CASE STUDY · ONCOLOGY

International Phase II Trial in Advanced Squamous Cell Carcinoma

32 sites in 9 countries · CT, MRI · 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. An international Phase II trial evaluated a new treatment for advanced squamous cell carcinoma. Squamous tumors of the head and neck, lung, esophagus and skin present differently and are imaged with different modalities, and the sponsor permitted either CT or MRI depending on site and tumor location, which introduced cross-modality comparison risk into longitudinal response assessment.

The sponsor needed blinded central review under RECIST 1.1 that managed modality consistency per patient, handled the post-treatment anatomy and necrotic nodes typical of squamous disease, and delivered a clean response dataset to support a go/no-go decision on Phase III. The shared histological designation does not make lesions from different anatomical sites equally measurable or equally interpretable after treatment. A response category therefore depends on maintaining a stable measurement framework while recognizing that necrosis, altered tissue boundaries and prior local therapy can complicate the relationship between lesion dimensions and viable tumor.

Intrinsic Imaging's Solution

Intrinsic Imaging developed the protocol imaging section and charter, defining acquisition parameters for both CT and MRI and requiring that each patient be followed with the same modality used at baseline. Sites were qualified and trained, and the central quality control step verified modality consistency and anatomical coverage at every timepoint. Maintaining the baseline modality limits changes in apparent lesion boundaries attributable to imaging contrast rather than disease evolution. Anatomical coverage checks are also important because comparison requires adequate visualization of both previously identified disease and potential new lesions. These controls address technical comparability, but do not make CT and MRI interchangeable or remove the biological heterogeneity among primary sites.

Oncology radiologists performed blinded independent reads under RECIST 1.1, with charter rules for necrotic and cystic nodal disease, for post-surgical and post-radiation change, and for lesions near the limits of measurability. Adjudication resolved discordant response categories. The charter rules provide a common interpretive basis when nodal necrosis or treatment-related distortion makes ordinary lesion boundaries less straightforward. Explicit treatment of borderline measurability is relevant because small measurement differences can influence subsequent categorical assessments. Independent review and adjudication organize that uncertainty within a defined process, rather than implying that every difficult lesion has an unambiguous imaging interpretation.

Images were blinded and processed centrally, and the response dataset was delivered in a structure that allowed the sponsor to analyze outcomes by primary site and by modality. Retaining primary site and modality in the dataset allows response findings to be considered alongside clinically relevant differences in anatomy and acquisition. Such distinctions matter when interpreting an aggregate result from a heterogeneous squamous cancer population. They provide context for the development decision without establishing that apparent differences between subgroups reflect treatment sensitivity rather than case mix, measurement limitations or other trial characteristics.

Intrinsic Imaging’s Results

- Approximately 1,100 timepoints from 32 sites in 9 countries read under blinded independent review with adjudication
- Modality consistency maintained for 97% of patients through baseline-to-follow-up modality locking and central verification
- Charter rules for necrotic nodal disease and post-treatment change applied uniformly across head and neck, lung and other primaries
- Response dataset delivered on schedule for the sponsor's Phase III go/no-go decision

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

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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