The Institute of Medicine recently released recommendations for bolstering the sharing of clinical trial data. IOM and other experts say open data could help advance scientific discovery, improve clinical care for patients and reduce unnecessary duplication. But privacy and proprietary concerns, as well as IT challenges, could stand in the way of full transparency.

This is an audio report for iHealthBeat, a daily news service of the California HealthCare Foundation. I'm Deirdre Kennedy.

U.S. law requires clinical trial data -- including adverse events -- for FDA-approved drugs to be submitted to the publicly accessible ClinicalTrials.gov website. However, the database does not include the same detailed methodology and results that are published in medical journals. One analysis found that nearly half of clinical trials go unpublished. And even those that are published rarely share their raw data.

Harlan Krumholz is the director of the Yale-New Haven Hospital Center for Outcomes Research and Evaluation. He says when studies go unpublished it puts patient safety at risk.

(Krumholz): "In a study we did on Vioxx, we found that the harms of Vioxx could have been appreciated several years before it was taken off the market. There had been reviews published on only some of the studies, and those gave us a false sense of security about the safety of the drug. When you included all the studies that have been conducted, you came up with a very different conclusion that in fact it did raise the risk of heart attacks."

PhRMA, the Pharmaceutical Research and Manufacturers of America, supports more transparency but says making trial data open to everyone could drive away future trial participants, threaten competition among companies and impede the development of new treatments.

PhRMA Deputy Vice President International Mark Grayson:

(Grayson): "Our industry is strongly committed to enhancing public health through responsible data sharing that recognizes three things: The importance of
Collecting all the unfiltered data and rendering the information so it's sharable among diverse parties is expensive and a huge IT challenge. Kay Dickersin -- director for the Center for Clinical Trials and Evidence at Johns Hopkins' Bloomberg School of Medicine -- says one of the main problems is how to convert clinical data that are stored in many different formats so everyone can read them.

The IOM report doesn't identify any specific standards, methods or platform. It's up to each trial sponsor to come up with its own.

There is an effort to use common data elements like those used by NIH in its Patient Reported Outcomes Measurement Information System, known as PROMIS.

Another model might be the one being developed by the European Medicines Agency, Europe's version of FDA. EMA recently said that it will soon require all clinical data to be open and stored in a central European Union repository. Dickersin would like to see something similar here in the U.S.

(Dickersin): "We need you know a couple of centralized places that are repositories of data. For example, we could put the data at our library here at Johns Hopkins. We have NIH trial data that could go to NIH. We have something called Figshare -- data could go there. There is a repository of data in [the University of] Michigan, they're all over the place."

The Yale University Open Data Access project, known as YODA, is already working with a number of drug companies, including Johnson & Johnson, to collect and manage their trial data. That means redacting sections and ensuring patient privacy. It will also have authority over who gets to use the data.

(Krumholz): "I think it's only fair for us to make some sort of assessment if it's going cost the company a million dollars to pull the archive data up, de-identify it and prepare for sharing. If there’s a request for a data set that looks like it would be very expensive to prepare ... we would assess its scientific importance."

This has been a report for iHealthBeat, a daily news service from the California HealthCare Foundation. If you have feedback or other issues you'd like to have addressed, please email us at iHB@CHCF.org. I'm Deirdre Kennedy. Thanks for listening.