

## Imaging in Oncology Trials

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



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# Artificial Intelligence is our DNA

## Transforming the science of medical 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.**

Since 2002, Median has been expanding the boundaries of the identification, analysis and reporting of imaging data in the medical world, with a dedicated focus on cancer and other chronic diseases. We are at the heart of innovative imaging solutions to advance healthcare for everyone and unlock the potential of precision and predictive medicine.

## Creating value from medical images: our two Business Units

### 4 technology pillars

- Advanced analytics
- Imaging technology
- AI tech
- Cloud solutions

### 3 core expertise

- Medical imaging
- Clinical trials
- Oncology



### Median iCRO services help deliver

- More meaningful data
- Faster Go/No go decisions
- Top integrity of data
- Better dossiers for FDA submission
- Value dossier for payers



*iBiopsy® helps stratify patients in clinical trials*

*iBiopsy® helps matching patients with the best treatments in precision medicine*

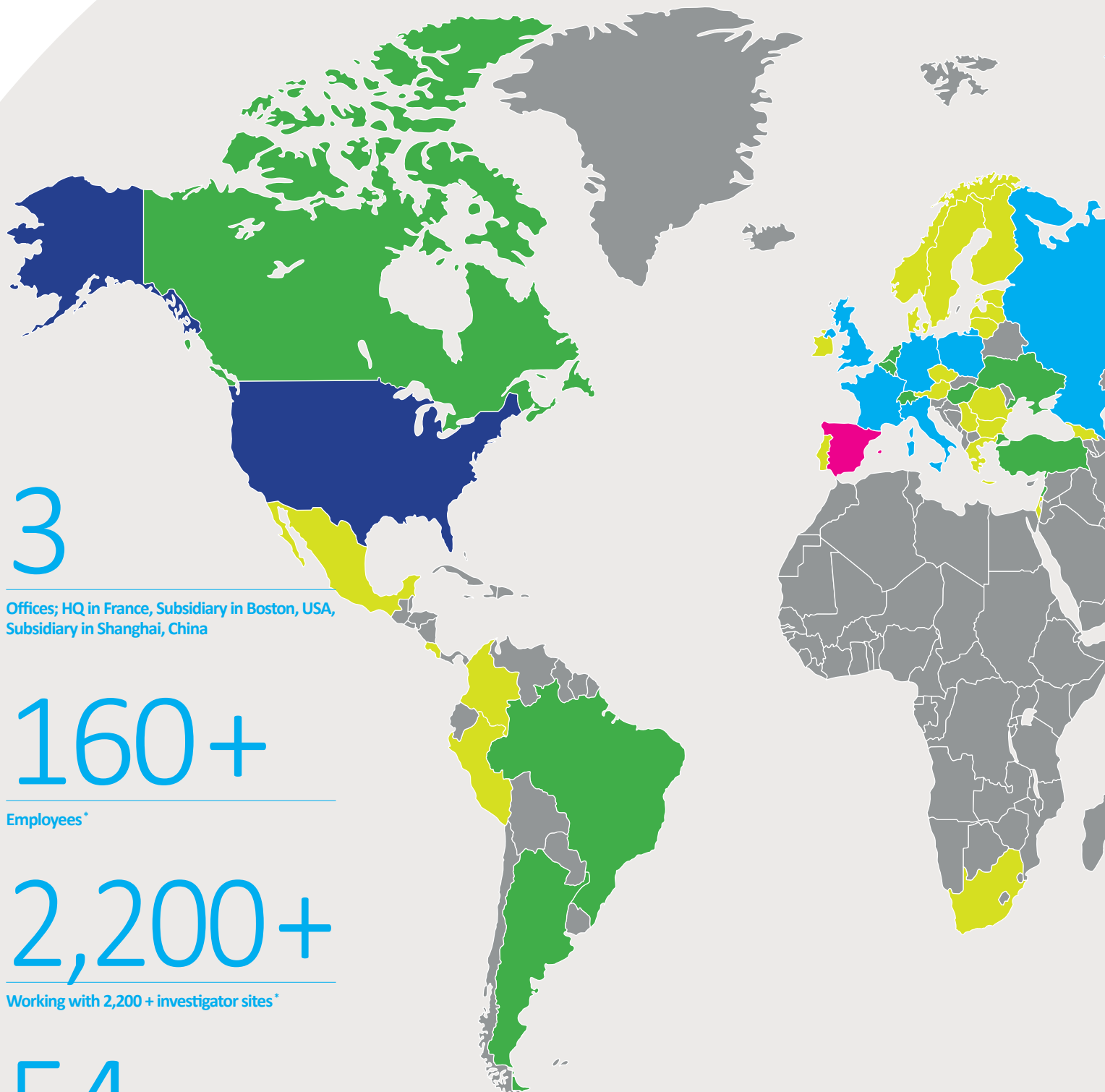
## iCRO

Our imaging solutions and services for oncology clinical trials are based on Median's imaging platform iSee®

## iBiopsy®

Leverages AI based imaging biomarkers to unlock the power of precision and predictive medicine

## A world-class imaging partner



3

Offices; HQ in France, Subsidiary in Boston, USA,  
Subsidiary in Shanghai, China

160+

Employees\*

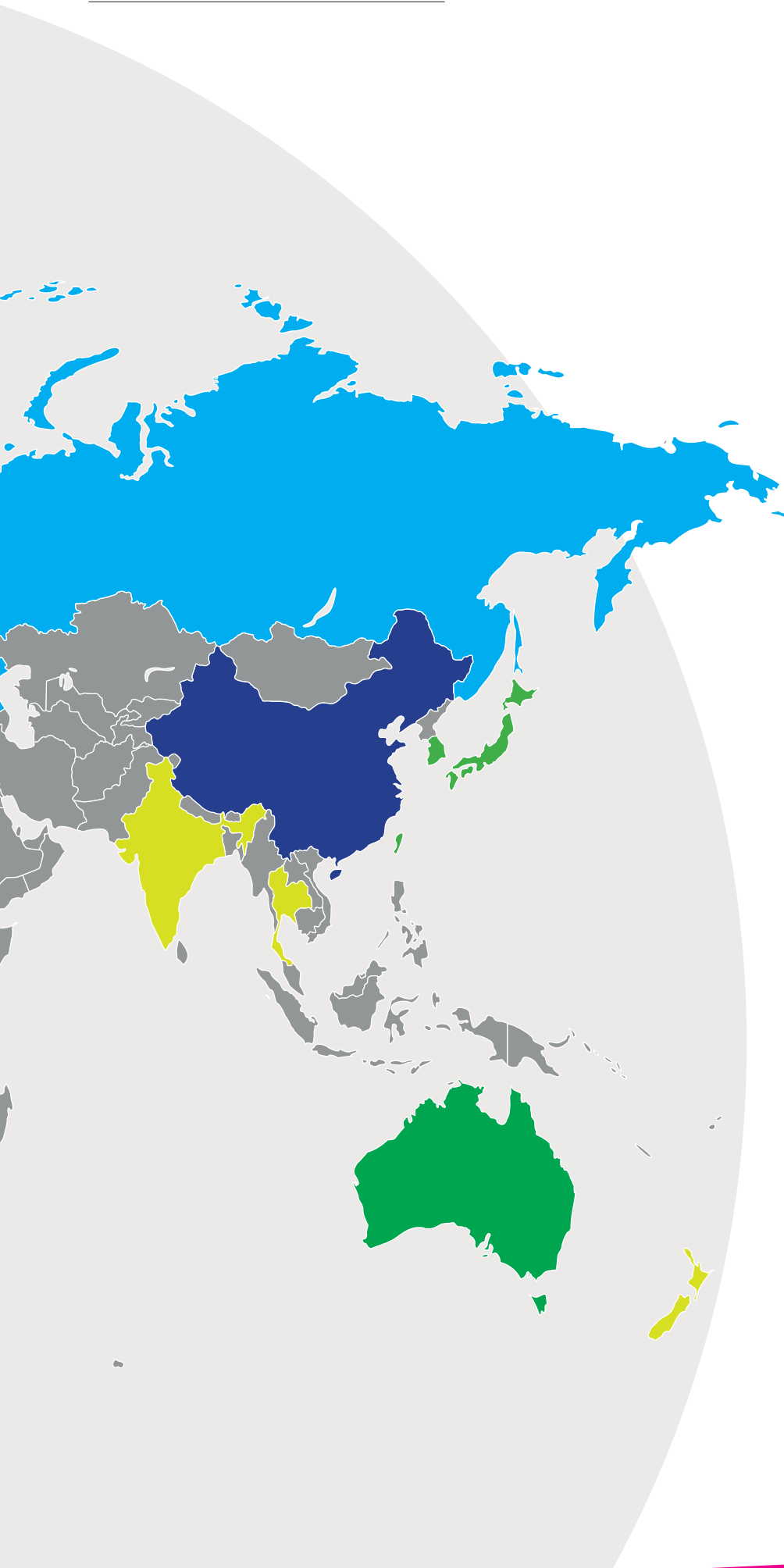
2,200+

Working with 2,200 + investigator sites\*

54

Working with 54 biopharma clients worldwide\*

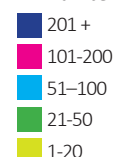
\* Figures as of June 2021



**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 medium-size biotech companies. Our footprint is global. With our HQ based in Europe (France), and our two subsidiaries in the US and China (Shanghai), 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 trials expertise. We are currently working with 2,200+ investigator sites through the world and more than 54 biopharma sponsors.

Number of sites



## 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 disease 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 June 2021, our company numbers 160+ employees worldwide with R&D totalling 20% 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.

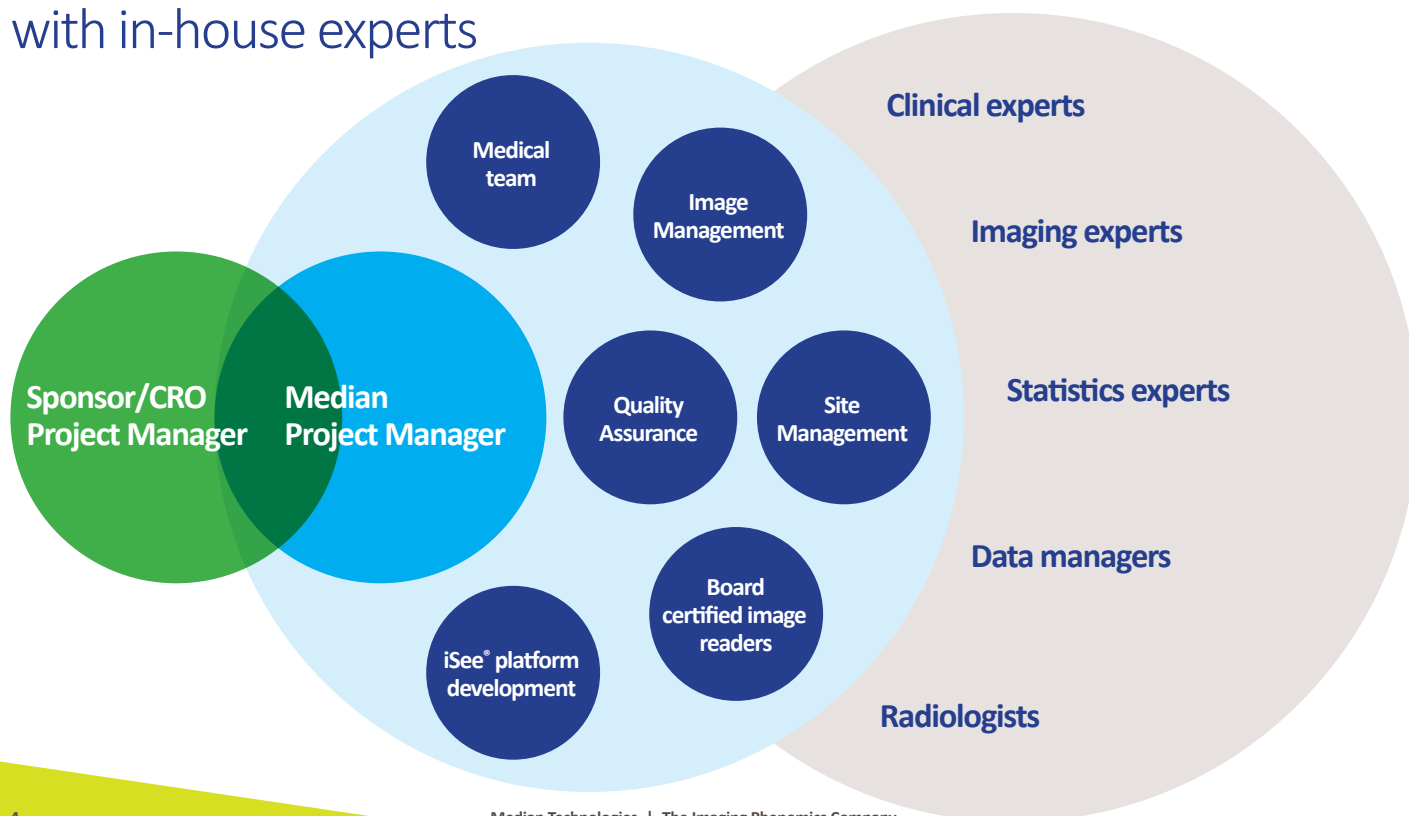
### Our values

As individuals and as a team, we are guided by four core values that are essential to us: leading 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.

### Read more:

[mediantechnologies.com/our-core-values/](https://mediantechnologies.com/our-core-values/)

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





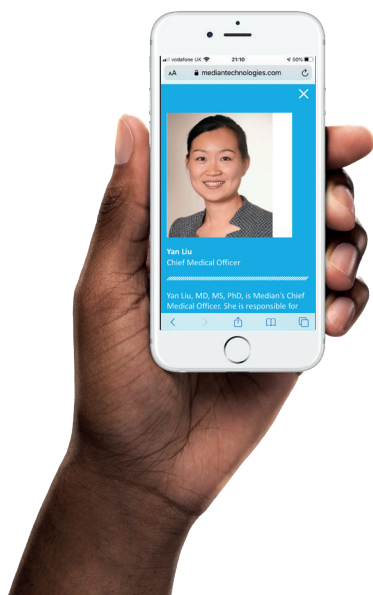
# A blend of sciences, technology, clinical expertise, and operational excellence

## 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 its responsibility.

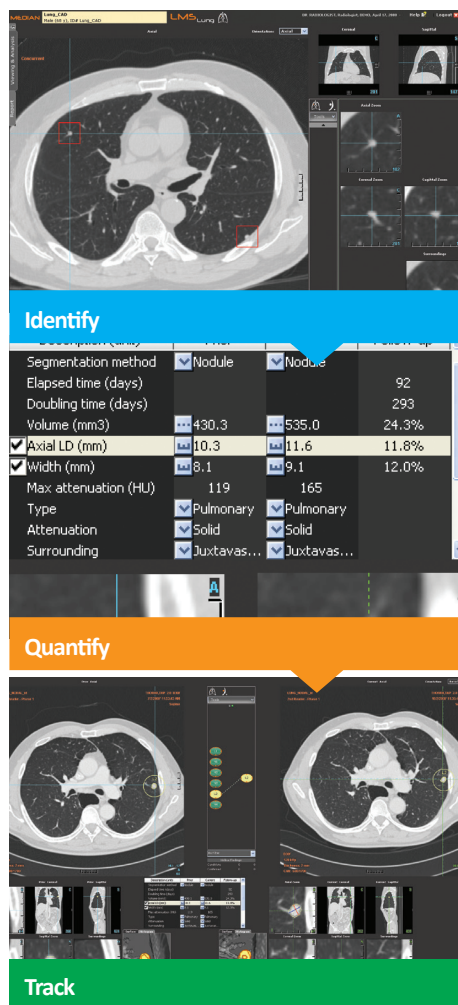
In addition to board certified radiologists, Median's medical team includes lead scientists, who collaborate whenever possible with sponsors, and identify potential scientific publications to be presented in international conferences and meetings – i.e., ASCO, ESMO, RSNA and ESR annual meetings, and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

Read more about  
our CMO on the website:  
[mediantechnologies.com/member-types/management-team](https://mediantechnologies.com/member-types/management-team)



## iSee®, our unique and proprietary imaging platform

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



## iSee®

- 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® 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® 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®. 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 know-how, 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

29

### Phase I trials

Including 14 trials with Immunotherapy

10

### Supported Regulatory approvals

21

### Phase I/II trials

Including 13 trials with Immunotherapy

2

### Successful FDA inspections

2017 and 2019

50

### Phase II trials

Including 20 trials with Immunotherapy

1

### Successful NMPA Inspection

2020

2

### Phase II/III trials

Including 1 trial with Immunotherapy

17,962

### Enrolled patients

43

### Phase III trials

Including 34 trials with Immunotherapy

78,735

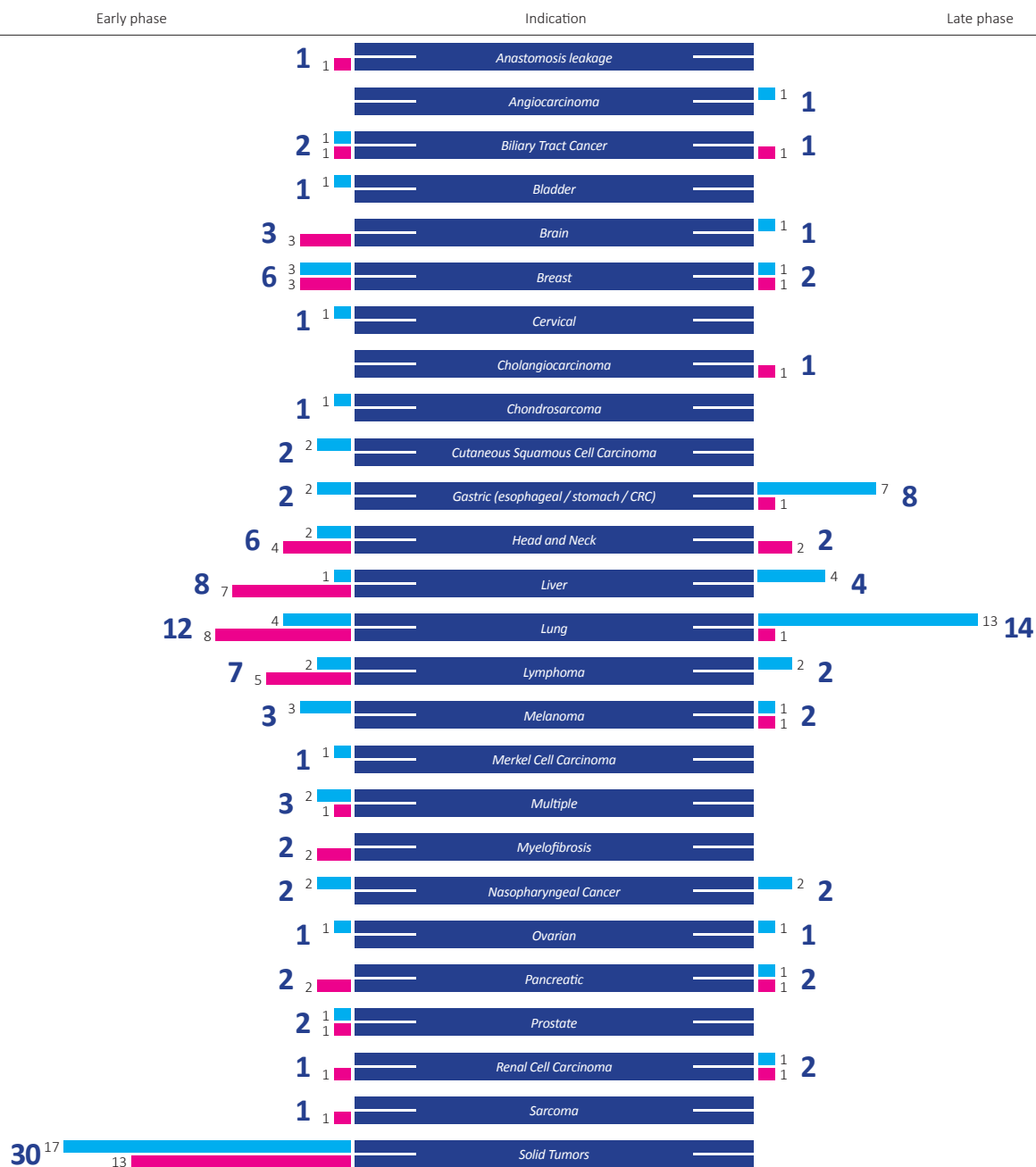
### Time points Quality Controlled

All figures as of June 2021



# Experience by primary cancer indication

145 studies\*



## Key

IO studies

Other studies (non IO)

\* Figures as of June 2021

# Median Technologies can help deliver for your oncology trials

Our expertise and end-to-end imaging services summarized in 6 points

## We extract the utmost meaningful information from medical images

Median's imaging platform iSee® provides automated and standardized image analysis.

iSee® covers a wide range of cancer indications (solid tumors).

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

iSee® extracts standard and novel biomarkers.

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

All our readers use iSee®, accessed through a web-browser.

## 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 including 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.

## 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 workflows:

- 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?

- 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

## 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

## What does this mean for your study?

- One size does not fit all
- 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.

## 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 than 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.

## 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 as international coverage.

Our senior PMs are PMP® certified.

Our iSee® platform core is a legacy of an FDA cleared 510K Medical Device.

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

In 2017 and 2019, we have successfully completed two FDA audits on three Big Pharma studies. FDA 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?

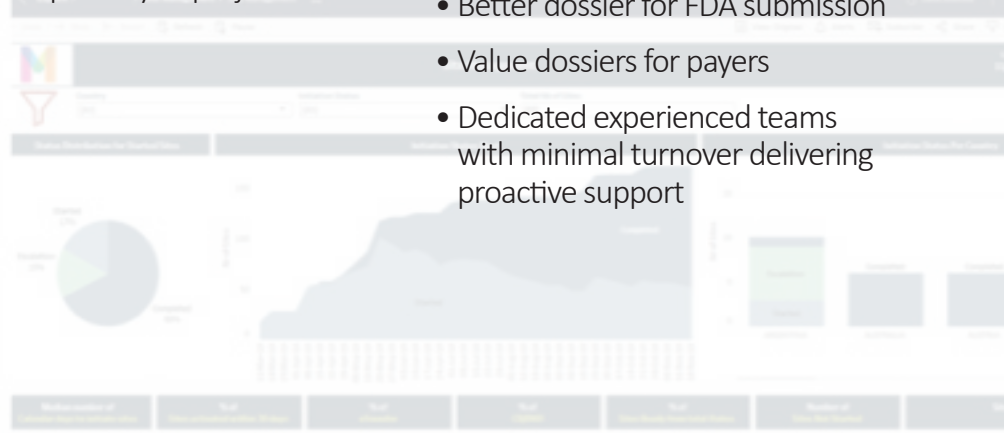
- For each study, reader selection according to their expertise in the indication, experience, monitoring results and workload
- Design and monitoring adapted to each trial and strictly monitored

## What does this mean for your study?

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

## What does this mean for your study?

- Quality beyond standard QA.
- Integrity of data.
- Better dossier for FDA submission
- Value dossiers for payers
- Dedicated experienced teams with minimal turnover delivering proactive support



**mediantechnologies.com**

#### About Us

As an imaging CRO, Median Technologies has unmatched clinical, technological and operational experience and expertise in oncology trials. With our offices based in the US, Europe and China, we operate globally to deliver best-in-class end-to-end imaging services for your Phase I to III oncology trials. We have a unique knowledge of the various standard imaging criteria used in clinical trials covering all solid tumor cancer indications, and we also provide innovative imaging biomarkers to ease Go/NoGo decisions in early phase studies. Median Technologies works with large pharma and biotech companies as well as global CROs, has a recognized track record with Phase III studies and has successfully passed FDA and China NMPA audits. We nicely complement the experience of global CROs we partner with by bringing our unique expertise in oncology imaging. We excel in all areas of managing oncologic images in clinical trials. There are many excellent reasons for selecting Median Technologies as your imaging CRO. Contact us to learn more!

**mediantechnologies.com**



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