IHI Call Days | Call 9

A Real-time 3D Histopathology Imaging Solution for Improved Cancer Diagnosis and Patient Outcomes

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Link to the IHI brokerage platform:

- Proposal sharing tool
- Participant profile

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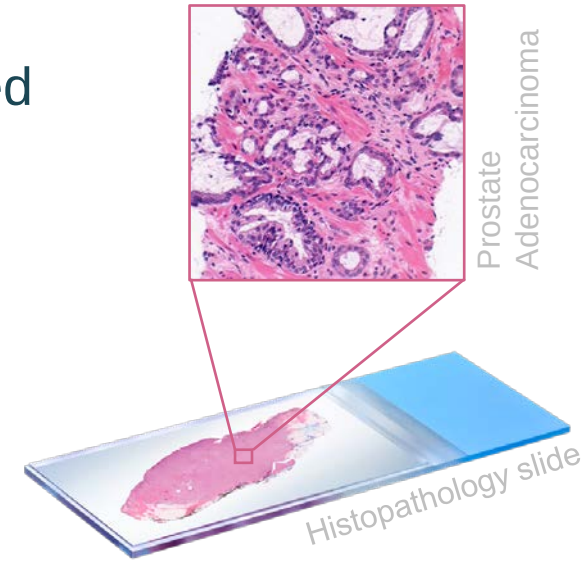
Since **1896**, the Histopathology is the gold standard for diagnosing cancer

- Around 2 300 000 000 histopathology slides are examined worldwide each year * **- this is 72 slides per second**

- Despite modernization and workflow optimization over the past 128 years, current histopathology methods do not fully meet the …



1. Diagnostic needs of cancer patients
2. Align with the demands of 21st-century healthcare systems

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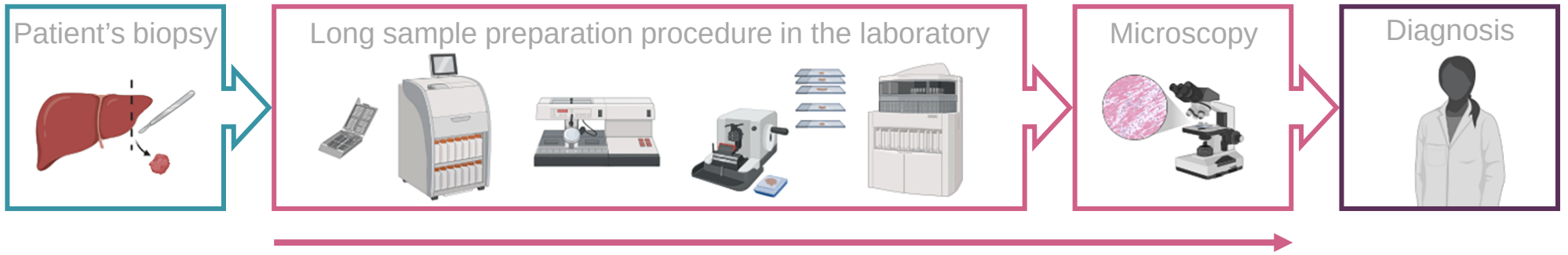
* Histology and Cytology Market Size & shar Report 2023-2030, Grand View Research

Challenges of current histopathological methodology for a fast and accurate diagnosis of cancer



- **Timely Diagnosis** - Long turnaround time, ~7 days for 70% of patient samples
- **Accuracy** - Provides only 2D information results in "histological sampling bias"
  - Low accuracy for early carcinoma diagnosis in breast, cervix, thyroid, and brain
- **Cost-Effective** - Not aligned with the Green Deal - High energy/waste demand

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The image was created using BioRender.com

Our technical solution to solve the problem:

- This proposal addresses the IHI specific **objective 2**

Instead of sending patient samples, 3D images will be sent directly to the pathologist.

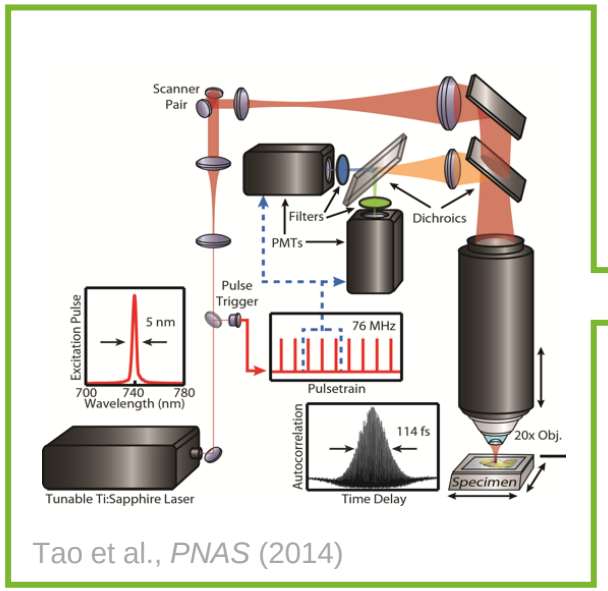
Next to the operation rooms

Doctors' offices

The image was created using BioRender.com

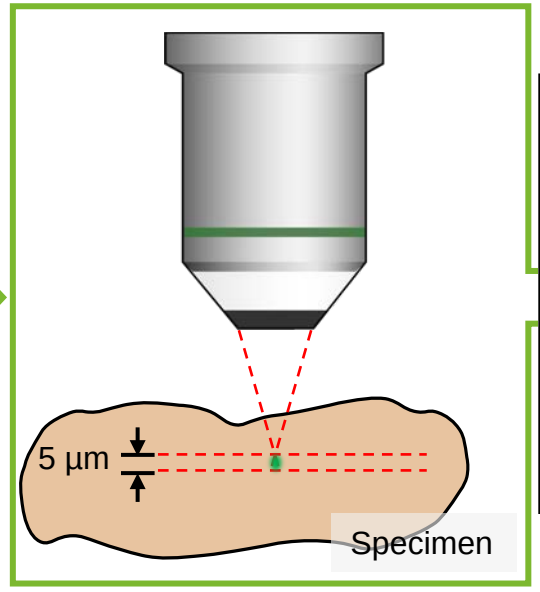
Real-Time 3D Histopathology Imaging

The methodology is based on Nonlinear Microscopy

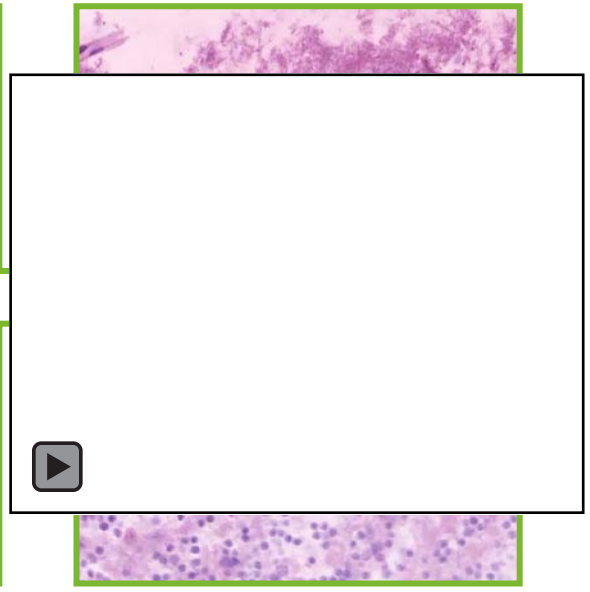


Tao et al., *PNAS* (2014)

Scanning the freshly stained sample



Generating 3D Images



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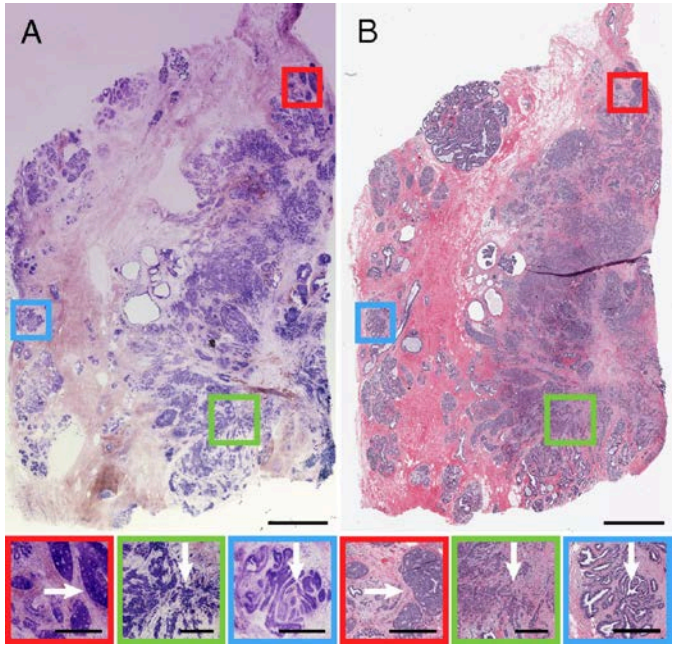
Real-Time Histopathology Imaging generates 3D images with 94.1% accuracy and 95.4% sensitivity*

Comparison*

Real-Time Histology Imaging	Paraffin-embedded Histology



Comparison

	Real-Time Histology Imaging	Paraffin-embedded Histology
Accuracy	Yes	Yes
Information	3D	2D
Further Analysis	Yes	No
Workflow	Very Short	Very Long
Turnaround Time	5 minutes	>7 days
Digital Result	Yes	No
Cost-Effective	Yes	No

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*N=179 from 50 patients; Tao et al., *PNAS* (2014)

Contribution of industry/private sector in this proposal

Real-Time Histopathology Imaging – A device with small footprint

Cooperation with Industry and the private sector is required to adopt this innovative technology into a cost-effective, user-friendly device and make it accessible for widespread use in **healthcare systems**.

The contribution of the following sectors is required:

- Medical Devices
- Optical Imaging
- Digital Health
- In vitro Diagnostics
- Medical Technology Regulations

Outcome and Impacts:

Integrating this technical solution in various healthcare settings, such as **next to operating rooms**, or in **doctors' offices** will result in…

- Outcome: An accurate histopathological diagnosis can be made immediately after collecting the patient's biopsy.
- Impact:
  - For Patients: (1) fast and accurate diagnosis, (2) reducing number of surgeries, (3) ensuring the right treatment, (4) reducing unnecessary hospital stays
  - For healthcare systems: (1) reducing costs, (2) more sustainability, (3) aligning with Green Deal
  - For Union's healthcare industry: High competitiveness, the histopathology market is valued at EUR 16 billion in 2023*

* Histology and Cytology Market Size & shar Report 2023-2030, Grand View Research

Expertise and Resources

- We have…
  - Strong expertise in **optical imaging**
  - Access to **pathologists** and **patients' samples** for validation
  - Experience in translational research
  - Access to 237 biological and medical imaging research infrastructures in 18 European countries through our association with **Euro-BioImaging**

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Expertise and Resources

- We are **looking for** partners from the industry/private sector to …

1) develop the **mechanics**, **lasers**, and **optical systems** for the device
2) develop **software solutions** essential for operating the instrument, enabling real-time imaging and integration with existing digital pathology platforms
3) develop **sample preparation kits**, enhancing compatibility with gold-standard histopathology
4) fulfill the **medical technology regulation**

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Interested in cooperation?

- You can contact each of the following persons (all are present at the IHI event):

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