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EDITORIALS

Clinical trial data: get them while you can

The window into the European Medicines Agency's archives may not be open for long

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Third party access to clinical trial data seems an obvious and uncontroversial core requirement for the production and dissemination of trustworthy medical evidence. For the past four years, the *BMJ* has actively campaigned to compel greater transparency of clinical trial data. Anybody following this matter will know that movement is occurring at many levels and involves a large number of actors including industry, politicians, regulators, academia, and medical journals. The debate encompasses which data should be shared and with whom, when, and under what conditions. However, even the most keen observers will probably be uncertain about just what has happened, is happening, and where things will eventually land.

One development to watch out for in 2014 will be the progress of the European Union's proposals on clinical trial regulation.[1 2] Other developments include the European Medicines Agency's (EMA) future policy on publication and access to the clinical trial data that underpin marketing authorisation decisions,[3] and the US Institute of Medicine's (IOM) consensus study on responsible sharing of clinical trial data.

The IOM is expected to release an interim report in January 2014, followed by public consultation and a final report in about a year's time.[4] If the committee endorses onerous restrictions on access to clinical trial data, this could have a chilling effect on transparency efforts worldwide. One concern is the project's funding: several large drug companies are listed among its financial supporters, including AbbVie, one of the major orchestrators of industry resistance to data transparency.

The EU's proposals for clinical trials regulation were agreed on by representatives from every member state last month and await ratification. If enacted, the regulation will mandate prospective registration of all trials carried out in the EU. It will also compel trial sponsors to post summary results on the EU Clinical Trials Register within one year of the trial's completion, thus bringing Europe into line with US transparency legislation.[5] The regulation will go a step further, however, by putting companies' full clinical study reports in the public domain. (Clinical study reports are documents produced by study sponsors primarily for drug regulators. They run to many hundreds or thousands of pages, comprising substantially more information about a trial than journal articles and providing relatively unbiased material for evidence synthesis.[6])

In 2013, much attention focused on the initiatives of big drug companies, most notably GlaxoSmithKline's new policy on access to anonymised patient level data from some of its trials. In GlaxoSmithKline's footsteps, Roche and Pfizer have set out similar policies. GlaxoSmithKline, Roche, Boehringer Ingelheim, Sanofi, and ViiV Healthcare will mediate access to data through a web portal (www.ClinicalStudyDataRequest.com).

Although these announcements may be steps in the right direction, the processes are new and largely untested, and how they will work remains to be seen. Of concern is that each company's policy includes terms and conditions that seem contrary to the spirit of openness. For example, GlaxoSmithKline, Roche, and Pfizer all largely exclude trials that tested off-label use of their drugs. With about a fifth of prescription drug use being off-label in the United States,[7] what legitimate reason is there to continue to treat these data as secret?

Furthermore, can initiatives by individual drug companies represent anything more than incremental progress? We must remember that drug companies have always entertained individual requests for data in their holdings. What is new is simply the heightened public attention and procedures to streamline access to those data. However, initiatives by individual companies will only ever cover trials sponsored by that particular company. If each company defines its own terms and conditions for access to its data, the metaphor for the end state of "data transparency" could easily be a maze. Current industry-wide proposals are not comprehensive (they exclude all previous trials and future trials of off-label prescribing) and, lacking compliance mechanisms, are essentially aspirational.[8]

Only medicines regulators hold vast archives of trial data across manufacturers. Therefore, positive transformation of the rules that govern third party access to data in regulators' holding could create a sweeping change in the landscape of open data. When the EMA launched its policy on access to documents on request in November 2010, it opened a window into the regulatory decision making process that had never been opened before. Since then, the EMA has provided third parties, including

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industry—with no terms or conditions and free of charge—around two million pages of clinical trial data and other administrative documents.[9]

Then, in mid-2013, as a result of two well known legal cases, semi-paralysis set in at the EMA, after an EU judge prevented the EMA from releasing clinical trial data requested for drugs marketed by AbbVie and InterMune. As a result of this injunction, the EMA soon began denying requests for types of trial data it had previously released.[9]

Now the access to data window is possibly wide open again—or at least as open as it could be—after the superior EU Court of Justice struck down the lower court's injunction late last November.[10 11]

So get your data while you can. The AbbVie and InterMune lawsuits against EMA remain active, and if they are not withdrawn before the final decision, a victory in favour of the companies may effectively terminate the EMA's current and planned future policy on access to clinical trial data. We hope that this window will stay open, but if it closes, this may be the last chance to take advantage of a truly unencumbered process for public access to data.

Requests for data may be submitted via the EMA's website.[12]

Competing interests: We have read and understood the BMJ Group policy on declaration of interests and declare the following interests: The *BMJ* applied to the European General Court to intervene in the case of AbbVie *v* EMA. PD knows some regulators at EMA, and the US Institute of Medicine (IOM) paid for his travel and lodging to speak at an October 2012 workshop on sharing clinical trial data and has offered to do the same for an upcoming meeting of the ongoing IOM consensus study. EL has also participated in IOM workshops and meetings related to data transparency and the IOM has paid for her travel and lodging in connection with those meetings. On behalf of the *BMJ*, all authors are actively campaigning for greater access to data from clinical trials, particularly as a cofounder of the AllTrials campaign.

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1 European Commission. Proposal for a regulation of the European parliament and of the council on clinical trials on medicinal products for human use, and repealing directive 2001/20/EC. 2012. http://ec.europa.eu/health/files/clinicaltrials/2012_07/proposal/2012_07_proposal_en.pdf.
2 European Commission. Health commissioner, Tonio Borg, welcomes agreement on the revision of EU rules on clinical trials. 2013. http://ec.europa.eu/health/files/clinicaltrials/memo-13-1190_en.pdf
3 European Medicines Agency. Publication and access to clinical-trial data. 2013. www.ema.europa.eu/docs/en_GB/document_library/Other/2013/06/WC500144730.pdf.
4 National Academies. Project: strategies for responsible sharing of clinical trial data. 2013. www8.nationalacademies.org/cp/projectview.aspx?key=49578.
5 Food and Drug Administration. Food and Drug Administration Amendments Act of 2007. 2007. www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FoodandDrugAdministrationAmendmentsActof2007/FullTextofFDAAALaw/default.htm.
6 Doshi P, Jefferson T. Clinical study reports of randomised controlled trials: an exploratory review of previously confidential industry reports. *BMJ Open* 2013;3:e002496.
7 Radley DC, Finkelstein SN, Stafford RS. Off-label prescribing among office-based physicians. *Arch Intern Med* 2006;166:1021-6.
8 Doshi P. EFPIA-PhRMA's principles for clinical trial data sharing have been misunderstood. *BMJ* 2013;347:f5164.
9 Doshi P. Transparency interrupted: the curtailment of the European Medicines Agency's policy on access to documents. *JAMA Intern Med* 2013;173:2009-11.
10 Court of Justice of the European Union. Order of the vice-president of the court. 2013. http://curia.europa.eu/juris/document/document.jsf?text=&docid=145282&pageIndex=0&doclang=en&mode=req&dir=&occ=first&part=1&cid=877340.
11 Court of Justice of the European Union. Order of the vice-president of the court. 2013. http://curia.europa.eu/juris/document/document.jsf?text=&docid=145281&pageIndex=0&doclang=en&mode=req&dir=&occ=first&part=1&cid=877683.
12 European Medicines Agency. Send a question to the European Medicines Agency. 2014. www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/landing/ask_ema_landing_page.jsp&mid.

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