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SCIENCE MEDICINES HEALTH

A Dedicated Post Authorisation Measure Submission Form

An improved way of submitting your PAM to the EMA

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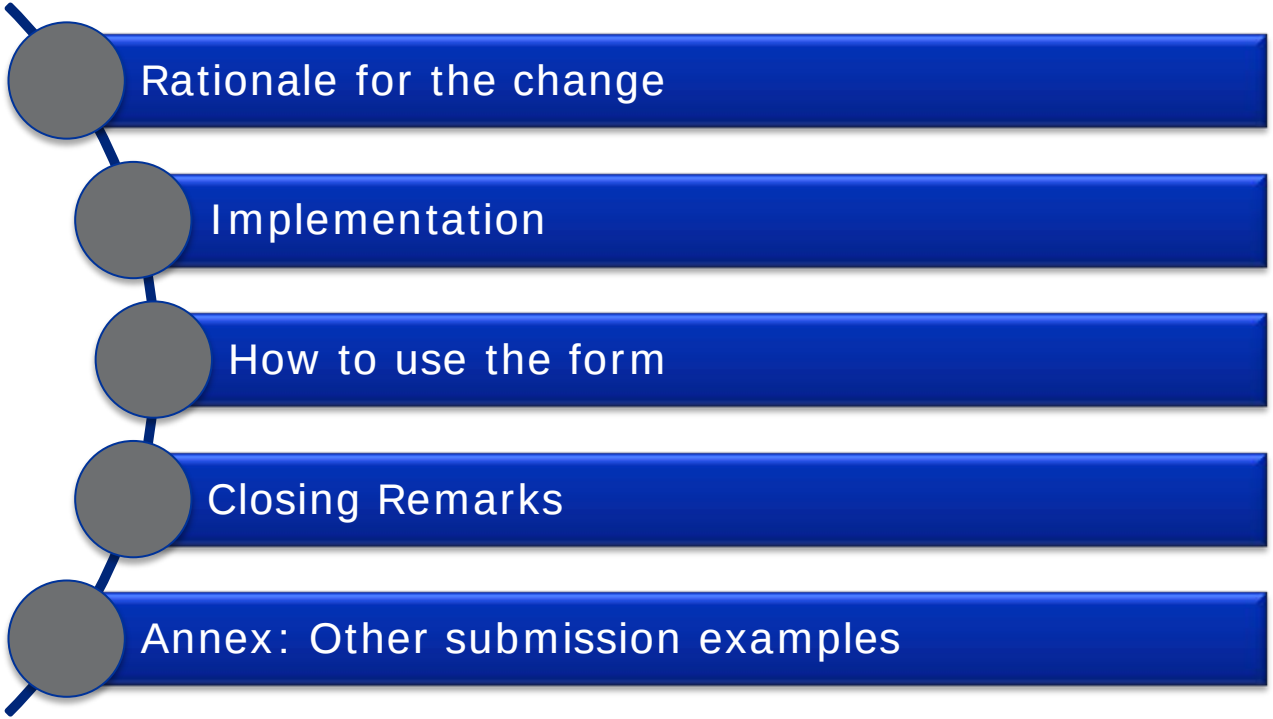
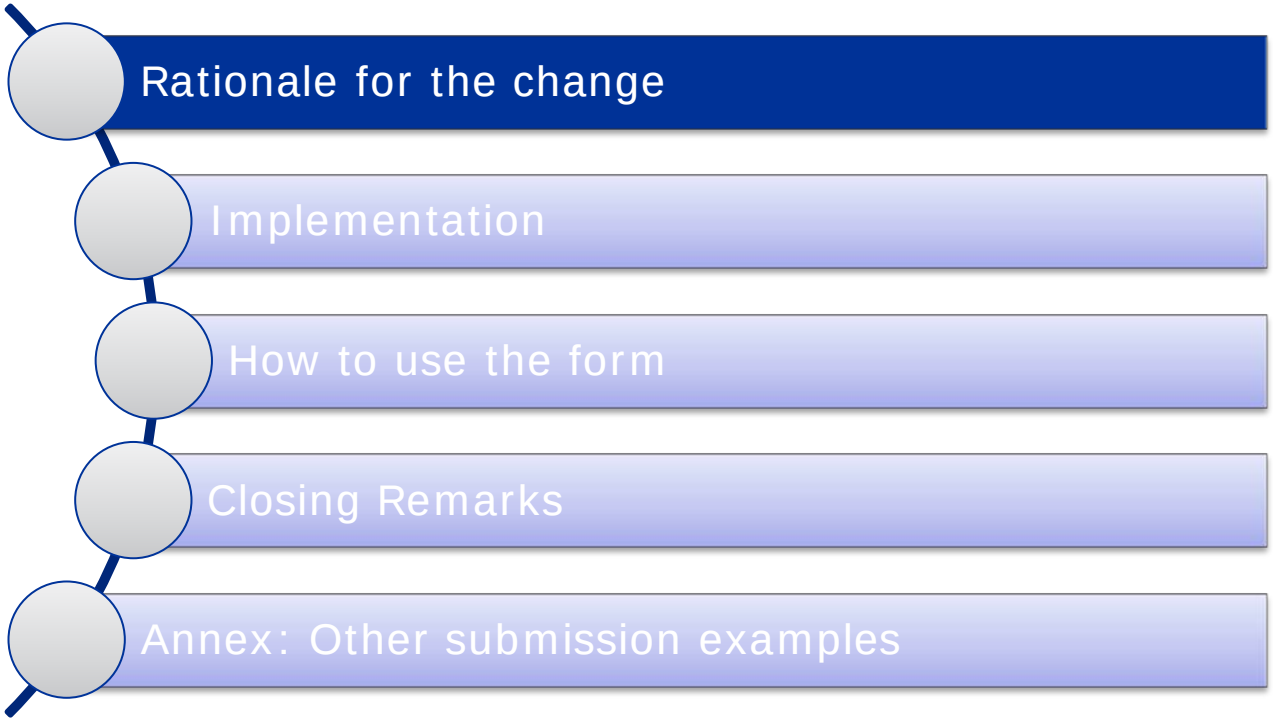
An agency of the European Union

Content Summary



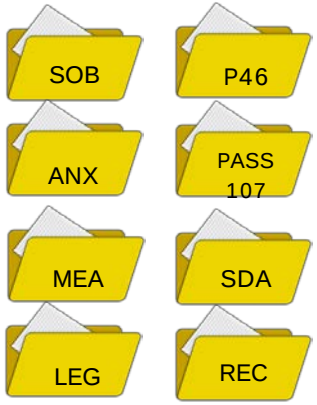

Rationale for the change
Implementation
How to use the form
Closing Remarks
Annex: Other submission examples

PAMs – Why a PAM submission form?

- PAMs are high volume procedures (~900 per year) involving various committees , EMA resources and different timelines based on the type of data (e.g. protocol, result, imposed, recommended etc.)
- From the submissions received there are uncertainties on the PAM classification.
- This increases the risk of misrouting the procedure to incorrect Committees , EMA resources and assign incorrect timelines.
- Currently a lot of effort is being put to ensure correct routing, resource allocation & timelines

➢ **Need to streamline this phase of the process & bridge the gap between the terminology used in the submissions & the operational language**

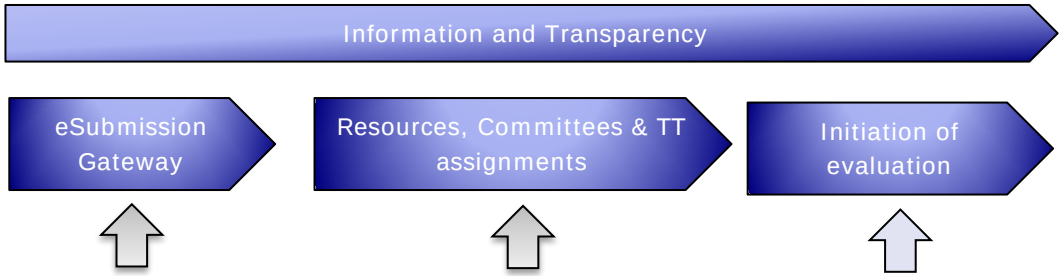
What changes?!



8 PAM types

***New* PAM Submission Form**

Improved



Improved *Submission*

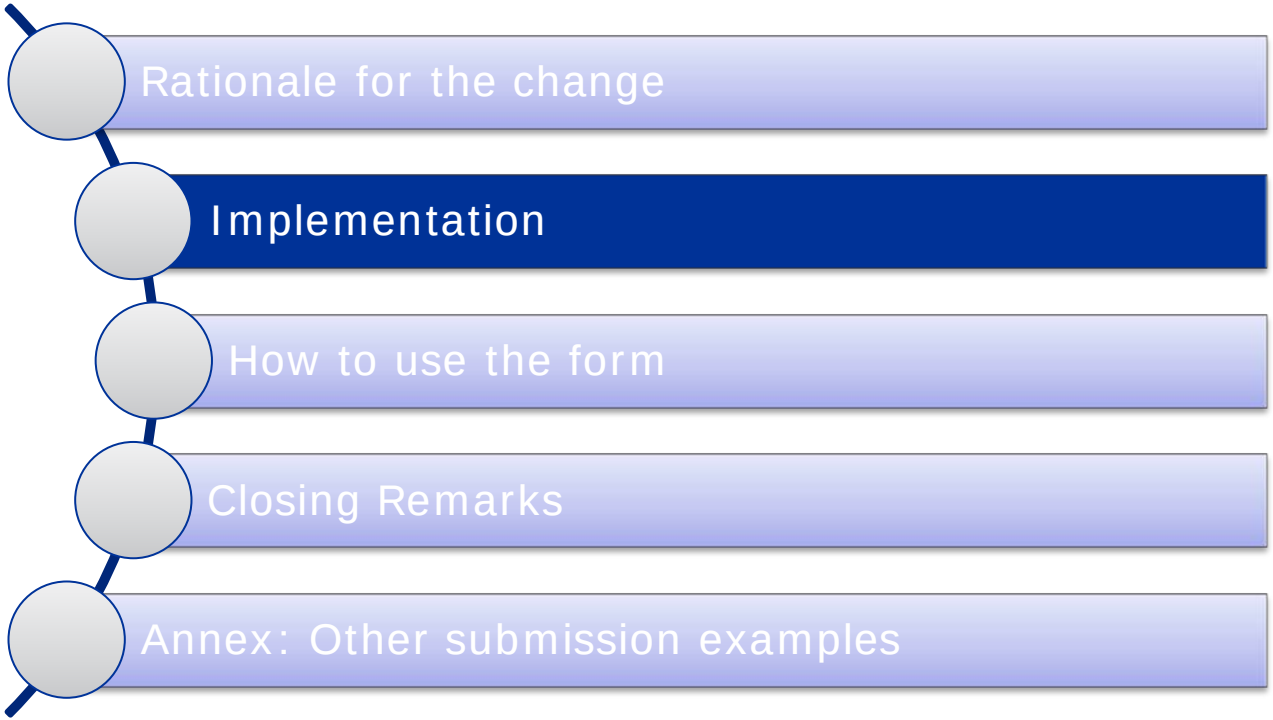
Improved *Allocation*

Improved *Start*

- Form is a link between the submission, gateway portal & internal EMA database
- Form ensures correct routing, allocation & timelines for the procedure (still a submission cover letter but simplified)

Expected Benefits

- Better end to end process by improving the submission & start phase
- Greater automation for the PAM submission
- Increased transparency for the Applicant
- Aligned terminology & operational language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Timelines for Implementation

4th CP Platform Meeting

July 2017

M	T	W	T	F	S	S
					1	2
3	4	5	6	7	8	9
10	11	12	13	14	15	16
17	18	19	20	21	22	23
24	25	26	27	28	29	30
31						

August 2017

M	T	W	T	F	S	S
	1	2	3	4	5	6
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30	31			

Last submission date using the current cover letter

September 2017

M	T	W	T	F	S	S
				1	2	3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	

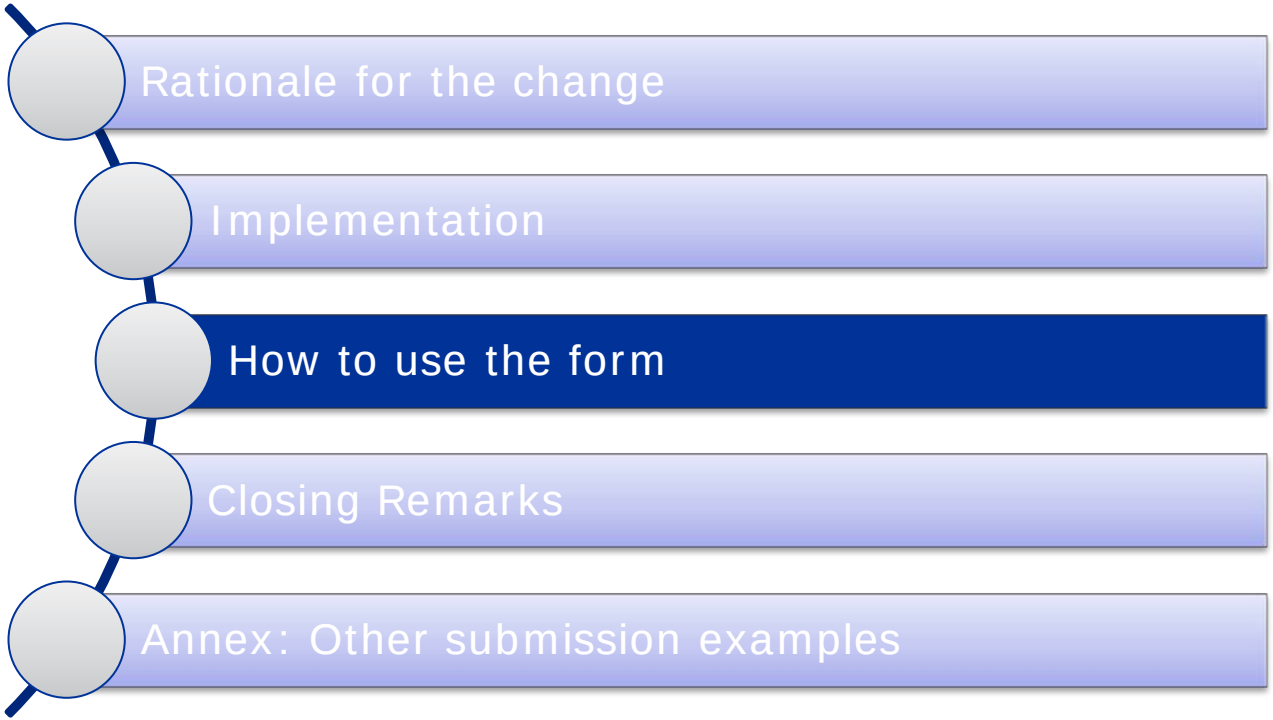
PAM submission deadline for September 2017

eSubmission Gateway update & new mandatory PAM submission form *

* Cover letter will also be simplified

Communication Plan

- 03 July 2017 – 4th CP platform Meeting
- Regulatory News Item
- Communication to Trade Associations
- 01 September 2017 – Go Live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Click on the **Reset** button to clear all the entries in the form.

Click on the **Information** button to find guidance in grey text that will help you answer each question.

Guidance in grey text.

Post Authorisation Measure Submission Form

Please complete the questionnaire below, which will assist you in identifying the type of post authorisation submission that you wish to make to the EMA.

Is the medicinal product an Advanced Therapy Medicinal Product (ATMP)? ○ Yes ✓ No

The criteria for ATMPs are set out in Article 17 of **Regulation (EC) No 1394/2007.**

Click on the **blue highlighted text** to access Directives, Regulations and EMA guidance.

The submission concerns:

Questions in black text.

Click on the **right-hand side arrow** to find a selection of answers to the question, from a drop down menu.

How to use the form – Select your submission type

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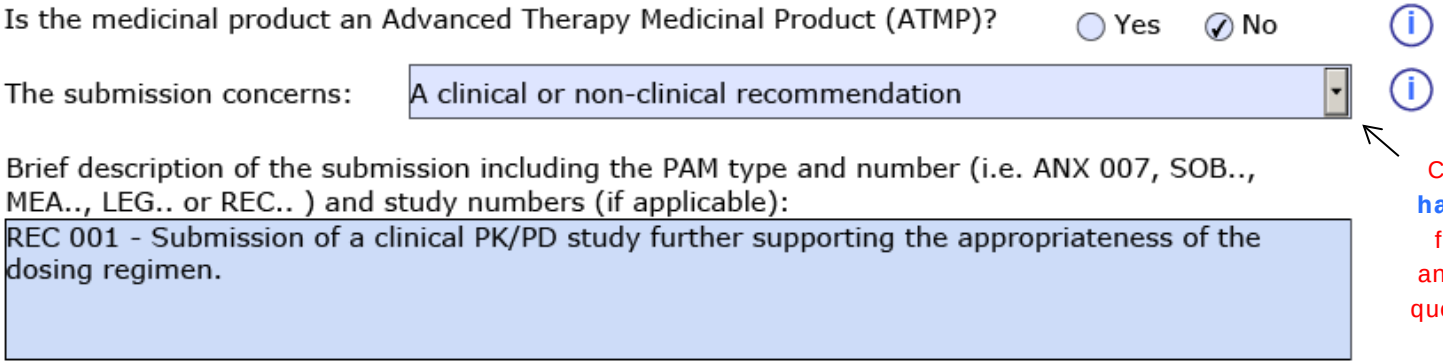
Select one of the two possible answers to the **first question**.



Click on the **right-hand side arrow** to find a selection of answers to the next question, from a drop down menu.

Complete the **description** of the submission in the box provided.

Click on the **Generate Output button** to find out how to present your submission to EMA. The results will appear automatically on the next page.

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Output

The **type** of submission, **Scientific Committees** involved and **timetable** appear here.

Submission instructions for the Gateway portal

You have chosen to submit a REC (Non-clinical or clinical, non-ATMP) involving CHMP, with a 60 days timetable by default. In the eSubmission Gateway, please select 'pam-rec' as the submisison type and 'CHMP only 60 Days PAM (H)' as the submission code for the delivery file user interface.

Follow the **instructions** provided to facilitate the submission via the Delivery file User Interface.

Validation Note - For EMA use only

Option 60: This assessment follows CHMP only 60 Days PAM (H) timetable and should involve the following resources at the beginning of the evaluation procedure: PM, PA.

These **notes** are for internal use at EMA to identify the right timetable for evaluation and team resources needed.

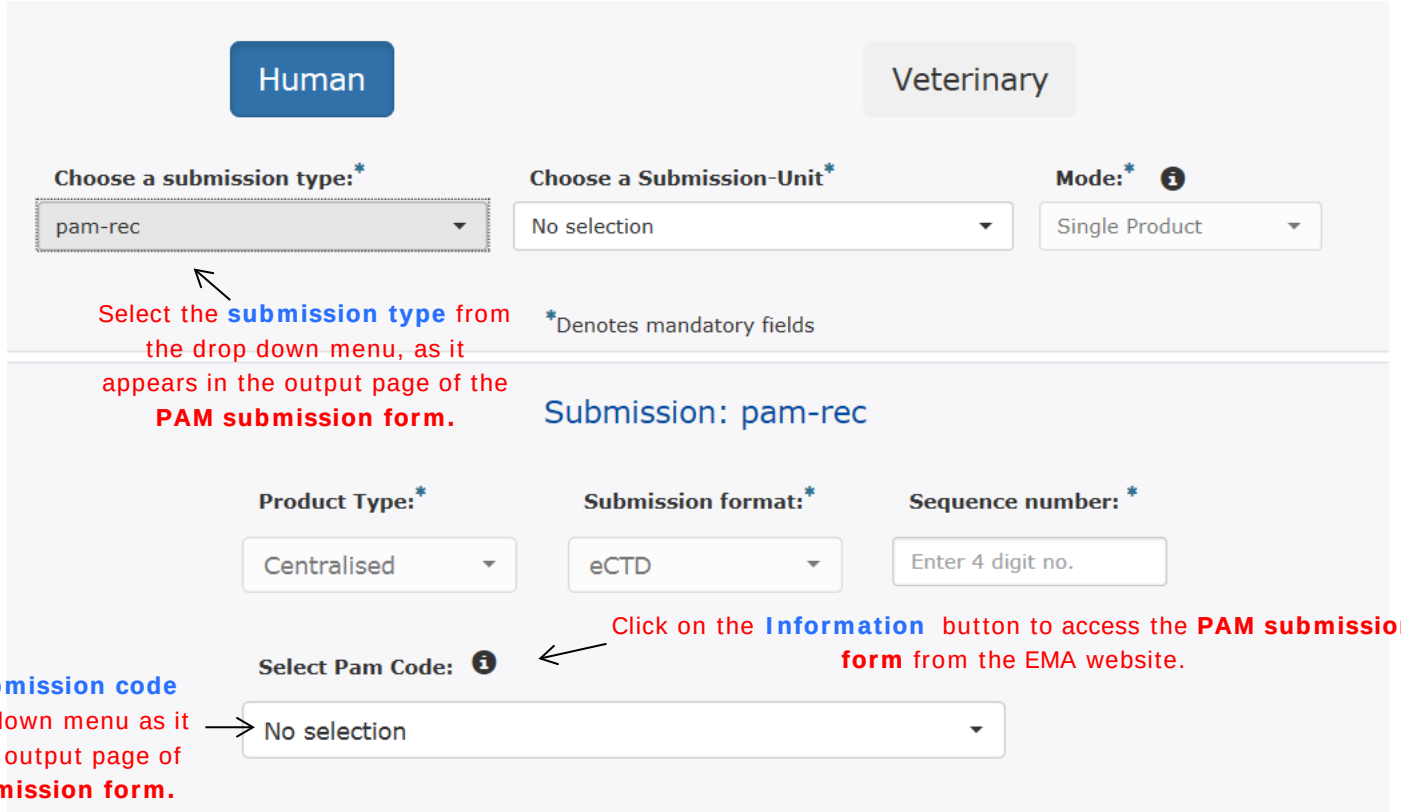
PAM Description:

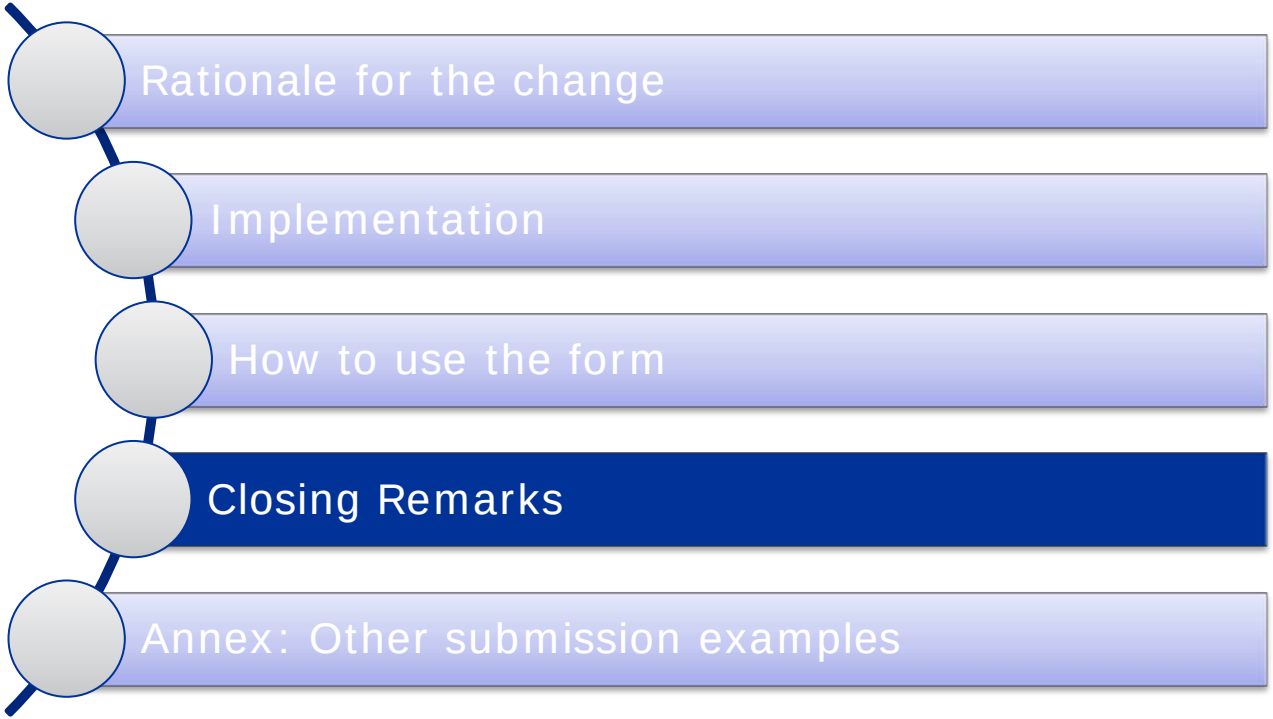
REC 001 - Submission of a clinical PK/PD study further supporting the appropriateness of the dosing regimen.

The **full description** of your submission as you entered it in the form, appears here.

Include the PAM submission form in Module 1 of your eCTD submission (appended to the cover letter).

How to use the form – Submit your PAM via Delivery File IU

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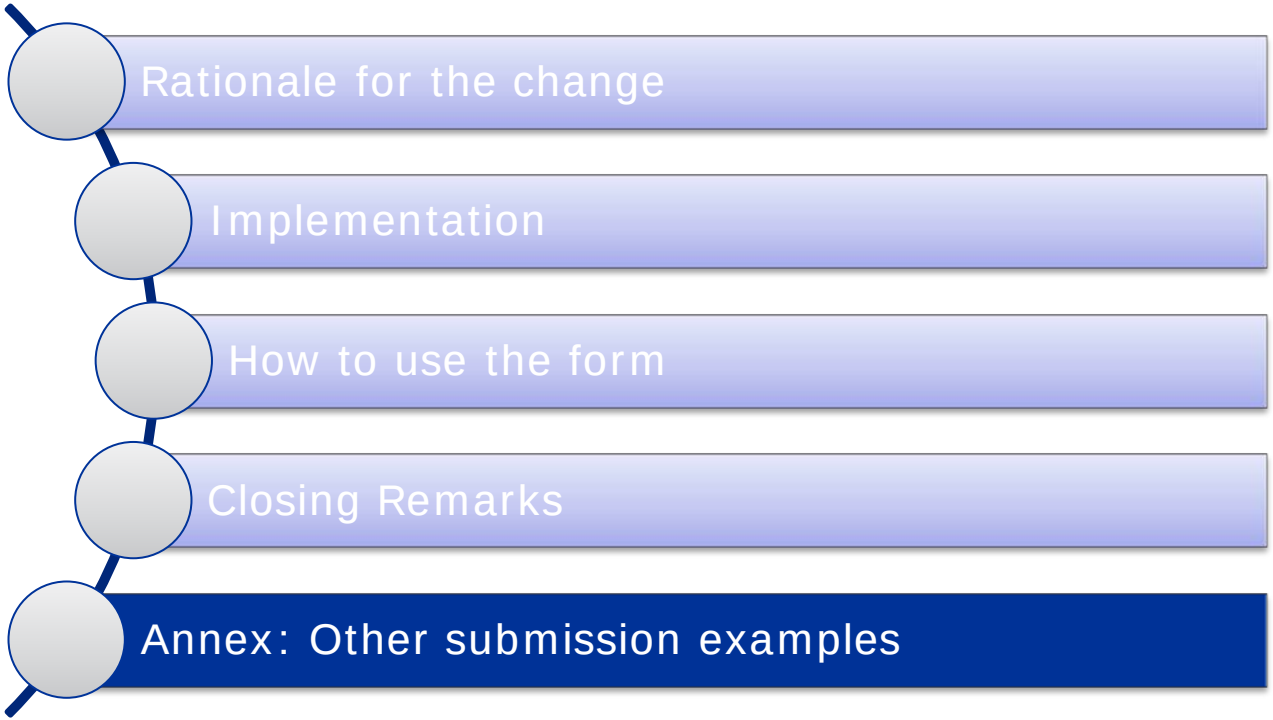
Closing Remarks

- **Go-Live** – **1st of September 2017**
- Keep a close look at our website for updates
- PM – your primary contact point
- Additional support – PAMquery@ema.europa.eu

We wish to make this a success for us all!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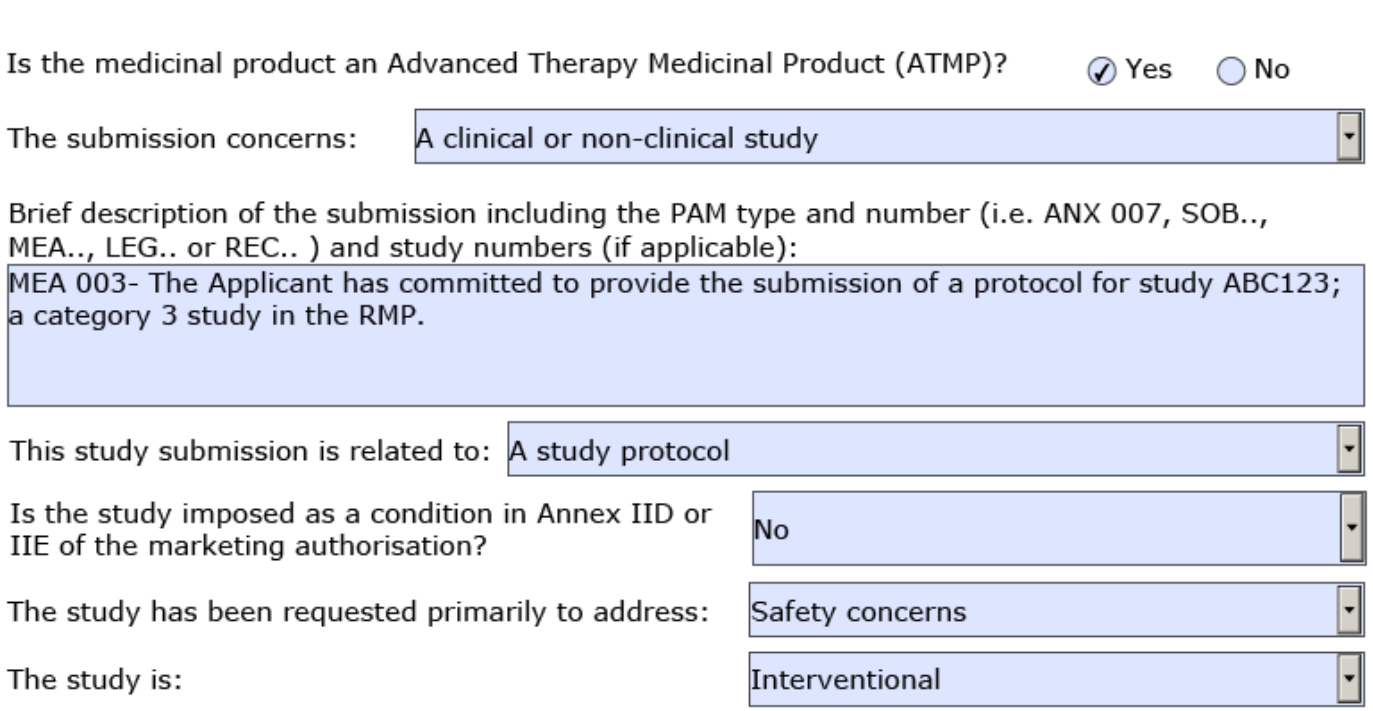
MEA

The following slides provide an example of a MEA submission.

How to submit a MEA



1. Select whether the product is an **ATMP or not.**

2. Select the submission **type** listed here.

3. Complete the **description** of the submission in the box provided.

4. Select whether the submission is a **protocol / interim results / final results**.

5. Select **No**

6. Select whether the study addresses **safety or efficacy concerns.**

7. Select whether the study is **interventional** or **observational**.

8. Click on the **Generate Output button** to find out how to present your submission to EMA. The results will appear automatically on the next page.

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Output

Submission instructions for the Gateway portal

You have chosen to submit a MEA (Non-imposed, interventional, safety study protocol, ATMP) involving PRAC, CAT, and CHMP, with a 74 days timetable by default. In the eSubmission Gateway, please select 'pam-mea' as the submisison type and 'PASS NII Protocol CAT PRAC CHMP 74 Days PAM (H)' as the submission code for the delivery file user interface.

Validation Note - For EMA use only

Option 1: This assessment follows PASS NII Protocol CAT PRAC CHMP 74 Days PAM (H) timetable and should involve the following resources at the beginning of the evaluation procedure: RMS, PA.

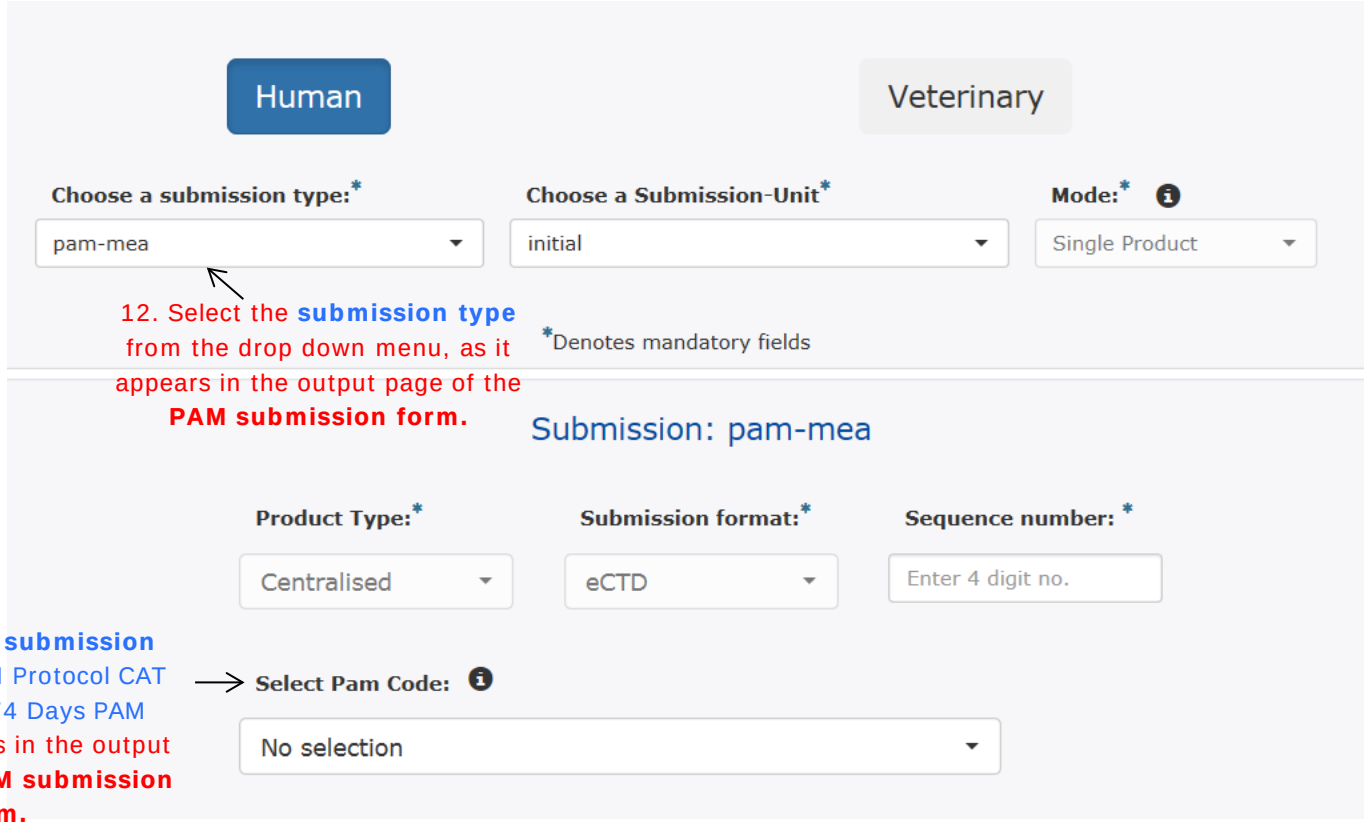
PAM Description:

MEA 003- The Applicant has committed to provide the submission of a protocol for study ABC123; a category 3 study in the RMP.

9. Use the **submission type** and **submission code** listed here for the delivery file User Interface.

10. Save the file as a **new PDF** on your desktop.

11. Make sure you submit the file together with your eCTD sequence as part of **Module 1**.



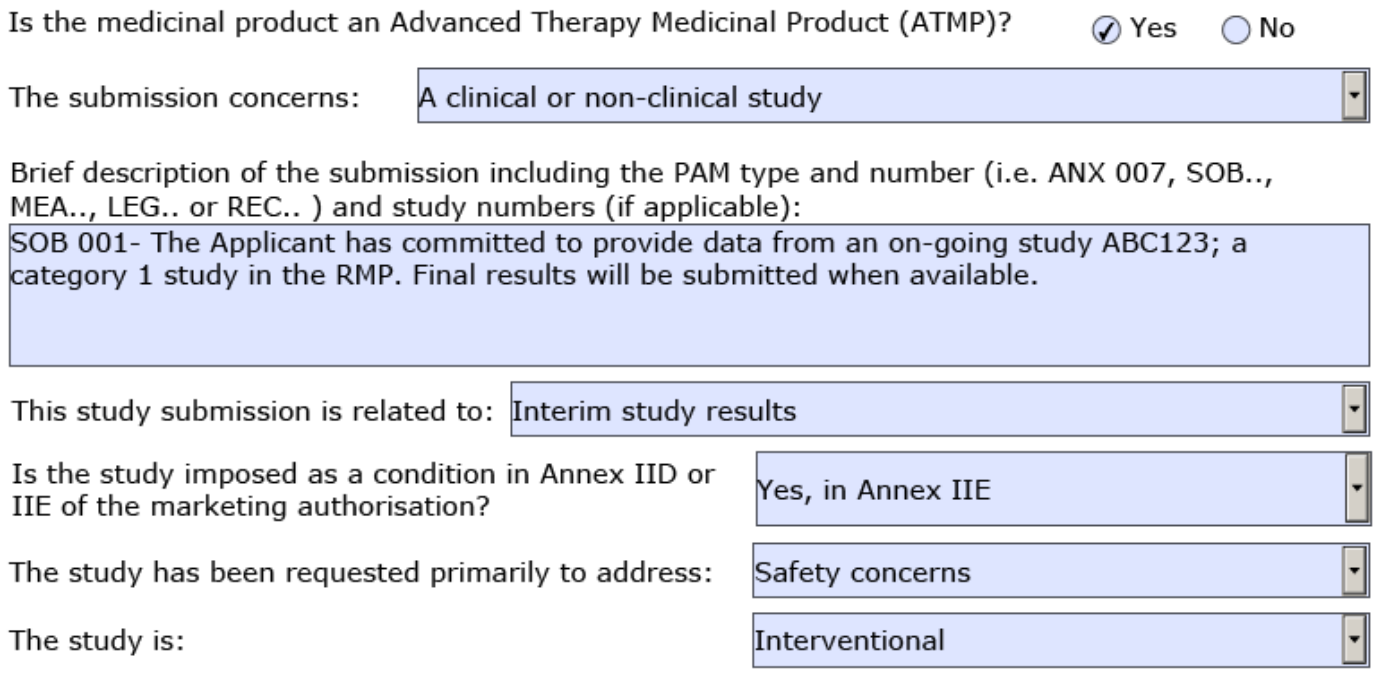
12. Select the **submission type** from the drop down menu, as it appears in the output page of the **PAM submission form.**

13. Select the **submission code** PASS NII Protocol CAT PRAC CHMP 74 Days PAM (H)as it appears in the output page of the **PAM submission form.**

SOB

The following slides provide an example of a SOB submission.

How to submit a SOB



1. Select whether the product is an **ATMP or not.**

2. Select the submission **type** shown here.

3. Complete the **description** of the submission in the box provided.

4. Select whether the submission is a **protocol / interim results / final results**.

5. Select **Annex II E.**

6. Select whether the study addresses **safety** or **efficacy** concerns.

7. Select whether the study is **interventional** or **observational**.

8. Click on the **Generate Output button** to find out how to present your submission to EMA. The results will appear automatically on the next page.

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Output

Submission instructions for the Gateway portal

You have chosen to submit a SOB (Imposed, interventional, safety study interim results, ATMP) involving PRAC, CAT, and CHMP, with a 74 days timetable by default. In the eSubmission Gateway, please select 'pam-sob' as the submisison type and 'CAT PRAC CHMP 74 Days PAM (H)' as the submission code for the delivery file user interface.

Validation Note - For EMA use only

Option 18: This assessment follows CAT PRAC CHMP 74 Days PAM (H) timetable and should involve the following resources at the beginning of the evaluation procedure: PM, PA.

PAM Description:

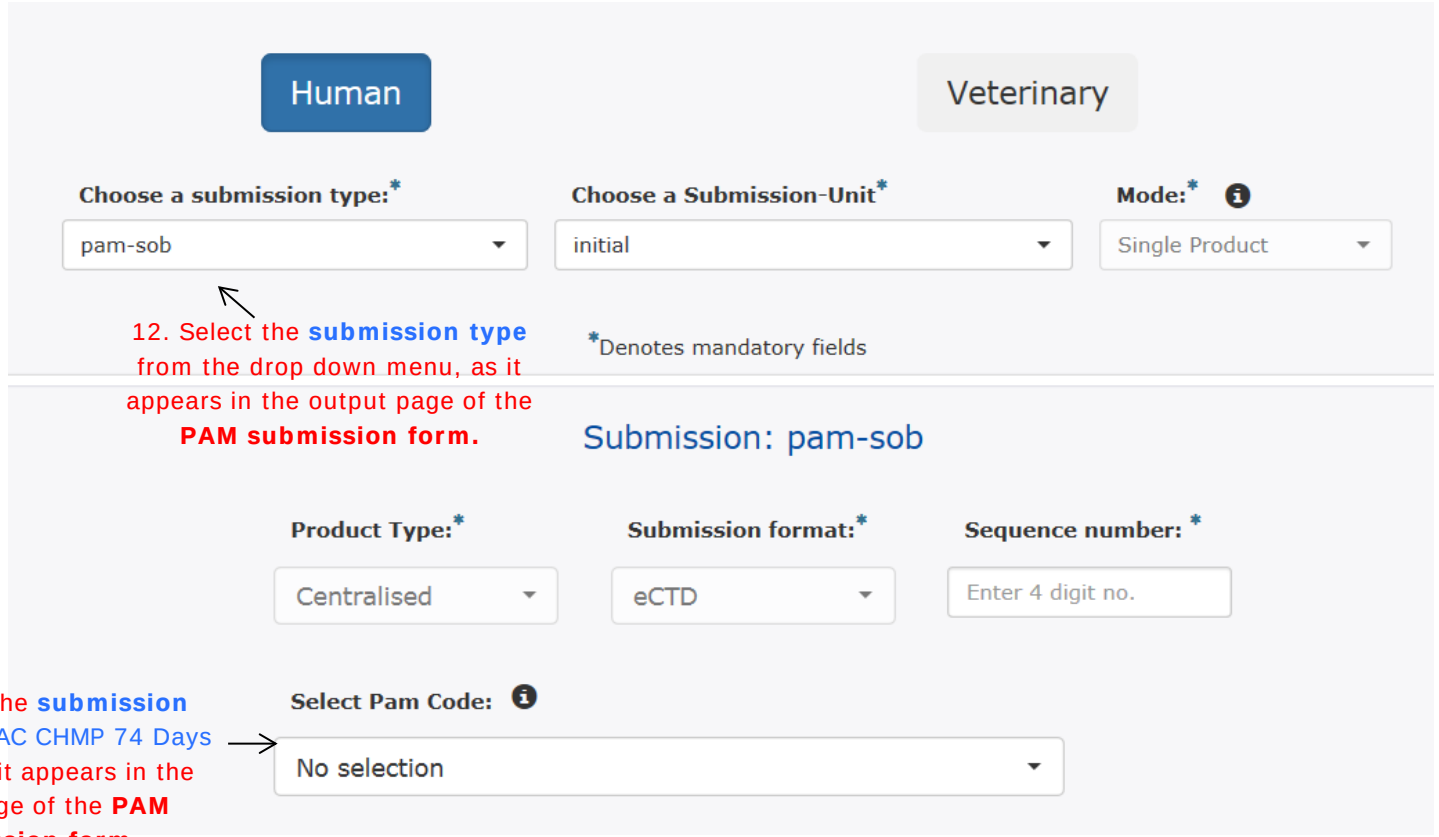
SOB 001- The Applicant has committed to provide data from an on-going study ABC123; a category 1 study in the RMP. Final results will be submitted when available.

9. Use the **submission type** and **submission code** listed here for the delivery file User Interface.

10. Save the file as a **new PDF** on your desktop.

11. Make sure you submit the file together with your eCTD sequence as part of **Module 1**.

How to submit a SOB



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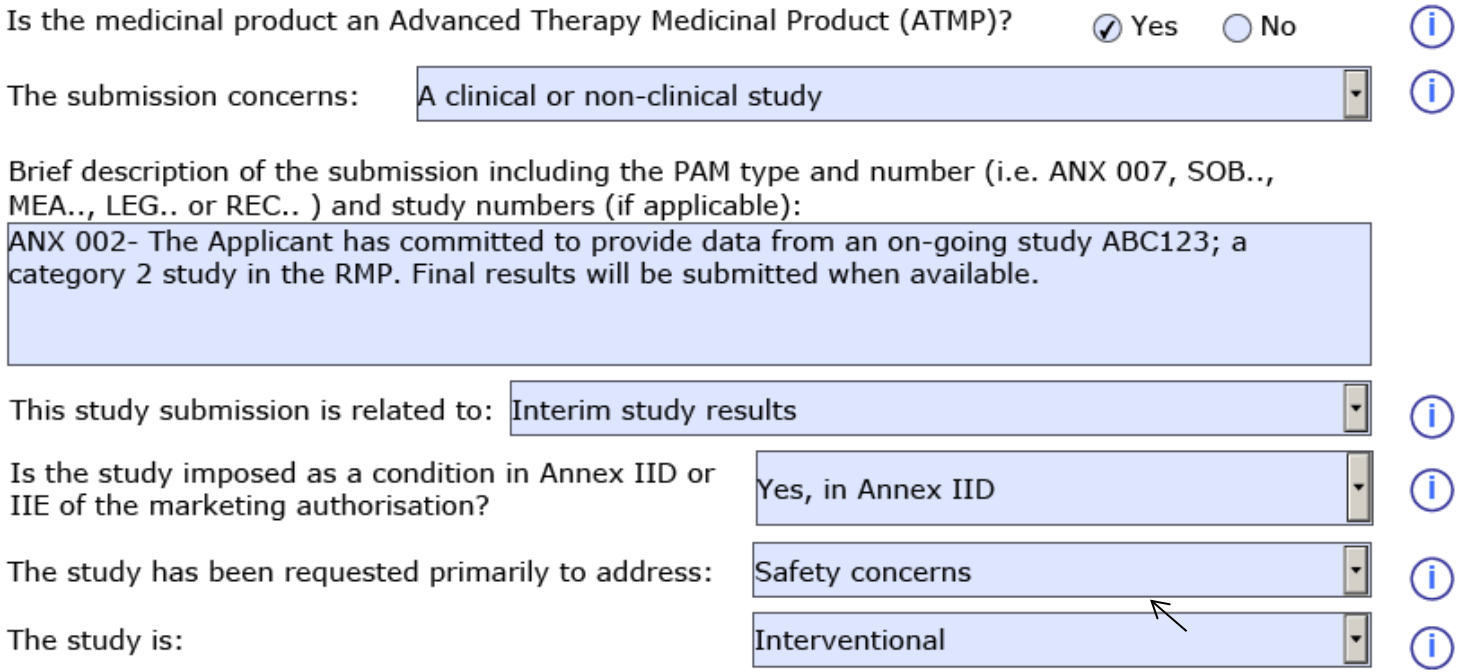
ANX

The following slides provide an example of an ANX submission.

How to submit an ANX



1. Select whether the product is an **ATMP or not.**
2. Select the submission type **clinical / non-clinical study** or **quality measure**.
3. Complete the **description** of the submission in the box provided.
4. Select whether the submission is a **protocol / interim results / final results**.
5. Select **Annex II D.**
6. Select whether the study addresses **safety** or **efficacy concerns**.
7. Select whether the study is **interventional** or **observational.**

8. Click on the **Generate Output button** to find out how to present your submission to EMA. The results will appear automatically on the next page.

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Output

Submission instructions for the Gateway portal

You have chosen to submit an ANX (Imposed, interventional, safety study interim results, ATMP) involving PRAC, CAT, and CHMP, with a 74 days timetable by default. In the eSubmission Gateway, please select 'pam-anx' as the submisison type and 'CAT PRAC CHMP 74 Days PAM (H)' as the submission code for the delivery file user interface.

9. Use the **submission type** and **submission code** listed here for the delivery file User Interface.

Validation Note - For EMA use only

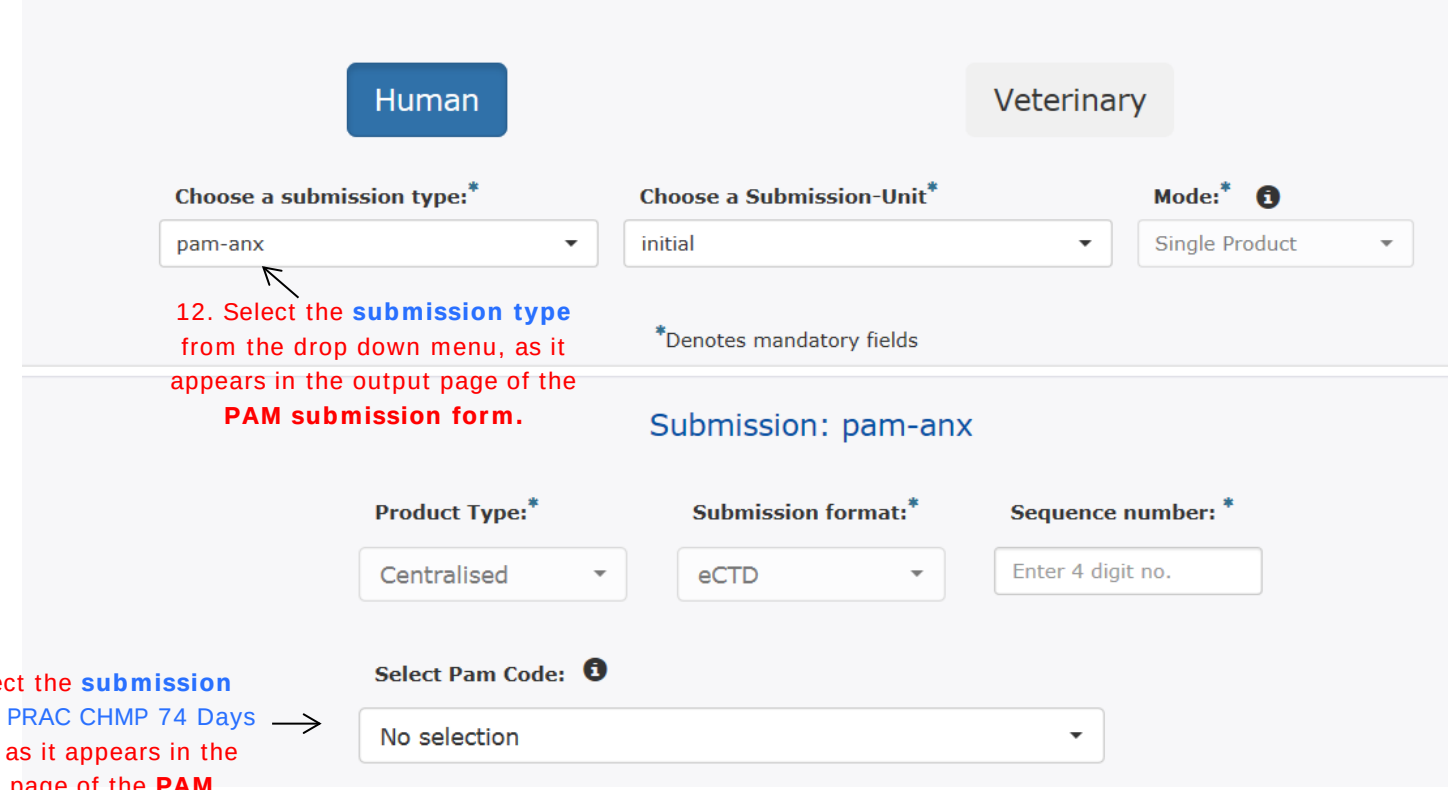
Option 17: This assessment follows CAT PRAC CHMP 74 Days PAM (H) timetable and should involve the following resources at the beginning of the evaluation procedure: PM, PA.

10. Save the file as a **new PDF** on your desktop.

PAM Description:

ANX 002- The Applicant has committed to provide data from an on-going study ABC123; a category 2 study in the RMP. Final results will be submitted when available.

11. Make sure you submit the file together with your eCTD sequence as part of **Module 1**.



12. Select the **submission type** from the drop down menu, as it appears in the output page of the **PAM submission form.**

13. Select the **submission code** CAT PRAC CHMP 74 Days PAM (H) as it appears in the output page of the **PAM submission form.**

Thank you for your attention

Further information

PAMquery@ema.europa.eu

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