CASE STUDY · ONCOLOGY

Metastatic Prostate Cancer With PCWG3 Review

65 sites · Bone scintigraphy, CT · PCWG3 and RECIST 1.1

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. Assessment of radiographic progression-free survival in metastatic prostate cancer requires consistent application of PCWG3 bone progression conventions, including the 2+2 rule and its lesion-count and confirmatory imaging requirements. Across 65 sites, the rule was being applied inconsistently, with the flare phenomenon and unconfirmed lesions variously counted or disregarded. Such inconsistency threatened the reliability of the rPFS endpoint and the reproducibility of progression event dating across the trial.

Bone scan interpretation added further complexity. Early increases in lesion conspicuity may reflect healing rather than progression, and new uptake may arise from degenerative disease, trauma or other benign causes. Soft-tissue disease also had to be evaluated separately under RECIST 1.1. Without a consistent workflow integrating these assessments, progression could be declared too early, too late or on different grounds at different sites. The sponsor required a structured application of PCWG3 alongside RECIST 1.1, with confirmation status and event dating explicit across the longitudinal record and each determination traceable to the examinations establishing it, so the progression sequence could be verified independently during data review.

Intrinsic Imaging's Solution

Intrinsic Imaging embedded PCWG3 decision logic directly into the central reading workflow. The workflow guided readers through baseline lesion identification, new lesion assessment, flare considerations and confirmatory scan review before a bone progression status could be assigned, and each decision was captured in a structured format that made clear when and why a progression event had been declared. Rather than relying on readers to recall and apply complex rules independently, the reading environment made the required decision sequence explicit at every step.

Central readers assessed bone scintigraphy alongside CT under RECIST 1.1 for soft-tissue disease, with the confirmatory requirement enforced systematically rather than left to individual judgment. Every progression event was dated according to a uniform convention. Sites received guidance on consistent bone scintigraphy and CT acquisition, each submission was reviewed for completeness before reading, and readers were trained and calibrated on PCWG3 and RECIST 1.1 conventions before the first assessment.

Project managers tracked confirmatory imaging so that unresolved findings did not remain open as the study approached database lock. Adjudication was invoked when primary readers disagreed on progression status or event timing; adjudicators reviewed the complete imaging history under the same structured workflow, and their decisions were documented in detail, giving the sponsor a clear rationale for every event included in the rPFS analysis, from first identified lesion to confirmatory examination.

Intrinsic Imaging’s Results

- 2,900+ bone scans assessed centrally under embedded PCWG3 decision logic, with soft-tissue disease evaluated in parallel on CT under RECIST 1.1
- Zero outstanding progression-logic queries at database lock, the direct consequence of tracking confirmatory imaging systematically throughout the study rather than at closeout
- Consistent rPFS event dating across all 65 sites, with every progression event traceable to the baseline, new-lesion and confirmatory bone scan examinations that established it
- Structured decision capture simplified data review and gave the sponsor a documented, inspection-ready rationale for each progression event included in the rPFS analysis

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

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 650 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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