

# Median Technologies

Corporate Update

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October 2021



European Rising Tech
LABEL
www.mediantechnologies.com



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### Innovation Is in Our DNA



"Many diseases, including cancer, do not kill if diagnosed early"

We help conquer cancer and other health-threatening diseases through routine Al-based 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 Sept 2021, 160+ employees worldwide (EU, US & China), 30% working in R&D Our locations: HQ in France with subsidiaries in the US and in China

#### **Our 2 Business Units:**

- iCRO: image management for oncology trials
- iBiopsy®: Imaging platform for Albased biomarker discovery



## **Company View**



#### Yan Liu, MD, MSc, PhD Chief Medical Officer

- Board-certified radiologist
- Biomarker expert with more than 15 years of clinical research experience
- Former head of translational research, radiotherapy, and imaging department at EORTC





- Co-founded the company in 2002, bringing years of technology company expertise gained in business development, fundraising, and IPOs
- Previously served as board member and Senior Executive VP of Health Center/ Focus Imaging



Corporate Support

Jean-Christophe Montigny

Chief Financial Officer



iCRO Business Unit Nicolas Dano Chief Operating Officer



iBiopsy® Business
Unit
Thomas Bonnefont
Chief Operating and
Commercial Officer

## **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* 

## H1, 2021 results



## As of June 30th, 2021

### H1, 2021 revenue at €10.1m

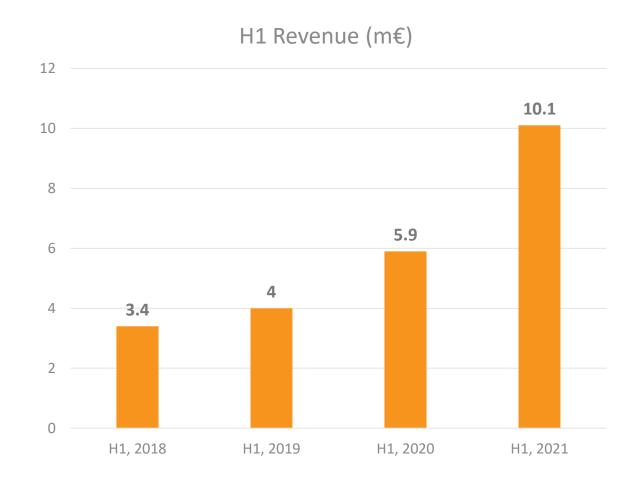
 An increase of 71% compared to the revenue in the first half of 2020 (€5.9m).

### Order backlog at €52.5m

 Stable compared to order backlog as of March 31<sup>st</sup>, 2021.

### Cash and cash equivalents at €36.9m

 Cash position strengthened by the capital increase by private placement finalised on March 25<sup>th</sup>, 2021 for an amount of €28.1m, corresponding to €26.6m net of fees and commissions.



## Q3, 2021 Toplines



## As of September 30th, 2021

### Q3, 2021 revenue at €5.3m

 An increase of 51% compared to the revenue in Q3, 2020 (€5.3m).

### Order backlog at €54.2m

 + €1.7m compared to order backlog as of June 30<sup>th</sup>, 2021.

### Cash and cash equivalents at €42.6m

 + €5.5m compared to cash position as of June 30<sup>th</sup>, 2021 (€36.9m)

#### Focus on cash position

- Median received €6m in equity funding through the exercise of 1,344,440 warrants over Q3.
- These warrants had been issued on September 29<sup>th</sup>, 2014, and were expiring on September 29<sup>th</sup>, 2021, giving right to acquire 672,220 shares.



# **iBiopsy**®

"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



# iBiopsy® Platform: Image Sequencing, Integrated Al



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



# The iBiopsy® platform leverages Median's expertise and capabilities in:

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

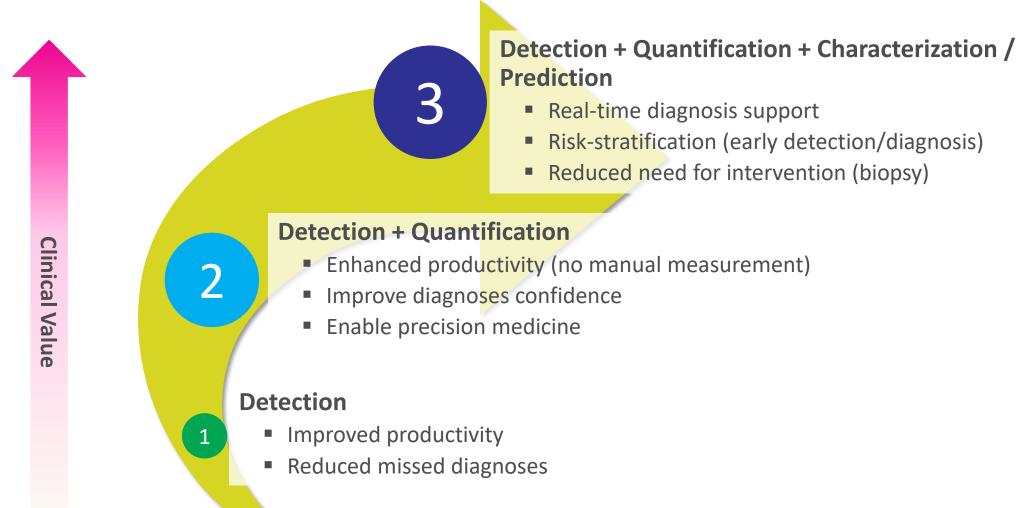
#### To:

- Drive the development of our Pheno-iDx 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



# **Lung Cancer Screening**



Lung cancer screening using LDCT has been shown to reduce mortality by 44 % (NELSON results) [1]

### **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: Pheno iDx LCS

- 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

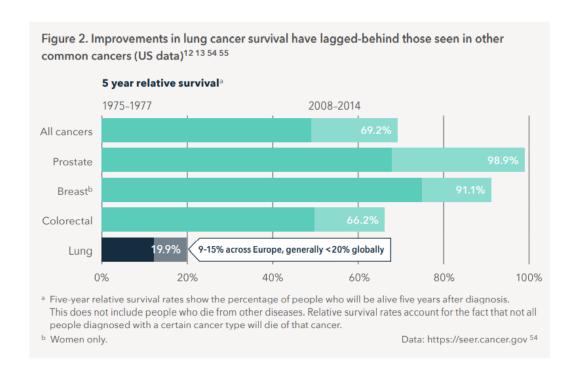
National/s programs	upranational LCS	Reimbursement procedures	Target population	Test ASP	Annual TAM
US	Yes – USPSTF screening guidelines	Yes – Reimbursed by CMS	Based on NLST criteria: 14.12m individuals eligible for lung cancer screening	\$100-500	\$1.4 – 7B per year
Europe	Under discussion at EU level	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 (general population)	107m individuals eligible	\$100	\$10.7B

# Unmet medical needs - A disease we need to detect early

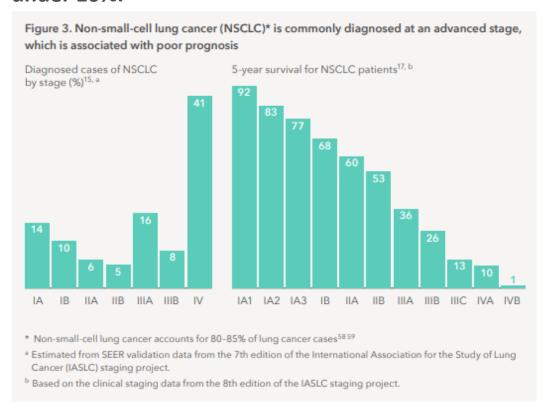


## The relevance of early Prognosis and Diagnosis of Lung Cancer

Prognosis for lung cancer is poor compared with most other cancers, largely due to a high proportion of cases being detected at an advanced stage.



Around 20% of people with lung cancer are diagnosed at stage I, when their likelihood of surviving 10 years is 92% (*I-ELCAP study*), compared with more than 40% of people being detected at stage IV, when their likelihood of surviving 5 years is under 10%.



# **Lung Cancer Treatments**

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- Surgery to remove tumors: lobectomy, pneumonectomy, segmentectomy
- Chemotherapy drugs to shrink or kill cancerous cells
- Radiation therapy
- Targeted therapy (or biological therapy)
   to inhibit molecular pathways or mutant
   proteins that are critical to tumor growth:
   monoclonal antibodies, small molecule
   drugs

### The next big hope:

 Immunotherapy for early-stage lung cancer to stimulate the patient's own immune system to recognize cancer cells as foreign bodies and destroy them



Stage	Description	Treatment Options	
Stage I a/b	Tumor of any size is found only in the lung	Surgery	
Stage II a/b	Tumor has spread to lymph nodes associated with the lung	Surgery	
Stage III a	Tumor has spread to the lymph nodes in the tracheal area, including chest wall and diaphragm	Chemotherapy followed by radiation or surgery	
Stage III b	Turnor has spread to the lymph nodes on the opposite lung or in the neck	Combination of chemotherapy and radiation	
Stage IV	Turnor has spread beyond the chest	Chemotherapy and/or palliative (maintenance) care	

Source [4]

# AI/DS Lung Cancer Screening Promising Results



- Nodule-wise characterisation on NLST data:
  - Cohort of 1,696 patients (15,608 nodules)
  - Training set: 1,224 patients (11,392 nodules)
  - Test set: 472 patients [330 benign, 142 malignant (4,216 nodules)]

Original Scan
(CT)

Reference Labels
(GT)
Segmentation

Malignant

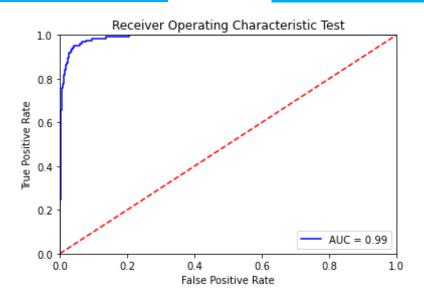
Benign

 Innovative Deep Architecture with outstanding performance

Test AUC = 0.991

Sensitivity = 95.2 %

Specificity = 95.7 %



#### Nota:

**Sensitivity:** the ability of our AI algorithm to correctly identify cancerous pulmonary nodules. **Specificity:** the ability of our AI algorithm to correctly identify benign pulmonary nodules.

# **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 IV  18% 43% 81% 93%	99%
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: <a href="https://www.healthnewsreview.org/toolkit/tips-for-understanding-studies/understanding-medical-tests-sensitivity-specificity-and-positive-predictive-value/">https://www.healthnewsreview.org/toolkit/tips-for-understanding-studies/understanding-medical-tests-sensitivity-specificity-and-positive-predictive-value/</a>

# **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 www are at risk, over
   27m in the US and Europe

### Our proposed solution: Pheno iDx Liver

- 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: Pheno iDx 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)
<ul> <li>Target population: 50m individuals in the US and EU have NASH</li> <li>ASP: \$100 per test</li> </ul>	US & EU alone: \$5B TAM

# How Big Is the Market Opportunity, Market Segments M median

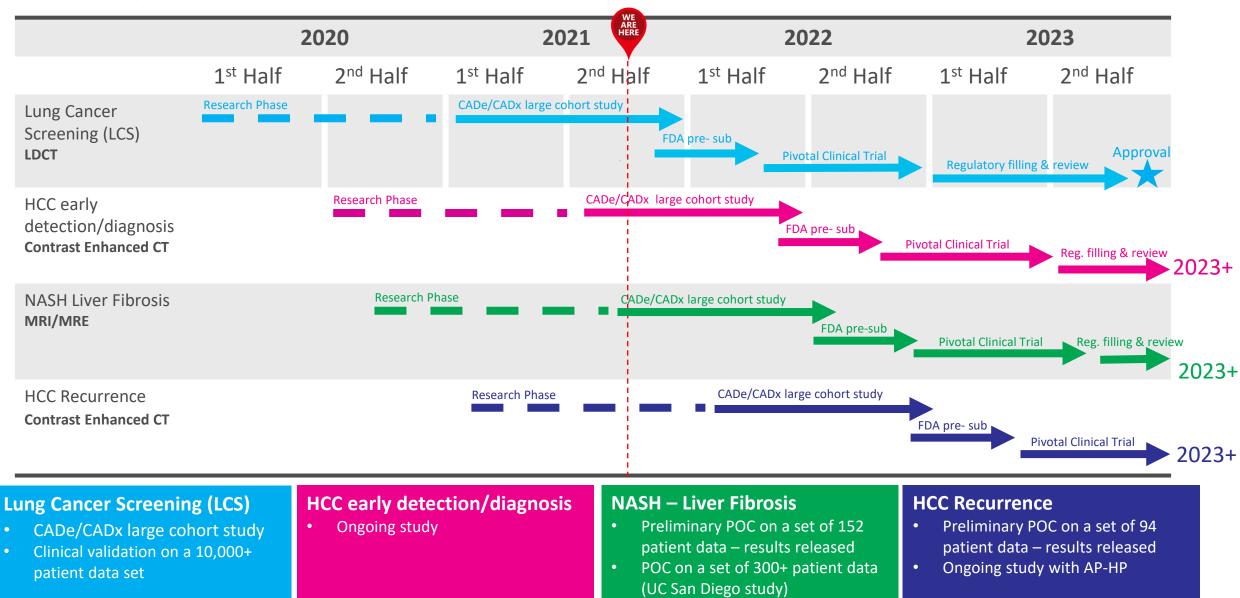


U.S. ANNUAL T	OTAL ADDRESSABLE MARKET (	(TAM): \$30-\$130B
Early Cancer Detection/Screening	High Risk Detection/Screening	Cancer Recurrence Monitoring and MDR
~\$5-50B	~\$2-5B depending on the indication	~\$20-75B
<ul> <li>Key Assumptions</li> <li>107MM individuals aged 50-79</li> <li>\$100-500/test</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

# iBiopsy® Product Roadmap





# Payer Coverage and Reimbursement



We can help payers reduce diagnostic and treatment costs while improving clinical outcome

We believe our test offer significant health economic values in the following ways:

- Detect early disease in high-risk individuals to increase chances of survival & treatments
- Monitor & Predict disease recurrence in cancer survivors and NASH patients
- Reduce the need for a repeat invasive biopsy.
- New guidelines for reimbursement are being implemented due to the impact of technology on diagnostics.
- FDA is also reviewing its guidelines for regulatory pathways for Al-based diagnosis solutions



# iBiopsy® Landscape: Comparables



	Liquid biopsy	Image biopsy	Market caps (as of October 21, 2021)
<b>GUARDANT</b>	<b>\</b>		NASDAQ: GH \$10.8B
GRAIL	<b>/</b>		Acquired by Illumina in Sep 2020 at \$8B
nferVision		<b>/</b>	Private Chinese company
EXACT SCIENCES	<b>/</b>		NASDAQ: EXAS \$16.4B
median		<b>/</b>	\$0.24B



# iCRO Business

Solutions and Services for Image Management in Clinical Trials

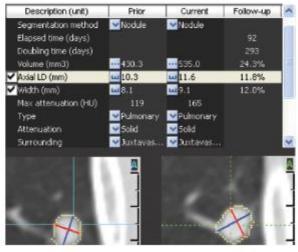


# **Imaging CRO Solutions and Services**



Bringing more meaning to image data: iSee®







#### Identify

Quantify

Track

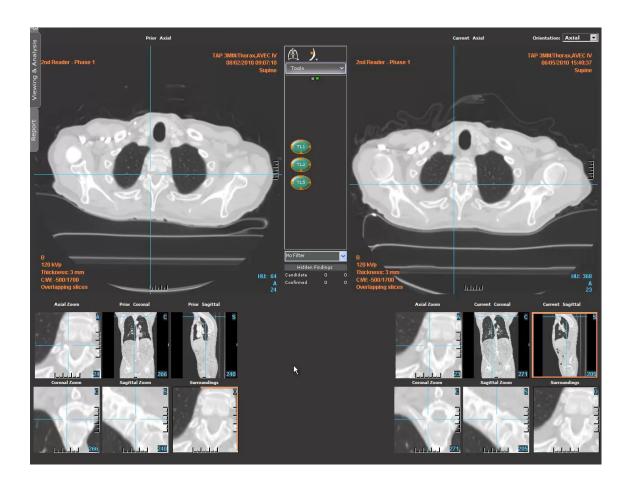
- Image analysis and data management platform
- Extracts more data from an image than any other system
- Delivers the highest quality data for better informed decisions

- 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**

median

Bringing more meaning to image data: iSee®



# **Experience by Phase**



### 145 studies

29

Phase I trials
Including 14 trials with Immunotherapy

21

Phase I/II trials
Including 13 trials with Immunotherapy

50

Phase II trials
Including 20 trials with Immunotherapy

2

Phase II/III trials
Including 1 trial with Immunotherapy

43

Phase III trials
Including 34 trials with Immunotherapy

### Key business indicators:

- 40+ clients in the US and Europe
- 10+ clients in China, including the three
   Top 3 Chinese Biopharmas
- 9 supported regulatory approvals
- 17,962 enrolled patients
- 78,738 quality-controlled timepoints
- 2 successful FDA inspections (2017 & 2019)
- First Chinese NMPA on site inspection for an NDA approval

As of 6/31/2021

# 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 (1/2)

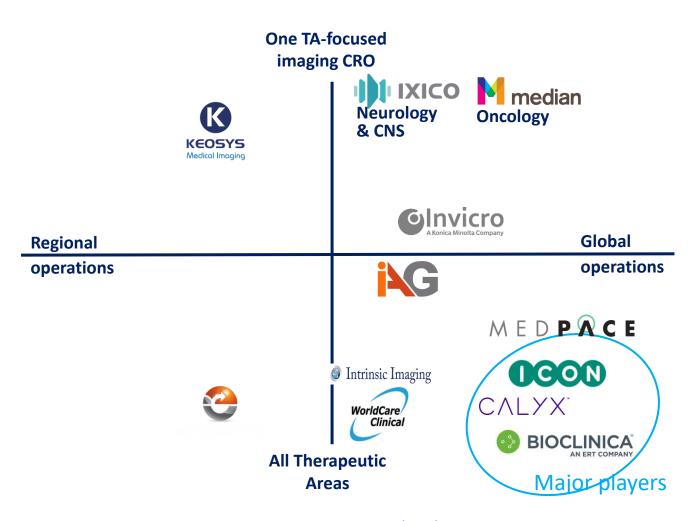


#### Landscape

- 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

### **Competitive positioning and differentiators**

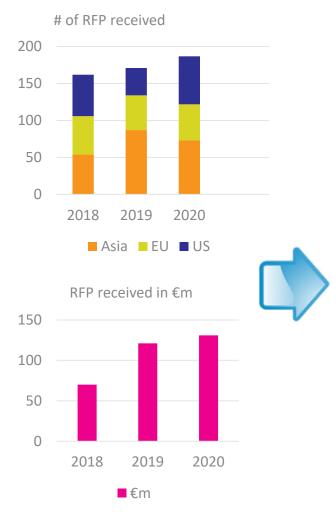
- Median is the only oncology-focused imaging CRO with a global footprint and partners with global CROs
- Strong technology differentiators with our proprietary platform, iSee® and evolutions
- Unique Al competitive advantages



Competitive imaging CRO landscape: Fragmented with 3 major players

# iCRO Growth Opportunities (2/2)





# iCRO Business Development triggers:

- Access to RFPs
- 2 Win rate
- 3 Phase III #

### **Tactics:**



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

#### 2020 Win rates

- Repeat Business: 52% (based on contract values)
- New clients: 14% (based on contract values)

# Median Al Competitive Advantage



## Provide additional insights for clinical trials

### **More & Better Efficacy Biomarkers**

- Additional measurements on tumor pixel data (Radiomic or Multiparametric Analysis)
- Automated tumor detection & measurements to reduce variability (CAD)

### **Explainability for the Results**

- Offer population fragility index (body composition)
- Offer comparison of a cohort to other trials (Analytic)

### **Imaging Biomarkers for Toxicity trials**

- For phases I, help identify the Maximum Tolerated Dose
- For phases II & III, identify tolerance to the dose

### **Optimize the Drug Development Plan**

- Identify true vs pseudo progression on 1 TP
- Identify responders vs non-responders
- Analysis of the radio-phenotypic impact of the molecule
- Interpretation and explanation of the clinical trial results
- Build companion predictive tests
- Build companion Dx tests

# 2021 and Beyond



### **iBiopsy**®

- Early detection and diagnosis are key and have the potential to save patient lives
- Very strong push for non-invasive biomarkers from patients, regulatory agencies (FDA, EMA) and payers
- Continued clinical validations studies for Lung Cancer, HCC, NASH
- Clinical and technology partnerships for additional validation studies
- Major total addressable market
- A strong US market positioning

#### **iCRO**

- Major potential for growth in a very dynamic market
- Very strong technology differentiators for clinical trials: iSee®
- Strong position in the fast-growing global market





### **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.



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## Sources



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