

## **Imaging in Oncology Trials**

Delivering best-in-class imaging services and expertise to clinical sponsors worldwide



#### Contents

Artificial Intelligence is our DNA	
Transforming the science of	
medical imaging	

1

2

4

5

6

8

of

Creating value from medical images: our two Business Units

### A world-class imaging partner

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Peop	ole p	ushi	ng t	he	bour	darie

imaging technology

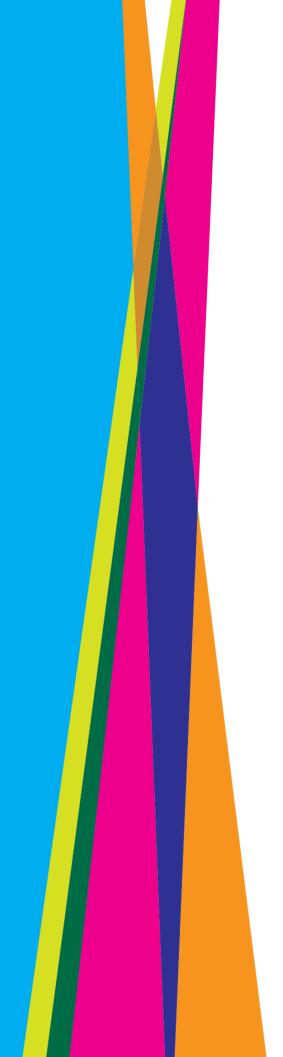
A smart, proactive and responsive team backed-up with in-house experts

A blend of sciences, technology,	
clinical expertise, and operational	
excellence	

**Cancer therapy and immunotherapy clinical trials using Median** Facts and figures

**Experience by primary cancer indication** 156 studies

Median Technologies can help deliver for your oncology trials Our expertise and end-to-end imaging services are tailored to your studies



## **Redefining the patient journey with AI-powered imaging**

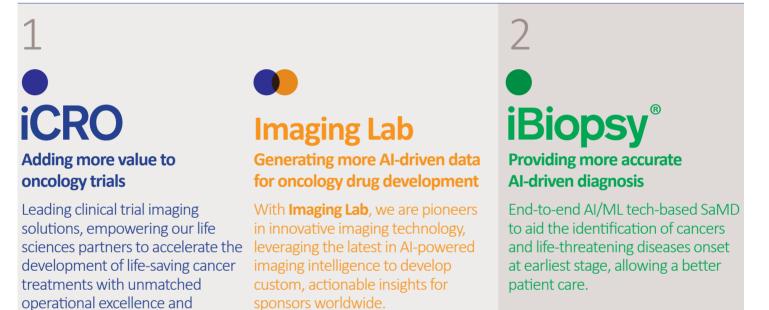
Medical images reveal the disease as it really is, at every stage and allow to monitor its evolution in a non-invasive manner. Harnessing the true power of medical images is key to accelerate clinical innovations, drug development and improve patient care.

At Median, we transform medical images into meaningful, actionable insights to help better diagnose, treat, and monitor patients. We harness the power of medical images by using the most advanced Artificial Intelligence technologies, to increase the accuracy of diagnosis and treatment of many cancers and fibrotic diseases at their earliest stages and provide insights into novel therapies for patients.

#### Our two Business Units:

reliability.

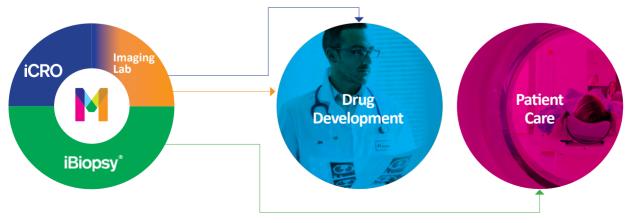
#### Translating medical images into valuable clinical insights



Applying Median's offer to drug development and patient care

iBiopsy<sup>®</sup> is for research use only – not to be used for diagnostic procedures

Al/ML: Artificial Intelligence/Machine Learning; SaMD: Software as Medical Device.



iCRO: Imaging services for oncology trials

## A world-class imaging partner

Offices: Boston, USA - Sophia Antipolis, France - Shanghai, China

230 +

Employees\*

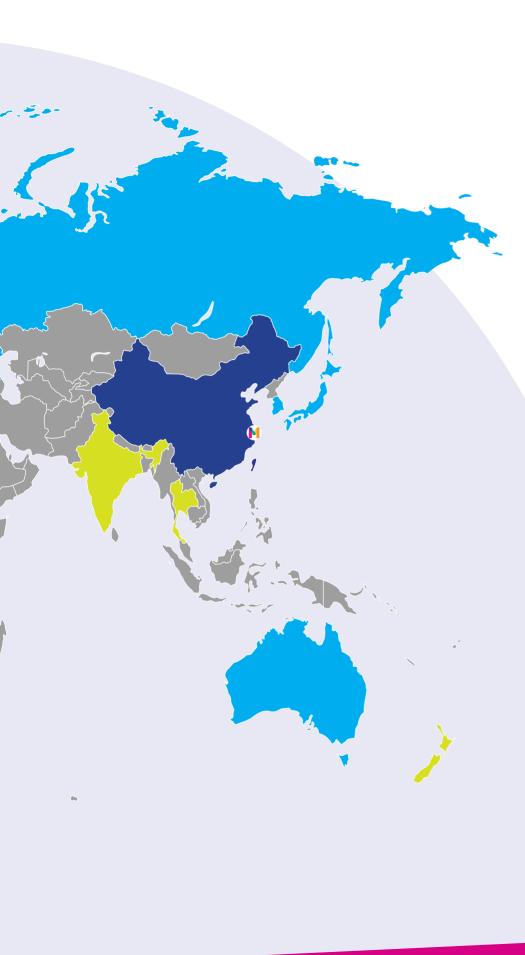


Working with 2,800 + investigator sites\*\*



**Oncology clinical trials supported**\*\*

\* As of December 31st, 2022 \*\* As of June 30th, 2023



Median delivers on a global scale. Our reach stretches from the USA, the world's largest healthcare and drug development market, across Europe, and into Asia, an increasingly important region for clinical development and healthcare markets.

As an iCRO, we deliver end-to-end imaging services for Phase I – Phase III clinical trials and are committed to top quality and operational excellence. Our focus is oncology, a therapeutic area representing the widest proportion of clinical trials worldwide; we have developed a considerable expertise in the field. We work with sponsors of all sizes, from major pharma organizations to small- and mediumsize biotech companies. Our footprint is global. With our offices in Europe, the US and China, we deliver globally, providing best-in-class imaging services to our biopharma clients. We also partner with major Contract Research Organizations (CRO), for whom our imaging solutions complement their traditional clinical trial expertise. We are currently working with 2,800+ investigator sites through the world and more than 50+ biopharma sponsors.

 Number of sites

 201 +

 101-200

 51-100

 21-50

 1-20

## The Median advantage People pushing the boundaries of imaging technology

Median has unmatched clinical, technology and operational expertise in oncology trials. Our talented, dedicated people keep pushing the boundaries of what our unique, specialist knowledge and technologies can achieve.

Our efforts are changing the way images are used in clinical trials; extracting the highest quality, most advanced non-invasive imaging biomarkers so it becomes the standard for developing new therapies, diagnosing diseases and treating patients.

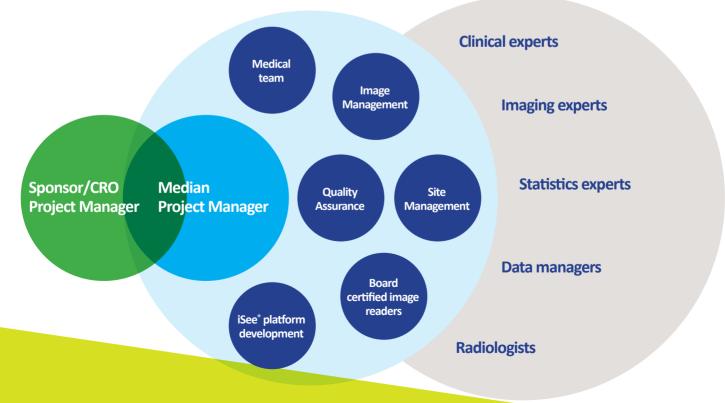
When you work with us, you benefit from a senior level team who stays with you every step of the way throughout your trial. We always remain flexible and adaptable to best serve your needs, be it offering transparency to your project and data, or proactive support. In fact, we pride ourselves on high engagement and flexibility from our small dedicated team approach. As of December 2022, our company is made up of 230+ employees worldwide with R&D totalling 25% of the total headcount.

In our day-to-day work, there is no greater satisfaction than making a difference that has the potential to help save or improve the lives of millions of people.

#### **Our values**

As individuals and as a team, we are guided by four core values that are essential to us: leading health innovation with purpose, committing to quality in all we do, supporting our customers in achieving their goals. and putting the patient first. These values define who we are, what we do, the way we do it, and what we. as Median Technologies, aspire to. We strive to apply these values in the relationships we have with one another, our customers and partners, and the solutions we provide. This is what it means to be a part of Median Technologies.

# A smart, proactive and responsive team backed-up with in-house experts



**Median Technologies** 

# A blend of sciences, technology, clinical expertise, and operational excellence

#### An experienced medical team

As part of the Medical Affairs department, our medical team is key for our iCRO activities. Placed under the responsibility of our CMO, the medical team supports all operations from RFPs to study close-out. The team is responsible for providing key expertise on protocol design and imaging criteria selection, mostly at the beginning of studies. Reader selection, training, ongoing quality monitoring (based on intra- and inter-reader variability measurements) are also under his/her responsibility.

In addition to board certified radiologists, Median's medical team includes lead scientists, who collaborate whenever possible with sponsors, and identify potential scientific publications to be presented in international conferences and meetings – i.e., ASCO, ESMO, RSNA and ESR annual meetings, and peers reviewed articles.

## Empower your oncology trials with Artificial Intelligence

At Median, we harness the power of medical images by using advanced AI technologies to provide insight into novel therapies for patients. We established our Imaging Lab to deliver additional metrics and analysis for better understanding drug profiles by leveraging artificial intelligence technologies. Using AI can assist you to:

- Triage patients
- Predict response to therapy
- Assess drug effects in advance
- Improve drug safety

## iSee<sup>°</sup>, our unique and proprietary imaging platform

Median is at the heart of innovative imaging solutions with iSee<sup>®</sup>, our oncology-focused image analysis and data management software. This innovative software is advancing the development of new drugs. iSee<sup>®</sup> helps radiologists automatically identify, quantify, and track lesions across time points. All our readers use iSee<sup>®</sup>, accessed through a web-browser for all imaging projects we manage.



	Identify				
	Description (unit)	Prior	Cu.	Follow-up	^
	Segmentation method	Nodule	Nodule		
	Elapsed time (days)			92	
	Doubling time (days)			293	
	Volume (mm3)	···· <mark>430.3</mark>	···· <mark>535.0</mark>	24.3%	
~	Axial LD (mm)	<b>10.3</b>	<b>11.6</b>	11.8%	
V	Width (mm)	<mark>ш</mark> 8.1	<mark>ш</mark> 9.1	12.0%	
	Max attenuation (HU)	119	165		
	Туре	Pulmonary	✓Pulmonary		
	Attenuation	Solid	Solid		
	Surrounding	VJuxtavas	─ Juxtavas		~
	00000	<u>a</u>			A

#### Quantify



### iSee<sup>°</sup>

- Limits reader subjectivity
- Increases accuracy and reproducibility
- Reduces inter-reader variability
- Streamlines data management
- Decreases data queries
- Provides both routine and
- advanced imaging biomarkers
- Delivers superior reporting

## Operational excellence and quality are at the core of everything we do at Median

We leverage our experience, know-how, and technology in each area of clinical development:

**Regulatory compliance and quality:** Our team has extensive practical knowledge of clinical trial regulatory requirements for image management. Our clinical services and technology platform iSee<sup>®</sup> comply with ICH/GCP guidelines, FDA, EMA and NMPA regulations, and clinical study protocols.

**Project management:** Our team includes collaboration professionals with a thorough understanding of project management practices, tools, and skills. Our project management processes and practices are derived from the international PMI standard and adapted to specific clinical trial requirements.

#### Data management and quality control:

Our iSee<sup>®</sup> platform provides structured image and lesion data handling. Our automated and standardized processes enforce image management and quality control with automated checks conducted as early as possible and throughout the entire data collection process using iSee<sup>®</sup>. Our solutions provide seamless, automated interoperability with clinical trial management and electronic data collection systems.

**Biostatistics and data analysis:** Median provides significant data analysis and biostatistics capabilities, including knowhow, tools, and methodology, for use in our customers' clinical trials.

**IT capabilities:** Our cloud-based IT infrastructure is optimized to increase uptime, while our remote data centers provide power and connection redundancies, ensuring continuity of operations and scalable services.

# Cancer therapy and immunotherapy clinical trials using Median

## Oncology overall:

230+ Total oncology trials supported

140 +

Phase I and II oncology trials supported



Phase III oncology trials supported

Immunotherapy:

120+

Immunotherapy studies supported

70+

Phase I and II immunotherapy trials supported

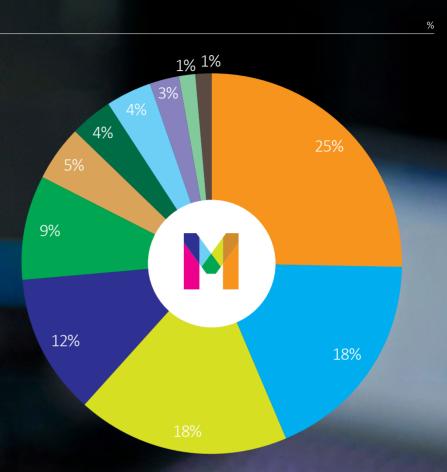
50+

Phase III immunotheraphy trials supported

Early and late phase trials numbers refer to cumulative contracted/awarded studies since the beginning of the iCRO activity, with awards of less than 12 months. All numbers are as of June 30, 2023.

# **Experience by primary cancer indication** 235 studies

Indication	Studies
Thoracic (Lung)	60
Gastrointestinal	43
Solid tumors	42
Gynecologic	28
Head and neck	21
Blood cancer	11
Skin	9
Urologic cancer	9
Neurology	6
Sarcoma	3
Other	3
Total	235



## Median Technologies can help deliver for your oncology trials Our expertise and end-to-end imaging services are tailored to your studies

#### We extract the utmost meaningful information from medical images

Median's imaging platform iSee<sup>®</sup> provides automated and standardized image analysis.

iSee<sup>®</sup> covers a wide range of cancer indications (solid tumors).

iSee<sup>®</sup> provides expert oversights of images, standardizing lesion detection, selection, quantification and tracking.

iSee<sup>®</sup> extracts standard and novel biomarkers.

iSee<sup>®</sup> provides multiple imaging criteria, from RECIST 1.1 to more specific criteria such as mRECIST or iRECIST.

# What does this mean for your study?

- More meaningful data from an image
- Highest quality data for better informed decisions including Go/NoGo decisions
- Increased data statistical power by limiting reading variability and increasing reproducibility of measures

# We provide a unique scientific and medical expertise

We deliver imaging expertise for oncology trials from phase I to phase III.

We focus on the evaluation of new oncology drugs including immuno-oncology drugs, and provide a high level of customization, depending on your trials and objectives.

We have a strong expertise in imaging protocol design and adapt reading design to protocol.

Our expertise covers a wide range of imaging criteria such as RECIST, iRECIST, mRECIST, irRC, RECIL, Lugano or RANO.

As a developer of cutting-edge imaging technologies, we pioneer the use of high-tech such as AI, or radiomics for image analysis in clinical trials.

# What does this mean for your study?

- 100% tailored imaging protocol design
- Enriched information for subsequent development phases or other trials through side by side comparison of routine and advanced imaging biomarkers
- Improved drug evaluation using emerging technologies and notably AI technologies
- Joint promotion of study results and scientific advances in scientific journals and conferences

# We manage end-to-end imaging workflows

Our service offer covers the full range of all you need to manage images in your oncology trials.

We deliver end-to-end imaging worflows:

- Study start up
- Image and clinical data management
- Scientific consulting
- Reader services, independent reviews
- Image data processing and site support
- Study close-up

# What does this mean for your study?

- Configurable software and flexible workflows quickly tailored to align with your operations and to match the needs of the trial
- Our small, dedicated, and experienced teams provide flexible, adaptable level of service for your project

## We implement stringent reading process

By utilizing a limited reader pool, we ensure high quality without compromising productivity.

Our network of readers includes only independent board-certified radiologists in the US, EU and China.

All our readers are trained to GCP/CFR21 part 11, and study specifics, through clinical/ technical sessions.

Our reader processes are adapted to each trial and strictly monitored.

We cover all reading designs based on protocol (Collect & Hold, Single or Double Independent Central Reviews) and implement strong rules to ensure quality.

## What does this mean for your study?

- For each study, reader selection according to their expertise in the indication, experience, monitoring results and workload
- Design and monitoring adapted to each trial and strictly monitored

## We provide online reporting tool for your studies

The Median Online Reporting Portal (ORP) is a configurable system providing ongoing status/ metrics on studies.

Each report provides status and performance metrics, evolution charts, data trackers that can be filtered and exported.

The ORP includes four specific reports to monitor four main activities:

- Site management
- Images collection
- Queries management
- Reads management

The ORP can be used by sponsors and Median project management teams.

# What does this mean for your study?

- Dedicated tracking access to your images and data
- Transparency to project and data

## We place quality at the core of everything we do

We apply stringent quality control processes that go beyond the industry standards.

Our dedicated QA team has an international coverage.

Our senior PMs are PMP<sup>®</sup> certified.

All our operations teams are trained (and regularly retrained) on GCP/CFR21 part 11.

In 2017, 2019 and 2021, we have successfully completed three FDA audits. We have also passed 5 NMPA audits between 2020 and 2021. Health authorities inspections are a daunting challenge for any provider, but we see them as an opportunity for continuous improvement.

On average, we are audited by our clients more than 10 times a year, which gives our QA team a very good experience and track record

# What does this mean for your study?

- Quality beyond standard QA
- Integrity of data
- Better dossiers for submission to health authorities
- Value dossiers for payers
- Dedicated experienced teams with minimal turnover delivering proactive support



#### About Us

At Median, we transform medical images into meaningful, actionable insights to help better diagnose, treat, and monitor patients. We harness the power of medical images by using the most advanced Artificial Intelligence technologies, to increase the accuracy of diagnosis and treatment of many cancers and other metabolic diseases at their earliest stages and provide insights into novel therapies for patients. Median's Imaging CRO business provides leading oncology clinical trial imaging services, empowering our life sciences partners to accelerate the development and delivery of life-saving cancer treatments with unmatched operational excellence and reliability. And we don't stop there. We are forging the way when it comes to innovative imaging technology, leveraging the latest in Al-powered imaging intelligence to develop actionable insights for sponsors worldwide.

mediantechnologies.com





Hendon

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