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# REVAMP update

## From optimisation to NPL

Caroline Pothet

CP industry platform meeting, 20-Nov-26



# Four years of co-development



*Assuring the Network's Sustainability*

## via collaboration with CHMP, CAT, PRAC, assessors, industry & internal EMA stakeholders

### End 2022

- **WORD versions of key documents** in eCTD *Working Documents* folder
- **Response template**

### Oct 2023

- New **D80 clinical and non-clinical** reports

### End 2024

- **Completed first AR iteration** for initials
- **Completed D80 quality report** templates

### Jan 2025

- Move to **co-authoring** between Rapp teams (after D82)
- Include quality templates in co-authoring pilot

### Mar 2025

- **Extension application** template updated

### May & Oct 2026

- Optimisation and scope broadening
- Product information revamped

### Dec-23 – Dec-25

- **(co-authoring) pilot with industry**

### Jul 2025

- Quality reports revamped
- (Updated) REVAMP overview

### End 2025

- REVAMP Survey

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# Key achievements



Aligned AR templates & process encompassing all legal bases with IRIS go-live



**Aligned templates/guidance & process across** initials, extensions and indication extensions



**Responses to questions** managed via the **separate assessment report**



**Homogeneous way** to provide feedback **on product information**



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# From REVAMP to NPL

- **Develop future ‘reporting’ model** balancing processes efficiency, stakeholder needs and NPL requirements, e.g. EPAR expected to include:
  - Summary of the AR written ‘in a manner that is understandable to the public’
  - Section relation to the conditions of use of the medicine,
  - Summary of ERA and results,
  - Antimicrobials specifics, SAG summaries, key areas of scientific advice, for priority medicines, key areas of enhanced scientific/regulatory support, etc.

- **Leverage shift from documents to data and artificial intelligence tools**



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To be continued….

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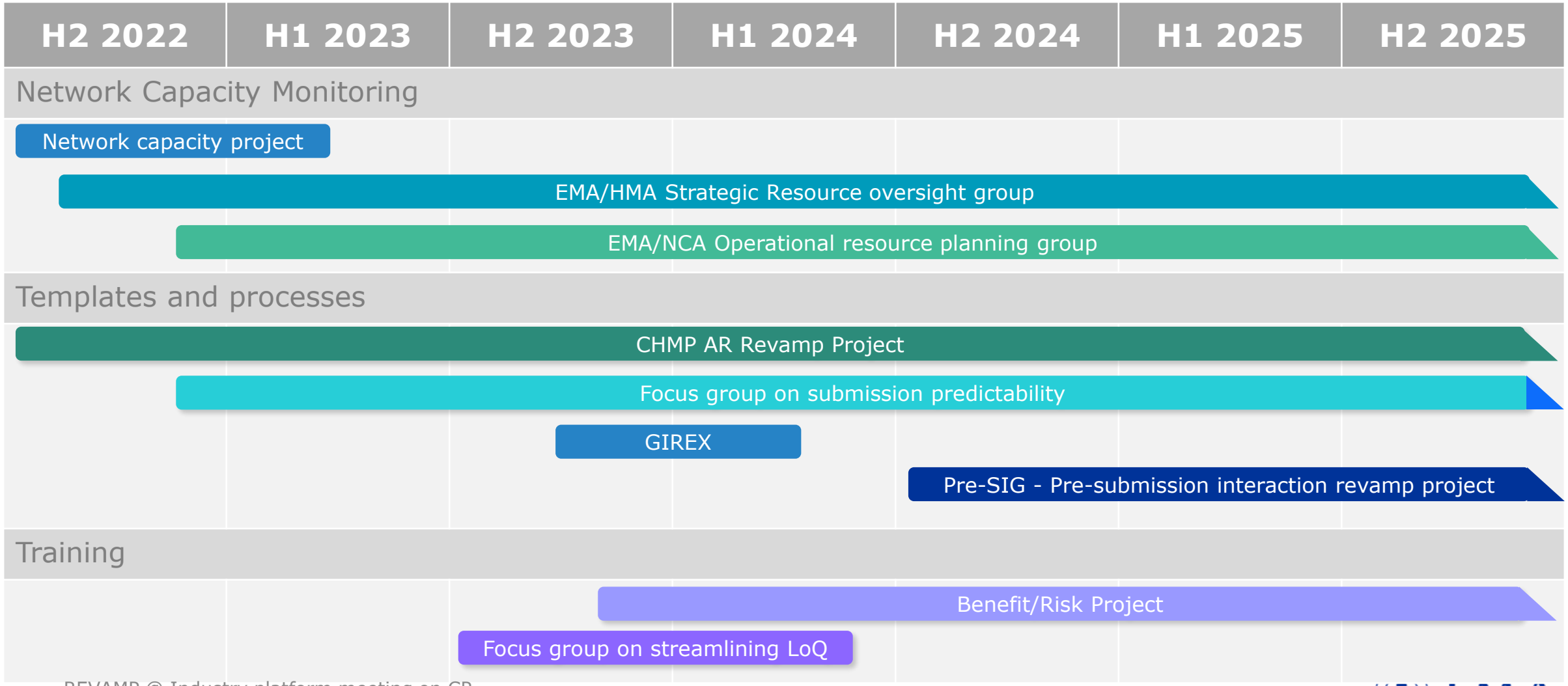
# Reminder – projects



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