



Genetic Alliance UK
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Consultation Response

The Academy of Medical Sciences

Review of the regulation and governance of medical research

Response by Genetic Alliance UK (formerly Genetic Interest Group) and Rare Disease UK

1. Genetic Alliance UK (formerly Genetic Interest Group) is the national charity supporting all those affected by genetic conditions. Genetic Alliance UK aims to improve the lives of people affected by genetic conditions by ensuring that high quality services and information are available to all who need them. Our membership represents 138 voluntary organisations working for a wide range of conditions, many of which have no cure or treatment.
2. Rare Disease UK is the alliance for people with rare diseases and all who support them. It is a joint initiative of Genetic Alliance UK and other key stakeholders including over 125 patient organisations, clinicians, academics, industry and interested individuals brought together in response to the unmet care needs of the estimated 3.5 million people affected by rare disease in the UK.
3. Genetic Alliance UK and Rare Disease UK speak from the perspective of those who look toward research as a means to deliver effective therapies for currently untreatable conditions. We welcome this review and the opportunity to respond.

Introduction

4. The opening statement of the call for evidence for this review states the position well: “[t]here is widespread concern that the process of medical research is being jeopardised by a regulatory and governance framework that has become unnecessarily complex and burdensome”; Genetic Alliance UK and Rare Disease UK share this concern.
5. The current research governance framework is cumbersome, bureaucratic and its emphasis seems overly risk averse. Since reorganisation, there is an assumption that the system is working. Whilst we recognise that the process is more streamlined, we are concerned that the emphasis appears to be on process rather than outcomes. Genetic Alliance UK and Rare Disease UK would like to see a more flexible approach that takes better account of the needs and opinions of patients.

Patients as beneficiaries and subjects of research

6. Patients are the ultimate beneficiaries of all medical research; their views should be sought on all aspects of research, and should not be second-guessed. Patients do not just wait at the end of the research pathway for products and therapies to be delivered to them; they are a vital part of medical research, and should be considered as equal partners. Genetic Alliance UK and Rare

Disease UK believe that the current research governance system does not take proper cognisance of the views of patients and families who are potential subjects of the research.

7. Patients are left with the feeling that they have not been properly consulted regarding decisions made “in their interests”. These decisions appear to the patient community as overly risk averse and frequently fail to capture patients’ and families’ perspectives on the research.
8. Research ethics committees should allow patients and their representatives to contribute to benefit risk analyses and other governance decisions on an equal basis, and overcome the apparent assumption that patients and patient representatives are not capable of judging which research pathways are worth pursuing.
9. There is of course the risk that overly enthusiastic researchers could use influence to sway patient opinion, and that naive patients may exercise insufficient criticism; but these can be assuaged by training and diversity of committee membership.
10. The quality of research governance decisions will increase if systematic engagement with patient representatives is embraced; and we believe this will in turn increase the likelihood of research projects being proposed that bring benefit to patients.

Patient involvement in clinical trials

11. Genetic Alliance UK is a partner in a three year project within the 7th Framework Program funded by the European Commission entitled PatientPartner, which sets out to promote the role of patient organisations in the clinical trials context.
12. The project is based on the belief that involving patient organisations as equal partners at all stages of clinical trials delivers research that is better adjusted to the real needs of patients. This project will lead to a well-organised and sustainable communication platform to enable mutually beneficial interactions between patients and clinical trials professionals.
13. PatientPartner will deliver its final report in May 2011, but the project is already delivering recommendations for greater visibility of clinical trials in Europe; public engagement strategies; and the delivery of tools to assist patients’ understanding of the complexities of the clinical trial process.
14. The PatientPartner website is www.patientpartner-europe.eu

Patient organisations as funders of research

15. The complications of the regulatory and governance framework are amplified when viewed from the perspective of a small or medium sized patient organisation.
16. Navigating research governance and ethics committee approval for a modest two year project for example, can take three months (if the application is successful), which is more than 10% of the project’s timescale. This process is a drain on funds, time and expertise for a small organisation that may only be launching a single project every five years. Once the project is over, and the researcher leaves, expertise regarding these complicated procedures is lost.

17. Patient organisations with small budgets should be supported through the research ethics approval process. Expertise should be shared and procedures to support fast-tracking of simpler projects implemented.

Conclusions

18. Genetic Alliance UK and Rare Disease UK believe that a greater focus on outcomes over processes is necessary within the regulation and governance of medical research.

19. The quality of research governance decisions will be improved if systematic engagement with patient representatives is embraced.

20. Organisations with small budgets should be supported through the research ethics approval process.

21. The aim of medical research is to address unmet health needs. If governance is unduly restrictive, potentially fruitful research options may not be realised, thereby continuing avoidable suffering.



Director
Genetic Alliance UK

Chair
Rare Disease UK