

Independent clinical research in Europe

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The role of clinical research

Clinical research is the instrument for translating basic scientific discoveries into innovative therapies. The past two decades have witnessed an unprecedented increase in our knowledge of the basic mechanisms of diseases: the expansion of molecular biology and genetic studies has revealed the genetic basis of a great number of pathologies. However, there does not seem to have been a comparable interest and rigor in translating the results into clinical practice. The Academy of Medical Sciences in the UK recently underlined the widening gap between basic and clinical science, a consideration that can probably be extended to the rest of Europe.¹

Clinical research plays a very important part in shaping clinical practice so it has considerable impact on prescriptions and in decision-making for health policies.² However, many areas of medicine remain inadequately explored by clinical research. There is a lack of evidence of the real burden of many diseases;³ clinical practice varies among European countries⁴ making it difficult to establish pan-European clinical research initiatives;⁵ basic research is now disproportionately well funded by comparison with clinical research; and clinical research is becoming increasingly expensive and cannot be undertaken without the support of industry.

The pharmaceutical industry is driving clinical research

The pharmaceutical industry has always been the major provider of medicines,⁶ and has always led technological progress. The enormous benefits to patients that have come from the industry's discovery of vast numbers of drugs and medical devices has to be acknowledged. The pharmaceutical industry's success over the past decade has also earned it very high profits, and has generated the need to maintain a high output of new drugs.⁷ Analysts have shown, however, that innovative medicinal products appear on the market all too rarely.^{8,9} Many drugs are just copies or analogues of products already on the market ("me-too" drugs). Furthermore, there is a gap between the development of new drugs and patients' real interests.

As an example, in 2002, of 89 drugs newly approved by the US Food and Drug Administration (FDA), none were antibiotics, and only nine new antibiotics have been approved since 1998, while the resurgence of old killers such as tuberculosis and the emergence of infections resistant to existing antimicrobial agents pose a global threat to health.¹⁰

Rare and neglected diseases offer an interesting example of how the research agenda is dictated by profit. Rare diseases do not usually attract much interest from the pharmaceutical industry, because they are difficult to study, and even if a drug is potentially available, its

development is often considered uneconomic—ie, too costly for a tiny market.¹¹ Tropical diseases are also largely neglected because they affect people who cannot pay for expensive medicines.¹² It is not only a matter of making available drugs for diseases, such as AIDS, at affordable prices in poor countries, but also of investing in research for new treatments for communicable diseases that are confined to poor countries, and still lack effective therapies.¹³

Clinical research is also largely dominated by a pharmacocentric approach. Several important health issues still need investigation, but may not necessarily be treatable with drugs. Tallon and colleagues,¹⁴ in a recent paper, used osteoarthritis as an example to show that available research evidence is dominated by pharmaceutical interventions, with little effort spent on the effects of simple instruments to help people to cope with the disease.

The quality of scientific information is also low when it comes to assessing new technologies that are often very expensive and consume a significant proportion of health budgets. For example, special beds are prescribed to prevent or relieve pressure ulcers; these are very costly but no clinical trial has ever shown that they actually help heal the ulcers.¹⁵ Results of controlled studies are seldom available on medical devices, and good surgical trials comparing different procedures are also needed. The consequence is that new surgical techniques are often rapidly adopted before their long-term benefits are assessed.¹⁶

Clinical research influences clinical practice, so the quality of published reports is crucial. However, industry sponsored research could be flawed, as several analyses have reported.¹⁷ Two reports might be indicative in this respect. A study by Melander and colleagues¹⁸ suggests that results of clinical studies sponsored by the pharmaceutical industry that reach the public domain are subject to selection. They investigated 42 placebo-controlled trials of selective serotonin reuptake inhibitors (SSRI) submitted to the Swedish drug regulatory authority between 1983–99 and compared the published results with the full reports. Of 42 reports, half were in favour of SSRI, whereas the other half could not distinguish the effects of these drugs from those of the placebo. However, the published reports did not reflect this proportion because positive reports were published in a greater number of primary and ancillary publications than were negative ones.

Lexchin and colleagues¹⁹ reviewed 30 studies that compared research sponsored by the drug industry and research funded in other ways. Although the quality of the methodology and the conduct of research were comparable, industry sponsored trials were four times

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