ASCAPE Open call sub-call 1 description

Sub call 1 name: Evaluation of ASCAPE Open AI infrastructure in healthcare institutions

Expected ASCAPE contribution: €40.000 (extra points/funding will be awarded in case applicants will bring/use their own datasets), access to ASCAPE framework, synthetic data samples, technical guidance and support, communication services.

Admissibility conditions: Proposals must be submitted through the ASCAPE page at fundingbox.com. Specific requirements are provided there.

Eligibility conditions:

- Only countries and legal entities indicated as eligible in Guide for Applicants can be funded. In any other case your proposal will be excluded.
- Data used must be anonymized.

Deadline: December 10, 17.00 CET.

Scope: ASCAPE aims to take advantage of recent developments in Big Data and artificial intelligence to support the quality of life and health of breast and prostate cancer patients after treatment. ASCAPE AI models, based on large amounts of data, will provide physicians (not only oncologists but also primary care professionals) with an additional source of knowledge, complementing existing knowledge from clinical trials, guidelines, and clinical experience. The knowledge gathered in ASCAPE AI models can be immediately applicable in cases of individual patients to (a) provide predictions about their state of health and (b) suggesting to doctors Quality-of-Life improving health interventions. This will be done with the help of a user-friendly interface that will allow the doctor to explore different options and visualize their effect. ASCAPE aims at making these tools available to large-and small-sized healthcare providers, to primary care centers supporting cancer patients after cancer treatment, individual doctors, researchers, SMEs, or any other party that could utilize them for the benefit of cancer patients.

Sub-call 1 aspires to set the testing ground for the evaluation of ASCAPE AI open platform in a variety of external to the project settings including hospitals, a primary healthcare institutes, and a setting supporting patients remotely in parallel with their existing healthcare providers. The

ASCAPE sub call 1, aims to demonstrate ASCAPE's ability to live up to its objectives and provide the necessary feedback to focus the technical effort to address medically related problems shaping the ASCAPE framework in a way that ensures its application to the multitude of requirements arising from the heterogeneity of cancer treatment landscape.

Given their focus on QoL, the sub-call 1 will need sufficient relevant data points from breast and prostate cancer (or even different kinds of cancer) patients for the ASCAPE AI framework to be tested. Ideally, large quantities of relevant data would be available by the participants of the sub-call 1 and efforts would concentrate on optimizing what ASCAPE can do and how well using the available data. However, in the medical domain, there are significant challenges in sharing non-aggregated anonymized patient data, let alone sharing them. As a result, any knowledge obtained from data collection in a study is restricted on general trends and not made available to AI algorithms that could apply it to specific patient cases.

ASCAPE's differentiation is that it allows knowledge from data collected at one site, either as part of a study or as part of a healthcare provider's standard protocols of patient monitoring, to be captured in AI models that can be shared and applied to individual patient cases. ASCAPE pilots will engage in data bootstrapping initiated with retrospective datasets collected from the ASCAPE consortium coupled with prospective data (optionally and with more funding if included) collected during the sub-call1 used to continuously update the AI models. As the data for ASCAPE knowledge increases and predictions and intervention suggestions can be made with greater confidence, ASCAPE functionalities available to the doctors will gradually increase during the call.

The evaluation of the ASCAPE AI-based framework in healthcare regarding physicians' views and experience needs to consider different aspects. The evaluation of ASCAPE will be focused on three axes:

(a) Impact of ASCAPE on relevant metrics in clinical practice: Within this aspect, the following evaluation metrics can be considered:

- ASCAPE's efficiency to capture relevant QoL issues on time.
- Changes in management or referrals could be made due to ASCAPE.
- Usefulness of the information provided by ASCAPE.
- Acceptability of integrating ASCAPE services into clinical practice.
- Assessment of the time needed to use ASCAPE in clinical practice.

(b) Interaction between ASCAPE and physicians

This aspect includes issues related to the interaction between the ASCAPE platform and applicants as usability, accessibility, and qualitative assessment of the interface.

(c) Experience using the ASCAPE platform

This aspect includes the more general issues on physicians 'experiences in using the ASCAPE platform as trustworthiness, how confident physicians are regarding the reliability of ASCAPE, and

psychological aspects in using an AI-based platform in clinical practice as perceived substitution crisis and behavioral intention.

Expected outcomes:

- You should demonstrate how the results of the trials can improve the services to support cancer patients and the quality of life of them and their families.
- Demonstrate the level of scalability of your trials plan i.e., how it can be adapted to address medical conditions or type of cancers of wider groups (end-users).
- At the end of the clinical evaluation, you are expected to provide a detailed user experience report and provide your recommendations for improvements that the ASCAPE framework may include in future releases.

Inclusion and Exclusion Criteria for applicants bringing their data

This section intends to throw light on the inclusion and exclusion criteria laid down separately by each participant in ASCAPE Open Sub-call 1 on the requirements for recruitment of research participants or use of their data (in the case applicants plan to test the ASCAPE platform with their data). Note that the research provided under certain proposals provides for the use of both prospective data and retrospective data for the purpose of ASCAPE Open Call.

(A) Breast Cancer

(AI) Inclusion Criteria for Breast Cancer patients

Early breast cancer

- Histologically proven breast cancer (any subtype)
- Must be above the age of 18
- No clinical evidence of metastatic disease
- Able for curative treatment with surgery with or without oncological treatment (endocrine therapy, chemotherapy, radiotherapy as neoadjuvant or adjuvant)
- No prior malignant tumor during the previous 5 years, except for in situ carcinomas of the cervix or basal or squamous cell carcinomas of the skin adequately treated
- Signed informed consent before study entry
- Ability to utilize smartphone, apps, and wearables.

Metastatic breast cancer (early phase)

- Histologically proven breast cancer (any subtype).
- Must be above the age of 18
- Under 1stor 2ndline oncological therapy.
- Life expectancy of at least 6 months.
- Signed informed consent before study entry
- Ability to utilize smartphone, apps, and wearables.

(AII) Exclusion Criteria for Breast Cancer patients

Early breast cancer

- Metastatic disease not amenable for curative treatment.
- Known history of allergy to the wearable material.
- Inability to give informed consent.
- Inability to utilize smartphones, apps, or wearables.
- Metastatic breast cancer (early phase)

Newly diagnosed metastatic breast cancer

- Less than 2 prior lines of treatment in metastatic setting for breast cancer
- Life expectancy of less than 6 months
- Known history of allergy to the wearable material
- Inability to give informed consent
- Inability to utilize smartphones, apps, or wearables.

(B) Prostate Cancer

(BI) Inclusion Criteria for Prostate Cancer patients

Early-stage prostate cancer

- Histologically proven prostate cancer
- Must be above the age of 18
- No clinical evidence of metastatic disease
- Able for curative treatment with surgery and/or radiotherapy13
- No prior malignant tumor during the previous 5 years, except for in situ carcinomas or basal or squamous cell carcinomas of the skin adequately treated
- Signed informed consent before study entry
- Ability to utilize smartphone, apps, and wearables.

Non-curative prostate cancer

- Histologically proven prostate cancer
- Must be above the age of 18
- Any treatment line for hormone-sensitive prostate cancer or 1st line treatment for castration-resistant prostate cancer.
- Life expectancy of at least 6 months
- Signed informed consent before study entry
- Ability to utilize smartphone, apps, and wearables.

(BII) Exclusion Criteria for Prostate Cancer patients

Early-stage prostate cancer

- Metastatic disease not amenable for curative treatment.
- Known history of allergy to the wearable material
- Inability to give informed consent.
- Inability to utilize smartphones, apps, or wearables.

Non-curative prostate cancer

- 1 prior line of treatment for castration-resistant prostate cancer.
- Life expectancy of less than 6 months
- Known history of allergy to the wearable material
- Inability to give informed consent
- Inability to utilize smartphones, apps, or wearables