

## SOUNDING BOARD

## Data Sharing from Clinical Trials — A Research Funder's Perspective

Robert Kiley, Tony Peatfield, Jennifer Hansen, and Fiona Reddington

The Wellcome Trust, the Medical Research Council, Cancer Research UK, and the Bill and Melinda Gates Foundation share a common vision for maximizing the value of data that are generated through the trials we fund. We are committed to ensuring that the data from published clinical trials can be accessed by researchers so they can validate key findings, stimulate further inquiry, and ultimately deliver lifesaving results.

The sharing of data during the outbreak of Ebola virus disease in West Africa that began in 2014 helped researchers to trace the origins of the final few cases and bring the epidemic under control.<sup>1</sup> And the challenge organized by the *Journal* to encourage researchers to use data from the Systolic Blood Pressure Intervention Trial (SPRINT) demonstrated the vast potential for those data to be reused to develop new applications and uncover new knowledge.<sup>2</sup>

The recent announcement by the International Committee of Medical Journal Editors (ICMJE) on data-sharing statements for clinical trials<sup>3</sup> is a step in the right direction but falls short of realizing our vision. The ICMJE has not mandated data sharing as a requirement for publication, and we find the example statements it provides to be vague and open to interpretation. Crucially, the requirements do not recognize that some research funders already have mandates for data sharing.

### POLICY

As funders of medical research, we recognize the importance of the appropriate sharing of clinical-trial data for reasons of transparency, good practice, and accelerated dissemination of results to the broader community. There is now a clear consensus that the results of all clinical trials must be reported in a timely manner, as set out in a joint statement by the World Health Organi-

zation regarding public disclosure of results from clinical trials.<sup>4</sup> In addition, all our organizations have implemented data-sharing policies requiring that the data from studies we have funded will be made available to other researchers at the time of publication. This requirement applies equally to clinical trials.

These policies, however, do not mean that such data have to be openly available for anyone to access on the Web. We fully recognize that some data — and especially clinical-trial data — may contain sensitive, personal information about research participants, and these data need to be shared in a manner that protects participants' privacy and confidentiality and respects the terms under which they consented to take part in the study. Such an approach might include the use of managed-access procedures, whereby requests to access data are reviewed by an independent committee, and of data-access agreements that place appropriate restrictions on how the data may be used.

As funders, we also recognize the many challenges to data sharing<sup>5</sup> — most notably, those related to resources, equity, and incentives.

### RESOURCES

Sharing data is not a cost-free activity. Data need to be collected, preserved, curated, and stored in standardized formats in order to be useful to the scientific community. We need to support technical solutions that enable researchers to easily discover, access, and reuse the data in order to reap the benefits of accelerating discovery, enabling research reproducibility, and preventing redundancy. In addition, funding bodies are increasingly requiring that researchers develop data-management plans as part of research proposals, and we support the justified costs of delivering these plans as an integral part of funding the research. We anticipate that the data-sharing

statements required by the ICMJE can, in part, be derived from researchers' data-management-and-sharing plans.

Funders are actively working in partnership to support the development of community resources that facilitate access to clinical-trial data and reduce the burden on trialists. In particular, our organizations are planning to participate in the ClinicalStudyDataRequest.com platform,<sup>6</sup> which currently includes trial data from 13 pharmaceutical companies, as a mechanism for listing and providing managed access to data from clinical trials that we have funded.

#### EQUITY

Particular concerns have been raised over the effect of more stringent requirements for sharing data from clinical trials that are conducted in low-income and middle-income countries — specifically, that requiring researchers in such countries to share data with better-resourced groups elsewhere may put them at an unfair disadvantage and that benefits will not necessarily be shared with the communities that participated in the research.

Our organizations are strongly committed to establishing trusted and equitable systems for data-access governance in these settings, which may include terms that require users to contribute to training and capacity development or to share the resulting outcomes. However, the fundamental requirement to ensure that data are accessible at the time of publication still holds firm.

#### INCENTIVES

Arguably, the biggest challenge to data sharing is the sense that researchers are not given incentives to share data — and worse, many researchers believe they are disadvantaging themselves by doing so. A recent survey of Wellcome Trust-funded researchers showed that the potential loss of publication opportunities — along with the belief that publishing is the only currency for successful grant funding and academic advancement — was a key factor in the inhibition of data sharing.<sup>7</sup>

As funders, we need to tackle this issue head-on and demonstrate that we value the sharing of data — as well as other outputs, such as software and materials (e.g., antibodies, cell lines, and reagents) — and will take these outputs into account when reviewing grant and job applica-

tions. In parallel, we will make it clear that we focus on the scientific content of an article, rather than its publication metrics or the name of the journal in which it was published. We commit to clearly communicating these values to the members of our grant-reviewing panels.

But we need to do more. The Wellcome Trust is reexamining its grant-application process to see how it can shift the emphasis from publications to a wider set of outputs. The Wellcome Innovator Awards program invites applicants to describe their key achievements and the significance in their field. These statements can be supported with reference to peer-reviewed articles, but also with other research outputs, such as patents, data sets, software, and materials.<sup>8</sup> Such a model could be applied more broadly. Asking applicants to explain how they support the values of open research — transparency, reproducibility, and early access to results — is also worthy of consideration.<sup>9</sup>

More broadly, there is a need to support and foster community-wide efforts in this realm. Such efforts include accelerating the uptake of consistent approaches for data citation that allow the use of data to be acknowledged and tracked. The recently announced initiative exploring the value of awarding “data authorship” to researchers whose data are used or reused is also one we are following with interest.<sup>10</sup>

#### CONCLUSIONS

Medical research saves lives, and as the challenges in our world continue to outweigh the resources, collaboration and cooperation among members of the global research community will be essential in maximizing the effect of funded research. It is simply unacceptable that the data from published clinical trials are not made available to researchers and used to their fullest potential to improve health.

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From the Wellcome Trust (R.K.), the Medical Research Council (T.P.), and Cancer Research UK (F.R.) — all in London; and the Bill and Melinda Gates Foundation, Seattle (J.H.).

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