CLINICAL INVESTIGATION

The need for even further progress with clinical trial data sharing efforts: patients are waiting

"...the steps we take must be focused on keeping patients, participants and overall public health interests at the forefront of our collective efforts."

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The Johnson & Johnson vision for data sharing

We believe in responsible sharing of clinical trial data that advances science and respects individual participants, who give their time and even take risks to contribute to medicine. In keeping with that belief, our company, Johnson & Johnson (NJ, USA), has established a data sharing agreement with the Yale Open Data Access Project, an independent academic institution, to review and decide, based on scientific merit, whether requests for access to our clinical trial data, for both pharmaceutical and medical device products, will be fulfilled [1]. Sharing clinical trial data has the potential to improve public health by providing a better understanding of physiology and pathophysiology, as well as both the benefits and risks of all types of treatments, including medicines and devices. Importantly, it also enables a powerful approach to address important questions that could not be addressed within individual studies by using either a combined analysis or meta-analysis, enabling a far deeper understanding of diseases, subgroups of patients who might respond differently and strengthening the evidence base for future studies, treatment guidelines, regulatory, payer and medical decisions [2].

Recently, the Institute of Medicine released a comprehensive report, which offers recommendations for responsible data sharing and a vision of an ecosystem in which clinical trial data from all sources are more broadly accessible to the research community [3]. We support the Institute of Medicine's recommendations and agree on the need to move forward, through multi-stakeholder groups, some of which are already working on various aspects of data transparency and approaches to harmonization, including the multiregional clinical trial forum [4] and TransCelerate [5]. We agree that the greatest value from data sharing efforts will only be realized if data sharing is agreed and embraced broadly. This will require all stakeholders who conduct clinical trials of all types and of all interventions to participate in data sharing, as well as an effort towards more common data collection tools and standards. Of course, all efforts have to be aimed at maintaining the highest possible scientific principles.

Review of current work & collaborations in the field

A recent *New England Journal of Medicine* study assessed reporting rates on ClinicalTrials.gov, which includes only summary data from posted clinical trials, focusing on trials that were highly likely to be subject to the requirements for reporting, as mandated by the US FDA Amendments Act (FDAAA) (as determined by the authors). The study concluded that "most trials that were funded by the NIH or other government or academic institutions and were subject to FDAAA provisions have yet to report results at ClinicalTrials.gov, whereas the medical products industry has been more responsive to the legal mandate of the FDAAA" [6]. Having acknowledged the progress made by the industry, the paper went on to state that overall, insufficient progress has been made by all research producers.

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We believe that all clinical trial sponsors should develop processes for responsible sharing of participant level data, to maximize the scientific and medical value of our collective clinical trial efforts [2]. The Pharmaceutical Research and Manufacturers of America, the European Federation of Pharmaceutical Industries and Associations, and the Biotechnology Industry Organization have all publicly announced principles that support sharing of clinical trial data (Biotechnology Industry Organization, 2014; Pharmaceutical Research and Manufacturers of America, 2013) [3]. In addition, the Gates Foundation has very recently instituted an Open Access policy effective for all new research funding agreements [7]. The policy will require publication of all Gates-funded research and access to the underlying data sets at the individual participant level. The NIH is also taking on a more active role in encouraging sharing of data for NIH-funded research and has recently issued for comment a Notice of Proposed Rulemaking regarding clinical trial registration and results disclosure [8]. We are greatly encouraged by these actions and believe that they will engender greater participation in data transparency efforts; however, we feel that much more needs to be done to engage a wider range of stakeholders in the process of data sharing.

Completeness of data sets is the key to robust analyses

Generation of the most complete and robust data sets to answer important medical and scientific hypotheses depends upon the ability to source and combine data sets efficiently. Finding all trials that might be applicable to a particular research question is currently difficult because of the existence of multiple clinical trial registries globally [9–12], each of which contains different types of studies, different metadata and different 'cuts' of data from even the same studies. Additionally, these registries are not able to communicate with one another, so that, for example, a search for trials of a given therapy and a given condition requires looking into multiple registries. A single shared registry, or at the very least, a common set of data elements and a single interface, is sorely needed and we encourage key stakeholders, including the agencies that support public data registries, to work together to harmonize global data sources as much as possible, thereby removing unnecessary barriers.

An additional area of data sharing that requires further discussion and an aligned set of recommendations relates to patients' ability to enroll in a study and 'opt out' of data sharing. If the expectation moving forward is that trial data will be made available for secondary research, those secondary analyses may be compromised as different datasets are used for different analyses. From the perspective of the secondary researcher, patients who opt out would be unavailable for analyses, regardless of whether they opt out or never enter the trial. This issue is complex, since it could deny an important potential therapy to a patient who is not willing to share his or her data, and could also bias the potential enrolled patient population.

Conclusion

As we work through these and other issues, the steps we take must be focused on keeping patients, participants and overall public health interests at the forefront of our collective efforts. Stakeholders in the clinical research community will need to work together in this regard to maintain and cultivate an even healthier and more exciting research and development of ecosystem that fosters innovation and great advances in science and medicine.

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5 TransCelerate BioPharma Inc. Releases recommended approach for protecting personal data in clinical study reports. www.prnewswire.com

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9 US National Library of Medicine clinical trials registration site. www.clinicaltrials.gov

10 European Union clinical trials registration site. www.clinicaltrialsregister.eu

11 Internet portal of the German Clinical Trials Register (DRKS). https://drks-neu.uniklinik-freiburg.de

12 Australian New Zealand clinical trials registry. www.anzctr.org.au/