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The Need for Resources for Clinical Research

Proceedings of a Policy Conference held at the European Heart House, 27–28 June 2002: Executive Summary¹

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The medical profession, in particular cardiologists, acknowledge the fact that during the last 30 years, much of the progress made in the field of medicine has resulted from fruitful and close collaboration between academia and the pharmaceutical industry. However, during the last decade, this relationship has changed considerably. The industry increasingly carries out its own research, development of drugs and trials, according to its own agenda. As a result, academia has lost its influence.

This has led to a dramatic increase in the cost of clinical randomised trials. In the meantime, academic careers and research have become less attractive to physicians. Funding for research is increasingly devoted to basic science, in particular genomics, and little is left for clinical research. As a result, many important clinical trials in various areas of medicine, including cardiology, remain unfunded.

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A policy conference

In June 2002 the European Society of Cardiology (ESC) assembled important actors in the field of cardiovascular research to a Policy Conference at its headquarters, the European Heart House, in Sophia Antipolis, France. Clinical investigators from the academic world met representatives from non industry and industry driven contract research organisations (CRO), industrial research divisions, European medical research councils, health authorities, the US National Institute of Health, the Directorate General XII of the European Commission, European Heart Foundations, editors in chief of prominent medical journals as well as the leadership of ESC for two days of intense

debate. Different aspects of inadequately funded clinical research were extensively reviewed and discussed. The first part of the conference addressed successful achievements but also failures in clinical trials, surveys and registries, as well as the cost of organising clinical trials. Furthermore, career possibilities for clinical scientists were reviewed. During the second and third parts of the meeting, present funding of clinical research at different levels, national and European, was put in perspective and compared with the situation in the USA. The role of Heart Foundations and alternate means of funding were examined. This report contains some of the highlights from the conference. The full text can be found on the website of the ESC at www.escardio.org. Excerpts from this conference have also been published.¹

The demand for physician/scientists

The declining interest and incentives in clinical research have led to a scarcity of

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physician-scientists adequately trained in research. Inadequate funding for clinical research leads to lower salaries than those available in the private sector, and less attractive career opportunities combine to widen the gap between clinical and basic research. Funding to clinical research in Europe is decreasing, with budget allocations often disproportionate to the actual burden of disease. Promises by EU nations to increase the proportion of the GNP devoted to research have yet to be fulfilled. In addition, the strong position of the industry in directing research has attracted many physician-scientists away from academic medicine. The industry has gradually become less dependent on the collaboration of academia, as many large companies now have the financial and material capacities to carry out their own research. All in all, the general level of interest in clinical research is on the decline, and this situation needs to be addressed.

Clinical research projects devoid of funds

It is an unfortunate fact that much clinical research is dominated by commercial interests, with the result that many research projects of great interest to the medical community remain unfunded because they are of little commercial interest to the industry. There are many examples of this in all medical disciplines, and particularly in cardiology. Over the last few years, the ESC has made considerable efforts in this area by funding surveys and registries aimed at providing crucial information about incidence and prevalence of cardiovascular diseases throughout Europe. However, like many projects, these efforts are hampered by insufficient funding. The lack of resources allocated to clinical research must be overcome to open the door for clinical research in scientifically useful, but financially unrewarding areas.

The cost of clinical research

For many researchers trying to launch projects without funding, the cost of industry-driven research is prohibitive. Depending on the complexity of the study, the number of centres, and other factors, costs can range from 5,000 to 10,000 Euro per patient for a randomised trial organised by the industry. Simplifying the organisational procedures could make it possible to reduce these costs. For example, data monitoring and processing could be carried out by networks of university-based researchers, and other cost saving measures could be employed to bring the cost of independent

research down to affordable levels. It is estimated that the cost of a clinical randomised trial could be reduced by a factor of 10 to 20, compared to commercially driven research.

Institutional support to clinical research

In contrast to the United States, the institutions of the European Union accord a limited portion of the total available funding to clinical research. The American National Institutes of Health (NIH) provide a centralised framework with considerable financial resources, with an annual budget of 28 billion US dollars, of which 31% is allocated to clinical research. The NIH is capable of supporting several thousand research projects. In Europe, however, the situation is more fragmented and heterogeneous. There are considerable disparities between funding allocations and research potential in the EU member states, creating a climate in which research is often duplicated, and institutional funding hard to obtain. From one country to another, research varies greatly both in quality and in quantity. The VIth Framework Programme (FP6) of the EU aims to address these structural problems by creating a more favourable environment for research, with better integrated structures through networks of excellence and simplified administrative procedures.

Overall, only a small part of the FP6 budget is earmarked for clinical research. Within FP6, life sciences represent only one branch, and will receive 2.25 billion Euros over a period of 5 years. Basic science will receive a greater proportion of available resources than clinical research, so the concrete impact of this programme on funding for clinical research remains to be seen.

However, centralised funding from the EU institutions are not the only possibility for finding funds for research in Europe. Other funding channels can be found, such as individual initiatives by EU member states. Many nations reserve a portion of their national budget for funding research, and these channels have proven their efficacy in the past in several countries.

The role of independent providers of research funding

The role of Heart Foundations, active in fundraising and budget allocation for clinical research in some European countries, is considerable. Many European countries have very active Heart Foundations that rely on diverse and innovative initiatives among the public for raising funds. It must not be ignored that these organisations are proof that

proper organisation and a good understanding of the mechanisms of fundraising can be extremely effective in raising much-needed funds outside of the usual structures. Possibilities for international co-operation are hampered by the fact that there is little or no co-ordination in fund-raising and budget allocation across Europe, but in individual cases, Heart Foundations are one example of an often lucrative source of independent fund-providers.

The European Science Foundation (ESF) is an association of major national funding agencies devoted to scientific and clinical research throughout 27 countries. The proposal is to pool funding from different organisations and countries to channel it into four to five major clinical trial projects per year. The ESF takes the responsibility of finding financial support from its members and affiliate bodies. This initiative, another interesting idea for independent funding, has not yet proven its efficacy.

Ways into future European clinical research

Although there are no immediate or magic solutions to the existing problem, it is obvious that the use of already existing resources must be optimised. This is perhaps best done through an improved organisation of clinical research at national and in particular supra-national levels. An immediate step towards a better future would therefore be improved research co-ordination across Europe. Furthermore it is appropriate that a larger proportion of already available resources are devoted to clinical science.

If we really want European clinical research to compete with US efforts and others on equal terms, a unified European research agency, mirroring the NIH, would offer the best perspective. At present however, there is a lack of political motivation and vision from the EU member states. Meanwhile funding of research will continue within the context of Framework Programmes. The amounts of such funding need to increase up to a level that acknowledges that it is only through continued research that we will be able to improve the health of the European population and deal with the rising costs of health care. Life sciences research and investigator-driven clinical trials must move upwards on the agenda.

At national level, there is also a lack of coordination of research efforts between countries.

Besides, clinical research could be funded from a variety of sources: from non-pharmaceutical

industry; from insurance companies, which would gain financially from decrease in disease; from research charities; from governments, whose research would be made more efficient by international coordination; from the European Commission, whose present funding mechanisms may be used in coordination with other organisations. Such resources might be shared in a joint fund to be established as a trust organised by an independent party such as a professional body.

In addition, national governments and the institutions of the European Union should recognise that there are certain clinical problems in European society that can only be recognised by a comparison of incidence and practice across national boundaries. Professional medical bodies independent of short-term political needs, or national economic restraints, would be the best candidates to carry out this analysis of what studies really need to be done for the health of European citizens, particularly in the field of clinical trials.

Last but not least, dialogue between the pharmaceutical industry and academics must be re-established, to return to the fruitful relations known in previous times, and to escape from the often ambiguous relationship with elements of master and servant in both directions, which currently prevails.

The role of the ESC in this context might be to co-ordinate networks of investigators in Europe. One example of this is the Euro Heart Survey Programme carried out by the ESC. However, other very active groups already exist in Europe, such as the GISSI group in Italy, the ALKK in Germany, the RIKS group in Sweden and others. We suggest that the ESC should continue as an organiser of surveys and registries rather than of randomised trials and should be more an advisory body than an operational entity. In this respect, the ESC may promote European funding of clinical research. Creating an ESC-driven research foundation remains beyond reach for the moment.

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References

1. Bassand JP, Martin J, Ryden L et al. The need for resources for clinical research: the European Society of Cardiology calls for European, international collaboration. *Lancet* 2002;**360**: 1866–9.