

# Newsletter



Intoinworld Co., Ltd., a people-focused company.  
"From people to people, connecting the value of clinical research."

Intoinworld Co., Ltd. strives to be a bridge of trust between patients, investigators, and sponsors, ensuring that the value of medical innovation is safely delivered to people. Founded in 2015, we are a contract research organization (CRO) that conducts diverse clinical studies across pharmaceuticals, biotechnology, medical devices, investigator-initiated trials (IITs) and observational studies, guided by a people-centered mindset.



## Which patient and when to use it.. Anticancer clinical trials shifting to a patient-centered approach

BI Medison Korea says its 3D strategy and in-house clinical team improved trial speed by about 30% over industry average. The company highlighted a shift toward patient-centered oncology trials, biomarker-driven design, and more complex combination studies. Korea remains attractive for clinical research, but regulatory complexity and the long-term sustainability of skilled clinical resources remain key challenges.

## "Increased R&D Despite Slowing Sales"... Pharmaceutical Investment Sees Double-Digit Growth in Q1

Listed Korean pharma companies increased first-quarter R&D spending by 10.2% despite weak sales, signaling renewed commitment to innovation. Top investors led the rise, with the top 10 accounting for 64% of total R&D spending, while exports also grew strongly. Policy incentives tied to drug pricing reform are expected to further support investment expansion.



## Korea approves 1st advanced regenerative medicine treatment, opening era of 'pre-approval therapy'

Korea's first approved advanced regenerative medicine treatment plan marks a shift toward "pre-approval therapy," allowing patients to access novel treatments before formal product approval. The case demonstrated promising safety and relapse-reduction data, while introducing a risk-sharing payment model to lower patient burden. It also signals the practical launch of Korea's regenerative medicine system and could help generate real-world evidence for future formal approvals.



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## 'MFDS Regulatory Consulting' Proved Effective in Approval of First Domestic CAR-T 'Limcato'

Korean drugmakers avoided the harshest U.S. pharmaceutical tariffs, and biosimilars received a one-year exemption, limiting immediate disruption. However, the new policy clearly favors companies with U.S. manufacturing, increasing pressure on Korean firms to localize production. For now, impact appears manageable, but future tariff reviews could reshape market access and strengthen the strategic value of onshoring.

## Timing of First Supplementary Notice for New Drug Approval Moved Up, Amid Criticism of Being 'Too Late'

The MFDS has unveiled a draft reform of Korea's new drug review process centered on earlier feedback, parallel review, and stronger pre-submission coordination. The plan would move the first substantive review comments far earlier, introduce pre-NDA meetings, and provide checklists to improve predictability and reduce late-stage surprises. While industry may welcome faster and more transparent review, practical implementation and checklist burden remain key issues.



## MFDS Issues New Guideline to Streamline Oncology Clinical Trials

MFDS's new dose-expansion cohort guideline is expected to speed oncology drug development by allowing Phase 1 and 2 elements to proceed within a single continuous trial. The approach reduces repeated IND and IRB procedures, improves operational efficiency, and helps sponsors move faster once early signals emerge. It is seen as especially valuable for smaller biotech firms seeking more practical, predictable development paths.

