

## Use of Digital Analysis Software Versus Manual Histoscore for Biomarker Quantification in Pancreatic Adenocarcinoma

**McKay, F.M.**<sup>1</sup>; Ali, A.<sup>2</sup>; Orange, C.<sup>3</sup>; Waller, J.<sup>1</sup>; Sherry, L.<sup>1</sup>; Duthie, F.<sup>3</sup>; Oien, K.<sup>3</sup>; Bell, S.<sup>4</sup>

<sup>1</sup>OracleBio Limited, Biocity Scotland, Bo'Ness, United Kingdom; <sup>2</sup>Beatson Institute of Cancer Research, Glasgow, United Kingdom; <sup>3</sup>Institute of Cancer Sciences, College of Medical, Veterinary and Life Sciences, University of Glasgow, Glasgow, United Kingdom; <sup>4</sup>Department of Pathology, Queen Elizabeth University Hospital, Glasgow, United Kingdom

**PURPOSE OF THE STUDY:** Assessment of biomarker staining in tumours is important for diagnosis, prognostication and prediction of treatment benefit in research and clinical tissue samples. Manual scoring is complex and time-consuming. Automated digital image analysis (DIA) software may accelerate this process. Pancreatic Ductal Adenocarcinomas (PDAC) are particularly difficult to diagnose due to their complex architecture. We aimed to train and test an automated system and compare its analysis of tissue samples with manually scored data.

**METHODS:** Two sample sets of images from tissue microarrays (TMAs) were used: first, relatively homogeneous, pre-clinical patient-derived xenograft (PDX) tumour tissues stained for HER-2; second, more heterogeneous PDAC clinical samples stained for KOC, S100P, Maspin and Mesothelin. Indica Labs HALO®DIA software was used to create tissue-specific classifiers to identify tumour areas for assessment and applied to modifiable analysis algorithms to quantify staining. A Histoscore method was used for comparison.

**SUMMARY OF RESULTS:** DIA software provided quantification of HER-2 staining in the pre-clinical PDX models; there was a range of HER-2 staining and models with high expression were easily identified. The classifier created for clinical tissues highlighted both stained and non-stained tumour, successfully separating these from areas of stroma, and provided quantitative scores. The automated system and manual scoring produced similar Histoscores with R<sup>2</sup> values of 0.94 for KOC, 0.83 for S100P and 0.74 for Maspin.

**CONCLUSIONS:** Automated image analysis for quantifying tissue biomarkers appears to provide results of at least similar quantity to manual scoring, potentially even in complex tumours, and may accelerate biomarker development and analysis.