

"India has bright future for conducting clinical trials"

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"India has to adopt the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) guidelines for good clinical practice to establish and to compete in the international market," said John Kolthammer, CEO, The Institute of Clinical Research (ICR), UK. Delivering a lecture on the "Good Clinical Practices, the new imperatives" organized by ClinTec International at Bangalore, he said the ICH harmonized tripartite guidelines were developed with consideration of the current good clinical practices of the European Union, Japan and the USA as well as those of Australia, Canada the Nordic countries and the World Health Organization. He maintained that although India is not a signatory for this guideline, it will benefit from following the ICH harmonized tripartite guidelines to enter into the global market. He observed that the future for conducting clinical trials in India is bright.

Explaining about the essentials of having Good Clinical Practices (GCP), Kolthammer said GCP is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects.

Kolthammer said, the objective of the ICH-GCP is to provide a unified standard for the EU, Japan and the USA to facilitate the mutual acceptance to clinical data by the regulatory authorities in these countries. Since 1997, ICH GCP has been the acceptable way of conducting pharmaceutical clinical research, he said. At present 5000 skilled people are working for ICR.