Clinical Trials in the European Union: A Roadmap to Greater Transparency

Report | 6 February, 2019 | Download PDF

Clinical trials are at the core of the pharmaceutical research and development (R&D) process. The results of these studies inform decision-making on market approval, medicines pricing and reimbursement, and clinical practice. Clinical trial transparency is therefore extremely important for policy makers, public health bodies, the research community, healthcare professionals and patients.

Nevertheless, important information on clinical trials remains hidden from public and scientific scrutiny, even where research is publicly funded. This report discusses transparency concerns related to the current European Union (EU) trial registry, the forthcoming clinical trials portal and database, and barriers to the effective utilisation of clinical study reports (CSRs).

There are many reasons that greater transparency for clinical trials is important. Not only does it improve the allocation of public health resources, it also curbs the waste of medical research funds and avoids unnecessary repetition of trials. Furthermore, it accelerates medical progress and the discovery of new treatment and cures, and improves decision-making by healthcare professionals and patients. Finally, it improves patient safety by ensuring that all harms are reported.

This report concludes with nine actionable policy recommendations for the European Commission, the European Medicines Agency (EMA), and national competent authorities (NCAs) in EU Member States.

Read more...