

Update on ongoing initiatives in the centralised procedure

Stakeholders Platform Meeting
Topic #3

Fran Day

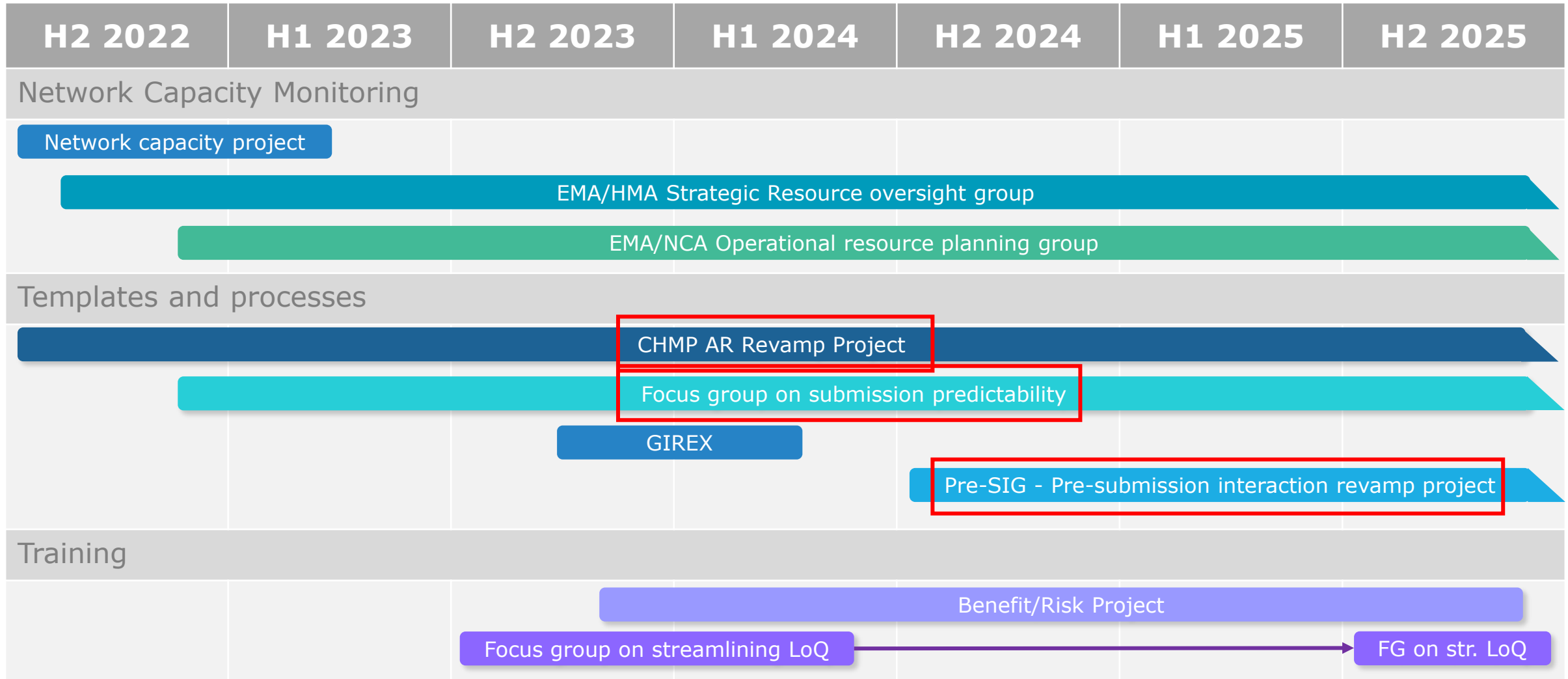
28-11-2025



Reminder – projects



Assuring the Network's Sustainability



Focus group on submission predictability



Intensive monitoring of submission delays during 2023 (report published Q2 2024)



Annex to Letter of Intent



Multistakeholder workshop in Sept 2024



Intensive monitoring 2 – H2 2025 **(ongoing)**

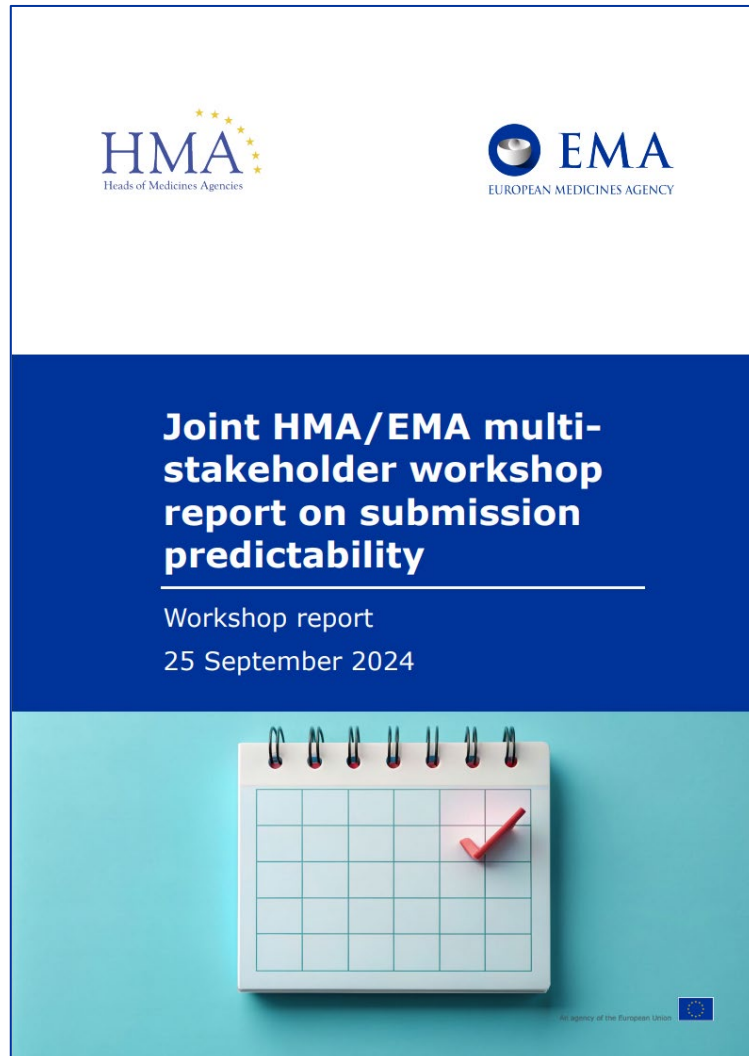


DIA info day on 03 December 2025

Outcomes



Assuring the Network's Sustainability



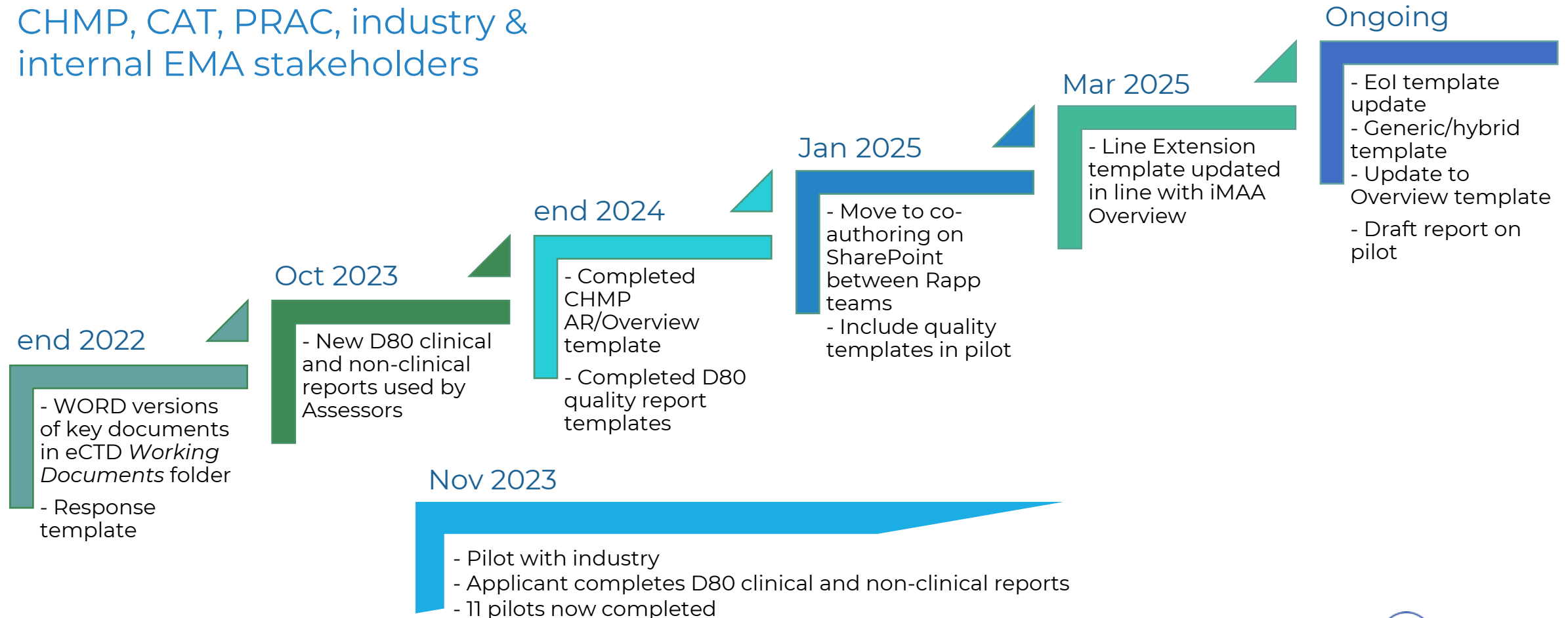
- The workshop was well attended and received a good level of media attention
- Key messages:
 - Enhanced communication
 - Maturity of dossier
 - Submission readiness
- The DIA Info Day on 03 Dec aims to reproduce some of those key messages

Revamp achievements



Assuring the Network's Sustainability

Throughout, collaboration with
CHMP, CAT, PRAC, industry &
internal EMA stakeholders



New templates



Line Extension template

completed – differs from overview only in the administrative sections.



Indication Extension template

ongoing – will be also based on the overview



Biosimilars template – on pause
(included in main overview)



Generic/hybrid template –
ongoing, targeting transition to
IRIS

Initial feedback on overview process



Assuring the Network's Sustainability

- The advantages of co-authoring are clear
- Some concerns regarding the SharePoint settings and many many versions created
- Some initial teething problems
 - Access issues
 - NCAs don't have as many permissions in SP as EMA staff (some work-arounds needed)
 - Revamp launch overlapped with IRIS launch – some confusion as the processes for Type IIs and LEs are not exactly the same for initial MAAs + use of different templates
 - Some confusion related to generic/hybrids being in SP, but the template is not geared up for co-authoring and the PRAC D94 stand-alone report still needs to be created (if there is an RMP)

Eol template being revamped, overview under review,
then concentrate on generic/hybrids

Update on Revamp Pilot



Assuring the Network's Sustainability

Product	Kick-off meeting	Actual submission date	D80	Post-D80 meeting	D120	D210
1	05-Oct-23	23-Nov-23	18-Mar-24	10-Apr-24	25-Apr-24	12-Dec-24
2	13-Nov-23	21-Dec-23	22-Apr-24	13-May-24	30-May-24	14-Nov-24
3	08-May-24	23-May-24	09-Sep-24	25-Sep-24	17-Oct-24	25-Apr-25
4	12-Jun-24	22-Jul-24	04-Nov-24	04-Dec-24	12-Dec-24	24-Jul-25
5	10-Oct-24	11-Oct-24	20-Jan-25	04-Mar-25	27-Feb-25	18-Sep-25
6	12-Sep-24	11-Nov-24	17-Feb-25	15-Apr-25	27-Mar-25	exp 11-Dec-25
7	05-Sep-24	25-Nov-24	17-Mar-25	03-Jun-25	25-Apr-25	exp 11-Dec-25
8	10-Jan-25	04-Mar-25	16-Jun-25	25-Sep-25	24-Jul-25	exp 29-Jan-26
9	29-Apr-25	05-May-25	11-Aug-25	02-Oct-25	12-Sep-25	exp 23-Apr-26
10	09-Apr-25	05-May-25	11-Aug-25	12-Sep-25	18-Sep-25	exp 23-Apr-26
11	08-May-25	02-Jun-25	08-Sep-25	28-Oct-25	16-Oct-25	exp 21-May-26

Include quality templates

- All pilots have now completed
- Preliminary feedback: a lot of work for applicants and not much value for assessors
- Report in preparation – draft will be shared with participants by end 2025

Pre-SIG

(pre-submission
interactions group)



Jan 2025: focus group kick-off



Representatives from EMA, network and industry



Held a number of meetings during the course of 2025



The group agreed on a moving Rapp appointment before Lol and reinforcing pre-submission interactions



Oct 2025: Presentation to wider CAT/CHMP – Lots of feedback received, requiring follow-up



Dec 2025/Jan 2026: Will re-convene the group to discuss any possible amendments to the proposal

Issues with translations



In recent months, we have noticed a gradual worsening of the quality of SmPC/PIL translations, including inconsistencies between clean and TC versions



Leads to corrections of opinion packages (pre EC decision) or corrigenda (post EC decision)



Protracted exchanges during the translation review phase (Day +5 to Day +25)



In some cases, delays to EC decisions



This is a call to all applicants – translation accuracy is key to the correct and safe use of the medicine – please take it seriously

EPAR process

(Problem statement and ongoing considerations)



We have noticed a gradual increase in the number of interactions regarding the CCI/PPD checks pre EPAR publication



It is not unusual to have 4 or even 5 rounds of consultation



Reminder: the consultation process should be only to remove CCI/PPD and (exceptionally) to correct any factual mistakes



Factual mistakes refers to data errors (e.g. 10.5 incorrectly reported as 1.05)



EMA in the process of clarifying the scope in the communications that are sent to applicants (target Q1 2026)

Timing for clock-stop extension requests



There has been some confusion regarding the timing for applicants to submit requests for clock-stop extensions

Assuring the Network's Sustainability



For request at the time of adoption of LoQ/LoOI/RSI:



Applicant knows already they will need more time



Request must be submitted by the Wed of CHMP week



For additional requests when already in clock stop:



Applicant is in clock stop and realizes they will need more time than originally thought



Request must be submitted by the Monday of the week before CHMP, prior to the already agreed restart



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Thank you

francesca.day@ema.europa.eu

Follow us

