

Training on Scientific Advice

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PCWP/HCPWP meeting

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Training for academia on Scientific Advice

- **Project goal:** support academic developers through the creation and offering of tailored training materials on scientific advice
 - Reduce common hurdles, equip academics with practical knowledge, improve quality and interaction and maximise benefits of scientific advice
 - Training useful for any stakeholder interested in / considering to apply for Scientific Advice
- **Training offering**
 - Online narrated video with different clickable modules
 - Slide deck
- **Collaborating expert project** with Rosan Vegter, EATRIS
- In collaboration with **EMA colleagues, SAWP members, academic researchers**

Fee reductions for academic sector for Scientific Advice

- Encourage researchers and developers from academic sector to advance developments
- Fee waiver can be requested by **not-for-profit entities**
 - Under new Fee Regulation, as of 1 January 2025
 - Fee reductions for scientific advice, qualification advice and protocol assistance
 - Verification of **compliance** with the working arrangements for Regulation (EU) 2024/568 on fees and charges payable to EMA. [Fee Regulation Working Arrangements](#)
 - Other fee reductions (e.g., protocol assistance free of charge to academics developing orphan medicines, reductions for small and medium enterprises, advanced therapy medicinal products, medicines for paediatric use, public health emergencies and imperative reasons)

[Section 1.8 Entity not engaged in an economic activity of the Fee regulation Working Arrangement](#)

Training development – ADDIE Model



Interviews with EMA colleagues, SAWP members, academic researchers and developers to identify **common hurdles and suggestions**



Develop clear learning objective
Create a detailed storyboard



Creation of a **detailed script** and **slide deck**.
Iterative review of material: EMA, SAWP, academic researchers and developers



Recording of materials and supporting resources. **Offer training** in multiple formats through EMA and EATRIS platforms



Measure **use and value** through post-training surveys and KPI tracking



Training for Academia on Scientific Advice – Modules

- 1 What is scientific advice
 - What is SA
 - Who can apply
 - What are the benefits of SA and when useful
 - Fee waiver & procedural steps
- 2 Online submission portal IRIS
- 3 How to write your briefing document
 - Introduction
 - Overview of product development
 - Questions and applicant's position
 - References and Annexes
- 4 Scientific advice questions
 - Scope and structure questions
 - How to formulate questions
 - Developing your position
 - Out of scope questions
- 5 How scientific advice works
 - Process, timeline, who is involved
- 6 Other EMA interaction pathways
 - Protocol assistance, QoNM, national SA, ETF, Academia BM, ITF, ACT-EU Helpdesk, SME

- Direct offering of support, to also help reduce common hurdles for applicants, especially academic developers
- Increased awareness among academics and other stakeholders on Scientific Advice, how to prepare, how to frame questions and make effective use of the Scientific Advice process
- Reduced administrative barriers and improved quality of Scientific Advice submissions



Feedback / suggestions?





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