News

South Korea and Australia offer solutions for radiopharma trial bottlenecks

Multiregional strategies are needed to navigate global regulatory landscapes radiopharmaceutical clinical trials.

Irena Maragkou | December 23, 2025

Share

Stacy Lee discussed trial bottlenecks in radiopharmaceuticals at OCT & CTS meeting in Seoul, South Korea. Credits: Arena International

In the context of the increasing prevalence of chronic diseases, the global radiopharmaceutical market is gaining momentum and is projected to exceed $10bn by 2030. This growth is driven by several factors, such as an increase in the prevalence of chronic diseases, the adoption of radiopharmaceuticals in earlier treatment lines,

expanding target pipelines across new indications, and the acquisition of radiopharma assets by big pharmaceutical companies, said Stacy Lee, senior global clinical project manager at Novotech.

At the 10th Annual Outsourcing in Clinical Trials (OCT) and Clinical Trial Supply (CTS) Korea, which took place on 2 and 3 December in Seoul, South Korea, Lee delivered comprehensive insights and strategies on running radiopharmaceutical clinical trials while exploring alternative regions as clinical trial sites.

The early diversification of radiopharmaceutical supply across regions can greatly reduce operational vulnerability, especially since even minor logistical setbacks like customs delays can render time-sensitive doses unusable for a patient, Lee advised. Thus, establishing multiple global production hubs can help shorten delivery routes, stabilise timelines and navigate import/export differences.

Australia and South Korea offer multiple advantages

The past five years have seen a sharp rise in oncology trials researching radiopharmaceuticals, with the US leading globally by a significant margin, as per Lee. The Asia–Pacific (APAC) region follows closely behind as another fastest-growing region, especially China and Australia, Lee said. This shift shows that radiopharmaceutical innovation is no longer concentrated in one region but has become a strictly global effort, the speaker emphasised. Most radiopharmaceutical oncology trials are still early in development, with 38% in Phase I and 49% in Phase II, indicating a rapidly evolving pipeline that is oncology-heavy, which creates both opportunity and pressure for multi-regional strategies, Lee added.

Lee highlighted Australia and South Korea as countries that benefit from centralised healthcare access, while the US offers a large, diverse population pool, which creates a balanced recruitment ecosystem.

While the US offers a clear regulatory pathway for radiopharmaceuticals, start-up timelines for radiopharmaceutical trials can take up to 12 months. Lee described Novotech's experience in leveraging regional CDMO networks and smaller private centres that can be activated in under four months, thereby reducing competition and accelerating recruitment.

To offset slow startup times in the US, Australia can be a key mitigation region thanks to its streamlined Clinical Trial Notification (CTN) pathway, one of the fastest regulatory pathways globally, said Lee. Also, Australia's Schedule 7 exemption enables working with smaller private radiopharmacies that follow GMP principles without needing full GMP licensing. These private centres offer quicker ethics reviews and faster startup times, and offer strong referral networks, she noted.

Simultaneously, South Korea's advanced imaging capabilities and integrated radiopharmacy policies enable highly targeted feasibility studies and rapid site selection, while typical startup timelines of five to six months position the country as an effective bridge between fast-activating Australia and slower US sites. Lee added that multi-region enrollment distributes operational burden compared to a single cluster of sites in one region. A globally distributed site network leverages regional strengths, she concluded.

Overcoming operational challenges in radiopharma trials

Highly time-sensitive radioisotopes are scarce and dependent on a small number of specialised facilities worldwide, with fragile clinical supply chains. Any disruption can jeopardise clinical supply, said Lee, adding that radioisotope shortages have forced a pause in enrollment for a Phase III study. Additionally, short half-lives and limited product stability make logistics even more complicated, but establishing redundant global supply networks requires significant time and coordination.

Lee mentioned that pursuing parallel regulatory submissions further decreases reliance on any single country's review pace. Multi-country programmes create early dialogue with multiple regulators, which "can improve alignment and future global dossier readiness", she added.

Moreover, cross-regional data from multiple populations strengthens understanding of target prevalence and treatment efficacy, informing later-phase strategy, she said.

Most radioligand therapies target prostate cancer, central nervous systems (CNS), lung and gastrointestinal cancers (GI) cancers and neuroendocrine tumours, but the field is seeing a clear momentum towards new areas, said Lee. In August, the FDA released a draft guidance on oncology therapeutic radiopharmaceuticals, signifying that regulators are trying to catch up with development in the clinical trial space, she said.

Yet none of these advantages matter without the clinical capacity to treat patients, which Lee defined as a "clinical infrastructure paradox." Radiopharmaceutical trials demand a concerted, multidisciplinary infrastructure, and only a limited

number of sites worldwide can support this complexity. These sites bear the high operational burden and are frequently overused, slowing feasibility and delaying recruitment, Lee pointed out.

Expanding trials globally in countries with available infrastructure helps relieve this pressure and helps leverage various healthcare frameworks, such as centralised networks and referral pathways for patient enrollment.

Share