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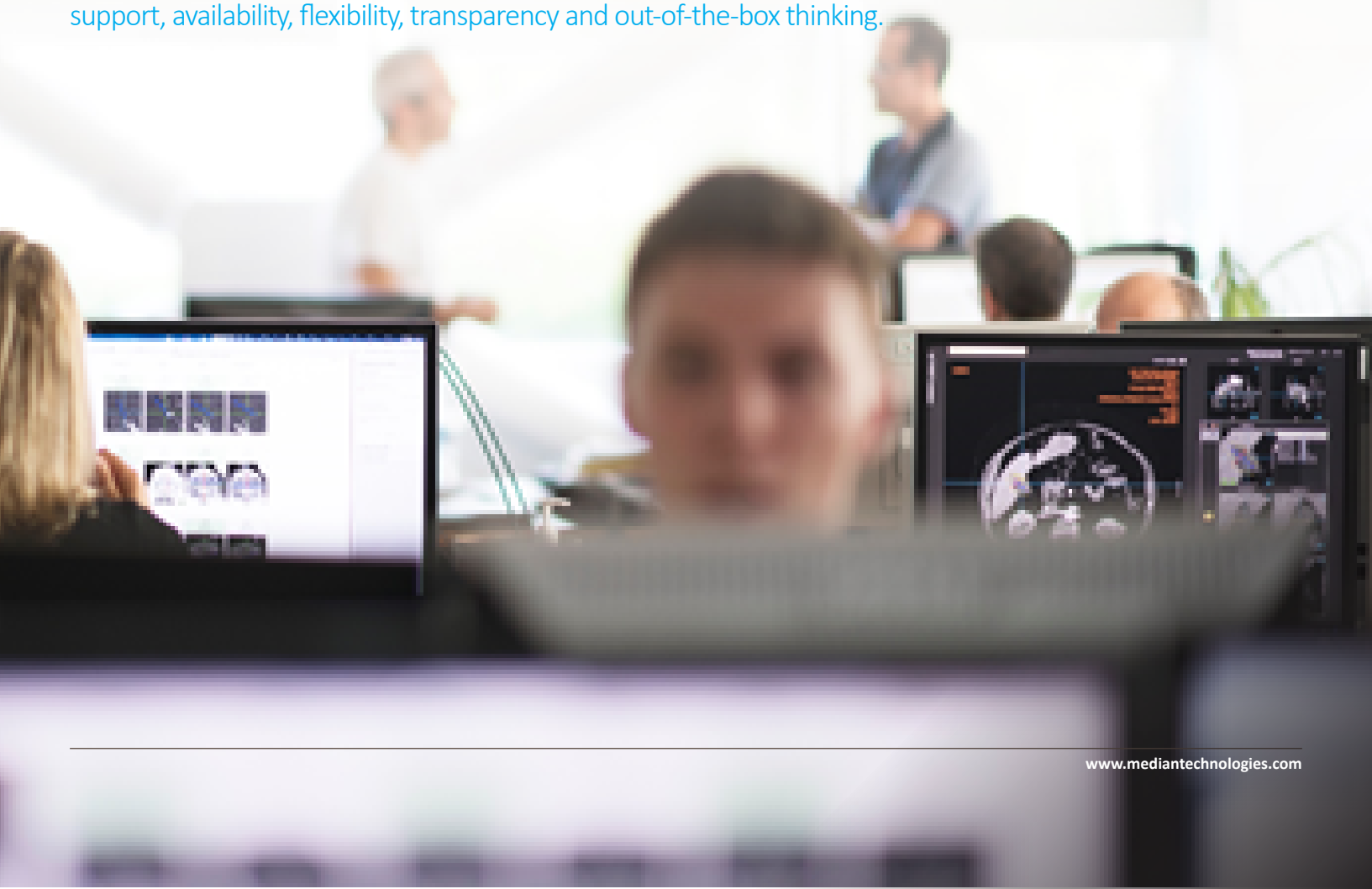
Top 8 criteria

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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1

Expertise

Therapeutic research expertise

- Specialists with formal training and experience in evaluating, designing and executing a study
  - — Rapid turnaround time and fewer logistical challenges
  - — Valuable insights into study design

State-of-the-art analysis

- Standardized and automated
- Multiple analysis techniques and criteria, e.g., RECIST 1.1, iRECIST, volumetric assessment, etc.
- High sensitivity and specificity
- Low inter-reader variability
- Thought leaders 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 training for researchers, clinicians and technicians at remote study sites
- Easy data sharing and access

Consultant strength

- Most effective path to drive Go/No Go decisions
- Experience with clinical trial regulations (FDA/EMA, etc)

Imaging modality diversity

- Expertise with 2-dimensional (e.g., ultrasound, X-ray, confocal) and 3-dimensional (e.g., CT, MRI) imaging modalities
- Multiple options and combinations to achieve optimal study end-point measurements

2

Technological capabilities

Advanced technology

- Standardized and automated image management and analysis systems for identifying and tracking lesions
  - — Objective, quantitative data
  - — Elimination of error-prone tedious manual searches
  - — Harmonized data sets in multi-center studies
- Simultaneous management of advanced imaging markers (Choi, Cheson, iRECIST, mRECIST, etc.)

IT capabilities: in-house and adept in the latest technologies

Image management capabilities

- Smooth transfer of images with built in quality control
- Access to images and data rich reporting
- Integration with eCRFs

3

Track record

Global capacity and international footprint

References from well-established pharmaceutical and biotech organizations

Successful collaboration with sponsors in presenting and defending study data to regulatory agencies

A strong track record of minimizing risk and maximizing 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
- From a small number of sites in a few countries to a large set of investigators in many countries

Project management
- Processes and best practices inferred from the international standard (PMI)

5

Regulatory compliance

Clinical services conducted according to ICH-GCP guidelines

Compliant with FDA regulations and EMA directives

6

Out-of-the-box-thinking

Identified problems are quickly and efficiently solved
For example, if a client has a need for an enhanced analysis feature that would optimize results in its clinical study, an ICRO would ideally be able to engage its software engineers to quickly develop and validate this novel image analysis feature.

7

Pricing

Competitive proposals

Transparency

Respect for the sponsor's budget

8

Cultural Fit

Mutual trust and transparency

Good fit with your team and ways of doing business

Mission and vision alignment: bringing better therapies to market to help make a healthier world

Median checks all the boxes!

Since 2002, Median has been doing one thing and one thing only - expanding the boundaries of the identification, interpretation, analysis and reporting of imaging data in the medical world. Median is at the heart of innovative imaging solutions to advance healthcare for everyone. As The Imaging Phenomics Company®, Median provides insights into novel therapies and treatment strategies. Our unique solutions, MediScan® for patient care, iSee® for clinical trials, and iBiopsy® for imaging diagnostics, together with our global team of experts, are advancing the development of new drugs and diagnostic tools to monitor disease and assess response to therapy.

Median Technologies supports bio-pharmaceutical sponsors and healthcare professionals around the world in bringing new and targeted treatments to patients in need with an eye on reducing overall costs. This is how we are helping to create a healthier world.

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Top 8 criteria: Selecting the Best Imaging CRO v1.5

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