



# Corporate Presentation

March 7, 2023

Cowen & Co 43<sup>rd</sup> Health Care Conference  
Boston | MA | USA



*Fredrik Brag*  
CEO & Founder



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# Early Diagnosis Saves Lives

We are helping conquer cancer and fibrotic diseases by extracting powerful clinical insights from patients' medical images.

Our strength is our people: 230+ highly qualified professionals in the US, Europe and China, 25+ nationalities.

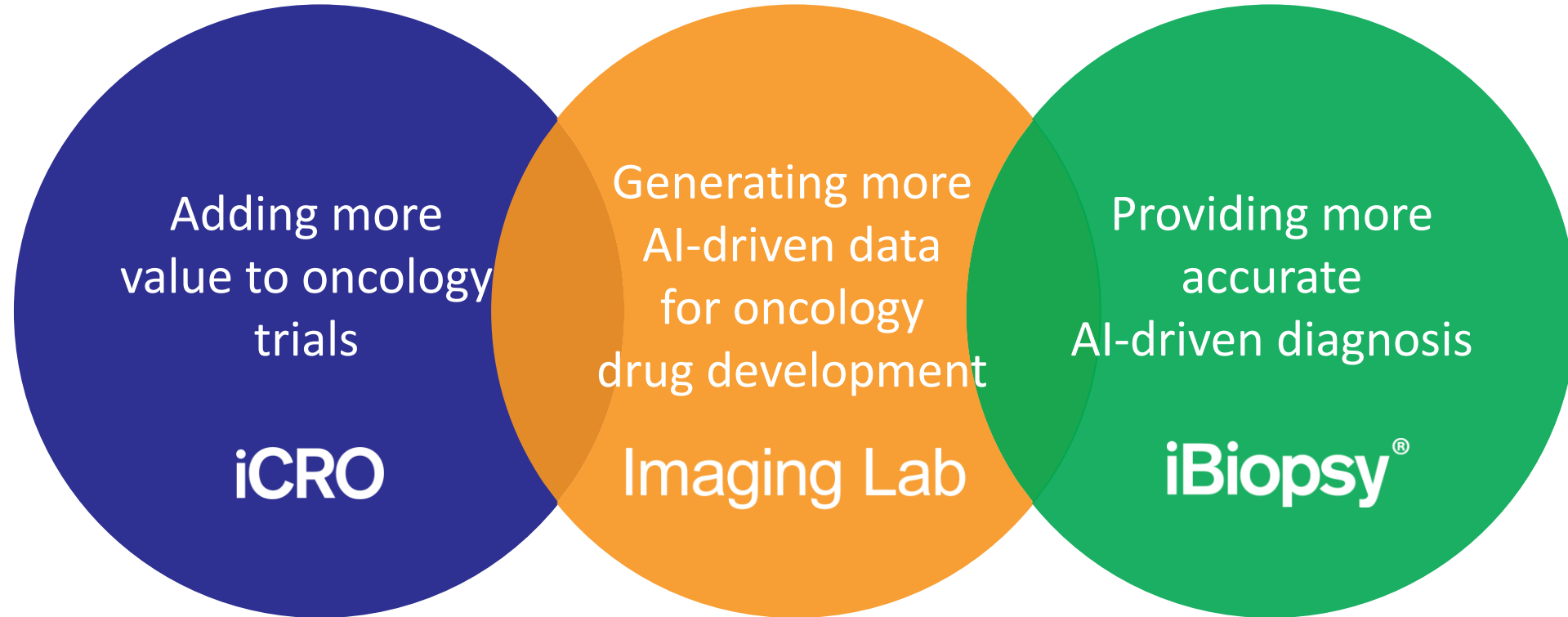
Our growth is powered by proprietary AI, computer vision and signal processing technologies, strong KOL connections, and medical, scientific, technology partnerships.

With **iBiopsy®**, our AI-powered imaging platform for the development of Software as Medical Device, we help enable clinicians to diagnose patients earlier. We intend to launch our iBiopsy® Lung Cancer Screening SaMD in the US in 2024.

Our **iCRO** imaging solutions and advanced **Imaging Lab** offer help our 80+ biopharma clients drive their oncology clinical studies toward successful approval, using AI-driven image insights.



# AI-Powered Imaging and Data-Driven Approaches Are Redefining the Entire Patient Journey



- Extract drug efficacy data
- Streamline the clinical process

- Select early-stage patient
- Discover predictive imaging biomarkers

- Develop noninvasive, early-stage diagnostic solutions
- Market SaMDs for routine clinical use
- Develop companion diagnostics

# Executive Committee



Fredrik Brag

*CEO & Founder*



Jean-Christophe  
Montigny

*Chief Financial Officer*



Yan Liu

*Chief Medical Officer*



Thomas  
Bonnefont

*Chief Operating &  
Commercial Officer  
iBiopsy®*



Nicolas Dano

*Chief Operating Officer  
iCRO*

# 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*

# Strong Business Momentum

As of December 31, 2022 (\*)

## 2022 revenue at €23.8M

- An increase of 16% compared to 2021 revenue (€20.5M).

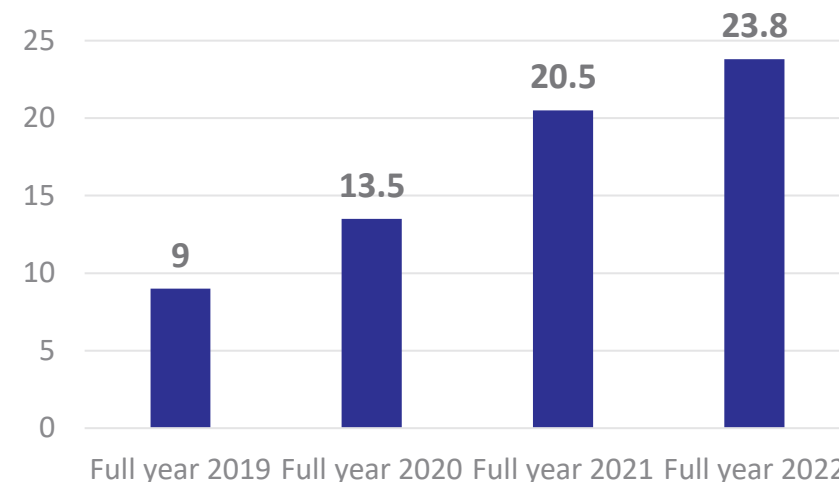
Nota: company revenue comes from the iCRO activity, as iBiopsy® doesn't generate revenue at this stage (R&D)

## Order backlog at €60.8M

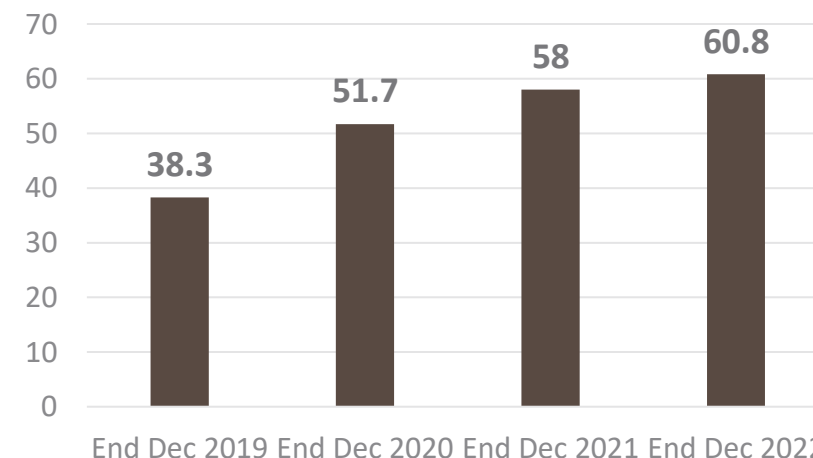
## Cash and cash equivalents at €21.5M

(\*) These numbers are unaudited

Revenue 2019-2022 (m€)



Order backlog evolution  
2019-2022 (m€)



# 2023 & Beyond: Transformative Developments

## Growing penetration of AI imaging in patient care

- Lung cancer is the N°1 killer of all cancers with 94% mortality at 5 years for late stage which is the case for most patients
- **Lung Cancer is curable** when diagnosed in stage 1
- In March 2023, we announced breakthrough results for our Lung Cancer Screening (LCS) CAdE/CADx SaMD with a sens. of 96.5% at a spec. of 97.2% (malignant vs benign)
- 14.5M are now eligible for imaging LCS in the US. EU countries have announced the launch of LCS programs in the coming years. European eligible population is 20M+
- A new CPT reimbursement code of \$650 for quantitative CT tissue characterization is active
- The LCS TAM for Median is \$10-20bn for the US & EU and could double with Asia
- We have similar programs for early diagnosis of IPN, liver cancer (HCC) and NASH

## Growing penetration of AI imaging in the pharma industry

- Median core iCRO business is expected to grow significantly
- Pharma companies are operating a stage shift to treat early-stage disease to increase chance of success
- **AI Imaging is revolutionizing drug development through:**
  - **Cancer detection & characterization**
  - **Molecular status prediction**
  - **Response predictions / Companion diagnostics**
- Median Imaging lab can provide state of the art solutions

# iBiopsy<sup>®</sup>

## Shifting the Early Diagnostic Paradigm with Artificial Intelligence

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We are developing the next generation AI/ML tech-based Software as Medical Device (SaMD) to help:

- Detect, diagnose & monitor early-stage lung and liver cancer patients
- Detect, diagnose & monitor early-stage NAFLD/NASH patients



**Lung Cancer**



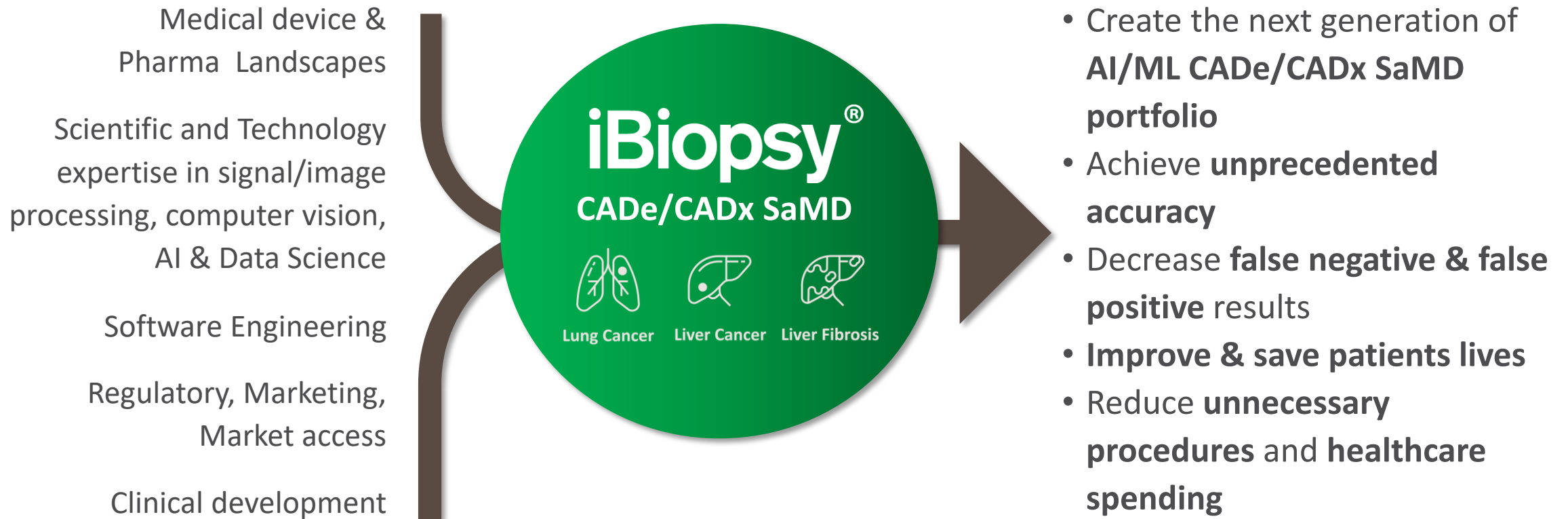
**Liver Cancer**



**Liver Fibrosis**

# iBiopsy® Platform

iBiopsy® leverages Median's expertise and capabilities to design the most advanced AI/ML tech-based CAdE/CADx SaMD



## We published breakthrough results & obtained endorsement from the medical community

- Publications of significant scientific and clinical results for iBiopsy® LCS CAdE/CAdx SaMD
- Much stronger results vs liquid biopsies for early stages
- 5 presentations in major medical/scientific conferences (ESMO, RSNA, MICCAI, ECR)
- Creation of a prestigious Lung Cancer KOL advisory board

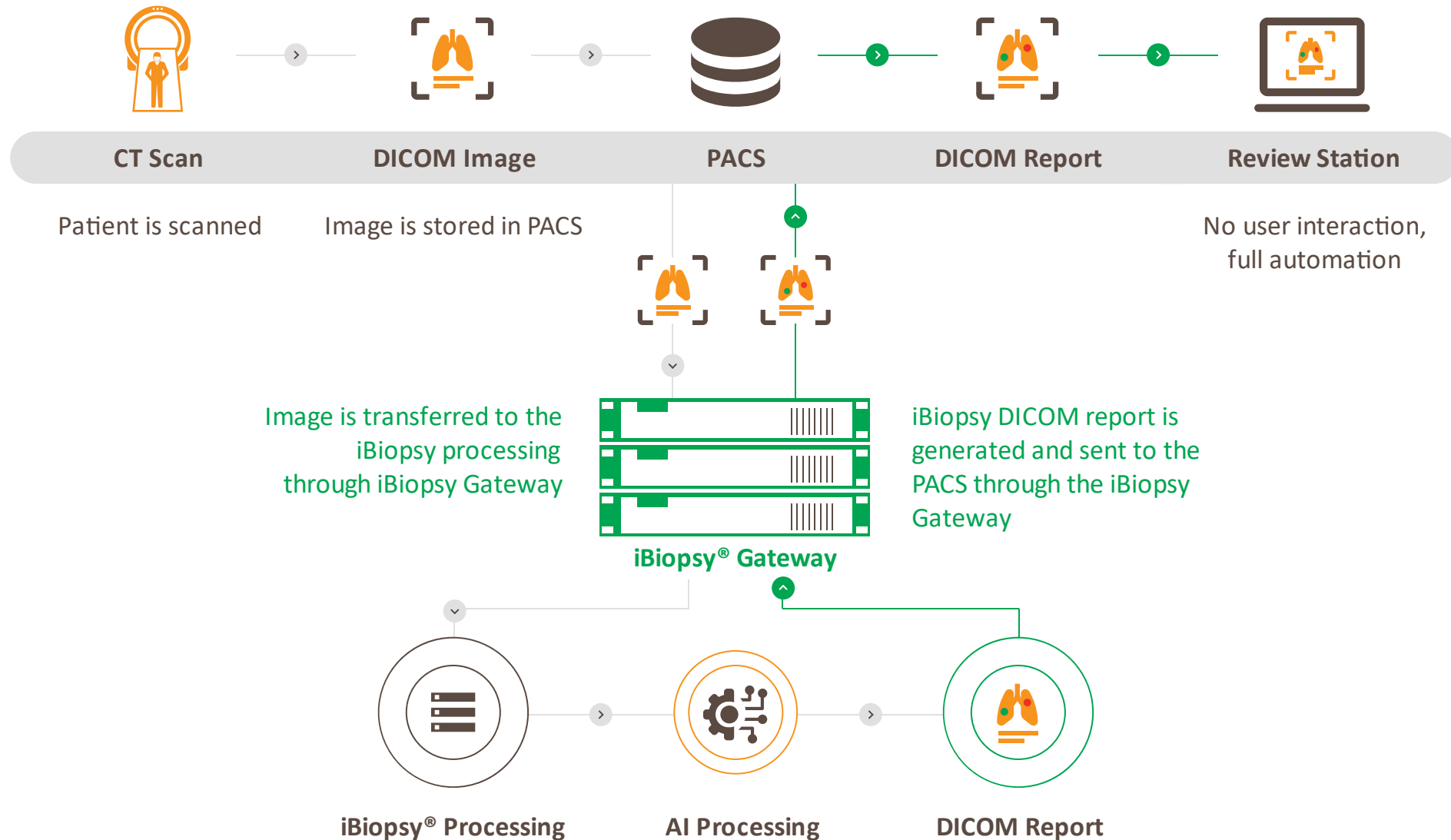
## We prepared our pivotal clinical studies

- Design of the LCS pivotal clinical studies
- Clinical data acquisition: first data in house since December 2022
- Reader training initiation
- Finalized FDA Q-sub meeting, on trajectory for 510(k) clearance
- Preparation for CE Mark

## We prepared the next steps

- Design of LCS SaMD market access
- CPT code in place for \$650 that could be applicable to Median
- Many partnership discussions
- Launch of IPN program, increasing our lung cancer TAM
- Continued progress on IPN, HCC & NASH as per roadmap

# iBiopsy® Integration in the Radiology Workflow



# iBiopsy® Total Addressable Market

High opportunity across all indications

	Lung Cancer Screening	Incidental Pulmonary Nodules	HCC Detection and Diagnosis	NAFLD/NASH Detection and Diagnosis
Total Addressable Market	~\$10-20bn	~\$5-10bn	~\$1-3bn	~\$16-50bn
Market Facts	N°1 Killer with 5% survival in late-stage vs 92% in stage 1	10M people in the US & EU monitored for IPN's	N°3 killer, 3% survival at late stage	NAFLD prevalence of 25% in the US & EU; NASH 3-5% of population
Target populations	High risk smokers	Incidental findings with detected nodules	At risk HCC patients with nodule ( $\geq$ ) 1 cm	NAFLD Patients
Target populations	US: 14.5M (USPSTF) EU T5: 22M (e) Asia T3: 100M (e)	US: 5M (e) EU T5: 5M (e) Asia T3: 24M (e)	US: 2.3 (e) EU T5: 7.4M (e) Asia T3: 48.4M (e)	US: 90M (e) EU T5: 70M (e) Asia T3: 500M (e)

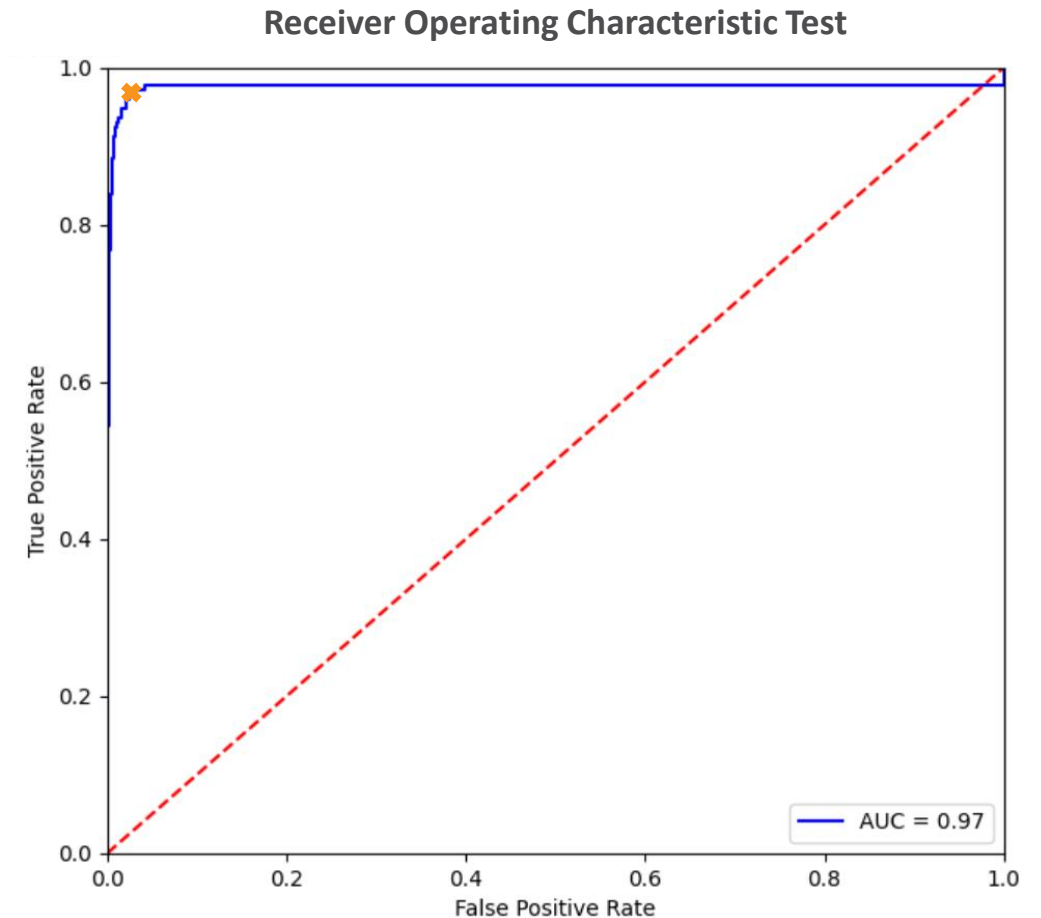
# AI-based Software as Medical Device Landscape in the US

- The recognition of AI-SaMD value has translated:
  - in specific temporally NTAP (new Technology Add-on Payment) reimbursement codes,
  - in a growing number of AI imaging CPT (Current Procedural Terminology ) III codes.
- These CPT codes allow a national payment for medical procedures performed using FDA-cleared AI-based Software as Medical Devices. Recently, specific CPT III codes for \$650 have been created, for the reimbursement of AI imaging solutions for quantitative CT tissue characterization (0721T/0722T), effective since July 1, 2022.

# iBiopsy<sup>®</sup> LCS: Setting the Bar in Lung Cancer Screening

Lung nodule detection & characterization on all lung cancer stages

- Nodule Level Performance
  - **AUC = 0.974**
  - Max Youden Index Operating Point ✖:  
**Sensitivity = 96.5 %**  
**Specificity = 97.2 %**
- Dataset
  - **Training (LIDC\_IDRI + NLST):** 7,687 patients (225 malignant) – 158,686 Nodules
  - **Test (NLST):** 2,176 Patients (independent from Train) - 37,257 Nodules (172 malignant)
- Model: Combination of Deep Neural Networks (2D + 3D), 3D-Morphological and Radiomics features (Patents Pending)



Results presented at the European Congress of Radiology, March 1-5, 2023  
in Vienna, Austria - AIX Theater Industry Sessions: March 1 & March 2, 2023  
Press release on February 28, 2023

# Clinical Validation Plan: A Two Study Approach

Objective: Meet the regulatory requirements (USA, EU, etc) for End-to-End CADe/CADx

## Standalone Performance Study

- 4-6 Centers, ≥294 cancer, ≥521 benign
- Objectives:
  - › Assess software's standalone performance in characterizing positive and negative patients.
  - › Assess system's standalone performance in detecting and characterizing malignant/suspicious nodules.

**Cohort: 4-6 Centers in EU and the US**  
≥294 cancer, ≥521 benign

### Reference Standard Generation

- › Radiologist Identified nodules: location, segmentation, status (benign/malignant)

### iBiopsy® Software Image Analysis

- › Automated analysis via AI CADe/x
- Finding detection, segmentation localization and malignancy score.  
Report suspicious/malignant findings.

### Statistical Analysis

Compared AI output- report based on suspicious and malignant findings - to the Radiologist Reference Standard.

**“How good is iBiopsy®”**

## Multi-Reader Multi-Case Study

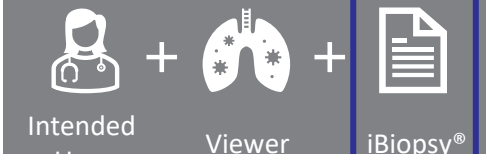
- 360 total patients, 4-6 centers: 120 cancer, 240 benign
- 16 readers analyze each case with and without iBiopsy® Software
- Objectives:
  - › Demonstrate that iBiopsy® improves clinician performance in analyzing LDCT lung screening scans, reducing FPs and unnecessary follow-up procedures.

**360 Patients, 16 Readers**

### Control Arm



### Test Arm

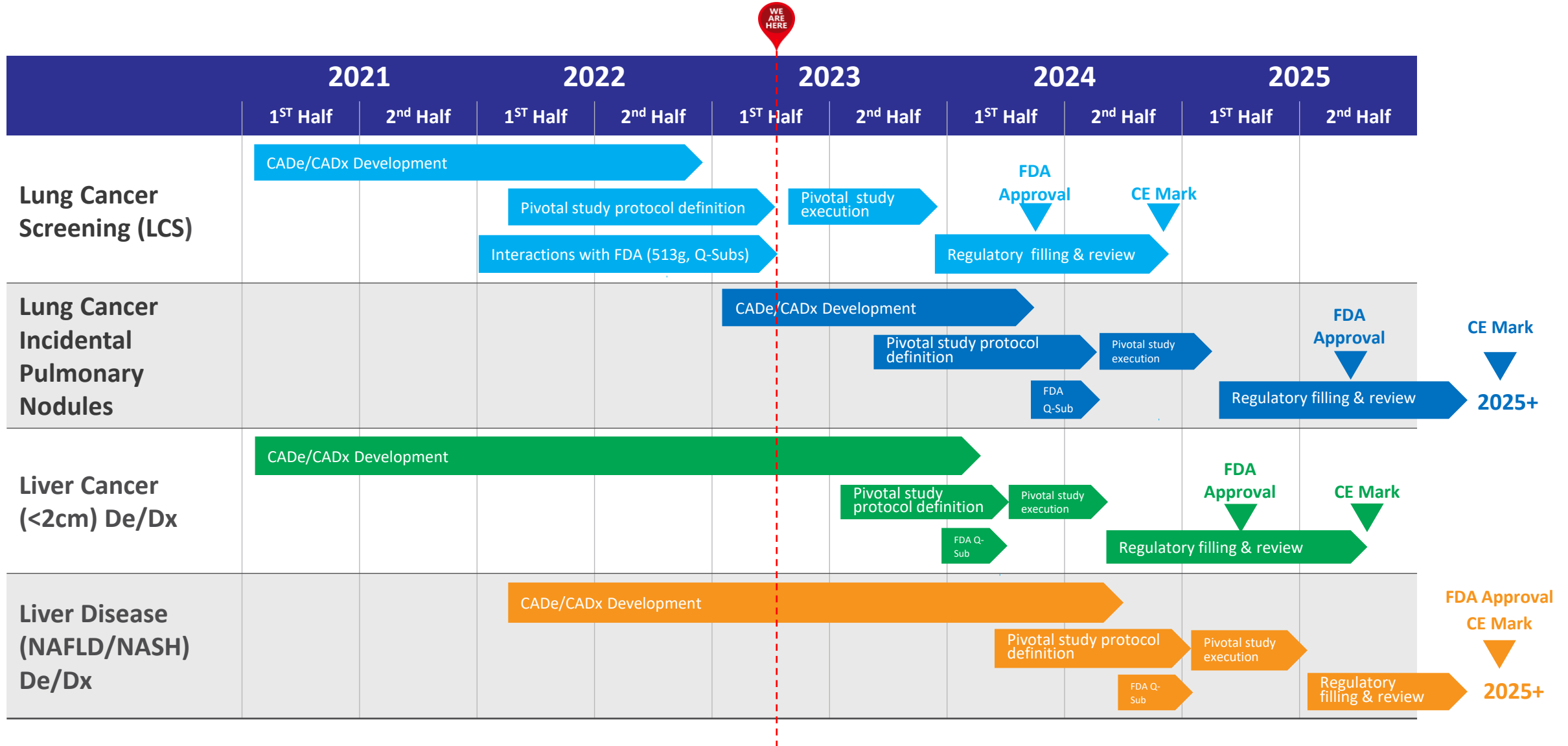


### Statistical analysis

Compare Readers performance in evaluating and managing the patient with vs without the iBiopsy® report support.

**“How much better is the clinician with iBiopsy®”**

# iBiopsy® Lung & Liver SaMD suites roadmap



# iBiopsy®: Strategy and Key Plans for 2023

1.

LCS SaMD pivotal  
clinical studies

2.

LCS SaMD 510(K)  
filing with FDA

3.

LCS SaMD Go to  
Market plans  
  
Reimbursement &  
HE studies

4.

Continue to develop  
strategic relation-  
ships with major LC  
clinical institutions &  
KOLs

5.

Develop a strategic  
partnership with a  
major market player  
for LCS SaMD  
distribution

6.

Continued progress  
on IPN, HCC & NASH  
as per roadmap

# iCRO

## Adding more values to oncology clinical trials and drug development programs

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We provide our global biopharma customers:

- With key data on patient response from phases I to phases III,
- With Imaging Lab services, driving drug development success with transformative AI insights.

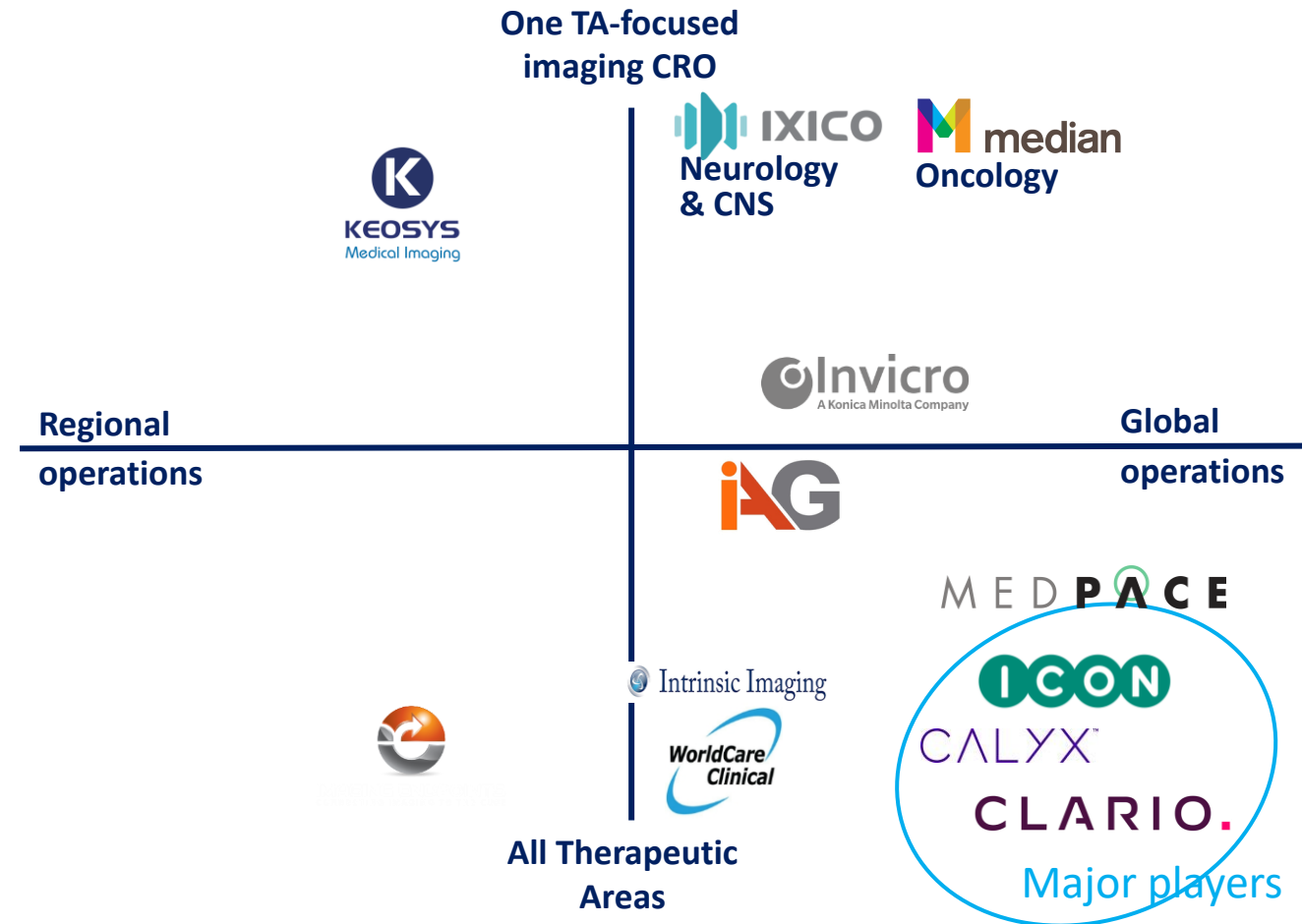
# iCRO Landscape and Differentiators

## Landscape

- The imaging CRO market size was valued at USD 1.5bn in 2021. 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

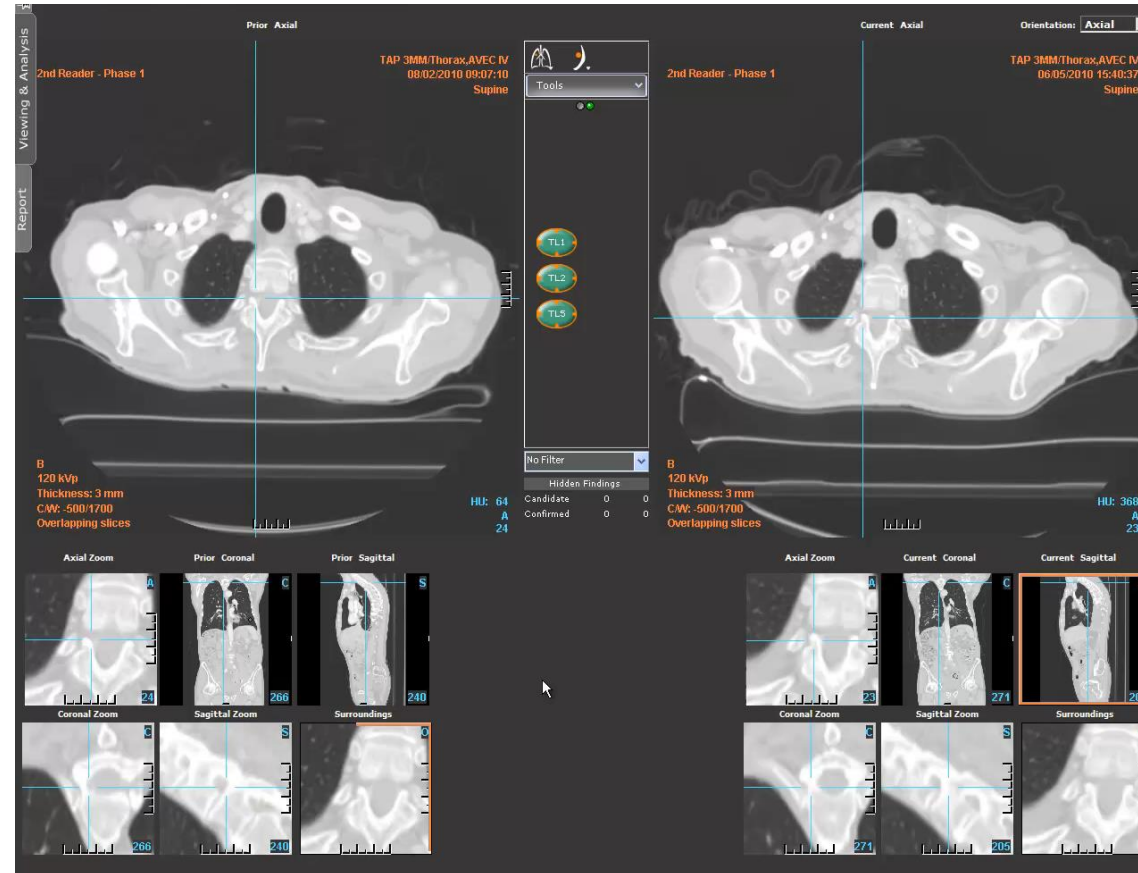
- Median is the only oncology-focused imaging CRO with a global footprint and partners with global CROs
- Strong technology differentiators with our proprietary platform, iSee® and evolutions
- Unique AI competitive advantages through our Imaging Lab



*Competitive imaging CRO landscape:  
Fragmented with 3 major players*

# Imaging CRO Solutions and Services

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



# iCRO Global Experience and Oncology Expertise

As of December 31, 2022



**220**

## Oncology Studies

**32**

Phase I  
trials

*Including*

**18**

*trials with  
Immunotherapy*

**109**

Phase II  
trials

*Including*

**52**

*trials with  
Immunotherapy*

**79**

Phase III  
trials

*Including*

**51**

*trials with  
Immunotherapy*



**55**

Clients in the US  
and Europe

**20+**

Clients in China, including  
the Top3 Chinese Biopharmas

**17**

Supported Regulatory  
Approvals

**3**

FDA Inspections, no  
findings

**11**

NMPA Inspections, no  
findings

**26,000+**

Enrolled Patients

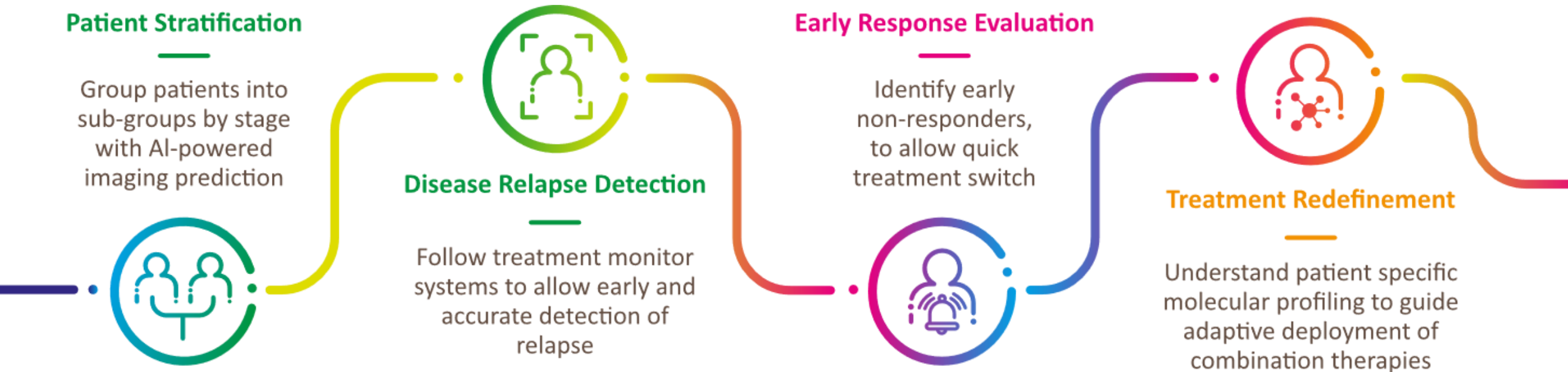
**130,000+**

Images Managed

Cumulative contracted and less than 12-month awarded studies, since the beginning of the iCRO activity, and until December 2022

# Imaging Lab: Median's added value in the Life Cycle of Drug Development

Image Intelligence all along the Patient Journey & Drug Development Process



# iCRO: Strategy and Key Plans for 2023

1.

Continue to scale &  
grow the core  
business

2.

Become preferred  
partner with  
additional large  
pharmas

3.

Strike major Imaging  
Lab deals with Top  
Pharma Companies,  
based on an Artificial  
Intelligence offer

# Wrap Up messages - 2023 & 2024: Transformative developments

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## iBiopsy® Lung Cancer Screening AI-based CAdE/CADx SaMD:

- iBiopsy® LCS CAdE/CADx pivotal study execution in 2023
- iBiopsy® LCS CAdE/CADx expected FDA approval H1 2024

## AI is very rapidly becoming a Must Have in drug development:

- Median to continue to scale & grow the iCRO core business
- Strike major Imaging Lab deals with Top Pharma Companies, based on an Artificial Intelligence offer



## 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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**ALMDT**

EURONEXT  
GROWTH

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