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Researchers, pharma experts offer recommendations to expand access to clinical trial data

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A new report by researchers from Harvard University and others in a working group convened by the Multi-Regional Clinical Trials Center (MRCT) at Harvard proposes recommendations for addressing a problem that has vexed drug regulators: how to expand public access to data from clinical trials while protecting patients' privacy and weighing pharmaceutical companies' business interests. Recently, the European Medicines Agency (EMA) announced it will provide public access to participant-level data submitted in applications for marketing approval in Europe, prompting questions about whether the U.S. Food and Drug Administration should follow suit. Data releases by the EMA have spurred litigation by drug companies and heated debate about whether clinical trial data should be protected as proprietary information or widely shared.

The report, published online October 21, 2013 in *The New England Journal of Medicine*, was released to coincide with the first meeting of the Institute of Medicine's Committee on Strategies for Responsible Sharing of Clinical Trial Data on October 23. The Institute of Medicine convened the committee on an accelerated timetable to develop a framework for expanded public access to clinical trial data. An initial report is expected in January 2014.

"Our experiences with Vioxx, Avandia, and other widely prescribed drugs that were revealed to have serious safety risks show how important

it is to give independent scientists access to clinical trial data," said Michelle Mello, professor of law and public health at the Harvard School of Public Health and lead author of the report. "The question is, how can we achieve the powerful public health benefits of data sharing while protecting research participants' privacy, avoiding 'junk science,' and minimizing burdens on trial sponsors?"

According to the authors, expanding access to participant-level data could both serve as a check on trial sponsors' characterizations of a product's safety and effectiveness, as well as open up new avenues of scientific inquiry beyond the scope of the original study. However, there are concerns that research participants' identities could be discovered, and that competitors and others could use the data to produce flawed analyses. The FDA historically has treated participant-level clinical trial data submitted to the agency as confidential.

The authors recommend that a system of expanded access to clinical trial data apply to trials of all approved prescription drugs, medical devices, and biologics; and treat all trial sponsors and qualified data requesters evenhandedly. It should have mechanisms to ensure that all sponsors and data users adhere to minimum standards—for example, rules should specify what must be shared, and data users should commit to following a scientifically sound analytical plan. If sponsors are permitted to influence which data requests get granted, they should be required to apply explicit decision criteria and publicly explain the reasons for denials. Using an independent intermediary organization to make those decisions, however, may be preferable.

"As in other areas of health care, the push for greater transparency in the area of clinical-trial data appears inexorable," the authors wrote. "The question is not whether, but how, these data should be broadly shared. The potential risks to research participants and trial sponsors must be thoughtfully addressed in the design of any new data-sharing system but

need not block progress toward achieving the promise of 'big data' in the clinical trials context."

"The European Medicines Agency has hastened to impose regulatory mandates for data sharing, which may indeed be needed," said Mark Barnes, a partner at Ropes & Gray LLP and the Harvard faculty co-director of MRCT, "but such mandates need to be carefully considered, to avoid harms to participants and to preserve commercial incentives for industry to invest in vital research."

More information: "Preparing for Responsible Sharing of Clinical-Trial Data," Michelle M. Mello, Jeffrey K. Francer, Marc Wilenzick, Patricia Teden, Barbara E. Bierer, and Mark Barnes, *NEJM*, online October 21, 2013, DOI: 10.1056/NEJMhle1309073

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