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An Open Letter in Support of FDA's Clinical Study Report Pilot Project

In January 2018 the US Food and Drug Administration (FDA) launched a [pilot project](#) designed to enhance transparency around drug approval and assess the value of publicly disclosing Clinical Study Reports (CSRs). CSRs contain company-generated summaries of clinical trial methods and results, including more detailed information than the [published literature](#). In March, [one CSR](#) underpinning the approval of a new drug was made available by the FDA with the consent of the sponsor, and posted on the FDA's website. At the time of the pilot's launch, up to eight additional CSRs were expected to follow.

The pilot project is an important step forward by the FDA. It marked a renewal of the FDA's [longstanding authority](#) to disclose regulatory data that is generally not publicly available. CSRs are, in fact, unabridged reports of clinical studies of pharmaceutical interventions. The reports exist for all clinical studies sponsors undertake (irrespective of whether such studies are eventually published in the biomedical literature) and are submitted to regulators as part of the licensing application. While FDA is furnished with additional data (such as electronic, participant-level datasets) and does not rely solely on CSRs to arrive at its decisions, disclosure of CSRs can help better explain the basis for FDA's decisions, and in turn, inform prescribers and patients about the evidence underlying a given drug.

Further, CSRs have enormous potential to improve public health by identifying unpublished, underreported, and misreported trials in the published medical literature. Consider the case of paroxetine (Paxil). On the strength of a 2001 article reporting the results of "study 329," paroxetine was widely prescribed for treatment of depression, including amongst teenagers. In 2002, however, an FDA reviewer (with access to the study 329 CSR) reported that the trial had shown the drug was not more effective than placebo—a report that was buried, even though publicly available, on the FDA's website. It was not until 2015, when independent researchers finally gained access to the full CSR, that the 2001 journal article results were effectively called into question through the republication of the trial. This is one of several cases in which the disclosure of CSRs can amplify important findings made by the FDA to the benefit of public health.

Despite the value of disclosing CSRs, a year after its launch the pilot project appears to have stalled. No additional CSRs have been posted on FDA's website.

We, the undersigned, therefore write to express our support for FDA's CSR Pilot Project. We urge the FDA to not only see the Pilot Project through to completion, but to make public disclosure of CSRs mandatory. The fact that only one company has volunteered to participate in the Pilot Project to date indicates that a policy of mandatory disclosure—a

policy that is already in place in [Europe](#) and is being implemented in [Canada](#)—is necessary to improve transparency of CSRs submitted to the FDA.

If FDA were to publicly disclose all CSRs following a decision to approve a new drug or biologic or a new indication for an existing drug or biologic, we will—as members of a research community dedicated to evidence-based medicine—use CSRs in the following ways for the purpose of improving public health: (1) to learn more about safety and efficacy evidence supporting FDA’s approval decisions; (2) to include additional data from CSRs in systematic reviews along with other regulatory data; (3) to conduct methodological research to better characterize how to use CSRs in evidence synthesis; (4) to ensure the reports of trials in the biomedical literature (the building blocks for the majority of systematic reviews and clinical practice guidelines) are reported fully and accurately, with mechanisms available for public access to underlying data.

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