

## Median Technologies

Corporate Update

Fredrik Brag, CEO and Founder

March 2022



European Rising Tech LABEL

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"Many diseases, including cancer, do not kill if diagnosed early" We help conquer cancer and other diseases through routine Albased imaging tests and imaging services for drug development

Our Growth: Powered by proprietary technology, strong KOL connections, and medical, scientific, technology partnerships

Our People: As of Dec 2021, 190+ employees worldwide (EU, US & China), 25% working in R&D Our locations: HQ in France with subsidiaries in the US and in China  Our 2 Business Units:
 iCRO: imaging services for oncology trials

 iBiopsy<sup>®</sup>: imaging platform for AIbased routine diagnostic solutions Our iBiopsy<sup>®</sup> clinical partners

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## **Board of Directors**



# Bringing significant industry, medical, financial and strategic expertise to the company



Oran Muduroglu *Chairman* 



Fredrik Brag Director



Kapil Dhingra Director



Oern Stuge Director



Tim Haines Director

### 2021 Key Performance

### *As of December 31, 2021*

#### 2021 revenue at €20.5M

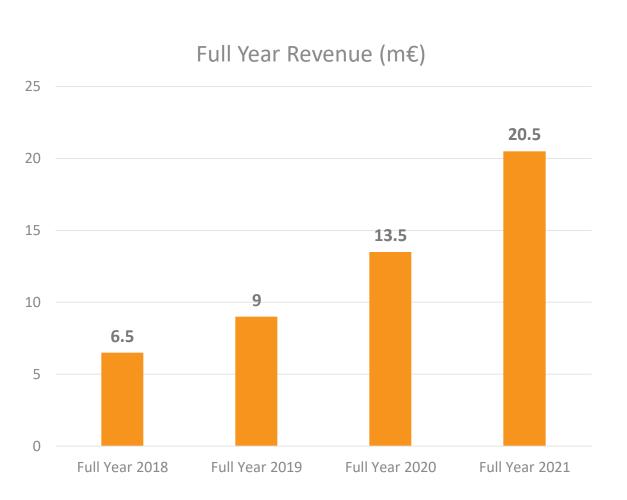
 An increase of 52% compared to 2020 revenue (€13.5M).

### Order backlog at €58M

 An €6.3M increase compared to December 31, 2020.

### Cash and cash equivalents at €39M

Cash position strengthened by the capital increase by private placement finalised on March 25<sup>th</sup>, 2021 for an amount of €28.1M and by the exercise of 1,344,444 warrants between July 1 and September 29, 2021, for gross cash funds of over €6M.



### M median

## iBiopsy<sup>®</sup> Addressing the unmet medical need

### "Many diseases do not kill if diagnosed at their earliest stage"

We are developing the next generation imaging tests to help:

- Detect, diagnose & monitor early-stage cancer patients
- Detect, diagnose & monitor early-stage NASH patients



### How: iBiopsy<sup>®</sup> Platform: Image Sequencing, Integrated AI



Help conquer cancer through routine imaging tests applying AI, advanced analytics and cloud solutions



## The iBiopsy<sup>®</sup> platform leverages Median's expertise and capabilities in:

- Imaging technology
- AI and data science
- Clinical development
- Regulatory and reimbursement

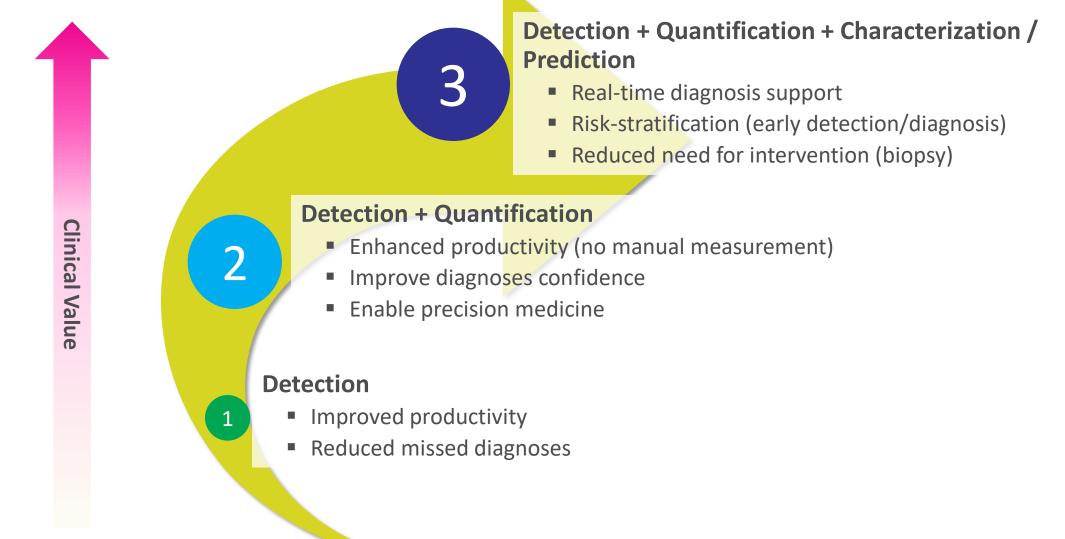
#### To:

- Drive the development of our portfolio of products
- Drive commercial adoption
- Lower healthcare costs
- Improve patient clinical outcomes

## **Our Differentiators**



### Whole organ & real time end-to-end AI cloud-based solution



## How Big Is the Market Opportunity, Market Segments Median

U.S. ANNUAL TOTAL ADDRESSABLE MARKET (TAM): \$30-\$130B					
Early Cancer Detection/Screening	High Risk Detection/Screening	Cancer Recurrence Monitoring and MDR			
~\$5-50B	~\$2-5B depending on the indication	~\$20-75B			
<ul> <li>Key Assumptions</li> <li>107MM individuals aged 50-79</li> <li>\$100-500/test</li> <li>Annual or biennial testing</li> <li>Age expansion would increase TAM</li> </ul>	<ul> <li>Key Assumptions</li> <li>Examples include monitoring tools for smokers, liver disease, and esophageal cancer</li> <li>TAM is highly dependent on number of cancers included</li> </ul>	<ul> <li>Key Assumptions</li> <li>~1.8MM new cancer dx/year</li> <li>Assuming use in new survivors, total survival penetration could be ~50% in 5 years</li> <li>ASP: ~\$1-3K/ test at varied intervals</li> </ul>			
Major Cancer Indications Lung, Breast, Colorectal, Liver, Ovarian, Esophagus, Pancreas and many others	Major Cancer Indications Lung, Liver, esophageal, hereditary	Major Cancer Indications Colorectal, Blood-based, Breast, Lung			

Source: Cowen report, 2020

#### 10 www.mediantechnologies.com | March 2022

### Lung Cancer Screening LCS using LDCT reduce mortality by 44 % (NELSON results) [1]

92% survival rate at 15 years when diagnosed at stage 1 (I-ELCAP study) vs 5-10% surviving at 5 years for stage 4

#### **Facts and Figures**

Leading cause of cancer mortality worldwide with an estimate of 1.8m deaths, accounting for 18% of all cancer deaths in 2020 [2]. Estimated to be 2.4m in 2030

**5-year survival rate** [3]:

• 5% for distant tumors (metastases)

#### **Our proposed solution: iBiopsy® Lung Cancer Screening**

- Build a cloud based end-to-end approach performing both localization and lung cancer risk categorization
- Replicate the radiologist's workflow, including full assessment of LDCT volume, comparison to prior imaging when available and calibration against biopsy-confirmed outcomes
- Demonstrate the potential for deep learning models to increase the accuracy, consistency and adoption of lung cancer screening worldwide

National/s programs	supranational LCS	Reimbursement procedures	Target population	Test ASP	Annual TAM
US	Yes – USPSTF screening guidelines	Yes – Reimbursed by CMS	Based on NLST criteria: 14.12m individuals eligible for lung cancer screening	\$100-500	\$1.4 – 7B per year
Europe	Under discussion at EU level	Under discussion	Based on NELSON criteria: 34m individuals considered at risk	\$100-500	\$3.4 – 17B per year
China	N/A yet	N/A yet <b>(general</b> population)	107m individuals eligible	\$100	\$10.7B



### **iBiopsy<sup>®</sup> Lung Cancer Screening** *Stage 1 (1A+1B) lung cancer characterization performance*

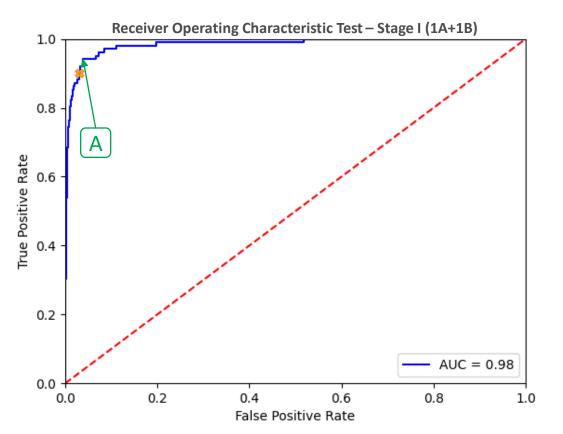
Unprecedented performance beyond the state of the art

#### Nodule-wise characterization on NLST sub-set

Cohort of 1,737 patients (16,249 nodules) Training set: 1,239 patients (11,676 nodules) Test set: 498 patients [330 benign, 168 malignant] (4,573 nodules)

#### **Test AUC = 0.984**

- Youden Index Operating Point \*: Sensitivity = 89.2 %, Specificity = 96.8 %
- Operating point A: Sensitivity 93.1% at Specificity 96.2%





## iBiopsy<sup>®</sup> Lung Cancer Screening



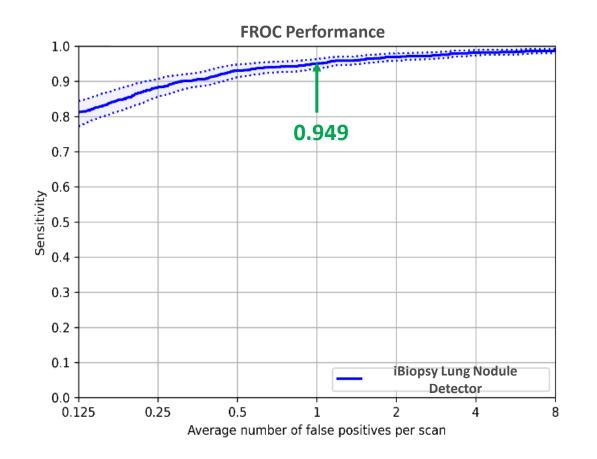
Automatic Lung Nodule Detection

### LIDC/IDRI Cohort (Luna16 Grand Challenge)

- Lung CT scans of 888 patients annotated by 4 experienced radiologists for a total of 1,186 nodules
- Training set: 800 patients
- Test set: 88 patients
- Training/testing using 10-fold cross-validation method

### **Encoder-Decoder Deep Architecture**

- Results obtained by aggregating the ten test folds
- Sensitivity of 94.9% for a false positive rate of 1 per CT scan.



## Competitive Data on Sensitivity, Specificity & FP/Scan Median

#### CADe/CADx Software as Medical Device

COMPANY	PRODUCT	TEST TYPE	SENSITIVITY	SPECIFICITY
Google/Ardila et al [*]	Data based on clinical study	AI CADe/CADx	91%	96%

#### **CADe Software as Medical Device**

COMPANY	PRODUCT	TEST TYPE	SENSITIVITY	FALSE POSITIVE/SCAN
MEDIAN TECHNOLOGIES	iBiopsy®	AI CADe	94.9%	1
RIVERAIN TECH	Clear Readt CT	AI CADe	83%	0.75
ARTERYS	Lung Al	AI CADe	93%	1.53
AIDENCE	Veye Lung Nodules	AI CADe	88%	1.04

#### **CADx Software as Medical Device**

COMPANY	PRODUCT	TEST TYPE	SENSITIVITY	SPECIFICITY
MEDIAN TECHNOLOGIES	iBiopsy®	AI CADx	95.2%	95.7%
OPTELLUM	Virtual Nodule Clinic	AI CADx	99%	28%

A radiological CADe device is "intended to identify, mark, highlight or otherwise direct attention to portions of an image that may reveal abnormalities during interpretation of images by the clinician." (Source: FDA)

A CADx device is "intended to provide information beyond identifying abnormalities, such as an assessment of disease." (Source: FDA)

## Liquid Biopsy Data



### Lung cancer detection by cancer stage

COMPANY	PRODUCT	TEST TYPE	SENSITIVITY	SPECIFICITY
GRAIL	GALLERI	LIQUID BIOPSY LUNG Early Detection	All stages: 59% Stage I Stage II Stage II Stage I 18% 43% 81% 93%	V <b>99%</b>
EXACT SCIENCE	CANCERSEEK	LIQUID BIOPSY LUNG Early Detection	All stages: 27%	99%
Sensitivity: the ability to correctly generate positive results for cancer patients (true positive rate) Specificity: the ability to correctly generate negative results for non cancer patients (true negative rate) Source: <u>https://www.healthnewsreview.org/toolkit/tips-for-understanding-studies/understanding</u>			atients (true negative rate)	

medical-tests-sensitivity-specificity-and-positive-predictive-value/

## HCC Early Detection/Diagnosis



Hepatocellular Carcinoma accounts for 90% of all primary liver cancers [5]

### **Facts and Figures**

3<sup>rd</sup> leading cause of cancer mortality worldwide with an estimated 830,000 deaths, accounting for 8% of all cancer deaths in 2020 [2]

Trend: 1,1 million deaths projected in 2030 [2]

5-year survival rate: 20% [6]

High risk population [7]:

- Risk factors: HBV, HCV, NAFLD, cirrhosis, heavy alcohol use, obesity, T2 diabetes
- 328m individuals ww are at risk, over
   27m in the US and Europe

### **Our proposed solution: iBiopsy® HCC**

- Build a cloud based end-to-end approach performing both
   localization and HCC cancer risk categorization
- Replicate a more complete part of a radiologist's workflow, including full assessment of HCC volume, focus on regions of concern, comparison to prior imaging when available and calibration against biopsy-confirmed outcomes
- Show the potential for deep learning models to increase the accuracy, consistency and adoption of HCC screening worldwide

### **Market opportunity**

Key assumptions	Annual Total Addressable Market (TAM)
<ul> <li>Target population: 27m individuals in the US and EU</li> <li>ASP: \$100 per test</li> </ul>	US & EU alone: \$2.7B TAM

## NASH – Non-Alcoholic Steatohepatitis



NAFLD and NASH are a global silent epidemics [8]

### **Facts and Figures**

NAFLD affects 25% of the global population. 20% of NAFLD patients progress to NASH, with a risk at developing cirrhosis and liver cancer [9]

Trends: NASH prevalence is increasing in Western countries and Asia [10]

Diagnosing NASH early is key, as, in its early stages, the disease is reversible by a change in eating habits and lifestyle

NAFLD Annual US economic burden [11]

- \$103 billion from direct medical care costs +
- \$188 billion in societal costs

### Our proposed solution: iBiopsy® NASH

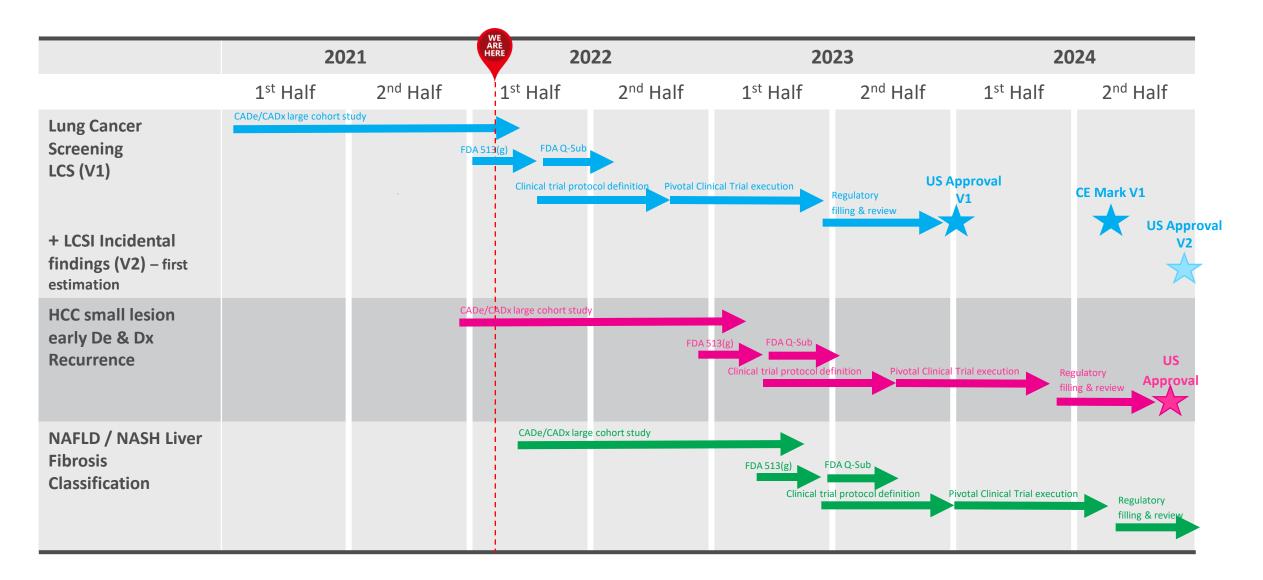
- Build a cloud based diagnostic test to assess early stage of NASH / Fibrosis to identify patients with reversible disease burden
- Show the potential for deep learning models to increase the accuracy, consistency and adoption of NASH diagnosis worldwide

#### **Market opportunity**

Key assumptions		Annual Total Addressable Market (TAM)
	Target population: 50m individuals in the US and EU have NASH ASP: \$100 per test	US & EU alone: \$5B TAM

## iBiopsy<sup>®</sup> Product Roadmap





## LCS Proposed Pivotal Clinical Study Design



Standalone Trial	Multi-Reader Multi-Cases Trial (MRMC)
<b>Design:</b> Multinational (EU & US) multicenter retrospective study to evaluate an image-based AI CADe/CADx which detects and characterizes suspicious pulmonary nodules	<b>Design:</b> Multinational (EU & US) multicenter retrospective study to evaluate the clinician performance when utilizing an AI based CADe/CADx
<ul> <li>Objectives</li> <li>Primary: Assess system performance in characterizing cancer positive and cancer negative patients on LDCT images (per patient malignancy scoring)</li> <li>Secondary: Assess system performance in detecting and characterizing nodules on LDCT images (per lesion malignancy scoring)</li> </ul>	<ul> <li>Objectives</li> <li>Primary: Demonstrate that iBiopsy has increased performance to clinicians in correctly managing patients at high risk of lung cancer</li> <li>Secondary: Demonstrate that iBiopsy has increased performance to clinicians in correctly detecting and managing nodules suspicious of cancer, and decreases the time of analysis</li> </ul>
<b>Endpoints:</b> AUC, Sensitivity, Specificity, False positive / negative rate, NPV/PPV, system performance vs. sites, regions, CT manufacturers, lesion type.	<b>Endpoints:</b> AUC, Sensitivity, Specificity, False negative / positive rate, NPV/PPV, image reading time & inter-reader evaluation
Sample size: Statistically powered to allow for robust analysis of the primary & secondary clinical objectives	<ul> <li>Sample size:</li> <li>Pilot MRMC study: 4 readers,</li> <li>Paired-split-plot MRMC: 16 readers</li> </ul>

### iBiopsy<sup>®</sup> Landscape: Comparables



	Liquid biopsy	lmage biopsy	Market caps (as of March 4, 2022)
<b>GUARDANT</b>	$\checkmark$		NASDAQ: GH \$5.9B
GRAIL	$\checkmark$		Acquired by Illumina in Sep 2020 at \$88
<b>û</b> Infer <b>Vision</b>		$\checkmark$	Private Chinese company
EXACT SCIENCES	$\checkmark$		NASDAQ: EXAS \$11.8B



## iCRO Business

Solutions and Services for Image Management in Clinical Trials

## iCRO Growth Opportunities (1/2)

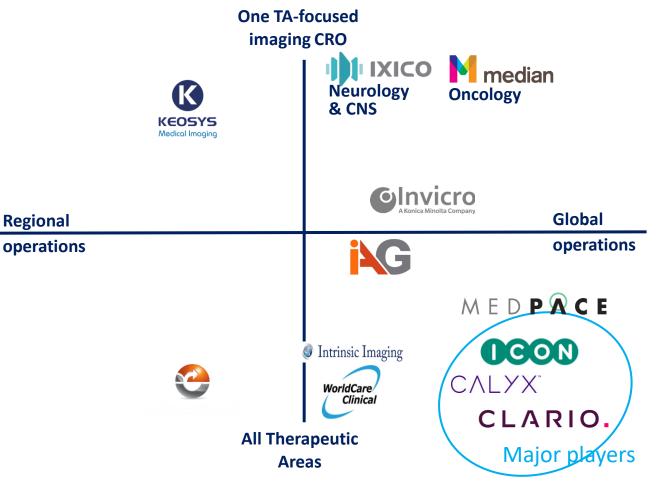


#### Landscape

- The global contract research organization (CRO) services market size was valued at USD 38bn in 2018 and is projected to reach USD 91bn by 2026 [13]
- The imaging CRO market size was valued at USD 1.3bn in 2020. The largest market segment is for oncology.
- On April 28, 2021, ERT and Bioclinica closed their merger in a \$7.8bn deal -> Clario

#### **Competitive positioning and differentiators**

- Median is the only oncology-focused imaging CRO with a global footprint and partners with global CROs
- Strong technology differentiators with our proprietary platform, iSee<sup>®</sup> and evolutions
- Unique AI competitive advantages



Competitive imaging CRO landscape: Fragmented with 3 major players

## **Imaging CRO Solutions and Services**



Bringing more meaning to image data: iSee<sup>®</sup>

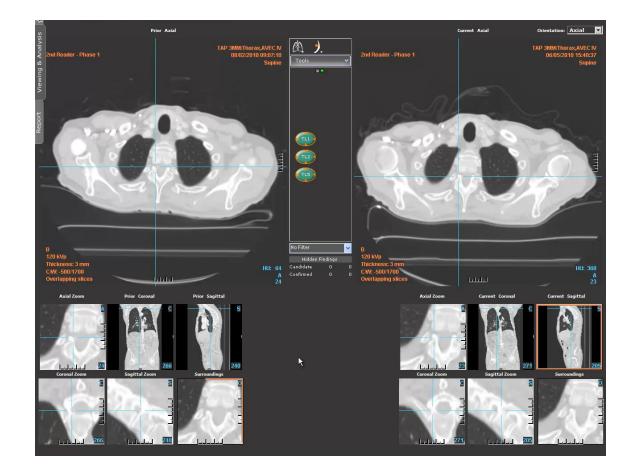


- Image analysis and data management platform
- Extracts more data from an image than any other system
- Delivers the highest quality data for better informed decisions
- Limit variability and increases reproducibility by automatically identifying, quantifying, and tracking lesions across all time points
- All readers use this advanced proprietary tool, accessed through a web-browser
- Based on a 510K FDA cleared platform

## **Imaging CRO Solutions and Services**



Bringing more meaning to image data: iSee<sup>®</sup>



## Median AI Competitive Advantage



Provide additional insights for clinical trials



Better selection of patients

Prediction of response to therapy



2

Early assessment of drug effects



## **Experience by Phase**



### 156 studies \*

32 Phase I trials Including 14 trials with Immunotherapy

> Phase I/II trials Including 13 trials with Immunotherapy

> Phase II trials Including 21 trials with Immunotherapy

2

46

22

54

Phase II/III trials Including 1 trial with Immunotherapy

Phase III trials Including 35 trials with Immunotherapy

### "156 studies" also means:

- 40+ clients in the US and Europe
- 10+ clients in China, including Top 3 Chinese biopharmas
- **3 successful FDA inspections** (2017, 2019 and 2021)
- **5 successful NMPA inspections** (2020 and 4 completed in 2021)
- 10 Supported Regulatory Approvals
- 22,224 enrolled patient
- 2,300+ clinical sites

<sup>[\*]</sup> Cumulative contracted and awarded studies since the beginning of the iCRO activity, and until 12/31/2021

## iCRO Business Development Accelerator

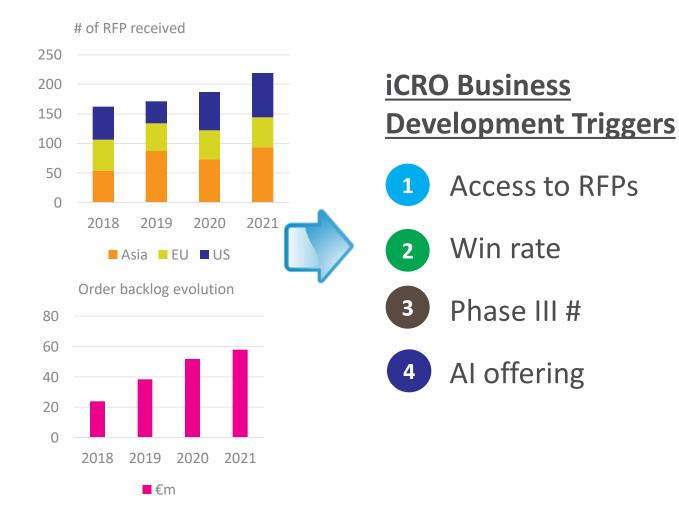


Median Technologies confirmed as a preferred vendor by one of the Top 3 pharmaceutical companies in the world

- Renegotiation of terms of an existing Master Service Agreement (MSA) with this major big pharmaceutical company.
- The new scope of the MSA covers Phase III clinical trials for major indications in oncology and the terms are valid for 3 years.
- This partnership will contribute to sustain Median's future bookings and revenues growth.

## iCRO Growth Opportunities (2/2)





#### **Tactics**

- Develop partnerships with global CROs
- Increase repeat business with Top Pharmas
- Target Top 200 biotech companies



The Imaging Phenomics Company<sup>®</sup>

### **Our Core Values**

#### Leading innovation with purpose

Combine the spirit of innovation with our passion and conviction to help cure cancer and other debilitating diseases.

#### Committing to quality in all we do

Be dedicated to quality in everything we do. Quality begins with us and we are committed to it.

#### Supporting our customers in achieving their goals

Listen to the needs of our customers and help make their goals our goals through our innovation, imaging expertise, superior services, and quality solutions.

#### Putting the patient first

There is a person at the other end of the images we analyze who is counting on us to do everything we can to help make them healthier.



European Rising Tech

www.mediantechnologies.com

### Sources



- [1] <u>https://www.healthimaging.com/topics/oncology-imaging/nelson-trial-ct-lung-screening</u>
- [2] <u>https://gco.iarc.fr/</u>
- [3] <u>https://www.lung.org/lung-health-diseases/lung-disease-lookup/lung-cancer/resource-library/lung-cancer-fact-sheet</u>
- [4] <u>https://slidetodoc.com/lung-cancer-overview-a-slide-presentation-for-oncology/</u>
- [5] <u>https://www.nature.com/articles/s12276-020-00527-1</u>
- [6] <u>https://www.cancer.net/cancer-types/liver-cancer/statistics</u>
- [7] <u>https://www.cancer.org/cancer/liver-cancer/causes-risks-prevention/risk-factors.html</u>
- [8] <u>https://www.nature.com/articles/s41575-020-0315-7</u>
- [9] <u>https://www.researchgate.net/publication/327427978 Global Perspectives on Non-alcoholic Fatty Liver Disease and Non-alcoholic Steatohepatitis</u>
- [10] <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7154715/</u> and <u>https://www.the-nash-education-program.com/what-is-nash/</u>
- [11] <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6366581/</u>
- [12] Biopharma 2019 ranking, based on revenue <u>https://www.fiercepharma.com/special-report/top-20-pharma-companies-by-2019-revenue</u>
- [13] <u>https://www.fortunebusinessinsights.com/industry-reports/100864</u>