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Novotech strengthens clinical trial capabilities in South Korea

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Strategically aligning with the amendments to the Advanced Regenerative Bio Act



Novotech, a global leading full-service clinical Contract Research Organization (CRO), and Acrostar, a provider of Site Management Organization (SMO) services, have entered into a strategic partnership by signing a Memorandum of Understanding (MoU) with Kyungpook National University Hospital (KNUH). The partnership will support clinical trials across KNUH's prestigious institutions including the Advanced Clinical Trials Center, the KNUH main campus, and the Chilgok KNUH in South Korea.

This collaboration is a key milestone for the advanced clinical trials in South Korea, strategically aligning with the amendments to the Advanced Regenerative Bio Act. This agreement builds upon the recent inauguration of KNUH's Advanced Clinical Trials Center opened in November last year, marking its first official partnership post-amendment of the Bio Act.

The amendments to the Advanced Regenerative Bio Act expanded the scope of advanced regenerative medicine, allowing the use of investigational therapies in clinical trials and expanding the number of authorized regenerative medicine institutions. Previously limited to severe, rare, and incurable diseases, regenerative medicine applications will now extend to a broader range of conditions, including general diseases.

Patients outside of clinical trials will also gain access to regenerative medicine services, while the range of applicable technologies—including cell and gene therapies (CGT) and tissue engineering—has significantly expanded.

Under the previous framework, CGTs required formal drug approval for clinical application. With these regulatory changes, CGTs in clinical trials can now be utilised upon review committee approval, streamlining access to innovative therapies.