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Top 7 criteria

# Selecting the best imaging CRO

## Overview

In the clinical trials process, high quality imaging used as surrogate endpoints significantly improves the evaluation of novel cancer therapies. Evaluating imaging data plays an invaluable role in assessing disease status and drug efficacy over multiple therapeutic cycles and throughout the clinical trials process. Image analysis can be highly subjective: for example, several radiologists may interpret the same image differently. In addition, technological variations in imaging data may exist across multiple study sites involved in the same clinical trial.

By choosing an Imaging Contract Research Organization (ICRO) with expertise in imaging protocols and state-of-the-art image acquisition and analysis, data management and quality control, there is a shift to more objective, less variable, and more sensitive analysis, which greatly enhances results and the strength of the study. Successful outcomes and reduced risks are a reflection also of your ICRO's therapeutic expertise, track record, global capacity, project management support, availability, flexibility, transparency and out-of-the-box thinking.

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## Expertise

**•Therapeutic research expertise and diversity**
- Access to specialists with formal training and experience in evaluating, designing and executing a study
  - Rapid turnaround time and fewer potential logistical challenges
  - Provides significant value when helping with study design

**•State-of-the-art analysis**
- Standardized and automated
- Offers multiple analysis techniques and criteria: RECIST 1.0/1.1, volumetric assessment, etc.
- High sensitivity and specificity
- Low inter-reader variability
- Thought-leaders or experts in technologies for data acquisition and analysis

**•Data management and quality control**
- Automated and standardized to reduce bias
- Coordination of central review of images by trained radiologists
- Highly informative reports and documentation
- Image acquisition and data management consultation to researchers, clinicians and technicians at remote study sites
- Easy data sharing and access

**•Consultant strength**
- Devise most effective path to drive Go/No Go decisions
- Comply with regulations (FDA/EMEA, etc)

**•Imaging modality diversity**
- Expertise with both 2-dimensional (e.g., ultrasound, xray, confocal, etc) and 3-dimensional (e.g., CT, MRI, etc) imaging modalities
- Provides multiple options and combinations to achieve optimal study end-point measurements

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## Technological capabilities

**• Advanced technology**
- Standardized and automated image management and analysis systems for identifying and tracking lesions
  - Provides objective, quantitative data
  - Removes error-prone tedious manual searches
  - Produces harmonized data sets in multi-center studies
- Simultaneous management of most advanced imaging markers (Choi, Cheson, irRECIST, mRECIST, etc)

**•IT capabilities**

**•Image management capabilities**
- Smooth transfer of images with built in quality control
- Access to images and data rich reporting
- Integration with eCRFs

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## Track record

- **Global capacity and international footprint**
- **Can provide references from well-established pharmaceutical and biotech organizations**
- **Successfully worked with sponsors to present and defend study data to regulatory agencies**
- **A strong track record that minimizes risk with evidence of success**


**References**

1. Kola, I. and J. Landis, Can the pharmaceutical industry reduce attrition rates? Nat Rev Drug Discov, 2004. 3(8): p. 711-716.
2. Rubin, D.L., Informatics in Radiology: Measuring and Improving Quality in Radiology: Meeting the Challenge with Informatics. RadioGraphics, 2011. 31(6): p. 1511-1527.


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## Structuring a project for success through training, support and management of investigator sites

- **Support and guidance**
  - Imaging criteria selection
  - SOP selection
  - Reader and Site Qualification
- **Centralized databases**
- **Scalable**
  - Small number of sites in a few countries to large set of investigators in a high number of countries
- **Project management**
  - Processes and best practices inferred from the international standard (PMI)


## Regulatory compliance

- **Clinical services conducted according to ICH-GCP guidelines**
- **Compliant with FDA regulations and EMA directives**


## Out-of-the-box-thinking

- **Identifies problems, quickly designs solutions and implements solutions efficiently and effectively**
  - For example, if a client has a need for an enhanced analysis feature that would optimize results in their clinical study, an ICRO would ideally be able to engage their software engineers to develop and validate this novel image analysis feature within a fast turn-around time to meet the needs of the client.


## Pricing

- **Competitive proposals**
- **Transparency**
- **Respect of budget**




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**Median checks all the boxes!**

Median is the right imaging solution for your oncology clinical trials. By bringing together image specialists, superior technology to automate and standardize image management and expert data & project management teams, we provide you with the most meaningful data so you can make better and quicker decisions about your cancer therapy. Median Technologies is a full service global imaging clinical research organization with experience in Phase I - III oncology trials.



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The Imaging Phenomics™ Company

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