Newsletter

Autumn 2022

ProCAncer-I

ProCAncer-I has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 952159

European Commission

In this issue

The Clinical Vision of the project and added value for patients

By Prof. Daniele Regge, Chief of the Radiology Unit, Candiolo Cancer Institute (FPO)

One man in eight is diagnosed with prostate cancer during his lifetime and among them, approximately one in 7.5 will die from the disease. To detect prostate cancer, men are invited to perform PSA, usually after the age of 50-55. Unfortunately, PSA has a high rate of false positives, leading to an unnecessary number of second level investigations, including biopsy.

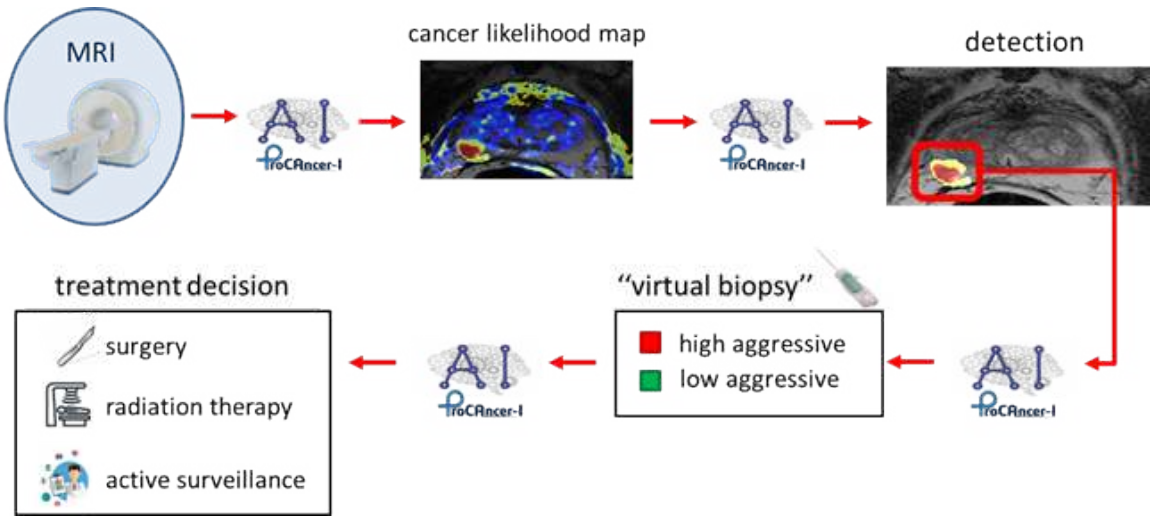
To improve diagnosis, since 2020 urological guidelines recommend Magnetic Resonance Imaging (MRI) because of its high accuracy in detecting clinically significant cancer lesions, i.e. those that need treatment. Moreover, when MRI detects cancer, it provides urologists with information on tumour spatial localization allowing accurate targeting and reduction of the number of retrieved samples, thus limiting procedure related complications. MRI would be even more beneficial if it could classify lesions according to their risk of progression, a sort of "virtual biopsy", since in this case biopsy could be entirely avoided. The second important reason for performing MRI is that when small size, low risk lesions are detected, patients could avoid treatment and undergo follow-up. Indeed, MRI could monitor patients signalling if lesions are turning more malignant.

Unfortunately, MRI provides a visual, necessarily limited, subjective interpretation, which is strongly affected by radiologist experience. Moreover, there is an increasing demand of MRI examinations following the implementation of the new guidelines which is not currently balanced by an adequate number of facilities and dedicated staff.

The vision of ProCAncer-I, an EU funded project involving more than 20 research partners across Europe, is to support radiologists, and other clinicians, with state-of-the-art artificial intelligence (AI) MRI based algorithms with the aim of improving diagnosis and treatment in prostate cancer patients.

Above all, AI tools developed within the consortium aim at distinguishing tumours that are born to be good, requiring no treatment, from those that are born to be bad. The latter grow over time, disseminate and transform into a deadly disease. Moreover, ProCAncer-I seeks to predict which cases will metastasize, which could relapse or are suitable for active surveillance programs. Knowing which patients are likely to relapse or develop metastatic disease will guide the clinical decisions, optimising the choice of treatments, planning close follow-ups if necessary, and possibly minimising treatment toxicity.

ProCAncer-I results will bring medicine from the era of "sick care", in which patients are cured because they have symptoms, to that of "prevention", where lesions are found and treated before they can grow and become aggressive. This will be possible using AI, that can perceive information in medical images such as MRI, that are hidden from human perception, and give them value.



The ProCAncer-I value for patients in which artificial intelligence (AI) supports the clinical decision making process at different levels

Clinical Challenge: Can machine learning and artificial intelligence of primary prostate cancer identify patients at risk of metastatic disease as early as possible?

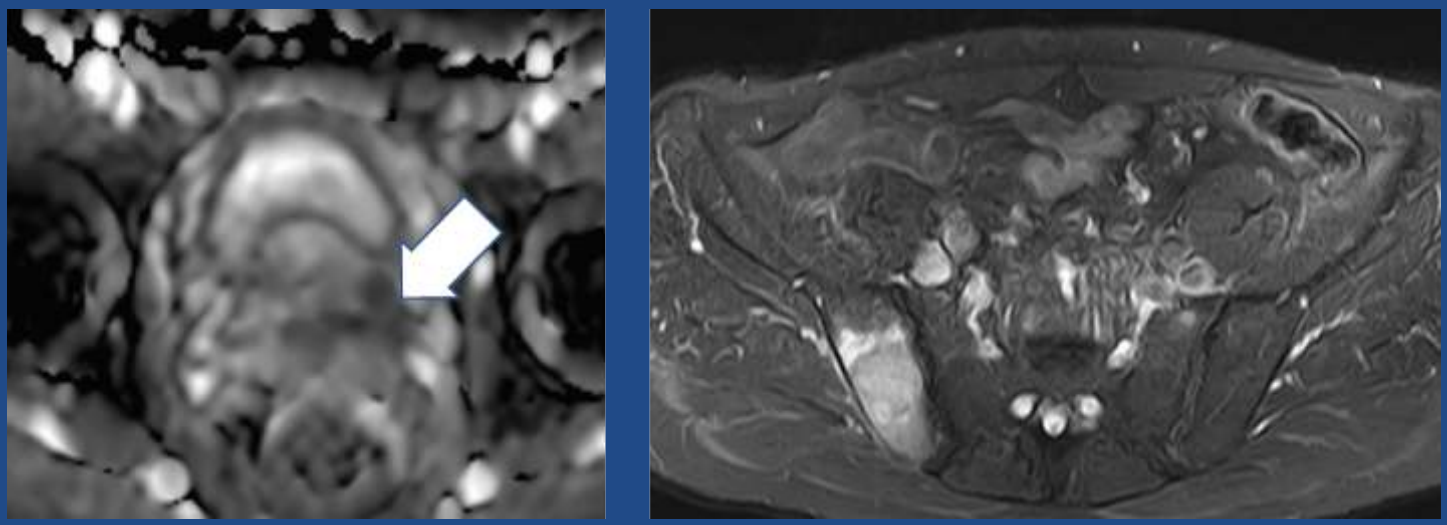
By Prof Mu Koh, Consultant Radiologist & Professor in Functional Cancer Imaging, the Royal Marsden NHS Foundation Trust (ICR)

Primary prostate cancer is a heterogeneous disease in terms of disease aggressiveness and long-term outcomes. Many men who are diagnosed with prostate cancer will have indolent disease and die of other causes. However, some men have aggressive disease that results in cancer spreading to other parts of the body, particularly the bones. Approximately 50% of men diagnosed with local prostate cancer will develop metastases in their lifetime. In particular, bone metastasis is associated with significant morbidity including bone pain, pathological fracture and spinal cord compression. Hence, confident identification of patients at risk for early metastatic disease can influence diagnostic, surveillance and treatment strategies to improve patient outcomes.

Different multivariate models and nomograms have been proposed to identify the risk of cancer progression based on clinical and laboratory data. These include parameters such as the serum PSA levels, the Gleason score of the primary tumour at biopsy, patient age at diagnosis, clinical tumour stage and the percentage of biopsy core samples positive for cancer. However, many of these models have been developed in the context of biochemical recurrence, usually after treatment. Nonetheless, using the CAPRA score, it has been shown that each point increase in the score was associated with an increased risk of bone metastases (HR for metastasis = 1.47, 95% CI = 1.31. to 1.48) and increased risk of mortality.

The use of artificial intelligence and machine learning in primary prostate cancer has the potential to uncover novel imaging features that informs upon the likelihood of early metastatic disease. Prior studies using traditional radiomics methods on prostate MRI has achieved good diagnostic performance (AUC 0.76 to 0.93) for identifying patients with nodal or bone metastases. However, the potential to use more advanced machine learning techniques and deep radiomics methods to uncover novel meaningful signatures has not been established.

In the ProCAncer-I study, we will use our well-curated multicentre imaging dataset to extend current knowledge by applying advanced artificial intelligence and machine learning techniques to identify patients at a high likelihood of developing early metastatic disease. We will evaluate standard clinical and radiological features alone and in combination of our imaging models to identify early metastatic disease. Patients who have developed metastases in the first year of diagnosis will the positive class in our model, while patients without metastases will be the negative class.



A 57 year-old man with a PI-RADS 5 lesion at the left base of the prostate gland shown here on the ADC map (arrow). STIR MR imaging shows a synchronous bone metastasis within the right ilium.

Prostate cancer MRI as an AI challenge

By Prof Jurgen Futterer & Prof Henkjan Huisman, RadboudUMC (RUN)

Professors Jurgen Futterer and Henkjan Huisman are both affiliated with Radboudumc, Nijmegen, The Netherlands. They have a long-standing collaboration and are part of the EU H2020 project ProCAncer-I team, which aims to develop an AI platform integrating imaging data and models, supporting precision care through prostate cancer's continuum.

Jurgen chairs the Minimally Invasive Image-Guided Intervention Center (MAGIC, https://magicnijmegen.nl/). His group has its roots in MRI-guided prostate treatment that has expanded to CT-, US-, and MR- image-guided oncologic interventions, for example, biopsy of prostate, bone, and liver; (non-) thermal ablations of pancreas, liver, kidney, prostate and vascular malformations.

Henkjan chairs a group within the Radboudumc AI unit (DIAG, diagnijmegen.nl) on deep learning AI applications for prostate and pancreas cancer and adhesions. His group focuses on diagnostic and interventional AI to improve workflow and accuracy of healthcare. He is the project lead of the EU project PANCAIM and co-lead of the Dutch project FastMRI.

Radboudumc has been pioneering challenges in medical image analysis that became popular after the Grand Challenges for Medical Image Analysis organization at the MICCAI conference in 2007. Radboudumc and Mevis Fraunhofer created Grand-Challenge.org (GC) in 2010 to make it easy for organizers of challenges to set up a website for a particular challenge. It aimed to bring all information on challenges in the domain of biomedical image analysis available in a single place. GC initially allowed Challenge organizers to upload the code that computes the score for submission in the form of a Docker container. This system has been operational since 2017.

GC recently added the option to upload an AI algorithm. Algorithms allow using confidential test data. Whether an algorithm is designed as a submission to a Challenge or as its own entity, physicians and clinical researchers can upload their data, have the algorithm process these, and download the results. Over 70,000 user GC accounts have been created on Grand Challenge from countries all across the globe. Radboudumc processes around 2,000 submissions per month, totaling almost 80,000 evaluated submissions that have been placed on a leaderboard.

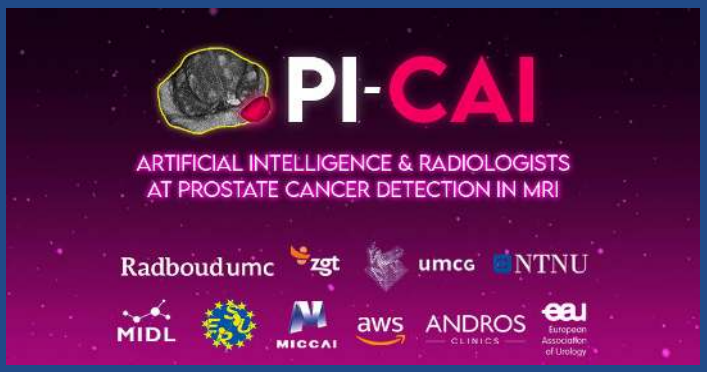
The GC team has extended the platform to support various medical viewers that run in the browser and to set up Reader Studies. In a Reader Study, a user is presented with images and questions. Questions can include annotations, for example, "Segment the prostate". The organizers of the Reader Study can download the results via the website or the API. With Reader Studies, researchers can carry out observer studies or set up annotation efforts that are usually needed to run a challenge. You can even set up training programs for physicians; providing a ground truth can provide immediate feedback after a question has been answered.

PI-CAI (Prostate Imaging: Cancer AI) is an all-new grand challenge, with over 10,000 carefully-curated prostate MRI exams to validate modern AI algorithms and estimate radiologists' performance at csPCa detection and diagnosis. Key aspects of the study design have been established in conjunction with an international, multi-disciplinary scientific advisory board (16 experts in prostate AI, radiology and urology) - to unify and standardize present-day guidelines and to ensure meaningful validation of prostate-AI towards clinical translation (Reinke et al., 2021). The 2022 edition of PI-CAI will focus on validating AI at automated 3D detection and diagnosis of csPCa in bpMRI. The PI-CAI challenge realizes some of the goals of ProCAncer-I and more. It involves ProCAncer-I researchers Anindo Saha, and Jasper Twilt, but includes many more from other projects and institutions.

PI-CAI consists of two sub-studies to estimate the performance of the average radiologist at detection and diagnosis of csPCa in MRI and compare that with AI. Firstly an AI Study (Grand Challenge): An annotated multi-center, multi-vendor dataset of 1500 bpMRI exams (including their basic clinical and acquisition variables) is made publicly available for all participating teams and the research community at large. Teams can use this dataset to develop AI models, and submit their trained algorithms (in

Docker containers) for evaluation. At the end of this open development phase, all algorithms are ranked, based on their performance on a hidden testing cohort of 1000 unseen scans. In the closed testing phase, organizers retrain the top-ranking 5 AI algorithms using a larger dataset of 7500–9500 bpMRI scans (including additional training scans from a private dataset). Finally, their performance is re-evaluated on the hidden testing cohort (with rigorous statistical analyses), to determine the top 3 AI algorithms for automated 3D detection and diagnosis of csPCa in bpMRI (i.e. the winners of the grand challenge).

Secondly, a Reader Study: 64 international prostate radiologists perform a reader study using a subset of 600 scans from the hidden testing cohort.



ProCAncer-I eCRF and Data Upload Tools

By Joao Correia, Innovation Manager at Biotronics3D Limited (B3D)

The ProCAncer-I eCRF (electronic case report form) and Data Upload Tools support ProCAncer-I clinical partners in the process of compiling the required information and follow the defined protocols for uploading data to the project's cloud repositories. The ProCAncer-I eCRF is a set of digital forms used to collect the clinical data of the patients that are involved in the project research. The forms were designed iteratively with the Clinical Partners and the AI developers to collect specific information for 9 Use Cases defined in the project.

Aligned with the anonymisation strategy, the tools were designed to be used for data collection locally, inside the networks of the clinical partners, and execute a white-list anonymisation step before uploading to the ProstateNET cloud repositories. The tool integrates with the RSNA CTP anonymisation tool and with the ProCAncer-I repository services such as authentication, DICOM API

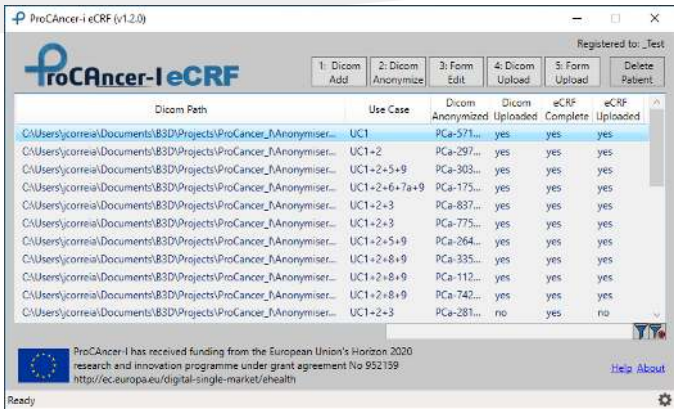


Figure 1. eCRF and Data Upload Tool main window

Gateway and Metadata Catalog API, enabling the anonymisation and upload of data using methods that comply with data protection, privacy and security requirements. The tool is designed to follow a 5 steps workflow from the selection of the folder containing the DICOM files, to the anonymisation, edition of the clinical information and upload of DICOM and clinical information data.

The ProCAncer-I eCRF and Data Upload Tool, shown in Figure 1, is a windows application that should be installed on Windows 10 or above computers with internet connection. The tool also has a command line version, the eCRF_Batch, that allows bulk upload of data for Clinical Partners that can programmatically retrieve the clinical data and generate the specific json files.

The workflow starts with "1: DICOM Add" for the selection of a case folder which contains the DICOM studies for the patient. The second step "2: DICOM anonymise" runs the CTP anonymisation tool with the pre-defined anonymisation script that completely anonymises the DICOM files as defined in the project. The third step "3: Form Edit" allows the user to select for each patient a particular form according to the available clinical, imaging, pathology, treatment, follow-up information. Since a single patient could be useful in more than one single Use Case, we optimized data collection in the eCRF, to avoid duplicates and time-consuming data entry by clinical partners. The fourth step "4: DICOM upload" allows to upload the anonymised DICOM files of the selected case.

he final step in the workflow is “5: Form Upload” that allows to upload the clinical information of the selected case to the ProCAncer-I cloud repository.

The eCRF Forms enable users to select different Forms according to the imaging and non-imaging data available for each patient.

Each Form contains different sections to be filled with clinical, imaging, pathology, treatment and follow-up information. Each tab will contribute to form a specific subgroup of patients which will be used to create the final dataset for one or more Use Cases. In Figure 2, two forms are depicted for Use Cases 1 and 2.

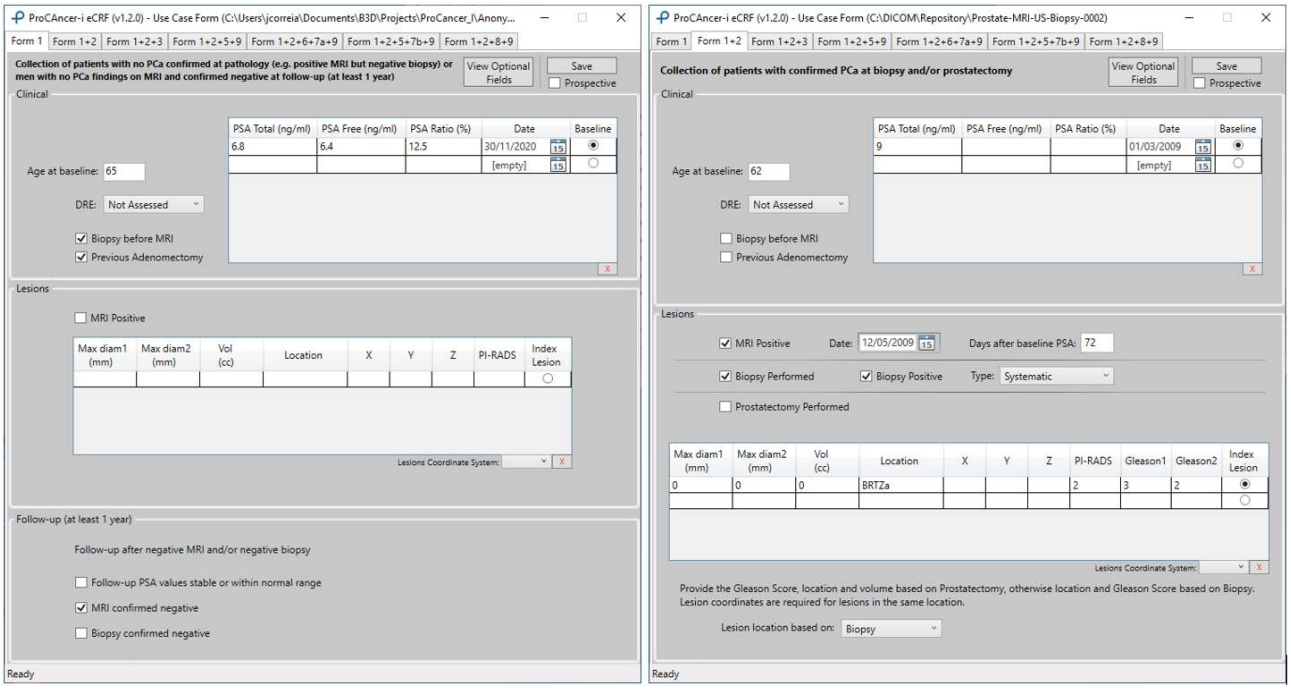


Figure 2. eCRF forms for Use Case 1 and 2

The eCRF batch mode is intended to support partners contributing a large volume of data to upload, who have already a database with the clinical information and also have the means to transform the clinical data into the defined JSON formats.

The batch mode provides a standard way for partners to implement their mechanism to export existing DICOM and clinical data and metadata to the eCRF format. Partners are required to extract the information in their current format (e.g., spreadsheet and databases) using their preferred scripting/programming language and generate JSON files along with a copy of all the DICOM data following a defined directory structure.

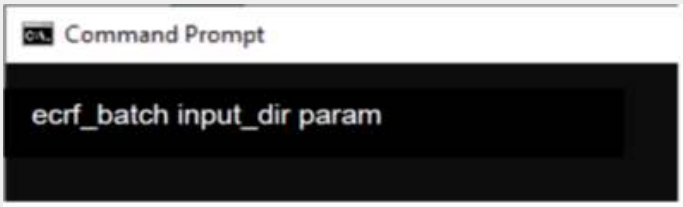


Figure 3. eCRF batch mode command line

As shown in Figure 3, the eCRF Batch is a Windows based binary program that reads the corresponding files from the folders specified in an input directory, verify their correctness and upload them without the need of the current workflow-guided eCRF version. DICOM data is anonymized using the CTP anonymisation tool from RSNA, following the whitelist script designed and provided by the ProCAncer-I project.

Besides several design iterations of the eCRF to reach a balance between data requirements, data availability and data collection effort, the need to comply with different network architectures and restrictions led to several updates of the data upload tools.

Up to November 2022, using the eCRF and Data Upload tools, the Clinical Partners of ProCAncer-I project have uploaded to the ProstateNET cloud repositories +8,000 cases, corresponding to +16,000 data points, containing almost 5 million images.

The Value of Data in Health Research

By Theresa Henne, University of Vienna (UNIVIE), Clara Saillant University of Vienna (UNIVIE) & Varvara Kalokyri, Foundation for Research and Technology (FORTH)

Data is increasingly regarded as a valuable resource, in particular for the development of Big Data and AI-driven technology. Hence, a debate emerged concerning the question of how the value of data can be better protected by legal means, especially in the domain of health data. One of the most dominant streams of argumentation in this debate revolved around the concept of "data ownership", suggesting that data should be owned by individuals or groups similar to other goods and assets. Under the existing EU law, however, no legal framework exists that attributes "data ownership" rights to any entity.

The General Data Protection Regulation (GDPR), for example, provides a number of means for individuals, referred to as data subjects, to oversee and control the processing of their personal data. According to Chapter III of the GDPR data subjects are granted the rights of access, of rectification, of restriction of processing and of erasure (also called the right "to be forgotten"). Yet, data subject's rights are not absolute and can be restricted. For example, the right to erasure under Article 17 can be limited, if the controller can demonstrate that the deletion of the data would seriously impair the achievement of a scientific research project. The GDPR does not assign 'data ownership' to the data subjects nor to the data controller, which is the entity responsible for the processing. The term "ownership" itself is not even used in the GDPR regarding personal data.

Intellectual property (IP) law grants property rights to certain non-rival resources, such as original literary, scientific and artistic work. IP law aims at protecting the innovation itself and rewarding the effort put into its creation. This means that, even though someone's art piece or scientific publication can be copied and accessed an infinite amount of times – hence being a non-rival resource – the author still has rights attached to its work limiting the ways it can be used by others. However, the EU's IP framework does not protect data itself since the collection of information and facts is not considered an act of creation.

So far no common understanding of the concept of "data ownership" could be established. Various, sometimes conflicting responsibilities and rights are discussed under the generic term of 'data ownership' (Hummel et al., 2020). Oftentimes, 'data ownership' is envisioned as a bundle of rights, such as the right to use the data, the right to share data or limit access, the right to sell data or the right to inherit any income generated by the data. Also, different opinions exist concerning the question, who is entitled to be the owner of the data. On the one hand, Fezer (2019) envisions "data ownership" as a citizen's rights enabling the individual to have more control over their personal data and to counter the power asymmetries within the data economy.

On the other hand, Montgomery (2017) argues that the entity, which invests resources in the data collection, curation and analysis, creates the actual value and therefore should own the data. Ballantyne (2018) is in favor of a broader, relational account of "ownership". She argues that rather than data belonging to the patient, data is about the patient. Since clinical data is co-created by multiple actors, including the patient and health care professionals, the attempt to confer an exclusive ownership right to only the patient must fail.

According to Ballantyne, rather than conceptualizing data as private property, the solution is "to reconnect patients with their data and engage them in debates and decision-making about secondary uses" (p.290). Similar to Ballantyne, also Prainsack and Forgó propose that "[i]nstead of endorsing individual-level property rights to data, we should consider health data as collective property" (p. 1990). Thus, local communities, states or international organizations could collectively own data and define for which purposes the data should be used.

In any case, when we are discussing how to modify the existing legal framework governing the use of health data for research, we should clarify that the overall aim must be to facilitate and promote data generation, curation and sharing that enables health research that is beneficial to the people of the EU and protect the fundamental rights of the data subjects (see Evans 2011). The legal framework shall provide incentives to research that is sustainable and beneficial to past, current and future patients as well as contribute to building the knowledge bases.

In order to move forward in the debate regarding the value of data in health research the following questions need to be answered:

- In what regard is the current legal framework hindering the achievement of this objective?

the existing legal or technical securities, e.g. ways to control data access and usage, insufficient? What kind of legal or technical securities are necessary?

• What kind of incentive or reward needs to be provided to whom? Shall the reward be monetary, an acknowledgment of intellectual contribution or contribution of another kind, or provide rights in technology that is developed based on the data?

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Presentation of partners

Fundacio Institut D'Investigacio Biomedica De Girona Doctor Josep Trueta (IDIBGI)

The Girona Biomedical Research Institute (IDIBGI) aims to promote translational research to improve people's health. Located in Girona area, in Catalonia (Spain), its activity aims to increase knowledge of numerous diseases to improve their diagnosis, treatment and prevention, while also improving people's quality of life.

IDIBGI is dedicated to research in six areas of health, one of which is Medical Imaging. In this regard, the research institute is linked to the Catalan Institute of Diagnostic Imaging (Institut de Diagnòstic per la Imatge – IDI in Catalan), that provides medical imaging services at the Josep Trueta University Hospital and Santa Caterina Hospital in Girona. Both are pioneer centres in the utilization of Magnetic Resonance for the early diagnosis of prostate tumor.

The IDIBGI Medical Imaging Research Group is involved in the ProCAncer-I European project. The group research is focused in using advanced imaging techniques to develop associative or predictive imaging biomarkers that would make it possible to understand the clinical condition and course of disease.

Researcher Dr. Kai (Joan Carles) Vilanova is leading IDIBGI's participation in the project, which consists of collecting clinical and MRI data from prostate cancer, that will be key to train the Artificial Intelligence algorithm. The MRI and clinical data will be uploaded to the eCRF platform developed for the project, to be used for model development and validation. Another important part of IDIBGI participation will be the clinical evaluation of artificial intelligence models, checking the detection of cancer with high accuracy both in the peripheral and transition zone of the prostate.

Biotronics3D Limited (B3D)

Biotronics3D was established in 2004 in London, opened an R&D Centre in Cambridge in 2009, opened a Central European Operations office in Bucharest in 2014, and established its Innovation Centre in Edinburgh during 2017. Biotronics3D recently integrated the OpenRad group with the mission to revolutionise healthcare by delivering an open diagnostic network.

B3D develops and commercialises innovative cloud-based medical image platform (PACS/Advanced Viewer/RIS/Tele-radiology/Patient portal/Referrer Portal) with advanced visualisation, analysis and reporting tools for the diagnostic imaging industry. B3D provides cutting edge software technologies to improve healthcare by better extracting diagnostic data and transforming it into usable information available at the point-of-care.

By applying a novel and innovative technology and business model to an old market, the company achieved fast market growth in the UK and Europe, and is developing Middle East and US markets. The main product, 3Dnet (www.3dnetmedical.com), a zero-footprint cloud-based Medical Imaging solution for the management, transfer, storage, distribution, collaboration, visualisation, analysis and reporting of DICOM images from all modalities, has received CE mark for medical device class IIa on 2010 under EU MDD and completed the transition to EU MDR on 2020. 3Dnet is being used by +50,000 users and managing a few petabytes of medical imaging data, across a cluster of datacentres.

3Dnet not only provides a unique solution based on a Software-as-a-Service model, but it is also a development platform for external innovators to integrate their specific processing tools and products into 3Dnet market place.

B3D team have large expertise in medical imaging systems, cloud and web technologies, computer graphics, scientific visualisation, advanced image processing, development and integration of AI/ML modules, and especially advanced medical visualisation. B3D team have huge experience in translating healthcare users' requirements and clinical workflows into specifications and product functionalities. B3D team have deep knowledge of GDPR and data security and protection. B3D operates under a certified EN ISO 13485:2016 QMS for medical devices and implements the regulatory medical devices' standards through the complete product life cycle.

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News

1st ProCAncer-I Project Dissemination Event in Vienna

The 1st ProCAncer- I Dissemination Event, presenting the vision of the project, took place in Vienna on the 15th of July 2022 as a special session during the ECR 2022. At the presentation and discussion panel participated members both of the ProCAncer-I project and the FUTURE–AI initiative: Manolis Tsiknakis, Nickolas Papanikolaou, Daniele Regge, Luis Marti-Bonmati, Hariet C. Thoeny, Mustafa Nasuh Özmen, Emanuele Neri, Kostas Marias and Ioannis Seimenis.

The session with the title "Building bridges. From radiomics /AI research to clinical practice: The ProCAncer–I vision" was an opportunity for the researchers to engage with different stakeholders as well as the general public since the attendees of the ECR came from all areas of the radiology arena: radiology professionals, radiographers, physicists, medical imaging in general and industry representatives.

The FUTURE-AI initiative at the IEEE BHI-BSN Conference 2022 in Ioannina

The ProCAncer-I together with the other AI4HI funded projects organised a workshop with the title “Developing open, standard-based, interoperable Cancer Imaging Repositories in Europe: Issues, Experiences and Challenges” within the IEEE BHI-BHS Conference in Ioannina (27-30 September 2022)

This workshop focused on presenting the results delivered by these working groups analyzing the existing landscape, solutions and challenges based on a concrete set of clinical use cases related to a number of cancer types (lung, breast, liver, colorectal, prostate, brain, etc).

ProCAncer-I at the National Congress TURKRAD 2022 in Antalya

Our partner Hacettepe University, School of Medicine, Department of Radiology (HACETTEPE) participated at the 43rd Turkish National Radiology Congress (TURKRAD 2022) in Antalya (02-06/11/2022). Prof. Deniz Akata presented ProCAncer–I project, the aim and its expected results. The presentation was followed by a very interesting discussion on various aspects of the project.

ProCAncer-I at the International Cancer Imaging Society Meeting in Boston

Prof Mu Koh from The Royal Marsden Hospital and Dr Nickolas Papanikolaou from Champalimaud Foundation organised a Workshop with the title “Practice-oriented Cancer Imaging AI technology applications for clinical use” at the 21st Annual Teaching course at the International Cancer Imaging Society Meeting in Boston. During the workshop, they focused on explaining questions that the end user should ask the AI developer before choosing and using an AI model.

The ProCAncer-I project featured in the Agència Catalana de Notícies

The ProCAncer-I project was in the Agència Catalana de Notícies in the Girona region. The radiologist who heads the project in Girona, Dr. Kai Vilanova, explains that the ProCAncer-I will allow to define the diagnosis and prognosis of the patient, based on magnetic resonance and clinical data.


Intel·ligència artificial per millorar el tractament del càncer de pròstata

ProCAncer-I at the RSNA 2022 in Chicago

Dr Nickolas Papanikolaou our Scientific Manager, will be present at the 108th Scientific Assembly and Annual meeting with an educational session entitled "Radiology AI Innovation: Academics vs Industry" . This panel discussion will include Dr Mona Flores and will be chaired by Dr Rowland Illing, discussing the role of Academia and Industry in bringing AI innovations in Radiology

more news

Publications

1] Haridimos Kondylakis, , Esther Ciarrocchi, Leonor Cerda-Alberich, , Ioanna Chouvarda, , Lauren A. Fromont, Jose Manuel Garcia-Aznar, Varvara Kalokyri, Alexandra Kosvyra, Dawn Walker, Guang Yang, Emanuele Neri (2022), “Position of the AI for Health Imaging (AI4HI) network on metadata models for imaging biobanks”, European Radiology Experimental 2022 Jul 1;6(1):29. doi: 10.1186/s41747-022-00281-1.

2] Luis Marti-Bonmati, Dow-Mu Koh, Katrine Riklund, Maciej Bobowicz, Yiannis Roussakis, Joan C. Vilanova, Jurgen J. Fütterer, Jordi Rimola, Pedro Mallol, Gloria Ribas, Ana Miguel, Manolis Tsiknakis, Karim Lekadir and Gianna Tsakou (2022), “Considerations for artificial intelligence clinical impact in oncologic imaging: an AI4HI position paper”, https://doi.org/10.1186/s13244-022-01220-9, Online 10/05/2022

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