Open access to clinical data – what our stakeholders say

Recent studies find journal articles to be an incomplete source of information on new medicines—particularly their adverse effects—compared with clinical study reports. EMA's policy will go a long way towards ensuring access to detailed information on medicines that enter clinical use. As editor of a medical journal, I look forward to the improvements in drug development and clinical care that will result from peer-reviewed analyses of this newly transparent data.

Larry Peiperl
Chief Editor, PLOS Medicine

The publication of clinical studies reports significantly benefits patients and public health, both in terms of progress in medical research and in terms of access to vital information. This move is much needed to considerably boost transparency in the pharmaceutical sector. It will also help increase consumers' trust in regulatory authorities and ultimately in the safety of medicines.

Ilaria Passarani
Head of the Food and Health Department
BEUC – the European Consumer Association

Prospective availability of clinical study reports will allow service users, physicians, researchers and all those interested in healthcare to access detailed documents reporting design, evolution and results of clinical trials and other studies on humans. Provided text redactions are kept to a bare minimum, this initiative will help to minimise the effects of reporting bias of trials which blights large swathes of contemporary "scientific" literature.

Tom Jefferson
Honorary Research Fellow, Centre for Evidence Based Medicine, Oxford, UK

The launch of EMA's much discussed Policy 0070 marks the second of the European regulator's landmark — and still unparalleled — achievements in democratizing access to clinical trial data and other regulatory documents. Whereas other regulators have taken a "hands off" approach, EMA has proactively re-examined its approach to claims of commercial confidentiality - and generally moved in favor of public health. Policy 0070 promises a near barrier-free way for anybody with an internet connection to access clinical study reports of trials for new medicines. It confirms EMA's conviction that the transparency of clinical study reports and regulatory documents is fundamental to achieving its public health mission. Other regulators should take heed.

Peter Doshi
Department of Pharmaceutical Health Services Research
University of Maryland School of Pharmacy, US

This is a sound step for transparency in science. Opening up access to trial results has the potential to boost knowledge sharing, drive innovation and ultimately accelerate the development of lifesaving drugs and vaccines. This could benefit researchers, patients and global health as a whole.

Seth Berkley
CEO, Gavi, The Vaccine Alliance

We owe it to those who take part in clinical trials to make the most of their contribution. Ensuring responsible access to trial data enables innovative research and should accelerate the development of new treatments. EMA's policy is a significant step towards this goal, ensuring the important information contained in clinical reports is available for wider scrutiny and re-use.

Nicola Perrin,
Head of Policy, Wellcome

Patients are waiting for more effective medicines - and sometimes even cures. The researchers in my member companies have learnt that we can be much more productive if we share all the information we collect. My companies are involved in many data-sharing programs, and more will come. EMA's new policy is a major step forward in the same direction.

Richard Bergström
Director General, European Federation of Pharmaceutical Industries and Associations (EFPIA)

It is very welcome news that EMA is starting to publish all clinical study reports it receives. The 700 organisations in the AllTrials campaign, who between them represent hundreds of millions of people worldwide, have been calling for this. We all now hope that other global medicines regulators will follow EMA's great lead.

EMA's new policy means there will be a lot more information about our future medicines available for scrutiny. This is fantastic. However, the majority of medicines we use now, and will continue to use for years to come, were approved in the past. And it's the information on these medicines that remains hidden. Regulators like EMA need to do everything they can to ensure all information about all our medicines is available to doctors and researchers.

Síle Lane
Director of Campaigns and Policy, Sense about Science

EMA continues to strengthen their position as the patients' advocate in Europe with another important deliverable that helps define the landscape and educate on the critical opportunities from data sharing. CDISC supports and embraces all moves towards greater transparency and structure of patient data through the use of global, freely available consensus-based clinical data standards that will facilitate data sharing to advance research at an optimum rate and more readily unlock cures.

Rebecca D. Kush
Founder, President and CEO, Clinical Data Interchange Standards Consortium (CDISC)

The European Association of Clinical Pharmacology (EACPT) welcome EMA's policy aimed to make publicly available results from individual clinical studies. The EACPT believes that this is a critical step forward toward the transparency that society demands. The initiative of making available to the public scrutiny these data will mean a clear signal to industry and regulators to increase the quality in producing and assessing the data.

Gonzalo Calvo
European Association for Clinical Pharmacology and Therapeutics (EACPT) and co-Chair of EMA's Healthcare Professionals Working Party (HCPWP)

Scientifically robust, transparent, verifiable data are critical components of decision-making throughout the life cycle of medical products – from discovery to use by patients. While respecting personal privacy, complete data sets from all trials allow stakeholders globally to make better and truly informed decisions. Access to such data will give us better knowledge; how we apply that knowledge will define our wisdom.*

Murray M. Lumpkin
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