Founded
2007

Funding Received
100k EUR – DIH-HERO
2,1mln EUR – NCBR

Experienced Team
Bartłomiej Stańczyk, PhD
robotics engineer
Prof. Konrad Karcz MD PhD
15 highly qualified development engineers

Proof of Concept
ARIA – based robotic arm

Phase Plan
Finalize prototype for demonstration (August 2021)
R&D Phase (2021-2023)
Animal Trials (May 2023)
Clinical Trials (October 2023)

Compliance to standards
ISO 13407 User-centered design
TS 15066 Collaborative Robots
ISO 13485 Quality management systems for medical device
IEC 60601-1-8 Medical electrical equipment safety

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BONITO
Robotic Needle Guidance System for Biopsies

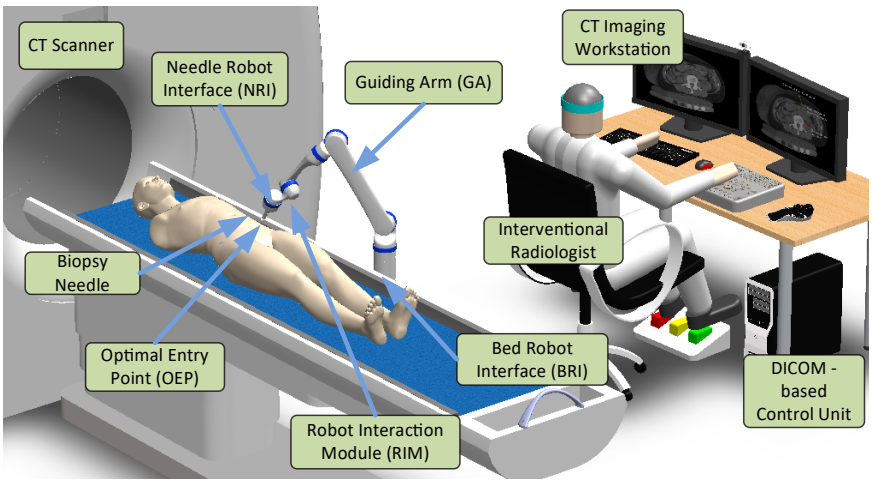
Innovation Summary
In the modern ageing societies, the demand for specialized medical care becomes higher, whereas a worldwide lack of physicians is observed. Forecasts warn that this lack will grow worse in the near future [actionforglobalhealth.eu]. Robotics plays a key role in a mankind development. When we take into account gradually rising healthcare demands, we need to pay attention to the role of medical robotics.
Thanks to the specific approach, facilitating the use of specialized equipment designed to work inside the body cavities through one or more trocars, the surgery itself is especially beneficial for the patient, as causing less trauma, pain and blood loss, while leaving smaller skin scars, effectively reducing the duration of hospital stay.

What's the problem
Image-guided biopsy procedure is an area where accuracy and space efficiency is essential. Despite robotic device's paramount precision, its cost-effectiveness is invaluable due to the workforce reduction with simultaneous capacity increase. Additionally, in a time of an increase in a number of patients, time saving is crucial. Within the field of oncology, percutaneous strategies have developed, in which biopsy and removal of tumors are performed by means of a needle through the skin utilizing image-guidance.

Solution
Robot-assisted biopsy procedure is another alternative that can help out the surgeon to inject the needle precisely, while omitting the risk of medical errors due to tremor, fatigue etc.
Since 2019, ACCREA Engineering Poland has been developing an assistive robotic device aimed at helping diagnosticians by motorizing the movement of a needle for a biopsy procedure. The first functional prototype device is based on an off-the-shelf ARIA/BATEO robotic arm designed by ACCREA in the course of an R&D grant-based project L2R. The target system is destined to reach Clinical Trials Phase by October 2023, supported by PL NCBR grant agreement.
The proposed system will utilize the tailor-made medical image processing software paired with state-of-the-art robotic devices, allowing for an easy, point&click biopsy procedure planning and execution, performed based on ultrasound (a - prostate) or CT scans (b – abdomen, chest) of desired tissues.

Features
- Automatic retrieval of the entry point, automatic angulation of the needle guide, automatic determination of the insertion depth
- Manual insertion of the needle by the physician to insure the safety and haptic sensation
- Inherently safe mechanical construction: the manipulator will be lightweight and compliant, equipped with various safety mechanisms (speed limits, force sensing and limiting, collision and impact detection), no sharp edges, no clamping;
- Natural physician – robot interaction: intuitive control modalities, freely to choose between manual repositioning, joystick, automated movement;
- Intuitive procedure planning: based on the 3D visualization of the patient's body, limited to pointing the target and the entry point of the needle, and entering the needle's length

System Description
The complete system consists of 3 main sub-systems: Passive Arm with Robotic End-Effector (ab), Robotic Arm (b – see Figure), Control Software. Each robotic component works independently, relying only on a universal Control Software.

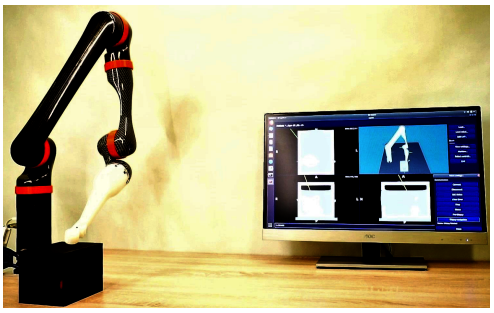


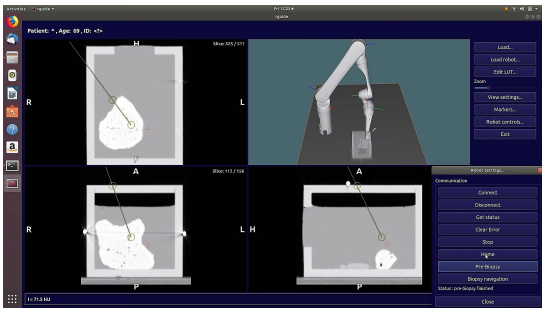
BONITO

Robotic Needle Guidance System for Biopsies

Proof of Concept

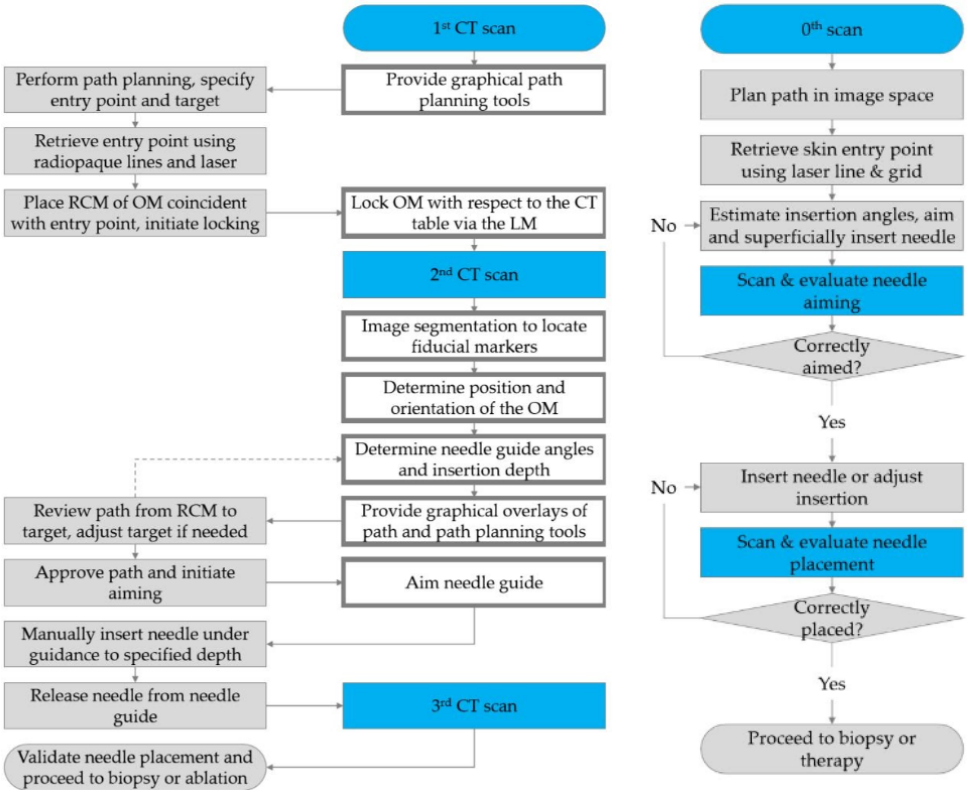
At the current stage of the development, ACCREA has facilitated and modified their ARIA Version 1.1 anthropomorphic robotic arm and paired it with experimental control software calculating the trajectory of the needle and aligning the arm's end-effector to this path.





Robotic Biopsy Workflow

Modelling the biopsy procedure is a crucial part of new device development. For the most challenging field of automated biopsy under CT scan supervision, a proposed workflow is demonstrated below, with comparison to conventional procedure.



Challenges

The success of the procedure relies strongly on the correct connection of coordinate systems of CT images and the robot. For this purpose, ACCREA proposes a novel solution – Robot Arm Mounting Base integrated with a CT scanner's bed, equipped with CT-compatible markers for precise detection of the base on the image.

As there are multiple CT systems on the market, it is crucial to distinguish the most frequent systems in use, and to find the least invasive method of integrating a robotic arm with CT scanners' beds.

Questions

- Would you be willing to contribute to the project by allowing ACCREA to study the CT scanner you use/distribute?
- Based on your experience with traditional biopsy (prostate, abdomen, chest) and/or other needle guiding devices, would you agree with the above-mentioned workflow for the automated biopsy procedure? Are there any changes in the workflow you would like to see implemented in BONITO system?

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