

29 June 2017  
EMA/404060/2015 Rev.3  
Human Medicines Evaluation

The timetables in this document may be subject to revision

## Non-interventional, imposed, Post-Authorisation Safety Study (PASS) protocols, protocol amendments and final study results<sup>1</sup> (CAPs and NAPs<sup>2</sup>)

	Deadline for Submission (*)	Start date	PRAC Rapporteur AR	Comments from PRAC (~)	Updated PRAC Rapporteur AR (#)	PRAC conclusion	CHMP/CMD(h) members comments (**) (~)	CHMP Opinion/CMD(h) position (**)
A1	23/01/2017	06/02/2017	07/03/2017	22/03/2017	27/03/2017	06/04/2017	12/04/2017	21/04/2017
A2	21/02/2017	07/03/2017	05/04/2017	20/04/2017	25/04/2017	05/05/2017	11/05/2017	18/05/2017
A3	28/03/2017	11/04/2017	10/05/2017	24/05/2017	01/06/2017	09/06/2017	15/06/2017	22/06/2017
A4	24/04/2017	08/05/2017	06/06/2017	21/06/2017	26/06/2017	06/07/2017	13/07/2017	20/07/2017
A5								
A6	20/06/2017	04/07/2017	02/08/2017	17/08/2017	22/08/2017	01/09/2017	07/09/2017	14/09/2017
A7	17/07/2017	31/07/2017	29/08/2017	13/09/2017	18/09/2017	28/09/2017	05/10/2017	12/10/2017
A8	15/08/2017	29/08/2017	27/09/2017	11/10/2017	16/10/2017	27/10/2017	03/11/2017	09/11/2017
A9	18/09/2017	02/10/2017	31/10/2017	15/11/2017	20/11/2017	30/11/2017	07/12/2017	14/12/2017
A10	31/10/2017	14/11/2017	13/12/2017	03/01/2018	05/01/2018	12/01/2018	18/01/2018	25/01/2018
A11	27/11/2017	11/12/2017	09/01/2018	24/01/2018	29/01/2018	08/02/2018	15/02/2018	22/02/2018
A12	22/12/2017	08/01/2018	06/02/2018	21/02/2018	26/02/2018	08/03/2018	15/03/2018	22/03/2018
A13	29/01/2018	12/02/2018	13/03/2018	28/03/2018	05/04/2018	12/04/2018	19/04/2018	26/04/2018
A14	06/03/2018	20/03/2018	18/04/2018	03/05/2018	08/05/2018	18/05/2018	24/05/2018	31/05/2018
A15	03/04/2018	16/04/2018	15/05/2018	30/05/2018	04/06/2018	14/06/2018	21/06/2018	28/06/2018

	Deadline for Submission (*)	Start date	PRAC Rapporteur AR	Comments from PRAC (~)	Updated PRAC Rapporteur AR (#)	PRAC conclusion	CHMP/CMD(h) members comments (**) (~)	CHMP Opinion/CMD(h) position (**)
A16	30/04/2018	14/05/2018	12/06/2018	27/06/2018	02/07/2018	12/07/2018	19/07/2018	26/07/2018
A17								
A18	25/06/2018	09/07/2018	07/08/2018	22/08/2018	27/08/2018	06/09/2018	13/09/2018	20/09/2018
A19	23/07/2018	06/08/2018	04/09/2018	19/09/2018	24/09/2018	04/10/2018	11/10/2018	18/10/2018
A20	20/08/2018	03/09/2018	02/10/2018	17/10/2018	22/10/2018	01/11/2018	08/11/2018	15/11/2018
A21	17/09/2018	01/10/2018	30/10/2018	14/11/2018	19/11/2018	29/11/2018	06/12/2018	13/12/2018
A22	05/11/2018	19/11/2018	18/12/2018	03/01/2019	08/01/2019	17/01/2019	24/01/2019	31/01/2019
A23	03/12/2018	17/12/2018	15/01/2019	30/01/2019	04/02/2019	14/02/2019	21/02/2019	28/02/2019
A24	20/12/2018	14/01/2019	12/02/2019	27/02/2019	04/03/2019	14/03/2019	21/03/2019	28/03/2019
A25	28/01/2019	11/02/2019	12/03/2019	27/03/2019	01/04/2019	11/04/2019	17/04/2019	26/04/2019
A26	04/03/2019	18/03/2019	16/04/2019	02/05/2019	07/05/2019	16/05/2019	22/05/2019	29/05/2019
A27	02/04/2019	16/04/2019	15/05/2019	29/05/2019	04/06/2019	14/06/2019	20/06/2019	27/06/2019
A28	29/04/2019	13/05/2019	11/06/2019	26/06/2019	01/07/2019	11/07/2019	18/07/2019	25/07/2019
A29								
A30	24/06/2019	08/07/2019	06/08/2019	21/08/2019	27/08/2019	05/09/2019	12/09/2019	19/09/2019
A31	22/07/2019	05/08/2019	03/09/2019	18/09/2019	23/09/2019	03/10/2019	10/10/2019	17/10/2019
A32	19/08/2019	02/09/2019	01/10/2019	16/10/2019	21/10/2019	31/10/2019	07/11/2019	14/11/2019
A33	16/09/2019	30/09/2019	29/10/2019	13/11/2019	18/11/2019	28/11/2019	05/12/2019	12/12/2019
A34	04/11/2019	18/11/2019	17/12/2019	03/01/2020	08/01/2020	16/01/2020	23/01/2020	30/01/2020
A35	02/12/2019	16/12/2019	14/01/2020	29/01/2020	03/02/2020	13/02/2020	20/02/2020	27/02/2020
A36	19/12/2019	13/01/2020	11/02/2020	26/02/2020	02/03/2020	12/03/2020	19/03/2020	26/03/2020
A37	04/02/2020	18/02/2020	18/03/2020	02/04/2020	07/04/2020	17/04/2020	23/04/2020	30/04/2020
A38	02/03/2020	16/03/2020	14/04/2020	29/04/2020	04/05/2020	14/05/2020	20/05/2020	28/05/2020
A39	30/03/2020	13/04/2020	12/05/2020	27/05/2020	02/06/2020	11/06/2020	18/06/2020	25/06/2020
A40	27/04/2020	11/05/2020	09/06/2020	24/06/2020	29/06/2020	09/07/2020	16/07/2020	23/07/2020
A41								

	Deadline for Submission (*)	Start date	PRAC Rapporteur AR	Comments from PRAC (~)	Updated PRAC Rapporteur AR (#)	PRAC conclusion	CHMP/CMD(h) members comments (**) (~)	CHMP Opinion/CMD(h) position (**)
A42	23/06/2020	07/07/2020	05/08/2020	20/08/2020	25/08/2020	04/09/2020	10/09/2020	17/09/2020
A43	20/07/2020	03/08/2020	01/09/2020	16/09/2020	21/09/2020	01/10/2020	08/10/2020	15/10/2020
A44	17/08/2020	31/08/2020	29/09/2020	14/10/2020	19/10/2020	29/10/2020	05/11/2020	12/11/2020
A45	14/09/2020	28/09/2020	27/10/2020	11/11/2020	16/11/2020	26/11/2020	03/12/2020	10/12/2020
A46	30/10/2020	16/11/2020	15/12/2020	04/01/2021	07/01/2021	14/01/2021	21/01/2021	28/01/2021
A47	30/11/2020	14/12/2020	12/01/2021	27/01/2021	01/02/2021	11/02/2021	18/02/2021	25/02/2021
A48	21/12/2020	11/01/2021	09/02/2021	24/02/2021	01/03/2021	11/03/2021	18/03/2021	25/03/2021
A49	26/01/2021	09/02/2021	10/03/2021	25/03/2021	30/03/2021	09/04/2021	15/04/2021	22/04/2021
A50	22/02/2021	08/03/2021	06/04/2021	21/04/2021	26/04/2021	06/05/2021	12/05/2021	20/05/2021
A51	29/03/2021	12/04/2021	11/05/2021	26/05/2021	31/05/2021	10/06/2021	17/06/2021	24/06/2021
A52	26/04/2021	10/05/2021	08/06/2021	23/06/2021	28/06/2021	08/07/2021	15/07/2021	22/07/2021
A53								
A54	22/06/2021	06/07/2021	04/08/2021	19/08/2021	24/08/2021	03/09/2021	09/09/2021	16/09/2021
A55	19/07/2021	02/08/2021	31/08/2021	15/09/2021	20/09/2021	30/09/2021	07/10/2021	14/10/2021
A56	16/08/2021	30/08/2021	28/09/2021	13/10/2021	18/10/2021	28/10/2021	04/11/2021	11/11/2021
A57	20/09/2021	04/10/2021	03/11/2021	17/11/2021	22/11/2021	02/12/2021	09/12/2021	16/12/2021

(1) Applicable only to the assessment of non-interventional, imposed PASS under Articles 107 n-q of Directive 2001/83/EC, including protocols (article 107n procedure), protocol amendments (article 107o procedure) and final study results (article 107q procedure). For protocols and protocol amendments of non-interventional, non-imposed PASS, the timetable of PAMs assessed by the PRAC applies instead. For the assessment of results from such studies, type II variations should be submitted.

(2) CAPs: Centrally Authorised Products; NAPs: Nationally Authorised Products

(\*) The Agency strongly recommends submitting the application before the legally binding submission deadline. This is to avoid missing the target start date as a result of a technically invalid eCTD submission, in which case the submission is considered void and it needs to be re-despatched.

(~) Comments from PRAC, CHMP and CMD(h) members are not made available to Marketing authorisation Holders (MAHs).

(#) An updated AR is optional and dependent on the comments received from PRAC members which create the need for the update.

(\*\*) Step only applicable in case of proposed changes to the Product Information.