Newsletter

Summer 2023

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 Value of Health Data - Results from the CPDP Moot Court

Editorial by Theresa Henne and Clara Saillant (UNIVIE)

"Honoured judge,

We stand in front of your Court today to seek justice and clarity on a matter that is of great concern to our society. My company has been alleged of unfittingly rewarding our partners for their contribution to the development of our AI application. In light of the ambiguous wording of the newly adopted European Health Data Space, we strive for legal clarity concerning the question by which means – financial or of other kind - the provision of data for the training and testing of the AI technology should be rewarded."

In the near future, we might witness a court case similar to the one described above, in which a health technology company and a clinical data provider turn to courts to resolve a highly challenging matter. At the core of this fictional court case lies the question of what value we assert to health data in the process of AI innovation, and by which means we incentive the provision of such data.

The awaited framework of the European Health Data Space (EHDS) is expected to provide answers to this question. The latest draft of the EDHS already sets the general direction by outlining that data providers may charge fees for the provision of data that is derived from the cost resulting from the collection, enrichment and provision of the data, including the processing of the request.

Notably in the proposal is the criteria of the compensation. Indeed, only the human labour and technical resources put into the data are taken into account. A calculation based on the value generated by the data and taking into consideration future innovations would result in much higher sums paid to the data provider. Hence according to the narrative of the existing draft, the actual value creation is considered to take place as soon as the data has been handed-over to the data provider, who "reaps" the data's value by employing it for the means of the development of AI technology.

Two questions arise from the current debate:

1) If accepting the "compensation approach" of the current proposal, how exactly shall the fee for collecting, enriching and providing data be determined? Can a data provider also include long-term investments in technical equipment or additional staff in the fee?

2) If the "compensation approach" is challenged, how to shape a governance framework, acknowledging value creation from data providers in order for them to receive a share on such created value?

The proposal of the European Health Data Space is only in drafting stage, therefore many open questions remain. In particular, it is unclear whether the EDHS framework would out rule any alternative data sharing frameworks, so that all sharing of health data in the EU would need to be conducted via the EDHS.

Until clarity is provided by the final legislative text and preceding Court rulings, the question of how to compensate for the arising costs or reward data providers for the valuable contribution in the development of AI technology remains in the void. This issue is also of crucial concern to the ProCAncer-I project, which is currently discussing an internal policy on the matter. In order to reach out to the community of lawyers and health-professionals, who are facing similar challenges, UNIVIE conducted a workshop at the Computer, Privacy and Data Protection Conference (CPDP) which took place on 25th of May in Brussels.

In the workshop, the participants were witnesses to the fictional court case outlined above and could engage with experts from the Consortium and beyond in order find possible solutions.In a nutshell, our fictional court case's judge ruled that it needs to be clarified between the parties whether the fee paid is considered a compensation for the costs or a share of profit. If the first is the case, the number of patients and the costs incurred by providing the data must be taken into consideration in order to determine the compensation. If the latter is the case, the judge refers the case to the CJEU for preliminary ruling on how to share the profits.

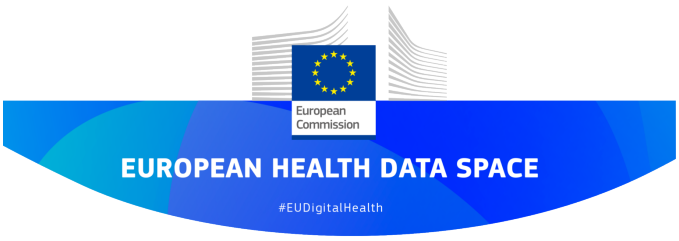
We thank:

María José Alarte Aceñero, *Head of Legal at Quibim for her marvellous performance as the defendant to the case, namely a Spanish AI technology company*

Aline Blankertz *from Wikimedia Germany for representing the interest of the patients in front of the fictional court*

Daniele Regge, *Associate Professor in Radiology, for his stunning performance as the claimant to the case, namely ContraCancer Unit of Turin Hospital and*

Lorraine Maisnier-Boché *from McDermott Will & Emery for playing the judge to our Court case, who had undoubtedly the most difficult task of deciding on the matter*



Clinical Challenge: Can radical prostatectomy patients help promote a biological validation of radiomics signatures?

By Ana Castro Verde, Ph.D. student and research technician at Computational Clinical Imaging Group, Champalimaud Foundation

Prostate cancer patients with less aggressive tumors would benefit from being in active surveillance instead of undergoing treatment with potential complications. Magnetic resonance imaging (MRI) offers high sensitivity to diagnose prostate tumors but is limited by variability in the radiologists' interpretations. With the advent of Artificial Intelligence (AI) in medical imaging it is possible to improve patient stratification and to guide the best treatment options. A sub-field of AI, the so-called radiomics, treats images as mineable data by extracting features that are not observable through the human eye. For a clinical implementation of radiomics, it is missing a causal relationship between radiomics features and clinical outcomes. To promote the usage of AI models in clinical practice, one of the main challenges in the field is to perform a biological validation of the radiomics features using the biopsy ground truth.

Dr. Nikolas Papanikolaou, Principal Investigator in Oncologic Imaging at the Fundação Champalimaud, is leading the fourth clinical ProCAncer-I use case (UC4) on the Radiologic – Histopathologic correlation to provide biology-based validation of AI models. Patients undergoing radical prostatectomy offer an opportunity to correlate radiomics features with the ground truth from the prostate specimen. Prostate segmentations are automatically generated using Deep Learning algorithms developed within the Computational Clinical Imaging Group and validated by a radiologist from the Radiology Department at our institution. These segmentations are used for the creation of patient-specific 3D-printed molds developed in collaboration with the Hardware and Software Platform (Figure 1). The patient-specific molds allow the histopathology technicians to cut the prostate specimen with the same spacing as the MRI slices.

Figure 1: MRI-based patient-specific 3D-printed prostate molds

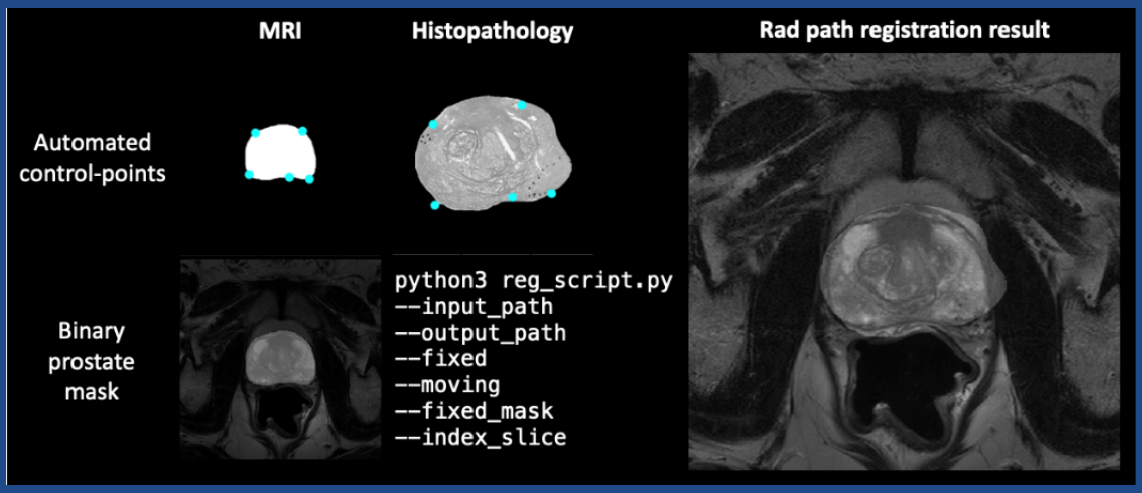


Figure 2: Rad-path registration result for corresponding images, guided by automated control points and binary prostate mask

Afterwards, Python scripts are developed for stitching of prostate tissue quadrants to reconstruct a pseudo-whole-mount histopathology prostate section and for rad-path registration by registering histopathology sections to the corresponding MRI slides (Figure 2). These algorithms, guided by the usage of patient-specific molds, have shown promising results to promote a direct correspondence between both imaging modalities. Extracted radiomics features will be correlated with the biological ground truth. One potential application of this work is the detection of invisible lesions in MRI, only observable through the analysis of biological tissue.

The next steps include the prospective acquisition of more than 80 prostatectomy patients to validate our algorithms and to eventually join efforts with other ProCAncer-I clinical partners - La Fe University and Polytechnic Hospital in Spain and Istituto di Candiolo - Fondazione del Piemonte per l'Oncologia in Italy - to increase the sample size. In the close future, we expect to be able to prevent unnecessary surgeries by using solely imaging characteristics to promote early cancer detection.

Enabling AI Models Traceability through ProCAncer-I AI Model Passport

By Prof Kostas Marias Hellenic Mediterranean University, Head Computational BioMedicine Lab - FORTH

Artificial intelligence (AI) has brought great economic and social prospects to human society with a great impact on several areas. Specifically, in the health domain, recent advances in AI have proven to match or even surpass humans in several tasks, e.g., radiological tasks. However, to realize the full potential of AI in medical applications, one should take into consideration the potential risks and ethical implications of health AI solutions. Stakeholders have pinpointed the trustworthiness issue of such systems, as these are perceived as black boxes, which are hard to fathom and explain.

For achieving the vision of Trustworthy AI a set of key requirements should be met. One of those requirements is transparency, a complex construct that according to the High-Level Expert Group on AI consists of three components, i.e., traceability, explainability, and open communication about the limitations of the AI system. In relation to the ProCAncer-I project, our initial emphasis was on traceability, which refers to the mandate to document the whole development process and to track the functioning of an AI model or an AI-based system used to support further analysis and interpretation. Since the variability of AI is high, this documentation should be complete and detailed. More specifically, the data sets, the processes, the reference clinical gold standards, and any human-made decision that takes part in an AI system should be documented to the best possible standard in order to achieve the realization of traceability. Both the scientific community and the industry have already recognized the necessity of a data model and the relevant tools for capturing the pertinent information. However, existing approaches focus only on some of the steps of the AI model development and usage ignoring significant parts of the whole process.

Within the ProCAncer-I project we introduce for the first time the notion of the AI passport for tracking and documenting all steps involved in the AI model training and usage starting from data collection, data curation, training data preparation, model training, and validation as well as model monitoring in production.

The concept of the AI model passport enables end-to-end traceability of the whole AI lifecycle. This involves documenting the entire development process of an AI model/system, including the data utilized during training and validation, the actors involved, and the processing and fine-tuning procedures implemented. This approach is particularly critical in high-stakes sectors such as healthcare, where delivering a traceable AI solution is an essential prerequisite. By ensuring complete traceability, the AI solution can be reliably integrated into clinical practice, making it a vital and safe solution.

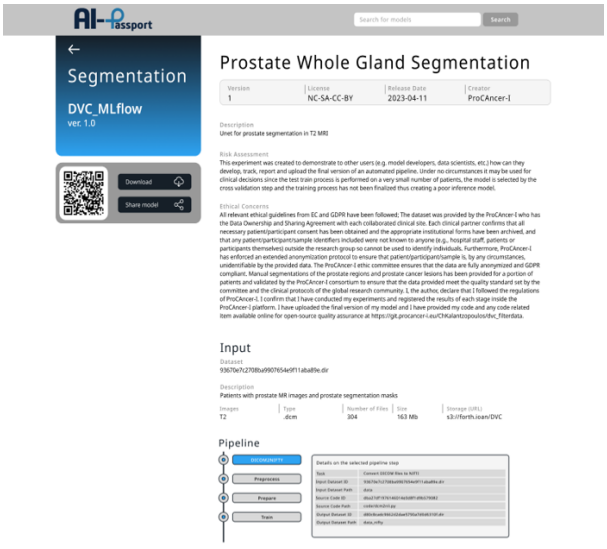


Figure 3: Example AI-Passport for a Segmentation AI model

How can the results of the ProCAncer-I project help radiologists?

Interview with Dr. Kai Vilanova, Director MRI Clínica Girona, Coordinator Radiology, Faculty of Medicine, University of Girona. Director School of MRI-ESMRMB (IDIBGI)

What are the problems that professionals encounter today in diagnosing, treating and monitoring prostate cancer, does this project want to solve?

Prostate cancer is currently diagnosed with an MRI scan. MRI consists of the acquisition of different images that provide morphological and physiological information of the prostate. The MRI scan provides about 500-1000 images that the radiologist has to analyze to provide a final report of the degree of suspicion of having prostate cancer. This analysis of each scan involves identifying many parameters manually. The possibility of having software that allows all the necessary parameters in an MRI scan to be identified and evaluated automatically would be a great advantage for the radiologist's work. This is precisely one of the main objectives of the project; to develop intelligent analysis software to aid in the diagnosis of prostate cancer.

What advantages will this tool have for clinical practice?

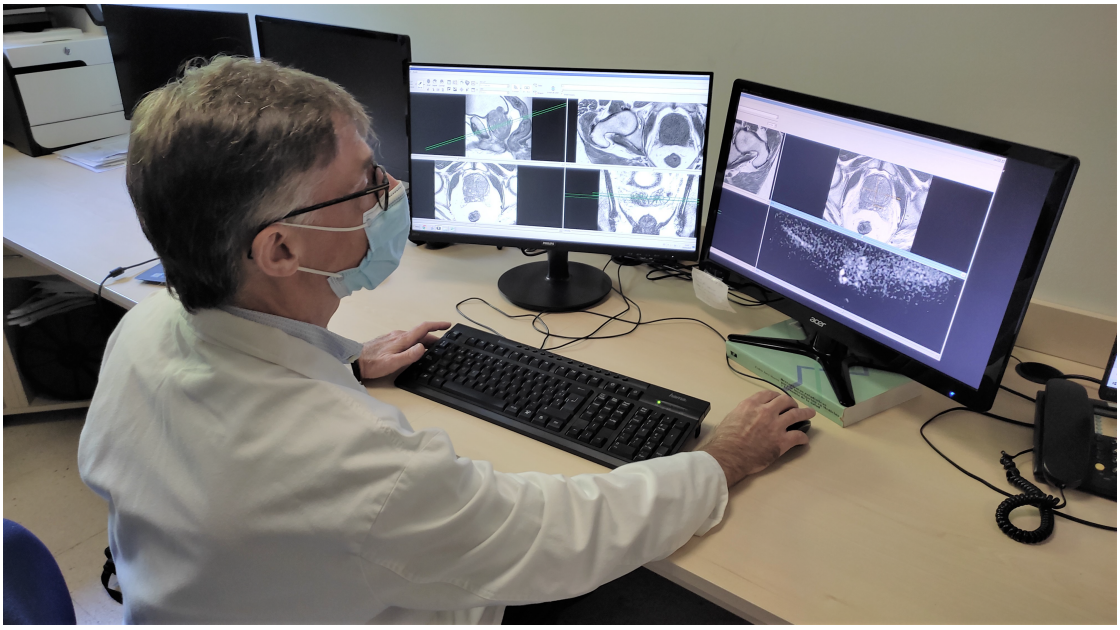
The possibility of having an intelligent prostate MRI software means a great saving in analysis time, but also the most important is to improve the diagnostic accuracy to better detect cancer. These tools can detect and classify suspicious prostate cancer lesions, especially useful in cases where lesions are very small or difficult to detect with the naked eye. The artificial intelligence software can automatically segment the prostate, which saves time and improves accuracy by delineating the contours of the prostate gland. It also allows automatic report generation, which helps standardize and streamline the reporting process for the radiologist. Artificial intelligence can analyze the MRI results and generate a report containing relevant findings and recommendations for the patient.

The technological tools developed by the project will improve the results of prostate MRI analysis performed by radiologists at all stages of cancer; from diagnosis, staging, prognosis, treatment and avoiding cancer recurrence.

In addition, these technological tools that the ProCAncer-I project has developed, give us healthcare personnel the opportunity to free up part of our working day, dedicated to healthcare visits, and use it to continue with research to improve the health of our patients.

What are the challenges, and how will you overcome them?

The main difficulties in the development of these tools are at different levels. Firstly, the difficulty in recruiting the large amount of MRI data and clinical data from



Dr. Kai Vilanova

more than 15.000 patients and also the need to anonymize all this data. On the other hand, one of the main challenges of these intelligent software programs is the difficulty in being able to integrate into all the computer systems of the different hospitals. These tools may work when they are developed in the laboratory, but in real clinical practice they may not work properly. Therefore, one of the difficulties is to be able to validate these intelligent software programs for their real utility in any hospital.

Although their adaptation and operation involves some difficulty, the fact of incorporating radiologists like us into the international consortium of ProCAncer_I also allow us to include our perspective of how the hospital works and take it into account from the very beginning of the design of the tool.

In short, we are sure that the advantages of this new system will make it worthwhile to take this next step of integration in the future, so that the public can benefit from the results of the project.

Presentation of the European Federation for Cancer Images Introducing EUCAIM: A Pan-European Initiative

by Luis Bonmati, Scientific Coordinator of EUCAIM project

The goal of EUropean Federation for CAncer IMages (EUCAIM) is to build a pan-European digital federated infrastructure of cancer-related radiological and nuclear medicine images and other related digital information, which will be used to develop Artificial Intelligence (AI) tools for Precision Medicine. Our mission is to facilitate seamless access to de-identified, high-quality real-world data, and to foster collaboration among clinicians, researchers and innovators.

To allow this, EUCAIM will provide a comprehensive dashboard for data discovery, federated search, metadata harvesting, annotation and distributed processing, including federated and privacy-preserving learning. EUCAIM will also build a central hub hosting the Atlas of Cancer Images as part of its infrastructure, which will be fully interoperable with the other European Health Data Space components while preserving the data sovereignty of providers.

EUCAIM will also shape the legal grounds for health data sharing on a pan-European scale, adapting to the particularities of different countries in the management of clinical data. To do so, EUCAIM will implement a federation of providers compliant with this legal ground, defining common data models, ontologies, quality standards, FAIR principles, and de-identification procedures. As a European transborder health data repository, EUCAIM is aligned with the European Infrastructures for the secondary use of health data that will be promoted by the future European Health Data Space regulation.

EUCAIM targets clinicians, researchers, and innovators, providing the means to build reproducible clinical decision-making systems supporting diagnosis, treatment, and predictive medicine. We aspire to become the leading European hub for cancer research communities by bringing together oncological data and AI innovation. Through unifying fragmented datasets into an extensive Atlas of Cancer Images and ensuring data sovereignty and ethical standards, EUCAIM will unlock the immense potential of imaging and big data in oncology, paving the way for a future where personalized and effective care is accessible to every patient.

EUCAIM as a mean for sustainability for ProCAncer-I results

Thanks to EUCAIM, datasets from other EU-funded projects, such as ProCAncer-I, that are intended for additional research will find a sustainable home within EUCAIM's central hub collections. This integration guarantees not only the accessibility and availability of these datasets but also their long-term sustainability. Significantly, this alleviates the consortium partners from incurring additional costs for maintaining and managing the collections after the end of an EU-funded project.

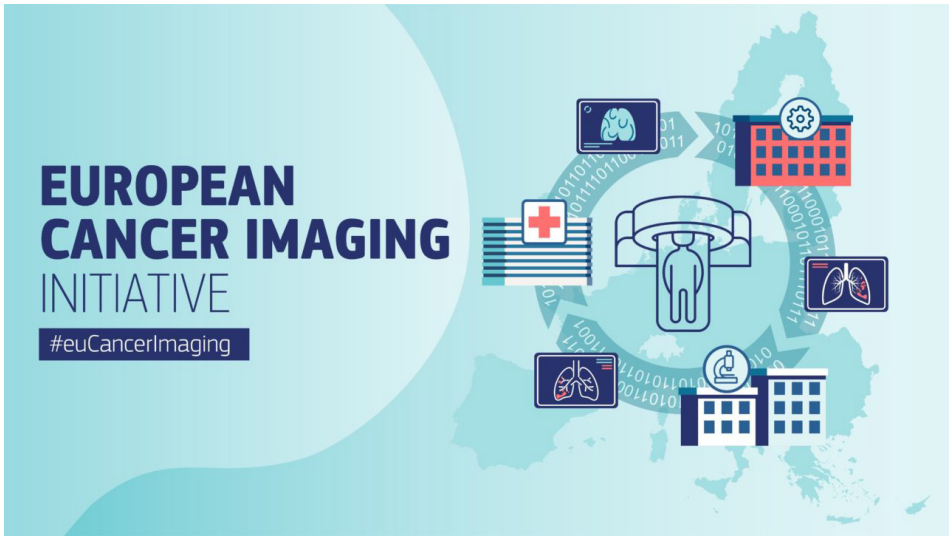
Pilot deployment, sustainability and an invitation to participate

This 4-year initiative started on January 1st 2023, co-funded by the European Union under the Digital

Europe programme, DIGITAL-2022-CLOUD-AI-02-CANCER-IMAGE "Federated European infrastructure for cancer images data".

By the end of 2024, a pilot infrastructure with prototype federated learning will be made available, laying the groundwork for federation of new cancer image databases from additional sites and countries. The EUCAIM project will also launch an open call for new beneficiaries to join the consortium, who will receive funding under the same co-funding conditions as consortium partners. This open call will pursue: i) the onboarding of new data providers, increasing the geographic dimensions, data modalities or cancer targets; and ii) the uptake of new trustworthy AI algorithms trained on the repository's data. The ultimate goal is to target 30 distributed data providers in 15 countries by 2026.

We invite clinicians, researchers, innovators, and stakeholders to join us in this endeavor. Your expertise and contribution can help in making the EUCAIM project a lighthouse for change, ultimately contributing to saving lives and improving the quality of healthcare across Europe.



Presentation of partners

ADVANTIS Medical Imaging

Established in 2016, Advantis Medical Imaging makes advanced medical imaging more accessible, user-friendly and data-driven by merging it with cloud technology. By providing AI-driven, reliable and automated MRI software solutions, Advantis is on a mission to alleviate the growing workload of radiology departments. The company has introduced an FDA cleared medical imaging software suite for the analysis of brain and prostate MRIs, Advantis Platform.

Advantis' team is composed of experienced researchers, software engineers, quality professionals, business and marketing specialists and medical imaging experts. In ProCAncer-I Advantis leads the tasks related to 'Sharing and Curation Tools' and 'Exploitation and Business Planning'. The company also participates in tasks related to AI model development, regulatory compliance strategy and further sustainability of the project. The team will continue striving for excellence for the ProCAncer-I Project in all areas.

ADVANTIS
MEDICAL IMAGING

National Cancer Institute (NCIV)

National Cancer Institute is the only specialized oncology institution in Lithuania. The Institute acts as the clinical cancer center, certified and accredited by the Organization of European Cancer Institutes.

- In order to achieve our strategic objectives, we cooperate with colleagues both in Lithuania and in the European research area. The diverse international level researches, related to nano-technologies, molecular biology, genetics and the most advanced immunotherapy are performed in the National Cancer Institute.
- We have a multidimensional clinic, the foundations of which are divisions of various cancer localizations - breast, lung, gastrointestinal, gynecological and urological, head and neck divisions.

NCI has a prostate cancer diagnostic and treatment competence center, certified by the European Council of Urologists for the sixth year - the only one of its kind in the Baltic States. Urological centers, where prostate cancer is diagnosed and treated using the most advanced and latest methods and possibilities, are accredited by the European Council of Urologists. A prerequisite is that such a center combines clinical work with research. And when it comes to prostate cancer diagnosis, accurate radiological imaging tests and other necessary invasive tests allow for personalized prostate cancer treatment for our patients.

NCI is involved in ProCAncer-I European Horizon 2020 project, dedicated to artificial intelligence (AI) tools that facilitate the diagnosis of prostate cancer. Dr. Jurgita Ušinskienė is leading NCI participation in the project, together with radiologists dr. Rūta Briedienė, Audrius Untanas, radiation oncologist Kristina Slidevska, urologist dr. Albertas Ulys. The NCI input consists of collecting prostate cancer cases, clinical and MRI data to train and validate AI models. The MRI and clinical data will be uploaded to the icloud platform developed for the project. Another important NCI task is participation in clinical evaluation of AI models and leading work package of prediction of treatment response in case of radiation therapy. Thanks to the ProCAncer-I project, we cooperate and share experience with European prostate cancer reference centers and professionals, also acquire necessary tools for prostate cancer MRI diagnosis and biopsy.

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NEWS

Our 5th Consortium Meeting in Turin

The 5th ProCAncer-I Consortium Meeting took place on the 7th and 8th of November, 2022 at ILO Campus, in Turin. The meeting was hybrid and more than 65 people attended the meeting. This was the first physical meeting where almost all partners were present, and we were glad to get to know each other. During the project, the progress and various issues for the implementation of the project were discussed.

2nd ProCAncer-I Project Dissemination Event in Lisbon

We will be part of the "AI and Machine Learning in Cancer Imaging 3.0 – Enhancing Healthcare through AI" event on 30th June & 1st July 2023 in Lisbon, Portugal. The event is organised jointly by the Champalimaud Foundation and the International Cancer Imaging Society. It aims to promote the better understanding and application of AI and machine learning in cancer imaging, and provide a multidisciplinary forum for radiologists, technicians, radiographers, scientists and industry partners to discuss and interact.

A special Session will take place, presenting and discussing on the ProCAncer-I project with the title: "The best practises on machine learning for multicentric approaches".

ProCAncer-I at the European Congress of Radiology 2023

The European Congress of Radiology 2023 took place in Vienna (01-05/03/2023). Dr. Papanikolaou presented some early results of ProCAncer-I project regarding "AI modelling strategies with multi-centric data". Also, the Hacettepe University Hospital gave three presentations concerning the developments on monitoring prostate cancer patients, in which ProCAncer-I was also involved, by Ö. Önder, Y. Yaraşır, V. Gürler, M. Ayva, M. S. Yazici, B. Akdogan, M. Karçaaltincaba, M. N. Özmen and D. Akata.

ProCAncer – I and the EUCAIM project featured in the "El País Medicina"

An article from our partner, Gloria Ribas, Clinical Data Scientist del Grupo de Investigación Biomédica en Imagen (Instituto de Investigación Sanitaria La Fe) was published on the 25th of February 2023 in the special Medical Edition of the El País newspaper.

The article deals with major advances in medicine, made possible by a combination of technological innovation and research developments.

ProCAncer-I at the International Scientific Conference in Vilnius

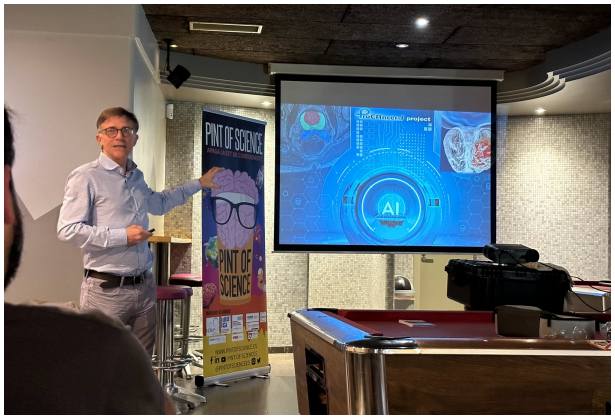
On the 15th and 16th of May, 2023, the National Cancer Institute (NVI) held an International Scientific Practical Conference titled "Local prostate cancer diagnosis". The event was organized by the Department of Diagnostic and Interventional Radiology of NVI with guest lecturer prof. Joan C. Vilanova from the Girona Clinic, Lithuanian Urological Society and European Council of Urology certified Prostate Cancer Treatment Competence Center - NVI Oncourology Department.

Moot Court Workshop focused on "The Value of Health Data"

The Department of Innovation and Digitalization in Law of the Universität Wien organized the workshop. In this fictional court case, participants engaged in stimulating discussions regarding how data providers should be appropriately rewarded for their significant contributions to the development of medical AI applications. The workshop was facilitated by Theresa Henne and Clara Saillant, with great contribution of María José Alarte, Daniele Regge, Aline Blankertz and Lorraine Maisnier - Boché.

Pint of Science brings IDIBGI's biomedical research to Girona's bars

On the 22th of May, the SBAR-JO bar hosted the lecture: "Artificial intelligence and medicine: Where are we and where are we going? Prostate cancer, MRI and artificial intelligence". Dr. Kai Vilanova, spoke about the European project ProCAncer-I, which is creating an artificial intelligence tool to improve the prostate cancer pathway. Can artificial intelligence (AI) replace doctors? One of the main fields of introduction of AI in medicine is radiology, due to the large amounts of information that must be processed and the possibility of automating the diagnosis of diseases.



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