



18 September 2019
EMA/444946/2017
Rev.2
Scientific Evidence Generation Department

Dates of 2020 SAWP meetings and submission deadlines

Scientific advice, protocol assistance, qualification of biomarkers and parallel consultation EMA/ EUnetHTA requests

SAWP Meeting dates 2020	
1 st meeting	13 January – 16 January 2020
2 nd meeting	10 February – 13 February 2020
3 rd meeting	9 March – 12 March 2020
4 th meeting	14 April – 17 April 2020*
5 th meeting	11 May – 14 May 2020
6 th meeting	8 June – 11 June 2020
7 th meeting	6 July – 9 July 2020
8 th meeting	31 August – 3 September 2020 updated
9 th meeting	28 September – 1 October 2020
10 th meeting	26 – 29 October 2020
11 th meeting	23 – 26 November 2020

Letter of intent latest template:

http://www.ema.europa.eu/docs/en_GB/document_library/Template_or_form/2009/11/WC5000119_10.pdf

*Tuesday start

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2020 Submission deadlines - Scientific advice, protocol assistance, qualification of biomarkers

Presubmission phase					Evaluation phase					
Start of procedure	Presubmission meeting**			Final briefing document by	SAWP1	SAWP2	D40	SAWP3	D70	PRAC endorsement (PASS procedures only)
	Yes		No		Start of procedure	Reports discussed	CHMP Adoption	Discussion Meeting (if required)	CHMP adoption	
	Letter of Intent and draft briefing document by	Dates of presubmission meeting	Letter of Intent and draft briefing document by							
13 – 16 Jan 2020	4 Nov 19	11 Nov 19 – 3 Jan 20	6 Dec 19	10 Jan 20	13 – 16 Jan 20	10 – 13 Feb 20	24 – 27 Feb 20	9 – 12 Mar 20	23 – 26 Mar 20	14 – 17 Apr 20
10 – 13 Feb 2020	6 Dec 19	16 Dec 19 – 31 Jan 20	17 Jan 20	7 Feb 20	10 – 13 Feb 20	9 – 12 Mar 20	23 – 26 Mar 20	14 – 17 Apr 20	27 – 30 Apr 20	11 – 14 May 20
9 – 12 Mar 2020	17 Jan 20	27 Jan 20 – 28 Feb 20	14 Feb 20	6 Mar 20	9 – 12 Mar 20	14 – 17 Apr 20	27 – 30 Apr 20	11 – 14 May 20	25 – 28 May 20	8 – 11 Jun 20
14 – 17 Apr 2020	14 Feb 20	24 Feb 20 - 3 Apr 20	20 Mar 20	8 Apr 20	14 – 17 Apr 20	11 – 14 May 20	25 – 28 May 20	8 – 11 Jun 20	22 – 25 Jun 20	6 – 9 Jul 20
11 – 14 May 2020	20 Mar 20	30 Mar 20 - 30 Apr 20	17 Apr 20	8 May 20	11 – 14 May 20	8 – 11 Jun 20	22 – 25 Jun 20	6 – 9 Jul 20	20 – 23 Jul 20	31 Aug – 3 Sep 20
8 – 11 Jun 2020	17 Apr 20	28 Apr 20 - 29 May 20	15 May 20	5 Jun 20	8 – 11 Jun 20	6 – 9 Jul 20	20 – 23 Jul 20	31 Aug – 3 Sep 20	14 – 17 Sep 20	28 Sep – 1 Oct 20
6 – 9 Jul 2020	15 May 20	25 May 20 - 26 Jun 20	12 Jun 20	3 Jul 20	6 – 9 Jul 20	31 Aug - 3 Sep 2020	14 – 17 Sep 20	28 Sep – 1 Oct 20	12 – 15 Oct 20	26 – 29 Oct 20
31 Aug - 3 Sep 2020	12 Jun 20	22 Jun 20 - 21 Aug 20	17 Jul 20	28 Aug 20	31 Aug - 3 Sep 2020	28 Sep – 1 Oct 20	12 – 15 Oct 20	26 – 29 Oct 20	9 – 12 Nov 20	23 – 26 Nov 20
28 Sep – 1 Oct 2020	17 Jul 20	17 Aug 20 - 18 Sep 20	4 Sep 20	25 Sep 20	28 Sep – 1 Oct 20	26 – 29 Oct 20	9 – 12 Nov 20	23 – 26 Nov 20	7 – 10 Dec 20	11 – 14 Jan 21
26 – 29 Oct 2020	4 Sep 20	14 Sep 20 - 16 Oct 20	2 Oct 20	23 Oct 20	26 – 29 Oct 20	23 – 26 Nov 20	7 – 10 Dec 20	11 – 14 Jan 21	25 - 28 Jan 21	8 – 11 Feb 21
23 – 26 Nov 2020	2 Oct 20	12 Oct 20 - 13 Nov 20	30 Oct 20	20 Nov 20	23 – 26 Nov 20	11 – 14 Jan 21	25 – 28 Jan 21	8 – 11 Feb 21	24 – 27 Feb 21	8 – 11 Mar 21

2020 Submission deadlines – Parallel Consultation (Written only format & F2F format)

Start of procedure	Presubmission & validation phase			Evaluation phase							
	Presubmission meeting		Final briefing document by	Written-only format				F2F format			
	Yes (exceptionally)	No (default)		SAWP 1	SAWP 2	D40	D55	Written answers by applicant (to EUnetHTA, if F2F format)	SAWP 3	D70	D75
	Letter of Intent and draft briefing document by	Letter of Intent and draft briefing document by		Start of procedure	Reports discussed	CHMP Adoption	EUnetHTA / HTAB final recommendation letter (if Written-only format)		Face to face meeting (applicant, regulators and HTAs, if F2F format)	CHMP adoption	EUnetHTA/ HTAB final recommendation letter (if F2F format)
13 – 16 Jan 20	4 Nov 19	6 Dec 19	10 Jan 20	13 – 16 Jan 20	10 – 13 Feb 20	24 – 27 Feb 20	28 Feb 20	n/a	9 – 12 Mar 20	23 – 26 Mar 20	27 Mar 20
10 – 13 Feb 20	6 Dec 19	17 Jan 20	7 Feb 20	10 – 13 Feb 20	9 – 12 Mar 20	23 – 26 Mar 20	27 Mar 20	n/a	14 – 17 Apr 20	27 – 30 Apr 20	04 May 20
9 – 12 Mar 20	17 Jan 20	14 Feb 20	6 Mar 20	9 – 12 Mar 20	14 – 17 Apr 20	27 – 30 Apr 20	04 May 20	n/a	11 – 14 May 20	25 – 28 May 20	29 May 20
14 – 17 Apr 20	14 Feb 20	20 Mar 20	8 Apr 20	14 – 17 Apr 20	11 – 14 May 20	25 – 28 May 20	29 May 20	n/a	8 – 11 Jun 20	22 – 25 Jun 20	26 Jun 20
11 – 14 May 20	20 Mar 20	17 Apr 20	8 May 20	11 – 14 May 20	8 – 11 Jun 20	22 – 25 Jun 20	26 Jun 20	n/a	6 – 9 Jul 20	20 – 23 Jul 20	24 Jul 20
8 – 11 Jun 20	17 Apr 20	15 May 20	5 Jun 20	8 – 11 Jun 20	6 – 9 Jul 20	20 – 23 Jul 20	24 Jul 20	n/a	31 Aug–3 Sep 20	14 – 17 Sep 20	18 Sep 20
6 – 9 Jul 20	15 May 20	12 Jun 20	3 Jul 20	6 – 9 Jul 20	31 Aug–3 Sep 20	14 – 17 Sep 20	18 Sep 20	n/a	28 Sep – 1 Oct 20	12 – 15 Oct 20	16 Oct 20
31 Aug–3 Sep 20	12 Jun 20	17 Jul 20 ¹	28 Aug 20	31 Aug–3 Sep 20	28 Sep – 1 Oct 20	12 – 15 Oct 20	16 Oct 20	12 Oct 20	26 – 29 Oct 20	9 – 12 Nov 20	13 Nov 20
28 Sep – 1 Oct 20	17 Jul 20	4 Sep 20	25 Sep 20	28 Sep – 1 Oct 20	26 – 29 Oct 20	9 – 12 Nov 20	25 Nov 20	09 Nov 20	23 – 26 Nov 20	7 – 10 Dec 20	11 Dec 20
26 – 29 Oct 20	4 Sep 20	2 Oct 20	23 Oct 20	26 – 29 Oct 20	23 – 26 Nov 20	7 – 10 Dec 20	22 Dec 20	07 Dec 20	11 – 14 Jan 21	25 – 28 Jan 21	29 Jan 21
23 – 26 Nov 20	2 Oct 20	30 Oct 20	20 Nov 20	23 – 26 Nov 20	11 – 14 Jan 21	25 – 28 Jan 21	10 Feb 21	22 Jan 21	8 – 11 Feb 21	24 – 27 Feb 21	26 Feb 21

¹ All requests for Parallel Consultations with EUnetHTA must follow the procedure outlined in the Open Call for ED Requests and the Parallel Consultations Guidance document