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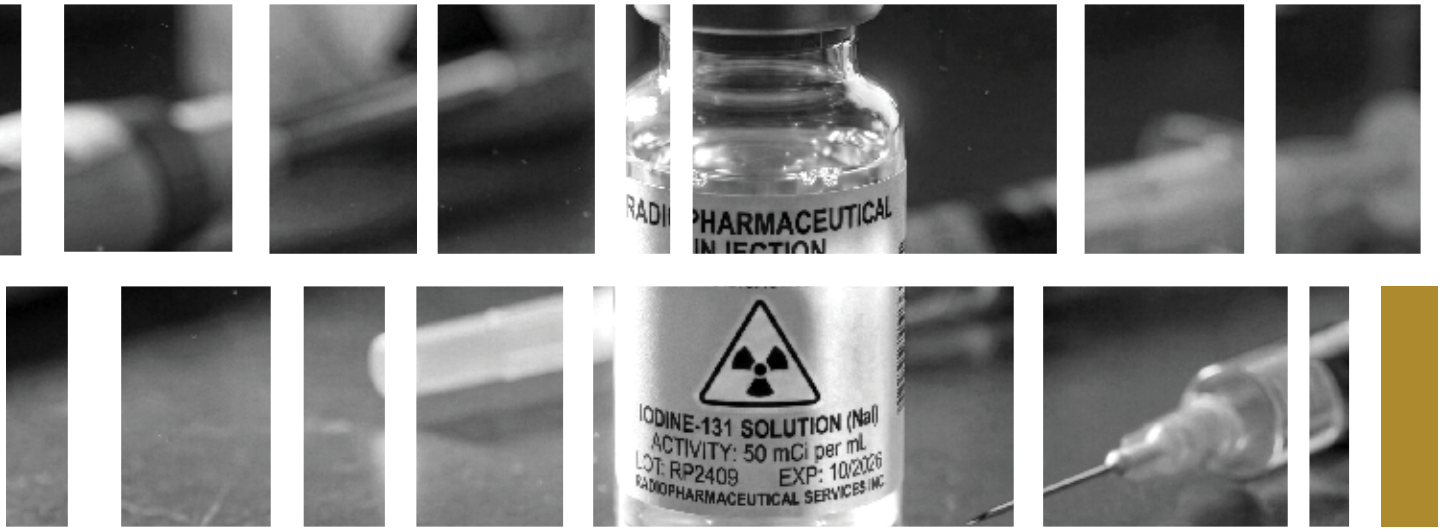

A WHITEPAPER FROM INSTITUTE@PRECISION

Navigating Global Regulations for Radiopharmaceutical Development

Understanding regional requirements, gaps, and practical implications across the US, EU, and APAC

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Executive Summary

Radiopharmaceutical development involves specific regulatory considerations beyond those applicable to other therapeutic modalities. While regulators globally share a focus on patient safety and product quality for radiopharmaceuticals, regional frameworks differ in their expectations and structure. Understanding these regional distinctions is essential for reducing regulatory risk, avoiding delays, and ensuring efficient program progression.

This whitepaper provides a comparative overview of radiopharmaceutical regulations across the US, EU, and APAC; highlights common challenges that developers encounter; and outlines practical considerations to support effective cross-regional trial planning and execution.

The Regulatory Landscape for Radiopharmaceutical Development

Radiopharmaceutical development combines the requirements of pharmaceutical development with radiation safety oversight and specialized administrative procedures, introducing regulatory considerations beyond those associated with other therapeutic modalities.

Regulatory frameworks for radiopharmaceutical development also vary across global regions. Although regulatory authorities share a focus on patient safety and product quality, expectations differ in their prescriptiveness and requirements for non-clinical data, dose justification, radiation exposure limits, manufacturing standards, and trial conduct. Developers must therefore tailor their regulatory and clinical strategies to each target region.

These complexities introduce challenges across the radiopharmaceutical development lifecycle. In early-phase development, developers must ensure that non-clinical packages are sufficiently robust to support regulatory approval for first-in-human trials while also meeting dose-optimization and safety-justification requirements, which may be inconsistently defined across jurisdictions. In later phases, challenges shift to coordinating multi-regional programs, aligning regulatory submissions, and maintaining consistent safety and dosimetry approaches in global trials where regional requirements differ.

A lack of regulatory insight and understanding here can have material consequences. Misalignment with regional expectations may lead to delayed trial initiation, additional data requests from regulators, and operational or logistical inefficiencies that affect timelines, program costs, and, ultimately, competitive standing.

This whitepaper draws on the authors' cumulative 40+ years of regulatory experience to provide a clear, high-level reference for developers navigating radiopharmaceutical regulations globally. The paper highlights key areas where regulatory expectations diverge across regions, and outlines practical considerations to support effective regulatory planning and clinical trial execution.

US regulations

In the United States, radiopharmaceuticals are regulated by the FDA in coordination with the Nuclear Regulatory Commission (NRC) and Institutional Review Boards (IRBs). Requirements may vary depending on jurisdiction and site, so developers must account for federal-, state-, and institutional-level expectations when planning clinical programs.

The FDA has issued draft guidance addressing both the progression to first-in-human (FIH) studies and radiopharmaceutical clinical development in oncology.[1,2]

Transitioning from non-clinical development to first-in-human studies

The FDA expects non-clinical biodistribution, dosimetry, and toxicity data to be sufficiently robust to support extrapolation from animal models to humans. These data should enable estimation of absorbed radiation doses in human organs and identification of potential dose-limiting normal tissues prior to clinical exposure.

The proposed FIH administered activity must be justified using extrapolated human dosimetry derived from animal studies and adjusted to remain within tolerated organ dose limits. Additional considerations may include the type of radionuclide (for example, alpha emitters and associated relative biological effectiveness assumptions) and the contribution of any cold-mass dose where relevant.

Clinical development considerations

FDA draft guidance outlines several expectations for radiopharmaceutical clinical development.[2]

Participant population

Trials designed to define maximum tolerated dose (MTD), or that exceed historical radiation exposure limits, are expected to enroll participants with advanced disease, where delayed toxicities may be considered acceptable. Higher-risk dosing strategies should be restricted to populations with less favorable prognoses.

Clinical trial design

Developers are encouraged to use fixed-cycle dosing in radiopharmaceutical therapy trials in order to control cumulative radiation exposure. These protocols should justify cumulative administered activity limits based on available safety and efficacy evidence, and dose selection should integrate multiple data sources, including pharmacokinetics, safety findings, and clinical outcomes, rather than relying solely on MTD.

Safety monitoring

Because radiation-related toxicities may be delayed or cumulative, the FDA advises extended follow-up. Specifically, developers should plan for follow-up periods of five years or longer to monitor for late adverse events. During this time, developers should monitor participants for long-term radiation effects and correlate prior radiotherapy exposures.

Dosimetry and dose optimization

Dosimetry is central to radiopharmaceutical development, and early data should guide optimized dosage development. Where possible, developers are encouraged to employ direct imaging methods, such as PET or SPECT, and ensure protocols detail imaging acquisition and dose calculation methods. If developers expect dosimetry data to be limited at submission, they should engage with the FDA early to align on expectations.

Practical implications for developers

Given the above, developers should ensure their strategy:

- Anticipates a higher evidentiary threshold to justify FIH studies compared with conventional therapeutics
- Employs fixed-cycle dosing to account for cumulative radiation exposure
- Integrates a defined dosimetry strategy early in development
- Accounts for extended safety follow-up, including long-term monitoring requirements
- Addresses provider training and patient safety education associated with radiopharmaceutical administration

Early and proactive engagement with the FDA is crucial here, as it can reduce uncertainty, clarify expectations, and mitigate regulatory risk.

EU Regulations

In the European Union, radiopharmaceuticals are regulated at multiple levels. The European Medicines Agency's (EMA) centralized procedure for authorization of medicines does not automatically include radiopharmaceuticals, but it does issue guidance and may provide centralized scientific evaluation. In addition, national competent authorities oversee implementation within individual Member States, ethics committees review and approve clinical trial protocols at the country level, and country-specific safety protocols or licensing may exist around radiopharmaceutical transport and radiation safety controls. As a result, sponsors must navigate both EU-wide procedures and country-specific requirements, which may vary across jurisdictions.

Current EMA guidance

Unlike the FDA, the EMA has not yet issued dedicated clinical guidance specific to radiopharmaceutical development. Existing guidance applies at a general level but does not address radiopharmaceutical-specific considerations such as administered activity, absorbed dose, and dosimetry-driven optimization strategies.[3]

However, the EMA has published a concept paper outlining the anticipated scope and direction of future guidance for radiopharmaceuticals in oncology.[4] While the concept paper does not constitute regulatory requirements, it does give insight into the EMA's regulatory priorities, and highlights areas likely to receive scrutiny in current submissions.

Emerging expectations for radiopharmaceutical development

The EMA concept paper highlights several themes that inform current regulatory expectations.[4]

Standardized terminology

A key focus area is standardizing terminology to improve clarity and comparability across submissions. Clear definitions are needed for "dose" in relation to "administered activity" and "absorbed dose," as well as for "activity" in the context of anti-tumor effect and the quantity of administered radiopharmaceutical.

UK considerations

In the UK, radiopharmaceutical clinical development is regulated by the Medicines and Healthcare products Regulatory Agency (MHRA), the Health Research Authority (HRA), and the use of radioactive substances in medical practice must be authorized by the Administration of Radioactive Substances Advisory Committee (ARSAC). Developers seeking market entry in the UK must therefore plan for this separately from EMA submissions.

Range of administered activity

The concept paper emphasizes the need for systematic approaches to determining the range of administered activity. The systematic approach should establish maximum tolerated activity or absorbed dose, identify acute dose-limiting toxicities, characterize the relationship between administered activity and absorbed dose, and begin evaluating dose-response relationships for late radiation-induced toxicity.

Dosimetry

The paper also advises a systematic approach for dosimetry. Posology should support individualized planning of absorbed doses and include a recommended target absorbed dose range for tumor lesions, as well as defined absorbed dose limits for organs at risk. The paper acknowledges the technical challenges in performing direct dosimetry analyses for certain products, including alpha-emitters and beta-emitters with low photon emissions, and expects scientifically justified methodologies in such cases.

Toxicity management and treatment optimization

Study designs should support efficient development and timely approval while incorporating plans for post-authorization data collection and long-term follow-up to detect late toxicities. Product-specific risk mitigation strategies may be necessary depending on the radiopharmaceutical and treatment setting.

Acceptable benefit-risk profiles

The paper recognizes that acceptable benefit-risk profiles vary according to treatment intent. In late-stage symptomatic disease, tumor shrinkage and symptom control may be prioritized over long-term toxicity risks. In curative settings, higher rates of acute but reversible toxicity may be acceptable, whereas tolerance for irreversible long-term toxicity depends on its frequency and impact on survival and quality of life.

EANM dosimetry approach

While the EMA Concept Paper highlights the need for systematic incorporation of dosimetry into future guidance for therapeutic radiopharmaceuticals, the European Association of Nuclear Medicine (EANM) has responded by emphasizing that robust evidence demonstrating the clinical benefit of personalized dosimetry over simplified or fixed-activity approaches remains lacking.5 Consequently, the question of whether dosimetry should be fully incorporated into formal guidance remains a matter of active debate, with the EANM urging further evidence before endorsing extensive individualized dosimetric requirements.

Practical implications for developers

The absence of formal, prescriptive EMA guidance creates uncertainty for developers. Because a concept paper reflects regulatory intent rather than enforceable requirements, sponsors should expect an evolving framework and closely monitor further EMA publications and scientific advice outputs. For the same reason, developers should design early-phase trials that can adapt as guidance evolves.

Given the more prescriptive nature of existing FDA guidance, US regulatory positions may provide insight into future EMA regulatory direction. However, developers should not assume alignment between these authorities, and must engage early with the EMA and relevant national authorities to confirm expectations. For example, if the EMA chooses to relax dosimetry requirements in official guidance based on the EANM response, this would create disparity with the FDA approach.

Given the lack of clarity, sponsors should consider engaging regulatory and radiopharmaceutical-specific experts to support compliant and efficient EU submissions.

APAC Regulations

Radiopharmaceutical development in the Asia-Pacific (APAC) region is governed by country-specific regulatory systems layered on top of common international good clinical practice (ICH GCP) standards, rather than a single harmonized framework. The requirements vary across Japan, China, Australia, South Korea, Singapore, and Taiwan, with some consistent features across the region.

Radiopharmaceuticals are regulated as medicinal products under ICH-aligned clinical trial frameworks and local clinical trial regulations. At the same time, they are treated as radioactive materials under national radiation and nuclear safety laws. This dual nature impacts program design, site selection, and start-up timelines.

Clinical trials must comply with ICH E6 GCP and ICH E8/ E8(R1) principles, alongside local clinical trial legislation, ethics oversight, and country-specific submission pathways.6,7 Radiation protection regimes govern the licensing of facilities, authorized users, and the storage, transport, and disposal of radioactive substances. These regimes are typically administered by separate regulators and may require site-specific approvals, specialist service licensing, and documented radiation safety controls in addition to medicinal product authorization.

For innovative radioligand therapies and theranostic programs, APAC regulators increasingly encourage early scientific advice for novel radioligand/theranostic agents on dosimetry methodology, non-clinical data, first-in-human dosing, imaging endpoints, or biomarker strategies.

As a result, developers must navigate a complex interplay of both regional and country-specific regulatory requirements in APAC. Some key country-specific regulations are summarized in Table 1.

Table 1. APAC country-specific regulations

	Japan (PMDA/ MHLW)[8,9]	Korea (MFDS + KINS/ NSSC)[10]	China (NMPA/ CDE)[11-13]	Australia (TGA CTN/CTA)[14]	Singapore (HSA + HCSA + NEA)[15, 16]
Therapeutics Regulations	PMD Act; CTN to PMDA (30-day review, if no objection, the trial can start)	Pharmaceutical Affairs Act; Investigational New Drug approval from MFDS	Drug Administration Law; CTA to NMPA/ CDE (60-day review default)	Therapeutic Goods Act; CTN (notify only) or CTA (TGA approval)	Health Products Act; CTA/CTN for therapeutic products, CTC for medicinal products
Ethics Regulations	Site IRB (parallel)	IRB (parallel/ sequential)	Ethics Committee (parallel)	HREC (pre-CTN/ CTA)	IRB (parallel for CTA, post for CTN)
RPT-Specific Guidance	Guideline for diagnostic radiopharmaceutical clinical evaluation[17, 18]	General GCP + PET/ radiopharmaceutical practice[19]	Technical guidelines for diagnostic/ therapeutic radiopharmaceutical (nonclinical/ clinical/ Chemistry, Manufacturing and Controls)[20-22]	Guidance 20: Radio-pharmaceuticals[23]	Risk-based clinical trial guidance (no radiopharm-specific CTA)[24]
Radiation/ Nuclear Regulations	National radiation laws; site licensing only	KINS/NSSC radioisotope application + Safety Manager (Radioisotope General License)	Three licenses (production/ distribution/ use)[25]	ARPANSA codes/ import permits + state licenses[26]	NEA Radiation Protection (Ionising Radiation) Regulations[27]
Service Licensing	General hospital rules	Hospital + nuclear centres	Hospital + nuclear approvals	State facility + radiation	HCSA Nuclear Medicine Service license[16, 28]
Trial Complexity	Flexible CTN; guidance-rich	Dual regulatory path	Guideline stack + industrial licensing	CTN for early-phase	Triple-stack (drug/ service/ radiation)

Abbreviations: ARPANSA, Australian Radiation Protection and Nuclear Safety Agency; CDE, Center for Drug Evaluation; CTA, Clinical Trial Application; CTC, Clinical Trial Certificate; CTN, Clinical Trial Notification; HCSA, Healthcare Services Act; HREC, Human Research Ethics Committee; HSA, Health Sciences Authority; KINS, Korea Institute of Nuclear Safety; MFDS, Ministry of Food and Drug Safety; MHLW, Ministry of Health, Labour and Welfare; NEA, National Environment Agency; NMPA, National Medical Products Administration; NSSC, Nuclear Safety and Security Commission; PMDA, Pharmaceuticals and Medical Devices Agency; PMD Act, Pharmaceuticals and Medical Devices Act; TGA, Therapeutic Goods Administration.

Practical considerations for developers

Developers should plan for dual or triple-track regulatory strategies, as therapeutic product approvals must be integrated with radiation and nuclear safety approvals in each target country. This requires early mapping of all relevant authorities, including medicines agencies, nuclear regulators, and healthcare facility licensing bodies, and deliberate sequencing of applications so that drug, site, and radiation permissions converge in time to support the first patient in.

Early engagement with regulators and ethics bodies is increasingly important for first-in-human and novel theranostic programs. Scientific advice from agencies such as the Pharmaceuticals and Medical Devices Agency (PMDA), National Medical Products Administration (NMPA), Therapeutic Goods Administration (TGA), Ministry of Food and Drug Safety (MFDS), Taiwan Food and Drug Administration (TFDA), and Health Sciences Authority (HSA) can help align expectations on dosimetry strategy, risk–benefit justification, and imaging endpoints. Such proactive alignment reduces the likelihood of late-stage queries that can delay or reroute development programs.

Finally, developers should standardize core documents to ICH GCP requirements, with jurisdiction-specific addenda covering local Clinical Trial Authorisation (CTA)/ Investigational New Drug (IND) processes, applicable national clinical trial legislation or human biomedical research requirements, and radiation licensing documentation. This approach supports consistency across the program while accommodating local regulatory expectations.

Region Themes

Across all regions, patient safety remains the primary regulatory priority. Accordingly, regulatory authorities consistently require robust non-clinical justification, appropriate risk-benefit assessment, and careful monitoring for acute and long-term toxicities.

The importance of dosimetry is also increasing globally. Regulators in the US, EU, and many APAC jurisdictions recognize that absorbed dose estimation, organ-at-risk protection, and optimization of administered activity are central to radiopharmaceutical development.

Despite shared principles, meaningful differences exist in regulatory structure, prescriptiveness, and operational execution. These regional variations are summarized in Table 2.

Table 2. Summary of regional variations in radiopharmaceutical regulatory approaches

	US	EU*	APAC	Regional Variations
Status	FDA draft guidance (August 2025) for near-term implementation	EMA concept paper (October 2024) outlining direction for future guideline development	Fragmented, country-specific frameworks with no APAC-wide guidance. Dual/triple track approvals of drug, radiation, and facility licenses via national medicines and nuclear authorities	• FDA guidance is implementation-ready • EMA remains conceptual • APAC lacks regional harmonization, with parallel approvals and variable start-up timelines
Dosimetry	Strong emphasis on early, detailed dosimetry, including micro-scale modeling and uncertainty analysis	Advocates individualized dosimetry; critical of fixed dosing; aims to standardize terminology	Nationally defined requirements aligned to ICH and radiation-protection principles. Expectations vary by country; individualized dosimetry is encouraged in some markets but constrained by site licensing and infrastructure	• FDA allows flexibility • EMA pushes for individualization and standardization • APAC expectations are heterogeneous, and feasibility depends on nuclear medicine capability
Dose Escalation	Allows exceeding EBRT limits with justification; supports randomized dose-response trials	Encourages wide dose exploration in early trials; focuses on MTD and DLT management	Governed by national radiation protection rules and authorized-user requirements, potentially limiting escalation options versus US/EU	• FDA allows higher dosing with safeguards • EMA emphasizes toxicity control • APAC escalation latitude varies and may be more constrained
Trial Design	Fixed-cycle dosing, cohort backfilling, and long-term follow-up	Supports treatment-setting-specific optimization (curative vs palliative)	Trial design must incorporate isotope logistics, import permits, and facility readiness. Dual/triple approvals often drive sequencing, pacing, and conservative enrollment	• FDA promotes uniform structure • EMA supports contextual flexibility • APAC logistics and licensing often dictate design and timelines
Safety Monitoring	Recommends ≥5-year follow-up for radiation-associated AESIs; biomarker collection encouraged	Addresses acute and long-term toxicity, with less specificity on follow-up duration	Oversight is governed by both drug and radiation legislation. Acute and long-term monitoring expected, but duration and requirements vary by country	• FDA mandates extended follow-up • EMA leaves duration open • APAC monitoring is tied to national radiation laws
Patient Population	High-dose trials limited to patients with poor prognosis; separate cohorts for prior RPT/EBRT	Emphasizes minimizing toxicity in curative settings; supports individualized treatment	Patient selection is influenced by nuclear site capacity and logistics. Conservative risk–benefit expectations for early or high-activity cohorts	• FDA uses prognosis-based stratification • EMA focuses on treatment intent • APAC's nuclear site readiness may affect recruitment and stratification
Regulatory Engagement	Requires early and frequent FDA meetings for dose justification	Future guidance is expected to clarify engagement pathways	Engagement typically involves multiple medicines and nuclear/radiation authorities, increasing coordination complexity	• FDA offers a single-agency pathway • EMA is evolving • APAC multi-agency processes are a common source of misalignment

*Note that EU recommendations are informed by the EMA concept paper and do not constitute official guidance

Abbreviations: AESI, adverse event of special interest; DLT, dose-limiting toxicity; EBRT, external beam radiotherapy; MTD, maximum tolerated dose; RPT, radiopharmaceutical therapy.

Level of prescriptiveness and harmonization

The United States currently has the most prescriptive radiopharmaceutical-specific guidance, with FDA draft documents outlining detailed expectations for first-in-human progression, dosimetry, clinical design, and long-term follow-up.

In contrast, the European Union has no formal prescriptive guidance specific to radiopharmaceutical clinical development in oncology. While overarching oncology guidance exists, radiopharmaceutical-specific expectations are currently informed by an EMA concept paper rather than formal guidance. This creates interpretive variability and places greater emphasis on early regulatory dialogue.

Across APAC, the level of prescriptiveness varies by country. Some jurisdictions have issued technical guidance for diagnostic or therapeutic radiopharmaceuticals, while others rely primarily on general GCP frameworks supplemented by radiation regulations. The absence of regional harmonization increases the complexity of multi-country development strategies.

Multiplicity of authorities and licenses

In many APAC markets, regulatory responsibilities are fragmented across medicines regulators, nuclear or atomic energy agencies, and healthcare service licensing bodies. Sponsors may therefore need to secure multiple approvals and undergo separate inspections for each trial and site. Moreover, drug approval, radiation licensing, facility authorization, and import permits often proceed through distinct channels.

By comparison, the US and EU generally operate through more integrated or centrally coordinated systems, even though radiation safety remains separately regulated. In the US, review is centralized within the FDA, where oncology radiopharmaceuticals are assessed by the relevant oncology division within the Office of Oncologic Diseases in collaboration with the Division of Imaging and Radiation Medicine (DIRM). When imaging or device components are involved, additional review may be conducted by the Center for Devices and Radiological Health.

In Europe, however, country-specific bodies—such as the HRA and ARSAC—illustrate that national overlays still influence implementation. Fragmentation is therefore less pronounced than in many APAC jurisdictions, but not absent.

Operational lead times and logistical sensitivity

APAC development timelines are often highly sensitive to operational constraints; import permits for isotopes, customs clearance processes, licensed nuclear medicine services, radiopharmacy capacity, and radioactive waste management requirements can all influence site activation. These variables may introduce a level of unpredictability not typically encountered in the US or EU.

For multi-country trials, the slowest radiation or facility approval frequently becomes the rate-limiting step for regional start-up. As such, even where medicinal product approval proceeds efficiently, operational readiness at the site level may determine overall timelines.

Planning for Global Radiopharmaceutical Development

Global radiopharmaceutical development requires deliberate, careful attention to regional regulatory requirements. While patient safety, scientific justification of dose, and long-term monitoring underpin regulatory oversight around the world, meaningful differences remain across the US, EU, and APAC. These differences affect submission strategy, trial design, site activation, and operational execution.

Understanding regional expectations early supports more efficient trial planning, reduces regulatory risk, and improves the scalability of development programs. Sponsors that anticipate variations in prescriptiveness, approval sequencing, radiation licensing, and infrastructure constraints are better positioned to avoid delays and unnecessary rework.

Importantly, radiopharmaceutical developers must integrate medicinal product approvals, radiation safety requirements, facility licensing, and logistical planning from the outset, as regulatory strategy does not exist in isolation. In doing so, they can strengthen program resilience across regions and increase the chance of successfully delivering for patients.

To read more about the unique challenges posed by radiopharmaceuticals, explore our whitepapers: *Managing Operational Complexity in Early-Phase Oncology Radiopharmaceutical Trials* and *Challenges and Opportunities for Radiopharmaceutical Commercialization.*

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About Precision for Medicine

Drawing on deep oncology and radiopharmaceutical expertise, Precision for Medicine partners with sponsors to design global trials, accelerate clinical development, and ensure scientific and regulatory integrity.

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Harpreet Singh, MD, is the chief medical officer of Precision for Medicine and a former Director of the FDA's Division of Oncology 2. At the FDA, Dr. Singh oversaw the development and approval of more than 40 therapies across various solid tumors, including breast, lung, head and neck, and other cancers. While at the FDA, Dr. Singh also spearheaded Project Pragmatica, a program to streamline clinical trials and enhance patient centricity. In addition, Dr. Singh was the Associate Director for Cancer in Older Adults and Special Populations at the FDA Oncology Center of Excellence (OCE) and a Fellow at the National Cancer Institute. Dr. Singh is a world-renowned expert in oncology.

JingPing Yeo, PhD, MBA

JingPing Yeo, is the Vice President of Clinical Operations and Head of APAC at Precision for Medicine. She leads the clinical delivery team across APAC, driving growth, operational excellence, and organizational leadership. She brings nearly three decades of experience across pharmaceutical companies, CROs, and healthcare institutions. Her leadership portfolio includes senior roles at Emerald Clinical Trials (George Clinical), Cytel, Parexel, Quintiles, Novo Nordisk, and SingHealth. She chairs the DIA Singapore Advisory Committee, the Singapore Clinical Research Professionals Association, and the DIA Asia Committee, contributing actively to advancing clinical research standards in the region.

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