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Novotech highlights South Korea's plans on clinical trials advancements

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Asia-Pacific specialist CRO Novotech has welcomed the South Korean Comprehensive Five-year Plan for the Advancement of Clinical Trials aimed at further establishing the country as a leading research and clinical trial destination in the region and globally.

Novotech identified key points expected effective in 2019 from the Comprehensive Five-year Plan that will be of particular interest to US biotech.

- Promoting early phase trials: A specific review team is being launched this year – the Clinical Trial Review Division to expedite pre-IND review/ prior-review and streamline IND submission.
- Support IoT based clinical trials : New guideline release for electronic ICF
- Acceptance of GLP data from non-OECD country (e.g. China) : Revision of regulatory requirement for pre-clinical data to allow submission of non-OECD countries' GLP data if the company has secured credibility through a fact-finding study

Besides the changes in 2019, differentiating approval systems for multi-national phase III trials to have already obtained the nod in major would be applied in 5 years.

According to the Korea Biomedical Review the new Comprehensive Five-year Plan will involve a significant increase in expert staff to support rapid approval processes.

The Five-year Plan will focus on:

- Establishing a clinical trial safety management system, and a patient communication system
- Increasing international competitiveness
- Expanding treatment opportunities including for rare and intractable diseases

Novotech CEO Dr John Moller said:

“South Korea is already a top 10 location globally for clinical trials and the capital Seoul is the top-ranked globally.” He said the new five-year plan will deliver valuable improvements that will attract even more international biotechs.

“We have a strong Novotech CRO team based in Seoul which has grown by over 25% over the past year to accommodate the increasing demand for trials in South Korea - particularly from US biotechs.”

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In an interview with Life Science Leader, KONECT mentioned:

- Sponsors like the speed and quality they get from performing trials in South Korea
- The population density ensures a strong availability of patients
- The Korean healthcare system provides universal coverage via clusters of technologically advanced hospitals concentrated in large cities such as Seoul, Busan, and Incheon
- The hospitals are monitored continuously by the government through accreditation and evaluation programs

“With 66 hospitals per million people, South Korea ranks second among OECD (Organization of Economic Cooperation and Development) members. Rapid recruitment and startup are enabled by optimized recruitment practices and the large volumes of daily patient traffic,” KONECT said.

Novotech, known as the Asia-Pacific CRO, has offices and teams through the region as well as partnerships and long-term relationships with major hospitals that directly benefit clients.

Novotech’s in-country relationships enable a more comprehensive understanding of local regulatory changes, access to leading PIs, strong site connections, and productive patient populations to deliver success for our clients within timelines and budgets.

Novotech was established in 1996, headquartered in Australia with offices in 11 countries across the region, and over 20 site partnerships with major health providers.