EU Mission on Cancer

Remaining questions from HPP webinar held on 24 November 2021[1]

A. Presentation on the EU Mission on Cancer[2]:

Preamble: The Commission kindly refers stakeholders to the implementation plan[3], which outlines objectives, actions and synergies with a focus on the period 2021-2023.

1. **How will the UNCAN.eu platform underpin the Mission priorities? What will be the different roles in the governance and the rules to join the platform? What about GDPR and interoperability aspects?**

   Purpose: The 'UNCAN.eu' platform will be a unique federated, digital platform where researchers from all over the world share and access high-quality research data to further the understanding of cancer. It will bring all relevant players and information together, based on existing efforts and initiatives in Europe and beyond. It will combine data on/from research, patient health and any other relevant sources (*e.g.* longitudinal cohorts, geographical observation, climate, environmental exposure, social sciences, consumers, nutrition, diet and lifestyle data) at an unprecedented scale. A key expected outcome of UNCAN.eu is that its outcomes will underpin the other three main Cancer Mission objectives that focus on cancer control[4] and will eventually provide solutions for other chronic diseases which often have risk factors in common with cancer.

   Governance and interoperability: A critical part of a future UNCAN.eu platform will be to ensure agreement on issues like governance, a secure data environment, data interoperability and re-utilisation, while guaranteeing full protection of privacy and applying FAIR[5] data principles as per the General Data Protection Regulation. Hence, the platform will build on proven concepts such as privacy-by-design, differential privacy and federated learning, as such fully contributing to the European Data Strategy.

2. **How could Horizon Europe contribute to the implementation of the two new Medical Devices Regulations?**

   The placing on the market, the making available on the market or the putting into service of medical devices and *in vitro* diagnostic medical devices, are regulated by two Regulations:

   - **Regulation (EU) 2017/745** of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC; and

[1] https://ec.europa.eu/info/events/eu-mission-cancer-and-europes-beating-cancer-plan-2021-nov-24_en

[2] https://ec.europa.eu/info/sites/default/files/research_and_innovation/events/presentations/cancer_mission_presentation_j_van_de_loo.pdf

[3] https://ec.europa.eu/info/sites/default/files/research_and_innovation/funding/documents/cancer_implementation_plan_for_publication_final_v2.pdf

[4] to reduce the incidence, morbidity and mortality of cancer and to improve the quality of life of cancer patients in a defined population, through the systematic implementation of evidence-based interventions for prevention, early detection, diagnosis, treatment, and palliative care

[5] FAIR principles: Findable, Accessible, Interoperable, and Reusable

- **Regulation (EU) 2017/746** of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU.

Horizon Europe has no direct role in implementation. Instead, the Horizon Europe work programme 2021-2022 supports research and innovation on medical devices. Extensive work is being carried out by the relevant Commission services and the Member States to facilitate the implementation[6].

3. Can you share information on the process and criteria for the establishment of the new Mission Board?

The call to establish new Mission Boards for each mission will be launched early January 2022 and will specifies the process, the requested expertise and selection criteria.

4. Does the Mission on Cancer foresee actions on patient safety?

Patient safety is at the core of actions foreseen under the Horizon Europe Mission on Cancer. Safety will be addressed by three of the four main objectives of the Cancer Mission: prevention; optimize the diagnosis and treatment of cancer; and quality of life. This includes patients having access to the latest, personalised, minimally invasive treatments, and with minimal side effects. The unique biology and needs of children, adolescents and young adults affected by cancer will be taken into account when developing new treatment and care solutions.
The establishment of a network of Comprehensive Cancer Infrastructures by 2025 is a concrete example that will also contribute to enhance patient safety. This action will ensure that patients have an access to comprehensive cancer structures in their country, which apply high standards of care, benefitting from improved diagnostics and treatments.

In close synergy with the Mission on Cancer and the Europe's Beating Cancer Plan, the recently launched Strategic Agenda for Medical Ionising Radiation Applications (SAMIRA)[7] aims at securing the supply of medical radioisotopes in Europe, improving quality and safety of diagnostic and therapeutic applications of ionising radiation, and promoting research and innovation in medical applications of ionising radiation.

For the 2021-2025 period, the Research and Training Programme of the European Atomic Energy Community (EURATOM) will support research on the protection of patients receiving diagnostic and cancer therapies involving radiation sources.

5. Is there any indication on what the RIA topics are likely to be?

The first four topics to support the goal and four main objectives of the Mission on Cancer were published in 2021[8]. Future topics will address the main areas and actions as described in the implementation plan.

[6] https://ec.europa.eu/health/md_sector/new_regulations_en
[7] https://ec.europa.eu/energy/sites/default/files/swd_strategic_agenda_for_medical_ionising_radiation_applications_samira.pdf
[8] https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/wp-call/2021-2022/wp-12-missions_horizon-2021-2022_en.pdf

6. **In 2023, the Commission shall provide a mid-term review of the Mission to the European Parliament. What would constitute success?**

   By 2023, preparations to establish the main initiatives of the Mission will have started. In particular, the blueprint for a fully-fledged UNCAN.eu platform will have been created, with researchers starting to share and having access to high quality data. Moreover, the Mission will have set a common strategic R&I agenda on cancer, in close consultation with Member States, the European Parliament and stakeholders, which will help steer national efforts and streamline investments towards its objectives. The Mission will have established structured dialogues with stakeholders and citizens to co-create EU-supported cancer activities and policies.

7. **What efforts / inputs are expected from Member States to support the Mission?**

   Concrete Member States' support is essential for the Cancer Mission to deliver results by 2030, as they are responsible for the organisation of nationalresearch programmes, health systems, setting national cancer priorities and making available the necessary resources, all of which vary between Member States. At the same time, the Mission on Cancer will support Member States with strategic tools and governance to work closer together, generating new evidence, allowing efficiency gains as well as leveraging considerable funding at EU level in support of implementation.

   For example, to ensure a continuous dialogue with and between Member States, DG SANTE and DG RTD created a joint subgroup on cancer[9] under the Steering Group for Health Promotion and Disease Prevention (SGPP)[10], composed of experts from research and health ministries. Thematic groups have been set up under this subgroup to focus on the implementation of a cancer inequalities registry and a network of comprehensive cancer infrastructures/centres.

8. **How will the Commission interact with stakeholders in the implementation phase of the Cancer Plan?**

   As part of the joint governance structure of the Mission on Cancer, DG SANTE and DG RTD have established a dedicated stakeholder contact group under the EU Health Policy Platform[11]. The group will be consulted in its entirety on a regular basis, but also *via* its thematic subgroups on an *ad hoc* basis to discuss implementation aspects of the Europe's Beating Cancer and the Mission on Cancer.

9. **How does the Commission envisage utilising, encouraging, regulating and investing in *in silico* medicine and computer modelling/simulation to further support cancer treatment development?**

   In silico medicine and modelling/simulation will be supported by calls for proposals to be launched under objective 3 of the Cancer Mission (Horizon Europe Programme), by calls for proposals under the Europe's Beating Cancer Plan (EU4Health Programme) and by the Digital Europe Programme[12]. The latter is managed by DG CNECT, which is in charge of digital policies.

[9] https://ec.europa.eu/health/health/non_communicable_diseases/events_en#anchor3
[10] https://ec.europa.eu/health/non_communicable_diseases/steeringgroup_promotionprevention_en
[11] https://webgate.ec.europa.eu/hpf/
[12] https://digital-strategy.ec.europa.eu/en/activities/digital-programme

10. Can you explain more about the clinical trials programme for diagnostics? How providers or genomics industry groups can contribute?

Under objective 3, the Mission on Cancer will support an innovative clinical trial programme focused on diagnosis optimisation, building on existing and minimally invasive diagnostic techniques, including imaging, and implementation research of validated diagnostic methods (*e.g.* imaging, tissue, fluid, clinical biomarkers). Stakeholders will be consulted through the stakeholder contact group under the EU Health Policy Platform (see also question 8).

11. Timelines for the different actions

The timelines for the different actions foreseen under the Mission on Cancer can be found in its implementation plan[13].

12. Eligibility conditions for third countries' participation in the next Mission Work Programme topics

Association to Horizon Europe is governed by the Horizon Europe Regulation 2021/695[14].The list of countries that are now formally associated to Horizon Europe:

- Norway
- Iceland
- Turkey
- Moldova
- Georgia
- Israel
- Montenegro
- Serbia

More specifically on Switzerland:
Currently Switzerland is considered as a third country. No association related negotiations are ongoing, all engagements are on hold.

In general, any legal entity, regardless of its place of establishment, including legal entities from non-associated third countries or international organisations is eligible to participate (whether it is eligible for funding or not), provided that the conditions laid down in the Horizon Europe Regulation have been met, along with any other conditions laid down in the specific call topic which may provide for limitations or restrictions in certain cases.

Legal entities established in Switzerland are currently not automatically eligible for funding in Horizon Europe. Negotiations regarding the association of Switzerland to the next generation of EU programmes are currently on hold, therefore Switzerland is considered as a non-associated third country, and remains eligible for Horizon Europe participations under the conditions applicable to non-associated third countries. As a matter of consequences, legal entities

[13] https://ec.europa.eu/info/sites/default/files/research_and_innovation/funding/documents/cancer_implementation_plan_for_publication_final_v2.pdf

[14] Regulation (EU) 2021/695 of the European Parliament and of the Council of 28 April 2021 establishing Horizon Europe – the Framework Programme for Research and Innovation, laying down its rules for participation and dissemination, and repealing Regulations (EU) No 1290/2013 and (EU) No 1291/2013 (OJ 12.5.2021 L 170/1).

established in Switzerland are not eligible for funding, except if provided for in the specific call conditions, or if their participation is considered essential for implementing the action by the granting authority, for example in view of their outstanding competence/expertise, access to particular research infrastructures, access to particular geographical environments or access to particular data. Therefore, and if not exceptionally eligible for funding, legal entities established in Switzerland would participate as associated partners instead and would not be eligible to declare costs in EU grants.

All relevant information on the eligibility of Swiss entities, in a form of an FAQ, is available in the EC's Funding and Tender Portal[15].
Please also consult this page:
https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/list-3rd-country-participation_horizon-euratom_en.pdf

More specifically on the United-Kingdom:
The United-Kingdom will be associated by means of a Protocol (Protocol I) to the Trade and Cooperation Agreement (TCA). However, there is no date set yet for the EU-UK Specialized Committee to adopt the Protocol. Association will take place in due course. Therefore, transitional measures in place for Horizon Europe. The work programmes of Horizon Europe state that legal entities established in countries listed in the HE Programme Guide are treated, from an eligibility perspective during the submission and evaluation of proposals, as if they were established in already associated countries. This is conditional upon the entry into force (or provisional application) of the association agreement with a given third country by the time of the signature of the grant agreement.

13. What is the expected role of comprehensive cancer centres in the deployment of the Mission on Cancer?

The Mission on Cancer foresees support to creating a Network of Comprehensive Cancer Infrastructures (CCIs) by 2025. These CCIs will consist of either national and/or regional infrastructures that provide resources and services to support, improve and integrate cancer care, research, training of care professionals and education for cancer patients, survivors and families/carers. Once set up at regional and/or national level, the CCIs are envisaged to form a network between Member States to enable cross-border cooperation that will improve patients' access to high-quality cancer care and clinical trials on innovative diagnostics and treatments.

14. Will a definition of "personalised medicine" be available? Is it limited to precision medicine or does it also include patients' preferences?

While there is no universally accepted definition, the EU Health Ministers, in their Council Conclusions on personalised medicine for patients published in December 2015[16], defined personalised medicine as: 'A medical model using characterization of individuals' phenotypes and genotypes (*e.g.* molecular profiling, medical imaging, lifestyle data) for tailoring the right therapeutic strategy for the right person at the right time, and/or to determine the predisposition to disease and/or to deliver timely and targeted prevention.'

[15] https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/support/faq;type=0,1;categories=;programme=null;keyword=Switzerland%20in%20Horizon%20Europe;period=null;status=0,1;sortQuery=relevance;faqListKey=faqSearchTablePageState
[16] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:C:2015:421:FULL&from=EN

B. Presentation on the Europe's Beating Cancer Plan[17]:

1. **When extending targeted cancer screening and prevention why not consider a "transversal" approach that addresses cancers with shared triggering/risk factors? For example, scientific evidence shows a role for HPV in oral and oropharyngeal cancer similarly to cervical cancer and a potential beneficial impact of HPV vaccination in head-and-neck cancer. A similar thing might apply to tobacco's role in lung and, again, in oral cancer.**

   The Commission already follows a transversal approach when it comes to preventing cancers that are caused by the same risk factors (for example HPV vaccination, alcohol and tobacco consumption). Screening approaches would need to be site- and risk group-specific, taking into account available technologies, effectiveness and cost-effectiveness. Through the Cancer Mission, the Commission has published the following call for proposals: *HORIZON-MISS-2021-CANCER-02-01: Develop new methods and technologies for cancer screening and early detection*[18]. Applicants could address risk-based and transversal approaches that would allow screening for several cancers at the same time.

2. **When will the tender for the EU mobile applications for cancer prevention be launched?**

   Tenders will be announced on the website of the European Health and Digital Executive Agency (HaDEA). Specific timelines cannot be given.

3. **When are Council Conclusions on strengthening the European Health Union expected?**

   These Council Conclusions were adopted at the Employment, Social Policy, Health and Consumer Affairs Council of 7th December 2021[19].

4. **Can you provide information on how to be a member of the general assembly?**
   Further information available on this page: https://ec.europa.eu/newsroom/sante/newsletter-archives/32249

5. **When will the six thematic groups be announced? How they will differ from the Stakeholder Contact Group?**
   Membership for the thematic groups will be announced at the latest in January 2022. The thematic groups are sub-groups of the Stakeholder Contact Group.

6. **When will the new European initiative on colorectal cancer start?**
   The initiative has already been launched: https://healthcare-quality.jrc.ec.europa.eu/ecicc.

[17] https://ec.europa.eu/info/sites/default/files/research_and_innovation/events/presentations/cancer_mission_presentation_m.schuppe.pdf
[18] https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/wp-call/2021-2022/wp-12-missions_horizon-2021-2022_en.pdf
[19] https://data.consilium.europa.eu/doc/document/ST-14886-2021-INIT/en/pdf