

Medical imaging plays a key role in evaluating the efficacy and safety of new oncology treatments. 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 reduce risk to key areas of clinical development, offering the flexibility and scalability necessary to meet your oncology project needs. Our decades of experience include advanced capabilities in small early phase molecular imaging studies to large, more complex, late phase registrational trials.

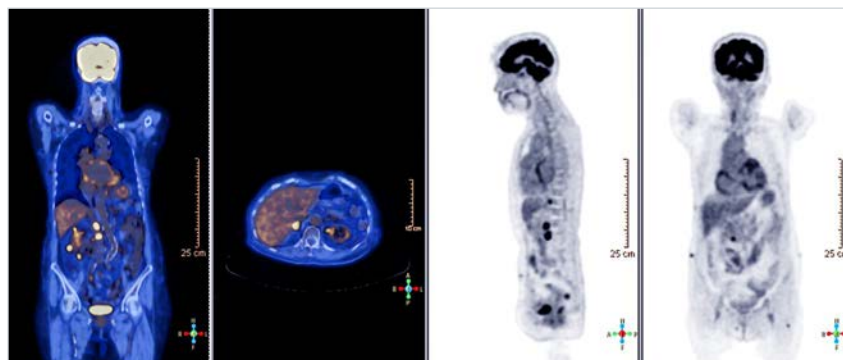
### Expert Independent Review

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 can analyze all images from baseline through follow-up with fast turnaround times and can provide a blinded, comprehensive oncology response review.

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

### Key Features

- On-staff oncologists and radiologists complemented by a worldwide network of key opinion leaders, led by our Chief Medical Officer, Michael O'Neal MD
- Medical and scientific experts with advanced knowledge of imaging modalities including CT, MRI, PET, and bone scan
- Oncology Project Management teams leveraging phase, indication and assessment criteria experience focused on your timelines, metrics and budgets
- Global offices in North America, Asia, and Europe
- Unparalleled regulatory experience with 100+ FDA oncology approvals
- Study and protocol design consulting
- Site imaging capability oversight and training to help ensure important standardization across sites
- Complete image data receipt, archival, and workflow with 21 CFR Part 11 compliant fully-integrated solution
- Experience in operationalizing new and evolving response criteria in real time
- Real-time read monitoring for all projects
- Experienced medical writing professionals driving Imaging Review Charter development leveraging internal and external experts



## Immuno-Oncology

Recent advances in Personalized Medicines and Immunotherapies have given rise to an increase in the conduct of immuno-oncologic drug development. Bioclinica offers detailed understanding of established assessment criteria as well as extensive expertise in the application of several different approaches including iRECIST and irRECIST.

## Cardio-Oncology

The association of many oncology drugs with cardiotoxic side effects necessitates that sponsors include cardiac safety endpoints, such as cardiac imaging (Echo and cardiac MR) as well as electrophysiology (ECG) and hemodynamic (BP) to define the potential cardiac safety signal and benefit-risk considerations in the therapeutic agents development plan. 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 counsel that shape new guidance for imaging endpoints. Our experts have a detailed understanding of Imaging Review Charter requirements and protocol development, adhering to recommendations and feedback from the FDA, EMA, and other international regulatory agencies. We have substantial skill in supporting regulatory submissions and inspections.

## Trial Indication Experience

Our team has experience with an array of disease indications. The breadth of experience includes single indications with single or multiple response criteria and extends to multiple indications and multiple response criteria. Bioclinica is able to utilize all applicable response criteria.

- Acute Lymphocytic Leukemia (ALL)
- Acute Myeloid Leukemia (AML)
- Bladder Cancer
- Brain Cancer
- Breast Cancer
- Chronic Lymphocytic Leukemia (CLL)
- Colorectal Cancer (CRC)
- Cutaneous Squamous Cell Carcinoma (cSCC)
- Endometrial Cancer
- Gastric Cancer
- GI Stromal Tumor
- Glioblastoma
- Head and Neck Cancer
- Hepatocellular Carcinoma
- Hodgkin's Lymphoma
- Interstitial Lung Disease
- Liver Cancer
- Melanoma
- Mesothelioma
- Multiple Myeloma
- Myelofibrosis
- Non-Hodgkin's Lymphoma (NHL)
- Non-Small Cell Lung Cancer (NSCLC)
- Ovarian Cancer
- Pancreatic Cancer
- Prostate Cancer
- Renal Cell Carcinoma (RCC)
- Sarcomas
- Small Cell Lung Cancer (SCLC)
- Thyroid Cancer
- Urothelial Cancer
- Waldenstrom Macroglobulinemia

## Molecular Imaging Expertise

Advances in molecular imaging enable the ability to measure functional changes in tumor microenvironments. Bioclinica supports a full range of molecular imaging modalities used to identify, stage, and monitor various cancers.

- $^{18}\text{F}$ -fluorodeoxyglucose (FDG)
- 3'-deoxy-3'- $^{18}\text{F}$ -fluorothymidine (FLT)
- $^{18}\text{F}$ -fluoromisonidazole (FMISO)
- $^{18}\text{F}$ -NaF
- $^{111}\text{In}$ -octreotide
- $^{123}\text{I}$ -metaiodobenzylguanidine (mIBG)
- $^{99\text{m}}\text{Tc}$ -MDP
- $^{68}\text{Ga}$  PSMA PET and  $^{68}\text{Ga}$ -DOTATATE

With decades of imaging experience, over 1,200 oncology trials, and 100+ FDA approved oncology trials, Bioclinica leads the industry.

## Tumor Response Criteria

Our 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 1999/2007
- Choi
- CNS RECIST 1.1
- EORTC
- Hallek 2008/2018
- ILD Assessment
- IMWG
- Lugano
- LYRIC
- Novel tracer diagnostic/theragnostic
- Olsen
- Owen
- PCWG2/PCWG3
- PERCIST
- Photography Assessment
- RANO/iRANO
- RECIST 1.0/1.1
- RECIL
- iRECIST
- irRC
- mRECIST
- WHO Methodology
- irRECIST
- Tumor Volume