

CASE STUDY · ONCOLOGY

International Phase II Trial in Advanced Squamous Cell Carcinoma

32 sites in 9 countries · CT, MRI · RECIST 1.1

Challenge

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.

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.

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.

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.

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

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 750 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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