Workshop on Health Research Strategic Needs in Europe

University Foundation, Egmontstraat 11, 1000 Brussels (BE)

Friday 13 March 2015

Workshop Report

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11:00 – 13:00	**Plenary session**	
11:00	Discussions on the White Paper II and presentation of EMRC and SRG-MED/Science Europe MED statement: H2020 healthcare budget per year per person for health	Roger Bouillon
11:10	Pan-European Clinical trials, EU Clinical Trials Regulation	Øyvind Melien
11:20	Implementation of medical research in clinical practice	Gerd Antes
11:30	Patients' involvement and empowerment	Ingrid Klingmann
11:40	Personalised Medicine	Angela Brand
11:50	Open access in biomedical research	Stephane Berghmans
12:00	European Commission's point of view on: • 12:00: Personalised Medicine and Clinical Trials • 12:15: Open Access	 Cornelius Schmaltz Jean-François Dechamp
12:25	Discussion (best practices in European countries, other high-level topics of interest)	
13:00 – 13:45	LUNCH BREAK	
13:45 – 15:15	**Parallel sessions**	
	Parallel session 1: EU Clinical Trials Regulation Moderator: Nathalie Kayadjanian / Rapporteur: Insa Bruns	
	Parallel session 2: Open Access in Biomedical Research Moderator: Bernard Rentier / Rapporteur: Maria Manuela Nogueira	
	Parallel session 3: Implementation of medical research in clinical practice Moderator: Stig Slørdahl / Rapporteur: Kirsten Steinhausen	
15:15 – 15:30	COFFEE BREAK	
15:30	**Plenary session**	
	• 15.30: Presentation of results of parallel sessions by each Rapporteur	
	• 15.45: Conclusion on gaps: What is missing in Europe?	Karin Sipido, Roger Bouillon
	• 16.10: Recommendations for next steps and action plan	Richard Frackowiak, Stig Slørdahl
16:30	**End of the meeting**	

The European Science Foundation was established in 1974 with a membership consisting of research-funding and research-performing organisations across Europe. A central aim of the ESF has been to shape European science policy and strategy by bringing together experts to survey the landscape and make recommendations for policy makers to promote cross-border collaboration within Europe in research, funding and science policy.

In recent years these functions of the ESF have gradually been transferred to a new Brussels-based organisation, Science Europe. In March 2015, the Scientific Review Group for the BioMedical Sciences (2013–2015, successor to the European Medical Research Councils or EMRC, 1971–2012) of the ESF met for the last time. It was considered timely to review some of the recent reports that the then EMRC had produced in areas of strategic importance to European biomedical sciences, to assess what progress had been made in meeting the recommendations of the reports, and to identify those gaps that remain to be addressed by Europe's policy makers. The three principal areas of debate were pan-European clinical trials, open access publishing, and the implementation of research into clinical practice. There was also a brief presentation on issues of funding of biomedical research in Europe. This paper represents, therefore, something of an 'end of term' evaluation of these topics.

Overview of the meeting

Pan-European Clinical Trials

In 2009, the ESF published a Forward Look document on Investigator-driven Clinical Trials (non-commercial clinical trials that are usually carried out within an academic setting) [1] in advance of a new European Clinical Trials Regulation that would supersede the existing Clinical Trials Directive, in which a number of weaknesses had been identified.

The ESF report produced five main recommendations. Broadly these were to improve education, training and career structure for scientists involved in academic trials, to increase funding levels, to adopt a 'risk-based' approach to the regulation of trials, to streamline procedures for authorisation, and to ensure that trials were carried out with an appropriate number of subjects in order to produce a statistically valid result.

The new Clinical Trials Regulation, which is already in place, is showing significant progress, although areas of concern remain.

Regarding adoption of a risk-based approach, the new Regulation identifies a new category of clinical trials, 'low- intervention clinical trials', which are subject to more proportionate rules relating to certain aspects of the clinical trial process, including monitoring, documentation, insurance, traceability and storage of investigational medicinal products. To be considered as low interventional, a clinical trial will have to be conducted with medicines which are already authorised and used in accordance with the terms of the marketing authorisation or, in case of use off label, their use should be evidence-based and supported by published scientific evidence on safety and efficacy.

However, whether this two-risk categorisation for trials is the best approach remains a matter of debate. The OECD Global Science Forum recommends three categories of trial [2]. These are based on the marketing authorisation status of the health product. These categories are (a) a health product used under an already licensed indication, (b) a new indication or population for an already marketed product, and (c) a new health product without marketing authorisation. The report also recommends that tools and guidelines be developed to aid the risk-assessment process. It would be worth revisiting this issue in, say, five years to assess whether the risk categorisation stipulated by the new Clinical Trials Regulation has been sufficient to alleviate the administrative burden on clinical trials organisers that pertained under the old Directive.

The new Regulation has sought to streamline and harmonise the application process for multinational clinical trials within Europe with the introduction of a single application portal with a single application dossier, which should significantly reduce the amount of time required for multiple member states to approve multinational trials.

Notable gaps in the Regulation remain, however. Earlier drafts of the Regulation made provision for a national indemnity scheme, in the face of rapidly escalating costs of insurance for a trial. This does not appear in the final Regulation, which is regrettable and which should be re-visited at the earliest opportunity. Important issues relating to trials involving non-medicinal products also remain. An increasing number of studies involve a combination of medicines with surgery, medical devices, nutrition or psychotherapy, which are not covered by the new regulation.

The Regulation clarifies that it is possible for participants to give broad consent so that data generated from the clinical trial in which they participate can be used for future scientific research. This is to be welcomed. However, there are concerns that this may be in conflict with the EU's new General Data Protection Legislation, which is due to be adopted imminently.

Other problems remain with pan-European clinical trials. According to Cornelius Schmaltz, deputy head of the infectious diseases and public health unit in the European Commission Directorate General for Research and Innovation, the vast majority of clinical trials funded by the EU are delayed, through a combination of slow regulatory approval, patient enrolment and retention, and poor initial planning and management (overoptimistic timelines and lack of contingency measures). There still needs to be better education and training of personnel, with core competencies clearly defined.

Implementation of Research into Clinical Practice

In 2011 the ESF published a Forward Look, 'Implementation of Research in Clinical Practice' [3]. A central theme of the report was the wastefulness of much research, through poor design protocols, a lack of reproducibility, and the failure to review systematically the evidence that already exists before embarking on new research. There is growing awareness that this is a significant problem that needs to be urgently addressed. Last year the Lancet published a special issue devoted to increasing the value of research and reducing waste [4], and in June 2014 the NIH held a joint workshop with the Nature Publishing Group and Science on the issue of reproducibility and rigour of research findings, attended by representatives of 30 research journals. The journals agreed to adhere to a number of key principles to ensure the robustness of the research results that they report.

Progress on reducing the degree of waste in research remains slow, and, within a European context, there are a number of measures that could be taken to significantly improve matters. There is too much variation between countries on the approach to systematic reviews. A common framework for systematic reviews within Europe is needed, coupled with a regular update of reviews. There needs to be an agreed structure on the processes that need to be followed to achieve the best available evidence. Transparency of research findings is also poor across Europe as a whole, and common guidance is needed on how best to ensure acceptable levels of transparency. Mechanisms are needed to keep track of all human studies that do not get published. The World Health Organization has issued a statement on public disclosure of clinical trial results, emphasising the need for registration of all clinical trials in a publicly available, free to access and searchable registry, regular updating of the progress of trials, and the reporting of trials within a given timeframe, as well as other criteria aimed at improving transparency [5].

There is an important role for education and training of professionals, and for greater involvement and empowerment of the citizen. Healthcare professionals who participate in clinical research must be appropriately trained and qualified, and public funds should be made available to educate and involve the citizen in issues such as assessing research priorities. Greater involvement of the citizen at all stages of the research process could have an important impact in ensuring that research findings are implemented in practice. Given the increasing trend for patients to be treated in primary care settings rather than in hospitals, there is a growing need for research to be carried out within primary healthcare, and for

practitioners in primary care to be appropriately educated and trained to participate meaningfully in such research.

Open Access

In 2012 the ESF published a Science Policy Briefing on 'Open Access in Biomedical Research' [6]. The broad conclusion of the document was that biomedical science would be best served by results becoming immediately and freely available upon publication. This is achieved through the so-called gold route to open access, where authors pay the journal's publisher an 'article processing charge'. The alternative approach is the 'green route', which involves researchers depositing in an institutional or subject-based repository copies of the articles they publish, whether in an open access or a traditional journal that requires a subscription from readers or their libraries. The repository then makes those copies available to the public after an embargo period of typically six months. In other words there is a delay between publication of the article in a journal and its free access through the repository.

According to Stephane Berghmans, of the Global Academic Relations team at Elsevier, in 2013, just over 2 million articles were published in subscription journals in 2013, and just under 300,000 open access articles. But while subscription content is growing at around 3–4% each year, that for open access content is around 20%. In 2013, Elsevier published more than 6000 'gold' open access articles. Clearly, therefore, the concept of open access publishing is gaining attraction.

The aspiration remains for all results to become immediately available upon publication, that is for a universal 'gold' system of open access. However, this must be 'fair' gold, in particular in relation to article processing fees, and one way to arrive at this may be for a consortium made up of representatives of national universities and research-performing and research-funding bodies to negotiate with publishers.

Related to the issue of open access for research results is open access to research data. This brings with it many challenges concerning data storage and management, and issues of confidentiality and data protection, which need to be resolved, particularly with regard to EU copyright and data protection legislation.

On the topic of publishing, new ways need to be developed to evaluate the contribution of researchers who work as part of large, multi-national consortia. Conventional systems of evaluation that tend to rely on an individual's record of publication in prestigious, high-impact journals do not adequately reflect the contribution of researchers who work in large transnational collaborations.

Funding issues

Finally a note on biomedical research funding in Europe. By almost every measure the EU spends substantially less than the US on health and health research. In 2012, the EMRC calculated that the then 25 Member States of the EU (EU25) collectively spent the equivalent of 2.73 euros per person per year on global health care. The equivalent figure for the US was 6.4 euros [7]. In 2009, healthcare and public research expenditure in Europe, as calculated by the EMRC, was 42 euros per person per year, as against 143 for the US. The broad accuracy of these figures was substantiated in two subsequent independent studies [8,9], showing respective figures of $53 (Europe) versus $154 (US) in 2012, and $52.3 and $155 in 2011.

How does this discrepancy in funding relate to research outputs? A study by Glänzel and others [10] based on data from the Thomson Reuters Web of Science showed that between 1996 and 2011 the EU, perhaps unexpectedly given the funding discrepancies, consistently published more papers in biomedical research than did the US. However, analysis of citations over a similar period shows the reverse pattern, that is US papers are cited significantly and consistently more frequently than those from the EU. Furthermore, if only the top 18 journals in the biomedical sciences are taken into account, the US scores substantially are better by both publication and citation. In 2007–2012, for example, the US had 78 publications per million of its population, compared with only 39 in Europe. For citations over the same period the figures are 1640 versus 819, respectively.

From these studies it seems reasonable to conclude that the US spends around three times as much per person on research, and in particular biomedical research, than does the EU, generating, in turn, a substantially higher output in terms of high quality research.

One immediate step to close this gap in output would be to close the gap in input, that is to increase funding into health research. An increase of 2 euros per person each year would achieve something closer to parity. This is equivalent the price of one cup of coffee for each citizen of the EU every year.

Summary of the Parallel Sessions

Parallel session 1: EU Clinical Trials Regulation
Moderator: Nathalie Kayadjanian / Rapporteur: Insa Bruns

Translating the information gained through basic discoveries into knowledge that will affect clinical practice and, ultimately, human health requires clinical research involving human subjects. Clinical research is facing increasing challenges including high costs, high attrition rates, lengthy process times, insufficient funding, a shortage of (qualified) investigators and willing participants, a lack of transparency, and regulatory burdens. As future clinical trials will target more specific patient populations, such as subgroups identified through genomic information, and face challenges similar to rare diseases, multi-national clinical trials will most likely be the norm in order to recruit a sufficient number of patients. In this context, the new EU clinical trial regulation (EU CTR) aims to simplify the submission of an application dossier and the evaluation of a request for authorisation and further harmonise the procedures for approving and conducting clinical trials in Europe. In this session we examined whether the new EU CTR responds adequately to clinical research challenges and made a number of recommendations.

Participants recognised that the new EU CTR is a positive move towards harmonisation of clinical trials with medicines. The implementation of a single portal for the submission of a clinical trial application and a coordinated assessment procedure of applications across the EU should facilitate and streamline the entire clinical trial process. The establishment of a central database for all EU clinical trials including published outcomes should also increase transparency and benefit overall the clinical research community.

Participants identified, however, a number of potential weaknesses. The new EU CTR covers only research with medicinal products, not other types of clinical research. Those could also benefit from the new procedures related to medicinal products if they prove to be effective. The participants highlighted the lack of a central knowledge database regarding national regulations that are specific to each country. Furthermore, studies are approved by two bodies, with the division of responsibilities between competent authorities and ethics committees left to Member States. Ethics committees do not function under harmonised procedures and standards, leading to a great variation in committees' quality within EU. Whilst the EU CTR allows broad consent for future re-use of data and samples for research, some articles of the proposed Data Protection Regulation voted recently by the EU parliament are seen as a major hurdle to clinical data sharing and medical research. In addition the new CTR has not achieved harmonisation regarding insurance cover for academic clinical trials. Finally, while the single portal is under construction under the auspices of EMA, there is still uncertainty on the types of data that will be publicly available and how commercially confidential information will be defined and processed.

Participants made a number of recommendations, including:

- Improving patient enrolment and retention through education and communication awareness aimed at citizens, patients and healthcare providers
- Improving insurance cover through the adoption of a unique insurance system (e.g. national indemnification scheme) for academic clinical trials in Europe, as was proposed originally by the European Commission
- Developing further funding mechanism for academic multinational clinical trials

- Exploring ways to improve access to clinical trial data for optimal use for all stakeholders (e.g. integration of real-world data, leveraging data from clinical trials, registries and medical records)
- Advocating the need to include broad consent in the Data Protection Regulation
- Evaluating new clinical trial designs and usefulness to foster personalised medicine
- Carrying out post-evaluation of risk categories implemented in the EU CTR
- Improving the coordination and quality of clinical trials
- Harmonising the assessment of investigators and sites
- Developing core competences in relation to the OECD project
- Developing best practices for ensuring data quality
- Identifying best practices at national level and/or within established networks to foster professionalisation and ensure a long-term support for research centres and stakeholders
- Encouraging the development of clinical scientists and support for a multi-disciplinary approach to clinical research.

Parallel session 2: Open access in biomedical research
Moderator: Bernard Rentier / Rapporteur: Maria Manuela Nogueira

It is necessary to distinguish between open access to publications and open access to data in biomedical research. The topic of open access to data was left aside, as it encompasses different issues to open access to publications: the explosion of big data (data management, data storage, need for infrastructure, data analysis), a review of EU copyright directive (ownership/IPR/licensing), proposals under the EU General Data Protection Regulation (data protection, data privacy, confidentiality).

The conclusions on open access to biomedical publications were as follows:

- If the gold route becomes the standard, it should be 'fair gold', that is it should provide real added value while avoiding the escalation of prices. But what does 'fair' mean in this context? What are the acceptable ranges of article processing charges (authors' open access fees)? Consortia (e.g. on behalf of national universities) could negotiate prices with publishers.
- In the meantime, both green and gold routes will co-exist.
- It is important to study the net cost to fully move to open access. Is it really useful to the broader public to have access to articles?

Parallel session 3: Implementation of medical research in clinical practice
Moderator: Stig Slørdahl / Rapporteur: Kirsten Steinhausen

There are still needs and challenges for the implementation of medical research results in daily clinical practice. Different areas need to be improved.

<u>Transparency and systematic reviews</u>

There is still a lack of transparency surrounding the publication and availability of research results. Science needs to deliver unbiased information, yet today many study results remain unpublished. We need a mechanism to keep track of all human studies which are not published, through an 'end of study report' in an open database. In addition, public–private collaboration could improve the evaluation of available data.

Furthermore, the integration of available information is still needed – in systematic reviews or HTA reports for example. We need a common framework in Europe for systematic reviews, HTA reports and the regular update of reviews.

<u>Medical research education</u>

Medical research education should be further improved in Europe. Essential qualifications should be defined at European level (undergraduate, graduate and postgraduate training). We should share best practice models for medical research education, such as the training of healthcare professionals at the

National Institute for Health Research in the UK. In addition there is an agreed need for lifelong learning in research for medical professionals.

Patient and citizen empowerment

The role of patients in clinical research has already been strengthened and should be further developed. In this context patient information should be improved further (best practice: testing treatment website and book [11]) and lay summaries of research projects in different languages to inform patients should be encouraged. Patients need more guidance to find the right information. Public funding should focus more on citizen literacy, empowerment and involvement. Implementation strategies of research in practice could be significantly improved by patient empowerment.

Primary healthcare

Primary healthcare is crucial for the implementation of research in clinical practice and should therefore be an important part of the research environment. More research capacity in general practice and more research education that area is therefore needed.

CONCLUDING COMMENTS

Richard Frackowiak, Chair, Science Europe Medical Sciences Committee

There are many good, strong policy documents that are produced within Europe but the question remains about whether their recommendations are implemented. An assessment of the impact of past EMRC publications as well as the extent of their implementation is needed.

We need to:

- Look outwards
- Look at all topics
- Look ahead
- Keep an eye on funding but funding is not all: funding will be backed up with clear arguments, with evidence-based medicine. Funding will follow excellent science
- Establish a stronger presence in Brussels and engage more directly with politicians through the creation of a network of MEPs with an interest in these areas and the development of contacts with key directorates in the Commission
- Set up a proper press and communications strategy that is not only reactive, but proactive

Stig Slørdahl, Chair, European Science Foundation Scientific Review Group for the Biomedical Sciences (SRG-MED)

It is important that all organisations that are engaged in biomedical and health research in Europe join forces in making recommendations for policy makers and society to promote cross-border collaboration in research, funding and science policy. In order to reach this goal all organisations will have to meet in the future. The Scientific Review Group for the BioMedical Sciences is confident that Science Europe will continue this important role.

References and links

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