EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Revamp pilot report

Experience gained with applicants pre-filling the factual sections of the D80 assessment reports for initial MAAs

Executive summary

This report summarises the outcomes of a pilot initiative aimed at streamlining the completion of the day 80 (D80) quality, non-clinical and clinical assessment reports (AR) by asking applicants to pre-fill them with factual information. The primary objective was to reduce duplication of effort, improve efficiency, and save time for assessors by transferring the initial data entry responsibility to the applicants.

A detailed comparative analysis of the text inputted by applicants and the final text in the adopted ARs, revealed a high retention. For quality reports (note: n=3, so the data should be interpreted with caution) 99% (median; range 83-100) of the text originally inputted by applicants was retained in the final D80 reports. For non-clinical (n=11) the corresponding figures were 84% for pharmacology (28-100%), 74% for PK (23-100%), and 70% for toxicology (24-99); for clinical the corresponding figures were 66% for pharmacology (9-100), 74% for efficacy (22-99) and 64% for safety (38-100).

While the concept was well-intentioned and aligned with efficiency goals, the pilot revealed that the majority of assessors did not find the approach beneficial. Despite applicants providing the information, assessors continued to spend time verifying its accuracy, supplementing the documents with missing information, or removing interpretative or promotional language, which ultimately negated the anticipated time savings.

Applicants, on the other hand, found the exercise very time consuming, at a time when the final submission dossier is being compiled, and saw little value in terms of enhanced communication or smoother assessment processes. The majority re-used text from the overview documents in Module 2 of the dossier, without much re-work, which explains the use of interpretative language, since the Overview are intended to be a critical review and interpretation of the data. Applicants also reported that tables, particularly in the safety and clinical pharmacology sections, were often difficult to complete or adapt to diverse study designs.

Based on these findings, the pilot did not meet its intended objectives. The following recommendations are put forward for consideration:

- Conduct a minimum of 5 more pilots for the quality D80 reports, since only 3 were included in the current pilot.
- For the non-clinical and clinical reports, only request the pre-completion of tables and not of text.
- 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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Introduction

The process of assessment of a dossier for a marketing authorisation application (MAA) is a complex one. Assessors are expected to complete a number of reports during the course of the assessment, in many cases copy/pasting information from the applicant's documentation and from one template to the next.

In 2022 a project was initiated (the Revamp Project), sponsored by the Committee for Medicinal Products for Human Use (CHMP), to streamline and update the assessment report templates used by assessors. The intention was to remove unnecessary duplication, improve the consistency between reports, and help save time and resources.

The Revamp Project Steering Group was originally composed of CHMP members and European Medicines Agency (EMA) staff. As the project progressed, Pharmacovigilance Risk Assessment Committee (PRAC) and Committee for Advanced Therapies (CAT) representatives joined and, *via* the Stakeholder Platform for the centralised procedure, a group of industry representatives was recruited to provide comments on templates and feedback on approaches.

To begin with, the D80 assessment report templates were revised and updated. They were restructured in such a way that there is now a distinction between the *factual data* submitted by the applicant and the *assessment* of said data by the assessor.

Once the new report templates were adopted (non-clinical and clinical to start with) in late 2023, the Revamp Project Steering Group also initiated a pilot project to see if the completion of the factual parts of the reports could be undertaken by the applicants rather than the assessors. This was in part inspired by the Assessment Aid, used by the United States' Food and Drug Administration's Oncology Centre of Excellence (FDA OCE), and indeed a meeting with FDA OCE colleagues was organised to understand their process and get their feedback on its usefulness. Feedback from FDA OCE was very positive and indeed they have seen a positive impact on their timelines and resources since the introduction of the Assessment Aid.

In November 2023, the EMA launched the Revamp Pilot.

Problem statement

Assessors are required to complete the D80 assessment report templates (quality, non-clinical and clinical) with data that is included in the electronic common technical document (eCTD) modules of the submission; in Modules 2, 3, 4, and 5. This exercise involves a large amount of copy/pasting from eCTD modules into the assessment report templates. Furthermore, given the heterogeneity of the submissions received, assessors often are required to complete tables that are not available in the eCTD dossier as-is, so they have to identify data points from a number of different documents and bring them together in one consolidated table. Overall, this data compilation effort is time-consuming and of limited value in terms of the quality of the actual assessment of the data.

Expected benefits of pilot

The main expected benefit of the Revamp Pilot was time gained for assessors. The process of copy/pasting data from the submission to the reports can be very time-consuming.

Depending on the quality and clarity of the dossier submitted, it can sometimes be challenging to find all the information that is expected to be included in the assessment reports, which often leads to assessors having to dig through multiple eCTD modules, or raising questions because the information needed is not readily accessible to them.

On the applicants' side, although it was acknowledged by all parties that the prefilling exercise would be an additional workload, the expectation was that there would be fewer questions raised, especially concerning the location or interpretation of data. In order to facilitate this, the pilot explicitly encouraged Rapporteur teams to send questions to applicants even before D80, through the EMA Product Lead (PL). These questions were intended to be technical/administrative in nature and not requiring endorsement by the committee. The intention was to help clarify inconsistencies, typos, etc, or locate data and information more easily, so that the assessment could proceed more smoothly. This could in turn lead to fewer questions adopted at the day 120 list of questions (D120 LOQ). The pilot also allowed for Rapporteurs to request a clarification meeting with the Applicant, even ahead of D80, if necessary. This too, was aimed at resolving simple queries and ensuring a smoother assessment and fewer questions raised at D120.

Objectives of pilot

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?

Goals of this report

This report aims to collect the learnings from the pilot and make recommendations to CHMP regarding a possible extension of the pilot, translation of the pilot into normal practice, return to previous practice or possible hybrid solutions.

Piloting the pre-filling of D80 assessment report template with data by applicants

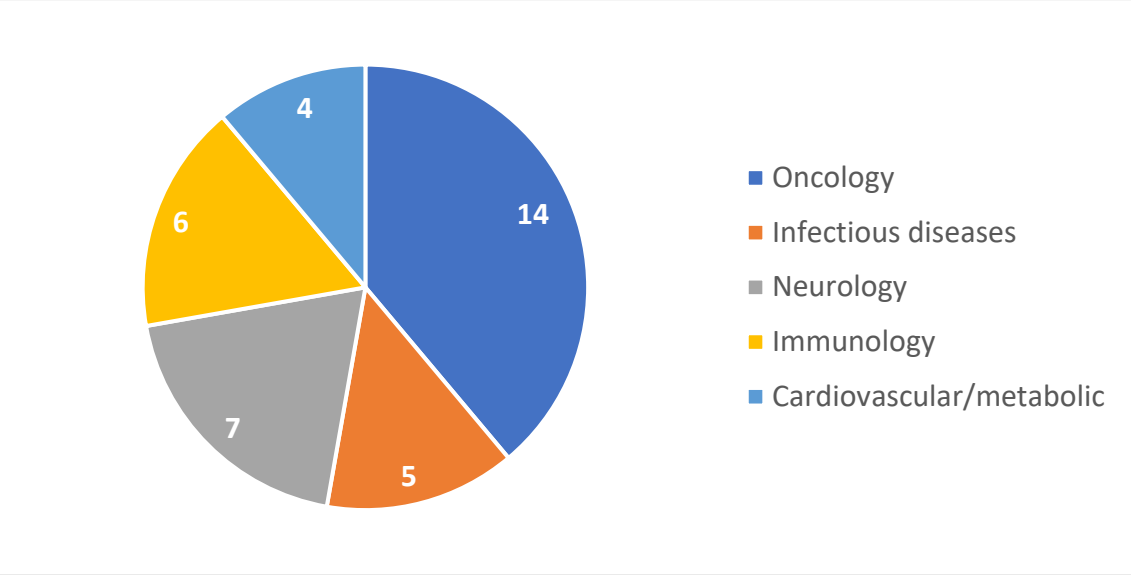
Candidate procedures investigated for inclusion in the pilot

It was agreed with the Revamp Steering Group that inclusion in the pilot would be by invitation; in short, EMA would examine the pipeline of expected submissions, agree with the Steering Group which ones to approach, and seek agreement by the applicants.

Initially, only oncology procedures were targeted, the rationale being that companies submitting oncology products would be more likely to have experienced the Assessment Aid by the FDA OCE and thereby be familiar with the concept.

It was also decided to target non-SMEs and non-ATMPs. The former, because of the expected burden on the applicants, and the latter because of the increased complexity of products and the involvement of CAT, which at the time was not represented in the Steering Group.

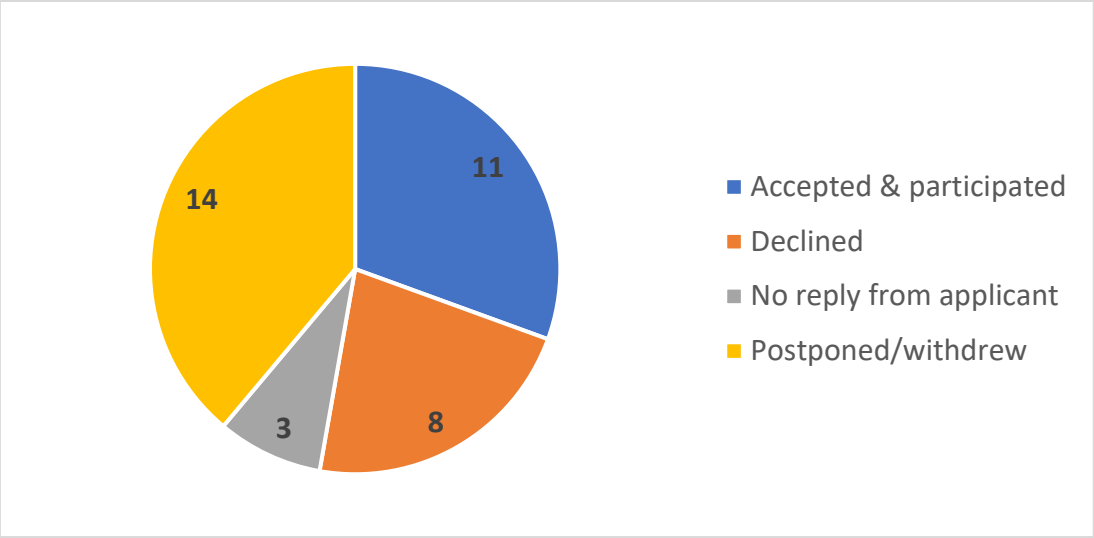
Figure 1: Number and type of procedures explored for inclusion in the pilot



Subsequently, and owing to the high percentage of companies which declined participation, or did not respond, the pilot was opened to all therapeutic areas and, upon the inclusion of the CAT Chair into the Steering Group, also to ATMPs.

Overall, 36 companies were contacted between July 2023 and March 2025 for participation in the pilot. In 8 cases, the companies declined participation upon the first request. In many cases, although the applicant agreed in principle to participate, they subsequently postponed their submission, which meant that the agency was often chasing submissions and having to approach more applicants.

Figure 2: Breakdown of procedures explored for inclusion in the pilot

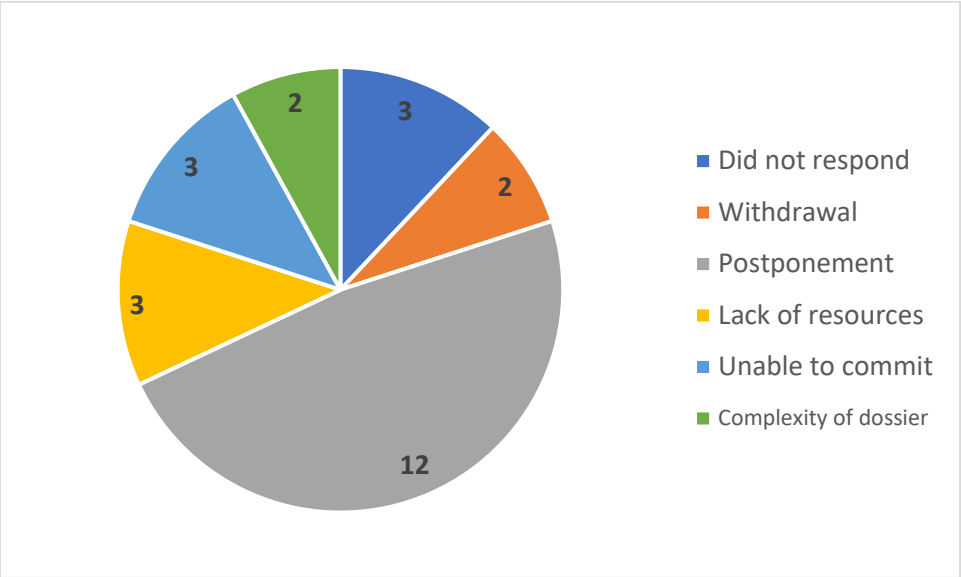


Applicants contacted and reasons for not participating

The primary reason for not participating in the pilot provided by applicants was a change in the planned submission date (12 out of 25 that declined, 48%). In two cases, the applicants withdrew the Letter of Intent due to their pivotal study failing its primary objective.

Three applicants did not respond. Eight applicants declined participation for reasons unrelated to the submission date. Three applicants quoted a lack of internal resources, three were unable to commit at the time (no further details provided), and two quoted the complexity of the dossier as a reason not to participate.

Figure 3: Breakdown of applications and reasons for non-participation



Procedures included in the pilot

Overall, 11 applications were included in the pilot. Although the majority of applicants contacted were for oncology applications, only 4 were included in the pilot in the end. Products in the cardiovascular/metabolic space also amounted to four.

Figure 4: Breakdown of products included by therapeutic area

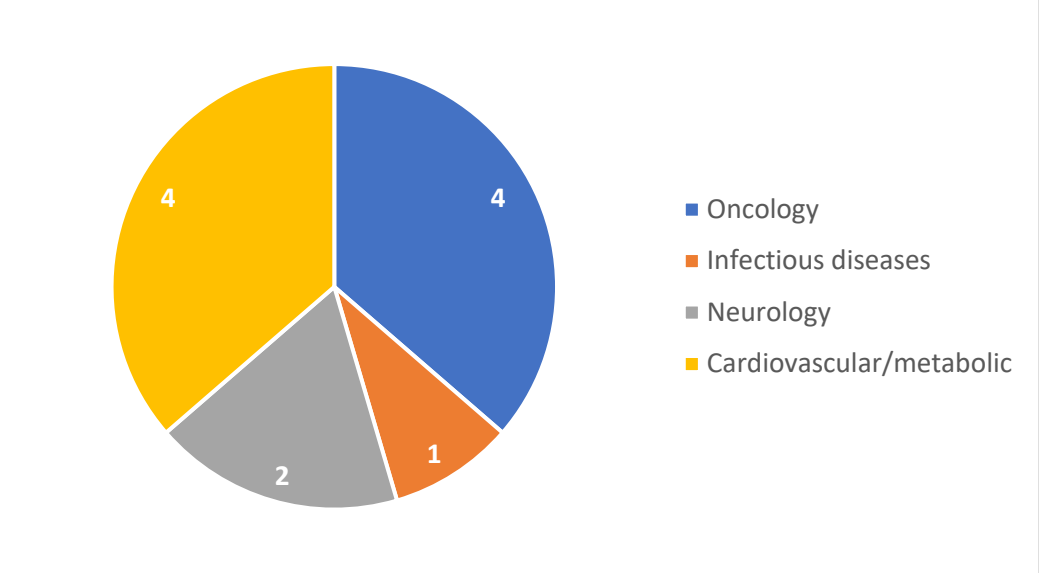


Table 1: Details of the products included in the pilot

	Kick-off	D80	Post D80 meeting	D120	D210
Product #1	05-10-2023	18-03-2024	10-04-2024	25-04-2024	12-12-2024
Product #2	13-11-2023	22-04-2024	13-05-2024	30-05-2024	14-11-2024
Product #3	08-05-2024	09-09-2024	25-09-2024	17-10-2024	25-04-2025
Product #4	12-06-2024	04-11-2024	04-12-2024	12-12-2024	24-07-2025
Product #5	10-10-2024	20-01-2025	04-03-2025	27-02-2025	18-09-2025
Product #6	12-09-2024	17-02-2025	15-04-2025	27-03-2025	29-01-2025
Product #7	05-09-2024	17-03-2025	03-06-2025	25-04-2025	11-12-2025
Product #8	10-01-2025	16-06-2025	25-09-2025	24-07-2025	29-01-2026
Product #9	29-04-2025	11-08-2025	02-10-2025	12-09-2025	~23-04-2026
Product #10	09-04-2025	11-08-2025	12-09-2025	18-09-2025	~23-04-2026
Product #11	08-05-2025	08-09-2025	28-10-2025	16-10-2025	~21-05-2026

~ = expected date

Upon acceptance by the Rapporteurs and the applicants in the pilot, a dedicated, product-specific, kick-off meeting was organised by EMA to present the aims the pilot to all relevant stakeholders for each procedure.

Although every effort was made to contact applicants with sufficient notice, kick-off meetings were generally conducted around 1-2 months ahead of the submission date. In one case, the meeting was held only 6 days before the submission.

For the first 8 products, the pilot only included the D80 non-clinical and clinical reports. For the last 3, the D80 quality template was also included.

Results of the pilot

After the D80 milestone for the procedure was passed, a feedback meeting was held with each participant. Feedback meetings included the applicants, Rapporteurs (including their assessor teams) and EMA staff, including the Product Lead.

The meetings were purposefully informal, with no minutes recorded, and intended to be as open and candid as possible. Rapporteurs and Applicants were encouraged to be truthful and constructive, since the feedback received would inform future iterations of the pilot, or potentially new ways of working for the whole of the European centralised procedure system.

Any feedback, not only on the benefits of the pilot, but also on the content of the AR templates was welcomed. All parties were also asked whether any questions and responses were exchanged before D80 and, if so, any feedback on the benefits of doing so.

In a few cases, applicants provided detailed slides ahead of the meeting, which was appreciated.

The meetings were run as a tour-de-table, with the Applicants generally starting the conversation, followed by the Rapporteur's team and then the Co-Rapporteur's team.

Feedback

Pooled feedback from Applicants

Participants highlighted substantial workload, complexity, and challenges in interpreting what would need to be provided in the AR templates. Participants reported difficulty distinguishing between clinical and non-clinical AR expectations (for example for PK data), aligning 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.

In addition, tables, particularly in safety and clinical pharmacology sections, were often difficult to complete or adapt to diverse study designs. Companies also noted ambiguity around when deviations from templates were permissible and suggested clearer guidance on mandatory versus flexible table formats.

Further concerns included 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, as well as better instructions on template interpretation.

A few applicants pointed out that, had they had sufficient notice, some of the data tables would have been programmed directly from their database; unfortunately, the short timelines meant that they had to be created manually instead.

While the instructional text in the templates was generally considered clear, 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.

Pooled feedback from Rapporteurs

A recurring concern, expressed by Rapporteurs, was the inclusion of excessive interpretative or promotional text in the factual portions of the templates. Assessors emphasised that templates should contain primarily objective data, tables, and figures. In several instances, assessors had to remove substantial applicant-added text, reconstruct clinical safety sections due to incorrect safety data sets, or supplement the documents with missing information, particularly regarding endpoints, estimands sections, environmental risk assessment content, and specific clinical and non-clinical study details. Difficulties also arose where tables were incomplete, 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.

Despite these issues, assessors highlighted several positive aspects. Pre-filled non-clinical tables were seen as highly valuable and timesaving, with a preference expressed for including more tables rather than fewer. The templates were considered helpful for reducing assessor workload in factual sections, although some subsections contained unnecessary detail while others lacked key elements. Assessors suggested earlier discussion of template expectations – at kick-off and pre-submission meetings – alongside clearer guidance on what applicants should complete, stricter limits on narrative text, clearer identification of applicant versus assessor responsibilities, and directing applicants to relevant European Public Assessment Reports (EPARs), or previous D80 reports for Applicants' products, as examples from which to draw inspiration. Overall, consistent completion, appropriate level of detail, and avoidance of interpretation remain areas for improvement. 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 texts

In order to have a more factual view of the usefulness of the pre-filled assessment report templates, an analysis was conducted to determine the amount of text originally provided by the applicants, that was eventually included in the Overview, prepared by the assessors and adopted by the CHMP/CAT at D120.

Baseline textual metrics

Baseline textual metrics were first summarised as absolute counts, stratified by document domain (Overview and D80 reports) and aggregated per product. This stratification reflects fundamental differences in document scope, authorship, and drafting purpose between domains and provides the empirical starting point for all subsequent overlap analyses. Only primary outputs of the text-matching pipeline are reported at this stage, namely total word counts, exact overlapping-word counts, and the number of exact matching spans. Derived measures, including overlap percentages and section-level summaries, are presented in later results sections.

Exact overlap analysis

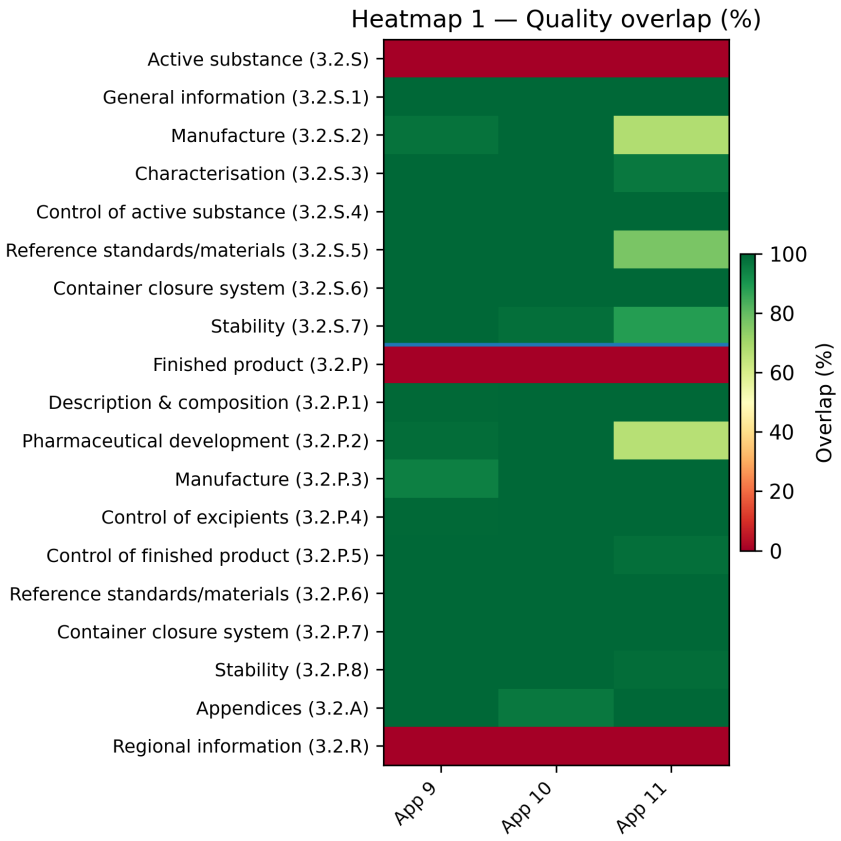
Following the calculation of baseline textual volumes and absolute overlap counts, exact overlap percentages were summarised to characterise the extent and variability of verbatim reuse of applicant-pre-filled factual content across report sections and procedural stages.

Exact overlap is expressed as the proportion of section-level words retained verbatim in the finalised regulatory documents and is reported using non-parametric summary statistics (see Table 5 - Table 8, in the Appendix).

Quality reports

As a reminder, the analysis for the quality reports is based on n = 3. The analysis shows very high levels of retention of text in the quality D80 reports, with median overlap values of 98.8% (IQR 90.7–99.3; range 82.6–99.9) for active substance sections and 98.5% (IQR 93.3–99.3; range 88.0–100.0) for finished product sections, while regional information shows no overlap (median 0.0%).

Figure 5: Heat map for quality reports overlap



The heat map in Figure 5 shows consistently high levels of overlap across active substance and finished product sections for the quality D80 reports, with limited variability between procedures, while no overlap is observed for regional information.

Non-clinical reports

The analysis in Table 10 (see Appendix) shows relatively high levels of retention of text in the non-clinical D80 reports, with the introduction section showing the highest median overlap of 92.0% (IQR 88.5–96.5; range 70.7–100.0). Lower median overlap values are observed for pharmacology (84.0%; IQR 67.5–97.8; range 28.4–100.0), pharmacokinetics (74.0%; IQR 31.1–99.8; range 23.0–100.0) and toxicology (69.5%; IQR 44.0–92.6; range 29.2–98.7).

Figure 6: Heat map for non-clinical reports overlap

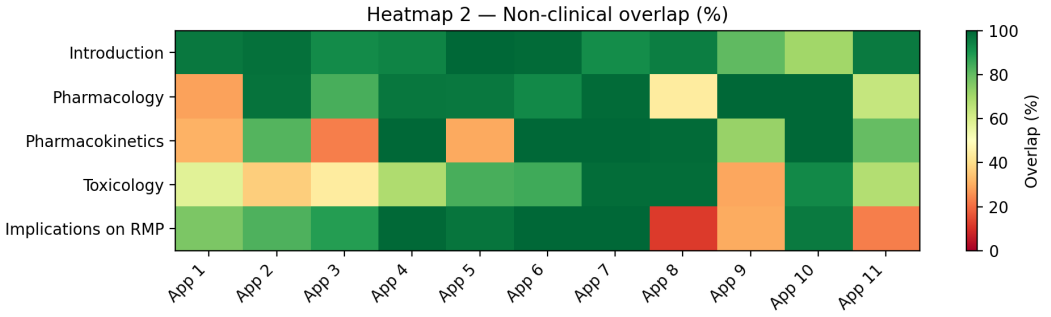


Figure 6 illustrates the distribution of exact textual overlap across non-clinical report sections and individual procedures. High overlap values are observed for the introduction section across most procedures, while greater variability is apparent in the pharmacology, pharmacokinetics and toxicology sections, with lower overlap values observed in some procedures. The implications on RMP section shows generally high overlap, with variability driven by a small number of procedures displaying lower overlap values.

Clinical reports

The analysis in Table 11 shows high levels of retention of text in the clinical D80 reports for the introduction (median 90.0%; IQR 73.5–100.0; range 69.1–100.0), risk management plan (96.0%; IQR 31.4–99.9; range 31.4–99.9) and pharmacovigilance system sections (99.0%; IQR 98.7–100.0; range 80.4–100.0). Lower median overlap values are observed for clinical pharmacology (66.0%; IQR 36.2–99.9; range 8.9–99.9), clinical efficacy (74.0%; IQR 53.9–98.9; range 22.4–98.9) and clinical safety (64.0%; IQR 51.2–97.5; range 38.1–99.9).

Figure 7: Heat map for clinical reports overlap

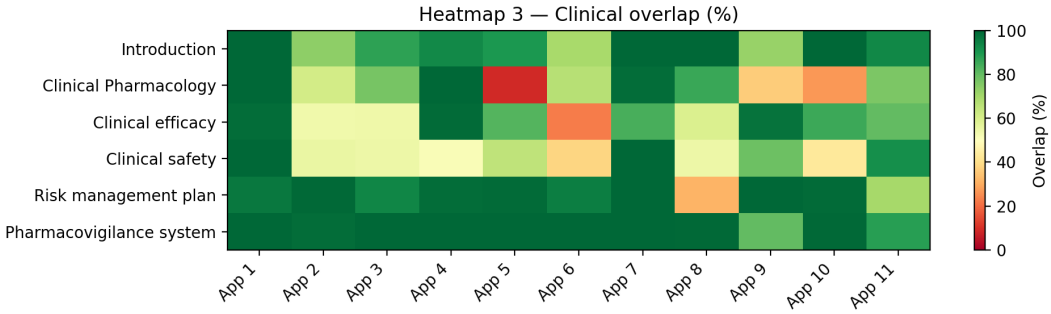


Figure 7 illustrates the distribution of exact textual overlap across clinical report sections and individual procedures. High overlap values are observed for the introduction, risk management plan and pharmacovigilance system sections across most procedures. In contrast, the clinical pharmacology, clinical efficacy and clinical safety sections show greater variability, with lower overlap values observed in a subset of procedures.

Table 9 - Table 11 (see Appendix) summarise section-level exact textual overlap in the quality, non-clinical and clinical D80 reports, with the corresponding distributions visualised in Figures 5–7.

For the **quality reports** (Table 5 and Figure 5), high median overlap values are observed across the active substance and finished product sections, with relatively narrow interquartile ranges. Appendices also show high overlap values. No overlap is observed for regional information. The heatmap shows a predominantly uniform pattern of high overlap across sections, with the exception of regional information. These results are based on a limited number of quality cases.

For the **non-clinical reports** (Table 6 and Figure 6), the introduction section shows the highest median overlap value. Lower median overlap values and wider interquartile ranges are observed for pharmacology, pharmacokinetics and toxicology sections. The heatmap shows greater heterogeneity across sections, with a wider spread of overlap values compared with the quality domain.

For the **clinical reports** (Table 7 and Figure 7), high median overlap values are observed for the introduction, risk management plan and pharmacovigilance system sections, while lower median overlap values and wider interquartile ranges are observed for the clinical pharmacology, clinical efficacy and clinical safety sections. The heatmap reflects this pattern, with higher overlap values concentrated in the former sections and greater variability in the latter.

Across all three domains, median overlap values for the analysed sections exceed 60%, while the degree of variability differs between domains and between sections within domains, as shown in both the tabulated summaries and the heatmap visualisations. Although the analysis for the quality reports is based on only 3 products in the pilot, the data clearly shows a much higher level of retention of text, versus the non-clinical and clinical reports. This is maybe not unexpected, given the very technical nature of the quality reports, which lends itself to a much more factual completion of data points rather than narrative text.

Reuse of text in the Overview

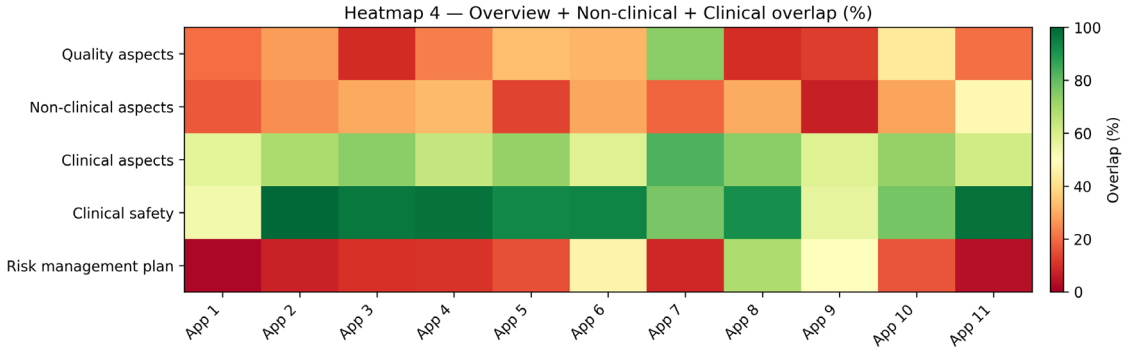
A similar assessment was carried out, comparing the Overview, produced at D120, with the original D80 reports, prefilled by the applicants. It is worth noting here that the Overview is authored entirely by the assessors, with no pre-filling by applicants. However, the sections in the Overview correspond very closely to those in the D80 reports (with the exception of the administrative parts and the benefit/risk or biosimilarity sections), and assessors, even when not participating in this pilot, tend to copy/paste extensively from the D80 reports into the Overview. The analysis is presented in Table 2 and Figure 8 below.

Table 2: Exact overlap between applicant-pre-filled reports and finalised Overviews (factual sections)

Domain	Median overlap (%)	IQR (%)	Minimum (%)	Maximum (%)
Quality	28.1	12.4–43.7	12.4	43.7
Non-clinical	24.9	13.6–29.8	6.7	50.7
Clinical efficacy	68.7	58.5–73.9	57.0	83.1
Clinical safety	83.5	76.9–97.5	53.3	99.4
Risk management plan	15.6	8.5–19.5	1.9	46.2

IQR = interquartile range

Figure 8: Heat map for overlap between Overview and individual D80 reports as finalised by the assessors



This analysis shows that, generally, the reuse of text is reduced from the D80 reports to the Overview. The quality sections show low levels of overlap. It is worth noting that reports for Products #1 to #8 had not been involved in the pilot, which indicates that there is generally a low level of overlap between the D80 quality reports and the Overview regardless. Participation in the pilot, for Products #9, #10 and #11, does not appear to have had an impact on the overlap. The clinical parts show the greatest level of reuse, while, maybe surprisingly, the RMP sections show the lowest level of reuse. This, however, is mostly likely due to the fact that the non-clinical and clinical D80 reports are mirrored very closely in the Overview. On the other hand, the D80 clinical report only includes the RMP section related to the safety specification, while the Overview also covers the pharmacovigilance plan and risk minimisation measures sections, which are completed by the PRAC Rapporteur later in the assessment process.

Analysis of questions

As part of the pilot, Rapporteurs and assessors were encouraged to ask technical, administrative questions during the assessment, before D80. The idea was that this opportunity would be used to clarify inconsistencies between modules, identify the location of data, and generally allow assessors to continue the assessment flow without interruption due to having to wait until the responses to D120 list of questions to seek these sorts of clarifications. These simple questions and answers would be managed via Eudralink/e-mail, without the need for eCTD sequence submission and the response time would be short (2 or 3 days), given the purely administrative nature of the requests. The process would be transparent, managed by the EMA PL or quality specialist, and both Rapporteurs would be aware of the requests sent to the applicants and the responses received.

Originally the intention was to analyse the average number of questions in the D120 reports and determine whether this exercise had resulted in reduced numbers versus a representative example of applications not in the pilot. Unfortunately, however, the opportunity to ask such questions was only used on a handful of occasions and only for 4 of the 11 applications. It was therefore felt that the exercise would not be worthwhile.

Table 3: Overview question counts

Section	#1	#2	#3	#4	#5	#6	#7	#8	#9	10	11	Av	SD
Quality	92	78	127	79	97	63	140	7	45	21	131	80.0	43.8
Non-clinical	16	13	11	7	26	4	5	5	14	7	30	12.5	8.7
Clinical	73	69	46	48	73	61	46	46	40	66	98	60.5	17.4
RMP + PhV	17	10	4	8	5	12	18	6	6	8	6	9.1	4.7

On average the majority of questions were on the quality and clinical aspects of the applications. The quality section had the greatest variability in numbers, with as few as 7 questions and as many as 140 questions.

There was very little difference between the numbers of questions in the D120 Overview, whether the assessors had asked questions during the assessment or not (Table 4). As mentioned though, questions were only asked in 4 of the 11 pilots.

Table 4: Overview question counts in relation to having asked questions during the assessment

	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

SD = standard deviation

Despite the question count not yielding the benefits expected, the feedback from both assessors and applicants was overwhelmingly positive for those few occasions in which questions were asked. In particular, assessors commented that asking questions during the assessment enabled them to carry on with the process and not have to pause while waiting for the answers. Applicants also found the exercise beneficial. The nature of the questions, and the fact that responses were expected only via Eudralink/e-mail, meant that the work for the teams was minimal. In all cases the responses were submitted within a few days, with no new data generation.

Discussion and recommendations

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, the outcomes of the pilot are much more nuanced.

While the feedback from assessors tended to be that not much time had been saved by receiving the pre-filled templates as a whole, there was a difference between the textual parts of the template, and the tables. Overwhelmingly, assessors thought that pre-filled tables were extremely useful and timesaving. However, even though the analysis showed that on average over 60% of the text originally inputted by applicants was retained in the D80 reports finalised by the Rapporteurs, most assessors were not of the opinion that the pre-filled text had been useful.

There was a difference between the type of templates, however. For the quality templates in particular, owing to the fact that they are generally much more factual and with very little narrative text, the assessors feedback indicated that they had indeed saved a considerable amount of time. In addition, the overlap analysis confirmed a very high level of reuse of text for the quality templates.

While there was no attempt in the pilot to measure time spent by assessors, and therefore quantify the time saved, the verbal feedback indicated unanimously that receiving pre-completed data tables did indeed save a lot of time, while the more textual parts did not necessarily. The extent of time saved seemed also in part to be related to the level of experience of the individual assessors, with more junior assessors spending longer to double-check the validity of the pre-filled templates, and more senior assessors being able to do so more readily.

Regarding the second question to be answered by the pilot, here too, it is difficult to quantify any advantage, given the low level of uptake. Even for the 4 products where assessors did ask clarifying questions, the numbers were low, generally only 2 or 3 questions, therefore it would be difficult to see any impact on the final number of questions at D120, given the very high variability.

Here too, though, verbal feedback indicated very positive feedback for those occasions in which questions were asked. As a result, EMA is already encouraging Rapporteurs' teams to ask technical, clarification questions during the course of assessment.

Preliminary recommendations for future implementation

The results from this pilot will be discussed with the Revamp Project Steering Group and with the Committees involved (CHMP, CAT and PRAC).

Given the variability of feedback on the usefulness of the exercise, it is not recommended to continue the pilot or to move towards requesting pre-filled templates for all new initial MAAs.

However, three proposals are put forward for consideration:

- For the non-clinical and clinical reports, instead of requesting applicants to pre-fill the entire D80 templates, it is recommended to only request the pre-completion of tables. A document containing all tables necessary for completion could be created and shared on the EMA website. Following a transition period, applicants would be expected to provide the collated tables as a Microsoft Word document with the eCTD submission as a working file. Pre-submission discussions could cover the tailoring of the tables to the specifics of the dossier. Indeed, applicants could be encouraged to prepare their module 2 documents in line with the template requirements, if applicable.
- Given that only 3 products in the pilot included the pre-completion of the quality D80 reports, it is recommended to collect additional data and conduct a minimum of 5 more pilots whereby only the quality assessment reports would be pre-filled by applicants. This would allow a more detailed analysis of the value of pre-completion for the quality sections.
- Allow systematically for clarification questions to be asked during the assessment period, without waiting until the formal adoption by the committee. These questions would be simple, technical and administrative in nature; answers would be managed via Eudralink/e-mail, without the need for eCTD sequence submission and the response time would be short (2 or 3 days). The process would be transparent, managed by the EMA PL or quality specialist for quality aspects, and both Rapporteurs would be aware of the requests sent to the applicants and the responses received.

This report was presented to the CHMP, CAT and PRAC and the recommendations endorsed by all three committees.

Appendix

Table 5: Product-level baseline textual metrics for the quality reports

	Total words	Exact overlapping words	Exact spans (count)
Product #9	56,158	55,430	76
Product #10	63,697	63,628	27
Product #11	22,482	19,186	62

Note: Values represent absolute counts aggregated across all analysed factual sections within the specified document domain.

Table 6: Product-level baseline textual metrics for the non-clinical reports

	Total words	Exact overlapping words	Exact spans (count)
Product #1	23,516	12,466	102
Product #2	21,327	12,004	133
Product #3	15,112	9,728	170
Product #4	62,884	53,395	329
Product #5	38,539	25,389	179
Product #6	42,294	39,110	104
Product #7	37,280	36,786	35
Product #8	14,624	11,175	45
Product #9	15,629	7,792	114
Product #10	22,943	21,157	68
Product #11	23,070	16,006	196

Note: Values represent absolute counts aggregated across all analysed factual sections within the specified document domain.

Table 7: Product-level baseline textual metrics for the clinical reports

	Total words	Exact overlapping words	Exact spans (count)
Product #1	52,962	52,693	49

Product #2	51,736	30,616	375
Product #3	32,190	21,808	282
Product #4	61,504	49,682	344
Product #5	97,951	56,921	965
Product #6	43,817	18,837	627
Product #7	27,272	25,471	80
Product #8	68,654	46,895	1,247
Product #9	35,029	27,646	176
Product #10	67,363	38,472	461
Product #11	58,567	47,283	352

Note: Values represent absolute counts aggregated across all analysed factual sections within the specified document domain.

Table 8: Product-level baseline textual metrics for the Overviews

	Total words	Exact overlapping words	Exact spans (count)
Product #1	46,831	18,233	885
Product #2	49,493	27,917	382
Product #3	45,314	18,713	422
Product #4	54,037	26,319	641
Product #5	81,050	45,043	1,283
Product #6	45,461	22,651	717
Product #7	32,325	18,466	385
Product #8	47,122	27,725	880
Product #9	62,282	22,873	498
Product #10	46,982	27,227	617
Product #11	66,303	36,641	493

Note: Values represent absolute counts aggregated across all analysed factual sections within the specified document domain.

Table 9: Exact overlap between applicant-pre-filled and finalised quality D80 reports (factual sections)

Section	Median overlap (%)	IQR (%)	Minimum (%)	Maximum (%)
Active substance (3.2.S)	98.1	88.5–99.0	78.9	99.9
General information (3.2.S.1)	100.0	100.0–100.0	100.0	100.0
Manufacture (3.2.S.2)	97.6	82.8–98.8	67.9	99.9
Characterisation (3.2.S.3)	99.9	98.0–99.9	96.1	99.9
Control of active substance (3.2.S.4)	99.9	99.9–100.0	99.8	100.0
Reference standards of materials (3.2.S.5)	100.0	88.5–100.0	76.9	100.0
Container closure system (3.2.S.6)	100.0	100.0–100.0	100.0	100.0
Stability (3.2.S.7)	98.4	93.6–99.2	88.7	100.0
Finished product (3.2.P)	99.4	98.1–99.7	96.8	100.0
Description and composition of the finished product (3.2.P.1)	100.0	99.7–100.0	99.4	100.0
Pharmaceutical development (3.2.P.2)	98.5	82.6–99.2	66.7	100.0
Manufacture (3.2.P.3)	99.8	97.2–99.9	94.6	100.0
Control of excipients (3.2.P.4)	100.0	99.8–100.0	99.6	100.0
Control of finished product (3.2.P.5)	100.0	99.2–100.0	98.4	100.0
Reference standards or materials (3.2.P.6)	100.0	100.0–100.0	100.0	100.0
Container closure system (3.2.P.7)	100.0	100.0–100.0	100.0	100.0
Stability (3.2.P.8)	100.0	99.3–100.0	98.6	100.0
Appendices (3.2.A)	100.0	98.2–100.0	96.4	100.0

Regional information (3.2.R)	0.0	0.0–0.0	0.0	0.0

IQR = interquartile range

Table 10: Exact overlap between applicant-pre-filled and finalised non-clinical D80 reports (factual sections)

Section	Median overlap (%)	IQR (%)	Minimum (%)	Maximum (%)
Introduction	92.0	88.5–96.5	70.7	100.0
Pharmacology	84.0	67.5–97.8	28.4	100.0
Pharmacokinetics	74.0	31.1–99.8	23.0	100.0
Toxicology	69.5	44.0–92.6	29.2	98.7
Implications for RMP	78.0	30.1–99.6	12.0	100.0

IQR = interquartile range

Table 11: Exact overlap between applicant-pre-filled and finalised clinical D80 reports (factual sections)

Section	Median overlap (%)	IQR (%)	Minimum (%)	Maximum (%)
Introduction	90.0	73.5–100.0	69.1	100.0
Clinical pharmacology	66.0	36.2–99.9	8.9	99.9
Clinical efficacy	74.0	53.9–98.9	22.4	98.9
Clinical safety	64.0	51.2–97.5	38.1	99.9
Risk management plan	96.0	31.4–99.9	31.4	99.9
Pharmacovigilance system	99.0	98.7–100.0	80.4	100.0

IQR = interquartile range

Glossary

AR	Assessment report
ATMP	Advance therapy medicinal product
CAT	Committee for advance therapies
CHMP	Committee for Medicinal Products for Human Use
D80	Day 80 of procedure
D120	Day 120 of procedure
D121	Day 121 of procedure
eCTD	Electronic common technical document
EMA	European Medicines Agency
EPAR	European public assessment report
FDA OCE	Federal Drug Agency Oncology Centre of Excellence
MAA	Marketing authorisation application
MAH	Marketing authorisation holder
NCA	National competent authority
PhV	Pharmacovigilance
PRAC	Pharmacovigilance risk assessment committee
RMP	Risk management plan
SME	Small and medium size enterprises

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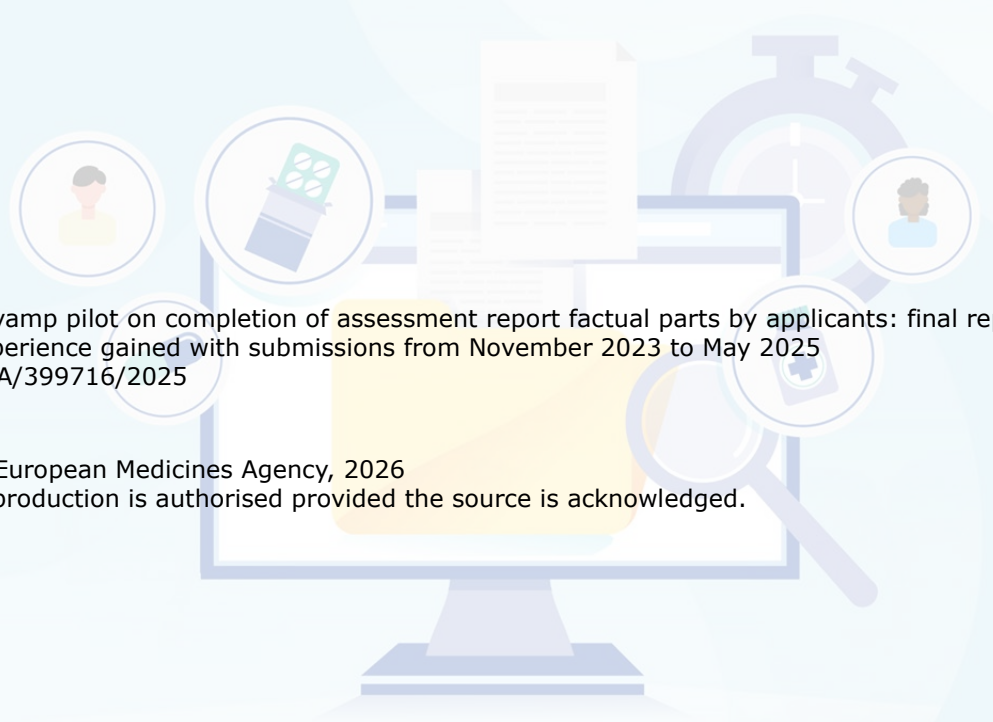

Revamp pilot on completion of assessment report factual parts by applicants: final report on the experience gained with submissions from November 2023 to May 2025
EMA/399716/2025