disease. Sepsis is a medical condition associated with an extreme reaction to infection or trauma. It is estimated that around 11 million sepsis deaths occurred in 2017; representing 19.7% of deaths worldwide[4].

The first cause of death for patients with sepsis is infection, and the mortality rate is very high. This is the case with severe forms of infections such as meningococcal bacteria. In these cases, it is crucial to treat patients with antibiotics to combat the infection. However, it is also important to address the reaction of the immune system of the patient to the infection, which is overwhelming in these cases (e.g. hyper-inflammation in meningococcal sepsis).

Hence, researchers have been trying to tackle this problem through different angles. A first alternative has been the development of anti-inflammatory therapy to fight against the very extreme reaction of the host's (patient's) immune system. Following this approach, more than 30 clinical trials have been designed to inhibit hyper-inflammation in sepsis (from anti-cytokine therapies such as anti-TNF and anti-IL1 to inhibitors of bacterial receptors such as anti-TLR4). However, many clinical trials have failed and literally tens of billions of euros have been spent.

Sepsis is a complex scientific problem that has been tackled both by scientists and industry. An explanation for the failure of earlier trials is that sepsis is a heterogeneous disease. Similar to cancer, sepsis does not consist of one, but of many diseases at the same time. For each type of sepsis there is a different response: sometimes the immune response of the patient is exacerbated and sometimes it is diminished. Often, the treatment for each patient needs to be adjusted; for some of them, the immune response needs to be inhibited, and for others it needs to be boosted. A possible solution to this problem is to obtain better information about how each individual is responding by measuring the involved parameters. The decision of whether to boost or to inhibit the immune response of each patient should then be based on this information.

However, while industry has stopped investing in this problem, there have been proposals from academia focusing on a personalized medicine approach. These proposals need public funding. For instance, under Horizon 2020, 3 consortia have worked on sepsis to test currently available therapies. Publicly funded programmes, including Horizon Europe, play a key role in supporting these types of trials.

[4] Rudd, Kristina E., et al. "Global, regional, and national sepsis incidence and mortality, 1990–2017: analysis for the Global Burden of Disease Study." *The Lancet* 395.10219 (2020): 200-211.

Complex medical challenges such as sepsis need to be addressed with a combination of the following aspects:

- Patience: long-term iterative improvements of clinical trials take time –this is also the case in the oncology field;
- A broad approach: a broad and multi-disciplinary approach is needed to integrate basic, clinical, translational and implementation studies at the same time;
- Collaboration: multi-disciplinary collaboration is needed between the public and the private sectors and is also necessary to motivate the pharmaceutical industry to re-enter the field of sepsis research;
- Innovation: investments in innovative technologies, systems biology and personalized medicine are also key to address complex medical questions.

Looking forward, a personalised medicine approach is necessary to select patients for clinical trials. It is crucial to divide patients with the help biological markers to test different alternative treatments. New technologies for the unsupervised stratification of patients (e.g. artificial intelligence, genomics, etc.) can support this approach. Overall, a **supportive ecosystem** that covers all the phases of research is essential to sustain clinical research in Europe:

- Basic research to understand the mechanisms of disease;
- Translational research to identify new targets and biomarkers;
- Clinical trials and large collaborations and consortia for multi-centre trials for the generation of a continuous iterative pipeline of products or therapeutic strategies;
- Consideration of important differences for various populations (e.g. East and West, North and South, men and women, children and elderly populations).

A good example of this approach is the LifeTime project[5], which brings together a wide consortium including EU pharma and public institutions and aims to build an ecosystem, from basic to applied, and to implementation research.

European Health Data Space

Andrzej Rys

Dr. Andrzej Rys started his intervention by mentioning that the European Health Data Space is currently being designed. Hence, he mentioned that his presentation would provide an overview of the beginning of this journey initiated by the European Commission (Directorate General Health, DG Sante) in collaboration with other DGs and with stakeholders.

The European Health Data Space builds on previous initiatives at EU level. In 2018, the EU Commission published its communication on the digital transformation of health and care, which addressed the potential of digital technologies (from health data to the use of digital technologies) for the whole

[5] https://lifetime-fetflagship.eu/

healthcare system[6]. These ideas were organised in 3 different strands: (1) give citizens better access to their health data everywhere in the EU; (2) connect and share health data for research, faster diagnosis and better health outcomes; and (3) use digital services for citizen empowerment and person-centred care.

The first strand concerns the way patients and citizens share their data. Assisted by the Cross-border Health Directive[7], there was progressive exchange of e-prescription and patients' summaries across a number of EU countries[8]. Subsequent work has concentrated on the sharing of electronic health records, which is a more complex step, and still work in progress.

The second strand of the work concentrated on a system for sharing data for research, prevention and personalised health and care. An example is the Declaration for delivering cross-border access to a genomic database of 1 million genomes that will be accessible by 2022[9]. Another successful example is the European Reference Networks for rare diseases, which offer cross-border possibilities to help patients with a rare disease. There are now 24 such networks in place to help patients access the right care[10].

The third and important strand of this work is strengthening the participation of citizens. Citizens should be at the centre as the system is created for them. There is a wide set of financial and other instruments in place to support citizens' empowerment and person-centred care through digital tools.

The new President of the European Commission, Ursula Von der Leyen, has recently called for the creation of a European Health Data Space[11]. Going forward, this plan will take into account all relevant aspects, including infrastructure, access to data, cyber security, preventing new inequalities, AI and ethical issues, regulatory gaps and barriers, and interoperability. A EU Health Data Space will be beneficial for everyone (e.g. people, healthcare systems, and the market), so, the active engagement of all sectors is needed.

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[6] EU Commission, Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society, COM (2018) 233 final.

[7] Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare.

[8] https://ec.europa.eu/health/ehealth/electronic_crossborder_healthservices_en

[9] https://ec.europa.eu/digital-single-market/en/news/eu-countries-will-cooperate-linking-genomic-databases-across-borders

[10] https://ec.europa.eu/health/ern_en

[11] See Mission Letter sent by President-elect of the European Commission Ursula von der Leyen to Health Commissioner Stella Kyriakides and mentioning the « creation of a European Health Data Space to promote health-data exchange and support research on new preventive strategies, as well as on treatments, medicines, medical devices and outcomes ».
https://ec.europa.eu/commission/sites/beta-political/files/mission-letter-stella-kyriakides_en.pdf

To achieve this ambitious plan, special attention to the following aspects is necessary: (1) a strong Governance framework; (2) quality of data; (3) infrastructure. The aim of this approach is to provide a better healthcare, better policymaking and better research and innovation.

At the moment, DG Sante is carrying out preparatory work for the creation of the European Health Data Space, including through the organisation of 3 workshops. The first of these will focus on the GDPR and will take place in January 2020, and the second and third one will be organised with stakeholders. In addition to these workshops, a study on regulatory gaps in cross-border digital healthcare will be launched during the first quarter of 2020, and a Joint Action on the European Health Data Space will be initiated during 2020-2023.

Opportunities for health research in Horizon Europe

Irene Norstedt

Horizon Europe is the next EU Research & Innovation Framework Programme proposed by the European Commission for the period 2021-2027. In spring 2019, a partial political agreement on most aspects of the Commission's proposal was reached by EU Member States and the European Parliament.[12]

Following the partial political agreement on the programme, the preparations towards the launch of Horizon Europe have been stepped up. Draft "Orientations towards the first Strategic Plan for Horizon Europe" was up for public consultation during the summer 2019 (June-October). As part of the co-design process with stakeholders and the wider public the first ever European Research and Innovation Days (EU R&I days) took place in 2019. In total, the new co-design approach allowed to gather input from more than 10.000 countries, organisations and individuals for the finalisation of the "Orientations".[13]

At the moment, a decision on the EU's future long-term budget (2021-2027), including all future EU programmes is yet to be taken by the Council. Discussions about the budget at the level of Member States play a key role in ensuring that the budget is large enough to support the needs and ambitions of the Horizon Europe programme.

As soon as discussions on the budget are concluded, the focus will shift to the implementation. The preliminary structure of Horizon Europe consists of 3 pillars plus a horizontal area on widening participation and strengthening the European research area. Health is included in all the 3 pillars but particularly in pillar 2, as it includes a dedicated cluster 'health'. The implementation of the health

[12] https://ec.europa.eu/info/horizon-europe-next-research-and-innovation-framework-programme_en
[13] https://ec.europa.eu/info/files/orientations-towards-first-strategic-plan-horizon-europe_en

cluster in pillar 2 is co-chaired by DG RTD and DG SANTE, in coordination and co-creation with several other DGs.

An important issue that should be highlighted within discussions about Horizon Europe is the need to look at other relevant EU programmes. This is necessary to build synergies between Horizon Europe and other EU programmes, for instance for supporting the uptake of research results and the deployment of innovative solutions. There is a wide set of other EU programmes, including the European Social Funds (ESF), the Life programme, the Erasmus programme and others, which should complement each other, where relevant and appropriate, to deliver concrete benefits and impact.

The "Orientations towards the first Strategic Plan for Horizon Europe" outlines six targeted impacts for the health cluster:[14]

1. Staying healthy in a rapidly changing society;
2. Living and working in a health-promoting environment;
3. Tackling diseases and reducing disease burden;
4. Ensuring access to innovative, sustainable and high-quality healthcare;
5. Unlocking the full potential of new tools, technologies and digital solutions for a healthy society;
6. Maintaining an innovative, sustainable and globally competitive health industry.

Apart from the collaborative research programme, there is a number of partnerships that will be developed along with Member States. These include institutional partnerships such as the next public-private partnership for health innovation, the Innovative Health Initiative (IHI), which will succeed and replace the Innovative Medicine Initiative (ex-IMI2). The participation of other sectors such as medical devices, medical imaging and digital technologies is being explored. Another partnership is the EU-Africa Global Health (ex EDCTP2). These two partnerships would be set up on the basis of a specific EU legislative act, which involves a specific impact assessment.

Co-funded partnerships in specific areas are also being considered such as on: the Assessment of Risk of Chemicals (PARC), Personalised Medicine, Rare Diseases, the transformation of health and care systems, One Health AMR, and fostering a European Research for Health Research. These partnerships require the involvement of Member States from the onset as their success depends on their willingness to take the lead, commit and contribute financial resources, while other funders might join and contribute as well.

Additionally, it is important to mention the importance of the Missions, including the Cancer Mission, for the health sector. At this stage, the Mission Board for Cancer is working to identify priority areas and a potential timeline. From February 2020 until June 2020 there will be a series of meetings to better define a Cancer Mission. These include a meeting with the Cancer Assembly in February, one with stakeholders in March, and meetings with stakeholders on each Member State. The Board will also define the engagement with citizens and stakeholders in more detail in the coming months.[15]

[14] https://ec.europa.eu/info/files/orientations-towards-first-strategic-plan-horizon-europe_en
[15] https://ec.europa.eu/info/horizon-europe-next-research-and-innovation-framework-programme/mission-area-cancer_en

Next steps for Horizon Europe include a continuous process of co-creation to prepare the first Strategic Plan 2021-2024 and the Work Programme 2021-2022, the preparation of the European partnerships, the engagement with citizens and stakeholders with the Mission Cancer Board, and the next EU R&I days on 22-24 September 2020.

Ms. Norstedt finished her presentation by mentioning an important aspect of the current and next programmes: the need for flexibility to address emerging challenges. This is evident in the current Coronavirus crisis (COVID-19), for which an open call to support research for clinical and public health responses was released later that day (31 January 2020).

Cross-sectoral round table discussion: proposed solutions to transform EU Health research

The roundtable discussion was chaired by Prof. Wilfried Ellmeier, President of the Biomedical Alliance in Europe. He introduced the panel and asked panellists what they see as concrete solutions to enhance health research in Europe.

Roger Bouillon, Emeritus Professor of Medicine, Endocrinology, KU Leuven, Belgium

- Health research is complex, long and costly. Despite this, and regardless of the importance of medical research, the estimation is that the EU budget for research for all life sciences is around 2 to 3 euro per person[16];
- This lack of an optimal funding mechanism for health research is more evident in areas where multinational collaboration is essential, such as in the development of new and better remedies for rare diseases and for many mayor diseases such as diabetes;
- It is necessary to establish a health research strategy in the EU linked to a funding mechanism for health research. This strategy should involve the European Research Council, in addition to other existing mechanisms that have already proved to be efficient. What we need is a funding mechanism modelled after research funding mechanisms at national level, for instance in the UK and other EU countries.

Francoise Meunier, Vice-President of FEAM

- Current stumbling blocks for the EU research area include the differences in research infrastructure and workforce that remain between Central and Eastern European countries. To diminish these inequalities, we need to significantly increase support for the countries that are lagging behind;
- We also need better coordination and involvement of all stakeholders. Public funds for clinical trials are needed, but so is the participation of industry. We need better models for collaboration between the public and the private sectors;

[16] Bouillon, Roger, et al. "Public investment in biomedical research in Europe." *The Lancet* 386.10001 (2015): 1335.

- Thirdly, and even though the provision of healthcare is a national competency, there is room for improvement and for avoiding duplication in Health Technology Assessment (HTA). HTA coordination across MS is an urgent need in order to assess the added value of innovative treatments –which should be the same among EU countries.

George Griffin, President of FEAM, Emeritus Professor of Infectious Diseases and Medicine, St. George's, University of London

- Science is an international pursuit and the impact of health research is amplified when collaboration is enabled;
- Ensuring a smooth transition and continuing collaboration in health after Brexit is essential to address complex health challenges requiring broad research collaboration across countries and sectors (e.g. for antimicrobial resistance);
- The Academies have a key role to play in promoting biomedical and clinical research and their application to benefit patients and citizens across Europe. A similar commitment from political leaders is also needed.

Magda Chlebus, Executive Director, Science Policy and Regulatory Affairs, EFPIA

- From fundamental to applied and implementation research, all partners have an important role to play;
- Europe has taken an inclusive approach in the past and we need to continue this, for instance with the health data initiative and in international cooperation, even after Brexit;
- Implementation research is key, for example the modernization of clinical trials, standardisation, regulatory science, etc. All stakeholders and sectors, including regulators, clinicians, patients, need to work together to boost translational research, through existing and on the new public private partnerships that are currently being shaped.

Katie Gallagher, Senior Policy Adviser, European Patients' Forum (EPF)

- Almost 150 million people live with multiple chronic conditions in Europe; they face specific needs and challenges that healthcare systems are still not well equipped to meet. No European country can successfully tackle this alone and solutions at European level are required;
- There must be clear priority-setting criteria based on potential impact on unmet health needs. Any entanglements of these priorities with other interests must be avoided.
- The European Patients' Forum emphasises the importance of people-focused, social, organisational and systems innovation that is often low-tech;
- Products and services developed with EU funding must be accessible and affordable to those who can benefit from them. Solutions tackling health inequalities should be implemented;
- The meaningful engagement of patients throughout the research and innovation cycle, from the "idea" stage to implementation and evaluation is key to achieve the above;
- Horizon Europe offers opportunities for Europe to lead on promoting genuine research partnerships. Meaningful involvement includes patients being involved early-on: in the call topic selection and in setting requirements for projects to analyse the potential impacts on patients and the public. The participation of patients in the evaluation of the project proposals to validate their potential real-world impact is also of vital importance. The criteria for

meaningful patients' involvement also need to be developed together with patient organisations, to avoid researchers treating 'patient involvement' as a tick-box exercise;
- The European Patients' Forum is open to collaborate with policymakers and academia by supporting the development of best practices for patient involvement in calls and projects and by organising a dialogue between researchers and patient organisations to discuss what could be done in practice.
- Patients' unique expertise and experiential knowledge bridges researchers' scientific expertise with the real world, ensuring that results have maximum social relevance.

Discussion

Transparency of clinical trials and knowledge sharing

Sharing knowledge and results of research is an obligation for researchers. The implementation of transparency provisions for clinical trials to ensure that results are published also depend on the involvement of academia. Transparency is therefore an important challenge; sufficient information sharing should occur to ensure that everyone in the scientific community is able to benefit from valuable information produced elsewhere. It is also key to avoid duplications in research.

Complexity in research

As evidenced by the presentations, health research is a very complex endeavour. In addition to this, digital technologies, biology and other emerging technologies need to be combined and integrated in a multi-sectoral approach. Partnerships (including public-private partnerships) are key in achieving this.

Addressing EU health research fragmentation through a European Health Research Council

A recurring message is that broad collaborations are needed. Although the proposal of a European health research council has not been realized yet, there should be progress on moving together towards a EU funding body.

EU and national health research funding

EU funding represents around 10 % of the overall funding for health research. This emphasises that the main challenge is to work and partner together with Member States and across sectors, including through public-private partnerships. Given the limited amount of public funding in EU, there are areas on which it is natural to prioritise cooperation, such as in rare diseases through the creation of European Reference Networks.

High expectations against available funding

An important problem arises in areas where expectations do not match the allocated budget. One key aspect that needs to be addressed is sufficient funding for research infrastructures. Research Infrastructures are vital in addressing potential gaps, e.g. between different Member States and geographical regions. On the other hand, it is also important to reflect on the importance of health research and to measure the available budget against this. Health research might be one of those areas where patients and citizens would agree on allocating larger budgets at EU level. However, health research is a long process and when measuring its impact for patients and discussing expectations, it is important to remember this timeline.

Closing remarks

Petra de Sutter, MEP

Dr Petra de Sutter closed the event by calling for a broad partnership between basic and applied research, between the public and the private sectors (including the next IMI programme), between the EU and the UK, and between the EU Commission and the Parliament and Member States as they are key for the next Multiannual Financial Framework (MFF). Finally, broad partnerships between stakeholders are also key and it was particularly important to hear the perspective of patients during this discussion.

Annex 1: final programme

11.00	**Welcome** MEP Maria da Graça Carvalho
11.10	**Introductory Remarks** MEP Cristian Bușoi
11.15	**Added-value of publicly-funded clinical trials: opportunities and challenges** Dr. Petra De Sutter, MEP, Professor of Gynaecology and former Head of the Department of Reproductive Medicine at Ghent University Hospital, Belgium
11.25	**Reengineering clinical research: a focus on converging research ideas into solutions for patients** Prof. Mihai Netea, Department of Infectious diseases, Radboud University, The Netherlands
11.35	**European Health Data Space: opportunities and challenges** Andrzej Rys, Director Health Systems, Medical Products and Innovation, DG Health & Food Safety, European Commission
11.45	**Opportunities for health research in Horizon Europe** Ms. Irene Norstedt, Acting Director People Directorate, DG Research & Innovation, European Commission
11.55	**Cross-sectoral round table discussion: proposed solutions to transform EU Health research** Chair: Prof. Wilfried Ellmeier, President of the Biomedical Alliance in Europe • Prof. Roger Bouillon, Emeritus Professor of Medicine, Endocrinology, KU Leuven, Belgium • Prof. Françoise Meunier, Vice President of FEAM • Dr. Magda Chlebus, Executive Director, Science Policy and Regulatory Affairs, EFPIA • Katie Gallagher, Senior Policy Adviser, European Patients' Forum (EPF) • Dr. Andrzej Rys, DG SANTE • Irene Norstedt, DG RTD
12.50	**Take home messages** Prof. George Griffin, President of the Federation of European Academies of Medicine (FEAM)
12.55	**Closing remarks** Dr. Petra De Sutter, MEP

Annex 2: Slides

All slides are available at:

https://www.feam.eu/events/the-future-of-european-health-research-31-january-2020-european-parliament-brussels/

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