# Curriculum – EU Network Training Centre:
Oncology pilot educational program for external experts

## Part 1: General Regulatory curriculum

<table>
<thead>
<tr>
<th>#</th>
<th>Topic</th>
<th>Contents</th>
<th>Presenter</th>
</tr>
</thead>
</table>
| G1 | Introduction: Overview of the regulation of medicines in Europe | The overall objective: protecting patients
Regulators’ role in the life cycle of a medicine
The European medicines regulatory network
EMA’s committees
Mandate of CHMP and how CHMP works | Harald Enzmann
CHMP chair
Head of European & International Affairs, BfArM - Germany |
| G2 | How does scientific advice work? | The mandate of Scientific Advice Working Party (SAWP) and how it works
Brief description of the various tasks
Interaction with other bodies/committees/working parties
Examples of what is in/out of scope of the SAWP | Paolo Foggi
SAWP chair
Head of Innovation and Pharmaceutical Strategy Division, AIFA - Italy |
| G3 | How do centralised procedures work? | Procedural steps of initial applications, type 2 variations and extensions
Time tables leading to decision making in centralised procedures at the CHMP | Martin Norta
Head of procedure management, BfArM - Germany |
| G4 | Propaedeutic for benefit-risk assessment | The basics of benefit risk assessment as the basics of regulatory decision making, with the focus on clinical efficacy and safety | Francesco Pignatti
Scientific adviser for Oncology, EMA - The Netherlands |
| G5 | Input CTD application, Output regulators’ assessment report | Explaining the eCTD structure and how the European Public Assessment Report evolves from it | Francesca Day
Head of Therapeutic Areas Department, EMA - The Netherlands |
| G6 | Case studies | Selection of examples, positive and negatives based on EPAR | Several speakers |
## Part 2: Oncology-specific curriculum

<table>
<thead>
<tr>
<th>#</th>
<th>Topic</th>
<th>Contents</th>
<th>Presenter</th>
</tr>
</thead>
</table>
| S1 | Overview of EMA-approved anti-cancer products        | High level overview on all centrally authorised oncology substances, based on mechanism and specific molecular target | Harald Enzmann  
CHMP chair  
Head of European & International Affairs, BfArM - Germany                                           |
| S2 | Overview of relevant guidelines                      | Orientation on relevant oncology guidelines and reflection papers; How to use guidelines in assessment | Francesco Pignatti  
Scientific adviser for Oncology, EMA -The Netherlands                                                   |
| S3 | Efficacy endpoints in oncology                        | Acceptability of endpoints for solid tumors and haematological malignancies, incl. particularities of MAUEC, CMA | Francesco Pignatti  
Scientific adviser for Oncology, EMA -The Netherlands                                                   |
| S4 | Biomarkers and companion diagnostics in oncology      | Biomarkers in initial assessment of a new medicine. Current status: previously approved products with biomarker. Cooperation with notified bodies in consulting procedure | Harald Enzmann  
CHMP chair  
Head of European & International Affairs, BfArM - Germany                                           |