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Submission of comments on ONC Workplan 2025-2027

Fields marked with * are mandatory.

Introduction to the survey on submission of comments on Oncology Workplan 2025-2027

Please click on the link below to donwload the draft WP Workplan 2025-2027.
ONCWP_Rolling_Work_Plan.pdf

The public consultation is launched on 10 September 2024 until 10 October 2024 11:59 pm, CET.

Those participating in the consultation are asked to please submit comments via the EU Survey tool, by using the specific table for each section. Please note that login is not required to fill in the survey.

If you respond on behalf of a company that is affiliated with an EU (trade) industry organisations, you are encouraged to share your comments to the respective affiliated EU (Trade) Industry organisation.

Before submission, a draft of the comments can be saved in the EU Survey tool. Once submitted, comments can be edited (by the deadline) by clicking on "Edit contribution" in the link https://ec.europa.eu/eusurvey/ and entering your ID contribution that can be found on the pdf copy of your submission sent via email.

You are invited to provide your organisation or name, country and email address below for the purpose of this public consultation (for further information, please see EMA's Data Protection Statement below).

Data Protection Statement

EMA Privacy Statement
All personal data provided within this survey questionnaire will be processed in accordance with Regulation (EU) 2018/1725 on the protection of individuals regarding the processing of personal data by the Union institutions and bodies on the free movement of such data.

This data protection statement provides details on how the Agency, in its capacity as data controller, will process the information that you have given in your questionnaire.
Internally, an 'Internal Controller' has been appointed to ensure the lawful conduct of this processing operation. The contact details of the Internal Controller are the following: Datacontroller.HumanMedicines@ema.europa.eu

Collection of data

EMA will collect all the personal data in this questionnaire, such as your name, organisation, your view on the topics subject to the survey, country of residence and your contact details. Please do not reveal any other personal data in the free text fields. EMA does not directly intend to collect personal data but to use the aggregated data for the purpose of this survey.
For the collection of data in this survey, EMA relies on the EU Survey external system. For more information on how EU Survey processes personal data, please see: https://ec.europa.eu/eusurvey/home/privacystatement

The EU Survey external system uses:

- Session "cookies" to ensure communication between the client and the server. Therefore, user's browser must be configured to accept "cookies". The cookies disappear once the session has been terminated.
- Local storage to save copies of the inputs of a participant to a survey to have a backup if the server is not available during submission or the user's computer is switched off accidentally or any other cause.
- The local storage contains the IDs of the questions and the draft answers.
- IP of every connection is saved for security reasons for every server request.
- Once a participant has submitted one's answers successfully to the server or has successfully saved a draft on the server, the data is removed from the local storage.

Your consent to the processing of your data

When you submit this questionnaire, you consent that EMA will process your personal data provided in the questionnaire as explained in this data protection statement. You may also withdraw your consent later at any time. However, this will not affect the lawfulness of any data processing carried out before your consent is withdrawn.

Start of data processing

EMA will start processing your personal data as soon as the questionnaire response is received.

Purpose of data processing

The purpose of the present data processing activity is to collect the views of stakeholders and/or concerned individuals in relation to the subject-matter of the survey. Your personal data may be used to contact you in relation to the feedback you have provided in response to the survey. No further processing of your personal data for any other purposes outside the scope of this specific context is envisaged.

Location of data storage

All data is stored within a secure data centre at the EMA premises which is password protected and only available to EMA staff members.

Publication of data

The following data collected in this questionnaire will be published on the EMA website at the time of issuing the final guideline subject to this survey:

- organisation name (the entity on behalf you respond to this survey)
- or your name (only if you do not respond to the survey on behalf of an organisation)
- your view/comments on the topics concerned

Country information and your email address will not be published.

Retention period

If you complete and submit this survey, your personal data will be kept until the results have been completely analysed and utilised. Your personal data will be deleted by EMA at the latest 5 years after the questionnaire response was submitted. The file of the data as published will remain stored for archiving purposes beyond the maximum 5 years-retention time of the submitted questionnaire responses.

Your rights

You have the right to access and receive a copy of your personal data processed, as well as to request rectification or completion of these data. You may also request erasure of the data or restriction of the processing in accordance with the provisions of Regulation (EU) 2018/1725. You can exercise your rights by sending an e-mail to Datacontroller.HumanMedicines@ema.europa.eu.

Complaints

If you have any complaints or concerns about the processing of your personal data, you can contact EMA's Data Protection Officer at dataprotection@ema.europa.eu.

You may also lodge a complaint with the European Data Protection Supervisor: edps@edps.europa.eu.

* Please confirm that you have read and understood the Data Protection Statement above and that you consent to the processing of your personal data.
  - (●) Yes
  - ( ) No

* Please confirm that you consent to possibly be contacted by EMA in relation to your survey responses to support the finalisation of the document subject this EU Survey.
  - (●) Yes
  - ( ) No

* Please confirm that you consent to the publication of your organisation name, your name (only if you do not respond to the EU Survey on behalf of an organisation) and your survey responses on the EMA website at the time of issuing the final guideline subject to this survey.
  - (●) Yes
  - ( ) No

Should you not want to give consent to publish, please send your objections to Datacontroller. HumanMedicines@ema.europa.eu.

Please be aware that the sender of the comments is responsible to not disclose any personal data of third parties in the comments.

When you have filled in the EU Survey, please use the submission button at the end of the form to submit the comments to the European Medicines Agency.

For additional information, please consult EMA's privacy statement.

Contributor details

* 1. First name

Katarina

* 2. Last name

Nedog

* 3. Professional email address

katarina.nedog@efpia.eu

* 4. Professional affiliation

EFPIA

5. Are you commenting on behalf of an organisation or stakeholder group, then please indicate the name and email of the main contact point (if it differs from the provided above)

- (●) Yes
- ( ) No

5.1. Name main contact point

-

5.2. Email address main contact point

katarina.nedog@efpia.eu

7. Please indicate the type of organisation you belong to

- [ ] Academia
- [x] Industry
- [ ] Healthcare professional
- [ ] Individual
- [ ] Patient and consumer
- [ ] Payers

7.1. Other - please specify

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1. General comments on the Workplan

1. General comments on the Workplan

	Stakeholder name *(to be repeated in all rows to facilitate extraction and identification of comments, thank you.)*	General comment

1	EFPIA	• We welcome the opportunity to comment on the proposed plan and appreciate the intent of collaborating with other regulators to support new drug development and proposed updates to guidelines. • Prioritization of strategic goals is important considering the current resource constraints within the network. Short/Long Strategic goals aimed at enhancing contribution to multistakeholder platforms is supported, it will help promote information exchange and alignment on key areas of interest through a structured dialogue including industry representatives. • The goal of “generating new and updating available guidance” should provide an added value to all stakeholders involved in development and maintenance of oncology drugs. • Reflection of recent trends and learnings in new / updated guidance is positive. Development of new / updated guidelines and reflection papers should always be pragmatic and the resulting documents easy to understand and apply for all stakeholders. The impact on time and cost for development or maintenance of oncology drugs should be estimated and reported as part of the process. This should enable stakeholders (including reviewers, applicants / MAHs and other legitimately interested parties) to better anticipate timing and resources for Oncology Drug Development. • Timelines for developing /updating guidelines can take long, leading them to being outdated before release and example would be the evaluation of anticancer medicines. As part of the working group’s short- and long-term goals, we recommend that the Oncology WP also considers how updates to this and other guidelines can be made in a timely and more frequent manner while still ensuring appropriate stakeholder input. • Operational goals consideration: Identify disease-area “experts” within ONCWP and strengthen collaboration on SA and application assessment (initial MAA and major variation). • Use of AI does not seem to be taken up in the workplan. Clarification how this technology could be leveraged in specific situations for oncology drug development, review / approval and maintenance would be appreciated. • Networking, information sharing and training should not be limited to assessors and “learned societies” but also include applicants / MAHs, to enable a better common understanding on the interpretation of applicable guidance – thus ultimately providing a benefit for patients.
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2. Specific comments on content of the Workplan

Section 1. Strategic Goals

Please include your comments on the long term and short term strategic goals

	Line number(s) of the relevant text *(e.g. 20-23)*	Stakeholder name	*(to be repeated in all rows)* Comment and rationale	Proposed guidance text
1	35-37	EFPIA	Recommend enlarging the source of information reviewed to determine the need for development of new guidelines /reflection papers e.g. SAG, Innovation Task Force, Oncology Portfolio meetings. This would increase efficiency on the need for development of new guidelines in Oncology	Present Review the need for development of new guidelines/reflection papers in Oncology based on emerging needs as identified from EMA scientific advice (SA)/protocol assistance (PA), qualification procedures, and from CHMP discussions. Proposed Review the need for development of new guidelines/reflection papers in Oncology based on emerging needs as identified from EMA scientific advice (SA)/protocol assistance (PA), qualification procedures, Oncology Scientific Advisory Committees, Innovation Task force discussions, Innovation Task Force discussions, and from CHMP discussions.

2	38-39	EFPIA	Recommend adding concrete examples regarding the most recent scientific insights. This would improve clarity for readers.	Present Revise current guidance documents to maintain up-to date information in line with ongoing based on the most recent scientific insights. Proposed Revise current guidance documents to maintain up-to date information in line with ongoing based on the most recent scientific insights e.g. Artificial Intelligence.
3	42-43	EFPIA	Strengthen training of national agency assessors to increase alignment.	Present Provide input to recurrent issues of interest upon request by CHMP with a view to provide guidance to assessors and maintain consistency in the evaluation of medicines. Proposed Provide input to recurrent issues of interest upon request by CHMP with a view to provide guidance to assessors via training sessions and workshops to maintain consistency / increase alignment in the evaluation of medicines.
4	45-46	EFPIA	It would be good to have more details about the expansion of the oncology ESEC	

5	58-61	EFPIA	More guidance needed to support clinical studies in EU	Present Foster collaborative evidence generation by delivering appropriate guidance documents, promote information exchange and contributing to multistakeholder platforms with the aim to further optimize oncology drug development, embrace innovation and contribute to a robust assessment of new cancer treatments. Add new This should also include content-driven guidance for national agency assessors to better support harmonized CTA (via CTIS) assessment, including strengthened participation in scientific advice activities.
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Section 2. Tactical Goals

Section 2.1. Guidance activities

	Line number(s) of the relevant text *(e.g. 20-23)*	Stakeholder name	*(to be repeated in all rows)* Comment and rationale	Proposed guidance text
1	66-75	EFPIA	No comments	
2	80	EFPIA	Activities to be started in 2025 mentions that a draft reflection paper will be released following the CMF workshop in April 2024. For future events it would be useful to know in any post-meeting reports if there are plans to draft reflection papers	
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Section 2.2. Training and workshop activities

	Line number(s) of the relevant text *(e.g. 20-23)*	Stakeholder name *(to be repeated in all rows)*	Comment and rationale	Proposed guidance text
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Section 2.3. Communication and stakeholder activities

	Line number(s) of the relevant text (e.g. 20-23)	Stakeholder name (to be repeated in all rows)	Comment and rationale	Proposed guidance text
1	95-96	EFPIA	• Recommend enlarging the scope with Cancer Drug Development Forum. Oncology WP representatives already interact with CDDF on relevant topics. This would reinforce the value of the publication from CDDF on relevant topics. • Strengthen ESMO interaction for example by organizing/contributing to dedicated sessions to facilitate an exchange on perspective from regulators and other stakeholder on cancer drug development.	Present Continue to engage in the EMA/EORTC / Cancer Medicine Forum and contribute to the publication of relevant outcomes. Proposed Continue to engage in the EMA/EORTC / Cancer Medicine Forum/ESMO; start engagement with Cancer Drug Development Forum and contribute to the publication of relevant outcomes.
2	102	EFPIA	• We recommend to also elaborate on how applicants will be involved in the communication between HTAs and Regulators for either transparency or participation reasons.	Present Contribute to potential collaboration and information exchange with HTA stakeholders to promote transparency and inform bridging from Benefit/Risk to relative effectiveness assessment Proposed Contribute to potential collaboration and information exchange with HTA stakeholders and applicants, e.g. via joint scientific consultations to promote transparency and inform bridging from Benefit/Risk to relative effectiveness assessment

3	104-106	EFPIA	• Stakeholder activities involving industry are welcome, at the moment there are not many opportunities to engage on a constructive dialogue with EU regulators with a focus on oncology. The CMF in April 2024 involving industry was very well received as an example.	
4	110-113	EFPIA	• On the international level, the focus is on new trends. • There are opportunities for learning /leveraging approaches from other regulators and their approach to reviews e. g., acting as an observer on ORBIS and the US RTOT procedure where rolling reviews are permitted and approaches to accelerated procedures such as PMDA's pioneer drug designation.	Add Explore leveraging approaches used by other regulators, acting as an observer in reviews (e.g., ORBIS and US RTOR) and exchanging experiences with other regulators who also offer accelerated procedures.
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Section 2.4. Multi-disciplinary collaboration

	Line number(s) of the relevant text (e.g. 20-23)	Stakeholder name (to be repeated in all rows)	Comment and rationale	Proposed guidance text
1	115-116	EFPIA	• It is important to engage with relevant parties such as the COMBINE, MDCG in order to ensure that any advances under these intiiatives are captured in the anticancer drug development and other relevant guidelines.	
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Section 3. Operational Goals

Please include your comments about pre-submission activities, evaluation and supervision activities

	Line number(s) of the relevant text (e.g. 20-23)	Stakeholder name (to be repeated in all rows)	Comment and rationale	Proposed guidance text
1	120-121	EFPIA	• Early product-related support via ITF is supported, these meetings offer a unique opportunity for industry to discuss latest innovative programs with regulators and involvement of the relevant oncology therapeutic expertise from the EU network would be key for discussions on oncology programs. • Participation in industry Pipeline meetings (or dedicated oncology Pipeline meetings) would also be of high value to gain understanding on the latest developments within the pharma companies, likewise industry would value therapeutic specific feedback in such meetings.	Add New Product-related support in the field of oncology upon request from relevant groups (e.g. Innovation 120 Task Force, Pipeline meetings) as needed.

2	122-123	EFPIA	• Recommend appointing disease-area “experts” within ONCWP to be part of SA and pre-submission meetings and not only upon request. This will enhance the relevance of scientific advice and pre-submission meetings, cross-fertilizing information within the OncWP.	Present The OncWP will provide product-related support in the Oncology field upon request from Committees (e.g. COMP, CHMP) and other working parties such as the SAWP during pre-submission phase. Replacement The OncWP will appoint disease-area “experts” from within OncWP to be part of scientific advice and pre-submission meetings.
3	126	EFPIA	Recommend appointing disease-area “experts” within ONCWP to be part on the review of initial MAA and major Extension of indication type II variation. This will allow to avoid potential Scientific Advisory Group and cross fertilize information with OncWP	Present Support in the field of oncology upon request from Committees and other Working Parties. Proposed The OncWP will appoint disease-area “experts” within ONCWP to be part of the review of initial MA and major extension of indication. Support in the field of oncology upon other requests from Committees and other Working Parties.
4	119-126	EFPIA	Regarding support of pre-submission as well as evaluation / supervision activities, a specific goal seems to be missing, such as broadening capacity or evolving the approach taken.	Proposed new Evaluate how pre-submission as well as evaluation / supervision activities can be managed sustainably in the light of emerging trends.

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Please feel free to suggest additional potential topics for workshops / training etc.

Thank you

Thank you for your contribution.

Contact

Contact Form