



26 January 2023
EMA/569306/2021 Rev. 1
Scientific & Regulatory Management Department

PMF Timetable¹: (60-day) – Period 2021-2024

Note: Important additional information and abbreviations (e.g. PER) on the use of the timetable are included at the end of this document

Ref.	Sub-mission	Start/or Response 30d clock stop	PER	BWP comments	TC	UER	BWP	CHMP
PMF60d1	12/11/2021	28/11/2021	22/12/2021	03/01/2022	06/01/2022	10/01/2022	19/01/2022	27/01/2022
PMF60d2	10/12/2021	26/12/2021	24/01/2022	31/01/2022	03/02/2022	07/02/2022	16/02/2022	24/02/2022
PMF60d3	07/01/2022	23/01/2022	21/02/2022	28/02/2022	03/03/2022	07/03/2022	16/03/2022	24/03/2022
PMF60d4	04/02/2022	21/02/2022	22/03/2022	29/03/2022	01/04/2022	05/04/2022	13/04/2022	22/04/2022
PMF60d5	04/03/2022	20/03/2022	19/04/2022	25/04/2022	28/04/2022	02/05/2022	11/05/2022	19/05/2022
PMF60d6	08/04/2022	24/04/2022	23/05/2022	30/05/2022	02/06/2022	07/06/2022	15/06/2022	23/06/2022
PMF60d7	06/05/2022	22/05/2022	20/06/2022	27/06/2022	30/06/2022	04/07/2022	13/07/2022	21/07/2022
PMF60d8	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
PMF60d9	01/07/2022	17/07/2022	16/08/2022	22/08/2022	25/08/2022	29/08/2022	07/09/2022	15/09/2022
PMF60d10	29/07/2022	14/08/2022	12/09/2022	19/09/2022	22/09/2022	26/09/2022	05/10/2022	13/10/2022
PMF60d11	26/08/2022	11/09/2022	10/10/2022	17/10/2022	20/10/2022	24/10/2022	04/11/2022	10/11/2022
PMF60d12	30/09/2022	16/10/2022	14/11/2022	21/11/2022	24/11/2022	28/11/2022	07/12/2022	15/12/2022
PMF60d13	11/11/2022	27/11/2022	22/12/2022	03/01/2023	05/01/2023	09/01/2023	18/01/2023	26/01/2023
PMF60d14	09/12/2022	25/12/2022	23/01/2023	30/01/2023	02/02/2023	06/02/2023	15/02/2023	23/02/2023
PMF60d15	13/01/2023	29/01/2023	27/02/2023	06/03/2023	09/03/2023	13/03/2023	22/03/2023	30/03/2023
PMF60d16	09/02/2023	25/02/2023	27/03/2023	03/04/2023	05/04/2023	11/04/2023	18/04/2023	26/04/2023
PMF60d17	10/03/2023	26/03/2023	24/04/2023	02/05/2023	04/05/2023	08/05/2023	17/05/2023	25/05/2023
PMF60d18	05/04/2023	23/04/2023	22/05/2023	30/05/2023	01/06/2023	05/06/2023	14/06/2023	22/06/2023
PMF60d19	05/05/2023	21/05/2023	19/06/2023	26/06/2023	29/06/2023	03/07/2023	12/07/2023	20/07/2023

¹ This timetable may be subject to revision



Ref.	Sub-mission	Start/or Response 30d clock stop	PER	BWP comments	TC	UER	BWP	CHMP
PMF60d20	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
PMF60d21	30/06/2023	16/07/2023	14/08/2023	21/08/2023	24/08/2023	28/08/2023	06/09/2023	14/09/2023
PMF60d22	28/07/2023	13/08/2023	11/09/2023	18/09/2023	21/09/2023	25/09/2023	04/10/2023	12/10/2023
PMF60d23	25/08/2023	10/09/2023	09/10/2023	16/10/2023	19/10/2023	23/10/2023	31/10/2023	09/11/2023
PMF60d24	29/09/2023	15/10/2023	13/11/2023	20/11/2023	23/11/2023	27/11/2023	06/12/2023	14/12/2023
PMF60d25	10/11/2023	26/11/2023	22/12/2023	03/01/2024	05/01/2024	08/01/2024	17/01/2024	25/01/2024
PMF60d26	08/12/2023	24/12/2023	22/01/2024	29/01/2024	01/02/2024	05/02/2024	14/02/2024	22/02/2024
PMF60d27	05/01/2024	21/01/2024	19/02/2024	26/02/2024	29/02/2024	04/03/2024	13/03/2024	21/03/2024
PMF60d28	09/02/2024	25/02/2024	25/03/2024	02/04/2024	04/04/2024	08/04/2024	17/04/2024	25/04/2024
PMF60d29	15/03/2024	31/03/2024	29/04/2024	06/05/2024	09/05/2024	13/05/2024	22/05/2024	30/05/2024
PMF60d30	12/04/2024	28/04/2024	27/05/2024	03/06/2024	06/06/2024	10/06/2024	19/06/2024	27/06/2024
PMF60d31	08/05/2024	26/05/2024	24/06/2024	01/07/2024	04/07/2024	08/07/2024	17/07/2024	25/07/2024
PMF60d32	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
PMF60d33	05/07/2024	21/07/2024	19/08/2024	26/08/2024	29/08/2024	02/09/2024	11/09/2024	19/09/2024
PMF60d34	02/08/2024	18/08/2024	16/09/2024	23/09/2024	26/09/2024	30/09/2024	09/10/2024	17/10/2024
PMF60d35	30/08/2024	15/09/2024	14/10/2024	21/10/2024	24/10/2024	28/10/2024	06/11/2024	14/11/2024
PMF60d36	27/09/2024	13/10/2024	11/11/2024	18/11/2024	21/11/2024	25/11/2024	04/12/2024	12/12/2024

***Highlighted fields are subject to change**

Important additional information on use of the timetable:

Interim dates/milestones such as BWP Comments, UER, TC and BWP **are not made** available to applicant during the procedure; however, they are reflected in the final ER as adopted during the relevant CHMP meeting/date. The adopted CHMP ER will be sent to the Applicant/PMF Holder.

Abbreviation/Notes

- PER (Preliminary Evaluation Report). This is circulated to the Applicants.
This report sets out only the preliminary conclusions of the Coordinator. This report in no way binds the BWP/CHMP and is sent at this point for information only.
- TC (Teleconference) – TC dates will be confirmed in writing to experts.
TC takes place with Coordinators and the European Medicines Agency staff to discuss the evaluation and critically analyse the different objections/concerns raised in the Coordinators' ER and BWP comments.
- UER (Updated Evaluation Report)
- BWP (Biologics Working Party) – Takes place the week previous to CHMP

- CHMP (Committee for Proprietary Medicinal Products)

For BWP/CHMP precise dates in the month see the relevant page on the [European Medicines Agency](https://www.ema.europa.eu/) website.

Guidance on PER and responses:

* Whenever the PER (i.e. draft ER) recommends a **List of Questions**, the PreER should be considered for information only and **the PMF-H should wait until its CHMP adoption, i.e. no interim responses can be submitted** prior to the CHMP Adoption (unless if ER's recommendation changes during the PMF comment phase or Teleconference from List of Question to interim clarifications on UER).

** Whenever the draft ER raises issues that only need clarification and not assessment (**interim clarifications** selected), the PMF-H clarification can be provided at the latest by the BWP comments deadline, with the aim to expedite the PMF certification without a List of Questions. If clarification is not timely submitted, not resolved or additional comments are raised during the PMF comment phase or Teleconference, the full List of Questions will remain to be resolved.

A standard clock-stop of **1 month will apply** and responses should be submitted in accordance with the timetables published on the EMA website (<https://www.ema.europa.eu/en/human-regulatory/research-development/non-pharmaceutical-products/plasma-master-file/plasma-master-file-pmf-submissions>). For 30d clock stop responses submission date, please refer to column "Start/ or response 30d clock stop" stating the latest date for 30d clock submission.

If the PMF-H considers the need for a longer or immediate response timetable, the date proposal together with the response TT reference proposal should send with a justification to the PMF EMA contacts as soon as possible, after the receipt of the Update ER.

Immediate responses (i.e. Monday/Tuesday after CHMP) can only be submitted whenever the coordinator has previously ticked 30d assessment and only when coordinator considered that the questions raised require minor assessment and a short 30d TT assessment.