

NEWSLETTER

OCT, 2025
VOL. 68



A company that thinks of people, Intoinworld Co., Ltd.

"From people to people, connecting the value of clinical trials."

We strive to become a bridge of trust that safely delivers the value of medicine to people, and to be a true partner that always grows together with our clients through people-centered thinking. Intoinworld Co., Ltd., established in 2015, is a Clinical Research Organization (CRO) that professionally conducts clinical trials in all fields, including pharmaceuticals, biotechnology, medical devices, IIT, and OS.

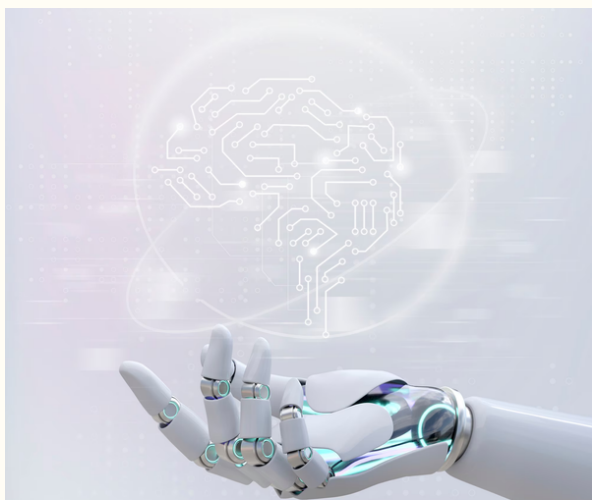
Seoul declares end to 20-month medical crisis after doctors end walkout

South Korea will end its top-level health crisis alert, declared during the 2024 doctors' strike, as the medical system stabilizes at 95% capacity. The alert, issued February 23, 2024, led to measures like extended hospital hours and temporary staff hiring. Effective initiatives like telemedicine and hospitalist programs will become permanent, while emergency reimbursements phase out.



AI cuts deeper into Korea's contrast market as hospitals weigh dose, cost and risk

Korean hospitals are reducing contrast agent use with AI-driven image reconstruction, aligning with global trends like the 2024 ESC guidelines promoting coronary CT angiography. Professors highlight patient-specific protocols and AI's role in lowering doses while maintaining image quality. Company A and Company B emphasize safety and efficiency, but smaller hospitals face AI adoption challenges.



Drug regulator requests 8.3% budget hike for 2026 to support biohealth, AI products

MFDS requested an 812.2 billion won (\$582.3M) budget for 2026, up 8.4% from 2025, focusing on biohealth innovation, AI product commercialization, food safety, and drug review modernization. Key allocations include 170.4B won for pharmaceuticals (15B for AI), 6.7B for orphan drugs, 11.4B for regulatory science, 187.1B for food safety, and 146.9B for drug approval automation.



www.intoinworld.com



bd@intoinworld.kr



02-515-8082

NEWSLETTER

OCT, 2025
VOL. 68

Korea to launch safe new drugs faster with 240-day approval target

The Korean government aims to lead global medicine launches by reforming regulations, targeting safe drug approvals within 240 days through parallel reviews. The Advanced Regenerative Bio Act will expand access to stem cell therapies for intractable diseases with clearer guidelines by 2025. Enhanced health insurance data access will support AI medical research, with a secure dataset and 2026 pilot project.



Medical cannabis drives Korea natural drug industry growth with CBD therapies

Korea's natural product new drug sector, led by medical cannabis (CBD), is gaining traction for treating epilepsy, cancer, and dementia. The 2024 global market is \$7.7B, projected to hit \$39.6B by 2034. Despite progress by Company A, strict regulations hinder clinical trials and commercialization. Deregulation could position Korea as a leader in natural drug innovation.



NEXBTBIOMEDICAL Announces First Patient Enrolled in U.S. FDA Pivotal Trial of Nexsphere-F™ for Knee Osteoarthritis Pain

Company A announced the first patient enrollment in the U.S. RESORB pivotal trial for Nexsphere-F™, a resorbable microsphere for knee osteoarthritis pain embolization. The FDA-approved IDE study compares it to corticosteroid injections across 126 patients at 10+ sites. With CE-MDD certification, Breakthrough Device Designation, and strong safety data from 155 patients (67% pain reduction at 6 months), overseas sales rose 40% in Q3 2025.

