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ABLE to set up Clinical Trial Commitee

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Realising the urgency for the industry to take a pro-active stance to create patient awareness and education about clinical research, The Association of Biotechnology Led Enterprises (ABLE) is planning to set up a clinical trials committee. This move is to assist the government and the industry to share information arising from drug trials in public domain in an accessible and properly anonymized form. However, this must be balanced with the need to ensure disclosure policies protect patients' personal data, companies' intellectual property rights and confidential commercial information in order to continue to develop innovative medicines in areas of unmet clinical need.

Ms Kiran Mazumdar Shaw (CMD Biocon) and Executive Committee member-ABLE said, "This initiative would significantly ease the concerns as well as ensure smooth and safe conduct of clinical trials to not only make new drugs available for Indian citizens but also meet the aspirations of scientists, researchers and the industry to enable India to remain a credible destination for Clinical Research."

While patients in other countries actively seek information about the latest medical advances and clinical trials, patients in India too should be empowered with adequate knowledge on clinical trials and reports on the trials that are being conducted in specific disease areas to make an informed decision in terms of participation. Hence it is crucial for the industry to actively support such a cause.

Dr P.M. Murali (President ABLE) said, "To ensure smooth operations, we are keen to support the regulatory body in terms of providing training (both class-room and on-site) as well as provide a more neutral platform for exchange of ideas between the regulator and the industry and also maintain a registry of Clinical Research Organisations, SMOs, ethics committees, Labs and Bio-pharma."

Given the delays in settlement in case of any untoward event, it is imperative to set up a quick, time-bound, fact-supported mechanism that uses scientific methods and reasoning to resolve issues. As per the Association, clinical trials represent an example wherein all stakeholders can and should work together with a common goal of making the whole clinical research process safe and transparent.