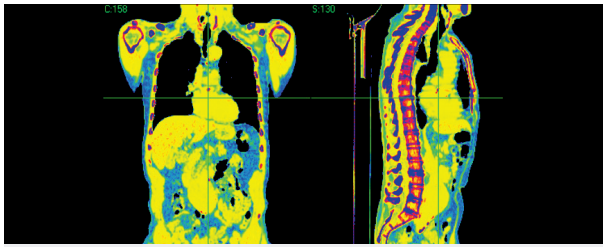
BIOCLINICA®
MEDICAL IMAGING

ONCOLOGY
Medical Imaging Expertise



KEY FEATURES

- On-staff oncologists and radiologists complemented by a worldwide network of key opinion leaders
- Medical and scientific experts with advanced knowledge of oncology imaging modalities including CT, MRI, and PET
- Oncology aligned project management team focused on your timelines, metrics, and budgets
- Unparallelled regulatory experience with 56+ FDA oncology approvals
- Study and protocol design consulting
- Site qualification and training to ensure important standardization across sites
- Complete image data archival and workflow with full 21 CFR Part 11 compliance

Medical imaging plays a key role in evaluating the efficacy and safety of new oncology drugs. As a sponsor, you require a solution that keeps pace with advances in oncology imaging and stays ahead of demanding timelines and budgets. Bioclinica combines world class scientific expertise with outstanding project management and unmatched regulatory insight to expedite oncology drug development.

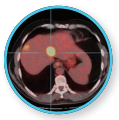
Bioclinica is specifically structured to bring clarity to key areas of clinical development, offering the flexibility and scalability necessary to meet your oncology project needs. Our decades of experience includes advanced expertise in small early phase molecular imaging studies through to large, more complex, late phase registration trials.

Expert Independent Review

Bioclinica's independent reviewers have experience with the latest advancements in tumor response criteria, imaging modalities and oncology biomarkers, ensuring an innovative solution and world class resources in support of oncology clinical trials with imaging endpoints. Bioclinica's team of board-certified, sub-specialty trained radiologists, nuclear physicians, and medical oncologists analyze all images from baseline to completion with fast turnaround times and can provide a blinded, in-depth oncology response review.

- Sophisticated algorithms for semi-automatic, bi-dimensional, and volumetric tumor measurements
- Custom-designed lesion tracking for longitudinal studies
- Real time derivation for accelerated calculations and reduced error
- Automatic transfer of image analysis data into eCRFs

Molecular Imaging Expertise



Advances in molecular imaging enable precise measurements of molecular targets and biochemical changes in tumors. Bioclinica supports a full range of molecular imaging modalities used to identify, stage, and monitor various cancers.

- ^{18}F-fluorodeoxyglucose (FDG)
- 3'-deoxy-3'-^{18}F-fluorothymidine (FLT)
- ^{18}F-fluoromisonidazole (FMISO)
- ^{111}In-octreotide
- ^{123}I-metaiodobenzylguanidine (mIBG)
- Technetium-99m

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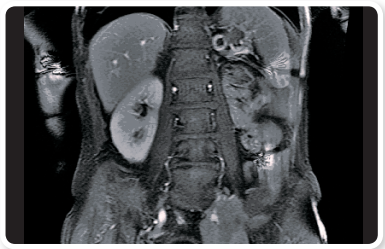
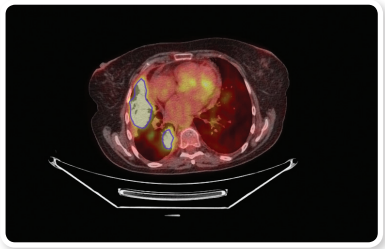
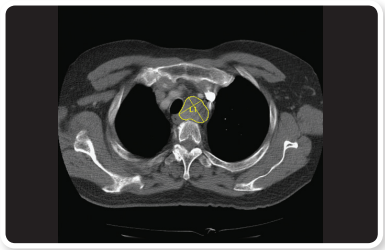
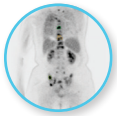






With decades of imaging experience, over 1,100 oncology trials, and more than 56 FDA approved oncology drugs, Bioclinica leads the industry.

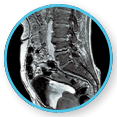
Tumor Response Criteria



Our oncology team has expertise with conventional and advanced tumor response criteria which take into account tumor burden, metabolism, proliferation, lipid turnover and hypoxia, providing sponsors with a wide range of oncology endpoints.

- Cheson
- Choi
- EBMT
- EORTC
- Hallek
- IHP
- Lugano
- Macdonald
- PCWG2
- PERCIST
- RANO
- RECIST 1.0/1.1
- Modified RECIST for HCC (2008)
- WHO Methodology
- Wolchock Immune Related (irRC)
- Volume

Immuno-Oncology



Recent advances in Immuno-Oncology therapies have given rise to an increase in the conduct of oncologic drug development focused on Immuno-therapies. Bioclinica offers detailed understanding of established assessment criteria as well as extensive expertise in the application of modified RECIST or irRECIST criteria.

Cardio-Oncology

The association of many oncology drugs with cardiotoxic side effects necessitates sponsor vigilance and independent cardiac safety studies. Bioclinica has extensive expertise in planning and supporting successful cardiac safety studies facilitating risk assessment for oncology drugs early in clinical development.

Regulatory Leadership

Bioclinica senior management continues to play a leadership role in the establishment of processes, methods and guidelines that shape new guidance for imaging endpoints. Our experts have a detailed understanding of Imaging Review Charter (IRC) requirements and protocol development, adhering to guidance from the FDA, EMA, and international regulatory agencies.

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