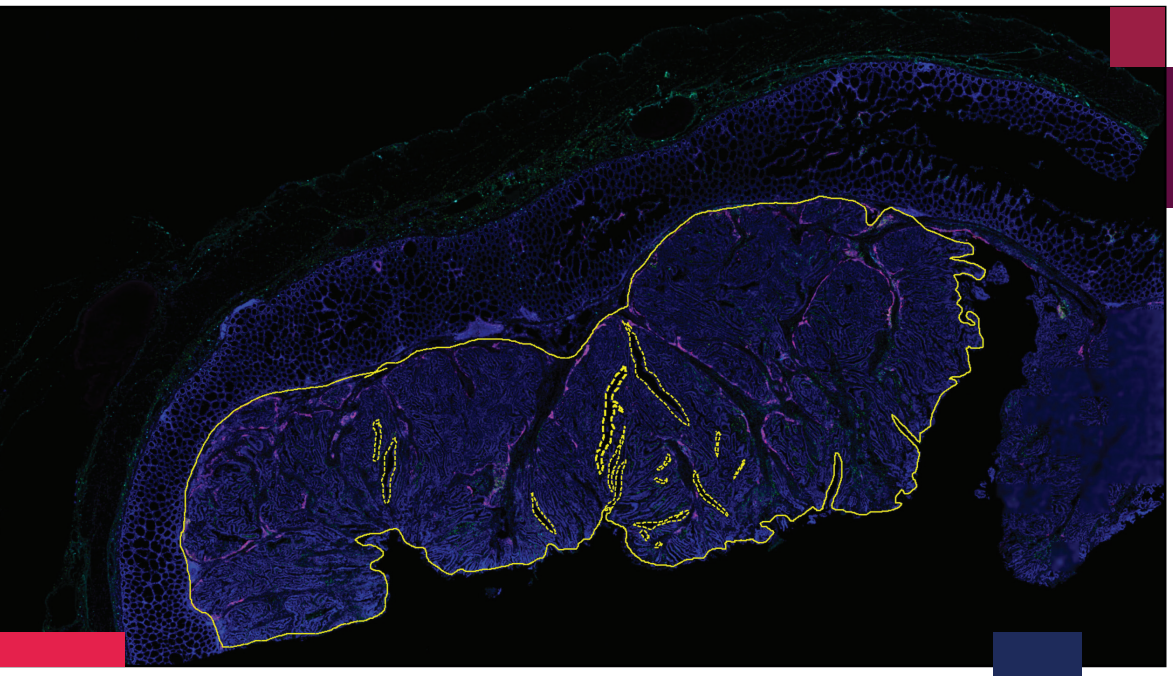
Comprehensive Digital Image Analysis Workflow

CellCarta



CellCarta offers a comprehensive, **21 CFR-part 11 compliant** digital image analysis workflow that ensures high-quality clinical insights. We provide detailed **H&E and IHC/IF/ISH** image analysis using advanced software with AI capabilities, alongside Reveal Biosciences' highly bespoke imageDx™ algorithm development, to support your clinical studies.

Image Management › **Image Annotation** › **Image Analysis** › **Data Reporting**

IMAGE MANAGEMENT

High-quality images are critical in ensuring accurate image analysis. Our pathologists are connected **globally** through our digital pathology cockpit (LabKick), which combines LIMS information with Pathomation's powerful whole-slide image viewer. Thus, allowing them to collaborate on any project. Our experts also utilize advanced digital analysis platforms such as HALO, Visiopharm, uPath, and inForm. We adhere to strict criteria before accepting images for analysis, divided into three evaluation metrics.

Image Quality

- The quality of each image is assessed prior to image analysis. Only images without the presence of imaging artifacts are analyzed.

Sample acceptability based on H&E evaluation by pathologist

- Sufficient presence of region-of-interest to ensure representative results. For instance, at least 100 tumor cells must be present.

Slide section integrity and staining acceptability

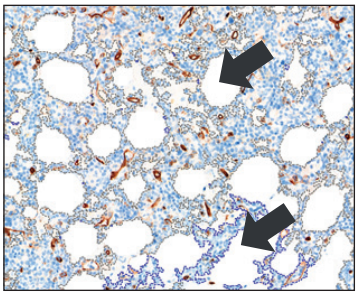
- Loss or exclusion of region(s)-of-interest due to detachment or exclusion of artifacts must be limited to ensure representative and consistent results.

IMAGE ANNOTATION

Proper image annotations can identify critical components of regions of interest (ROIs), including tumor regions. Tumor regions are specifically delineated on the H&E image by the pathologist and subsequently transferred and further finetuned on the IHC/IF image by our scientific team. Quality checks are completed at every step by our experts.

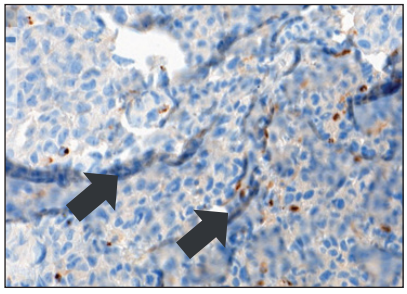
Fine-tuning IHC/IF image annotations with quality at every step

Whitespace regions, necrosis, and normal tissue must be excluded from analysis.



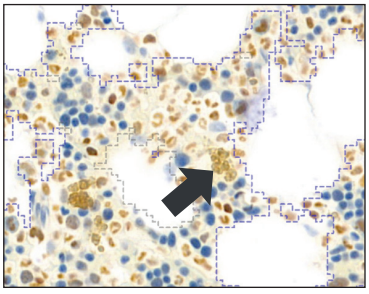
DAB-stained sample: image showing regions of whitespace (arrows).

Crushing, folding, ink, thermal damage, fading artifacts, and non-specific or background staining can disrupt analysis (via out-of-focus regions, false positives, etc.) and are excluded from analysis.



DAB-stained sample: image showing folds (arrows).

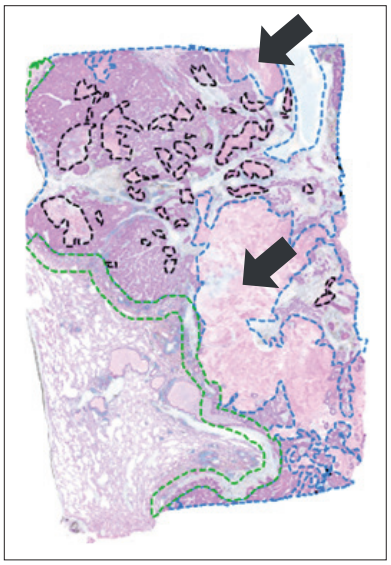
Pigmentation can be falsely detected as a positive cell target by the algorithm, in which case it is excluded from analysis.



DAB-stained sample: image showing hemosiderin pigmentation (arrow).

Annotation of regions of interest by pathologist

HE-image with tumor (black line) and invasive margin (green line) annotation.



PanCK-CD8 image with finetuned, tight annotation of the tumor (blue line) and invasive margin ROIs (green line) with exclusion of necrosis (arrows), whitespace and artifacts.

IMAGE ANALYSIS

Our comprehensive algorithm development and validation procedures ensure that our image analysis algorithms are best suited for your clinical studies. For each digital image analysis algorithm, we assess the following:

- **Analysis time:** optimal and fast turn-around-time
- **Whole-slide scanner concordance:** reassuring analysis consistency across the globe
- **Sampling rate:** minimal number of regions/cells for representative quantification in case of subsampling
- **Observer variability:** concordance between analysts
- **Accuracy:** qualitative and quantitative evaluation of the accuracy of the algorithm by pathologist

In addition to the validation work that goes into the algorithm, the analysis of every image is quality checked again by our team of experts before submitting the data, ensuring optimal performance of the algorithm across the entire study.

Enhanced and customized analysis with imageDx

With our very own cutting-edge platform, we can go even further to **quantify** specific cell types/tissue features, **explore** tissue micro-environment spatial information, and even **predict** clinical insights that cannot be seen by eye, all in an interactive web-based environment nurturing a collaborative approach between our and your scientific teams.

DATA REPORTING

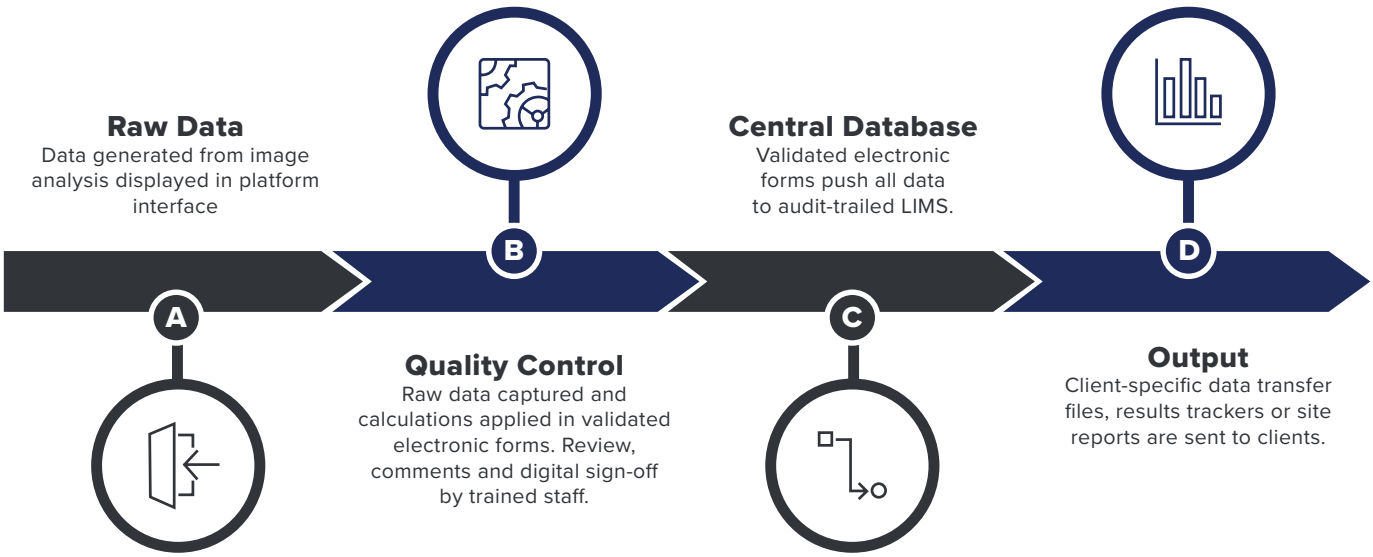
With our complete digital image analysis workflow, you can generate a diverse array of data types and visualizations. Our easy-to-navigate reports provide informative answers to all your clinical questions.

Types of Data Generated

- **Area**
- **Density**
- **Proportion of cell types**
- **Relative marker area**
- **Densities**
- **Relative numbers**
- **H-score**
- **Complex output**
  - Distances
  - Inside/outside mask
  - Density heatmaps and hotspots
  - Infiltration analysis
  - Spatial indexes

From the initial generation of data to the final reporting stage, every aspect is meticulously managed in an end-to-end, validated, and 21 CFR-compliant manner.

Data reporting flow



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ABOUT CELLCARTA

Leading provider of specialized precision medicine laboratory services to the biopharmaceutical industry. Leveraging its integrated analytical platforms in immunology, histopathology, proteomics and genomics, as well as related specimen collection and logistics services, CellCarta supports the entire drug development cycle, from discovery to late-stage clinical trials. The company operates globally with 11 facilities located in Canada, USA, Belgium, Australia and China.

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