EACR 2026

08-11 June 2026

Budapest, Hungary

QUALIFICATION OF TRANSLATIONAL SPATIAL BIOMARKER PANEL TO ENABLE PREDICTIVE TISSUE PROFILING IN ONCOLOGY DRUG DEVELOPMENT

Aliri BIOANALYSIS

D. BONNEL[1], A. LE[1], A. GERSTENBERG [1] and C. RAMOS[1]

[1] ALIRI, 152 Rue du Docteur Yersin, 59120 Loos, France

INTRODUCTION

Spatial biology technologies are transforming translational oncology by enabling high-resolution characterization of tumor–immune ecosystems. However, the clinical utility of spatial biomarkers remains limited by a lack of standardized, qualified panels capable of generating reproducible and decision-enabling data across studies.

To address this gap, we developed a framework for the qualification of translational spatial biomarker panels designed to support drug development and clinical trial biomarker strategies. By integrating multiplex immunofluorescence, digital pathology, and AI-assisted image analysis, our objective was to establish reproducible workflows capable of generating biologically relevant and analytically robust spatial biomarkers suitable for translational oncology applications.

METHOD

FFPE oncology tissues were analyzed using a qualified multiplex immunofluorescence workflow integrating digital pathology and AI-assisted image analysis. The qualification strategy included antibody optimization, multiplex signal balancing, specificity assessment using isotype controls, image acquisition standardization, segmentation quality control, and reproducibility assessment across operators and runs.

Spatial feature extraction pipelines were developed to quantify tumor–immune organization and generate biologically interpretable metrics suitable for translational biomarker development.

CONCLUSIONS

- Qualified spatial biomarkers panels reproducibly captured biologically relevant tumor-immune spatial phenotypes.
- Standardized multiplex workflows enabled robust generation of quantitative spatial metrics associated with pharmacodynamic-relevant biology.
- This framework provides a foundation for predictive tissue profiling, translational biomarker development, and future spatially informed clinical trials strategies.

AIM

To develop and qualify translational spatial biomarker panels capable of reproducibly characterizing tumor-immune architecture and generating quantitative spatial metrics associated with pharmacodynamic-relevant biology in oncology drug development.

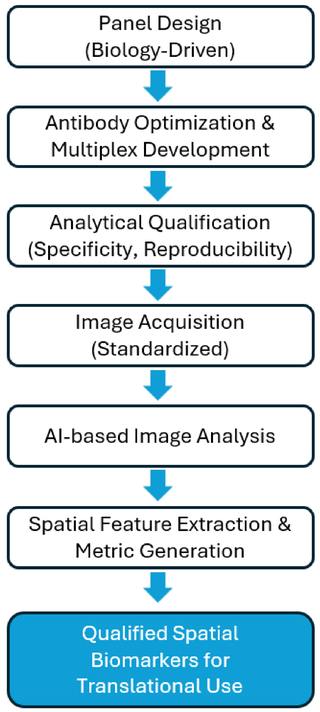
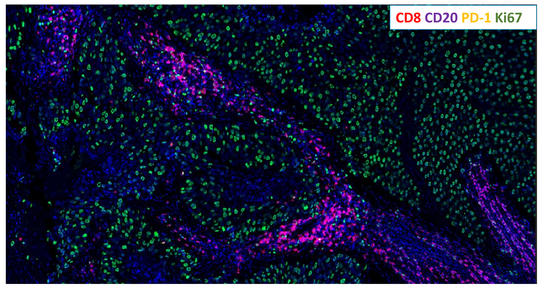


Figure 1. Qualification Workflow

RESULTS

Figure 2. Biologically Relevant Multiplex Spatial Profiling

A mechanistically driven Tumor-Immune Spatial Fingerprint panel captures multiple biological axes within a single FFPE tissue section.



Marker	Associated Biology
CD8	Effector immune infiltration
GranzymeB	Cytotoxic activation
FoxP3	Immune suppression
PD-1	Activation/exhaustion
CD68	Myeloid suppression
Ki67	Tumor Proliferation
CD20	TLS-like organization
PanCK	Tumor segmentation

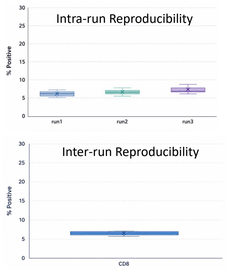
Figure 3. Qualification and Reproducibility Assessment

Comprehensive analytical qualification was performed to ensure specificity, robustness and reproducibility of the multiplex spatial workflow.

- ☑ Antibody optimization & multiplex balancing
- ☑ Controlled staining conditions
- ☑ Isotypes controls (specificity)
- ☑ Standardized acquisition parameters
- ☑ Segmentation quality control
- ☑ Intra-run reproducibility
- ☑ Inter-run reproducibility

Mean CV (intra-run) **5.56%**

Inter-run CV **7.77%**



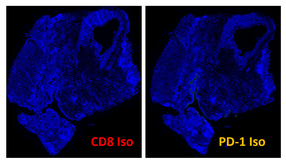
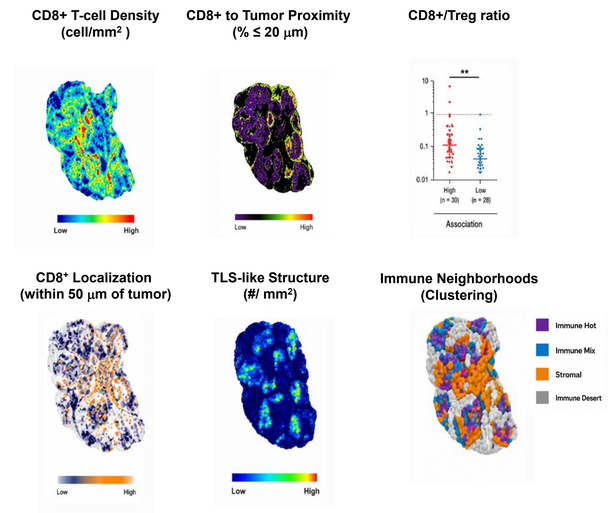


Figure 4. Quantitative Spatial Output

The qualified panels enable the extraction of biologically relevant spatial metrics associated with pharmacodynamic-relevant tumor-immune biology .



ACKNOWLEDGEMENT

The authors would like to thank the Spatial Biology, Bioinformatics, Digital Pathology, and Translational Bioanalysis teams at Aliri for their scientific and technical contributions to the development and qualification of the multiplex spatial biomarker workflows presented in this study.

This work was supported by internal R&D initiatives focused on predictive tissue profiling and translational biomarker development for oncology drug development applications.

REFERENCES

- Lewis SM, Asselin-Labat ML, Nguyen Q, et al. Spatial omics and multiplexed imaging to explore cancer biology. Nat Methods. 2023;20:33–52.
- He S, Bhatt R, Brown C, et al. High-plex imaging and spatial analysis in immuno-oncology biomarker discovery and clinical research. J Immunotherapy Cancer. 2024;12.
- Bagaev A, Kotlov N, Nomie K, et al. Conserved pan-cancer microenvironment subtypes predict response to immunotherapy. Cancer Cell. 2021;39(6):845–865.