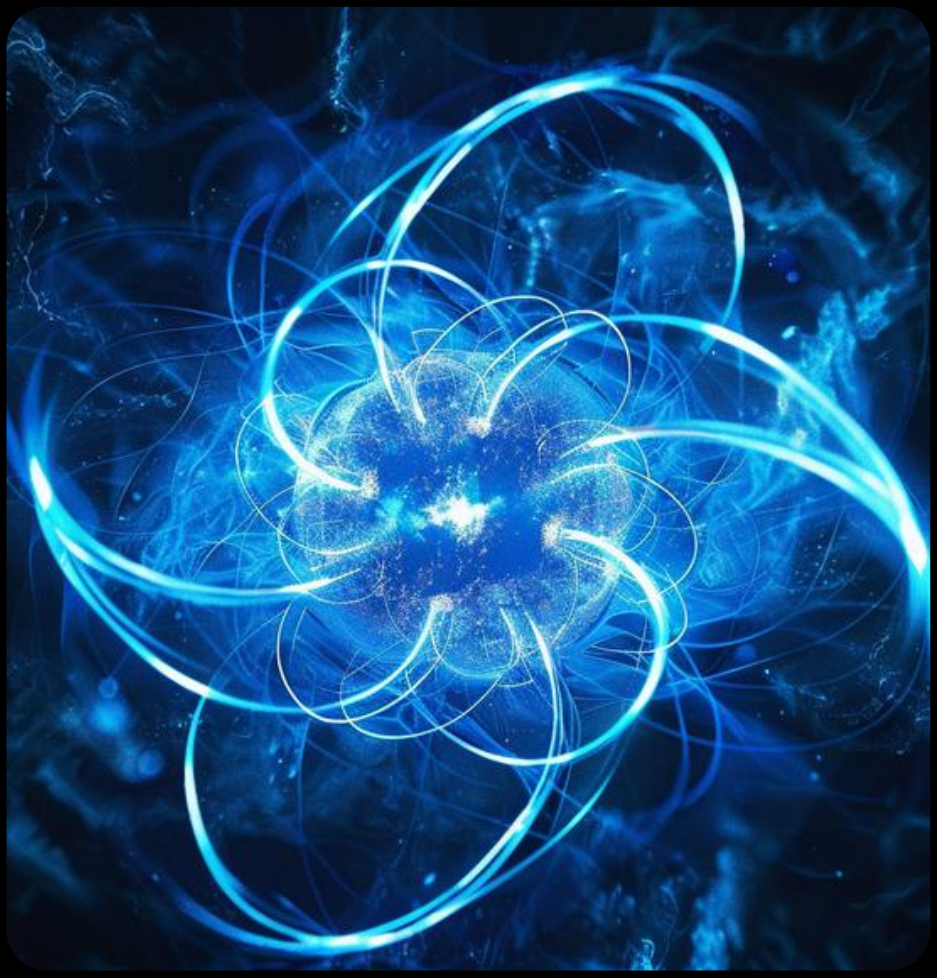
ProGen Search

Radiopharma's 4 Critical Questions:

A Pre-TRP Briefing

A strategic guide for CEOs, boards, and investors navigating the tensions in targeting, dosimetry, manufacturing, and commercialisation.



Prepared by

Byron Fitzgerald

Founder, ProGen Search

www.progensearch.com

ProGen Search partners with investors and leadership teams across Biotech, Pharma, CDMO, and CRO sectors to solve their most critical executive hiring challenges and build leadership teams that scale innovation. We were founded on the belief that executive search should be transparent, research-led, and deeply aligned to the future ambitions of the companies we serve.

Our story began from first-hand frustration with the traditional search model - one that often relied on opacity rather than insight. After 14 years in executive search - including scaling a consultancy to 36 consultants and refining an industry-leading model as co-founder of a specialist firm - ProGen's founder launched the business in December 2024 to deliver a more rigorous, open-source approach to leadership hiring.

Today, our clients trust us globally to identify, engage, and secure transformative talent - supported by deep sector research, transparent processes, and clear deliverables. Whether supporting scale-up biotech, investor-backed CDMOs, or emerging therapeutic platforms, we partner with clients not just to fill roles, but to shape the leadership needed to create long-term value.

Disclaimer

This document is intended for informational purposes only and should not be construed as formal investment, financial, medical, or strategic advice. The content has been synthesized from research materials collected from publicly available sources and proprietary analysis.

All views and insights expressed reflect our current understanding of the global radiopharmaceutical (RPT) industry - spanning target selection, clinical dosimetry, manufacturing, and commercialisation - as of Q4 2025. This briefing is designed to frame the critical strategic questions being debated within the industry, many of which are central themes of the upcoming 7th TRP Summit Europe. Readers are encouraged to conduct their own due diligence and consult appropriate professional advisors before making any investment or strategic decisions.

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Radiopharma's 4 Critical Questions: A Pre-TRP Briefing

Foreword: The Gold Rush Paradox

The radiopharmaceutical therapy (RPT) sector is navigating an era of unprecedented strategic intensity. The landmark successes of agents targeting PSMA and SSTR have validated the modality, unlocking billions in capital investment and triggering high-premium M&A activity, including the multi-billion-dollar acquisitions of RayzeBio by BMS, POINT Biopharma by Eli Lilly, and Fusion Pharmaceuticals by AstraZeneca. We are witnessing a veritable "gold rush," with the market projected to exceed $14 billion by the early 2030s.

Yet, this influx of capital and enthusiasm is colliding head-on with an unforgiving operational reality. We term this the Gold Rush Paradox: the pursuit of immense clinical and financial upside is constrained by profound, systemic bottlenecks that threaten the viability of even the most promising assets.

The fragility of the isotope supply chain, dependent on aging nuclear reactors, places multi-billion-dollar franchises on a precarious foundation. The manufacturing process itself is a gauntlet, governed by the tyranny of the half-life and a complex dual-regulatory burden. The clinical promise of personalized dosimetry is hampered by a critical shortage of specialized expertise. And in Europe, regulatory approval is merely the opening salvo in a protracted, fragmented battle for reimbursement.

The era of valuing radiopharma assets purely on scientific promise is over. We have entered an age of Execution Under Decay. The new valuation drivers are integration, operational mastery, and the ability to execute flawlessly from reactor to patient.
As strategic advisors to the leadership teams shaping this industry, ProGen Search analyzes these tensions to identify the mission-critical talent and strategies required to secure a competitive moat. This briefing deconstructs the four most critical strategic questions that every CEO, Board Member, and Investor must answer to successfully navigate the Gold Rush Paradox.

These are not questions with easy answers. They represent the core strategic debates defining the sector's future. And critically, the essential, cutting-edge discussions required to solve these problems are happening next month at the 7th TRP Summit Europe in Amsterdam. This report previews the high-stakes agenda that makes attendance a strategic necessity for any organization serious about leading the next wave of radiopharmaceutical innovation.

The Conversation Continues in Amsterdam

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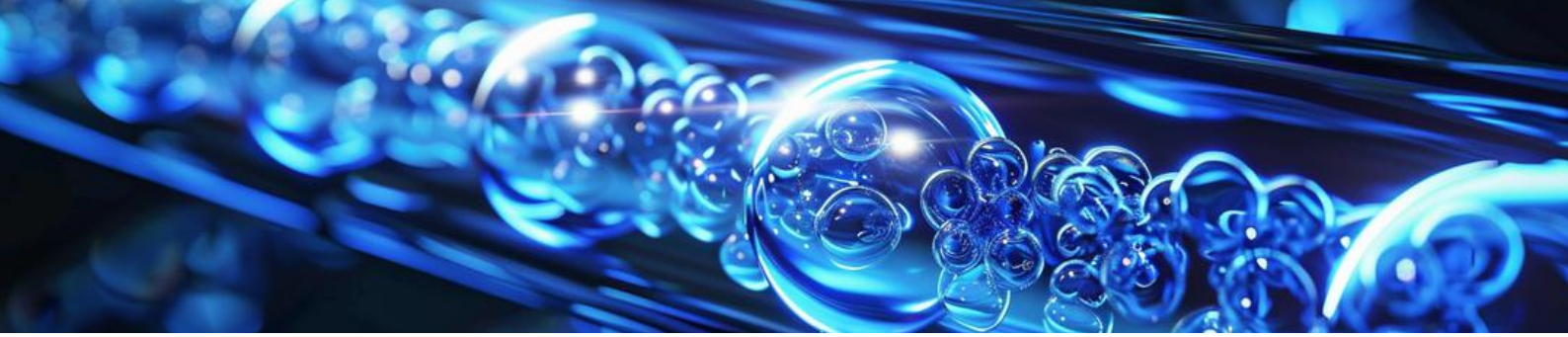

Chapter 1: The Target Dilemma: Innovation vs. Industrialisation

The clinical and commercial validation achieved by targeting PSMA and SSTR has catalyzed an aggressive expansion of the radiopharmaceutical pipeline. The strategic imperative has shifted from proving the modality works to identifying the next high-value biological targets. However, this expansion confronts developers with a fundamental dilemma: pursue novel, potentially transformative biology, or focus on industrializing validated pathways already targeted by other modalities.

The Big Picture

The industry is converging on a handful of key emerging targets, including FAP, HER2, DLL3, and GPC-1. The selection of these targets is a foundational capital allocation decision that dictates the potential market size, the risk profile, and the required development pathway. The challenge lies not merely in identifying a target, but in mastering the intricate science of drug design to create therapies with a decisive clinical advantage and a manageable safety profile.

The Underlying Tension: The Optimization Minefield

The core tension lies in navigating the intricate optimization minefield between innovation and industrialization. This is not a simple binary choice but a complex, multi-parameter optimization problem defined by what we call the Strategic Triad: the interplay between the Target's biology, the Targeting Moiety's pharmacokinetics, and the Isotope's physical properties.

The primary risk - and the most common point of clinical failure - is **on-target, off-tumor toxicity**. The immense potency of radionuclide payloads means that even minimal target expression on healthy tissues can lead to catastrophic toxicities. This tension defines the development landscape:

1. The FAP Paradox: Pan-Cancer Potential vs. Systemic Risk Fibroblast Activation Protein (FAP) represents the broadest commercial opportunity, expressed in the stroma of over 90% of epithelial cancers. However, this opportunity is tempered by the existential threat of toxicity in non-malignant fibrotic tissues and areas of inflammation. The winning strategy hinges entirely on engineering drug designs (such as albumin binders to optimize pharmacokinetics, exemplified by LNC1004) that can navigate this narrow therapeutic window.

2. The HER2 Minefield: Validation vs. Competition HER2 is a validated target with a massive addressable population. However, the RPT space must contend with the overwhelming efficacy of established Antibody-Drug Conjugates (ADCs) like Enhertu. The strategic path for a HER2-RPT is narrow: it must leverage the unique "bystander effect" of radiation to kill adjacent HER2-negative cells, thereby overcoming tumor heterogeneity where ADCs fail. This requires sophisticated engineering, such as the use of smaller nanobodies (~15 kDa) rather than full mAbs (~150 kDa) to improve tumor penetration.

3. The Novelty Premium: High Specificity, High Hurdles Targets like DLL3 (neuroendocrine cancers) and GPC-1 (pancreatic cancer) offer exceptional tumor specificity. DLL3, while validated, has a historically narrow therapeutic window demanding highly optimized drug design, especially with potent alpha-emitters like Ac-225. GPC-1 offers the cleanest safety profile but is less clinically validated.

The mastery of the Strategic Triad - co-optimizing the moiety's pharmacokinetics with the target's biology and the isotope's physical properties - is the true competitive differentiator.

Key Questions for Leaders

1. In validated spaces like HER2, is our differentiation strategy robust enough to compete with established ADCs, and are we leveraging the RPT bystander effect to specifically address tumor heterogeneity?

2.For high-potential targets like FAP, what specific engineering strategies (e.g., moiety selection, albumin binders) are we deploying to mitigate the known risks of on-target, off-tumor toxicity?

3.Are we optimizing the "triad" - target biology, targeting moiety pharmacokinetics, and radionuclide properties—or are we making suboptimal pairings that limit the therapeutic index?

ANALYST INSIGHT: The Search for the "Triad Master"

The complexity of novel target development exposes a critical talent bottleneck: the scarcity of R&D leaders who possess integrated expertise across the strategic "triad" of radiopharmaceutical design. The era of siloed expertise-biologists focused only on targets, chemists on linkers, and physicists on isotopes - is over.

The mission-critical profile is the **"Triad Master"**: a scientific leader capable of synthesizing deep knowledge of target biology, the nuanced pharmacokinetics of different moieties (mAbs, peptides, nanobodies), and the physical properties of various radionuclides (alpha vs. beta). This integrated understanding is essential for optimizing the therapeutic index and navigating the pervasive risks of toxicity and heterogeneity. Organizations that fail to recruit or develop this cross-functional leadership will struggle to generate differentiated assets and will remain vulnerable to clinical failure. Strategic acqui-hires focused on this translational capability are a key mechanism for gaining a competitive edge.

Where the Answers Are (The TRP Summit)

The critical debates surrounding target selection and optimization are central to the TRP Summit agenda. This is the forum to gain a competitive edge by stress-testing strategies against the latest data and industry leaders.

Key sessions addressing the Target Dilemma include:

- **Workshop A: Evolving Tumours & Smarter Targets: Advancing Novel TRPs with HER2 & FAP:** This session, featuring leaders from Affibody, is essential for understanding the strategies required to unlock these two high-priority targets.
- **HER2 Targeted Affibody Radioligand Therapy:** Fredrik Frejd (CSO, Affibody) will detail the rationale and first-in-human design for a HER2-targeted approach.
- **Towards Optimising Tumour Retention of FAP-Targeting Theranostics:** Andreas Goutopoulos (CEO, ActiThera) will address the critical challenge of optimizing FAP-targeted agents.
- **Discussions on Novel Modalities:** Insights from Molecular Partners (DARPins) and Bicycle Therapeutics (Bicyclic Radionuclide Conjugates) will explore the frontiers of moiety engineering.

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Chapter 2: The Dosimetry Debate: Precision vs. Pragmatism

The central strategic question confronting every radiopharmaceutical developer is deceptively simple: how should the patient be dosed? The answer, however, is a complex trade-off between the scientific ideal of personalized medicine and the harsh realities of operational feasibility and market scalability. This debate is no longer a niche technical discussion; driven by regulatory mandates and compelling clinical data, it is now a core determinant of competitive advantage.

The Big Picture

The industry is transitioning from an era of empirical, fixed dosing toward a paradigm of personalized, image-based dosimetry. This shift is driven by the recognition that fixed dosing inevitably leads to sub-optimal outcomes: undertreating some patients while exposing others to unnecessary toxicity. The goal is to prescribe a specific absorbed dose (in Grays), maximizing the therapeutic index for each individual. The challenge is implementing this complex approach at scale.

The Underlying Tension: The Dosimetry Trilemma and the Regulatory Hammer

The tension lies in navigating what we term the "**Dosimetry Trilemma**" - balancing Clinical Optimization, Operational Feasibility, and Commercial Scalability.

1. The Clinical Imperative vs. Operational Reality - The clinical evidence supporting personalization is powerful. The landmark DOSISPHERE-01 trial demonstrated that personalized dosimetry doubled the objective response rate compared to standard dosing. This establishes a clear ethical and clinical imperative.

However, the operational reality is stark. Widespread implementation is severely constrained by the "Human Capital Crisis": a critical global shortage of qualified medical physicists (QMPs) required for complex dose calculations. Furthermore, a significant "Standardization Gap" exists in quantitative imaging (QSPECT/CT) protocols and software validation, making reliable, multicenter dosimetry exceedingly difficult.
This creates a "Dosimetry Divide," separating elite academic centers from community practices, threatening equitable access and commercial scalability.

2. The Regulatory Hammer: Project Optimus and the End of the MTD Era - The regulatory landscape has undergone a seismic shift. The FDA's Project Optimus initiative, along with European directives (e.g., 2013/59/EURATOM), effectively ends the era of relying on the Maximum Tolerated Dose (MTD). Regulators now demand rigorous, evidence-based dose optimization.

This elevates dosimetry from a secondary safety assessment to a primary, evidence-generating tool for dose justification. The tension is clear: regulators demand sophisticated personalization, but the infrastructure and talent pool required to deliver it at scale do not yet exist.

3. The Economic Calculus - While personalized dosimetry appears expensive upfront, cost-effectiveness analyses reveal substantial long-term value by improving Quality-Adjusted Life Years (QALYs). This reframes the decision: implementing dosimetry is a strategic investment with a quantifiable return and a powerful tool for engaging with payers.

The strategic tension is acute: Can companies afford the operational burden of personalization? More critically, given the regulatory mandates and the potential for superior efficacy, can they afford not to? The emergence of "Dosimetry-as-a-Service" (DaaS) models represents a critical "bridging strategy."

Key Questions for Leaders

1.In the post-Optimus regulatory environment, is a fixed-dose strategy still viable for our asset, or are we exposing ourselves to significant regulatory risk and competitive displacement?

2.How are we addressing the "Human Capital Crisis" in medical physics? Are we strategically partnering with DaaS providers or specialist CROs to secure the expertise needed for our trials?

3. What is our strategy for navigating the "Dosimetry Divide"? How will we ensure our therapy can be delivered scalably in community settings that lack advanced physics support?

ANALYST INSIGHT: The Strategic Imperative of the 'Head of Clinical Dosimetry'

The regulatory pivot toward dose optimization has transformed dosimetry from a niche technical function into a strategic imperative. The traditional reliance on outsourced or ad-hoc physics support is no longer viable for organizations aspiring to leadership in RPT.

We advise our clients that establishing a dedicated, high-level role - a 'Head of Clinical Dosimetry' or equivalent - is now mission-critical. This leader must possess more than just technical expertise in radiation physics; they must have the strategic acumen to design and execute dosimetry-guided clinical trials that meet the rigorous demands of the FDA and EMA. This role is the linchpin connecting R&D, clinical operations, and regulatory strategy. In a market constrained by expertise, the ability to recruit and empower this profile is a direct driver of development speed and regulatory success.

Where the Answers Are (The TRP Summit)

The 7th TRP Summit is the critical venue for navigating the strategic, regulatory, and operational landscape of dosimetry. Leaders must attend to understand how competitors and regulators are approaching the precision vs. pragmatism dilemma.

Key sessions addressing the Dosimetry Debate include:

- **Translational Dosimetry Masterclass:** The Pre-Conference Workshop (Workshop B), "Bridging the Gap - Translating Dosimetry from Animal Models to Human Applications," led by Iron Fist Therapeutics and the University of Milan, is essential for understanding how to extrapolate preclinical data to inform clinical dosing.
- **The Precision vs. Pragmatism Debate:** The Roundtable Discussion (Day 1), "Rethinking Dose Strategy: Balancing Dosimetry with Practicality in Human Trials," will tackle the core operational and regulatory hurdles of implementing personalized dosing.
- **Dose Optimization in Practice:** Presentations by Precirix (Day 1) on translating dosimetry to understand biodistribution impact, and BAMF Health (Day 2) on comparing dose escalation versus accumulation strategies, provide real-world insights into optimizing treatment efficacy.

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CHAPTER 3: The Supply Chain Crisis: Vertical Integration vs. The Ecosystem

The entire radiopharmaceutical industry is built upon a foundation of profound fragility. The reliance on a small number of aging nuclear reactors, the extreme complexity of manufacturing, and the unforgiving logistics of radioactive decay have elevated supply chain management from a tactical function to a core determinant of corporate strategy and valuation.

The Big Picture

The radiopharmaceutical value chain - from isotope production to the delivery of the final drug product - is characterized by concentrated points of failure and formidable barriers to entry. The scarcity of key isotopes and the unique Chemistry, Manufacturing, and Controls (CMC) challenges form a competitive "moat" that is fundamentally reshaping the industry structure.

The Underlying Tension: The "Build vs. Buy" Crossroads

The central strategic tension is the "Build vs. Buy" decision. Companies must choose whether to invest hundreds of millions to "Build" vertically integrated capabilities or "Buy" services from a specialized, yet constrained, ecosystem.

Isotope Fragility and Scarcity:

- **Lutetium-177 (177Lu): The Fragile Workhorse.** 177Lu supply is dangerously dependent on a handful of aging research reactors prone to unexpected shutdowns. This fragility creates unacceptable risk for multi-billion-dollar franchises.
- **Actinium-225 (225Ac): The Technological Bottleneck.** The most promising alpha-emitter has been hampered by scarcity. While new accelerator-based production methods are emerging, they introduce a new bottleneck: process qualification. 225Ac from different sources has unique impurity profiles, requiring extensive CMC validation.
- **Lead-212 (212Pb): The Generator Imperative.** The extremely short half-life of 212Pb mandates a decentralized, on-site production model. The bottleneck here is the development and deployment of reliable, GMP-compliant generator systems.

The CMC "Moat": Manufacturing RPTs is defined by unique hurdles, including the "at-risk" release paradigm (releasing product before long-lead QC tests are complete) and the **Dual Mandate**. Manufacturers must satisfy both the FDA/EMA (GMP) and Nuclear Safety authorities (NRC/Euratom). This creates conflicting requirements, such as positive air pressure for sterility vs. negative pressure for radiation containment, necessitating expensive, purpose-built facilities.

The Strategic Response: Consolidation and Dependence:

This confluence of risk has triggered a strategic bifurcation:

1.The Vertical Integration Playbook ("Build"): Large Pharma is aggressively acquiring integrated platforms. Eli Lilly's acquisition of POINT Biopharma and BMS's acquisition of RayzeBio were explicitly driven by the desire to acquire their specialized manufacturing infrastructure and secured isotope supply agreements. This strategy optimizes for control but requires immense upfront investment.

2.The Ecosystem Reliance ("Buy"): For most biotechs, the CAPEX required for in-house manufacturing is prohibitive. They rely on a specialized CDMO ecosystem (e.g., Nucleus RadioPharma, ITM, AtomVie). However, demand currently outstrips supply, making access to high-quality CDMO slots a critical competitive differentiator.

The strategic calculus is clear: access to reliable manufacturing and isotope supply is now a core, value-driving asset.

Key Questions for Leaders

1.Have we truly stress-tested our isotope supply chain? Are we reliant on a single source, or have we diversified by securing agreements with multiple suppliers using different production technologies?

2.(For Big Pharma) If we have not vertically integrated, what is our strategy for mitigating the existential risk of supply disruption to a potential blockbuster drug?

3.(For Biotechs) How early have we engaged with specialized CDMOs? Do we have secured long-term manufacturing capacity, or are we exposed to the highly competitive spot market?

ANALYST INSIGHT: The Rise of the "Dual-Mandate Navigator"

The formidable CMC "moat" and the strategic imperative of securing the value chain have catalyzed the emergence of a new, mission-critical leadership profile: the Radiopharma Operations Executive. This is not a traditional pharmaceutical manufacturing role.

The required profile is the "Dual-Mandate Navigator": a leader who possesses a rare synthesis of expertise in nuclear engineering, pharmaceutical GMP compliance, and global just-in-time logistics. They must be capable of designing and operating facilities that reconcile the conflicting demands of the FDA and the NRC (the Dual Mandate), managing the complexities of "at-risk" release, and securing a fragile isotope supply chain. As vertical integration accelerates, the competition for this scarce talent pool will become a defining feature of the market. The Chief Manufacturing Officer is now a key architect of strategic value.

Where the Answers Are (The TRP Summit)

The 7th TRP Summit features an entire track dedicated to CMC & Sourcing, providing the essential platform for understanding the rapidly evolving supply chain landscape and forging critical partnerships.

Key sessions addressing the Supply Chain Crisis include:

- **CMC Strategy and Regulation:** The Pre-Conference Workshop (Workshop C), "Evaluating Regulatory Perspectives for CMC in Europe," led by **AstraZeneca, Telix Pharmaceuticals**, and **Bayer,** is essential for navigating compliance.
- **Isotope Supply Chain Resilience:** Discussions on mitigating supply challenges for **Actinium (Clarity Pharmaceuticals)** and optimizing global supply chain management (**Bayer**) will address critical bottlenecks.
- **Manufacturing Innovation:** Sessions on generator technologies (**ARTBIO**), optimizing control strategies (**RadioPharm Theranostics**), and navigating the centralised vs. decentralised manufacturing debate (**OncoOne**) will explore the future of production.
- **Logistics Management:** Workshop F, "Managing Logistics & Distribution Networks," featuring **ARTBIO** and **RadioPharm Theranostics**, will tackle the complexities of the just-in-time supply chain.

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7th Annual TRP Targeted Radiopharmaceuticals Summit EUROPE

Chapter 4: The Commercial Hurdle: European Approval vs. Actual Access

Achieving marketing authorization from the European Medicines Agency (EMA) is not the final victory; it is the entry ticket to the "European Gauntlet" - a protracted, complex, and fragmented battle for market access and reimbursement. This post-approval "valley of death" is where clinically promising therapies fail to achieve commercial viability.

The Big Picture

The central paradox of the European market is the disconnect between a unified regulatory pathway (EMA approval) and a fragmented reimbursement landscape. A single EMA authorization splinters into dozens of sovereign Health Technology Assessment (HTA), pricing, and reimbursement processes. This leads to profound delays; the average time to reimbursement for innovative treatments across the EU is 504 days. Compounding this is the acute "site readiness" bottleneck, where infrastructural limitations and specialized staff shortages constrain the capacity for adoption.

The Underlying Tension: Fragmentation and the Last-Mile Problem

The commercialization challenge in Europe is driven by two interconnected tensions: the fragmented payer landscape and the acute "site readiness" bottleneck.

1. The Fragmentation Gauntlet: Navigating the EU3 The divergence in HTA methodologies across Europe's major markets creates a complex strategic matrix.

- **Germany (G-BA): The Pricing Reckoning.** Germany offers the fastest access but presents a significant delayed risk. The AMNOG process assesses "additional benefit" after one year; a negative rating can destroy pricing power and trigger international reference pricing.
- **France (HAS): The Innovation Hurdle.** France requires upfront HTA. The ASMR (Clinical Added Value) rating dictates pricing power. Securing a high innovation rating is notoriously difficult, demanding robust comparative data.
- **UK (NICE): The QALY Barrier.** The UK market is dominated by NICE's cost-effectiveness evaluation, using a stringent cost-per-QALY threshold. Demonstrating value within this threshold is a formidable challenge, as seen in the initial rejection of Pluvicto®.

This divergence means a single evidence package is often insufficient. Clinical trials must be designed from the outset to meet the distinct requirements of each key market, not just the EMA.

2. The "Last-Mile" Problem: Site Readiness: Even with reimbursement secured, commercial uptake is severely constrained by the "last-mile problem" of site readiness. RPTs require specialized infrastructure (hot labs) and compliance with dual regulations (GMP and radiation safety). Critically, there is a systemic human capital deficit: a shortage of nuclear medicine physicians, radiopharmacists, and technologists.

This creates a "chicken-and-egg" problem: hospitals hesitate to invest without reimbursement, while payers question the budget impact if uptake is low due to a lack of ready sites. Successful commercialization requires companies to become "market-makers," actively investing in site identification and training years before approval.

Key Questions for Leaders

1.Are our pivotal clinical trials designed to generate the specific evidence required by the G-BA (comparators), HAS (clinical superiority), and NICE (QALY data)?

2.What is our launch sequence strategy for Europe? How are we balancing the rapid revenue opportunity in Germany against the risk of a negative G-BA rating?

3.How much capital are we allocating to proactive "site readiness" programs (training, infrastructure support) to accelerate uptake post-reimbursement?

ANALYST INSIGHT: The Demand for "Market Makers"

The European commercial challenge demands a fundamental shift in the profile of the commercial leader. The traditional model of launching a drug after approval and leaving adoption to the healthcare system is insufficient for RPT. The "Site Readiness" bottleneck requires leaders who are not just salespeople, but "Market Makers."

The mission-critical profile is the Head of European Commercial Operations who possesses a deep understanding of hospital infrastructure, clinical pathways, and the human capital constraints in nuclear medicine. These leaders must be capable of driving proactive, company-led strategies for site activation - mapping potential centers, providing educational grants, and supporting training programs.

Furthermore, the fragmented HTA landscape requires sophisticated Market Access Leaders who integrate payer requirements into early R&D. Organizations that fail to secure this specialized commercial and market access talent will find their assets stranded in the European "Valley of Death."

Where the Answers Are (The TRP Summit)

Navigating the European commercial gauntlet requires strategic foresight and operational excellence. The TRP Summit offers critical insights into these challenges:

- **Engaging Healthcare Providers (Workshop E):** A crucial session on models for successful implementation and transitioning theranostics to routine care, led by the **University Health Network (UHN)** (Luke Brzozwski) and **United Theranostics** (Munir Ghesani).
- **Global Harmonisation (Day 2): Debiopharm** (Angeliki Grammenos) will lead a session on understanding global differences in TRP procedure and regulation.
- **Building the Workforce (Day 2): University of Cape Town** (Stuart More) will discuss training and education strategies for TRP therapy delivery.
- **The Investor Perspective:** A panel discussion featuring **Seroba Life Sciences** and **Brookline Capital Markets** will provide insight into how investors evaluate commercial risk.

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Conclusion: A 5-Year Roadmap for Execution

The radiopharmaceutical sector is at a strategic inflection point. The "Gold Rush" phase, characterized by scientific validation and massive capital inflow, is yielding to a new era defined by the imperative of industrialized execution. The analysis presented in this report reveals a landscape where the mastery of complexity - across the entire value chain - is the ultimate competitive differentiator.

The strategic calculus is shifting. The fragility of the supply chain demands vertical awareness, if not full integration. The regulatory mandate for dosimetry requires a fundamental redesign of clinical workflows and a solution to the human capital crisis. The fragmented European market access landscape necessitates a sophisticated, evidence-driven strategy integrated into the earliest stages of R&D.
Success in the next five years will not be defined by the discovery of new targets alone, but by the ability to execute flawlessly from reactor to patient.

We offer the following high-level strategic recommendations for stakeholders focused on mastering execution:

1. For Drug Developers: Embrace Integrated Development and "Market Making" The siloed approach to R&D, CMC, and Commercialization is obsolete. Developers must integrate these functions from the outset. Design trials with the end-payer (e.g., NICE, G-BA) in mind and treat the supply chain as a strategic asset. Proactively invest in "market-making" activities, including site readiness and dosimetry capabilities, to accelerate adoption.

2. For Service Providers (CDMOs and DaaS): Solve for Scale and Standardization The ecosystem players are the essential enablers of the industry's growth. The winners in the CDMO space will be those who can offer true end-to-end solutions, integrating isotope supply, manufacturing capacity (including for alpha emitters), and last-mile logistics. Standardization is critical; the development of automated, modular manufacturing platforms and standardized dosimetry protocols will be key to bridging the "Dosimetry Divide" and enabling scalable delivery.

3. For Investors: Prioritize Execution Capability and Vertical Awareness The investment thesis must evolve beyond the lead asset. Due diligence must rigorously scrutinize the execution capability of the management team. This includes their understanding of the "Target-Moiety-Isotope Triad," the robustness of their supply chain strategy (Build vs. Buy), and the granularity of their European market access plan. Companies that demonstrate vertical awareness - understanding and controlling the process from raw material to clinical administration - will command premium valuations.

APPENDIX: My Curated Watchlist for the 7th TRP Summit

The following sessions at the 7th TRP Summit Europe (November 10-12, 2025, Amsterdam) directly address the critical issues raised in this report:

Target Innovation & Engineering:

- **(Mon, Nov 10, 9:00 AM)** Workshop A: Evolving Tumours & Smarter Targets: Advancing Novel TRPs with HER2 & FAP | Guido Wurth & Fredrik Frejd, Affibody
- **(Wed, Nov 12, 1:30 PM)** Internalisation of Targeted Radiopharmaceuticals: Strategic Imperative or Situational Choice? | Daniel Steiner, SVP, Research & Technology, Molecular Partners
- **(Wed, Nov 12, 2:30 PM)** Targeted Delivery of Radioisotopes to Solid Tumours Using Bicyclic Radionuclide Conjugates | Sandra Uhlenbroich, Director, Discovery, Bicycle Therapeutics
- **(Tues, Nov 11, 2:10 PM)** Towards Optimising Tumour Retention of FAP-Targeting Theranostics | Andreas Goutopoulos, CEO, ActiThera

Dosimetry and Clinical Strategy:

- **(Mon, Nov 10, 9:00 AM)** Workshop B: Bridging the Gap - Translating Dosimetry from Animal Models to Human Applications | Jeff Cleland, Co-Founder, Iron Fist Therapeutics
- **(Tues, Nov 11, 11:00 AM)** Engineering Targeted Radiopharmaceuticals: DEP Dendrimer Nanoparticles for Optimised Biodistribution and Efficacy | Jeremy Paull, CSO, Star Pharma
- **(Tues, Nov 11, 12:00 PM)** Translating Dosimetry to Humans to Understand the Impact of Biodistribution on Drug Efficacy | Josie Gayton, COO, Precirix
- **(Tues, Nov 11, 11:30 AM)** Rethinking Dose Strategy: Balancing Dosimetry with Practicality in Human Trials | Roundtable Discussion

Supply Chain, CMC, and Logistics:

- **(Mon, Nov 10, 9:00 AM)** Workshop C: Evaluating Regulatory Perspectives for CMC in Europe | Mark Fielding, AstraZeneca; Anil Lalwani, Telix Pharmaceuticals; Sandra Hennig, Bayer
- **(Mon, Nov 10, 1:00 PM)** Workshop F: Managing Logistics & Distribution Networks | Vimal Patel, RadioPharm Theranostics & Daniel Rossetto, ARTBIO
- **(Tues, Nov 11, 11:00 AM)** Strategies to Mitigate Isotope Supply Challenges for Actinium | Shaemus Gleason, EVP, Clarity Pharmaceuticals
- **(Tues, Nov 11, 4:30 PM)** Exploring Strategies for Improved Global Radio-Isotope & Therapy Supply Chain Management | Thomas Birger Eden-Jensen, Head, External Supply Management TRP, Bayer

Commercial Access and Implementation:

- **(Mon, Nov 10, 1:00 PM)** Workshop E: Engaging Healthcare Providers Before & During Radiopharmaceutical Rollout | Luke Brzozwski, University Health Network & Munir Ghesani, United Theranostics
- **(Wed, Nov 12, 9:00 AM)** Understanding Global Differences in TRP Procedure & Regulation | Angeliki Grammenos, Associate Lead, Global Regulatory Affairs, Debiopharm
- **(Wed, Nov 12, 1:30 PM)** Building a Skilled Workforce: Training & Education for TRP Therapy Delivery | Stuart More, Head of Department, Nuclear Medicine, University of Cape Town

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LET'S CONNECT

The conversations that solve the industry's biggest challenges don't happen in isolation - they happen in person.

The analysis in this report highlights the critical, unresolved questions facing every leader in the radiopharmaceutical space. The answers and next-level strategies will be forged at the **7th TRP Summit Europe in Amsterdam.**

I will be attending to connect with the leaders, innovators, and investors who are building the future of this modality. If you're tackling the challenges of talent, strategy, or execution in radiopharma, let's connect at the event.

Want to be part of the solution?

- Click the link below to register for the summit.
- Join the conversation that will define the next era of radiopharmaceuticals.
- **Register for TRP Summit Europe in November 2025.**

REGISTER NOW

7th Annual TRP Targeted Radiopharmaceuticals Summit EUROPE

Byron Fitzgerald
Founder, ProGen Search
www.progensearch.com