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Clinical Trials

Phase 3 Prostate Cancer Case Study: Radiopharm Imaging at Scale

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Radiopharmaceutical trials introduce a uniquely unforgiving clock. For this PSMA-targeted prostate cancer imaging study, investigational product had to be administered within two hours of delivery.

From dosimetry to scanner calibration, every detail had to be executed with speed, accuracy, and repeatability.

Clinical Trial Snapshot

Indication	**Prostate Cancer (Imaging Study, PSMA-targeted)**
Trial Phase	Phase 3, Imaging (non-interventional)
Population	Men with prostate cancer, many in "watch and wait" cohorts
Geography	United States and Canada
Study Duration	Multi-year, expanded enrollment
Sites Activated	10+ initially, expanded after success
Challenge	Radiologic constraints, infrastructure licensing, delivery timing for IP

The sponsor initially anticipated modest enrollment and limited geographic reach. But early results—and an abundant "watch and wait" patient population—suggested the trial could scale. That brought new pressures: Could the system hold under a heavier load? Could sites be vetted and activated fast enough to avoid bottlenecks? Could radiologic material be administered safely and compliantly at scale?

Success depended not just on infrastructure but on relationships—with nuclear medicine teams, imaging vendors, local pharmacies, and regulators.

The Precision Solution for this Radiopharmaceutical Clinical Trial

1. Site Selection Based on Infrastructure and Coordination, Not Just Volume

Precision's feasibility process focused on identifying sites with nuclear medicine expertise and radiopharmaceutical access—departments often siloed in traditional workflows. Each selected site needed:

- Licensing for radionuclide handling and radioactive IMP
- Dedicated hot rooms and dosimetry processes
- Clear internal coordination across oncology, radiology, and nuclear medicine
- Appropriate shielding, handling, and storage protocols

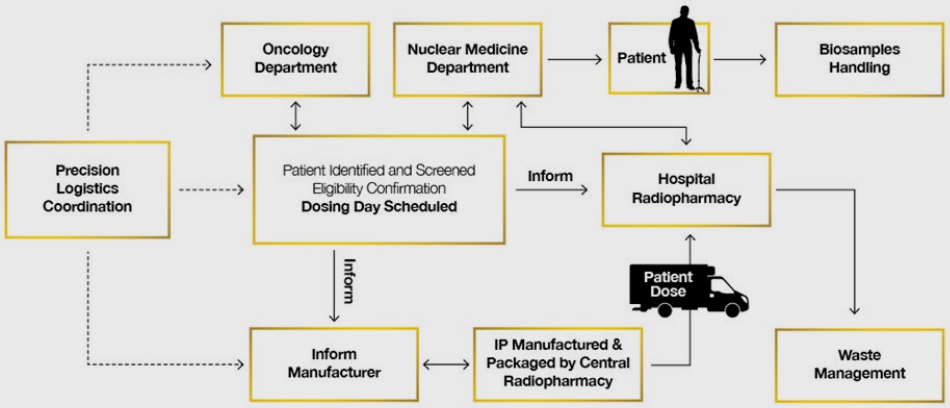
Sites also needed a track record of patient volume and an understanding of how to care for radiolabeled patients during and after administration.

2. Real-Time Chain of Custody Management

With IP half-life measured in hours, logistics had to be airtight. A dedicated Logistics Coordinator oversaw:

- Site-specific planning for each administration window
- Alignment of patient scheduling with drug delivery and scanner availability
- Coordination with manufacturers for QP release, labeling, and transport
- Pickup/drop-off timing with sample couriers and appropriate IATA-trained staff

This approach ensured no patient was ever dosed late, and no product expired in transit.



3. Seamless Site Activation—Despite Licensing Complexities

Site startup required multiple levels of regulatory clearance. Many sites needed license renewals or updates to accommodate radionuclide use for clinical trials. Precision:

- Created documentation playbooks to guide site licensing and certification
- Prepped site teams for IRB and radiopharmaceutical committee reviews
- Provided site initiation visit (SIV) guidance that integrated all training, escalation paths, and site-level SOP reviews

4. Patient and Imaging Management Infrastructure

Precision provided targeted training and materials to ensure safe and efficient trial execution:

- Central imaging vendor to calibrate and certify scanners
- ECG oversight, including central review and cardiologist engagement at sites
- Patient guidance materials and AE management plans for radiation-specific effects
- Oversight of image submission timelines to avoid protocol deviations

5. Continuous Engagement with Cross-Functional Teams

CRAs were supported through documentation, training tools, and backup from PM and CTA teams—essential as many sites operated with rotating nuclear med and pharmacy staff. Investigator meetings and site-level communications reinforced protocol fidelity, and risk mitigation was proactive rather than reactive.

Radiopharmaceutical Clinical Trial Case Study Results

- **Faster-than-expected enrollment:** Thanks to the large "watch and wait" patient population and high-performing sites, the trial exceeded enrollment targets, ultimately increasing to over 380 patients.
- **No dosing delays:** All radiopharmaceuticals were administered within the required timeframe.
- **Zero licensing-related shutdowns:** Every site maintained full authorization throughout the study.
- **Smooth scaling:** Infrastructure held steady even as patient numbers and geographic spread increased.

Why Sponsors Trust Precision for Radiopharmaceutical Imaging Trials

Radiopharmaceutical imaging trials demand more than precision—they demand orchestration. With logistics planned down the minute level detail, multilayered compliance, and siloed clinical infrastructure, even small errors can cascade.

Precision for Medicine delivers a complete solution, integrating nuclear medicine know-how with traditional oncology expertise. Our operational structure—with dedicated logistics, feasibility mapping, and teamwide reinforcement—ensures your imaging study doesn't just meet the mark, it exceeds expectations.

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