Clinical Trials Facilitation and Coordination Group CTFG

European Union Member States national pilot projects and participation in VHP-plus in support of the transition to the new Clinical Trial Regulation EU 536/2014

To facilitate implementation of the clinical trial regulation EU 536/2014, the European Union Member States (MS) have started pilots projects at national level. These national pilot projects focus on coordinated assessment by national competent authorities (NCA) and Ethics Committees of clinical trial application within one MS. The known Voluntary Harmonization Procedures (VHP) is still ongoing and addresses the coordinated multinational assessment of core documents by NCA, while within some MSs also Ethic Committees take part, in the so called VHP-plus.

The table below lists the MS and provides information on national pilot projects and participation in the VHP-plus by Ethics Committees. Also national pilot details or links to further information, are given.

Clinical Trials Facilitation and Coordination Group CTFG

Country	National Competent Authority	National Pilot Project	VHP plus participation
Austria	**AGES/BASG**	The project allows the coordinated assessment of initial CTAs between BASG and ECs within the current law mimicking the timeline for RMS assessment. This is a national project outside the VHP-plus. https://www.basg.gv.at/en/medicines/prior-to-authorisation/clinical-trials/pilot-project-for-clinical-trials-according-to-regulation-eu-5362014/	**No**
Belgium	**FAMHP**	**CTR pilot project.** This is the coordinated assessment between ECs and FAMHP of CTAs within timelines as defined in the current legislation (validation excepted) but following the CTR spirit. This is a national project outside the VHP. Information on FAMHP website: https://www.famhp.be/en/human_use/medicines/medicines/research_development/clinical_trials (FR, NL & EN) Guidance for sponsors: https://www.famhp.be/sites/default/files/content/procedure_ctr_pilot_project_for_sponsors_v3.0_1.pdf (English)	**Yes** From 1st March 2019 the VHP plus process will be part of the BE CTR pilot project. This is the combination of the VHP-plus process as described in the VHP guidance document for sponsors (with participation of the evaluating EC in the assessment of the VHP package) with the parallel submission of the part II of the CTA dossier to the national contact point in Belgium. See details on the FAMHP website: https://www.famhp.be/en/human_use/medicines/medicines/research_development/clinical_trials
Denmark	**DKMA**	**No**	**Yes** DK will be involved in VHP-plus only for clinical trials involving ATMPs and clinical trials involving children. Please note that clinical trials with ATMP and children that has been assessed in the VHP must be notified to National Research Ethic Committee

			for final ethic approval (and not the local REC), since it is the National Ethic committee that is involved in the VHP-procedure
Finland	**FIMEA**	**Clinical Trials Regulation (EU) No.536/2014 Pilot project.** Pilots starting in 2019	**No**
France	**ANSM**	**Pilot project EU-Regulation.** The project allows the coordinated assessment between ANSM and ECs of CTA in a defined timeline within current laws adapted as closely to upcoming clinical trial regulation. This is a national project outside the VHP-plus. Information on ANSM website http://ansm.sante.fr/Activites/Medicaments-et-produits-biologiques/Phase-pilote-application-du-Reglement-UE-N-536-2014-du-Parlement-europeen - Practical Information Guide for Applicants - assessment 6 months, 12 months, 18 months, 24 months	**No**
Germany	**PEI/BfArM**	**Pilotprojekt 'EU-Verordnung'** **(Pilot Project 'EU-Regulation').** Coordinated assessment of a initial clinical trials and their substantial amendments at national competent authority (BfArM, PEI) and ethics committee within current laws adapted as closely to upcoming clinical trial regulation. Information (mostly German) https://www.bfarm.de/DE/Arzneimittel/Arzneimittelzulassung/KlinischePruefung/Pilotprojekt/_node.html Guideline for sponsor (English)	**Yes** List of participating German ethics committees: https://www.pei.de/SharedDocs/Downloads/EN/pu/clinical-trials/list-ethics-committees-vhp.pdf;jsessionid=2DB8C05EA8DCE267E3290E69A79FE906.1_cid344?__blob=publicationFile&v=7

		https://www.bfarm.de/SharedDocs/Downloads/DE/Arzneimittel/Zulassung/klin-pr/pilotprojekt/Guideline.pdf?__blob=publicationFile&v=3	
Greece	**EOF**	**No**	**Planned for 2019**
Hungary	**OGYÉI**	**Pilot project for coordinated assessment of VHP** The project allows the coordinated assessment between National Institute of Pharmacy and Nutrition and ethics committee in case of initial clinical trial applications submitted through VHP+. This pilot project gives possibility for applicant to submit PART II documentation to ETT-KFEB in parallel to VHP+ application. The project started in November 2018. Details can be found at OGYEI homepage https://www.ogyei.gov.hu/vhp .	**Yes** See details on our website: https://www.ogyei.gov.hu/clinical_trial_submission_procedure
Ireland	**HPRA**	**Clinical Trials Regulation (EU) No.536(2014) Pilot project - Ireland** Coordinated review of initial clinical trials applications and their substantial amendments by HPRA and ethics committee within current laws Information Guideline	**No**
Italy	**AIFA**	**Pilot project for coordinated assessment of VHP** The project allows the coordinated assessment between AIFA and ECs of CT submitted through VHP. The aim of the project is to reach harmonized positions between AIFA and EC in a defined timeline. This is a national project outside the VHP-plus.	**No**
Latvia	**ZVA**	National pilot project with	**No**

		ethics committees planned after approval of National regulation regarding national ethics committees Pilot project planned in 2019	
Netherlands	**CCMO**	**Pilot project EU regulation** The Netherlands use VHP as a pilot for the Regulation, the Dutch ethics committees (12 accredited MREC and CCMO) are involved within the VHP. If the Netherlands participates in VHP then the ethics committee is always involved in the assessment.	**Yes** The Netherlands will be involved in VHP-plus. A list of participating ethic committees can be found on the CCMO website. Please see the link below: https://english.ccmo.nl/investigators/research-with-a-medicinal-product-voluntary-harmonisation-procedure-vhp
Norway	**NOMA**	**Pilot project for coordinated assessment of VHP** Norway will use VHP-plus as a pilot. The project allows the coordinated assessment between The Norwegian Medicines Agency and EC of CT submitted through VHP. The aim of the project is to reach harmonized positions between The Norwegian Medicines Agency and ECs in a defined timeline, and to prepare for the clinical trial regulation. This is the only pilot Norway will do. Norway will join VHP plus from April 1st 2019.	**Yes** Starting from April 1st 2019
Portugal	**INFARMED I.P./CEIC**	Pilot project for coordinated assessment between INFARMED and the National Ethics Committee for clinical research (CEIC) in preparation for the Clinical Trial Regulation is planned for 2019. National applications to INFARMED and CEIC are currently (separately) submitted via a common (national clinical research) Portal RNEC: http://www.rnec.pt/	**Yes**. Portugal participates in the VHP plus procedure since its beginning with the joint assessment of Protocol, IB and B/R assessment, being conducted both by INFARMED, I.P. and CEIC. INFARMED, I.P. liaises with CEIC to provide access to the CTA documentation as it becomes available and manages the procedure national and EU workflows thereafter according to a national timetable ensuring the assessment

			of the CTA is kept within the VHP procedure deadlines. http://www.infarmed.pt/web/infarmed/entidades/medicamentos-uso-humano/ensaios-clinicos/gfeec_ctfg Participating Ethis Committee - CEIC website: http://www.ceic.pt/
Slovenia	**HALMED**	A pilot project is in its conceptual phase. It will be a coordinated assessment by JAZMP and National Medical Ethics Committee of application dossier for the initial application mimicking the timelines and collaboration stipulated by the Regulation. CTs submitted will be authorised under current legislation.	**No**
Spain	**AEMPS**	Application of single decision in Spain is mandatory since 13th January 2016 according to national legislation (Royal decree 1090/2015) complementary to the CT Regulation EU Nº 536/2014, see https://www.aemps.gob.es/legislacion/espana/investigacionClinica/docs/Royal-Decree-1090-2015_4-December.pdf. AEMPS and Ethics Committees (CEIm) are involved in part I assessment and CEIm are responsible for part II assessment. Sharing of responsibilities between AEMPS and Ethics Committees is described in the "Memorandum on Collaboration and Exchange of Information between the Spanish Agency of Medicinal Products and Medical Devices and Ethics Committees for investigation with medicinal products" https://www.aemps.gob.es/en/investigacionClinica/medicamentos/docs/memorandum-collaboration-AEMPS-ethics-committees-investigation.pdf. National applications to AEMPS and CEIm should be	Yes. Spain is always joining VHPplus. According to the Royal Decree 1090/2015 complementary to the CT Regulation (UE) No. 536/2014, Ethics Committees are involved in the assessment of part I as indicated in the 'Memorando de Colaboración e Intercambio de Información entre la Agencia Española de Medicamentos y Productos Sanitarios y los Comités de Ética de la Investigación con medicamentos'. Therefore, in Spain it is necessary that sponsors involve Ethics Committees in the assessment of both initial and substantial modification applications submitted through VHP. The Spanish Agency of Medicines and Medical Devices will provide a single MS opinion (including common view by AEMPS and Ethics Committee) during the VHP and the final VHP opinion will be binding for both the AEMPS and the

		submitted via Portal ECM https://ecm.aemps.es/ecm/paginaPresentacion.do (see more information in "Instruction document of the Spanish Agency of Medicines and Medical Devices for conducting clinical trials in Spain" and its annexes available at https://www.aemps.gob.es/en/investigacionClinica/medicamentos/docs/Instrucciones-realizacion-ensayos-clinicos-EN.pdf and https://www.aemps.gob.es/en/investigacionClinica/medicamentos/anexos-instrucciones-AEMPS-realiza-EC.htm The list of Ethics Committees (CEIm) registered to evaluate clinical trials may be consulted at https://www.aemps.gob.es/en/investigacionClinica/medicamentos/docs/listado-comites-investigacion-clinica.pdf and their contact details may be found at https://www.aemps.gob.es/investigacionClinica/ceicsca.do In case of doubts, please contact AEMPS aecaem@aemps.es.	Ethics Committee. Further details may be consulted in section 38 of document ' Documento de instrucciones de la Agencia Española de Medicamentos y Productos Sanitarios para la realización de ensayos clínicos en España'. Both referred documents may be consulted in https://www.aemps.gob.es/investigacionClinica/medicamentos/ensayosClinicos.htm under NORMATIVA ESPAÑOLA.
Sweden	**MPA**	**Pilot project coordinated assessment in preparation for Clinical Trial Regulation** Coordinated assessment within the current legal framework between Swedish authorities simulating timelines for the collaboration when the Clinical Trial Regulation applies. The project started April 2017 and will continue until the clinical trial regulation applies. It includes coordinated assessment not only by the Swedish Medical Products Agency and by all Regional Ethics Committees, but also by the Biobank Sweden and by the Swedish Radiation Safety Committee. English summary:	**No**

		https://lakemedelsverket.se/upload/foretag/humanlakemedel/klinisk-provning/Pilotprojekt%20CT%20EU-536-2014/Summary-pilot-project-clinical-trials-EU-536-2014.pdf Extensive project information in Swedish: https://lakemedelsverket.se/malgrupp/Foretag/Lakemedel/Kliniska-provningar/Pilotprojekt-for-kliniska-lakemedelsprovningar-/	
The Czech Republic	**SUKL** .	**NO** According to the Czech legislation a pilot project can go live when Regulation goes live, otherwise we should be against our still valid legislation. We can participate only in VHP plus	**Yes** The Czech Republic will participate in VHP plus from February only partially see information on our webside: http://www.sukl.eu/medicines/important-information-for-applicants-for-clinical-trials