

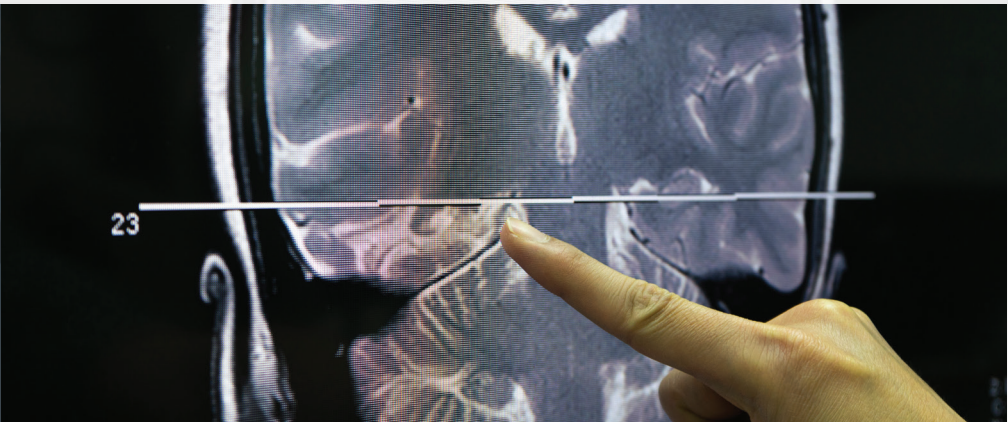
BIOCLINICA

MEDICAL IMAGING

Accelerate drug development with scientific and medical experts who can see more deeply into essential imaging data — and uncover important conclusions others might miss.

**BIOCLINICA IS COMMITTED
TO THE SUCCESS OF YOUR TRIAL**
– working together with sponsors
and sites, overseeing qualitative and
quantitative evaluations, and delivering
high-quality image data.

**When you compromise medical imaging, you
risk missing KEY INSIGHTS FROM YOUR DATA.**



**ON-STAFF, HIGHLY-QUALIFIED MEDICAL
IMAGING EXPERTS & GLOBAL KEY
OPINION LEADERS (KOLs):**

- » Radiologists
- » Neuroradiologists
- » Nuclear Medicine Physicians
- » Cardiologists
- » Imaging Scientists & Physicists
- » Oncologists
- » Imaging Technologists

SUPPORTING:

- » Regulatory & Compliance Decisions
- » Protocol Design
- » Selection of Modality & Endpoint
- » Preparation for Audits
- » Clinical Data Management & Biostatistics



**GLOBAL NETWORK
of Centers of Excellence
across three continents:**

**NORTH
AMERICA**

West & East Coast

EUROPE

**United Kingdom
& Germany**

ASIA-PACIFIC

China & Japan



THERAPEUTIC STRENGTHS

Bioclinica is the world leader in CENTRALIZED IMAGING SERVICES, providing comprehensive support across all major indications:

» Oncology

» Neuroscience

» Musculoskeletal

» Infectious Disease

» Cardiovascular

» Metabolic & Endocrinology

» Inflammation & GI

» Respiratory

» Diagnostic Agents

ENDPOINT SUPPORT FOR BREAKTHROUGH THERAPIES INCLUDING:

» Adcetris

» Avastin

» Crizotinib

» Erbitux

» Fosamax

» Ibrance



Therapeutically aligned teams have experience with the latest advancements in medical imaging modalities, molecular imaging tracers and disease biomarkers:

» Molecular Imaging (PET/CT),
Single-Photon Emission Computed
Tomography (SPECT)

» Nuclear Medicine

» Computed Tomography (CT)

» Quantitative CT (QCT)

» Dual-Energy X-Ray Absorptiometry
(DXA)

» MRI & Functional MRI (fMRI)

» Echocardiography

» X-Ray

» Angiography

» Ultrasound

» Endoscopy

» Keytruda

» Opdivo

» Remicade

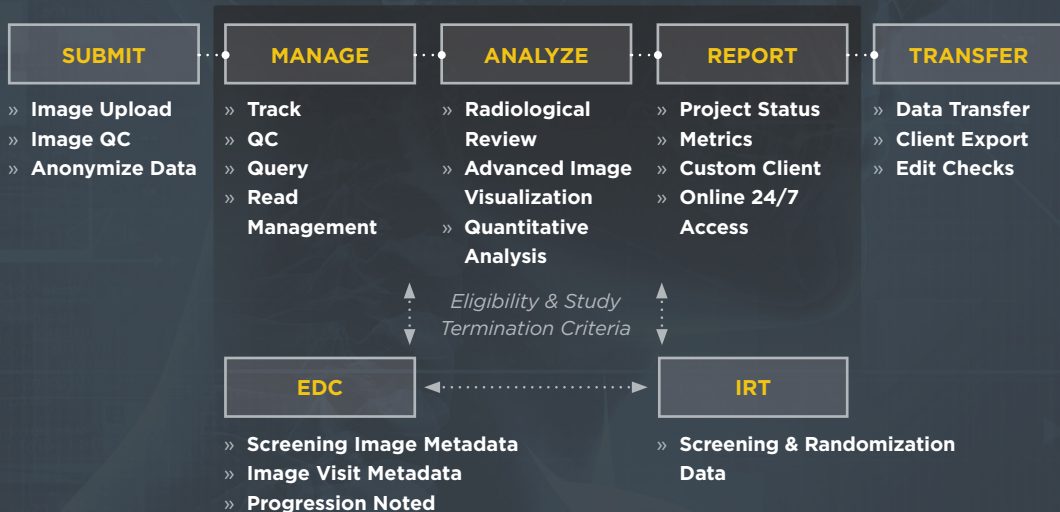
» Rituxan

» Xgeva

SCIENCE-ENABLED IMAGING TECHNOLOGY

Our robust suite of centralized medical imaging trial services – Bioclinica SMART – helps you manage the complex imaging process from image receipt and management to analysis and regulatory submission.

BIOCLINICA SMART ENABLES EASY ELECTRONIC SUBMISSION AND GUARANTEED DATA PRIVACY. ADDITIONALLY, THE INCORPORATION OF BEST-IN-CLASS ECLINICAL TECHNOLOGIES STREAMLINES CRITICAL PROCESSES TO ACCELERATE CLINICAL TIMELINES AND BUSINESS VALUE.



As the global leader in medical imaging core lab services, Bioclinica offers the scientific, medical & technology expertise to help you:

- » Ensure efficient, accurate, and consistent study timelines aligned with the protocol endpoints
- » Effectively manage imaging quality control & workflows in complex environments
- » Obtain timely & consistently high-quality image analysis for eligibility, safety, & efficacy studies
- » Access expert independent image review

BIOCLINICA PROVIDES SUPPORT FOR PRIMARY, SECONDARY & EXPLORATORY ENDPOINTS, SUPPORTING NEARLY 200 FDA-APPROVED THERAPIES TO DATE.

BIOCLINICA 'SMART SUBMIT'



- 2018 Clinical Informatics News Best Practices Award, Patient Data Management
- 2018 Informa CARE Award Finalist, Best Sponsor-Focused Technological Development





**SUPPORTING KEY
THERAPEUTIC AREAS**

**We have more experience
than any other core lab in designing
and conducting clinical trials.**

200+

**NEUROSCIENCE
STUDIES**

**Bioclinica has supported
the majority of**

PHASE III

**ALZHEIMER'S DISEASE
CLINICAL TRIALS
INCORPORATING
IMAGING ENDPOINTS**

NEUROSCIENCE

Advanced medical imaging can provide important, quantitative information on global and regional structural brain changes.

LEADERSHIP IN:

- » Alzheimer's Disease (AD) & other dementias
- » Multiple Sclerosis (MS)
- » Parkinson's Disease (PD)
- » Stroke

EXPERIENCE SUPPORTING:

- » Contrast agents/Radiopharmaceuticals
- » Cushing's disease/Acromegaly
- » Depression
- » Down Syndrome
- » Intracranial hemorrhage
- » Inherited diseases
- » Medical devices
- » Progressive supranuclear palsy
- » Psychiatric disorders
- » Spinal cord injury
- » Trauma

ONCOLOGY

Bioclinica is the world leader in oncology imaging, helping to assess efficacy and safety across thousands of clinical trials.

LEADERSHIP IN:

- » Breast
 - » Lung
 - » Lymphoma
- Medical imaging expertise to support multiple tumor types in Phase I-IV studies.
- Support for the latest developments in imaging endpoints and protocol design:
- » Oncology imaging endpoint analysis
 - » Molecular imaging biomarkers
 - » Theranostics
 - » Immuno-oncology
 - » Cardio-oncology

1,200+

ONCOLOGY STUDIES

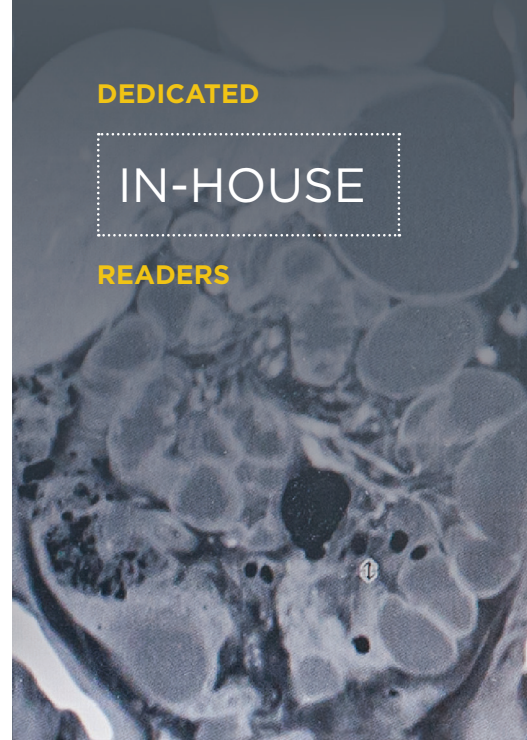
98+

**FDA-APPROVED
ONCOLOGY DRUGS**

DEDICATED

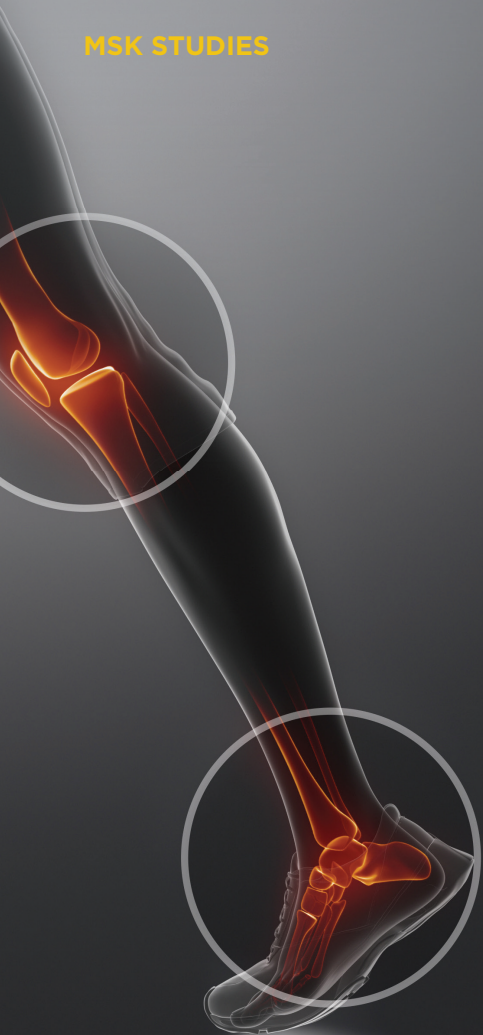
IN-HOUSE

READERS



550+

MSK STUDIES



MUSCULOSKELETAL (MSK) & MORE

Medical imaging endpoints are proven to shorten the decision-making process for MSK clinical trials.

EXPERIENCE WITH:

- » Rheumatoid arthritis
- » Psoriatic arthritis
- » Spondyloarthritis
- » Osteoarthritis
- » Osteoporosis
- » Orthopedics
- » Pediatric indications
- » Bone safety assessments

DEEP EXPERTISE IN:

- » Muscle wasting & myopathies
- » Women's health
- » NASH/NAFLD
- » Respiratory
- » Gastroenterology

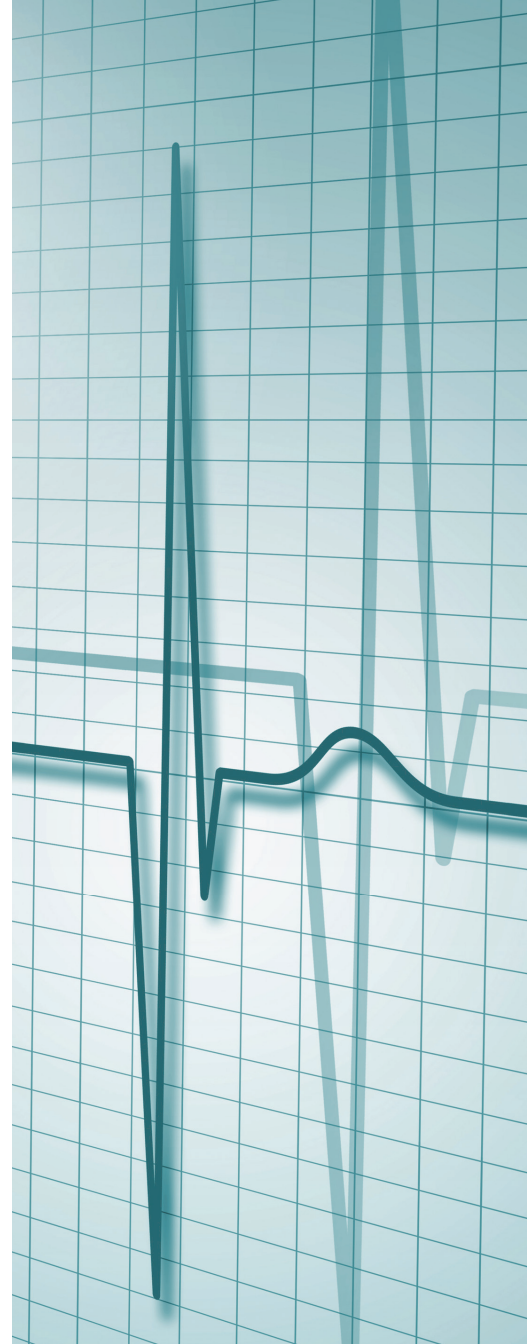
We are highly conversant with all major semiquantitative assessment scoring criteria and use numerous quantitative methods including joint space width, organ/tissue volume, tissue fat fraction, tissue stiffness, and T2/T2* mapping.

CARDIOVASCULAR

We deliver reproducible, high-quality data through quantitative analysis backed by the scientific expertise of board-certified cardiologists, radiologists, nuclear medicine physicians, registered radiologic technologists and sonographers.

COMPREHENSIVE EVALUATION OF CARDIAC STRUCTURE & FUNCTION:

- » Ejection fraction, cardiac volumes & mass
- » Heart valve assessment
- » Myocardial perfusion (viability, infarct size, scar tissue)
- » GL, LV, RV & LA Strain
- » Coronary artery calcium (CAC) scoring
- » Coronary and Peripheral Vascular disease assessments



850+

**CARDIOVASCULAR
SAFETY STUDIES**

60+

**CARDIO-ONCOLOGY
STUDIES**

100%

**US BOARD-CERTIFIED
CARDIOLOGIST ECG
OVERREAD**

CARDIOVASCULAR SAFETY

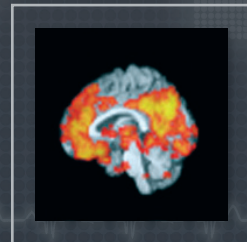
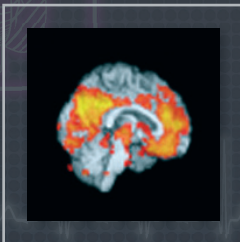
A 25+ year successful history in supporting drug development. Ongoing awareness of the changes in the cardiac safety regulatory arena.

- Cross-trained PMs in both cardiac safety & therapeutic imaging endpoints
- 12-lead ECG / Holter Monitoring Services
 - » TQT and IQT study design, conduct, analysis, reporting and submission
 - » Standard 12-lead and Holter ECG extraction
 - » In-clinic heart rate trend monitoring
 - » Arrhythmia monitoring
- Blood pressure (BP) monitoring services
 - » Ambulatory BP monitoring (ABPM)
 - » Centralized automated office BP monitoring (C-AOBP)
 - » Telemonitored self-measured BP monitoring (T-SMBP)
 - » Advanced non-invasive hemodynamic monitoring (PWA)

Bioclinica continues to ACCELERATE DRUG DEVELOPMENT.

We work in tandem with regulatory agencies and clinical research organizations to establish medical imaging standards, and participate in FDA meetings to actively lead the shaping of new guidance for imaging endpoints in clinical trials.

By collaborating with university, government and research foundation scientists, we continue to develop innovative image processing techniques and methodologies.





All processes, including complete image data archival, are fully compliant with 21 CFR Part 11.

Bioclinica takes careful measures to ensure the data you receive is of the highest quality and meets regulatory compliance requirements. We provide rigorous site authorization and training, image QC, independent eligibility and safety assessments, robust quantitative analysis, and validated software. We maintain close interactions with clinical and imaging sites, helping sponsors identify quality findings, resolve image queries and adhere to protocol workflow and timelines.



Ready to bring clarity to your clinical trial? Visit bioclinica.com.

bioclinica.com/contact

