

## TUMOR RESPONSE EVALUATION

In oncology, there are many imaging endpoints based on the assessment of tumor size or function. These endpoints include disease-free survival, objective response rate, time to progression, progression-free survival and time to treatment failure. The analysis of these endpoints may employ any number of response assessment criteria guidelines including:

- ⊗ **RECIST 1.0**
- ⊗ **RECIST 1.1**
- ⊗ **WHO Response Criteria**
- ⊗ **Cheson Criteria (1999 and 2007)**
- ⊗ **Macdonald Criteria**
- ⊗ **Volumetric Assessment**

### UNITED STATES

BioClinica - HEADQUARTERS  
826 Newtown-Yardley Rd.  
Newtown, PA 18940-1721  
+1-267-757-3000

BioClinica  
800 Adams Ave.  
Audubon, PA 19403-2325  
+1-484-928-6000

### EUROPE

BioClinica B.V.  
Schipholweg 117  
NL 2316 XC Leiden  
The Netherlands  
+31-71-524-8660

BioClinica, S.A.S.  
Adenine  
Bioparc  
60 Avenue Rockefeller  
F-69008 Lyon, France  
+33-4-26-23-05-05



**BIOCLINICA™**  
Global clinical trial solutions. Real-world results.

# ONCOLOGY

Expertise

BioClinica's experience extends to all these criteria, often employing two or more in a clinical trial. The complexity of this process is not just in the number of criteria assessed but also in the methodology selected for categorization of disease. Correct lesion identification and tracking is vital to ensure accurate and precise interpretation and ongoing evaluation.

[www.bioclinica.com](http://www.bioclinica.com)  
NASDAQ: BIOC | © 2010 BioClinica Inc.

**BIOCLINICA™**  
Global clinical trial solutions. Real-world results.

## IMAGING REVIEW CHARTER DEVELOPMENT

With an ever-increasing number of Imaging Review Charters (IRCs) submitted to regulatory authorities, BioClinica has an extensive track record in writing and preparing IRCs for a successful regulatory review. Our charter development process is second to none due to our comprehensive knowledge base with various protocol indications and endpoints.

BioClinica has created a dedicated IRC team to provide the assistance our clients need to develop these critical documents in a timely fashion. Under the direction of our Medical Director, our internal scientific staff, expert consultants and medical writers provide this vital service. Our process ensures that the IRCs are developed to meet both BioClinica's quality standards and the FDA's regulatory rigor.

Furthermore, BioClinica's staff actively participates in the FDA round table meetings, which help develop IRC criteria and independent review guidelines.

## MODALITY EXPERTISE

BioClinica provides medical imaging modality expertise in diagnosis, staging and assessment of therapeutic response. This domain knowledge is continually updated to reflect the latest developments in quantitative, semi-quantitative and qualitative image analysis. BioClinica's scientific staff is in continuous contact with the FDA to be aware of and implement any new regulatory guidance.

- ⊗ **Computed Tomography (CT)**
- ⊗ **Dynamic Contrast-Enhanced Magnetic Resonance Imaging (DCE-MRI)**
- ⊗ **Magnetic Resonance Imaging (MRI)**
- ⊗ **Molecular Imaging**
- ⊗ **Positron Emission Tomography / Computed Tomography (PET/CT)**
- ⊗ **Ultrasound**
- ⊗ **X-ray**

## INDEPENDENT REVIEW EXPERTISE

The independent blinded interpretation of the imaging data is of paramount importance in every clinical trial. BioClinica's Bio-READ™ system provides the platform for state-of-the-art radiological evaluation of the clinical trial data. The Bio-READ™ system allows the images to be displayed in a completely blinded fashion, eliminating potential bias associated with the review. The radiologists selected for these reads are all licensed, Board-certified experts; many of whom hold fellowship training in their respective therapeutic area and meet all FDA requirements as independent consultant readers. We generally select a minimum of two experienced independent readers and a separate adjudicator from different institutions. The radiologists are selected either by the client or from BioClinica's network of radiologists. Curricula vitae are available for client review and approval prior to the final selection of the readers.

## ONCOLOGY EXPERTISE

BioClinica has extensive experience and expertise in the management of medical images for oncology clinical trials. We have completed over 300 trials in a wide range of oncologic indications, including:

Astrocytoma  
Bladder  
Breast  
Central Nervous System  
- Primary  
- Metastatic

Cervical  
Colorectal  
Esophageal  
Gastric  
Glioblastoma  
Head and Neck

Hepatocellular  
Liver  
- Primary  
- Metastatic  
Lung  
- Small Cell  
- Non-small Cell

Lymphoma  
- Hodgkin's  
- Non-Hodgkin's  
Melanoma  
Mesothelioma  
Oral  
Ovarian

Pancreatic  
Prostate  
Renal Cell  
Sarcoma  
Testicular  
Thyroid