Project title: Readiness to call the Open Challenges

Grant Agreement: 952172

Call identifier: H2020-SC1-FA-DTS-2019-1

Topic: DT-TDS-05-2020 AI for Health Imaging

D8.1 Readiness to call the Open Challenges

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Work Package: WP8

Due date: Month 34

Actual delivery date: 30/06/2023

Type: Other

Dissemination level: PB

Due Date: 30/06/2023 M34

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Abbreviations

AI	Artificial Intelligence
CEP(s)	Clinical Endpoint (s)
CSV	Comma Separated Values
D	Deliverable
eCRF	electronic Case Report Forms
FAIR	Findable, accessible, interoperable, and reusable
GB	Gigabyte
GDPR	Regulation (EU) no. 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regards to the processing of personal data and on the free movement of such data (knows as the “General Data Protection Regulation”).
GPU	Graphics processing unit
JSON	JavaScript Object Notation
MS	Milestone
NIfTI	Neuroimaging Informatics Technology Initiative
PR	Public relations
T	Task
WP	Work package

Annexes

Documents used to upload information to Grand-Challenge.org:

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Disclaimer

The opinions stated in this report reflect the opinions of the authors and not the opinion of the European Commission.

1. Introduction

The D8.1 is undertaken as part of WP8 Internal & external validation of ChAImeleon repository framed under task T8.4 Organisation of the ChAImeleon Open Challenges to the AI Community for cancer management. This deliverable defines the overall strategy and procedure for the contractual, administrative, communication, legal and technical activities for the organisation and management of the Open Challenges.

The deliverable is divided in the following main sections: Objectives and description, previous steps for the organisation of the Open Challenges, selection of clinical questions for the Open Challenges, definition of the technical workflow, legal considerations: terms and conditions, communication plan: announcement, registration and start of the Open Challenges and conclusions and references.

2. Objectives and description

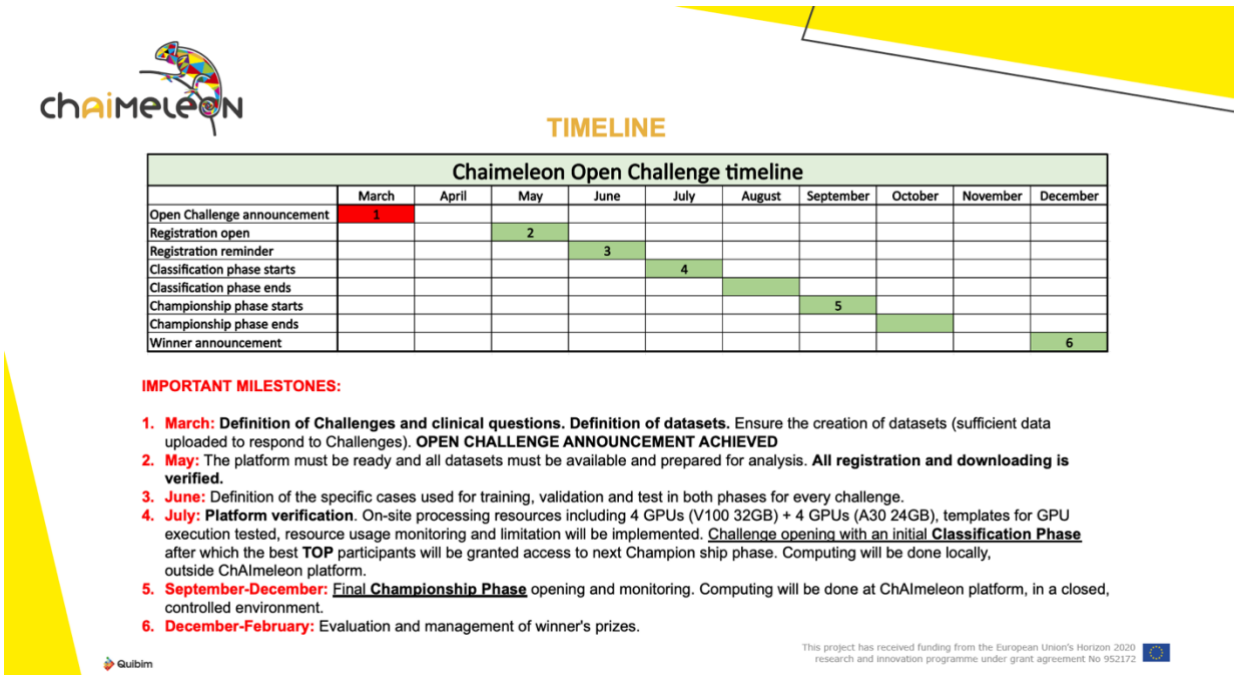
The usability and performance of the ChAImeleon repository as a tool fostering AI experimentation for cancer management will be validated, including a validation subphase by other world-class European AI developers, articulated via the organisation of the Open Challenges to the AI Community for a period of 6 months. The Challenges will be awarded to the higher evaluated tools for their relevance on addressing a specified clinical endpoint of high relevance in the management of each of our five targeted types of cancers (prostate, lung, breast, colon and rectum). The winners of the Challenges will be awarded with a total prize pool of 20k€ per challenge, split among the winners (allowance of 100k€ under Coordinator´s budget) and with the inclusion of their AI-based solutions for Clinical Validation in WP9 thus accelerating their path to market at no cost to them. The participants in the Challenge will need to commit providing ChAImeleon with feedback on their user experience and provide metrics on the performance of their AI-based solutions before and after their experimentation with ChAImeleon. This external validation based on the Open Challenge builds on the completed internal validation of WP8 (D8.2).

The present deliverable contains the detailed description of the Challenges, its two phases, Classification and Championship phases, the types of cancer, clinical endpoints and questions to be addressed in close collaboration with clinical partners, the definition and description of the open, transparent and fair process on the grandchallenges.org platform, the necessary legal considerations for both phases, elaboration of legal documents, terms & conditions, detailed description of the technical workflow and global communication and promotion plan.

3. Previous steps for the organisation of the Open Challenges

3.1 Open Challenges specific meetings and conclusions

The design and definition of the Open Challenges was agreed and discussed by all WP8 participants together with the WP5 clinical team and the project coordinators, in specific meetings aimed only at the organisation of the Open Challenge. Quibim organised these thematic meetings whose minutes, recordings and presentations are stored in the ChAImeleon project document repository. Quibim proposed to divide the organisation of the Open Challenges into several sections to discuss the clinical questions to be solved by the challenge that were most interesting for clinicians and for which we had quality medical images and other clinical variables of interest, the technical workflow, the legal framework and data protection, as well as the communication plan. The first discussions focused on the technical procedure of the challenge and its host platform, as it had to be based on the resources available at ChAImeleon and also on an objective, fair and transparent selection of the participants selected as the best. We established a very strict timeline with internal dates and milestones to be able to develop all the sub-activities of the challenge and to execute them in a timely manner:



TIMELINE

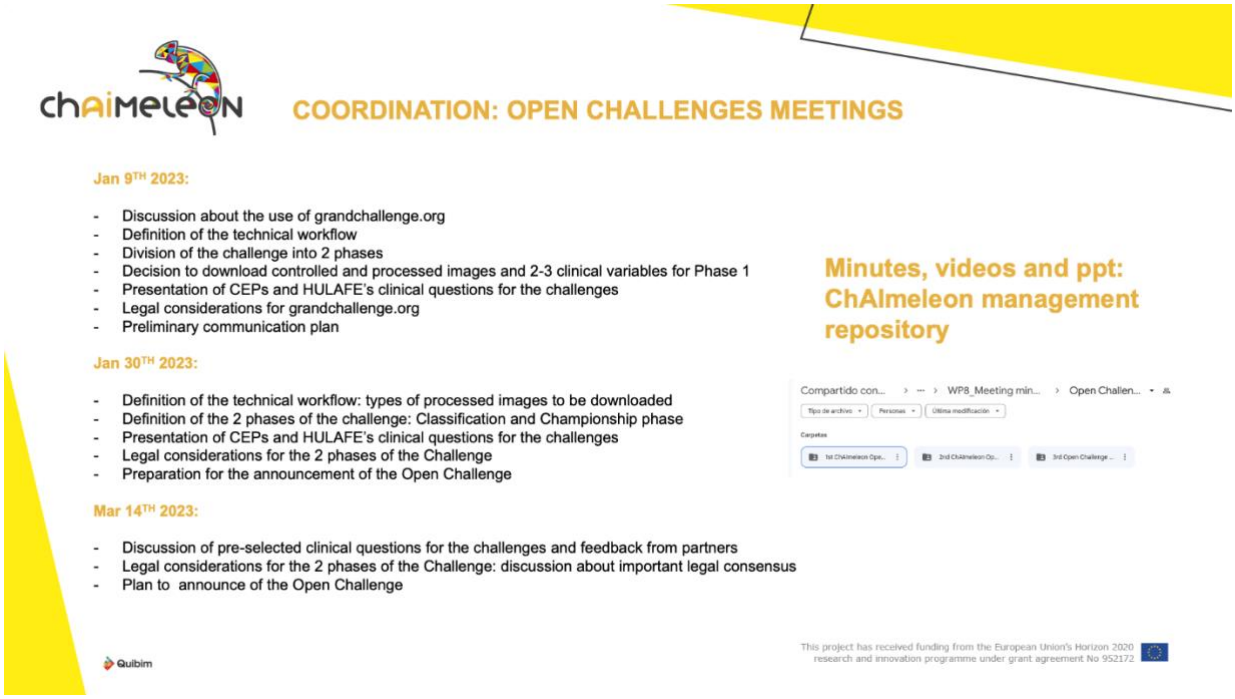
Chaimeleon Open Challenge timeline										
	March	April	May	June	July	August	September	October	November	December
Open Challenge announcement	1									
Registration open			2							
Registration reminder				3						
Classification phase starts					4					
Classification phase ends										
Championship phase starts							5			
Championship phase ends										
Winner announcement										6

IMPORTANT MILESTONES:

1. **March: Definition of Challenges and clinical questions. Definition of datasets.** Ensure the creation of datasets (sufficient data uploaded to respond to Challenges). **OPEN CHALLENGE ANNOUNCEMENT ACHIEVED**
2. **May:** The platform must be ready and all datasets must be available and prepared for analysis. **All registration and downloading is verified.**
3. **June:** Definition of the specific cases used for training, validation and test in both phases for every challenge.
4. **July: Platform verification**. On-site processing resources including 4 GPUs (V100 32GB) + 4 GPUs (A30 24GB), templates for GPU execution tested, resource usage monitoring and limitation will be implemented. Challenge opening with an initial **Classification Phase** after which the best **TOP** participants will be granted access to next Champion ship phase. Computing will be done locally, outside ChAImeleon platform.
5. **September-December:** Final **Championship Phase** opening and monitoring. Computing will be done at ChAImeleon platform, in a closed, controlled environment.
6. **December-February:** Evaluation and management of winner's prizes.

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 952172

The following describes the specific Open Challenge meetings and the topics that were discussed:



At these meetings, essential clinical, technical, legal and communication procedures for the development and organisation of the challenge were finalised among all partners. The selected option was to use biomedical imaging challenge website (grand-challenge.org) to publish the ChAImeleon Open Challenges to increase its visibility and to ease the management of the challenge (information publication, participants, leaderboard, etc). Grand-challenge.org allows to include in a single Challenge different tasks (one per cancer type) and phases, with different leaderboards. Some challenge's examples were followed, the PI-CAI Challenge, Multimodality Abdominal Multi-Organ Segmentation Challenge 2022 and auto-PET. There were some points to take into consideration when designing the Challenge: limited resources in the ChAImeleon platform not to be able to have more than tenths of users training models at the same time and we cannot have unlimited number of users accessing the platform to train AI models, due to (1) limited resources (8 GPUs) and (2) overhead accessing the data. Within the project it has been decided to allow to download data from the ChAImeleon environment and to divide the challenge in two phases as explained below: Classification and Championship phase. In addition, consensus was reached at these meetings on the legal terms and conditions of these challenges, which are explained in the corresponding section, as well as on the communication plan. Bilateral meetings with the technical (HULAFE, Medexprim, UPV), clinical (HULAFE, CERF) and legal partners of ChAImeleon (UV) have also been held to agree on more concrete details of the organisation and development of the Challenge which is explained in the next sections of this document.

4. Selection of clinical questions for the Open Challenges

The selection of clinical questions for the ChAImeleon Open Challenges was a collaborative effort involving the members of the consortium, specifically drawing from the clinical endpoints (CEPs) identified in the HULAFE proposal and input from the clinical leaders in Work Package 5. To streamline the process, Quibim compiled a compendium of these clinical questions, taking into account the availability of clinical variables collected in the electronic Case Report Forms (eCRFs). The selection process also involved a thorough technical review to assess the feasibility of addressing these questions, considering preliminary evidence and demonstrations of response. These questions were also discussed and assessed at the 3rd Open Challenge meeting on March 14, 2023, and presented at the Consortium meeting M31 ChAImeleon (Malaga, Spain) on April 11-12, 2023.

Therefore, the following clinical questions have been chosen for the Open Challenges:

4.1 PROSTATE

The challenge aims to differentiate between low-grade and high-grade prostate cancers using MRI imaging features. The goal is to avoid unnecessary aggressive procedures in low-grade patients while providing the most advanced therapy for high-grade cases. The key clinical variable collected in the eCRF for this challenge is the Gleason score, specifically predicting clinically significant prostate cancer, distinguishing between ISUP 1-2 (Gleason 3+4=7 and below) and ISUP 3-5 (Gleason 4+3=7 and above). Additionally, since this challenge will be open for the “Classification phase”, the following clinical variables will also be required:

- Patient age
- Malignant Neoplasm Histotype
- Total prostate specific antigen level (PSA) at diagnosis
- Prostate Imaging-Reporting and Data System
- Neural invasion
- Vascular invasion
- Lymphatic invasion

4.2 LUNG

In the lung cancer challenge, the objective is to assess baseline CT imaging and radiomics features in a diverse range of non-small cell lung cancer (NSCLC) patients undergoing immunotherapy, with the aim of predicting progression-free survival (PFS). The mandatory items captured in the eCRF for this challenge include the date of the baseline CT (considered the time of diagnosis) and the date of progression or last follow-up. In addition, since this challenge will be open for the “Classification phase”, the following clinical variables will also be required:

- Gender
- Age
- Smoking status

4.3 COLON

For colon cancer, the challenge focuses on using baseline CT imaging features to predict the progression-free survival (PFS). Similar to the lung challenge, the mandatory items in the eCRF for this challenge include the date of the baseline CT (considered the time of diagnosis) and the date of progression or last follow-up.

4.4 RECTAL

The rectal cancer challenge revolves around identifying imaging features on baseline MRI scans that can predict treatment response. The mandatory item in the eCRF for this challenge is the Tumor Regression Rate (TGR).

4.5 BREAST

In the case of breast cancer, the challenge seeks to determine which combination of multimodality imaging features (signature) can allow for the prediction of breast cancer histological subtype. The histological subtype is a mandatory field collected in the eCRF for this challenge.

The selection of these clinical questions ensures a diverse range of challenges related to different cancer types and specific clinical objectives. This comprehensive approach covers various stages of the patient journey, including the diagnostic stage for the prostate challenge, treatment response for the rectal challenge, progression evaluation for the lung and colon challenges, and histological subtype prediction for the breast challenge.

In addition, the "D5.2 Interim dataset provision by project"[1] report provides a detailed listing of all the collected clinical variables for each cancer type, presenting a comprehensive overview of the clinical data captured in the eCRF. By addressing these questions through the Open Challenges, the ChAImeleon project aims to advance cancer management and enhance patient outcomes by harnessing the power of artificial intelligence and multimodality imaging analysis.

5. Definition of the technical workflow

The scope of this section is to outline the technical methodology followed for the execution of the Open Challenges.

The consortium partners in charge of the task, after discussion and approval with the whole consortium, have selected to use Grand Challenge[2] platform. This is a comprehensive platform for the execution of challenges based in biomedical imaging. It provides a range of tools and resources that enable researchers, data scientists, and clinicians to collaborate, develop, and validate their AI models. By leveraging this platform, the ChAImeleon project can increase the visibility and publicity of the challenge, allowing it to reach a wider audience and facilitating its management.

The Grand Challenge platform offers several benefits, including the management of participants, the ability to generate real-time leaderboards of participants' performance, which keeps them motivated and engaged throughout the challenge or the access to a direct communication channel with the participants to solve any issue.

The idea is that participants use the ChAImeleon platform to access the data and train their models for the final validation of the platform itself and the tools developed in the project (e.g., image harmonization tools). However, only a limited number of participants can be hosted in the ChAImeleon platform to train their models. This is because of both limited resources, with only 8 GPUs available, and the overhead of accessing the data. This will make it difficult to provide a smooth user experience to hundreds of expected participants. Therefore, to ensure fairness and maintain the open nature of the challenge, the consortium partners have decided to split the challenge into two phases.

1. **Classification phase**: any interested participant can join this phase executed in the grand-challenge.org platform. Participants will be able to download a highly controlled dataset for two types of cancer (prostate and lung), with post-processed (i.e., harmonized) images associated with very specific clinical variables.

Imaging data will be shared in NIfTI format while clinical information will be provided in JSON format. Participants will use their own resources to train the models, and the top 40 participants on the leaderboard will be selected to move on to the Championship phase.

2. **Championship phase**: this phase will be conducted in the ChAImeleon platform, and participants who have passed the qualifying round cut-off point will be granted access to the whole data (imaging and clinical) of each cancer type (prostate, lung, breast, colon and rectum), together with the tools developed and integrated in the ChAImeleon platform. Each participant can train AI models for any of the five different challenges (one per cancer type) under the same conditions, including the same data, resources, and computation time.

By splitting the challenge into two phases, the consortium partners can ensure that a large number of participants can join the challenge while maintaining fairness and a level playing field in the championship phase, where all participants will have access to the same resources and data.

5.1 Participants registration

Participants will first need to register on the Grand Challenge website. This registration will allow them to access the challenge data and leaderboard. During registration, they will need to provide basic information such as their name, email address, and affiliation.

Once registered on grand-challenge.org, participants will be redirected to the ChAImeleon platform to formalize their registration and provide additional information through a questionnaire. This questionnaire will collect metrics and insights on the participants, including their institution, background, experience on AI models training, and other relevant variables. This information will help the organizers to better understand the participants' skills and experience and to improve the organisation of the challenge.

After completing the questionnaire, participants will be assigned an "External developer" role for their participation in the challenge. This role will grant them access to the ChAImeleon platform and the challenge data, as well as the ability to upload their AI models for evaluation if they continue in the championship phase.

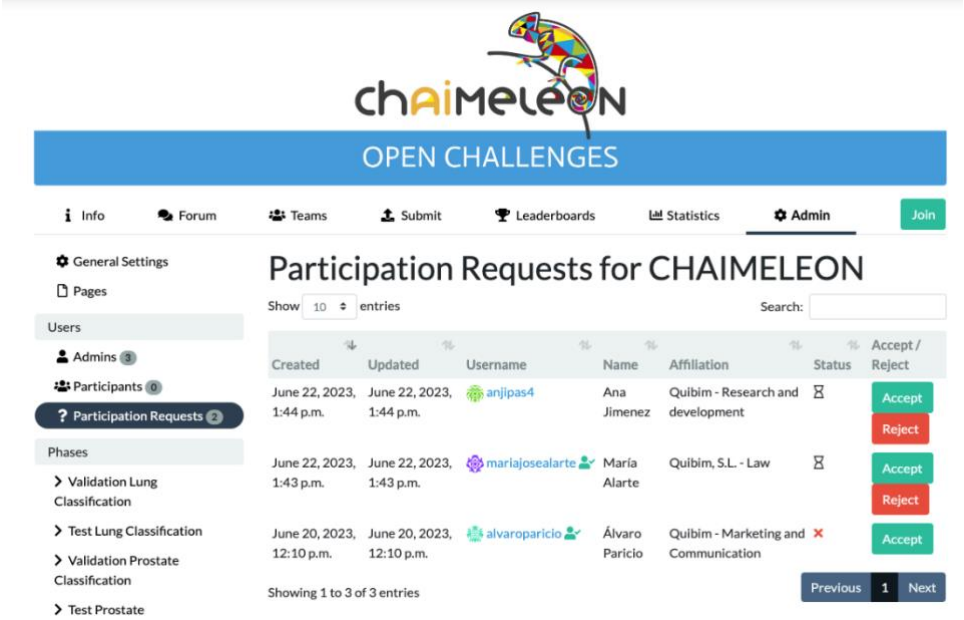
It's worth noting that all participants will be required to agree to the challenge terms and conditions during registration, which will include rules on data privacy and intellectual property rights.

5.2 Participants verification and approval

One of the requirements to participate in the challenges, clearly explained in the page https://chaimeleon.grand-challenge.org/, is that participants must download the Terms and Conditions, sign them and return them by email to chaimeleon@quibim.com. This is a security measure to confirm that the entries are real and valid. We will check that the institutions are valid and existing, that the participants include name and surname or that there are no bad words in the email, name of the participants or group.

Also, as stated in the Terms and Conditions, the participants have to be verified on the platform grand-challenge.org, so we'll also check that on the "Participation Requests" page, that only us as administrators can access. We'll only accept verified participants whose email with the Terms and Conditions signed we have received.

Participants approval page:



5.3 Challenge execution and evaluation

Classification phase

Figure 1 summarizes the steps for the execution of the classification phase.

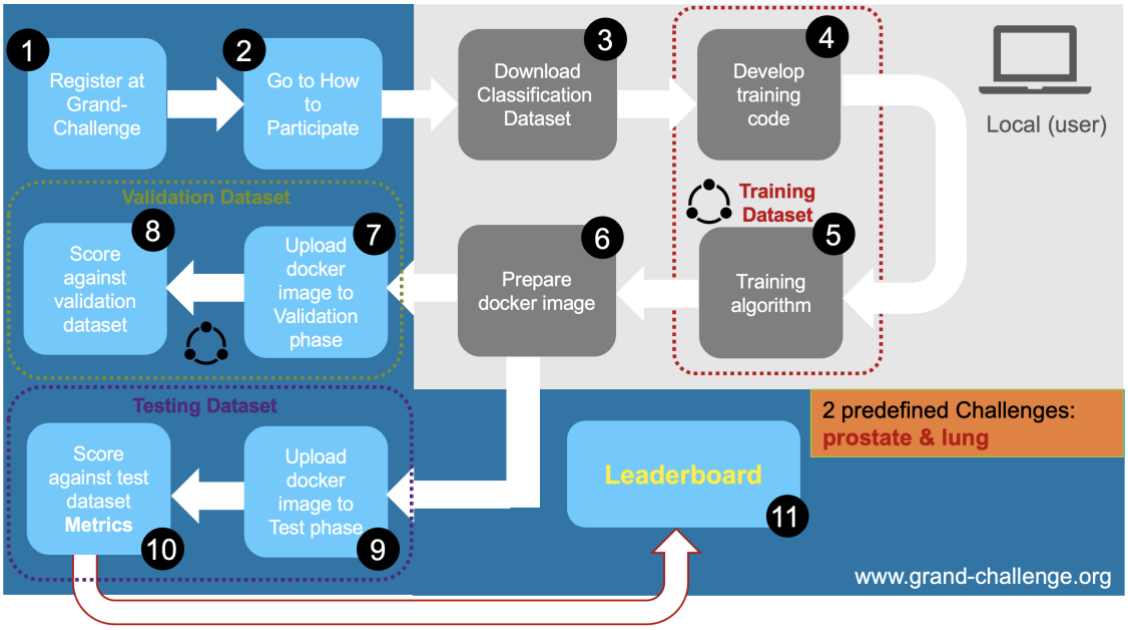


Figure 1. Steps for the execution of the classification phase.

Every participant must sign up for a Grand-Challenge account (at www.grand-challenge.org) (step 1) and send the organizer (to chaimeleon@quibim.com), an e-mail requesting to participate in the Challenge and attaching a signed version of the Terms and Conditions, completed with all information requested.

After careful assessment (section 5.2) the organizer will notify the selected participants of their acceptance to participate in the Challenge and will send data access links to them. During this phase, participants will download a highly controlled training dataset for prostate and lung cancers (step 3). The link shared with each participant will be a single-access link, therefore, once the link is clicked and the dataset downloaded, the link will expire and will not be accessible anymore. In this way, we avoid participants sharing this link with external members. In this same e-mail, we will share with participants a short survey we have built to collect some further information of the participants.

The survey is accessible in the following link (https://forms.gle/oEMiRyCMvMzxAMER9) and includes the following questions:

1. Where are you from? (Country)
2. Do you work on a public or private institution?
    a. Public.
    b. Private.
    c. I am a student.
3. Years of experience in AI model development.
    a. Less than 5 years.
    b. Between 5 and 10 years.
    c. Between 10 and 15 years.

   d. More than 15 years.

4. Have you ever heard before this Open Challenge about ChAImeleon project?
   a. Yes.
   b. No.
5. Have you participated previously in other Open Challenges?
   a. Yes.
   b. No.
6. What motivates you to participate in the ChAImeleon Open Challenge? (Select all that apply)
   a. Advancing cancer research and patient care
   b. Testing my skills and knowledge in AI
   c. Collaboration and networking opportunities
   d. Access to high-quality imaging and clinical data
   e. Prize incentives
   f. Other (please specify)
7. Do you have experience on medical imaging processing?
   a. Yes, I have previously trained other AI models based on medical imaging.
   b. No, but I have experience in other computer vision tasks.
   c. No, it is the first time I work in a computer vision task.
8. Have you worked previously developing AI solutions for any of the following cancer types? (Select all that apply)
   a. Prostate cancer
   b. Lung cancer
   c. Breast cancer
   d. Colon cancer
   e. Rectal cancer
9. Which kind of AI solutions have you used before?
   a. Deep learning (end-to-end solutions using the image as input).
   b. Traditional Machine Learning techniques based on tabular data.
   c. Both.
   d. I don’t have any experience with these techniques.
   e. Other (specify).
10. Are you familiar with image harmonization techniques?
   a. Yes, I have already used them before.
   b. Yes, but I have never used them before.
   c. I don’t know what you are speaking about.
11. Which harmonization techniques are you used to implement?

a. GAN-based solutions.
b. Diffusion models-based solutions.
c. Self-supervised learning techniques.
d. Traditional computer vision-based solutions.
e. Other (specify).

12. Are you used to combine imaging to other sources of information (e.g., clinical or molecular data)?
    a. Yes.
    b. No.

The dataset is composed by a set of NIfTI (imaging data) and JSON files (clinical data) for both prostate and lung cancer. Each dataset is split into three different subsets:

- Training: set of cases used to adjust model weights. It will be composed by 80% of the cases.
- Validation: set of cases used to validate the trained model on new unseen data. Additionally, this dataset can be used to tune some hyperparameters. It will be composed by 20% of the cases. This dataset will be hidden to the participants.
- Testing: set of cases used for the final evaluation of the trained model on completely independent cases. It will be composed by 20% of the cases. This dataset will be hidden to the participants.

Participants will use this training dataset to develop their proposed AI models using their own resources (steps 4 and 5). Once a model is ready to be evaluated, participants will prepare an inference container (step 6), this is a docker container which encapsules a trained AI algorithm together with all the components needed to load and prepare a new case (image and clinical data) and generate the corresponding output. These inference containers are equivalent to Grand Challenge Algorithms (https://grand-challenge.org/documentation/algorithms/). Participants will submit their docker containers to the corresponding challenge phase, docker images need to be exported as ".tar.gz" files. Once submitted, inference results will be compared with either validation or test datasets (depending on the users' submission). Therefore, the evaluation phase is split in two different phases:

- **Validation and tunning**: participants can upload the prepared docker image to the "Validation phase" (step 7) and the corresponding metrics will be extracted using the validation dataset (step 8). The associated leaderboard will be updated. The number of applications on the validation dataset will be limited to 3 submissions.
- **Test**: To avoid models' overfitting to the validation dataset, once a final model is selected by the participants, they will upload the docker image to the "Test phase" (step 9) and the corresponding metrics will be extracted using the test dataset (step 10).

The associated leaderboard will be updated. A single submission will be allowed in this phase.

Finally, we will use the leaderboard from the test phase to select the top 40 participants that will continue in the Championship phase (step 11).

Championship phase

As previously stated, top 40 participants from the Classification phase will participate in the Championship phase. Figure 2 summarizes the steps for the execution of the Championship phase.

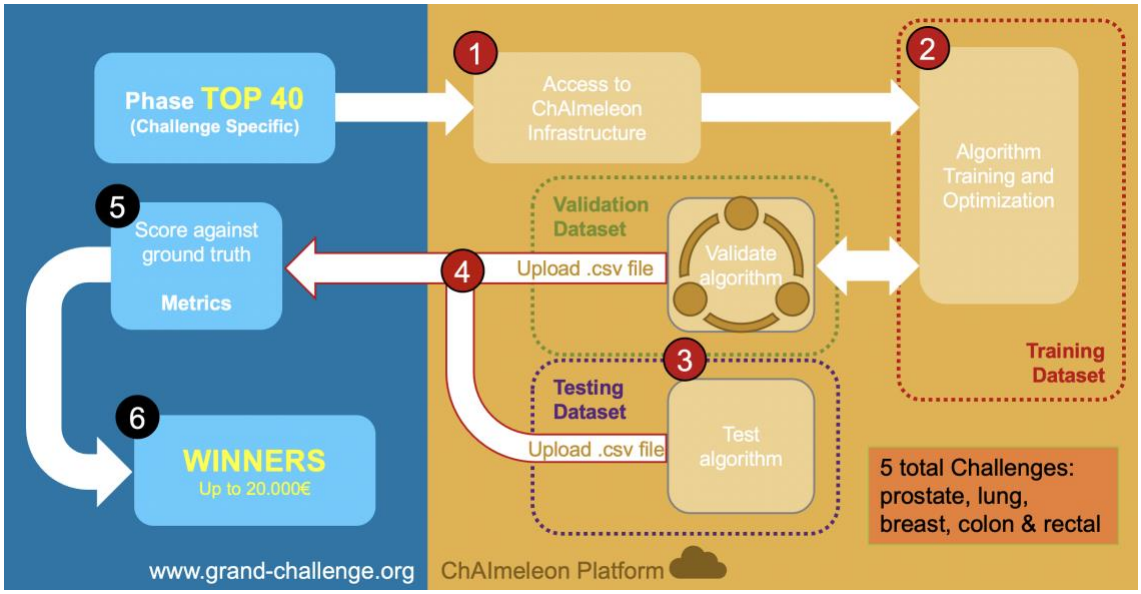


Figure 2. Steps for the execution of the Championship phase.

Models for the five cancer types will be developed in this phase, therefore, five different challenges will be conducted. Participants will be able to apply for any of them, we will allow participants to submit results for one or multiple challenges.

Model training will be performed within the ChAImeleon platform to validate the built architecture and the tools developed in the scope of the project (e.g., image harmonization tools). Therefore, each participant will have access to the same computational resources and computational time. Participants will have access to all the data collected for each cancer type. Each dataset will be split in training (80%), validation (20%) and test (20%) subsets as in the Classification phase. These datasets are only accessible within the ChAImeleon platform meaning that the data cannot be downloaded. Images will be available in DICOM format while JSON format will be used for the clinical data, however, in this phase, access all the variables included in the eCRF will be given.

First, the selected participants will need to register in the ChAImeleon platform (step 1). Participants will define their strategy and participate in the challenge they select.

Using the training dataset, participants will need to train their models (step 2). The harmonization tools provided by ChAImeleon and developed in the context of WP6 will be made available, this will allow us to test of the use of these tools increase models' performance. The evaluation phase is split in the same two phases as the Classification phase:

- **Validation and tunning**: participants will run their trained models over the validation dataset within the ChAImeleon platform. Participants will need to generate a CSV file with their predictions over this dataset, which will then upload to Gran Challenge associated to the "Validation phase". The number of applications on the validation dataset will be limited to 5 submissions per week.
- **Test**: To avoid models' overfitting to the validation dataset, once a final model is selected by the participants, they will compute their predictions over the test dataset within the ChAImeleon platform. These predictions will be stored in a CSV file which will be then uploaded to Grand Challenge associated to the "Test phase". A single submission will be allowed in this phase.

For a final submission to be evaluated, participants will need to upload a document or a link to a publication describing the solution they are proposing. Additionally, the source code used both for training and inference will be shared.

5.4 Evaluation

Participants will be scored according to the metrics obtained from their submitted solutions. The metrics that will be calculated to evaluate the proposed AI models will be the following according to each cancer type:

PROSTATE

- Clinical endpoint: Low vs. high-grade prostate cancer (Low grade: Gleason ≤ 3+4; high grade Gleason score ≥ 4+3).
- AI problem: Binary classification.
- Model output: participants will provide an output file with:
- Predicted probability.
- Predicted class (0: low grade, 1: high grade).
- Metrics: Different metrics will be used to provide a final score. The considered metrics are the following:
    - Area Under the ROC Curve (AUC)
    - Sensitivity
    - Specificity
    - Accuracy

The final score will be calculated as:

$$Score = (0{,}4 * AUC) + (0{,}2 * Sensitivity) + (0{,}2 * Specificity) + (0{,}2 * Accuracy)$$

BREAST

- Clinical endpoint: Histological subtype.
- AI problem: Multiclass classification.
- Model output: participants will provide an output file with:
- Probability of each class.
- Predicted class.
- Metrics: Different metrics will be used to provide a final score. The considered metrics are the following:
    - Area Under the ROC Curve (AUC)
    - Sensitivity
    - Specificity
    - Accuracy

The final score will be calculated as:

$$Score = (0{,}4 * AUC) + (0{,}2 * Micro\ Sensitivity) + (0{,}2 * Micro\ Specificity) + (0{,}2 * Accuracy)$$

Both sensitivity and specificity can be calculated as micro-averaged or macro-averaged, the macro-average approach calculates the metric independently for each class and then averages them; while the micro-average approach calculates class wise true positive and false positive and then use that to calculate overall metric. The micro-approach has been selected to consider class imbalance.

LUNG

- Clinical endpoint: progression free survival (PFS).
- AI problem: time-to-event prediction.
- Model output: participants will provide an output file with:
- Predicted PFS time in days (i.e., estimated time until disease progression or recurrence).
- Probability associated with the prediction.
- Metrics:
    - Concordance Index (C-index): measures the model's ability to correctly rank the predicted PFS times.

It compares the predicted PFS time of one patient to that of another patient and checks if the prediction is consistent with the actual outcome. A higher C-index indicates better performance.

- Time-dependent Area Under the Curve (AUC): evaluates the model's discrimination ability over different time intervals. It considers the predicted probabilities along with the actual survival outcomes and calculates de AUC under the time-dependent ROC curve. A higher time-dependent AUC indicates better predictive accuracy.

The final score will be calculated as:

$$Score = (0{,}5 * C\ index) + (0{,}5 * Time\ dependent\ AUC)$$

COLON

- Progression free survival (PFS)
- AI problem: time-to-event prediction.
- Model output: participants will provide an output file with:
- Predicted PFS time in days (i.e., estimated time until disease progression or recurrence).
- Probability associated with the prediction.
- Metrics:
  - Concordance Index (C-index): measures the model's ability to correctly rank the predicted PFS times. It compares the predicted PFS time of one patient to that of another patient and checks if the prediction is consistent with the actual outcome. A higher C-index indicates better performance.
  - Time-dependent Area Under the Curve (AUC): evaluates the model's discrimination ability over different time intervals. It considers the predicted probabilities along with the actual survival outcomes and calculates de AUC under the time-dependent ROC curve. A higher time-dependent AUC indicates better predictive accuracy.

The final score will be calculated as:

$$Score = (0{,}5 * C\ index) + (0{,}5 * Time\ dependent\ AUC)$$

RECTUM

- Clinical endpoint: Tumor Regression Grade (TRG).
- AI problem: Multiclass classification.
- Model output: participants will provide an output file with:
- Probability of each class.
- Predicted class.
- Metrics: Different metrics will be used to provide a final score. The considered metrics are the following:
    - Area Under the ROC Curve (AUC)
    - Sensitivity
    - Specificity
    - Accuracy

  The final score will be calculated as:

$$Score = (0{,}4 * AUC) + (0{,}2 * Micro\ Sensitivity) + (0{,}2 * Micro\ Specificity) + (0{,}2 * Accuracy)$$

5.5 Description grand-challenge.org hosting and related documents

We contacted Grand-Challenge.org in November 2022 to convey the intention to host the ChAImeleon Open Challenges on their platform. During these months we have been in contact with them by email asking questions and understanding better the functioning of their site to be able to host the challenges correctly.

At the end of May 2023, having gathered all the necessary information internally from Quibim, we completed and sent the Grand-Challenge.org form so that they could create the page and begin to set up the challenge and upload the information.

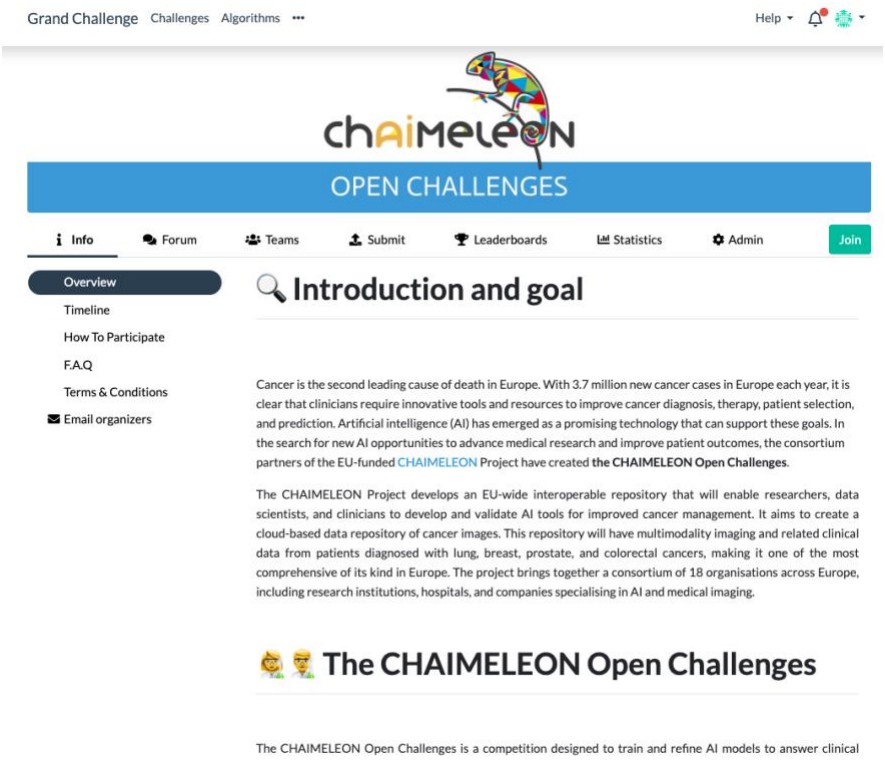
We received a reply from them via email asking for more details and clarifications in order to adjust the challenge to the functioning of the platform.

Once we reached an agreement, we held a video meeting with them on June 15, 2023 in which, with the challenge page created on Grand-Challenge.org, they helped us to configure the first technical steps of the challenge.

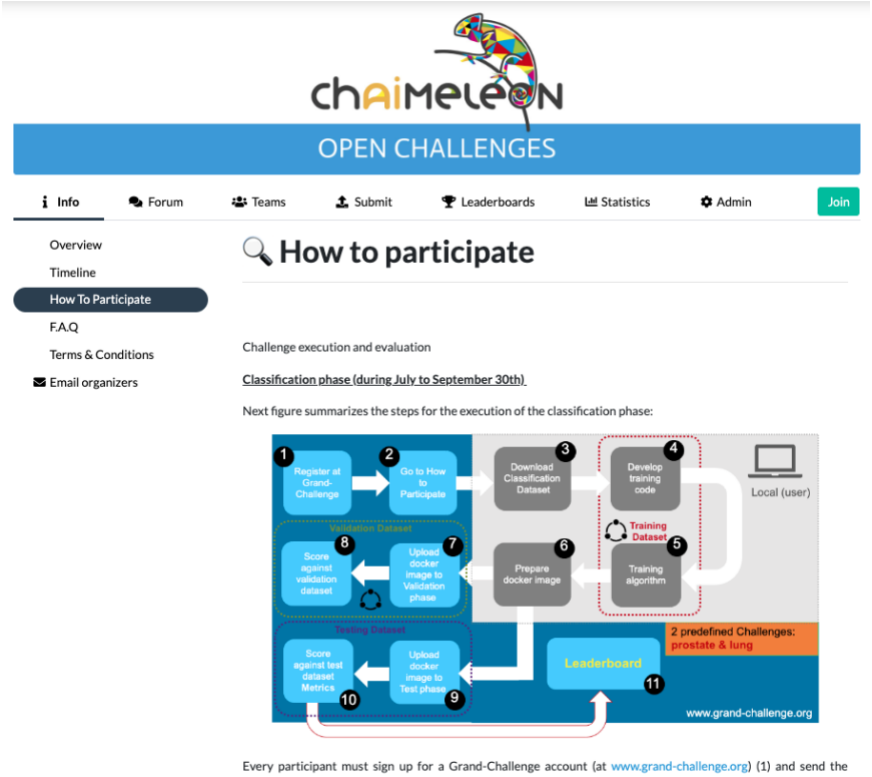
During the following days we were configuring the page https://chaimeleon.grand-challenge.org/ to make it ready to receive the participants' registrations and we opened it to the public on July 3rd2023.

Here are some screenshots of the main pages of the challenge on Grand-Challenge.org (specific documents are included in the annexes):

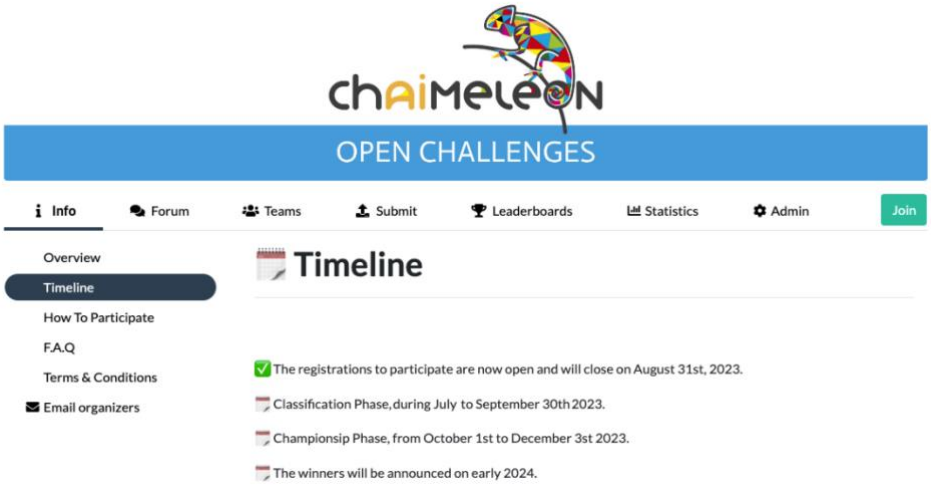
Main page:



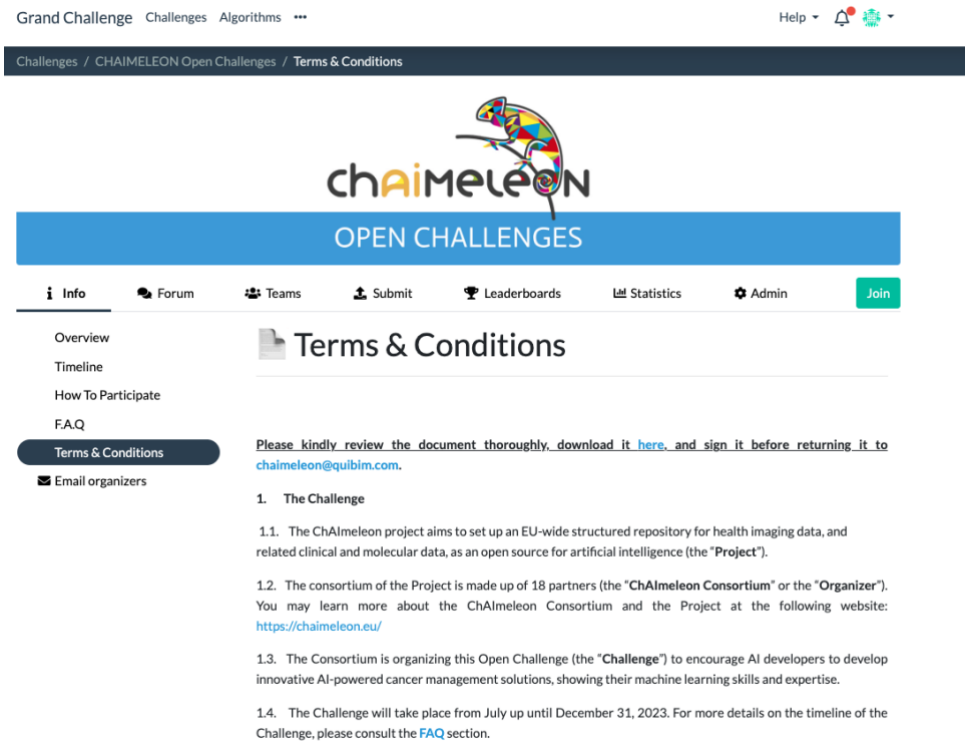
How to participate page:



Timeline page:



Terms & Conditions page:



6. Legal considerations: Terms and conditions

6.1 Throughout the various meetings held, legal discussions focused on the drafting of the terms and conditions, attached as **Annex 6.1** (hereinafter, the "**Terms**") that govern the participants' participation in the Open Challenges and the rules for its development.

6.2 The main provisions established in the Terms are the following:

- **Eligibility.** Participation in the Open Challenges is open to individuals at least eighteen (18) years old on the date of registration and prior acceptance by the Open Challenges' organizers. Members or employees of the ChAImeleon Consortium partners and their respective companies, affiliates, and subsidiaries, or individuals providing services to them, are not eligible to participate, hence, do not qualify for awards and will not be listed in the leaderboard.

- **Application**. Applications to participate will be accepted until August 31, 2023, inclusive. All participants shall sign up for a Grand-Challenge account (at www.grand-challenge.org), which shall be verified, and send the organisation of the Open Challenges (to chaimeleon@quibim.com) an e-mail requesting to participate, attaching a signed version of the Terms (which contain a form that shall be completed with all information requested). Participants shall assess which institutional policies, laws, and regulations apply to them. In accordance, they shall ensure that all ethics reviews or approvals that may be required for participation have been obtained.

  Anonymous participation is not allowed, and to qualify for ranking on the leaderboard, true names and affiliations must be displayed accurately on verified Grand-Challenge profiles.

- **Participation**. The Classification Phase will start in July 2023 and go on until September 30, 2023. During the Classification Phase, Participants will be able to download a highly controlled dataset, entailing post-processed (i.e., harmonized) images associated with concrete clinical variables, and they will use their own resources for participating. The top 40 participants on the leaderboard will be selected to move on to the Championship Phase, which will run from October 1, 2023 up until December 31, 2023, in the ChAImeleon Platform.

  Participants may drop out of the Open Challenges and forego any further participation. However, they will not be able to retract their prior submissions.

- **Data.** During the Classification Phase a highly controlled dataset will be made open with harmonized images in NIfTI format with limited clinical variables.

- The link shared with each participant (to access the controlled dataset) will be a single-access link, therefore, once the link is clicked and the dataset downloaded, the link will expire and will not be accessible anymore. Also, during the Championship Phase, participants will have access to the ChAImeleon Platform where certain original and associated clinical data, together with some image pre-processing and harmonization tools, will be shared with the participants (hereinafter, the "**Data**").

  It is established in the Terms that Participants acknowledge and accept that they will not acquire any intellectual property right or any other right over the Data. The Organizer grants the Participants a royalty-free, non-sublicensable, non-transferable, non-commercial, non-exclusive, revocable license to use the Data exclusively for participation in the Open Challenges and Participants warrant not to distribute, transfer, share or disclose it in any way or form.

- **Intellectual Property**. Participants warrant that their submissions are their original work and, as such, they are the sole and exclusive owners and rights holders of their respective Submissions, agreeing not to make any Submission that infringes any third-party proprietary rights, intellectual property rights, industrial property rights, personal or moral rights, or any other rights, including, without limitation, copyright, patent, trade secret, privacy or confidentiality obligations. The ownership of any intellectual property developed by the Participants during and within the scope of the Challenge will remain with the Participants.

- **Personal Data**. With regards to the Data (as defined above), Participants warrant that they will not, either alone or in concert with any other information, make any effort to identify or contact individuals who are or may be the source of the information in the Data and are strictly prohibited from generating or using images or comparable representations of the face, head, or body for facial recognition, reidentification, or other purposes that could allow the identities of individuals to be readily ascertained.

  Moreover, the Open Challenges' organisation may collect personal data (understood as information that relates to an identified or identifiable individual) from the Participants in the application process and throughout the Challenge. This personal data will only be used for communication by the Organizer with the participants relating to the Challenge and any Challenge-related information, such as the distribution of the Prizes.

In accordance with GDPR, participants may exercise their rights of access, rectification, erasure, restriction of processing, objection and portability by contacting the Organizer.

- **License**. All participants grant the Open Challenges organisation a sublicensable, royalty-free license for the use of their submissions if they are chosen by the end of the Open Challenges for implementation in the ChAImeleon Platform within the scope of the ChAImeleon Project. The further terms for licensing shall be negotiated individually between the selected participants and the Organizer under fair conditions.

- **Content.** Participants represent and warrant that the posting of their content does not violate the privacy rights, publicity rights, copyrights, contract rights, or any other rights of any person, and that the contest posted in the forum of the Open Challenges or within the ChAImeleon Platform, will not cause the breach of any law or regulation, and will not or could not be reasonably considered defamatory, offensive, abusive, in breach of confidence or breach of privacy. At any time, the Open Challenges organisation reserves the right to modify or remove any content posted by the participants at any time.

- **Winner**. After the Championship Phase, the final rank will showcase the top 25 participants, and the winners will be notified. Participants agree that the decision on the winner shall be final and binding and shall not be subject to dispute in a court of law. The award of the Prizes may be subject to verification of the participant's identity, qualifications, and role in creating the submission. The Open Challenges organisation may deem a participant ineligible to win if the organisation reasonably believes that the participant has attempted to undermine the legitimate operation of the Open Challenges by cheating, deception, or other unfair playing practices and the organisation may disqualify any participant or participating team, at any point in time, on grounds of unfair or dishonest practices.

- **Prizes**. The final rank of the winning participants will be announced by the end of January 2024. Monetary prizes will be payable to the winners as follows:

Clinical Endpoints solved	Prostate	Breast	Lung	Colon	Rectum
1st place:	6,000 €	6,000 €	6,000 €	6,000 €	6,000 €
2nd place:	5,000 €	5,000 €	5,000 €	5,000 €	5,000 €
3rd place:	4,000 €	4,000 €	4,000 €	4,000 €	4,000 €
4th place:	3,000 €	3,000 €	3,000 €	3,000 €	3,000 €
5th place:	2,000 €	2,000 €	2,000 €	2,000 €	2,000 €

By participating in the Open Challenges, all participants acknowledge and warrant that the Open Challenges organisation may select their AI solutions (developed through the Open Challenge) for testing them in a clinical setting through an in-silico validation. Particularly within Work Package 9 of the ChAImeleon Project (grant agreement No. 952172), with the aim of accelerating the path to market of the winning AI solutions, at no cost to the winners. Participants shall actively participate throughout the clinical validation, engaging with the organisation in the provision of feedback on their user experience and providing metrics on the performance of their solutions.

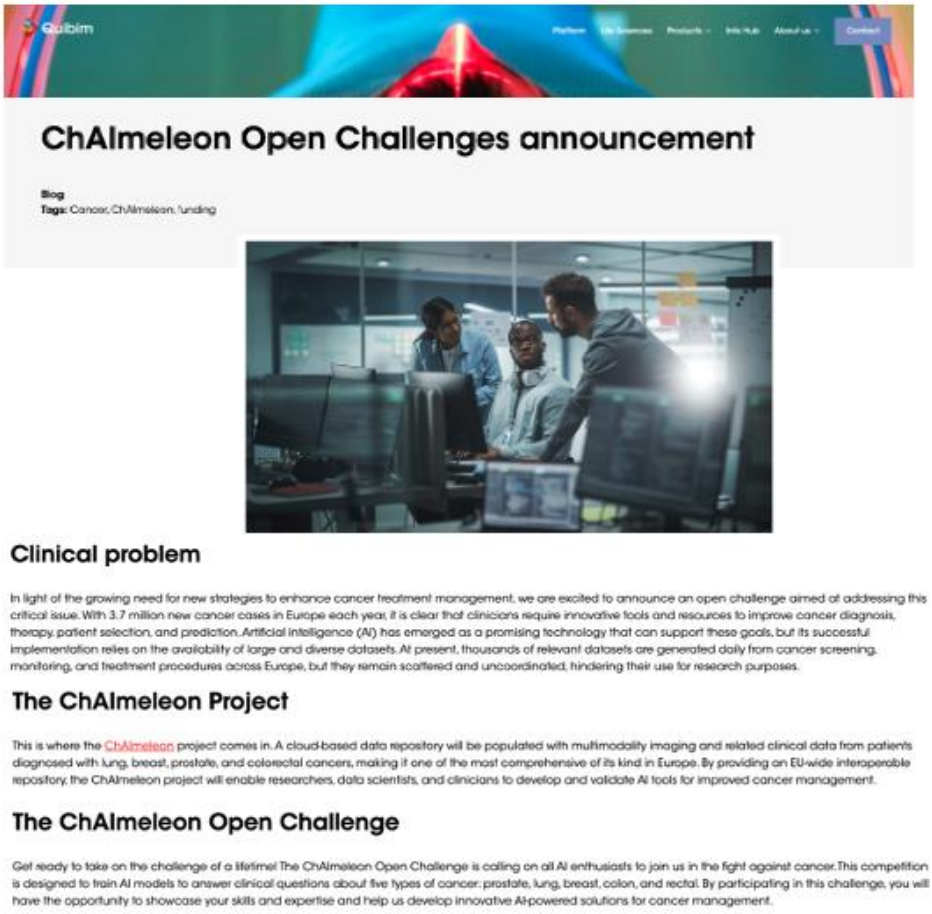
- **Acknowledgment** and **publications**. Participants agree to acknowledge the ChAImeleon Project in any publications derived from their submissions in the Open Challenges and the use of the Data, agreeing to obey the citation rules established in the Terms. In addition, after the Open Challenges finishes, the organisation may invite (discretionally) a reduced number of the winners to write a joint peer-reviewed journal paper that performs a complete analysis of the results and highlights the key findings and methods. More information on this will be provided to the selected individuals after completion of the Challenge.

7. Communication plan. Announcement (MS6), registration and start of the Open Challenges

On March 30, we openly announced the CHAIMELEON Open Challenges to the public.

Quibim published an article on our website (https://quibim.com/news/chaimeleon-open-challenges/) explaining the challenges and sharing the most relevant information, key dates and prizes. We extended the diffusion through our social media channels: LinkedIn and Twitter.

Blog post on Quibim.com announcing the Open Challenges:



ChAImeleon Open Challenges announcement

Blog
Tags: Cancer, ChAImeleon, funding

Clinical problem

In light of the growing need for new strategies to enhance cancer treatment management, we are excited to announce an open challenge aimed at addressing this critical issue. With 3.7 million new cancer cases in Europe each year, it is clear that clinicians require innovative tools and resources to improve cancer diagnosis, therapy, patient selection, and prediction. Artificial intelligence (AI) has emerged as a promising technology that can support these goals, but its successful implementation relies on the availability of large and diverse datasets. At present, thousands of relevant datasets are generated daily from cancer screening, monitoring, and treatment procedures across Europe, but they remain scattered and uncoordinated, hindering their use for research purposes.

The ChAImeleon Project

This is where the ChAImeleon project comes in. A cloud-based data repository will be populated with multimodality imaging and related clinical data from patients diagnosed with lung, breast, prostate, and colorectal cancers, making it one of the most comprehensive of its kind in Europe. By providing an EU-wide interoperable repository, the ChAImeleon project will enable researchers, data scientists, and clinicians to develop and validate AI tools for improved cancer management.

The ChAImeleon Open Challenge

Get ready to take on the challenge of a lifetime! The ChAImeleon Open Challenge is calling on all AI enthusiasts to join us in the fight against cancer. This competition is designed to train AI models to answer clinical questions about five types of cancer: prostate, lung, breast, colon, and rectal. By participating in this challenge, you will have the opportunity to showcase your skills and expertise and help us develop innovative AI-powered solutions for cancer management.

To announce the opening of the challenge registrations in Grand-Challenge.org we have designed a digital strategy that has two pillars: PR and social media advertising.

In the PR section we have worked together with our media agency Bemypartner to prepare a press release sent to European media on July 3,rd announcing that the registrations are open, sharing the phases, key dates and prizes for the winners.

In the area of social media advertising, we have worked with our digital marketing agency Esparta on a month-long ad campaign for Twitter and LinkedIn in which we target the target audience with different creatives to let them know about the opening of the challenge, prizes and other key details. This campaign has as landing page https://chaimeleon.eu/open-challenges/, the landing page created as the main destination of the campaign. From this page we link to the official page of the challenge on Grand-Challenge.org so that participants can register: https://chaimeleon.grand-challenge.org/.

Once we check one by one all the participants' requests (as explained in section 5.2), those we approve will receive an email from chaimeleon@quibim.com with the following information:

Subject: Welcome to the ChAImeleon Open Challenges!

Dear [Participant's Name],
We are delighted to inform you that your application for the ChAImeleon Open Challenges has been accepted! Congratulations and welcome to the competition!
The Classification Phase will start during July, and we'll update you on the official start date. We have prepared a comprehensive guide on how to participate, which you can access by visiting the following link: [https://chaimeleon.grand-challenge.org/how-to-participate/]. This resource will provide you with all the necessary information to get started and make the most out of this exciting opportunity.
Here you have the link to download the datasets needed to participate in this phase. ***Please be aware that the link is only valid for one download.***
To ensure that you stay updated with all the key dates and milestones, we kindly request you to review the official timeline of the challenge, available at: [https://chaimeleon.grand-challenge.org/timeline/]. It will help you stay on track and plan your engagement effectively.
If you have any questions, clarifications, or need assistance during the challenge, please feel free to reach out to us by replying to this email or utilizing the official forum on Grand Challenge. Our dedicated team is ready to support you and provide guidance whenever you require it.
We would also like to invite you to participate in a survey that aims to gather valuable feedback on your experience with the ChAImeleon Open Challenges. Your insights will aid us in enhancing future editions and delivering a more fulfilling competition. The survey is completely voluntary, and you can access it through this link: [https://forms.gle/6q6HLeHzv5vYoC576].
Once again, congratulations on being selected, and we look forward to witnessing your remarkable contributions to the ChAImeleon Open Challenges. Best of luck!
Sincerely,
The ChAImeleon Open Challenges team.

8. Conclusions

As specified in the Grant Agreement, Task 8.5 Execution of the Challenges and running of the External Validation period (start date: month 35), is devoted to the execution of the Challenges, which includes the review and acceptance of registered participants, to provide them with access to a functional and tested version of the Repository, to supervise their acceptance of

legal conditions for participation, to establish the criteria and process for review and evaluation of their AI-based solutions for assisting to ChAImeleon predefined CEP for their targeted cancer, and to supervise the execution of the review process.

Therefore, in this document, we have explained the preparation and organisation of the Open Challenges from a management point of view, theinterest of these challenges for the clinical and medical unmet needs, their technical workflow, steps and phases, the regulatory framework that welcomes these challenges and the communication and visibility strategy, so we are ready to start their execution in July 2023 (month 35) with all the details collected and the strategy well defined, as specified in this deliverable.

9. References

1) D5.2 Interim dataset provision by project (referenced in Section 4: Selection of Clinical Questions for the Open Challenges).
2) https://grand-challenge.org/

Annex 1: Overview

🔍 Introduction and goal

Cancer is the second leading cause of death in Europe. With 3.7 million new cancer cases in Europe each year, it is clear that clinicians require innovative tools and resources to improve cancer diagnosis, therapy, patient selection, and prediction. Artificial intelligence (AI) has emerged as a promising technology that can support these goals. In the search for new AI opportunities to advance medical research and improve patient outcomes, the consortium partners of the EU-funded CHAIMELEON Project have created the **CHAIMELEON Open Challenges**.

The CHAIMELEON Project develops an EU-wide interoperable repository that will enable researchers, data scientists, and clinicians to develop and validate AI tools for improved cancer management. It aims **to create a cloud-based data repository of cancer images**. This repository will have multimodality imaging and related clinical data from patients diagnosed with lung, breast, prostate, and colorectal cancers, making it one of the most comprehensive of its kind in Europe. The project brings together a consortium of 18 organisations across Europe, including research institutions, hospitals, and companies specialising in AI and medical imaging.

👩‍⚕️👨‍⚕️ The CHAIMELEON Open Challenges

The CHAIMELEON Open Challenges is a competition designed to train and refine AI models to answer clinical questions about five types of cancer: prostate, lung, breast, colon, and rectal.

Participants are challenged to collaborate and develop innovative AI-powered solutions that can significantly impact cancer diagnosis, management, and treatment. They will be evaluated considering a balance between the performance of their AI algorithms to predict different clinical endpoints such as disease staging, treatment response or progression free survival and their trustworthiness.

The challenges are open to the whole scientific and tech community interested in AI. They are a unique opportunity to showcase how AI can be used to advance medical research and improve patient outcomes within the CHAIMELEON project.

The challenges will be divided in two phases: the Classification Phase and the Championship Phase.

The **Classification Phase** will extend during July to September 30th, 2023. In this phase, any participant can join and download a highly controlled cancer dataset. The dataset will consist of post-processed (i.e., harmonised) images associated with specific clinical variables, ensuring a level playing field for all participants. The participants will train their AI models and compete to be among the top on the leaderboard.

The **Championship Phase** will extend from October 1st to December 31st, 2023. In this phase the top 40 participants from the previous phase will be invited to compete on an even grander stage, using the CHAIMELEON platform to train their algorithms. This phase will include five different challenges, one for each cancer type (prostate, lung, breast, colon, and rectal), with a total prize pool of 20.000€ per challenge, split among the winners. Original images and associated clinical data, along with different image pre-processing and harmonization tools, will be available to participants who have passed the qualifying round cut-off point. The same computational resources will be assigned to each participant; therefore, each participant can decide which challenges to tackle and apply their strategies accordingly.

🏅 Prizes

Those who take on the challenge can win a total prize pool of €20,000 per challenge, split amongst the winners, with €100,000 in prizes.

This phase will include five different challenges, one for each cancer type (prostate, lung, breast, colon, and rectal), with a total prize pool of 20.000€ per challenge, split among the winners:

Clinical Endpoints solved	Prostate	Breast	Lung	Colon	Rectum
1st place:	6,000 €	6,000 €	6,000 €	6,000 €	6,000 €
2nd place:	5,000 €	5,000 €	5,000 €	5,000 €	5,000 €
3rd place:	4,000 €	4,000 €	4,000 €	4,000 €	4,000 €
4th place:	3,000 €	3,000 €	3,000 €	3,000 €	3,000 €
5th place:	2,000 €	2,000 €	2,000 €	2,000 €	2,000 €

The winners of the Challenges will be awarded with a total prize pool of 20k€ per challenge, split among the winners (allowance of 100k € under Coordinator´s budget) and with the inclusion of their AI-based solutions for Clinical Validation in WP9 thus accelerating their path to market at no cost to them. The participants in the Challenge will need to commit providing ChAImeleon with feedback on their user experience and provide metrics on the performance of their AI-based solutions before and after their experimentation with ChAImeleon.

Organizers

The project brings together a consortium of 18 organisations across Europe, including research institutions, hospitals, and companies specialising in AI and medical imaging: Fundación para la Investigación del Hospital Universitario la Fe de la Comunidad Valenciana (ES), Universita di Pisa (IT), Universita Degli Studi di Roma la Sapienza (IT), Centro Hospitalar Universitário de Santo António (PT), Policlinico San Donato (IT), College des Enseignants de Radiologie (FR), Universiteit Masstricht (NL), Charité Universitätsmedizin Berlin (DE), Imperial College London (UK), Ben-Gurion University of the Negev (IL), Universitat Politècnica de Valencia (ES), GE Healthcare (DE), Quibim (ES), Medexprim (FR), Bahia (ES), Matical Innovation (ES), European Institute of Biomedical Imaging Research (AT), Universitat de Valencia (ES).

The CHAIMELEON project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 952172.

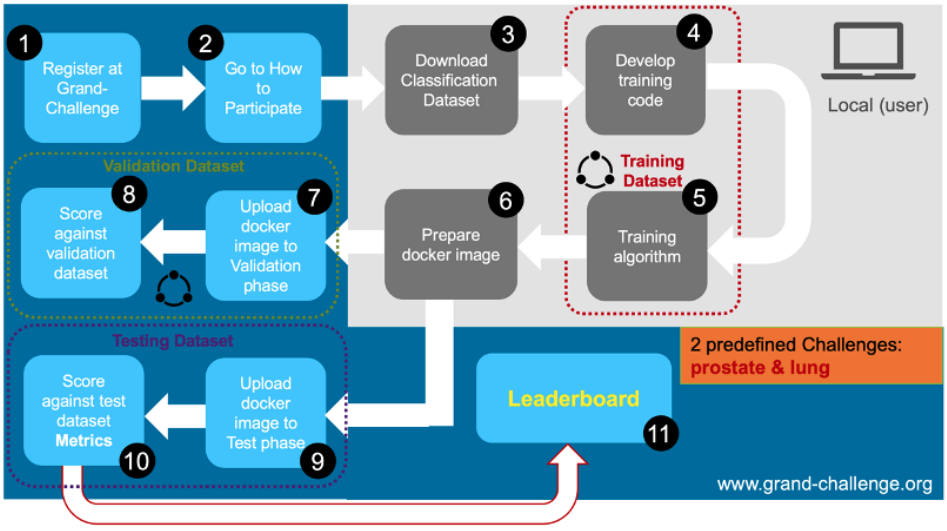
Disclaimer

Annex 2: How to participate

Challenge execution and evaluation

Classification phase (during July to September 30th)

Next figure summarizes the steps for the execution of the classification phase.



Every participant must sign up for a Grand-Challenge account (at www.grand-challenge.org) (1) and send the organizer (to chaimeleon@quibim.com), an e-mail requesting to participate in the Challenge and attaching a signed version of the Terms and Conditions, completed with all information requested.

After careful assessment, the organizer will notify the selected participants of their acceptance to participate in the Challenge and will send data access links to them. During this phase, participants will download a highly controlled training dataset for prostate and lung cancers (3). The dataset is composed by a set of NIfTI (imaging data) and JSON files (clinical data) for both prostate and lung cancer. Participants will use this training dataset to develop their proposed AI models using their own resources (4,5). Once a model is ready to be evaluated, participants will prepare an inference container (6), this is a docker container which encapsules a trained AI algorithm together with all the components needed to load and prepare a new case (image and clinical data) and generate the corresponding output.

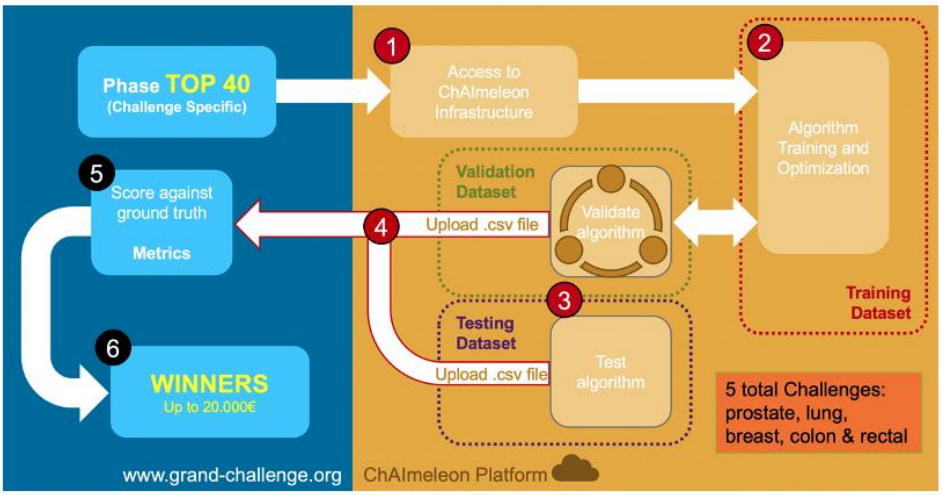
The evaluation phase is split in two different phases:

- **Validation and tunning**: participants can upload the prepared docker image to the "Validation phase" (7) and the corresponding metrics will be extracted using the validation dataset (8). The associated leaderboard will be updated. The number of applications on the validation dataset will be limited to 3 submissions.
- **Test**: Once a final model is selected by the participants, they will upload the docker image to the "Test phase" (9) and the corresponding metrics will be extracted using the test dataset (10). The associated leaderboard will be updated. A single submission will be allowed in this face.

Finally, we will use the leaderboard from the test phase to select the top 40 participants that will continue in the Championship phase (11).

Championship phase (from October 1st to December 31st)

Next figure summarizes the steps for the execution of the championship phase.



The selected participants will access the ChAImeleon platform to train their models on complete datasets for the five cancer types (1). Participants will define their strategy and participate in the challenge they select. ChAImeleon infrastructure will be used by participants to train their models (2), each participant will have access to the same computational resources and computational time. In addition, participants will have access to harmonization solutions, developed by ChAImeleon consortium, that can be used during training.

Once an AI model is trained a ready for validation, participants will conduct the validation in two phases:

- Validation and tunning: participants will execute their trained AI model over the validation dataset and generate a CSV file with the corresponding model outputs. This CSV will be uploaded to the “Validation phase” in grand-challenge platform (4). The number of applications on the validation dataset will be limited to 3 submissions per month.
- Test: participants will execute their trained AI model over the test dataset and generate a CSV file with the corresponding model outputs. This CSV will be uploaded to the “Test phase” in grand-challenge platform (4). The number of applications on the validation dataset will be limited to a single submission during the whole phase.

Detailed information of the structure of these CSV files will be given at the beginning of the Championship phase.

Access to the final solution need to be made accessible together with a paper with a detailed description of the solution to be awarded.

Annex 3: Timeline

✅ The registrations to participate are now open and will close on August 31st, 2023.
🗓 Classification Phase, during July to September 30th 2023.
🗓 Championship Phase, from October 1st to December 31st 2023.
🗓 The winners will be announced on early 2024.

Annex 4: Terms & Conditions

Open Challenge - Terms and Conditions

Please kindly review the document thoroughly, download it here, and sign it before returning it to chaimeleon@quibim.com

1. The Challenge

1.1 The ChAImeleon project aims to set up an EU-wide structured repository for health imaging data, and related clinical and molecular data, as an open source for artificial intelligence (the "Project").
1.2 The consortium of the Project is made up of 18 partners (the "ChAImeleon Consortium" or the "Organizer"). You may learn more about the ChAImeleon Consortium and the Project at the following website: https://chaimeleon.eu/
1.3 The Consortium is organizing this Open Challenge (the "Challenge") to encourage AI developers to develop innovative AI-powered cancer management solutions, showing their machine learning skills and expertise.
1.4 The Challenge will take place from July 2023 up until December 31, 2023. For more details on the timeline of the Challenge, please consult the FAQ section.

2. Eligibility

2.1 The Challenge is open to individuals (i) who are at least eighteen (18) years old on the date of registration for the Challenge and (ii) prior acceptance by the Organizer, which will be notified by e-mail.
2.2 Participation in the Challenge constitutes the Participant's full and unconditional agreement to and acceptance of these terms and conditions, otherwise referred to as rules of the Challenge ("Terms"). The term "you" refers to you, the "Participant".
2.3 Members or employees of the ChAImeleon Consortium partners and their respective companies, affiliates, and subsidiaries, or individuals providing services to them during the Challenge, are not eligible to participate in the Challenge, hence, do not qualify for awards and will not be listed in the leaderboard.
2.4 Participation in the Challenge is precluded to any individual that may have access to additional information (as established under Article 4.5 of Regulation (EU) no. 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regards to the processing of personal data and on the free movement of such data, the "GDPR") that under reasonable means would allow to attribute the Data (as defined in Clause 0 of this Terms) to specific data subjects. By accepting these Terms, Participants unequivocally declare that they have no access to information that may allow for the identification of data subjects and that they are not in violation of this provision.

3. Application

3.1 Applications will be accepted from July 3rd, 2023 to 11:59 pm CEST August 31, 2023, inclusive (the "Application Period").

3.2 Every Participant must sign up for a Grand-Challenge account (at www.grand-challenge.org), which shall be verified, and send the Organizer (to chaimeleon@quibim.com) an e-mail requesting to participate in the Challenge with a signed version of these Terms attached to it (click here for a downloadable version), duly fulfilled with all information requested.
3.3 After careful assessment, the Organizer will notify the selected Participants of their acceptance to participate in the Challenge and will send data access links to them, as established in Clause 0.
3.4 Participants should register with their real names, affiliation (including the full name of the university/institute/company) and affiliation e-mails. Anonymous participation is not allowed, and to qualify for ranking on the leaderboard, true names and affiliations must be displayed accurately on Participants' verified Grand-Challenge profiles.
3.5 Each Participant can only be a member of a single team.
3.6 Any individual participating with multiple or duplicate Grand-Challenge profiles will be disqualified.
3.7 The Organizer reserves the right to verify the eligibility of Participants and check their identities and reserves the right of admission based on its sole discretion.
3.8 Participants shall follow relevant institutional policies and applicable European and national laws and regulations (if any) concerning the completion of ethics review or approval that may be required for participation in the Challenge. When applicable due to their own circumstances, Participants shall submit an ethical approval validly issued by a duly accredited Ethics Committee and an ethical impact assessment (e.g. ALTAI methodology).
3.9 For more details on the registration process, please consult the Notice and FAQ sections.

4. Participation

4.1 Details on technical requisites to be followed for participation in the Challenge, the clinical questions to be solved by Participants, and the different phases of the Challenge can be found in the Overview, the FAQ and the How to Participate sections, which are hereby incorporated by reference and read, accepted and agreed upon by the Participants' participation in the Challenge.
4.2 Classification Phase will run from July 2023 up until 11:59 pm CEST on September 30, 2023. During the Classification Phase, Participants will be able to download a highly controlled dataset, entailing post-processed (i.e., harmonized) images associated with concrete clinical variables. Participants will use their own resources to train the models.
4.3 From this phase, the top 40 participants on the leaderboard will be selected to move on to the Championship Phase, which will run from 00:00 am CEST on October 1, 2023 up until 11:59 pm CEST on December 31, 2023, in the ChAImeleon Platform (the "Platform"). They will be notified using the email address used to register, as per Clause 3.2.
4.4 Participants acknowledge and accept that acceptance of the terms and conditions of the Platform shall be required in order to progress in the Challenge and participate in the Championship Phase.
4.5 The Organizer will not reimburse any expenses or costs for Participants.

5. Data

5.1 During the Classification Phase a highly controlled dataset will be made open with harmonized images in NIfTI format with limited clinical variables (which will be accessible through a single-access link), and during the Championship Phase, Participants will have access to the Platform where certain original and associated clinical data, together with some image pre-processing and harmonization tools, will be shared with the Participants (the "Data").
5.2 To ensure a fair comparison, Participants are not allowed to use any additional data or pre-trained models.
5.3 Data always remains the sole property of the Organizer and Participants acknowledge and accept that they will not acquire any intellectual property right or any other right over the Data, other than as set forth herein.
5.4 The Organizer grants the Participants a royalty-free, non-sublicensable, non-transferable, non-commercial, non-exclusive, revocable license to use the Data for the Challenge.
Participants expressly agree to exclusively use the provided Data for participation in the Challenge and not to distribute, transfer, share or disclose it in any way or form.
5.5 After the Challenge (or any time before upon request by the Organizer), the Participants must destroy all Data disclosed by the Organizer in their possession, stored electronically and/or on record-bearing media as well as any copies thereof. Upon request by the Organizer,

5.6 Participants shall confirm in writing within (14) fourteen days such destruction of the Data and any copies thereof.
5.7 Participants will not reverse engineer, decompile or disassemble the Data or the Platform, or encourage or assist any third party in doing so.
5.8 Participants will not, either alone or in concert with any other information, make any effort to identify or contact individuals who are or may be the source of the information in the Data and are strictly prohibited from generating or using images or comparable representations of the face, head, or body for facial recognition, reidentification, or other purposes that could allow the identities of individuals to be readily ascertained.
5.9 Participants expressly agree not to make more than one account for accessing and/ or downloading the Data (as defined in Section 5 of these Terms) and submitting their entries ("Submissions").

6. Intellectual Property

6.1 Participants warrant that their Submissions are their original work and, as such, they are the sole and exclusive owners and rights holders of their respective Submissions. Participants shall have the right to make the Submission and grant all required licenses.
6.2 Participants agree not to make any Submission that infringes any third-party proprietary rights, intellectual property rights, industrial property rights, personal or moral rights, or any other rights, including, without limitation, copyright, patent, trade secret, privacy or confidentiality obligations.
6.3 The ownership of any intellectual property developed by the Participants during and within the scope of the Challenge will remain with the Participants.

6.4 By joining the Challenge, Participants expressly authorize the Organizer to, within the scope of the Project, publish, communicate, and disclose orally, graphically, or in writing, and with no compensation involved, their Submissions.
6.5 The Participants shall not acquire any full or partial intellectual property right (or any other rights of any kind) over the Challenge, the Project, the Platform or the Consortium, nor on any names or trademarks associated with them, used alone, in association with or as part of another word or name.

7. Personal Data

7.1 The Organizer may collect personal data (understood as information that relates to an identified or identifiable individual) from the Participants in the application process and throughout the Challenge.
7.2 This personal data will only be used for communication by the Organizer with the Participants relating to the Challenge and any Challenge-related information, such as the distribution of the Prizes.
7.3 Explicit consent for any other uses of Participants' personal data will be requested if needed.
7.4 By entering the Challenge, Participants agree to give the Organizer access to the information they provide. This includes information you provide by your participation in the Challenge, forums or message boards, the information you provide to us if you contact us (for example, to report a problem or raise a query or comment), and details of the resources accessed.
7.5 In accordance with GDPR, Participants may exercise their rights of access, rectification, erasure, restriction of processing, objection and portability by contacting the Organizer via the Email Organizers section.
7.6 Participants will not use the Data, either alone or in concert with any other information, to make any effort to identify or contact individuals who are or may be the source of the information in the Data.
7.7 Privacy Policies of the Platform apply.

8. Confidentiality

8.1 All Confidential Information disclosed by the Organizer to Participants in connection with the Challenge:
- shall be used by Participants exclusively for participation in the Challenge;
- must not be distributed or disclosed in any way or form by Participants;
- must be kept confidential by Participants; and
- remains the sole property of the Organizer.

8.2 "Confidential Information" means any information and data, including, but not limited to, the Data (as defined in Clause 0 of this Terms), any kind of business, commercial, code, dataset or technical information, and data disclosed in connection with the Challenge irrespective of the medium in which such information or data is embedded.
8.3 After the Challenge (or any time before upon request by the Organizer), the Participants must destroy all Confidential Information disclosed by the Organizer in their possession, including Confidential Information stored electronically and/or on record-bearing media as well as any copies thereof.

9. License

9.1 Participant grants the Organizer a sublicensable, royalty-free license for the use of Participant's Submissions if they are chosen by the Organizer (discretionally) after the end of the Challenge, for implementation in the Platform within the scope of the Project.
9.2 The further terms for licensing will, in such an event, be negotiated individually between the selected Participants and the Organizer under fair conditions.
9.3 Nevertheless, the Participants agree that the license shall be granted on a royalty-free basis, given the research and scientific purpose of the Project itself.

10. Representations & Warranties

10.1 Participants represent and warrant that:

(i) The posting of your content (the "Content") within the scope of your participation in the Challenge (including the information you provide by your participation in the Challenge in forums or message boards) does not violate the privacy rights, publicity rights, copyrights, contract rights, or any other rights of any person.

(ii) The Content will not cause the Organizer to breach any law, regulation, code, or other legal obligation and will not or could not be reasonably considered defamatory, disparaging, seditious, offensive, threatening, abusive, in breach of confidence or breach of privacy.

(iii) The Content does not contain software viruses, or any other computer code, files, or programs designed to interrupt, destroy, or limit the functionality of any computer software, hardware, or telecommunications equipment.

10.2 The Organizer reserves the right to modify or remove any Content at any time.

11. Verification of Submissions

11.1 After the Championship Phase has finished, the final rank will showcase the top 25 Participants ("Winners"), and the Winners will be notified using the email address associated with the verified Grand-Challenge account used to register.
11.2 Participants agree that the decision on the Winners shall be final and binding for all Participants and shall not be subject to dispute in a court of law. Participants shall have no right to a justification of the decisions made by the Organizer.
11.3 The award of the Prizes (as defined in Clause 0) may be subject to verification of the identity, qualifications, and role of the Participant in the creation of the Submission.
11.4 The Organizer may deem a Participant ineligible to win if the Organizer reasonably believes that the Participant has attempted to undermine the legitimate operation of the Challenge by cheating, deception, or other unfair or dishonest practices.
11.5 In the event of a disqualification, the Organizer may award the applicable Prize to an alternate Participant.
11.6 The Organizer is not responsible for Submissions not received due to lost, failed, delayed or interrupted connections or miscommunications or other electronic malfunctions.

12. Monetary Prizes & Validation

12.1 After the Championship Phase has finished, the top 25 Participants will be notified by e-mail, and the Final Rank of the winning Participants (the "Winners") will be announced by the end of January 2024.
12.2 Monetary prizes will be payable to the Winners (the "Prizes") as follows:

Clinical Endpoints solved	Prostate	Breast	Lung	Colon	Rectum
1st place:	6,000 €	6,000 €	6,000 €	6,000 €	6,000 €
2nd place:	5,000 €	5,000 €	5,000 €	5,000 €	5,000 €
3rd place:	4,000 €	4,000 €	4,000 €	4,000 €	4,000 €
4th place:	3,000 €	3,000 €	3,000 €	3,000 €	3,000 €
5th place:	2,000 €	2,000 €	2,000 €	2,000 €	2,000 €

12.3 The Prizes will be sent wired to the Winners' bank accounts only after receipt by the Organizer of the required information or documentation (if any) for the delivery of the Prizes. Failure to provide the information necessary for the delivery of a Prize may result in delayed Prize delivery, disqualification of the Winner, or forfeiture of a Prize.
12.4 The Organizer shall have the right to make a Prize substitution of equivalent or greater value. The Organizer will not award a Prize if no eligible Submissions are entered in the Challenge.
12.5 Winners are responsible for any fees associated with receiving or using a Prize, including but not limited to wiring fees.

12.6 Winners are responsible for reporting and paying all applicable taxes in their jurisdiction of residence. The Organizer reserves the right to withhold a portion of the prize amount to comply with the relevant tax laws.
12.7 By participating in the Challenge, Participants acknowledge and warrant that Organizer may select (discretionally) their Submissions (i.e., AI solutions developed through the Challenge) for testing them in a clinical setting, through an in-silico validation, within the scope of the Project. Particularly, Work Package 9 of the grant agreement (no. 952172), with the aim of accelerating the path to market of Winners' AI solutions, at no cost to them. Participants agree to allow the testing and to actively participate in it, engaging with the Organizer in whatever is needed (giving feedback on their user experience and providing metrics on the performance of their AI-based solutions).

13. Publications & Acknowledgments

13.1 Participants agree to acknowledge the Project and the Organizer in publications derived from their Submissions and the use of the Data and agree to obey the citation rules. Please acknowledge the ChAImeleon Project in your publications as follows:
"De-identified data used in the development of this solution were prepared and provided by the ChAImeleon Project within the Open Challenges organized by its Consortium, funded by the European Union's Horizon 2020 research and innovation programme under grant agreement No. 952172, entitled 'Accelerating the lab to market transition of AI tools for cancer management'."

13.2 After the Challenge has finished, the Organizer may invite, discretionally, a reduced number of the Winners to write a joint peer-reviewed journal paper that performs a complete analysis of the results and highlights the key findings and methods. More information on this will be provided to the selected individuals after the Challenge and conditions may vary according to the development of the Challenge itself.

14. Termination

14.1 The Organizer may terminate your participation in the Challenge in writing (by e-mail) if you breach these Terms. This termination will take effect immediately after such termination e-mail has been sent.
14.2 We shall not be liable to you or any third party for any claims or damages arising out of any termination or suspension, or any other actions taken by the Organizer in connection therewith.
Participants may drop out of the Challenge and forego any further participation. However, they will not be able to retract their prior submissions till that point in time.

15. Miscellaneous

15.1 If a virus, bug, bot, catastrophic event, or any other unforeseen or unexpected event that cannot be reasonably anticipated or controlled (also referred to as force majeure) affects the fairness and integrity of the Challenge, the Organizer has the right to cancel, change, or suspend the Challenge. This right is reserved whether the event is due to human or technical error.

If a solution cannot be found to restore the integrity of the Challenge, the organisation reserves the right to select Winners from among all eligible Submissions received before the Challenge needs to be cancelled, changed or suspended.
15.2 Computer “hacking” is unlawful. If any Participant attempts to compromise the integrity or the legitimate operation of the Challenge by hacking or by cheating or committing fraud in any way, the Organizer may claim damages to the fullest extent permitted by law.
15.3 The Organizer reserves the right to modify these Terms at any time, without warning or notice, and to suspend, withdraw or cancel the Challenge for any reason and at any time, at its sole discretion and without incurring any liability.
15.4 The execution of the Challenge and the interpretation and enforcement of these Terms shall be exclusively governed by and construed by the laws of Spain. Any conflict regarding the Challenge or these Terms shall be subject to the exclusive jurisdiction of the courts of Spain.
15.5 If you have any questions about these Terms, please get in touch with us via the Email Organizers section.

----------Please add the following information ----------

I agree to the above Terms.
Full name of Participant:

_____
Grand-Challenge username:

_____
Institution: _____
Ethical considerations, if applicable: _____

_____
Email[1]: _____
Signature: _____. _____Date: _____, 2023.

I participate[2]: Individually ☐ In a Team ☐

If you participate as part of a Team, please add the following information:

Name of the Team[3]:

_____

Full name(s) of the other Team member(s)	Email(s) of the other Team members(s)	Signature of the other Team members(s)

Annex 5: Press release announcing the opening of registrations

The CHAIMELEON Open Challenges: a unique opportunity for European scientists to advance cancer research with AI

- **The CHAIMELEON Open Challenges offer a unique opportunity for researchers to collaborate and develop new solutions that can significantly impact cancer diagnosis and treatment.**

[1] Please, use the same e-mail as the one used to register and verify in www.grand-challenge.org.
[2] Cross, or mark in any other way, the applicable option.
[3] Please, only include lowercase letter and numbers. Do not use any special characters or spaces in the team's name.

- **The CHAIMELEON (Accelerating the lab to market transition of AI tools for cancer management) project is funded by European Union's Horizon 2020 research and innovation programme, which promotes scientific excellence, innovation, and international competitiveness.**
- **Quibim will coordinate and oversee the open challenges, leveraging the company's expertise in applying AI to cancer research and medical imaging.**

Valencia, Spain. July 3rd, 2023 – Cancer is the second leading cause of death in Europe[1]. With 3.7 million new cancer cases in Europe each year, it is clear that clinicians require innovative tools and resources to improve cancer diagnosis, therapy, patient selection, and prediction. Artificial intelligence (AI) has emerged as a promising technology that can support these goals. In the search for new AI opportunities to advance medical research and improve patient outcomes, the consortium partners of the EU-funded CHAIMELEON Project have created the **CHAIMELEON Open Challenges**.

The CHAIMELEON Open Challenges is a competition designed to train and refine AI models to answer clinical questions about five types of cancer: prostate, lung, breast, colon, and rectal. Participants are challenged to collaborate and develop innovative AI-powered solutions that can significantly impact cancer diagnosis, management, and treatment.

They will be evaluated considering a balance between the performance of their AI algorithms to predict different clinical endpoints such as disease staging, treatment response or progression free survival and their trustworthiness. Those who take on the challenge can win a total prize pool of €20,000 per challenge, split amongst the winners, with €100,000 in prizes.

The CHAIMELEON Open Challenges offers a unique opportunity for researchers to collaborate and develop new solutions that can have a significant impact on cancer diagnosis and treatment. The registration for the challenges will open on May 31st, 2023 and will be available until the end of August 2023. The challenges will be divided in two phases: the Classification Phase and the Championship Phase.

The **Classification Phase** will extend from July to September 2023. In this phase, any participant can join and download a highly controlled cancer dataset. The dataset will consist of post-processed (i.e., harmonised) images associated with specific clinical variables, ensuring a level playing field for all participants. The participants will train their AI models and compete to be among the top on the leaderboard.

The **Championship Phase** will extend from October to December 2023. In this phase the top 40 participants from the previous phase will be invited to compete on an even grander stage, using the CHAIMELEON platform to train their algorithms. This phase will include five different challenges, one for each cancer type (prostate, lung, breast, colon, and rectal), with a total prize pool of 20.000€ per challenge, split among the winners. Original images and associated clinical data, along with different image pre-processing and harmonization tools, will be available to participants who have passed the qualifying round cut-off point. The same computational resources will be assigned to each participant; therefore, each participant can decide which challenges to tackle and apply their strategies accordingly.

Quibim will be the leading specialised company managing the challenges, as it has vast experience in cancer research through AI. Ángel Alberich-Bayarri, CEO and co-founder of Quibim, says, "The excitement of being part of this one-of-a-kind project is immense; we get to participate in what will be a significant step forward in cancer research. The CHAIMELEON Open Challenges are an encouraging opportunity for the scientific community because they will enable researchers to leverage the power of AI to develop new solutions."

The challenges are open to the whole scientific and tech community interested in AI. They are a unique opportunity to showcase how AI can be used to advance medical research and improve patient outcomes within the CHAIMELEON project.

To learn more about CHAIMELEON Open Challenges, visit https://chaimeleon.eu/open-challenges

About the project

The CHAIMELEON Project develops an EU-wide interoperable repository that will enable researchers, data scientists, and clinicians to develop and validate AI tools for improved cancer management. It aims **to create a cloud-based data repository of cancer images**.

This repository will have multimodality imaging and related clinical data from patients diagnosed with lung, breast, prostate, and colorectal cancers, making it one of the most comprehensive of its kind in Europe. The project brings together a consortium of 18 organisations across Europe, including research institutions, hospitals, and companies specialising in AI and medical imaging: Fundación para la Investigación del Hospital Universitario la Fe de la Comunidad Valenciana (ES), Universita di Pisa (IT), Universita Degli Studi di Roma la Sapienza (IT), Centro Hospitalar Universitário de Santo António (PT), Policlinico San Donato (IT), College des Enseignants de Radiologie (FR), Universiteit Masstricht (NL), Charité Universitätsmedizin Berlin (DE), Imperial College London (UK), Ben-Gurion University of the Negev (IL), Universitat Politècnica de Valencia (ES), GE Healthcare (DE), Quibim (ES), Medexprim (FR), Bahia (ES), Matical Innovation (ES), European Institute of Biomedical Imaging Research (AT), Universitat de Valencia (ES).

[1] Eurostat. (March 2023). Causes of death statistics. Statistics Explained.

About Quibim

Quibim was born from the ambition of transforming imaging into a catalyst for precision health. They do this by designing pioneering tools that unlock imaging data to improve patient outcomes. The brand is linked to company values, based on a deep understanding of the modern science of imaging data and finding a way to transform this data into actionable predictions. To achieve this, Quibim partners with top-tier biopharma companies to detect pathologies early and to predict outcomes in oncology/immunotherapy, immunology, inflammation, and neurology using MRI, CT, and PET imaging, leading to new regulatory cleared Medical Devices marketed to healthcare providers. The company is specialised in the development of AI models created by the use of real-world evidence (RWE) projects and biopharma partners to extract new insights from images; thereby developing novel quantitative imaging biomarkers to deeply analyse disease mechanisms, advance drug development, and monitor treatment progress using a whole-body approach.

Quibim leads RWE studies with 100M+ de-identified research imaging registries from 150.000+ oncology patients.

EU funding

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 952172.

Disclaimer

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Annex 6: Social media advertising campaign

CONTEXT / ChAImeleon / Paid Media

ChAImeleon Open Challenges

The project: Quibim is participating in the European project Chaimeleon, which integrates Open Challenges. The European scientific community working with AI is granted access to a repository of project images to train their AI algorithms. This will contribute to the development of solutions to help fight cancer.
Prize: €100,000 to be distributed among the winners.

Objective: To promote the Challenge to the scientific community in Europe and drive traffic to the landing page hosted on the official project domain (chaimeleon.eu).

Target audience: Users interested in artificial intelligence, master's students, and those pursuing careers related to biomedicine, biotechnology, and related fields.

>> Next, we will analyze the most interesting **channels**, **segmentations**, and **investment** proposals.

CHANNELS / ChAImeleon / Paid Media

LINKEDIN ADS

Brand Awarness / Traffic Campaign

Audiences

Locations: Portugal, United Kingdom, Germany, Netherlands, Italy, Austria, France, Spain.

Member Groups: Bioingenieria y biofisica, Biomedicina, Biotecnologiaaldia, Bio Careers, Biotech and Pharma Professionals, Biomedical Engineering, Bio-IT World
Member Interests: Biotechnology
Member Skills: Biomedicine, Biotechnology Industry, Artificial Intelligence (AI), Biomedical Devices, AIOps, Generative AI, Biotechnology, Bioengineering
Fields of Study: Bioengineering and Biomedical Engineering, Biotechnology
Job Titles: Biomedical Scientist, Biomedical Technician, Biomedical Engineer
Company Industries: Biotechnology Research

Forecasted results

Target audience size: 8,100,000+

Recommended creativity formats
1 static image
1 carousel or short video

CHANNELS / ChAImeleon / Paid Media

TWITTER ADS

Traffic Campaign

Audiences

Locations: Portugal, United Kingdom, Germany, Netherlands, Italy, Austria, France, Spain.

Keywords: ai, artificial intelligence, biomedicine, bioengineer, bioingeniero, biomedicina, biomedical, #artificialintelligence, #ai, bioengineering, biotechnology, #artificial #intelligence, #biotech, imaging ai, #biotechnology, bioinformatics, bioscience, biosciences

Follower look-alikes: @chaimeleon_eu, @QuibimBiomarker

Forecasted results

Target audience size: 19.300,00 - 21.300,00

Recommended creativity formats
1 static image
1 carousel or short video

PLAN / ChAImeleon / Paid Media

We have made some forecasts of results based on data provided by advertising platforms. We propose two different investment scenarios for the campaigns in the targeted countries.

Option 1: We only have one campaign on LinkedIn with a reach objective, in order not to dilute the budget too much.
Option 2: We have a larger budget, where we would work on a reach campaign combined with a traffic campaign on LinkedIn, as well as a campaign on Twitter, targeting traffic. Once the campaigns are launched, we will be able to recognize which strategies and formats work best.

Timing (approximate, dates to be confirmed):
Start > May 15th (registration opens on)
End > On June 30th.
> Number of campaign days: 45

These estimates may vary depending on competition, ad quality, budget...

The platforms do not provide us with unique reach data for targeted traffic.

OPTION 1	BUDGET		REACH - Users		TRAFFIC - Clicks	
PLATFORM	Daily	45 days	Daily	45 days	Daily	45 days
LinkedIn Ads - Reach	22,00 €	990,00 €	4.174,57	187.855,79	/	/

OPTION 2	BUDGET		REACH - Users		TRAFFIC - Clicks	
PLATFORM	Daily	45 days	Daily	45 days	Daily	45 days
LinkedIn Ads - Reach	30,00 €	1.350,00 €	5.693	256.167	/	/
LinkedIn Ads - Traffic	15,00 €	675,00 €	/	/	21	925
Twitter Ads - Traffic	20,00 €	900,00 €	/	/	33	1.500
Total	65,00 €	2.925,00 €	5.693	256.167	54	2.425

KPI's	€	
LinkedIn Ads - Reach	5,27	CPM
LinkedIn Ads - Traffic	0,73	CPC

PLAN / ChAImeleon / Paid Media

RESUME | 45 days campaign

	platform	budget	reach	traffic/clicks
option 1	in	990€	188K	-
option 2	twitter in	2.925,00 €	256K	2.4K