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Human Medicines Division

Consolidated 3-year work plan for the Clinical Domain

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Work plan period: January 2026 – December 2028 (with a first review point after one year)

Dates of Domain Meetings: Three virtual meetings per year

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Introduction

This workplan provides a high-level framework and strategic direction for the activities that will be undertaken by the Clinical Domain over a three-year period, outlining key objectives and priority areas for all therapeutic areas. This domain workplan is implemented as of 2026.

The main objectives of the Clinical Working Parties (WPs), in line with the European Medicines Agencies Network strategy 2028 and current CHMP workplan, are:

- Develop state of the art guidelines, taking stock of the latest scientific and methodological advances, thus driving innovation and development;
- Engage with EMA's stakeholders;
- Provide scientific and regulatory support to EMA's scientific committees.

The Clinical Domain will also engage in cross-domain collaboration with particular attention to planning interactions with the Methodology Working Party.

This 3-year work plan will undergo an annual review in January 2026 and 2027 to ensure the goals, objectives, and underlying actions remain relevant. Adjustments will be made as needed, considering the unmet needs, evolving environment and ongoing stakeholder engagement. Public consultations will be conducted every 3 years (next planned in 2027), while targeted stakeholder consultation may be carried out more frequently as needed.

The following working parties are within scope of this workplan:

- Central Nervous System Working Party (CNSWP);
- Cardiovascular Working Party (CVSWP);
- Haematology Working Party (HAEMWP);
- Infectious Diseases Working Party (IDWP);
- Oncology Working Party (ONCWP);
- Immune and Inflammatory Diseases Working Party (IIWP);
- Vaccines Working Party (VWP).

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1. Working Party Mandate

The Mandate, objectives, and rules of procedure for working parties under the quality, non-clinical, methodology, clinical and veterinary domains was endorsed by all relevant committees in September 2025.

The final document can be accessed here. The mandate and general objectives of WPs are covered in Section 3. The following sections provide additional details on the activities of the clinical WPs.

2. Guideline Development and Revision

Key objectives:

- Update existing clinical guidelines to reflect advancements in therapeutic areas and methodologies.
- Develop new guidelines addressing unmet needs.
- Conduct public consultations to gather stakeholder feedback on draft guidelines.
- Contribute to the development of concept papers and reflection papers for new areas and topics

Lead WP	Guideline/ Reflection paper/ Q&A	Is this a new guideline?	Stage of development (Draft, concept paper etc.)	Public consultation date
CNSWP	Guideline on clinical investigation of medicinal products for treatment of migraine	No	Final guideline to be released Q3 2026	
CNSWP	Guideline on clinical investigation of medicinal products for the treatment and prevention of bipolar disorder	No	Final guideline to be released Q4 2026	
CNSWP	Guideline on clinical investigation of medicinal products for the treatment of Parkinson's Disease	No	Draft guideline be released Q4 2026	
CNSWP	Clinical investigation of medicines for the treatment of Alzheimer's disease	No	Draft guideline to be released Q4 2026	
CNSWP	Guideline on clinical investigation of medicinal products for the treatment of retinopathies	Yes	Concept paper to be released Q3 2026	
CNSWP	Guideline on clinical investigation of medicinal products for the treatment of myasthenia gravis	Yes	Concept paper to be released Q1 2025	
CNSWP	Guideline on clinical investigation of medicinal products for the treatment of ALS	No	Concept paper to be released Q2 2026	
to be started in 2026				
CNSWP	Guideline on clinical investigation of medicinal products for the treatment of nicotine addiction	Yes	Concept paper to be released Q2 2026	

Lead WP	Guideline	Is this a new guideline?	Stage of development (Draft, concept paper etc.)	Public consultation date
CVSWP	Reflection paper for evaluation of cardiovascular safety of oncology medicinal products.	Yes	Concept paper released for public consultation in 3Q2024	Draft Reflection Paper to be released for 6 months public consultation 1Q2026 Final Reflection Paper to be released in 2026
CVSWP	Paediatric addendum to CHMP Guidelines on the clinical investigations of medicinal products for the treatment of pulmonary arterial hypertension (CHMP/EWP/213972/10)	No	Concept paper was released for public consultation until 30 September 2023; EMA stakeholders meeting to discuss suitable endpoints in the paediatric pulmonary arterial hypertension took place on 25 Sep 2024	Draft Addendum to be released for 6 months public consultation in 1Q2026
CVSWP	Paediatric addendum on weight control in children (EMEA/CHMP/EWP/517497/2007)	No	Concept paper was released for public consultation until 28 Feb 2025	Draft Guideline to be released for 6 months public consultation 1Q2026
to be started in 2026				
CVSWP	Reflection paper on overlapping aspects of patients' health including CV, Kidney, Metabolic diseases.	Yes	CP to be released for public consultation in 2026	Draft Reflection Paper to be released in 2027
CVSWP	Guideline on clinical investigation of medicinal products in the treatment of hypertension	No	CP to be released for public consultation in 2026	Public consultation date: Q4 2026

Lead WP	Guideline	Is this a new guideline?	Stage of development (Draft, concept paper etc.)	Public consultation date
HAEMWP	Clinical investigation of human normal immunoglobulin for subcutaneous and/or intramuscular administration (SCIg/IMIg) (CHMP/BPWP/410415/2011	No	To be finalised and published on EMA website	Finalise guideline following public consultation Q1 2026

Lead WP	Guideline	Is this a new guideline?	Stage of development (Draft, concept paper etc.)	Public consultation date
	Rev. 2) and core summary of product characteristics for human normal immunoglobulin for subcutaneous and/or intramuscular administration (EMA/CHMP/BPWP/143744/2011 rev. 2)			
HAEMWP	Guideline on the clinical requirements for medicines intended for the treatment of sickle cell disease	Yes	Draft to be published for public consultation	Public consultation Q2 2026 Finalise guideline following comments received during public consultation Q1 2027
HAEMWP	Guideline on the clinical requirements for medicines intended for the treatment of beta thalassemia	Yes	Draft to be published for public consultation	Public consultation Q2 2026 Finalise guideline following comments received during public consultation Q1 2027

Lead WP	Guideline	Is this a new guideline?	Stage of development (Draft, concept paper etc.)	Public consultation date
IDWP	Draft the Concept Paper on the need to update the Guideline on the clinical evaluation of antifungal agents for the treatment and prophylaxis of invasive fungal disease (CHMP/EWP/1343/01 Rev. 1).	No	Concept Paper	Public consultation for the concept paper Q2 2026
IDWP	Finalise the update of the Guideline on the clinical evaluation of medicinal products intended for treatment of hepatitis B virus infection (CHMP/EWP/6172/03).	No	Public consultation	30 September 2025-31 March 2026

Lead WP	Guideline	Is this a new guideline?	Stage of development (Draft, concept paper etc.)	Public consultation date
to be started in 2026-2028				
IDWP	Develop the Guideline on the evaluation of medicinal products indicated for treatment of influenza (Concept Paper EMA/CHMP/EWP/808940/2016).	Yes	Concept paper	
IDWP	Develop a concept paper followed by a Guideline on the clinical evaluation of medicinal products intended for the treatment of hepatitis D virus infection.	Yes		
IDWP	Update the Guideline on the clinical evaluation of antifungal agents for the treatment and prophylaxis of invasive fungal disease (CHMP/EWP/1343/01 Rev. 1).	No	Concept paper to be drafted	
IDWP	Update the Reflection paper on the non-clinical and clinical development for medicinal products indicated for HIV pre-exposure prophylaxis (PrEP) (EMA/171264/2012).	No		
IDWP	Reflection paper on non-clinical and clinical requirements for antivirals and monoclonal antibodies during the COVID-19 pandemic and potential use of this experience for pandemic preparedness against other coronaviruses (Concept paper EMA/CHMP/70203/2024).	Yes	Concept paper	

Lead WP	Guideline	Is this a new guideline?	Stage of development (Draft, concept paper etc.)	Public consultation date
ONCWP	Guideline on the clinical evaluation of anticancer medicinal products, EMA/CHMP/205/95 Rev.7	No	Concept paper for revision 7 developed in collaboration with MWP released for public consultation in Q2 2025.	Draft updated guideline release for consultation targeted for Q4 2026.
ONCWP	Appendix 4 to the Guideline on the clinical evaluation of anticancer medicinal products, EMA/CHMP/205/95 Rev.7 - Condition –specific guidance – Revision 1	No; Release of individual sections as standalone reflection papers	Link to Concept paper for revision 7 developed in collaboration with MWP released for public consultation in Q2 2025 - Aim of the revision to restructure the Appendix and update its individual components	Draft reflection papers to be released for external consultation from Q3 2026 onwards.
ONCWP	Guideline on the clinical evaluation of therapeutic radiopharmaceuticals in Oncology	Yes	Draft Concept paper released for public consultation in Q3 2024.	Draft Guideline release for public consultation in 2026
ONCWP as contributor	Reflection paper on the patient experience data in clinical trials	Yes	Draft Reflection paper released for public consultation in Q3 2025, comments from the review anticipated by Q1 2026	
ONCWP as contributor	Reflection paper on Cardiovascular Safety in Oncology	Yes		Draft reflection paper released for public consultation: 1Q2026 Final reflection paper release in 2026

Lead WP	Guideline	Is this a new guideline?	Stage of development (Draft, concept paper etc.)	Public consultation date
IIWP	Guideline on the clinical investigation of medicinal products for the treatment of psoriatic arthritis	Revision of an existing guideline	Draft updated Guideline released	Final updated Guideline to be published by Q4 2026
IIWP	Guideline on the clinical investigation of medicinal products in the term and preterm neonates	Revision of existing guideline.	Concept Paper released	Draft updated guideline to be published for public consultation by Q2 2026.
IIWP	Guideline on the development of new medicinal products for the treatment of Crohn's Disease	Revision of the paediatric parts of the existing Guideline.	Concept Paper released	Draft updated Guideline on the paediatric parts to be published for public consultation by Q4 2026
IIWP	Guideline on the development of new medicinal products for the treatment of Ulcerative Colitis	Revision of the paediatric parts of the existing Guideline.	Concept Paper released	Draft updated Guideline on the paediatric parts to be published for public consultation by Q4 2026
IIWP	Guideline on the clinical development of medicinal products for the treatment of cystic fibrosis	Revision of existing Guideline.	Concept paper released	Draft Guideline to be published for public consultation by Q1 2026
IIWP	Guideline on requirements for clinical documentation for demonstration of therapeutic equivalence for nasal products	New Guideline.	Concept paper released	Draft Guideline to be published for public consultation by Q3 2026
IIWP	Guidance document on the clinical investigation of medicinal products for the treatment of Idiopathic Pulmonary Fibrosis (IPF)	New Guideline or reflection paper	Concept paper released	Draft Guidance to be published for public consultation by Q4 2026
IIWP	Guidance document on the clinical investigation of medicinal products for the treatment of Systemic sclerosis	Reflection paper	Concept paper released	Draft guidance to be published for public consultation by Q3 2026
IIWP	Addendum on renal transplantation to the Guideline on Clinical Investigation of Immunosuppressants for Solid Organ Transplantation (see above)	Addendum or targeted revision to an existing guideline	Concept paper to be finalized	Concept paper to be published for public consultation Q2 2026

Lead WP	Guideline	Is this a new guideline?	Stage of development (Draft, concept paper etc.)	Public consultation date
IIWP	Guidance document on clinical investigation of medicinal products for idiopathic inflammatory myopathies (IIM).	New Guideline	Concept paper to be drafted	2027

Lead WP	Guideline	Is this a new guideline?	Stage of development (Draft, concept paper etc.)	Public consultation date
VWP	COVID-19 vaccines guidance	The current guidance documents for vaccine development need to be revised based on current criteria for approval of new COVID-19 vaccines including guidance on immuno-bridging strategies and scenarios in which use of immune makers for inferring protection is not appropriate. This revision is done jointly with ETF.	The guidance is under revision.	2026
VWP	Guideline on Influenza Vaccines, Non-clinical and Clinical Module, EMA/CHMP/VWP/457259/2014	This guideline entered into force in 2017. Since then, several requests for CHMP scientific advice as well as new MAAs have pointed to the need to update and clarify certain sections of this guidance to make it clearer and more comprehensive on specific matters. This is done jointly with the ETF.	A concept paper to describe the proposed changes has been finalised and published for public consultation in 2023. The guidance is under revision.	2026
to be started in 2026				
VWP	Guidance on the development of vaccines against orthopoxviruses	Considering the latest developments in terms of vaccines against orthopoxviruses, there is the need to generate a new guidance which provides clear directions to developers and informs on the requirements for the development of vaccines also with novel platforms.	A concept paper on this matter is intended to be produced in 2026 jointly with the ETF.	2026
VWP	Reflection paper on the use of animal models	Relevant regulatory experience has been accumulated in recent years on	The reflection paper will be drafted in 2026.	2026

Lead WP	Guideline	Is this a new guideline?	Stage of development (Draft, concept paper etc.)	Public consultation date
	to demonstrate efficacy of medicinal products targeting health threats	the use of animal models as key evidence of efficacy for the approval of medical countermeasures for which no human efficacy studies can be conducted, including aspects of study design in animals and immunobridging to humans. This reflection paper will bring together the current scientific and regulatory considerations in the field, with focus on advances and challenges in the generation, interpretation and use of animal efficacy data for inferring efficacy in humans. This paper will be done in collaboration with ETF, MWP and NcWP.		

3. Stakeholder Engagement and Collaboration

Key objectives:

- Enhance collaboration with patient organisations, learned societies, healthcare professionals and industry, including organisation of bilateral meetings where relevant.
- Organise public workshops or other interactions/exchanges.
- Enhance communication to disseminate knowledge and gather insights.

Planned general interaction

- i.e. consultations on workplan and on guidance documents

Planned meetings*:*

Working Party	Planned Stakeholder meeting	Objective of meeting	Planned date or dependency (e.g. link to guideline)	Indication of: f2f/ remote/ closed/open
CVSWP	EMA public stakeholder workshop on supporting innovation in cardiovascular medicines and medical devices in the EU	To enhance understanding among stakeholders on the interplay of regulation and innovation in CV medicines and medical devices	Q3 2026	hybrid/ registration will open in February 2026

Working Party	Planned Stakeholder meeting	Objective of meeting	Planned date	Indication of: f2f/ remote/ closed/open
HAEMWP	Organise a workshop on the challenges in drug development, regulation and clinical practice for medicines indicated for the treatment of Immune Thrombocytopenia (ITP)	• To present the current regulatory requirements for the clinical development of medicines in ITP in support of an MAA. • To get clinicians' / HCPs' perspective on the management of ITP before updating the guideline and considering several medicines under development (as highlighted by SAWP). • To get patients' representatives and HTAs perspectives in ITP.	30th June 2026 (TBC)	Remote and open
HAEMWP	Organise disease specific online webinars via the EUNTC platform in the field of non-malignant haematology or topic concerned with plasma.	• To provide a comprehensive view of the disease, the overview of the authorised medicines in this indication, the study design and endpoints used in clinical trials, the challenges encountered in clinical practice; • To constitute training in EU NTC for capacity buidline purposes.	2026	Remote and closed

Working Party	Planned Stakeholder meeting	Objective of meeting	Planned date	Indication of: f2f/ remote/ closed/open
		• To anticipate challenges before submission of MA based on business pipeline data.		

Working Party	Planned Stakeholder meeting	Objective of meeting	Planned date	Indication of: f2f/ remote/ closed/open
IDWP	Interact with WHO experts and groups, FDA and other regulatory bodies, and the European Centre for Disease Prevention and Control (ECDC) via IDWP meetings or teleconferences, and contribution to Innovative Medicines Initiative (IMI) calls and projects on an ad-hoc basis.	To discuss regulatory topics on different topics, including antivirals, antifungals, antibiotics, HIV PEP, etc.	A few times in 2026	Remote and closed
IDWP	Organise a training programme related to the updated hepatitis B virus guideline	To inform and train assessors on the updated hepatitis B virus guideline.	Q3 2026	Remote and closed

Working Party	Planned Stakeholder meeting	Objective of meeting	Planned date	Indication of: f2f/ remote/ closed/open
ONCWP	Organise disease specific online webinars via the EUNTC platform in the field of oncology.	• To provide a comprehensive view of the disease, the overview of the authorised medicines in this indication, the study design and endpoints used in clinical trials, the challenges encountered in clinical	2026	Remote and closed

Working Party	Planned Stakeholder meeting	Objective of meeting	Planned date	Indication of: f2f/ remote/ closed/open
		practice; • To constitute training in EU NTC for capacity building purposes. • To anticipate challenges before submission of MA based on business pipeline data.		

	Planned Stakeholder meeting	Objective of meeting	Planned date	Indication of: f2f/ remote/ closed/open
VWP	Training of assessors identified as being, or likely to be, involved in the clinical evaluation of vaccines. The material would be taken from recent scientific advice and applications.	The trainings are given fully remotely and cover the following topics: • basic principles for clinical vaccine development • immunogenicity data to support licensure • vaccine efficacy studies • vaccine effectiveness studies • vaccine safety pre- and post-licensure • understanding of the regulatory remit and how regulatory decisions are used by PHAs (including NITAGs where appointed) and the WHO (for prequalification) The trainers are VWP members ± co-opted external experts to cover specific topics.	The training has taken place at the end of 2025 and will continue until early 2026 hepatitis B	Remote and closed

4. Scientific Advice and Product Support

Key objectives:

- Provide expert input on request of the Committees on product related topics and support upon request the Scientific Advice Working Party

5. Collaboration

WPs support training and capacity building within the European medicines regulatory network and collaborate outside the network in areas of interest.

Key objectives:

- Develop trainings for assessors on newly developed or revised guidelines.
- Conduct workshops to build expertise in specific clinical areas.
- Foster knowledge exchange among assessors to ensure consistent evaluation practices.
- Participate in international cooperation and collaborate with other regulatory authorities aiming to harmonise clinical evaluation standards.

6. List of Abbreviations

Abbreviation	
CHMP	Committee for Medicinal Products for Human Use
CNSWP	Central Nervous System Working Party
CVSWP	Cardiovascular Working Party
EMA	European Medicines Agency
F2F	Face to face
HAEMWP	Haematology Working Party
IDWP	Infectious Diseases Working Party
ONCWP	Oncology Working Party
PED	Patient Experienced Data
PROs	Patient-Reported Outcomes
RIWP	Rheumatology/Immunology Working Party
QoL	Quality of Life
VWP	Vaccines Working Party
WP	Working Party