



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Human Medicines Division

## Oncology Working Party (ONCWP) work plan Priorities for 2024

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Work plan period: January 2024 – December 2024



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# Priorities for 2024

## 1. Guidelines

### 1.1. EU Guidelines

#### *Action: Lead*

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#### **Guideline on the clinical evaluation of anticancer medicinal products, EMA/CHMP/205/95 Revision 7**

<b>Target date</b>	Concept paper to be agreed in Q2 2024 Adoption by the CHMP and Publication of the concept paper in Q3 2024
<b>Comments</b>	Lead: Pierre Demolis

#### *Action: Lead*

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#### **Guideline on the evaluation of therapeutic radiopharmaceuticals**

<b>Target date</b>	Concept paper release in Q1 2024 Guideline release for public consultation in Q4 2024
<b>Comments</b>	ESEC radiopharmaceuticals group

#### *Action: ONCWP involvement*

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#### **Reflection paper** on approaches to generate, collect and analyse patient experience data (PED)

<b>Target date</b>	1 <sup>st</sup> draft in Q2 2024 Adoption by the CHMP and Publication of the reflection paper in Q3 2024
<b>Comments</b>	Lead: EMA PED team, ONCWP involvement

#### *Action: in collaboration with the Cardiovascular working party*

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#### **Reflection Paper** for the assessment of cardiovascular safety of oncology medicinal products.

<b>Target date</b>	Concept paper to be released for public consultation 2Q 2024
<b>Comments</b>	To be developed in collaboration with the CVS WP

## 2. Training for the network and knowledge building

- In the framework of the Oncology ESEC, the WP will organise core trainings for the assessors working closely with the European Network Training Centre (EU NTC), ensure knowledge sharing on emerging issues and foster interactions between assessors in the oncology area.

- ESEC webinars are planned to continue to be focusing on conditions of high interest with convergent development, however trainings or awareness sessions may also be developed on any new or revised guidelines or following finalisation where appropriate.

### **3. Contribution to dialogue and engagement with stakeholders and external parties**

#### ***3.1. Workshops***

The following workshops are proposed in 2024:

- EMA/EORTC soft tissue and bone sarcoma multi-stakeholder workshop: How can we develop new treatments in ultra-rare sarcomas, as a model for ultra-rare tumours? (January 2024).
- EMA/EORTC multi-stakeholder workshop: how can PROs and HRQoL data inform regulatory decisions? (29<sup>th</sup> February 2024)
- ONCWP / EMA workshop; Brainstorming on identifying needs to be addressed in the Anticancer Medicinal products Guideline revision 7 (April 2024).
- EMA Multi-stakeholder Workshop on clinical end points and surrogates, in particular in the (neo)adjuvant setting.
- The ONCWP will continue to contribute to workshops organised by other stakeholders, interested parties (e.g. EHA, IMS) or other international regulators where appropriate.

#### ***3.2. Collaboration with Interested parties and other stakeholders***

- ONCWP will continue to participate to the discussion and meetings of the Cancer Medicines Forum (CMF), co-established by EMA and EORTC as a multi-stakeholder forum bringing together representatives from academic organisations and the network and serving as a communication channel with the academic community in oncology, to address questions and issues related to oncology drug development emerging from the academic community in a multidisciplinary environment.
- ONCWP participation to the collaboration between EMA and HTA stakeholders in relation to bridging from Benefit /Risk to relative effectiveness assessment.
- ONCWP members will continue to support interactions or events with relevant interested parties where appropriate, and look for opportunities to contribute to the deliverables from these interactions (e.g. publications).
- ONCWP members will continue to participate to relevant multi-stakeholder platforms, such as the Cardiac Safety Research Consortium (CSRC), ACCELERATE.
- Joint EHA-EMA symposium during the EHA Congress 2024 (June 2024).

### **4. International activities**

The ONCWP participates in the following International Activities:

- Participation in International Oncology cluster monthly teleconferences and joint activities with international regulators
- In collaboration with the FDA: Joint webinars/conversations on cancer
- ONCWP Involvement in paediatric Oncology activities with the FDA