Integrated analysis of digital pathology & multi-omic data for understanding the tumor micro-environment in precision immuno-oncology trials

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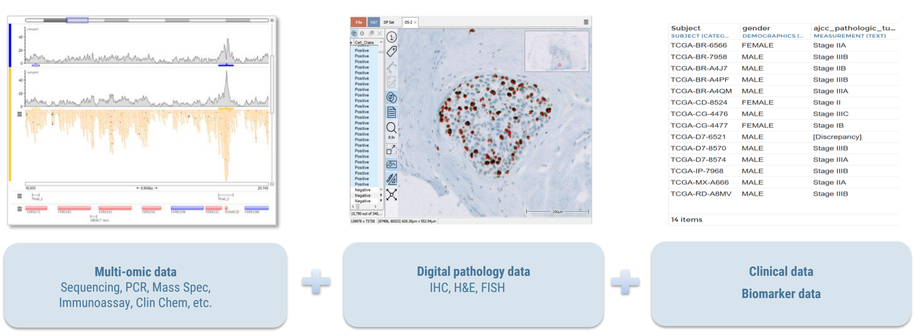
Value of integrated data analysis for precision immuno-oncology trials

- Digital pathology in conjunction with multi-omic, clinical and biomarker data allows for the assessment of tumor microenvironments in clinical & translational research
- The data can help predict whether the patient will likely benefit from immuno-oncology therapies and therefore improve treatment outcome
- Data analysis across clinical studies can help to understand the patient-drug interaction and improve future clinical trial design



The challenges

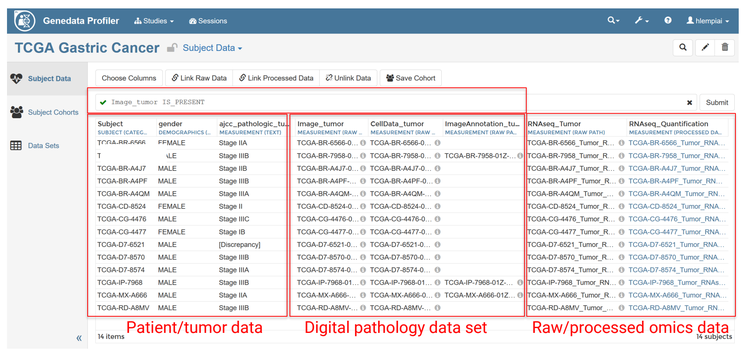
There are several challenges associated with the integration & analysis of digital pathology, multi-omic & biomarker data:

1.) Data is often siloed and spread across different locations within organizations which makes data access complex, time consuming, and error prone
2.) Data exchange capabilities and interoperability of different data readouts from various software platforms are limited and do not allow for comprehensive data and result utilization
3.) Chain-of-custody for complex, multi-step digital pathology workflows is often difficult to provide due to a lack of standardization
4.) Current data reporting processes to regulatory authorities requires usually manual error prone data convergence steps
5.) Increasing amount of data and users create challenges with respect to scalability and performance of data analysis and management solutions

Genedata Profiler® provides core capabilities addressing those challenges

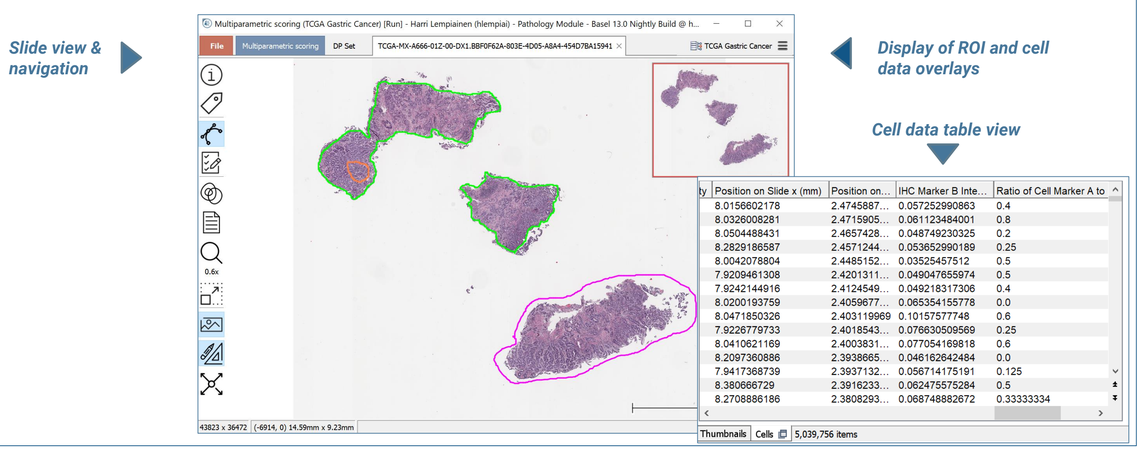
1.) Secure, study centric data management

- Integration of digital pathology data set with multi-omics, patient & tumor data
- Powerful search functionality, cohorts are saved and shared with study members



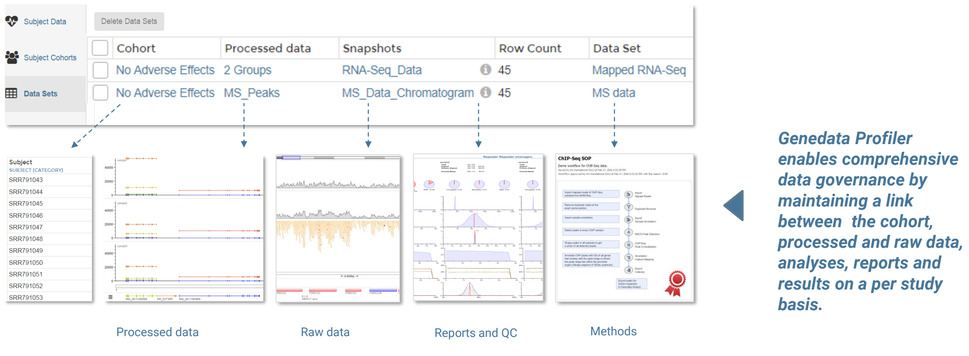
2.) Vendor agnostic image processing, viewing and sharing

- Table view of digital pathology data sets (e.g. from microscopy) incl. thumbnails and attributes
- Individual slide visualization, slide overview and navigation, ROI and cell data overlays



3.) Data governance and complete chain-of-custody

- Comprehensively tracking the chain-of-custody across the entire data lifecycle
- Documentation of who operated on the data, when and how



4.) Automated regulatory submission data preparation

- Regulatory submission-ready data reporting to CDISC SDTM format
- Electronic records and electronic signatures (21 CFR Part 11)
- Full audit trails

5.) Efficient and scalable operation in cloud and HPC environments

- Automated cloud deployment including full elasticity support, monitoring & continuous validation support

Summary

- Genedata Profiler provides a validated and scalable enterprise software platform for managing and processing of digital pathology & multi-omic data and biomarker readouts for translational and clinical research.
- The platform enables translational and clinical research organizations to achieve their vision of precision immuno-oncology by leveraging the full power of integrating digital pathology, multi-omic and biomarker data.