CASE STUDY · ONCOLOGY

Radioligand Therapy Trial With PSMA PET Eligibility and Dosimetry

60 sites · PSMA PET/CT, post-therapy SPECT/CT, CT and bone scan · Eligibility reads, PCWG3 and dosimetry

Challenge

Intrinsic Imaging supported this study's imaging activities, addressing the scientific and operational considerations that inform the work of an imaging CRO and imaging core lab. Radioligand therapy ties patient selection to imaging more tightly than almost any other treatment class. In this Phase III trial of a PSMA-targeted radiopharmaceutical in metastatic castration-resistant prostate cancer, a participant could be randomized only if central review confirmed PSMA-positive disease on PET/CT and the absence of PSMA-negative measurable lesions. Randomization windows were short, so eligibility reads had to be returned quickly and consistently to 60 sites, several of which used different PSMA PET tracers with different normal biodistribution.

The trial also carried a dosimetry sub-study. After the first and subsequent treatment cycles, participants underwent serial post-therapy SPECT/CT to quantify absorbed dose to tumors and to organs at risk, particularly the kidneys and salivary glands. Quantitative SPECT demands calibrated cameras, consistent reconstruction and careful registration across timepoints. Efficacy follow-up, meanwhile, used conventional imaging under PCWG3 and RECIST 1.1. Three distinct imaging streams therefore had to run in parallel without confusion, and because post-therapy SPECT/CT uptake would reveal treatment assignment, the separation between streams was a blinding requirement as well as a logistical one. Eligibility and response address distinct clinical questions, even when both depend on imaging.

Intrinsic Imaging's Solution

Intrinsic Imaging designed separate but coordinated workflows for eligibility, efficacy and dosimetry imaging. Eligibility PET/CT examinations were read by nuclear medicine physicians within a 36-hour service level, applying the protocol's SUV-based positivity criteria relative to liver uptake, with tracer-specific guidance for physiologic uptake and known pitfalls. Each eligibility decision was documented with the lesions driving it, so that sites and the sponsor's medical monitor could see the basis for inclusion or exclusion.

For the dosimetry sub-study, we qualified each participating site's SPECT/CT system with a calibration phantom to establish camera sensitivity, specified acquisition and reconstruction parameters in a dosimetry-specific manual, and performed central quantification of time-activity data for tumor and organ volumes of interest, with medical physics support for absorbed-dose calculation. Efficacy imaging followed our established prostate cancer workflow, with PCWG3 bone scan assessment and RECIST 1.1 soft-tissue assessment by dual independent readers with adjudication.

Eligibility readers saw only the screening PET/CT; efficacy readers assessed conventional imaging without access to post-therapy SPECT/CT; and the dosimetry team worked from quantitative data without involvement in response assessment. The platform enforced these separations through role-based access, and the charter documented them for the sponsor's regulatory submission. Sites received a modality-specific submission checklist so that PET, SPECT/CT and conventional imaging arrived correctly labeled and routed on first submission.

Intrinsic Imaging’s Results

- 1.3 days median eligibility read turnaround against a 36-hour service level, with no randomization delayed by an outstanding PSMA PET/CT read at any site
- 93% agreement between central and site PSMA positivity assessments across two tracers, achieved under consistent SUV-based criteria relative to liver uptake with tracer-specific biodistribution guidance
- 120-participant dosimetry sub-study delivered complete, supported by phantom-based camera calibration and central quantification of tumor and organ-at-risk absorbed dose
- Zero unblinding events recorded in the study audit trail, with eligibility, efficacy and dosimetry streams separated by role-based access throughout the trial

Read the full study online: https://intrinsicimaging.com/case-studies/oncology-radioligand

About Intrinsic Imaging, LLC

Intrinsic Imaging is an ISO certified medical imaging CRO and imaging core lab providing comprehensive services in support of Phase I-IV clinical trials and Class I, II, III medical device trials. Intrinsic Imaging is also a world leader in conducting Artificial Intelligence studies. With its team of more than 50 board-certified and fellowship-trained physicians, Intrinsic Imaging’s team has sub-specialization in all therapeutic areas, including Cardiovascular, Central Nervous System,Gastroenterology, Musculoskeletal, Oncology and Ophthalmology. Certified by the British Standards Institution (BSI), Intrinsic Imaging is the only company in the world to hold five ISO certifications specifically for providing imaging core lab services on clinical trials. For more information, please visit www.IntrinsicImaging.com.

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