EMA
EUROPEAN MEDICINES AGENCY

Focus group on submission predictability

Update

Stakeholder Platform Meeting – Centralised Procedure

Fran Day

15 June 2026

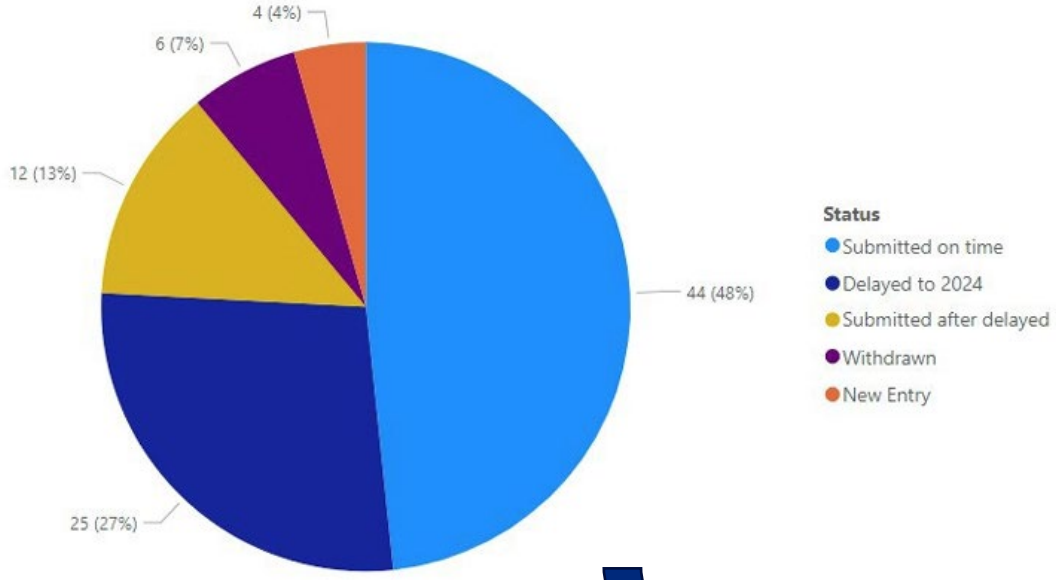
Focus group on submission predictability

- Intensive monitoring of submission delays during 2023 (report published Q2 2024)
- Annex to Letter of Intent
- Multistakeholder workshop in Sept 2024
- 2nd intensive monitoring exercise – H2 2025 (report published Apr 2026)
- DIA info day on 03 December 2025

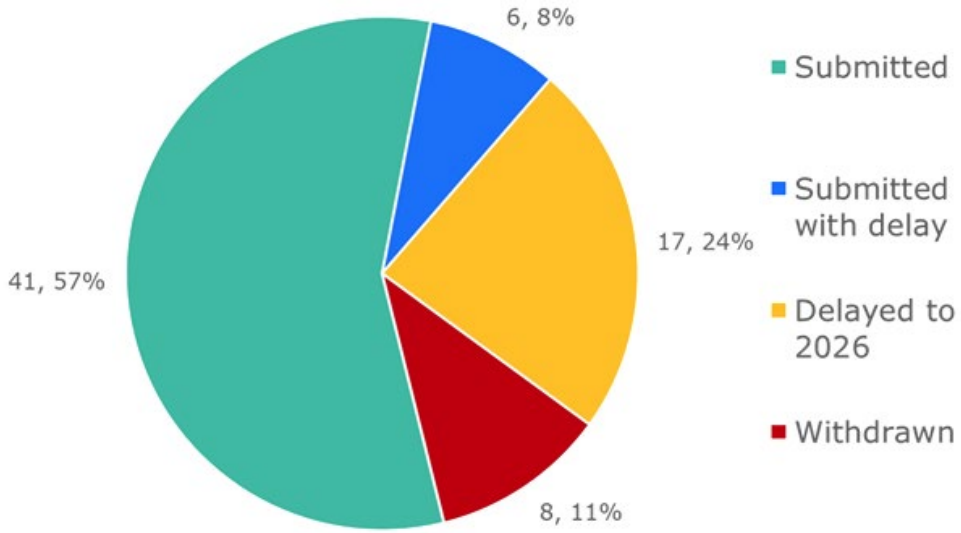
Outcomes

Assuring the Network's Sustainability

H2 2023



H2 2025



From 48% to 57% on time

What next?

- No plans for additional monitoring exercise
- The group will no longer actively meet, but remains as a forum for exchanges and sounding board if needed
- Continue with the messaging (importance of sticking to the date, impact on network, communication)
- Activities to enhance submission predictability will be transitioned to Pre-SIG and incorporated into other NPL activities
- Planning for a session at DIA Europe in 2027

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Revamp project - Pilot

Final report presentation

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Pilot with industry

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Background

During the pilot, a small number of companies were asked to pre-fill the D80 non-clinical and clinical report templates with factual information (clearly designated sections of the templates). Quality D80 templates were included late in the pilot.

Companies were contacted by EMA at least 3 months ahead of submission.

Participation in the pilot was voluntary (for Rapps and companies).

Expectations from companies

- Pre-fill the D80 AR templates with **factual information** (clear instructions provided in the templates).
- Provide the completed AR templates (in Word format via Eudralink – not part of eCTD) by the start date of the procedure (i.e. ~ 1 month after submission).

Close collaboration

- Dedicated meeting with EMA/Rapps prior to submission.
- Rapp teams to contact company for any clarifications once ARs received.
- Possibility of meetings with Rapp teams during the procedure.
- All coordinated via the PL.
- Aim to solve any concerns, reduce number and repetition of questions.

Pilot objectives

The questions the pilot sought to answer were:

Does receiving the D80 templates with the factual parts pre-filled result in a time saving for assessors?

Does allowing the option for assessors to ask technical, administrative questions to applicants before D80 lead to fewer questions adopted at D120?

Overview of procedures included

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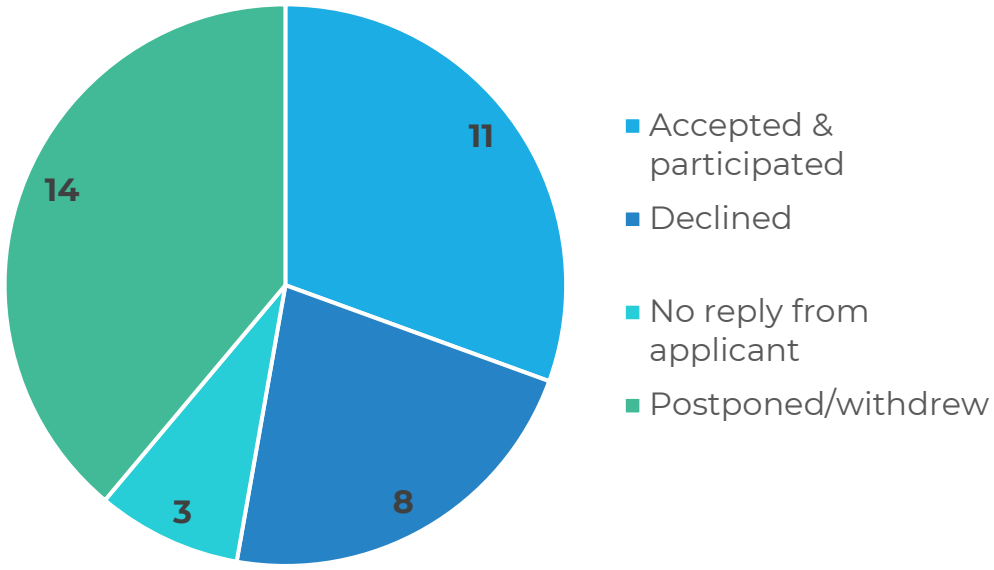
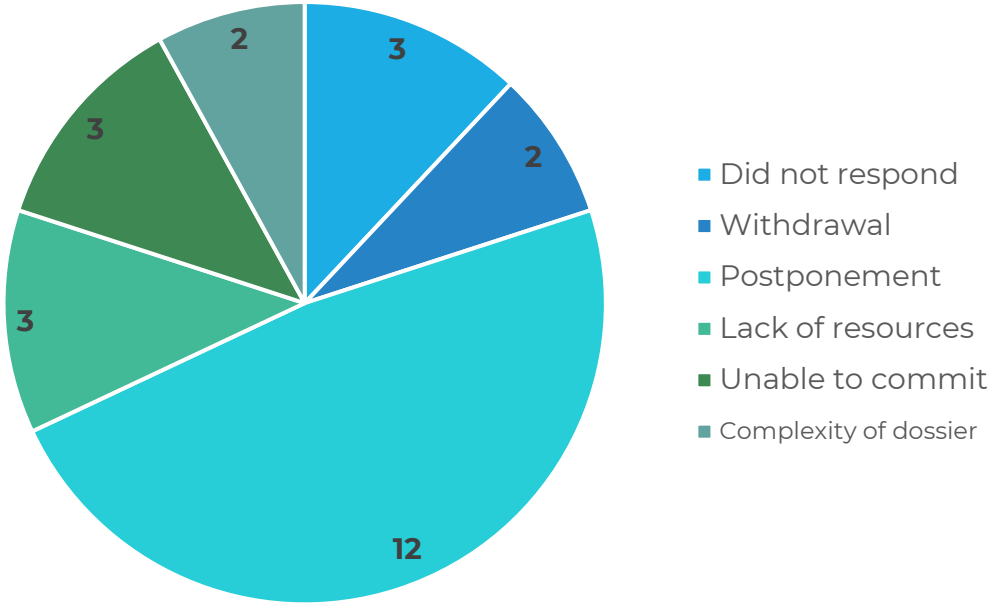


Initial response from applicant

Of the 25 that did not participate:



Reasons for not participating

Feedback from applicants

- Substantial workload to align AR content with other regulatory documents and managing extensive copy/paste requirements. Several sections – such as estimands – were not aligned with final submissions, therefore applicants found them difficult to complete.
- Tables, particularly in safety and clinical pharmacology sections, were often difficult to complete or adapt to diverse study designs.
- Difficult to manage the overlap between AR preparation and MAA timelines, limited opportunity for early planning, and uncertainty about the level of detail required. In all cases, the invitation to participate came once the study reports and Module 2 summaries had already been shaped. Participants suggested enhanced pre-submission and kick-off discussions.
- Given sufficient notice, some of the data tables could have been programmed directly from the databases; unfortunately, the short timelines meant that they had to be created manually instead.
- The process was more resource-intensive than expected and did not appear to reduce questions from Rapporteurs.
- Some companies noted that, having seen the expectations in terms of the reports that the assessors need to complete, future adjustments to Module 2 might be considered, where compatible with global submissions.

Feedback from assessors

- Applicants often included excessive interpretative or promotional text. In several instances, assessors had to remove substantial text, reconstruct clinical safety sections due to incorrect safety data sets, or supplement the documents with missing information, particularly regarding endpoints, estimands, ERA, and specific clinical and non-clinical study details.

- Difficulties with incomplete tables, inflexible, or misaligned with study designs, requiring assessors to rework or reword content. In some cases, assessors thought that applicants had included too much detail, in others, not enough.

- Pre-filled non-clinical tables seen as highly valuable and timesaving, with a preference expressed for including more tables rather than fewer.

- Assessors suggested earlier discussion of template expectations – e.g. at pre-submission meetings – alongside clearer guidance on what applicants should complete, stricter limits on narrative text, and clearer identification of applicant versus assessor responsibilities.

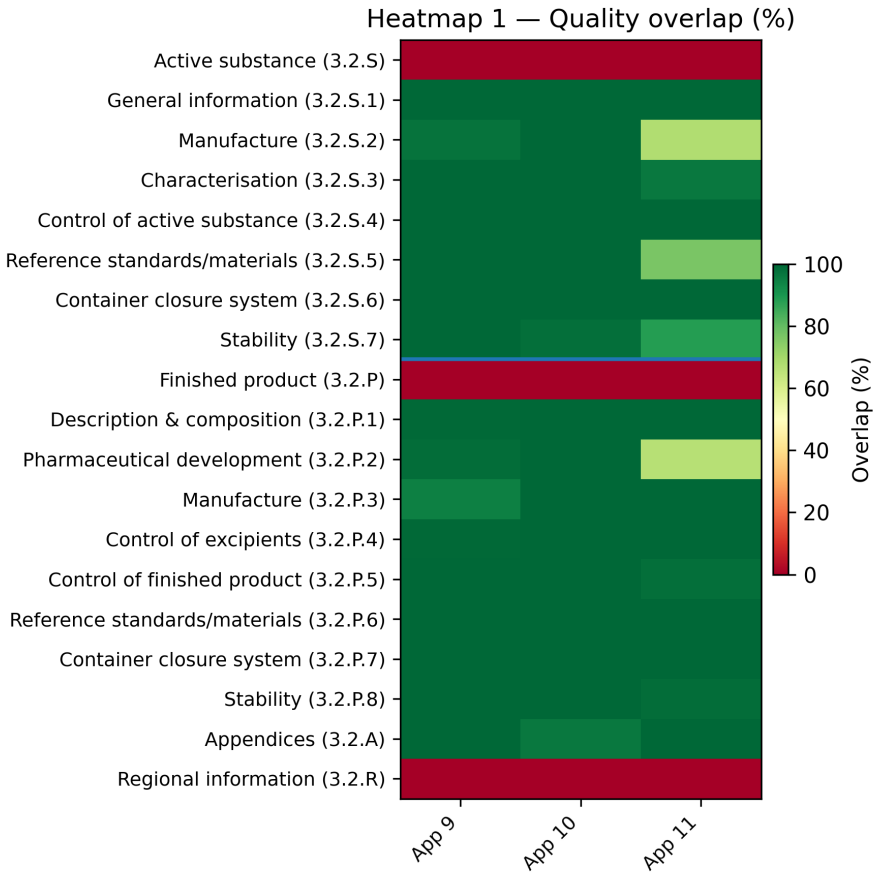
- Most assessors, with a few exceptions, did not think that the pre-filled textual parts had saved them time. All, however, agreed that the pre-filled tables had.

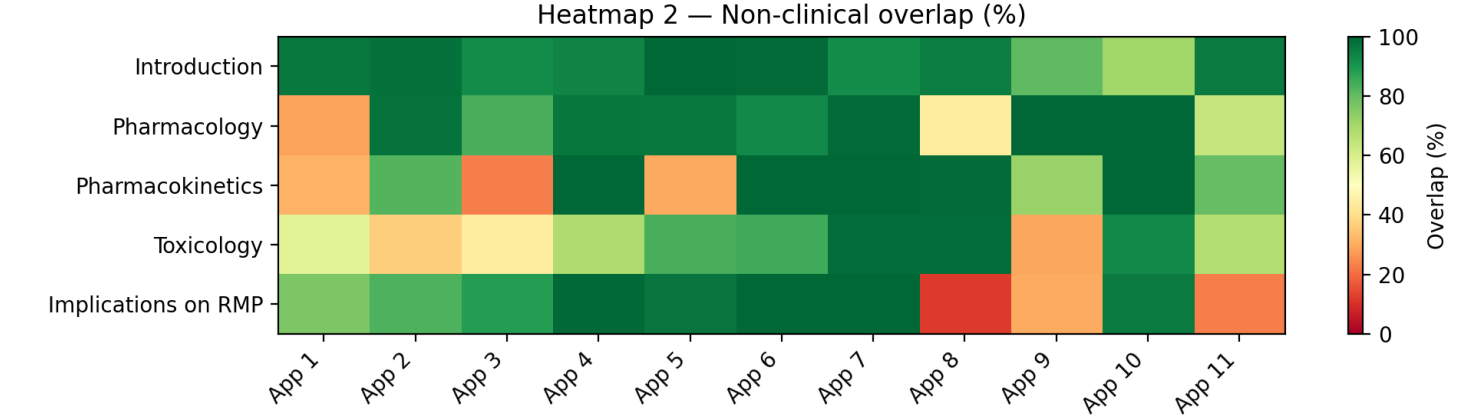
Analysis of text re-use

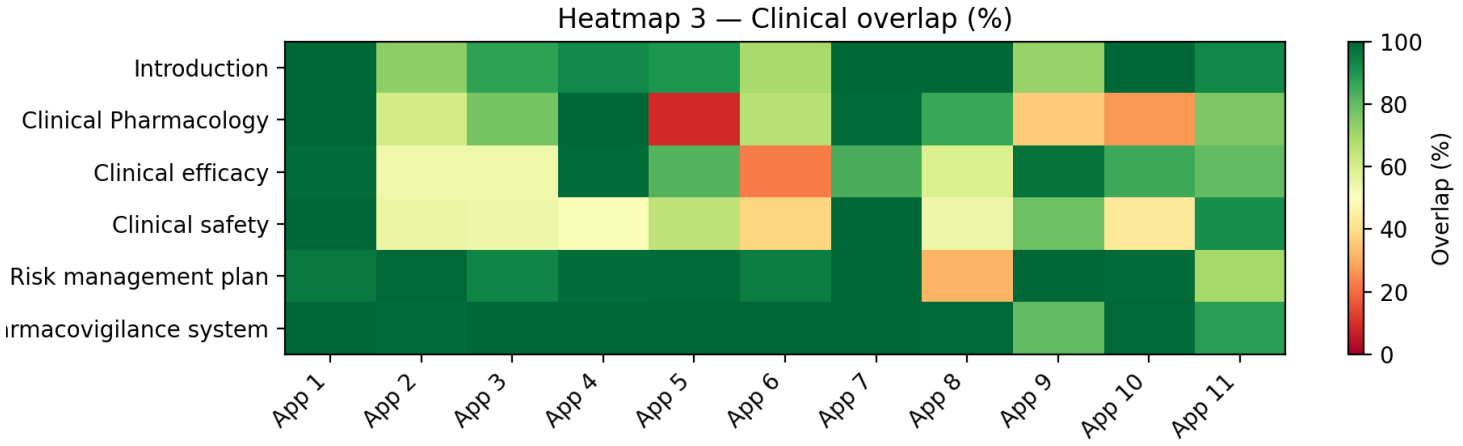
- We analysed how much of the text originally provided by applicants ended up verbatim in the D80 reports and then in the Overview.

- The next few slides show the overlap of text between the D80 quality, non-clinical and clinical reports provided by the applicants and the D80 reports finalised by the Rapporteurs and the Overview adopted at D120.

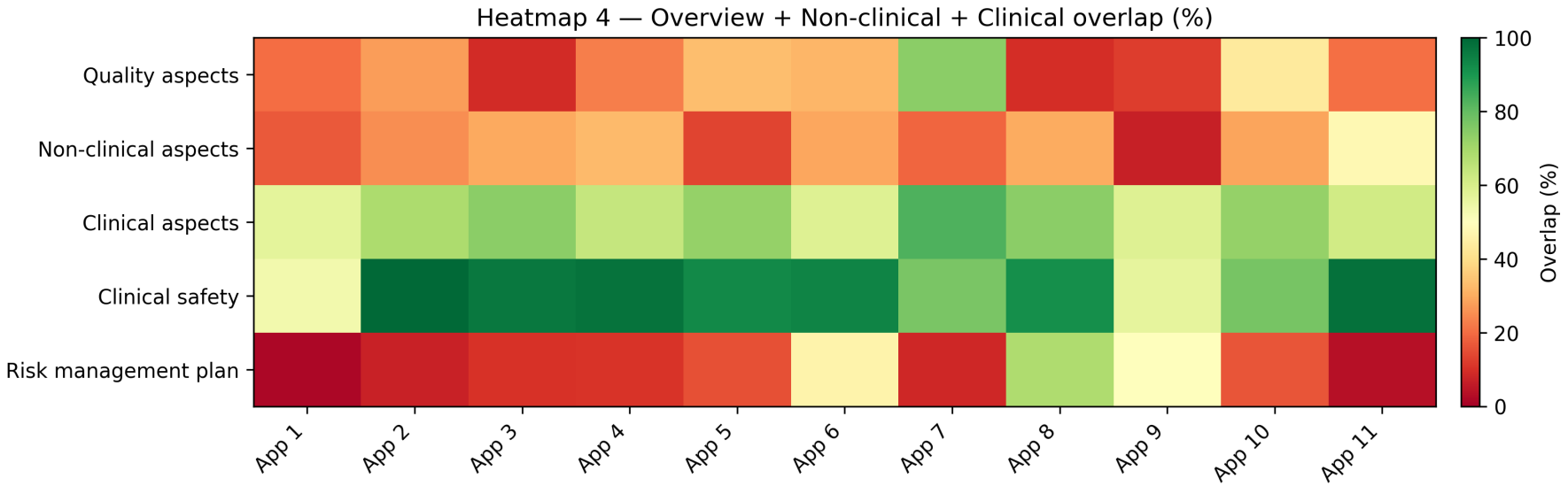
D80 Q, NC, C reports







Overlap with Overview



Analysis of questions

	Questions asked		No questions asked	
	Average	SD	Average	SD
Quality	84	38.0	77.7	49.6
Non-clinical	18.5	11.8	9.1	4.3
Clinical	68	24.2	56.3	12.4
RMP + PhV	7.25	3.2	10.1	5.4

There was very little difference between the number of questions in the overview whether the assessors used the opportunity or not

- As part of the pilot, Rapporteurs and assessors were encouraged to ask technical, administrative questions during the assessment, before D80.
- The questions could clarify inconsistencies, identify the location of data, and generally allow assessors to continue the assessment flow
- Assessors only took the opportunity in 4 of the 11 pilots

Conclusions

The Revamp Pilot was set up to answer 2 main questions:

- Does receiving the D80 AR templates with the factual parts pre-filled result in a time saving for assessors?
- Does allowing the option for assessors to ask simple, administrative questions to applicants before D80 lead to fewer questions adopted at D120?

In simple terms, the answer to both questions is negative.

However:

- Receiving pre-completed tables (not text) was found to be extremely helpful by all
- Quality assessors generally found it more helpful than other assessors to receive the pre-filled templates (evidenced by the high rate of re-use of text)
- Although it was not used much, the option to ask administrative questions during assessment was thought to be a helpful tool
- Applicants also found it helpful to be able to clarify aspects of the dossier prior to the formal list of questions

Recommendations

Systematically request applicants to provide the pre-filled data tables for the Overview (in MS Word format) at the time of submission

Conduct a minimum of 5 more pilots with pre-fill of the quality templates only, to collect more data and experience

Allow systematically for clarification questions to be asked during the assessment period, without waiting until the formal adoption by the committee

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Thank you

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Expectations going into the pilot

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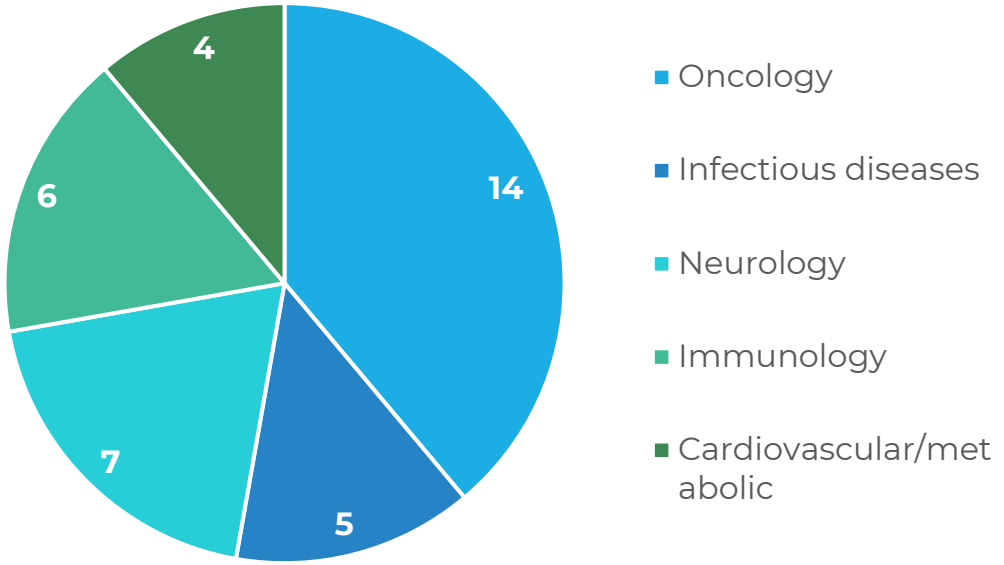
- The factual information provided by the company is in principle the building block for the factual sections of the overview/CHMP AR
- Expected to be time-saving for assessors
- Companies not expected to provide updates to the following ARs, just the first, completed version
- Once the assessor received the pre-filled AR template, it was their choice to change/update, or rewrite, as they saw fit
- Feedback from pilot would help develop accurate instructions to the company and would be part of a quality management process with feedback loops

Candidate procedures



- Initially the pilot targeted MAAs in oncology (applicants would be familiar with the FDA's assessment aid).
- But given the high rate of applicants that declined participation, the net was extended to include all TAs and also ATMPs.
- Overall, 36 applicants were contacted between July 2023 and May 2025.