ProGen Search

RADIOPHARMA CLINICAL DEVELOPMENT REPORT

The State of Clinical Development in Radiopharmaceuticals.

Prepared for Clinical Consultants, CRO Selection Decision-Makers, RLT Biotech C-Suite, and Investors.

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The State of Clinical Development in Radiopharmaceuticals – 2025 Outlook

An Insight-Rich Analysis for Biotech Executives, Clinical Consultants, CRO Decision-Makers, and Investors

Disclaimer

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Chapter 1. Executive Summary

The period from 2023 through 2025 marks a pivotal transformation for the radioligand therapy (RLT) sector. Validated by the blockbuster commercial success of Novartis's Pluvicto® and Lutathera®, the field has transitioned from a niche area of oncology to a strategic battleground for major pharmaceutical companies. This has fueled a surge in investment, M&A activity, and a robust pipeline of over 320 clinical trials. However, this explosive growth is colliding with a fragile, underdeveloped clinical infrastructure, creating a central paradox for the industry.

Key Insights & Inflection Points:

- **The Great Consolidation:** A wave of multi-billion-dollar acquisitions by Eli Lilly (POINT Biopharma, $1.4B), Bristol Myers Squibb (RayzeBio, $4.1B), AstraZeneca (Fusion Pharmaceuticals, $2.4B), and Novartis (Mariana Oncology, $1.75B) has fundamentally reshaped the competitive landscape. The strategic focus has been on acquiring not just drug candidates, but entire RLT ecosystems—including manufacturing facilities, specialized talent, and, most critically, access to the next generation of high-potency alpha-emitting isotopes.
- **The Alpha Emitter Revolution:** The strategic pivot toward alpha-emitting isotopes like Actinium-225 (^{225}Ac) and Lead-212 (^{212}Pb) is the dominant technological trend. These isotopes promise greater potency and the ability to overcome resistance to established beta-emitters like Lutetium-177 (^{177}Lu). This shift, however, exacerbates the critical bottleneck of isotope supply, making supply chain control a paramount strategic advantage.
- **A New Clinical Benchmark in Prostate Cancer:** The head-to-head battle in metastatic castration-resistant prostate cancer (mCRPC) has a clear victor. The success of Novartis's PSMAfore trial led to a landmark FDA label expansion for Pluvicto®, tripling its addressable market. In contrast, the competing SPLASH trial for PNT2002 (POINT/Lilly) failed to show a compelling overall survival benefit, leading to its discontinuation by the commercial partner. This outcome has set a new, higher bar for future market entrants.

- **The Clinical Support Gap:** The number of true RLT-specialist Contract Research Organizations (CROs) is dangerously small compared to the explosion in clinical development. This scarcity is forcing a structural shift where expert Contract Development and Manufacturing Organizations (CDMOs) and specialist consultancies are stepping in to provide critical clinical strategy and trial oversight, blurring the traditional lines between manufacturing and clinical services.
- **The Infrastructure Paradox:** The primary constraint on RLT development is not scientific potential but severe, interconnected infrastructure bottlenecks. A critical shortage of trial-ready clinical sites, specialized workforce (nuclear physicians, physicists, radiopharmacists), and advanced imaging capacity creates a fundamental ceiling on trial execution.

Strategic Implications:

For the period ahead, success will be defined by the ability to navigate this complex environment. The future belongs to integrated players with robust platforms, control over their manufacturing and isotope supply chains, and a pipeline diversified across both alpha- and beta-emitters targeting novel cancer pathways. Overcoming the systemic infrastructure deficits will require a concerted, multi-stakeholder effort involving investment in workforce development, adoption of hub-and-spoke clinical trial models, and creative partnerships with the few specialized service providers who possess true RLT domain expertise.

Chapter 2. The Evolving RLT Trial Landscape

The global clinical trial landscape for RPT provides a clear, data-driven picture of the industry's focus and trajectory. Analysis of active Phase I-III trials reveals a concentration of late-stage development in established targets using proven isotopes, alongside a surge of early-stage innovation exploring next-generation technologies.

ProGen Search's View: The current trial landscape reveals a clear bifurcation. Late-stage assets are dominated by ^{177}Lu-based therapies aiming for label expansion or "fast-follower" status in proven indications. In contrast, over 70% of new trial starts in the last 18 months have involved alpha-emitters or novel targets. This indicates that while near-term commercial battles will be fought with beta-emitters, the long-term value creation is predicated on the success of the alpha-emitter pipeline.

Global Registry of Active RLT Trials (Mid-2025 Snapshot)

The following registry (**next page**), compiled from ClinicalTrials.gov and the EU's CTIS, represents a snapshot of active radiopharmaceutical therapy trials.

Sponsor Name	Trial ID	Trial Phase	Therapeutic Agent & Isotope(s)	Therapeutic Target / Indication	Country / Region(s)
Phase III Trials					
Novartis Pharmaceuticals	NCT03972488 (NETTER-2)	Phase III	[^{177}Lu]Lu-DOTATATE (Lutathera®)	G1/G2 Gastroenteropancreatic Neuroendocrine Tumors (GEP-NETs)	Global
Novartis Pharmaceuticals	NCT04720157 (PSMAddition)	Phase III	[^{177}Lu]Lu-PSMA-617 (Pluvicto®)	Metastatic Hormone-Sensitive Prostate Cancer (mHSPC)	Global (20 countries)
Novartis Pharmaceuticals	NCT04689828 (PSMAfore)	Phase III	[^{177}Lu]Lu-PSMA-617 (Pluvicto®)	mCRPC (pre-taxane)	Global
RayzeBio (BMS)	NCT05477576 (ACTION-1)	Phase III	[^{225}Ac]Ac-DOTATATE (RYZ101)	GEP-NETs (post-^{177}Lu-SSTR RLT)	Global
ITM Isotope Technologies	NCT03049189 (COMPETE)	Phase III	[^{177}Lu]Lu-Edotreotide	G1/G2 GEP-NETs	Global
Telix Pharmaceuticals	NCT04876651 (ProstACT GLOBAL)	Phase III	[^{177}Lu]Lu-rosopatamab (TLX591)	mCRPC	Australia, Europe, USA
Actinium Pharmaceuticals	NCT02665065 (SIERRA)	Phase III	[^{131}I]I-apamistamab (Iomab-B)	Relapsed/Refractory Acute Myeloid Leukemia (AML)	USA, Canada
Phase II Trials					
Fusion Pharma (AstraZeneca)	NCT06402331 (AlphaBreak)	Phase II/III	[^{225}Ac]Ac-PSMA-I&T (FPI-2265)	mCRPC (post-^{177}Lu-PSMA RLT)	USA, Australia
Orano Med LLC	NCT05153772	Phase II	[^{212}Pb]Pb-DOTAMTATE (AlphaMedix™)	Neuroendocrine Tumors (PRRT-naïve and pre-treated)	USA
EORTC	NCT06783348	Phase II	[^{177}Lu]Lu-PSMA-617	Advanced Kidney Cancer (PSMA positive)	Europe
Phase I Trials					
Bayer	BAY 3547926	Phase I	[^{225}Ac]Ac-GPC3	Advanced Hepatocellular Carcinoma (HCC)	Not specified
Janssen R&D	NCT04644770	Phase I	[^{225}Ac]Ac-DOTA-h11B6	Advanced Prostate Cancer	USA
Perspective Therapeutics	NCT05636618	Phase I/IIa	[^{212}Pb] VMT-α-NET	Neuroendocrine Tumors (NETs)	USA

Note: This is an abbreviated list highlighting key representative trials. A full list would encompass hundreds of studies.

Chapter 3. Strategic Deep Dive: A Comparative Analysis of RLT Development Programs

The radioligand therapy landscape is a dynamic battlefield where leading companies are deploying highly differentiated strategies to secure a competitive edge. The approaches of Novartis, Eli Lilly/POINT, Actinium, AstraZeneca/Fusion, and Orano Med diverge significantly across every key dimension: choice of isotope, market positioning, clinical trial design, regulatory philosophy, and supply chain control.

Company (Acquirer)	Lead RLT Asset	Target & Biomarker	Isotope (Type)	Patient Population (Lead Indication)	Defining Strategic Feature
Novartis	Pluvicto	PSMA	^{177}Lu (Beta)	mCRPC (pre- and post-taxane)	**Expand the Empire:** Leverage first-mover advantage and scale to dominate existing markets while acquiring next-gen tech.
Eli Lilly / POINT	PNT2002	PSMA	^{177}Lu (Beta)	mCRPC (pre-taxane)	**Buy and Challenge:** Acquire late-stage assets and infrastructure to rapidly challenge the incumbent head-on.
Actinium Pharma	Iomab-B	CD45	^{131}I (Beta/Gamma)	r/r AML (BMT Conditioning)	**Niche Disruption:** Target high-unmet-need hematologic indications with novel biomarkers and alpha-emitters.
AstraZeneca / Fusion	FPI-2265	PSMA	^{225}Ac (Alpha)	mCRPC (post-^{177}Lu RLT)	**Post-Lutetium Alpha Attack:** Pure-play bet on ^{225}Ac superiority, targeting the growing market of beta-emitter failures.
Orano Med	Alpha Medix	SSTR	^{212}Pb (Alpha)	GEP-NETs (PRRT-naïve & post-PRRT)	**Vertical Integration Dominance:** Leverage nuclear heritage for a proprietary isotope (^{212}Pb) and an unrivaled supply chain.
Perspective Therapeutics	VMT-α-NET	SSTR	^{212}Pb (Alpha)	SSTR-Positive NETs (PRRT-naïve & post-PRRT)	**Self-Reliance Through Innovation:** Pioneering ^{212}Pb with a proprietary benchtop isotope generator to control supply.

Case Study 1: Novartis — The Incumbent's "Defend, Expand, Innovate" Strategy

- **Overall Strategy:** As the pioneer and market leader, Novartis is executing a classic incumbent strategy. They are defending their ^{177}Lu-based empire by methodically conducting large trials (PSMAfore, NETTER-P) to expand Pluvicto and Lutathera into earlier treatment lines, maximizing their commercial lifespan. Simultaneously, they are innovating to preempt disruption, acquiring alpha-emitter technology (Mariana Oncology) to ensure they lead, rather than are displaced by, the next wave of technology.
- **Trial Design & Regulatory Success:** Novartis wrote the regulatory playbook for RLTs, pairing each therapeutic with a companion diagnostic (e.g., Pluvicto and Locametz) to create a powerful theranostic franchise. The successful PSMAfore trial, which used rPFS to secure a label expansion despite confounded OS data, demonstrates their mastery of clinical design and regulatory negotiation.
- **Supply Chain as a Moat:** Having learned from early post-launch supply shortages, Novartis has invested massively in building a resilient global manufacturing network, including new facilities in Indianapolis and Carlsbad. This vertical integration is now a core component of their competitive strategy.

Case Study 2: Eli Lilly / POINT Biopharma — The "Buy and Challenge" Strategy

- **Overall Strategy:** Eli Lilly's $1.4B acquisition of POINT Biopharma was a textbook "buy, don't build" strategy, allowing it to instantly become a major player. The acquisition provided late-stage assets (PNT2002, PNT2003), a full pipeline, and turnkey manufacturing capabilities, positioning Lilly as a "fast-follower" to directly challenge Novartis.
- **Trial Design & Regulatory Setback:** The SPLASH trial for PNT2002 was a direct challenge to Pluvicto. While it met its rPFS primary endpoint, the benefit was less robust than Pluvicto's, and a high patient crossover rate led to a weak Overall Survival signal. This ultimately caused the commercial partner to terminate involvement and serves as a crucial lesson: in a competitive market, meeting the primary endpoint is not always enough.
- **A Disruptive Gambit:** In contrast, POINT's strategy for PNT2003, a generic version of Lutathera, is highly disruptive. By filing an Abbreviated New Drug Application (ANDA) with a Paragraph IV certification, they are challenging Novartis's patents, signaling a future of price-based competition for first-generation RLTs.

Case Study 3: AstraZeneca / Fusion Pharma — The "Post-Lutetium Alpha Attack"

- **Overall Strategy:** The $2.4B acquisition of Fusion represents a pure-play bet on the superiority of alpha-emitters. Their strategy with lead asset FPI-2265 is not to compete with Pluvicto, but to become the go-to therapy for patients *after* they have failed a ^{177}Lu-based RLT. This "successor therapy" approach targets a clear and growing unmet need.
- **Trial Design & Regulatory Clarity:** Fusion's pivotal AlphaBreak trial is strategically designed to enroll mCRPC patients who have progressed on Pluvicto. By aligning with the FDA on this design, they have a clear registrational path in a well-defined population, minimizing regulatory risk.
- **Supply Chain as a Weapon:** Fusion's core advantage is its obsessive focus on building a premier ^{225}Ac supply chain. Through multiple partnerships and innovative on-site generator technology, they have created a diversified and resilient supply network, a massive competitive advantage in the resource-constrained alpha space.

Case Study 4: Actinium Pharmaceuticals — The Niche Disruptor

- **Overall Strategy:** Actinium has deliberately avoided the crowded solid tumor space, focusing instead on the high-unmet-need of relapsed/refractory Acute Myeloid Leukemia (AML). Their lead asset, Iomab-B, is positioned not just to treat AML, but to enable more patients to receive a potentially curative Bone Marrow Transplant (BMT).
- **Trial Design & A Painful Regulatory Lesson:** The pivotal SIERRA trial for Iomab-B successfully met its primary endpoint of durable Complete Remission (dCR), which was previously agreed upon with the FDA. However, the FDA ultimately rejected the BLA, prioritizing the lack of a statistically significant OS benefit, which was confounded by high patient crossover. This setback is a critical cautionary tale for the industry about the supreme importance of the OS endpoint.
- **Isotope and Biomarker Strategy:** The company is now pivoting to its ^{225}Ac platform, leveraging its proprietary cyclotron-based production method. Their strategy of targeting CD45 and CD33 is unique and tailored to their hematology focus, and they are now exploring the use of their agents to deplete immunosuppressive cells in solid tumors, opening a new avenue for growth.

Case Study 5: Orano Med — The Vertically Integrated Innovator

- **Overall Strategy:** A subsidiary of a global nuclear technology leader, Orano Med is pioneering therapies based on a different alpha-emitter: Lead-212 (^{212}Pb). Their strategy is one of complete vertical integration, controlling every step from a proprietary isotope source to global manufacturing.
- **Trial Design & Clinical Success:** Their lead asset, AlphaMedix, targets the same SSTR receptor as Lutathera, allowing for a direct comparison of their alpha-emitter against the established beta-emitter. By enrolling both treatment-naïve and post-RLT patients, they are simultaneously pursuing a head-to-head and a successor therapy strategy. The strong early data led to AlphaMedix becoming the first-ever targeted alpha therapy to receive FDA Breakthrough Therapy Designation.
- **The Lead-212 Advantage:** Orano Med argues that ^{212}Pb offers an optimal half-life for smaller ligands and the unique advantage of built-in SPECT imaging capability. Their unrivaled, non-reactor-based supply chain insulates them from the isotope scarcity plaguing the rest of the field, positioning them as a dominant force in the future of alpha therapy.

Case Study 6: Perspective Therapeutics - The Self-Reliant ^{212}Pb Pioneer

- **Overall Strategy:** Perspective Therapeutics is executing a focused, vertically integrated strategy centered on pioneering the use of Lead-212. Rather than relying on external producers, their core strategy is to achieve "self-reliance" and de-risk their clinical programs by developing proprietary, scalable technology to secure their own isotope supply chain. They are targeting both well-validated pathways (SSTR in NETs) and novel targets to build a deep pipeline based on their platform.
- **Trial Design & Theranostic Focus:** The company's clinical programs are built on a true theranostic-pair model, using 203Pb for SPECT imaging to select patients and conduct dosimetry, followed by therapy with 212Pb. Their Phase I/IIa trial (NCT05636618) for VMT-α-NET in neuroendocrine tumors is designed to establish safety and preliminary efficacy, leveraging imaging data to confirm biodistribution and inform dose selection, in line with the FDA's Project Optimus principles.
- **Supply Chain as the Core Asset:** Perspective's most significant differentiating feature is its investment in a proprietary, benchtop isotope generator (VMT-α-GEN) for producing 212Pb. By controlling the means of production

at the point of care, the company aims to bypass the widespread isotope scarcity and logistical fragility affecting the broader industry. This approach not only supports their own clinical trials but is designed to be scalable for commercial-stage manufacturing, making supply chain control their central competitive advantage.

Chapter 4: The RLT Trial Execution Gauntlet: Deconstructing the Operational Bottlenecks

While the strategic chess match between RLT developers captures headlines, the true war is won or lost in the trenches of clinical trial execution. For radiopharmaceuticals, the conventional three-phase development pathway is merely a map; navigating the territory requires overcoming a gauntlet of unique operational, logistical, and physics-based hurdles that do not exist in traditional oncology.

A generalist approach to trial management is not just suboptimal here; it is a direct path to catastrophic delays, budget overruns, and program failure. This chapter deconstructs the five core operational and strategic bottlenecks that define the RLT trial, using highly specific, recent examples to illustrate the immense friction points where even the most promising science can be brought to a standstill.

The Site Activation Nightmare

Before the first patient can be dosed, a site must be deemed not just clinically capable, but radiologically competent. This is a multi-layered qualification process where most world-class oncology centers fail, often due to the isotope itself.

- **The Licensing Labyrinth: The Fusion Pharma Case Study:** The term “administrative complications” is often a euphemism for a multi-month licensing battle. A definitive real-world example is **Fusion Pharmaceuticals' FPI-1966 trial**, which experienced significant delays explicitly attributed to "administrative complications with various review boards for radiopharmaceuticals at the trial sites." The root of this issue lies in the physics of accelerator-produced Actinium-225, which often contains trace amounts of the long-lived impurity **Actinium-227 (t½ = 21.8 years)**. Under NRC regulation 10 CFR 30.35, possessing even microcurie amounts of this impurity can trigger a requirement for **Decommissioning Financial Assurance**—a substantial, long-term financial liability that many university hospitals are unwilling to assume for a single trial. This, combined with the need for costly, specialized long-lived radioactive waste disposal protocols, creates a formidable and often insurmountable barrier to site activation.
- **The Infrastructure & Physics Audit:** A site audit goes far beyond checking for clinic space. It is a rigorous physics and engineering assessment applying the core principles of radiation protection: time, distance, and shielding. Can the flooring in the proposed "hot lab" support the weight of multi-ton lead shielding? Are dose calibrators and contamination monitors (e.g., pancake probes) properly calibrated? Does the HVAC system provide the required negative air pressure to contain airborne particles—a direct conflict with the positive pressure required for sterile pharmaceutical cleanrooms? For alpha-emitters, the focus shifts from penetrating gamma radiation to the extreme hazard of microscopic airborne contamination, demanding even more stringent containment protocols.
- **The Ethics Committee (IRB) Education Gap:** Institutional Review Boards are experts in clinical risk, but often novices in nuclear physics. A protocol involving an alpha-emitter will inevitably face intense scrutiny on radiation safety and staff exposure. The sponsor must proactively provide a clear "risk-translation" package for the committee, including specific patient-facing consent language that accurately conveys radiation risks without being alarmist. Failure to manage this educational process can add months of back-and-forth queries to the approval timeline.

The "Just-in-Time" Patient Logistics Crisis

The radiopharmaceutical itself imposes a brutal, unyielding timeline on the entire clinical operation. The "melting ice cube" metaphor is not just a manufacturing challenge; it dictates every aspect of patient logistics.

- **The Tyranny of the Decay Clock:** The usable life of a dose begins its countdown long before shipment, as a significant portion of the isotope's half-life is consumed by the CDMO's own post-production sterility and quality control testing. Once shipped, a customs delay or a grounded flight is not an inconvenience; it is a direct threat to the patient's treatment, creating immense pressure on the entire on-site clinical team.
- **The Fragile Courier Ecosystem:** The transport of Class 7 radioactive hazardous materials is handled by a tiny, specialized ecosystem of providers. This lack of redundancy creates a critical single point of failure and gives these niche logistics players significant pricing power.
- **Decentralizing the Dose: The Jubilant/SIS Model:** The scarcity of RLT-capable sites is a major barrier to patient recruitment. To solve this, innovative "hub-and-spoke" models are emerging. A prime example is the 2024 partnership between **Jubilant Radiopharma** and **Simplified Imaging Solutions (SIS)**. Their model abstracts the complexity away from community-based "spoke" sites by offering a **"turnkey" service that consolidates the radiopharmaceutical, imaging equipment, certified technologists, and licensing into a single, flat fee per test.** This transforms a prohibitive capital investment into a simple operating expense, potentially enabling hundreds of community oncology practices to participate in RLT trials.

The Imaging & Dosimetry Data Quagmire

In an RLT trial, imaging is not merely a tool for assessing tumor response. It is the fundamental data acquisition process for determining the safety and activity of the drug.

- **Imaging as the True Phase I Endpoint:** A first-in-human RLT trial is, at its core, a human biodistribution study captured through SPECT/CT or PET/CT scans. The primary goal is to answer the question: "Where did the radioactivity go, and what absorbed radiation dose did it deliver to the tumor and healthy organs?" This patient-specific dosimetry data, often calculated using software like OLINDA/EXM, is the ultimate confirmation of the agent's safety profile.
- **The Industrialization of Dosimetry:** Historically, dosimetry has been a fragmented, site-specific academic exercise, creating data variability. This is now changing. A landmark example is the 2025 strategic partnership where the global CRO **Medpace designated Voximetry's AI-powered Torch® Dose Assessment software as a preferred solution.** This move signals the "industrialization" of dosimetry, centralizing analysis within a single, validated platform to ensure that data from a global, multi-center trial is consistent, harmonized, and suitable for regulatory submission.
- **The Dosimetry Workflow Bottleneck:** Despite advances in AI, the core process of generating a dosimetry report often relies on a physicist manually drawing "regions of interest" (ROIs) on hundreds of image slices. This introduces significant inter-reader variability and is a major data analysis bottleneck that directly impacts the speed of dose escalation decisions. While platforms like Torch® are automating this, their validation for use as a primary tool in a pivotal trial remains a high bar.

The On-Site Operational Maze

The final set of hurdles occurs at the clinical site itself, where the complex protocol must be executed flawlessly under intense time pressure.

- **The Radiopharmacy Pressure Cooker & the 14-Day Window:** The on-site radiopharmacist operates under immense pressure, created by the need to release a dose "at-risk" for administration *before* the traditional 14-day sterility test is complete. To solve this, the industry is adopting rapid microbiological methods (RMMs). A key example is the leading CDMO **Samsung Biologics selecting Rapid Micro Biosystems' Growth Direct® platform**, which can reduce the time to a final sterility result to as little as 1-3 days. This technology is a fundamental shift in risk management, enabling a true "test-and-release" model that de-risks the entire supply chain.
- **The Reverse Logistics of Radioactive Waste:** The operational burden does not end at administration. Every item that contacts the drug becomes low-level radioactive waste. More complex is the management of patient excreta, as patients may excrete up to 75% of the injected radioactivity. This requires dedicated, shielded bathrooms for inpatients and extensive education for outpatients on safely managing waste at home to prevent contamination and exposure to family members.

The Regulatory & Reimbursement Dissonance

Even with flawless execution, a final strategic hurdle remains: designing a trial that satisfies two different masters—regulators and payers.

- **The "Theranostic Pair" Challenge: A Cautionary Tale:** The path to securing reimbursement for a companion diagnostic PET agent can be a decade-long odyssey. The definitive cautionary tale is the history of **amyloid PET tracers for Alzheimer's disease.** For a decade, access was crippled by Medicare's restrictive **"Coverage with Evidence Development" (CED)** policy and a **"packaged payment trap"** where hospitals lost over $1,500 on every scan performed. It was only after intense advocacy and the approval of new anti-amyloid therapies that CMS reversed course.
- **The New $630 Reimbursement Threshold:** The resolution of the amyloid PET saga created a new strategic benchmark. Effective **January 1, 2025, CMS will unbundle and provide separate payment for diagnostic radiopharmaceuticals with a per-day cost exceeding a $630 threshold.** A diagnostic priced below this risks falling into the packaged payment trap, while one priced above it has a viable path to market. This policy will profoundly influence the pricing and market access strategies for all future theranostic pairs.

ProGen Search's View: These operational and strategic bottlenecks—not scientific potential—are now the primary rate-limiting factor in RLT clinical development. They represent a new front line where deep, specialist expertise is not just valuable, but essential for survival. Navigating this gauntlet requires a paradigm shift away from generalist outsourcing and towards partnerships with true experts who have the firsthand experience to anticipate and solve these complex, interconnected challenges. The companies that master this execution will be the ones that deliver on the immense promise of radiopharmaceuticals.

Chapter 5. The Talent Crisis: Assembling a World-Class RLT Clinical Team

The unique nature of RLTs has created unprecedented demand for a new, highly specialized type of clinical and operational leader. The scarcity of qualified individuals is now a primary gating factor for program progression and a key driver of M&A strategy, where acquiring intact, experienced teams is a core objective.

ProGen Search's View: We estimate that the demand for VPs of Clinical Development and CMOs with direct alpha-emitter experience now exceeds the available talent pool by a factor of 5 to 1. This talent scarcity is forcing companies to consider candidates with strong beta-emitter or ADC experience and is driving compensation packages to a 20-25% premium over equivalent roles in traditional oncology.

The "Tri-Brid" Profile: The Quintessential RLT Leader

The ideal clinical leader in an RLT organization is a rare "tri-brid" professional, embodying deep expertise across three distinct domains:

1. **The Clinical Oncologist:** An MD with board certification in Oncology or Radiation Oncology is the non-negotiable foundation.
2. **The Nuclear Medicine Expert / Physicist:** A profound, practical understanding of nuclear medicine, radioactive decay, radiation safety, and dosimetry is essential.
3. **The Seasoned Pharma Executive:** Comprehensive drug development experience is required to guide a product from lab to global commercialization.

What Does a World-Class Clinical RLT Team Look Like?

Assembling the right team is critical, especially when preparing for a pivotal trial like a Phase II alpha-emitter study. A lean but expert team must cover all core radiopharmaceutical competencies. Some innovative sponsors, like Curie Therapeutics, have made the strategic decision to build this entire clinical infrastructure internally to maintain control and avoid outsourcing to non-specialist partners.

Core Team Structure for a Phase II Alpha-Emitter Trial:

- **Chief Medical Officer (CMO) / VP, Clinical Development:** The "tri-brid" strategic leader.
- **VP/Director, Clinical Operations:** Manages the complex logistics of sites and isotope delivery.
- **Director, Regulatory Affairs (RLT Focus):** Navigates the dual FDA/NRC requirements and global submissions.
- **Head of CMC & Supply Chain:** Oversees isotope sourcing, manufacturing, and "hot" logistics.
- **Senior Medical Director:** Provides day-to-day clinical oversight of the trial.
- **Lead Imaging Scientist:** Manages the companion diagnostic strategy and imaging core lab.
- **Medical Physicist / Dosimetry Lead:** Responsible for the dosimetry plan and analysis.
- **Radiation Safety Officer (RSO):** Ensures compliance across all clinical operations.

Chapter 6: The Clinical Support Ecosystem: A Sponsor's Guide to Key Service Partners

Introduction: The unique scientific and logistical demands of Radioligand Therapy (RLT) trials have created a pivotal dependency on a small, specialized ecosystem of clinical support partners. As this report highlights, the number of Contract Research Organizations (CROs) with true, deep, end-to-end RLT expertise is dangerously small compared to the explosion in clinical development. A general background in oncology is insufficient; successful execution requires direct experience with isotope logistics, radiation safety, and nuclear medicine imaging protocols. For a sponsor, navigating this landscape is a mission-critical task, and choosing a non-specialist partner often leads to predictable setbacks. This chapter provides a guide to some of the key service partners who possess the requisite, demonstrated domain expertise. While not an exhaustive list of every company in the sector, the organizations profiled below represent a cross-section of the specialized capabilities available to sponsors and have been vetted for explicit, verifiable experience in the radiopharmaceutical field.

6.1. Full-Service & Specialist Radiopharmaceutical CROs

ProGen Search's View: The CRO landscape for radiopharmaceuticals is a clear example of a market struggling to keep pace with scientific innovation. The field is consolidating around a handful of trusted "Specialist Leaders" (PSI, ABX-CRO) who are repeatedly selected for high-stakes pivotal trials, creating a capacity bottleneck. This has created a vacuum, now being filled by global CROs (Worldwide, Fortrea) that have invested in dedicated RLT units and by preclinical specialists (like TRACER) who provide the critical early-stage support needed to get novel candidates into the clinic. For a sponsor, the key takeaway is that partner selection is not just a matter of capability, but of securing a slot with the few teams who have a proven track record of navigating the unique operational hurdles of RLTs.

- **PSI CRO (Switzerland):** A global CRO widely recognized as a "Specialist Leader" due to its dedicated radiopharmaceutical division and public track record of managing pivotal RLT studies, including expertise in isotope logistics and site selection.
- **ABX-CRO (Germany):** A German-based, full-service international CRO with a singular, foundational focus on nuclear medicine and radiopharmaceuticals, making it another undisputed "Specialist Leader".
- **Medpace (USA):** While a broad CRO, it is considered an "Integrated Powerhouse" in RLT due to its unique, formally structured model that combines full-service trial execution with in-house medical physics and dosimetry capabilities.
- **Worldwide Clinical Trials (USA):** A global CRO that backs its RLT trial capabilities with a dedicated "Radioligand Therapy (RLT) Clinical Trials" service line and expert team, managing complex operational requirements for this modality.
- **Fortrea (USA):** This global CRO provides comprehensive support for RLT trials through its dedicated medical imaging group, which has deep expertise in nuclear medicine and advanced data analysis for theranostics.
- **Ergomed (UK):** A global CRO focused on complex diseases. Its specialized oncology unit explicitly lists and manages radiopharmaceutical trials, leveraging its experience in navigating the demands of advanced therapies.
- **Radiomedix (USA):** A unique hybrid, operating as a clinical-stage innovator and a full-service CDMO. With firsthand experience guiding its own alpha-therapy pipeline through the FDA, it offers deep, practical clinical execution expertise to partners.

- **TRACER (Denmark):** A "niche enabler" focused on preclinical and early-phase development, providing critical support for companies transitioning their RLT candidates into the clinic.

6.2. Imaging Core Labs & Software Providers

ProGen Search's View: In radiopharmaceutical development, imaging is not merely a supportive endpoint; it is often the primary determinant of a drug's viability and a cornerstone of the "see it, treat it" paradigm. This elevates the role of the imaging core lab from a vendor to a central strategic partner. The players in this segment, supporting both preclinical (Minerva) and clinical (Perceptive, ICON) stages, are essential for ensuring the standardized, high-quality, and quantifiable imaging data required for regulatory submission. The rise of AI-powered analysis (Median, IAG) signals a future where image interpretation becomes faster, more objective, and capable of yielding novel predictive biomarkers, directly addressing the need to de-risk these expensive trials.

- **Minerva Imaging (Denmark):** A science-driven preclinical CRO and CDMO with a strong focus on *in vivo* pharmacology and advanced imaging to support radiopharmaceutical development from target validation through to first-in-human trials.
- **Perceptive (Invicro, a Konica Minolta company) (USA/UK):** A leading "Specialist Leader" in imaging, offering deep, integrated expertise in radiochemistry and radiopharmacology modeling to support novel radiotracer development and clinical trials.
- **ICON Medical Imaging (Ireland):** The highly specialized imaging division of ICON plc. It functions as a global imaging core lab with extensive, dedicated experience in PET/CT and SPECT/CT for large-scale RLT trials.
- **Clario (USA):** A major clinical trial data company with specific, dedicated technology and scientific expertise for managing nuclear medicine imaging, ensuring high-quality, standardized data across global trial sites.
- **WCG Imaging (USA):** A specialized imaging core lab that provides comprehensive services for clinical trials, including advanced protocol design, nuclear medicine site qualification, and centralized image analysis for RLTs.
- **Median Technologies (France):** An AI-focused company that develops and provides advanced software and services for medical image analysis (iBiopsy®), with a strong focus on enhancing precision in oncology and nuclear medicine imaging.
- **Keosys Medical Imaging (France):** An imaging CRO with a specific focus on nuclear medicine, providing centralized image collection, quality control, and expert reading services for trials in Europe and the US.
- **IAG, Image Analysis Group (UK):** An imaging-focused CRO that leverages AI and advanced analytics to de-risk trials, with platforms and expertise tailored to the unique imaging biomarker endpoints in RLT studies.
- **MIM Software (USA):** A key medical imaging software company whose vendor-neutral solutions (including MIM SurePlan MRT) are widely used for image fusion, quantitative analysis, and dosimetry in RLT trials.
- **Hermes Medical Solutions (Sweden):** A specialist in integrated software for nuclear medicine, providing comprehensive solutions for image processing, quantification, and dosimetry planning (OLINDA/EXM) with a strong theranostics focus.

6.3. Dosimetry Service & Software Providers

ProGen Search's View: The "Dosimetry Mandate" is no longer a future prediction; it is a present-day reality. Driven by regulatory initiatives like Project Optimus, dosimetry has shifted from an exploratory endpoint to a required component of the data package used to justify dose selection. This has transformed dosimetry providers from niche academic consultants into indispensable partners for any serious clinical program. The challenge for the industry remains establishing a standardized, scalable, and cost-effective workflow for multicenter trials. Companies that provide not just software but also centralized analysis services (Voximetry, MPC, Oncosia) are particularly valuable, as they allow sponsors to outsource this highly specialized function and ensure consistency across their trial network.

- **Oncosia Scientific GmbH (Germany):** A specialized start-up providing clinical trial services as a dedicated imaging and dosimetry vendor. The company offers an in-house, FDA-approved, and CE-marked dosimetry software solution, supported by a team of medical physics experts.
- **Voximetry (USA):** A "niche enabler" and key dosimetry specialist whose software and services are used for dosimetry calculation and analysis in clinical trials.
- **Radialogica (USA):** A software company providing platforms to centralize and analyze imaging and data for personalized radiopharmaceutical dosimetry and quality control.
- **DOSIsoft (France):** A specialist software provider whose PLANET® Dose platform is an FDA-cleared and CE-marked solution for 3D, patient-specific internal dosimetry based on PET/SPECT images.
- **Medical Physics Consultants (MPC), Inc. (USA):** A leading independent consulting firm providing radiation physics and medical physics services, including clinical trial dosimetry, quality assurance, and regulatory compliance support.
- **Mirion Technologies (USA):** A global leader in radiation measurement. Its services and wearable dosimeters are essential for monitoring occupational exposure and ensuring the safety of clinical site staff during RLT trials.

6.4. Specialized Lab & Analytical Services

ProGen Search's View: Central labs supporting RLT trials face a unique dual challenge: managing the complex logistics of time-sensitive, often radioactive patient samples while performing sophisticated biomarker analyses. The players in this segment are not interchangeable with standard oncology labs. They must possess the licenses, shielding, and expertise to handle radioactive materials safely. This has created an ecosystem that includes not only dedicated service lines from major labs but also, crucially, highly specialized services from European public research hubs (SCK CEN), academic-linked centers (CMIT), and niche providers focused on QC and early-stage analysis (CUP Contract Labs, Moravek).

- **SCK CEN (Belgium):** A globally recognized public research hub and a cornerstone of the European nuclear landscape that provides preclinical CRO services and specialized analysis through its extensive R&D partnerships.
- **CMIT (Center for Molecular Imaging and Therapy) (USA):** A research-focused institute that provides extensive and well-defined radiopharmaceutical quality control services to external partners.
- **CUP Contract Labs (Germany):** A GMP-certified contract laboratory focused exclusively on the chemical and microbiological analysis of radiopharmaceuticals, providing critical quality control and release testing services.

- **Medi-Radiopharma (Hungary):** While also a CDMO, this Hungarian firm has a distinct and established service line for GLP-compliant contract research and QC method development for external partners.
- **Moravek (USA):** A highly respected provider specializing in custom radiosynthesis of GMP-compliant Carbon-14 and Tritium labeled APIs for drug metabolism (DMPK) studies, a key part of the early-phase clinical package.

6.5. Strategic, Regulatory & Quality Consultancies

ProGen Search's View: These niche advisory groups are the most direct solution to the "Talent Crisis" this report details. They provide the on-demand strategic horsepower—the "tri-brid" expertise across clinical oncology, nuclear medicine, and pharma development—that is exceptionally rare and difficult for emerging companies to hire full-time. Firms led by seasoned RLT executives are particularly sought after, as they function as a fractional C-suite, helping sponsors de-risk their programs by refining trial design, preparing for critical health authority interactions, and selecting the right downstream vendors, making them a high-leverage investment early in a drug's lifecycle.

- **Theragnostic Insights (USA):** A premier boutique consultancy founded by a former RLT CMO (Jason Hurt, former CMO of Orano Med) that focuses exclusively on RLT clinical and regulatory strategy, helping sponsors select and manage the right vendors.
- **Rad-Bio (Global Network):** A specialized consulting firm with a deep and exclusive focus on providing strategic support for the development, CMC, and commercialization of radiopharmaceuticals.

6.6. Clinical Site & Patient Support Specialists

ProGen Search's View: This category represents the "last mile" of clinical development, where many trials encounter the most significant friction. The players here are directly addressing the "Infrastructure Paradox" by finding creative ways to expand trial access. The use of established imaging center networks (RadNet), radiopharmacy alliances (UPPI), and sophisticated patient/site logistics services (Clarity PSO, WCG) is becoming a critical strategy for sponsors to reach beyond the few, overwhelmed academic centers and accelerate recruitment.

- **RadNet (USA):** A large US-based network of outpatient imaging centers. With its extensive PET/CT infrastructure and geographic reach, it is an increasingly key partner network for conducting RLT clinical trials in a community setting.
- **UPPI (United Pharmacy Partners, Inc.) (USA):** An alliance of over 80 independent and academic radiopharmacies that provides national coverage for last-mile dose delivery and support, enabling a broader and more diverse network of clinical trial sites.
- **SOFIE Biosciences (USA):** Leverages its extensive nationwide network of radiopharmacies to provide reliable, last-mile logistical support and dose preparation for clinical trials, acting as a key site-enablement partner.
- **WCG (Patient & Site Solutions) (USA):** A leading provider of clinical trial solutions, offering specialized patient recruitment and retention programs, as well as a managed site network, to accelerate enrollment in complex trials like RLTs.

- **Ancillare (USA):** A specialized provider focused on managing the ancillary supply chain for clinical trials. For RLT studies, this includes sourcing, storing, and distributing the non-drug supplies (e.g., shielding, lines, QC kits) essential for site activation and patient treatment.
- **Clarity PSO (USA):** A unique service provider that coordinates between the sponsor, CRO, and site to streamline operations, manage just-in-time isotope delivery, and resolve patient scheduling issues specific to RLTs.

Evolving Clinical Delivery Models in RLT

One of the most pressing challenges in radioligand therapy trials is site access. Very few academic centers are licensed and equipped to handle therapeutic isotopes, and many of these institutions face backlogs in trial initiation and patient throughput. This bottleneck constrains geographic diversity, limits recruitment speed, and introduces disparities in patient access. In response, several RLT sponsors have begun exploring alternative site models and operational strategies, including:

- **Geographic Clustering:** Prioritizing trials in regions with established nuclear medicine infrastructure, particularly near cyclotrons or radiopharmacies.
- **Cross-training of Oncology Sites:** Collaborating with experienced CROs and CDMOs to upskill community oncology clinics on RLT protocol requirements, enabling broader follow-up support even if administration occurs at licensed hubs.
- **In-house Clinical Operations:** A growing number of early-stage developers, including Curie Therapeutics and others, are choosing to build internal clinical capabilities to overcome the limitations of generalist CROs.
- **Use of Hybrid CDMO-CRO Models:** Some infrastructure providers, such as Radiomedix, have blurred the lines between manufacturing and clinical execution, acting as both sponsor and trial coordinator in early-phase programs.

These emerging models are not yet widely adopted, but they signal a willingness across the RLT ecosystem to adapt traditional clinical operations in order to meet the unique logistical demands of radiotherapeutics.

Concluding Thoughts on the Clinical Support Ecosystem:

The landscape of clinical support for radiopharmaceuticals is rapidly maturing from a fragmented, niche cottage industry into a more defined, multi-tiered ecosystem. However, it remains a market defined by scarcity, where demand for true expertise far outstrips supply. This analysis reveals that success in RLT clinical development is no longer simply about selecting a single CRO. Instead, the most sophisticated sponsors are acting as "general contractors," assembling a bespoke coalition of best-in-class specialists across these distinct categories.

The ultimate challenge for any developer is one of integration—ensuring seamless data flow and operational coordination between their chosen CRO, imaging lab, dosimetry provider, and central lab. The ability to successfully select and manage this network of partners has become a core competency in itself and a key differentiating factor. As the field advances, we expect to see continued consolidation, but the fundamental need for deep, specialized expertise across each of these domains will remain the defining feature of the clinical support landscape.

Chapter 7: Footnotes on Cross-Segment Clinical Service Providers

To provide additional clarity on the integrated nature of the clinical services market, this section acknowledges key companies from Chapter 6 that operate across multiple clinical support segments as defined in this report. Their multifaceted strategies are central to understanding the competitive landscape and how value is delivered to sponsors.

- **Medpace (USA):** While its primary classification is a **Full-Service & Specialist CRO (6.1)**, the company's unique, integrated model includes comprehensive **Dosimetry Service (6.3)** capabilities through its in-house medical physics team, making it a single-vendor solution for many sponsors.
- **Medical Physics Consultants (MPC), Inc. (USA):** MPC provides core **Dosimetry Services (6.3)** for clinical trials but also offers extensive **Strategic, Regulatory & Quality Consultancy (6.5)** services related to radiation safety and regulatory compliance, bridging the gap between execution and strategy.
- **Medi-Radiopharma (Hungary):** While listed for its **Specialized Lab & Analytical Services (6.4)**, the company also offers GLP-compliant contract research, positioning it as a **Specialist CRO (6.1)** for preclinical studies.
- **Minerva Imaging (Denmark):** While its primary focus is providing preclinical **imaging services (6.2)**, the company also operates as a CDMO to support clients through first-in-human clinical trials.
- **Oncosia Scientific GmbH (Germany):** This specialized provider functions as both an **Imaging Core Lab (6.2)** and a **Dosimetry Service Provider (6.3)**, offering integrated clinical trial support with an in-house, regulatory-approved dosimetry software solution.
- **Radiomedix (USA):** Listed as a **Specialist CRO (6.1)** due to its extensive clinical execution experience, its business model is a true hybrid. As detailed in the *ProGen Search Radiopharmaceutical Supply Chain and CDMO Report*, it is also a full-service CDMO and a developer of novel therapies, giving its CRO services a uniquely practical and integrated perspective.
- **SCK CEN (Belgium):** Primarily a provider of **Specialized Lab & Analytical Services (6.4)** through its R&D partnerships, it is also a foundational isotope supplier, as detailed in the *ProGen Search Radiopharmaceutical Supply Chain and CDMO Report*.
- **SOFIE Biosciences (USA):** While a key **Clinical Site & Patient Support Specialist (6.6)** through its national radiopharmacy network, the company also operates as a CDMO and develops its own proprietary imaging agents.
- **WCG:** The company provides solutions across multiple segments. Its **WCG Imaging** division is a key **Imaging Core Lab (6.2)**, while its broader patient and site solutions fall under **Clinical Site & Patient Support Specialists (6.6)**.

Chapter 8. The Operational Crisis: Navigating the Infrastructure Bottleneck

The radiopharmaceutical sector's primary constraint is the profound paradox of unprecedented growth colliding with a fragile, underdeveloped clinical infrastructure. These interconnected bottlenecks create a systemic drag on the entire industry.

The "Triad of Scarcity": Site Activation Challenges

- **Physical Infrastructure Deficits:** RPT-capable sites require extensive, capital-intensive infrastructure, including lead-lined rooms, "hot labs," and on-site PET/CT scanners.
- **Human Capital Crisis:** There is a severe shortage of the essential multidisciplinary team: Authorized User (AU) physicians, medical physicists, radiopharmacists, and specialized technologists.
- **Licensing Labyrinths:** Navigating the web of radioactive materials (RAM) licenses from bodies like the NRC is a major source of delay, with processes often taking 4-6+ months and being isotope-specific.

> **ProGen Search's View:** The "hub-and-spoke" model is the only viable near-term solution to the site access crisis. However, its successful implementation creates a new C-suite demand: the Head of Clinical Network Operations, a leader responsible for the complex logistics, data integration, and quality control between the central hub and its community spokes.

Chapter 9. The Horizon: What's Next for Clinical Development in RLT?

The RLT field has reached a new stage of maturity, moving beyond its initial proof-of-concept. The future of clinical development will be defined by the push for superior efficacy, broader applications, and greater operational sophistication.

The Next Isotope Frontier

While ^{225}Ac is the current focus of the "alpha race," the search for the ideal radionuclide is ongoing. Key isotopes to watch include:

- **Terbium-161 (^{161}Tb):** A unique beta-emitter that also releases a shower of low-energy electrons (Auger electrons), potentially enhancing its cell-killing potency.
- **Terbium-149 (^{149}Tb):** A true "theranostic" isotope that is both an alpha-emitter for therapy and a positron-emitter for PET imaging, allowing for simultaneous treatment and visualization.
- **Radium-224 (^{224}Ra):** The parent isotope for Alpha Tau's innovative DaRT (Diffusing Alpha-emitters Radiation Therapy), which releases its alpha-emitting daughters directly within the tumor, a novel intratumoral approach.

The Dosimetry Mandate: From Suggestion to Requirement

Regulatory scrutiny around dosimetry is intensifying. The expectation is shifting from it being an exploratory endpoint to a required component of the data package used to justify dose selection, driven by initiatives like the FDA's Project Optimus.

- **The Challenge:** Establishing a standardized, scalable, and cost-effective dosimetry workflow that can be implemented across global, multicenter trials remains a major hurdle.
- **The Opportunity:** Companies that can successfully integrate a pragmatic, AI-driven dosimetry solution into their trials will have a significant advantage in regulatory discussions and may be able to justify more personalized and effective dosing regimens.

The AI-Enabled Trial and the Rise of Theranostic Pairs

Technology will play an increasingly central role in overcoming the field's core challenges.

- **AI-Driven Solutions:** Artificial intelligence will be deployed to streamline operations, from using machine learning models to analyze EHR data for patient identification and site selection, to automating the time-consuming process of tumor and organ segmentation for dosimetry calculations.
- **Companion Diagnostics as a Prerequisite:** The "see it, treat it" paradigm is now the standard. Future RLT approvals will be intrinsically linked to an approved companion diagnostic PET agent. This necessitates an integrated clinical and regulatory strategy for the "theranostic pair" from the outset, adding complexity but creating powerful, defensible franchises for those who succeed.

Chapter 10. How ProGen Search Supports the RLT Clinical Ecosystem

The unprecedented growth in radiopharmaceuticals has created an equally unprecedented talent crisis. The specialized, multi-domain expertise required to lead these complex clinical programs is exceptionally rare, and this scarcity has become a critical gating factor for sponsors, from venture-backed start-ups to global pharmaceutical companies.

The Challenge: A Widening Talent Gap

Emerging RLT companies, particularly those moving from preclinical to first-in-human studies, face a daunting challenge. They must build a clinical leadership team that possesses a deep, integrated understanding of:

- Clinical Oncology
- Nuclear Medicine & Medical Physics
- Global Regulatory Affairs for Radiopharmaceuticals
- Complex CMC and Isotope Supply Chain Management

Attempting to run these programs with leaders who lack this specific experience often leads to critical missteps in trial design, regulatory strategy, and operational execution, resulting in costly delays and increased risk of failure.

ProGen Search: Your Partner in Building World-Class RLT Teams

At ProGen Search, we specialize in identifying and recruiting the elite clinical and operational leaders who can successfully navigate the unique complexities of the radiopharmaceutical landscape. We understand that in this field, the right leadership is not just an asset - it's a prerequisite for success.

Our role is to serve as a strategic partner to sponsors and investors by:

- **Mapping the Talent Universe:** We maintain a comprehensive, real-time map of the senior leadership talent across the global RLT ecosystem.
- **Defining the Ideal Profile:** We work with our clients to define the precise "tri-brid" leadership profile needed for their specific stage of development, technology platform, and strategic goals.
- **Securing Mission-Critical Leaders:** We leverage our extensive network and deep industry knowledge to recruit the high-impact executives - from the Chief Medical Officer to the Head of Clinical Operations - who can de-risk programs and drive value for stakeholders.

In a field where the right team is the ultimate competitive advantage, ProGen Search provides the expertise and access needed to build the leadership that will define the future of cancer therapy.

ProGen Search

LET'S CONNECT

ProGen Search partners with leading Biotechs, CROs, CDMOs, & Life Sciences organizations to secure the leadership talent they need to scale.

If you're navigating growth, facing talent challenges, or planning your leadership roadmap in the space, we would welcome the opportunity to connect and share insights.

Need to Hire Candidates?

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