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Montana's "Right to Try" model could open US market access for Indian biopharma companies: Steve Eror

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Speaking at the CXO-level roundtable facilitated by the Association of Biotechnology Led Enterprises (ABLE) in Bengaluru



Montana could provide Indian biotechnology and biopharma companies with an alternative pathway to reach US patients, generate clinical experience and build data while progressing towards wider regulatory approval, said Steve Error, President, Montana Bioscience Alliance and CEO, Solo-Dex.

Speaking at the CXO-level roundtable facilitated by the Association of Biotechnology Led Enterprises (ABLE) during Montana Governor Greg Gianforte's India visit to Bengaluru on October 7, Error outlined Montana's experimental treatment and Right to Try framework, which he said could be particularly relevant for emerging therapies, personalised medicine and advanced treatments.

Error said the objective was to bring together India's capabilities in pharmaceutical and medical-device manufacturing with the US market and create a faster route for companies to begin working with patients.

From clinical development to patient access

According to Error, Montana's framework allows eligible patients to access experimental treatments after Phase I data has established an appropriate safety basis, subject to review by an independent board of medical professionals. He contrasted this with the conventional compassionate-use pathway, which he said can involve significant regulatory requirements and delays.

Under Montana's model, he said, companies can potentially treat patients while collecting real-world information that can contribute to subsequent clinical development. "The idea that you can get your Phase I data in India, present it to a board of five individuals, and they agree that you can go ahead and treat them, gives you an opportunity to move forward with that patient right away," Error said.

He stressed, however, that the model does not guarantee efficacy. The treatment must have sufficient safety data, while patients and treating institutions remain part of the decision-making process.

Opportunity for Indian developers

Error said the framework could be relevant to companies developing therapies that are still progressing through the conventional regulatory pathway, particularly where patients have limited treatment options. He pointed to CAR-T and personalised medicine as areas where the model could potentially have significant applications.

For Indian companies, he argued that the opportunity extends beyond patient access. Data generated through treatment could support subsequent clinical-development programmes, while companies could potentially generate revenue from treatment before achieving broader market approval. "The US is open," he said, encouraging Indian developers to consider Montana as a potential entry point into the US market.

Destination medicine model

Responding to a question on how an Indian company could operationalise such a programme while retaining its core infrastructure in India, Error said Montana could operate as a destination-medicine model. Under the approach described at the roundtable, a patient could travel to Montana, receive treatment at a participating clinic and have relevant data collected. The manufacturer would then receive the data, subject to patient privacy requirements, for use in its ongoing development programme.

Error said this could allow companies to generate clinical experience and revenue while continuing to work towards the regulatory approvals required for broader commercialisation in the US. He also indicated that Montana's approach could have applications beyond conventional pharmaceutical products, depending on the regulatory requirements and the nature of the product.

Montana Bioscience Alliance as a facilitator

Error said the Montana Bioscience Alliance, a consortium of companies, could help companies explore the opportunity and navigate the emerging ecosystem. He positioned the initiative as part of a broader effort to make Montana a destination for innovative therapies and personalised medicine, while also helping biotechnology companies access the US market.

The presentation underscored a potential area of India–Montana collaboration: combining India's biotechnology, pharmaceutical and medical-device capabilities with Montana's regulatory environment, clinical infrastructure and access to the US market.

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