Clinical trial transparency: many gains but access to evidence for new medicines remains imperfect

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Abstract

Background: Although selective and incomplete publication is widely acknowledged to be a problem, full access to clinical trial data remains illusive.

Sources of data: Authors’ personal files, key documents from Food and Drug Administration and European Medicines Agency and focussed searches of PubMed.

Areas of agreement: Existing sources of information provide an incomplete overview of scientific research.

Areas of controversy: Persistent arguments about commercial confidentiality and the potential difficulties in de-identifying raw data can block important progress. Current industry efforts are voluntary and only partially satisfy the need for complete data.

Growing points: Requirements for trial registration are increasing. Important regulatory changes in particular in Europe have the potential to result in the release of more information.

Areas timely for developing research: Documenting the effects of prospective trial registration and requirements for proactive clinical trial publication on healthcare decisions, public health and rational resource allocation.

Key words: pharmaceutical regulation, European Medicines Agency, Food and Drug Administration, clinical trial data transparency
Introduction

Double-blind randomized controlled trials are the ‘gold standard’ of scientific evidence on beneficial and harmful effects of medicines. They form a key part of the evidence base that companies must provide to national regulatory agencies to obtain market approval. Despite this central role, public access to information on clinical trial methods and results remains incomplete.¹ If the beneficial and harmful effects of pharmaceutical treatments are to be truly known so that medications can be used rationally, healthcare professionals, researchers and the public need access to the full body of scientific evidence. Without such access, informed treatment choice cannot be fully realized.

Access to information matters from a public health perspective, because incomplete knowledge of a medicine’s safety profile can lead to use by patients for whom it is too risky.²,³ This was the case with the arthritis medicine rofecoxib (Vioxx), estimated to have caused 80 000–140 000 heart attacks—about 40% fatal—in the USA during its 5 years on the market.⁴ In a Canadian study, hospitalizations among the elderly for gastrointestinal bleeding rose after its introduction, likely linked to incautious prescribing.⁵ A meta-analysis of the clinical trial evidence⁶ showed that the full scientific evidence indicated an unacceptable risk profile long before it was withdrawn from the market in late 2004. It is conceivable that full public access to this information could have saved thousands of lives through earlier restrictions on use.

In an analysis of trials of all new medicines approved in the USA in 2001 and 2002,⁷ those with primary outcomes favouring the drug were nearly five times as likely to be published as those with negative results. A systematic review of antidepressant trials submitted to the US Food and Drug Administration (FDA) found extensive evidence of selective trial publication, with 37/38 (97%) of positive trials published but only 8/24 (36%) of negative trials.⁸ These trials had assessed effectiveness in adults. Trials showing that selective serotonin reuptake inhibitor (SSRI) antidepressants were ineffective and potentially harmful in children and adolescents remained unpublished while prescribing rates grew in the 1990s and early 2000s.⁹ At GlaxoSmithKline (GSK), when Trial 329 failed to show effectiveness for paroxetine in adolescent depression, an internal memo stated that ‘It would be commercially unacceptable to include a statement that efficacy had not been demonstrated, as this would undermine the profile of paroxetine’.¹⁰ The published article concluded that paroxetine was well tolerated and effective,¹¹ despite higher rates of suicidality on paroxetine.

Selective publication also affected decisions to stockpile the influenza medicine oseltamivir (Tamiflu). The UK spent £424 million (US$ 710 million) on oseltamivir stockpiles and the USA, $1.5 billion.¹² When researchers obtained clinical study reports of unpublished clinical trials, they discovered that oseltamivir did not in fact prevent flu complications,¹³ although this had been claimed in a published pooled analysis of these trials.¹⁴

Reporting biases do not exclusively affect industry-sponsored trials. In an analysis of 13 327 trials for new drugs, biologics and devices registered in the database clinicaltrials.gov, those funded by the US National Institutes of Health (NIH), government and academic institutions were less likely than industry trials to report results within a year of completion, with differences attenuated or resolved by 5 years.¹⁵ In absolute terms, however, many more industry trials remained unreported. This reflects the industry dominance in this sector, with near exclusive industry sponsorship at a pre-market stage. Given the importance of pre-market clinical trials in elucidating the safety and efficacy of new medications, the focus of our analysis is primarily on industry-sponsored trials.

In discussing public data access, we define the ‘public’ broadly to include researchers, healthcare professionals, consumer and patient group representatives, organizations that produce health technology assessments, ordinary citizens and the media; in other words, anyone who is involved in evaluating the effects of medications and/or providing information for professionals and the public on medication use.

If the unavailability of clinical trial data makes cost-effectiveness assessments inaccurate, it affects medicine reimbursement decisions, sustainability of healthcare financing, and affordability and access to

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¹ Mintzes B, et al. 2015, Vol. 116

² B. Mintzes et al., 2015, Vol. 116
healthcare. All of these amount to a serious public health concern. Here, we describe the scope of the problem, recent initiatives to address it, especially in the European Union (EU), and continuing controversies around full data transparency.

Source of data
The authors are experienced in the intersecting areas of clinical trial data analysis, especially with respect to completeness and interpretation, transparency and pharmaceutical policy. We have compiled an extensive bibliography on these topics and drew from that literature for this article. In addition, we searched for key documents from major regulatory authorities such as the European Medicines Agency (EMA) and the FDA. Finally, we did focussed searches in databases such as PubMed for additional key literature.

Areas of agreement
The literature is in general agreement that existing sources of information such as journal articles, clinical trial registries and information available from regulatory authorities provide an incomplete overview of existing scientific research. The German Institute for Quality and Efficiency in Health Care (IQWiG), an independent health technology assessment agency, had access to the full unpublished clinical study reports for 101 trials evaluating 16 drugs for depression, diabetes, asthma, stroke and Alzheimer’s disease from 2006 to early 2011. For 86 of these 101 trials with clinical study reports, a journal article and/or a clinical trial registry report was publicly available. The clinical study reports reported 87% of treatment outcomes of relevance to public health, while publicly available registry reports or journal articles reported only 45%. Complete information was available for 86% of assessed outcomes in clinical study reports, 23% in journal articles and 22% in registries. Deficiencies included frequent lack of reporting on important public health outcomes, including mortality, serious morbidity, quality of life and drug tolerability.

An earlier IQWiG study compared reporting of methods and conduct of trials in the same three data sources. Clinical study reports provided the most complete data, followed by journal publications and clinical trial registries. These comparisons highlight how much basic information needed to judge the methods and outcomes of trials is missing from currently available sources. For instance, the information in clinical trial registries is often very brief and does not cover all elements, and study results often remain unpublished long after trial completion.

Reliance on only published articles can bias systematic review outcomes. Schroll and Bero recommend that authors of systematic reviews should always complement the published evidence with a search for clinical trial reports in regulatory review documents accompanying new drug approvals on the EMA and FDA websites. However, while the information in European Public Assessment Reports (EPARs) from the EMA or in the FDA review reports is valuable, it is also incomplete. Kohler et al. compared the information that manufacturers submitted to IQWiG with information in EPARs for 15 drugs evaluated from 2011 to early 2013. They found that key information for public health was absent from the EPARs; including mortality, clinical outcomes, quality of life, serious adverse events and withdrawals due to adverse events.

Many national regulatory agencies provide less information than the FDA or EMA. Since 2004, Health Canada has published a Summary Basis of Decision about newly approved drugs, broadly similar to EPARs. A total of 456 clinical trials, described in 161 Summary Basis of Decisions, lacked clear basic information such as trial participants’ age and sex, number of early withdrawals and whether results were statistically significant.

EMA stands out among regulators in providing information on non-approved applications for marketing authorization. In the USA, the decision not to approve and why are considered commercially confidential. FDA staff members compared the content of confidential FDA non-approval letters (n = 61) with what companies stated about the non-approvals in press releases. In total, 84% of safety concerns and 85% of efficacy concerns cited as reasons for non-approval in the FDA letters failed to be mentioned. If drug development is discontinued, even large clinical
trials often remain unpublished and unregistered in clinical trial registries. The scientific knowledge on drug safety and efficacy gained in these trials remains unavailable. This knowledge could help to inform the design of trials for products with a similar molecular structure or mechanism of action.

Areas of controversy

Despite growing consensus about the benefits to public health of clinical trial data transparency, arguments about commercial confidentiality and the potential difficulties in de-identifying raw data, i.e. removing any information that could potentially reveal the identity of patients, can block important progress in data transparency.

Commercial confidentiality

Public access to information about medicines’ safety and efficacy profile can facilitate informed treatment choice. On the other hand, the pharmaceutical industry continues to raise concerns that proactive disclosure of full clinical trial data sets poses a risk to innovation because it gives competitors access to companies’ alleged trade secrets and proprietary information.

The European Ombudsman has contested the argument that clinical trial data contain trade secrets and other proprietary information. In an assessment concerning an access to information request to the EMA by independent researchers, the Ombudsman found that clinical study reports and protocols contained no information that could be classified as trade secrets, commercial confidences or intellectual property. One legal scholar has also contested the argument that clinical trial data are protected by copyright. Nevertheless, the industry continues to try to control and limit data disclosure by invoking initiatives related to trade secrets protection and free trade agreements.

Pharmaceutical industry position on data sharing

Pharmaceutical companies have raised objections to data sharing since the early days of clinical trial registration. Laurence Hirsch, Vice-President of Medical Communications for Merck & Co, said in 2004 that Merck opposed trial registration because of the need to protect proprietary information and intellectual property, including ‘the very existence of certain studies’. While some companies have abandoned that position, arguments about commercial sensitivity remain common.

When a draft proposal on the implementation of transparency requirements enshrined in a new EU Regulation on clinical trials was announced, the UK Bioindustry Association, EuropaBio and the European Association for Bioindustries argued that Phase I trials (testing on small groups of healthy volunteers to establish dosing ranges) should be excluded because the information is commercially sensitive. The Bioindustry Association’s position was based on ‘the needs of developers and researchers to protect their investments and cutting-edge R&D of new innovative medicines’. These rationales for limiting the release of information are echoed in the ‘Principles for Responsible Clinical Trial Data Sharing’, a document released by the Pharmaceutical and Research Manufacturers of America (PhRMA) and the European Federation of Pharmaceutical Industries and Associations (EFPIA). The industry associations raised fears that trade secrets and proprietary information would be disclosed to competitors, allowing them a ‘free ride’, and reducing the incentive for companies to engage in biomedical research.

The same objections are evident in a letter that the industry association PhRMA sent to a US trade representative. Although PhRMA claims that it is ‘firmly committed to enhancing public health through responsible reporting and publication of clinical research and safety information,’ it also complains that the ‘EMA’s current and proposed data disclosure policies jeopardize these principles’ of ‘protect[ing] patient privacy, maintain[ing] the integrity of the regulatory review process, and preserv[ing] incentives for biomedical research’. The voluntary nature of industry data disclosure initiatives may still leave information unavailable. A comparison of clinical trials of antidepressants and antipsychotics registered on an industry-sponsored
registry named clinicalstudyresults.org with published reports found that most deaths (62%) and suicides (53%) reported in these summaries were not reported in published articles, and that overall, 43% of serious adverse events were not listed in published articles. The registry has since been dismantled, ending this source of data access.

More recently, a number of companies have committed themselves to increased data disclosure including GSK, Medtronic, Merck and Roche. In the case of Medtronic, one of the two disclosed studies of its bone-stimulating device found it no better than a bone graft and that it might increase cancer risk. Strom et al. have reported largely positive results from the first year of access to data from GSK. By mid-2015, 11 companies, including GSK, had agreed to make patient-level clinical trial data available to researchers via a website. Each company sets its own data release criteria; an external panel then reviews projects that the company deems potentially acceptable. From May 2013 to June 2015, 58 projects were approved.

On the other hand, Roche’s refusal in 2013 to allow full access to clinical trial data on oseltamivir prompted the British charity Sense about Science to describe Roche’s response to the campaign for transparency as ‘poor’, adding that the company ‘was on another planet’. Three of the four renowned scientists on a committee that Roche established to review oseltamivir data had conflicts of interest according to the director of the Centre for Evidence-Based Medicine in Oxford. In 2013, the pharmaceutical companies AbbVie and InterMune asked the European Court of Justice to annul regulatory decisions to grant access to clinical reports on two drugs, adalimumab and pirfenidone, claiming that EMA was releasing confidential commercial information. Between September 2013 and June 2014, the EMA and companies had differences of opinion on suggested redactions to 44 of the 95 documents to be released. The EMA claims that industry opposed release of individual patient-level data, a charge that industry representatives deny albeit they argue that it needs to be done in a ‘responsible’ manner. In 2015, a UK clinical trials company, Richmond Pharmacology, applied for a judicial review of plans by the UK Health Research Authority for mandatory registration of all trials. This legal challenge of mandatory trial registration indicates a lack of consensus for even this basic transparency measure.

Ongoing questions about a number of topics related to self-regulatory initiatives on data disclosure include the following: release of data from trials for all drugs, not just new drugs; the types of standards companies will establish and how much control they will retain; and whether data will be accompanied by other information necessary to interpret the data. The joint PhRMA and EFPIA statement commits, as a minimum, to making publicly available synopses of clinical study reports following approval of a new medicine or a new indication and to submitting for publication clinical trial results from phase III trials and for investigational medicines whose development programmes have been discontinued. However, clinical study reports, including patient level data, will only be made available following a successful research request and subject to potential redactions. This commitment does not apply to trials for medicines where approval was denied. The PhRMA/EFPIA document also allows each individual company to establish its own standards for data release and protection of privacy, and ‘ensuring that access to patient-level data does not jeopardize incentives for future investment in biomedical research’. The problem of differing standards has already come up. Other companies have tried to join the GSK system but insisted on conducting their own scientific review of data disclosure requests before passing them on to the GSK committee, a proposal that the committee rejected. But for any released data to be useful, they need to be accompanied by other documents such as database manuals, analysis files and other material necessary to address research questions, interpret data and replicate analyses. Again, this is an area where the PhRMA/EFPIA statement of principles is silent.

There seems to be general agreement, including from the US Institute of Medicine, that direct requests to companies for data will be filtered through independent review panels that are ‘charged with accepting or rejecting proposals on the basis of their scientific rationale and relevance to medical science or patient care’. While some members of the GSK committee
believe that all clinical trial data should eventually be
put into the public domain for unconditional, universal
access,40 the current system of limited data disclosure is
likely to remain in place for the foreseeable future.
Moreover, we need to remember that this is a system of
self-regulation and how well it will work it remains an
open question given the problems with self-regulation
in pharmaceutical promotion.51

Personal data protection

There has been an ongoing call for raw data from
clinical trials to be available to researchers for
re-analyses.52 Such analyses allow systematic reviews
to be carried out with greater precision than with
only summarized trial data and to address questions
that the initial trialists have not considered, such as
different effects of interventions on men and women.
Protection of privacy has become a recurring argu-
ment used by the pharmaceutical industry against
unconditional full clinical trial data transparency.53
Contrary to the view that it is potentially too difficult
to de-identify patient-level data and minimize risks,
regulators have argued that there are standards that
can be followed.48 Whilst de-identification can be
challenging, as in the case of rare diseases, these
situations are exceptional, and extra measures can be
used to protect privacy. There is a need for more con-
structive discussions among relevant stakeholders in
this area.

We fully support the need for privacy, but at the
same time, we want to emphasize two related points.
The first is the wide range of benefits to patients and
trial participants from the release of data, including
the accurate characterization of the benefits and risks
of medicines, the improved surveillance of medicine
safety and effectiveness, the enhancement of the
ability of patients and advocacy groups to learn more
about their specific medical problems, and ensuring
that research participants are not exposed to unneces-
sary risk and that their participation advances
science.54 Our second point concerns the need to
balance individual and collective rights that was elo-
quently raised by Trudo Lemmens who teaches law at
the University of Toronto: ‘A more complex human
rights approach invites us to look beyond purely
individual interest-related aspects of human rights
claims and to consider their social and public compo-
nents. It seems to run counter to such an approach to
invoke individual rights such as privacy in a manner
that indirectly undermines the health interests of the
very same people (and the relatives and community
members of those) whose health information is
claimed to be in need of protection.’55 One proposed
solution, at least for prospective trials, is to inform
trial participants ahead of time that their anonym-
ized data might be publicly released. Whether this
is needed, given the steps to preserve anonymity, is
the subject of debate. There is current widespread
acceptance of research use of anonymized adminis-
trative data in health insurance databases without
prior individual consent.

Growing points

Despite the ongoing and serious limitations of clinical
trial transparency discussed above, a number of
policy changes have helped to make a great deal of
previously hidden data publicly available. In 2005,
the International Committee of Journal Medical
Editors (ICJME) began to require registration of
trials as a precondition for publication. Since 2007,
with the passage of the FDA Amendment Act
(FDAAA), companies have been required to register
all clinical trials in clinicaltrials.gov56 supporting an
application to market a new drug in the USA, with
the exception of early ‘Phase I’ trials in healthy
volunteers.15 Despite the promise that registration of
trial protocols and results in universally accessible,
searchable trial databases would solve the problem
of publication bias, many limitations remain. For
example, an evaluation in 2013 of the publication
status of large clinical trials registered in clinical-
trials.gov that had been completed by 2009 found
that 23% remained both unpublished and with no
results reported.18 In addition, current requirements
for trial registration primarily affect newly marketed
drugs and newly conducted clinical trials, whereas
patients and healthcare professionals need access to
safety and efficacy information from all clinical trials
for drugs currently in use so that they can optimally
prescribe and use these medications.
Ben Goldacre, is a doctor, science writer and a champion of full clinical trial transparency and founding member of the AllTrials campaign, which is endorsed by 600 organizations, including, for example, the UK’s National Institute of Clinical Excellence (NICE), the Academy of Medical Royal Colleges, the European Consumer Organisation (BEUC) and many professional societies, journals and patient groups. AllTrials calls for all planned clinical trials to be registered, with a summary of the trial protocol, before the first participant is recruited and for making it impossible to obtain funding for a trial, including funding from government, or to sell a product, or to obtain permission to do a clinical trial, without proving registration. It also advocates for a summary of results to be made publicly available where the trial was registered, within 1 year of completion of the trial and for full reports for marketing authorization or any other purpose to also be made publicly available. Goldacre has proposed a solution to the ongoing problem of incomplete and tardy reporting in clinical trial registries. He calls for routine auditing of registries, with consequences for non-publication such as the $10 000/day fines that the FDA is entitled to levy, or refusal by ethics committees or institutional review boards to approve new trials if the sponsors and investigators have not published results of clinical trials within 1 year of completion.

A number of important EU policy developments have tried to address the problem of selective non-publication of clinical trial data. The year 2014 saw the adoption of a new EU Regulation that requires all clinical trials to be registered in a publicly accessible database before the trial starts and mandates publication of summary results within a year after completion. Clinical study reports submitted with an application for marketing are also to be made public after a regulatory decision is taken or the application is withdrawn. In exceptional cases, in which data in clinical study reports are considered commercially confidential, the information must nonetheless be disclosed when there is an overriding public interest.

As the organization responsible for developing and managing the publicly accessible EU clinical trials database, the EMA’s interpretation of commercial confidentiality is highly relevant. The EMA’s approach has shifted over time, in particular following an admonition in 2010 by the European Ombudsman for refusing to grant public access to clinical trial data. This led the EMA to review its transparency rules and adopt a more open access policy. Between November 2010 and April 2013, around 2 million pages of clinical trial data were disclosed on request. In parallel, the EMA began planning proactive disclosure of clinical trial data through a publicly accessible database.

In early 2013, however, two pharmaceutical companies, Abbvie and Intermune, sued the EMA over its decision to disclose information. Shortly after an out-of-court settlement with AbbVie, the details of which were not made public, the EMA adopted a more restrictive approach to its plans for proactive publication. Many stakeholders, including the European Ombudsman, believed that the EMA was unjustifiably backtracking from previous promises of transparency. The proactive publication policy was finally adopted in October 2014. The policy states that in general clinical data cannot be considered commercially confidential. However, this approach is undermined by the fact that it defines commercial confidentiality broadly, requires users to acknowledge that clinical reports are protected by copyright or other intellectual property rights and allows companies to sue them for violating the terms of use.

Although the EMA’s policy on proactive publication and the Clinical Trials Regulation present opportunities for more open access to trial data, the devil is in the detail, including how commercial confidentiality and the broader public interest are interpreted. Considerations about privacy protection and how best to disclose de-identified raw data will also be key in determining how much data will actually be disclosed. All these questions are driving the development of guidance documents for companies by the EMA on how to identify and redact commercial confidential information and anonymize clinical reports.

Besides recent developments on data transparency at the European level, other important initiatives have emerged globally. In April 2015, the World
Health Organization issued a statement in support of increased data openness. It defines reporting timeframes for trial results and calls for the publication of results for all trials, both old and unpublished ones, as well as newer drug trials. Other interesting initiatives include a proposal by the US Department of Health and Human Services and the NIH to expand requirements for clinical trial registration and results reporting beyond approved or licensed products and to include registration and reporting requirements for all trials funded by the NIH.67

As is noted above, several pharmaceutical companies have committed to providing anonymized participant-level data from clinical trials, but they impose limitations on access, with the company adjudicating requests, and without all trials conducted by the company necessarily included.52 To ensure higher standards of data transparency, we advocate for a legislated approach, rather than relying on companies to voluntarily release this information. To achieve the goal of transparency on medicines safety and efficacy, that safeguards public health, requirements for data disclosure should apply to all clinical trials, old and new. Clinical trial data must also be regarded as information in the public interest and full reports made freely available.

Areas of future research
Research is needed to document the effects of prospective clinical trial registration and EU requirements for proactive clinical trial publication on healthcare decisions, public health and rational resource allocation. We expect that access to more complete trial results, such as full clinical study reports, will have a positive effect on the accuracy and balance of published clinical trial reports, systematic review results and conclusions, clinical guidelines and reimbursement decisions. The impact of these changes will need to be evaluated and areas identified where transparency can be further improved.

Another important research question is the impact that open data access and re-analyses would have on understanding drug effects, evolution of clinical care and ultimately patient health. A potential outcome of such analyses would be the exploratory identification of patient subgroups that appear to respond better or worse to specific therapies, which could identify additional research questions to be addressed in prospectively planned studies. Although we reject arguments that more complete data disclosure could negatively affect innovation and increase the costs of new drug research, these questions also need to be explored. Hans-Georg Eichler, Senior Medical Officer at the EMA, and his colleagues believe that greater clinical trial data disclosure can benefit biomedical innovation, and we encourage further exploration into this area.48

The balance between the de-identification of patient-level data and the robustness of the data needs further discussion as well as appropriate data-sharing models including for those situations in which de-identification could be challenging. Another area of future research is in information technology and computer science, to make data more easily accessible. This includes methods to improve the efficiency of data retrieval and extraction, especially from regulatory documents and clinical study reports that are thousands of pages long. More research is also needed on statistical methods for individual patient-level meta-analysis.

Conclusions
Partial publication of clinical trials, selected by the sponsor to favour the tested product, is unacceptable because it distorts the scientific evidence and resulting medical care, harming public health. Within the past decade, some important initiatives have been introduced to address clinical trial transparency, including legislative and medical journal requirements for prospective clinical trial registration, and importantly, a shift within the EU to require at least partial public disclosure of clinical study reports for newly approved medicines. Public interest groups, healthcare professionals, researchers, health agencies and legislators all strongly advocated for these changes. The problem, however, is not yet solved. Clinical trial registry requirements are imperfectly enforced. Study results often remaining unpublished, and many medicines in common use escape registration requirements because they were approved before these rules were
introduced. The question of commercial confidentiality and the alleged difficulty of de-identifying patient-level data can block important progress. Despite these limitations, enormous advances have been made in the recognition of clinical trial data as a public good and in real and important changes to data access. We must now consolidate these advances and take them a step further for greater data transparency.

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Conflict of interest

B.M. is a member of the HAI Europe Association Board, an advisory board member of La Revue Prescrire and a member of the Therapeutics Initiative’s Executive Board. J.L. was advisory board member of La Revue Prescrire and a member B.M. is a member of the HAI Europe Association Board, an advisory board member of La Revue Prescrire and a member of the Therapeutics Initiative’s Executive Board. J.L. was chair of the HAI Europe Association Board from 2011 to 2014. A.I.S.Q. works as policy advisor for HAI.

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