Quibim

AI-enhanced imaging solutions for clinical trials

Radiomics for meaningful insights in drug development

Quantitative imaging: A basis for modern drug development

Quibim is a trusted imaging partner in clinical trials for drug development programs. Our expertise transcends conventional image reading services, offering a modality-agnostic platform for imaging data management enriched with AI radiomics-based tools to manage imaging data, streamline and systematize radiological readings.

Our panel of imaging biomarkers and radiomics is a key technology for improved patient stratification and modern drug development, offering:

- **Imaging-Based Drug Development Tools (DDT):** Diagnostic, pharmacodynamic, efficacy, and safety biomarkers.
- **Imaging-Based Companion Diagnostics (CDx):** Specialized imaging tools designed for specific therapeutics, facilitating personalized treatment strategies.

Our approach is designed to align with the core needs of biopharma companies, ensuring successful trials and robust outcomes.

Expertise across therapeutic areas

We provide easily deployable and scalable solutions across a broad spectrum of therapeutic areas to facilitate drug development and commercialization.

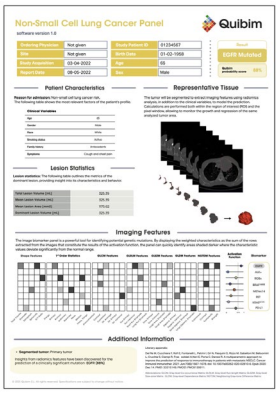
Our current focus includes, but is not limited to, oncological conditions such as lung, breast, and colorectal cancer, hematological malignancies like lymphoma, and a range of solid tumors, including prostate and pancreatic cancer; neurological disorders such as Alzheimer's and multiple sclerosis and chronic diseases like rheumatoid arthritis.

Radiomics and imaging biomarkers: The Frontier of Imaging Analysis

- **Radiomics**, a cutting-edge field, involves the extraction of a high number of quantitative features from medical images —such as MRI, CT, or PET scans— ranging from intensity distribution and spatial heterogeneity to higher-order statistical parameters.

- **An imaging biomarker** is a measurable parameter or a panel grouping several parameters derived from medical images that indicates a biological state or condition. It may reflect a normal biological, pathogenic, or pharmacologic response to a therapeutic intervention.

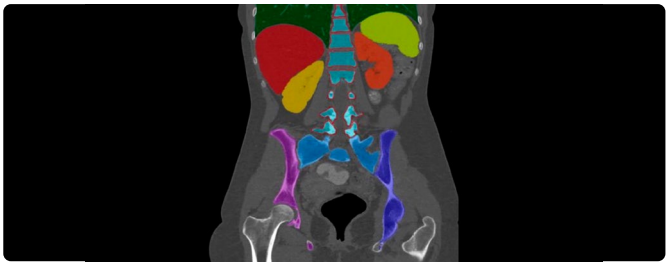
Extraction of radiomics and imaging biomarkers enables conversion of images into mineable data, from which actionable insights can be derived via application of advanced statistics or AI.
One or more features can be combined into a panel enabling **precision medicine** and enhancing their predictive and prognostic power and clinical utility.



Value proposition of quantitative imaging in clinical trials

1. Early and accurate assessment: In the critical early phases of clinical trials, quantitative imaging allows for precise treatment response and toxicity assessment, providing early indicators of efficacy and safety.

2. Streamlining drug development: During clinical trial phases II and III, our prognostic and predictive models are critical tools in patient stratification and treatment response evaluation, accelerating the drug development process and the potential for successful outcomes. The imaging exploratory endpoints enhance the pharmaceutical company's chances of progressing to the next development phase, offering a more straightforward path to regulatory approvals and market entry.



Understanding drug development program challenges: an imaging-based tailored approach for successful trials

We can accelerate drug development through:

- **Radiomics for enhanced screening:** refine and increase the efficiency of non-invasive patient screening processes and trial recruitment.
- **Innovation in early development:** identify novel radiomic features to boost value and investment potential.
- **Detailed evaluation of toxicity and dosimetry:** support breakthrough therapy designation (e.g., escalation dose or maximum tolerated dose).
- **Targeted patient stratification:** use radiomics to more accurately determine which patients will benefit most from specific treatments.
- **Critical evaluations:** side-effect profiling and endpoint verification in clinical trial phases II and III, providing a comprehensive safety and efficacy analysis.
- **Data harmonization for reproducible outcomes:** standardize imaging data to enhance quality and consistency across original equipment manufacturers (OEMs), field strengths, and sites.
- **End-to-end AI-based radiomics solutions:** provide additional imaging endpoints to enhance a pharmaceutical company's chances of progressing to the next development phase, offering a more straightforward path to regulatory approvals and market entry.
- **Expedited regulatory approvals:** provide robust data to meet the demands of regulatory authorities such as the FDA.

CASE STUDY 1

To revolutionize immune status diagnosis and immunotherapy response prediction through the quantitative assessment of novel radiotracers efficacy in PET/CT exams.

1. Modality

PET/CT

2. Therapeutic Area(s)

Melanoma, renal cell carcinoma, non-small cell lung cancer, head and neck squamous cell carcinoma, sarcoma spindle cell, squamous cell cancer with anal primary, esophagogastric and bladder cancer.

3. Unmet need

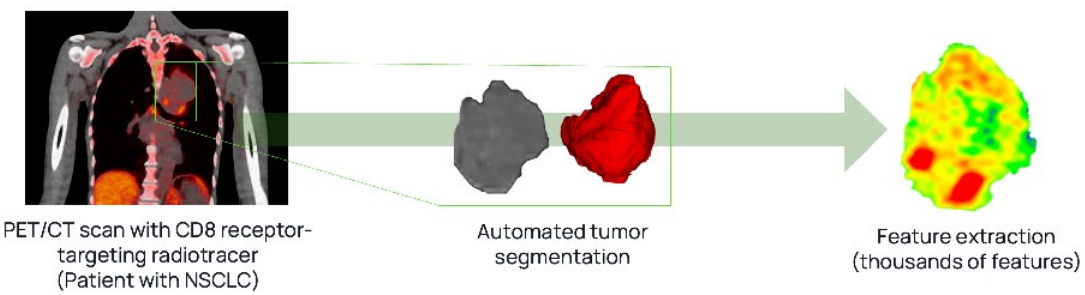
Immunotherapy has shown remarkable promise in treating cancer and other diseases, but accurately predicting the efficacy of these treatments remains a challenge. Novel radiotracers targeting the CD8 receptor on human T cells for quantitative, non-invasive PET imaging are currently under development, with their efficacy and predictive capabilities still being assessed.

4. Our solution

Quibim is creating an imaging-based algorithm to interpret PET/CT exams, with the aim of quantitatively assessing the efficacy of the 89Zr-labeled minibody in targeting the CD8 receptor in the tumor microenvironment.

The algorithm is using advanced image processing techniques to extract quantitative measures of tracer uptake in the tumor and surrounding tissues, enabling accurate assessment of the binding efficacy of the minibody to CD8 receptors.

The resulting quantitative data provides valuable insights into the minibody's biodistribution and targeting specificity to inform future clinical development of the imaging agent and its potential therapeutic application.



CASE STUDY 2

Harnessing AI-powered radiomics for immunotherapy response prediction in advanced non-small cell lung cancer through baseline CT scans.

1. Modality

CT

2. Therapeutic Area(s)

Non-small cell lung cancer (NSCLC)

3. Unmet need

Optimizing clinical trial design is crucial for the successful development of promising immunotherapy candidates in NSCLC. Failure can be mitigated by meticulous patient stratification. AI tools emerge as a potential solution, empowering drug development programs through enhanced screening of patient populations for optimal drug response.

4. Our solution

Quibim applied their proprietary software to harmonize 1000+ CT scans from 78 sites and 59 scanner models to standardize the quality of the imaging dataset.

The extraction of radiomics and deep features from the CT scans, input for the AI-based model, allowed the prediction of overall survival and best overall response with >75% accuracy.
This was highly useful for the biopharma partner, who wished to improve their screening process to better identify candidates for the trial.

Radiomics-based model pipeline

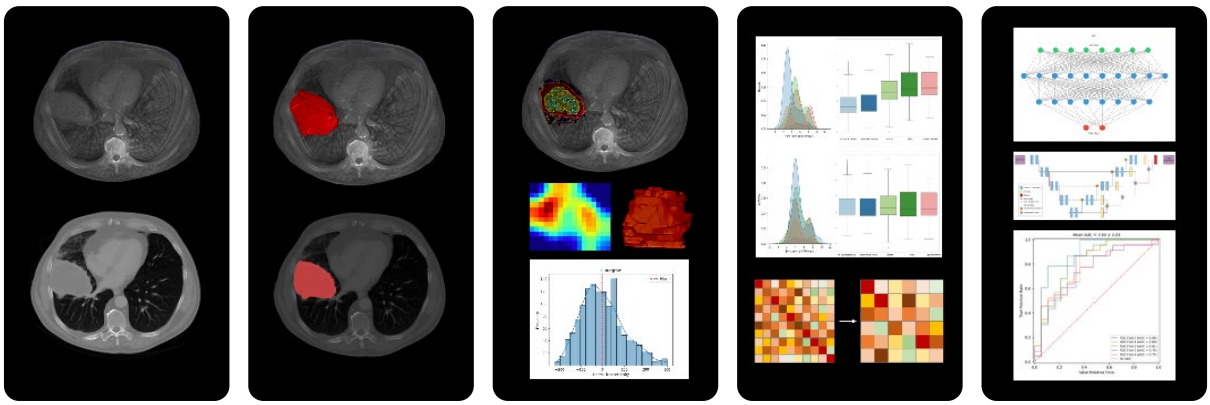


Image Acquisition
CT scans

Tumor Segmentation

Feature Extraction

Harmonization and Feature Selection

AI-based Predictive Models

Partner with Quibim
For more detailed information on how Quibim can contribute to your clinical trial success or to discuss a specific project, please get in touch with us at: contact@quibim.com