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ASIA EDITION

BIO shows the way on sharing clinical trials data

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In the past decade, clinical trials have become a controversial topic across the world despite the demonstrated effectiveness of the process in making available new drugs to suffering patients for over a century. The secrecy associated with the process, particularly the publication of final results, and controversies over manipulation of data to the advantage of sponsoring companies has been at the heart of the global debate over this issue.
In some key markets such as India, clinical trials is now a bad word with the near emasculation of the sector due to a combination of court judgments and civic society activism.

Can clinical trials regain their glory days as the harbinger of new medication, which is what it actually seeks to achieve? The US-based Biotechnology Industry Organization (BIO) which has almost all the major global biotech players as it members seems to be showing the way out of the clinical trials logjam.

After wide ranging consultation, BIO has released a set of guidelines which mandates all its member companies to share all the key elements of all their clinical trial data to researchers and the public. BIO believes that "responsible clinical trial data sharing advances public health and scientific discourse, honors research participants' expectations of privacy as outlined in their terms of informed consent, and promotes biomedical innovation."

This is a great step forward and one of the key elements of the new data sharing policy is that members will make available the results of all company-sponsored phase 3 clinical trials and clinical studies of significant medical importance regardless of

whether their outcomes are positive or negative. Recently Johnson & Johnson had taken the lead in deciding to share its vast clinical trials data with researchers through Harvard University.

With BIO taking the lead in the US, Asian companies should follow the example of their American counterparts in taking similar steps. After all, it is in Asia that there is stringent opposition to the conduct of clinical trials. Transparency in sharing of clinical trial data will blunt the criticism of activists who unfortunately show something amiss in every trial because of the wrong actions of a few players.

Meanwhile, some good news has come from the US regulator, FDA. In 2013, FDA has approved a record number of 31 orphan drugs for commercial release. According to an analysis by Medicitynews.com, this is a significant jump over the previous highest of 26 approvals in 2011. Orphan drugs are medications aimed at treating rare diseases which may not have huge markets but cost a lot to produce still. FDA changes the clinical trial conditions to provide fast track approvals for such drugs so that they reach patients fast. In the 21 years since the enactment of a legislation to empower FDA to handle orphan drugs differently, the US regulator has so far allowed the premature release of more than 450 drugs to treat various rare disease forms. More than 400 orphan drugs are under trials, mostly in the US and Europe to speed up availability of affordable drugs to treat people who need them desperately.

The US regulator and the companies that pursue this noble cause relentlessly to bring smiles on the faces of people afflicted with rare diseases deserve our best wishes.