

ENCePP Work Plan 2017-2019 Progress Tracking

Objective	Deliverable	Lead	SG sponsor	Milestones	Initial Deadline	Progress	Status	EMA BCP proposal
ENCePP delivering to the lifecycle of medicines	ENCePP input to regulatory decision-making throughout the product life-cycle.	SG	Tom MacDonald	ENCePP review of draft EMA Strategy on Real World Evidence	Q3 2018 Q3 2019	Presentation on progress of RWE initiative to SG at its May 2018 meeting.	pending	Draft EMA strategy to be circulated to ENCePP SG when available for comments
				Revised ENCePP mandate for adoption	Q4 2018 Q4 2020		pending	Defer to 2020
Support capacity for evaluating medicine safety in pregnancy	Recommendations for strategy on pregnancy research, including funding.	SIG Pregnancy	Corinne de Vries	Draft appendix to the Methods Guide with methodological aspects (high-level) specific to this area of research	Q1 2020	Updated inventory of data sources available through EMA-funded study 'Drug exposure during pregnancy' (May 2018); publication on ENCePP website under consideration	pending	Postponed : revision 8 of Methods Guide to start at end of 2019, with view to publishing in 2020
				Input into EMA pregnancy strategy and GVP special populations (III): medicines in pregnancy and breastfeeding	Q1 2019		pending	To be circulated to ENCePP for written consultation when available
				Develop proposed mechanisms for research infrastructure & funding	Q1 2020		pending	Proposal to be circulated when available
Explore additional models for good governance of PhEpi research	Third party funding mechanism for PAS.	EMA/SG	Tom MacDonald Xavier Kurz	Consult ENCePP and stakeholders on potential governance models. Deliver possible models for joint studies, including options of trustee administered industry funding	Q1 2020	*Xavier Kurz to draft a concept paper on governance of PE studies, building on both the ADVANCE and Tom MacDonald's proposals (preliminary deadline: October 2018) *Further discussion at SG meeting in October 2018, but presentation to Plenary considered premature * Awaiting publication of ADVANCE Blueprint	ongoing	ENCePP consultaton following impact assessment (see item below). ADVANCE Blueprint to be finalised end Sept 2018 and to be circulated to SG when published to assess impact for ENCePP.

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Address methodological aspects of the generation of evidence-based information supporting the needs of regulatory and HTA decision-making	Gap analysis of existing guidance documents in relation to efficacy and effectiveness, in particular taking account of new guidance on PAES	WG1	Hans Hillege	Recommendation to SG	Q1 2020	Presentation on b/r online tracking tool to SG (July 2018) Hans Hillege to draft contribution for next update to ENCePP Methods Guide (scheduled for publication in 2020)	ongoing	Revision 8 of Methods Guide to start at end of 2019, with view to publishing in 2020
	Revision of ENCePP Guide on Methodological Standards in Pharmacoepidemiology including possible new chapters on special population/topics	WG1	Olaf Klungel Vera Ehrenstein Rosa Gini	Publication of annual revision	Q1 2020 (Rev8)		pending	Publication of one revision covering period 2019/2020; revision to start towards end 2019
	Revision of the ENCePP Checklist for Study Protocols.	WG1	Olaf Klungel	Publication of revised checklist	Q3 2018 Q4 2018	*changes proposed by Vera Ehrenstein to be taken into consideration with next revision *proposed changes were discussed and agreed by WG1 on 28/09/2018 *revised checklist to be circulated to SG for written adoption, followed by publication on ENCePP website	ongoing	*Proposed changes to be discussed by WG1 on 28/09/2018 *SG to adopt revised checklist in writing
	Input into relevant aspects of the EMA Patient Registries initiative.	WG1	Xavier Kurz	Input into inventory of registries and quality criteria (if applicable)	Q4 2017 Q4 2018		pending	Reflection paper on registries to be published end of Sept 2018 and link to be circulated to ENCePP for written consultation of ENCePP community; finalisation Q4 2019

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Optimise functionality and utility of the ENCePP resources database and EU PAS Register	Improved functionality of the ENCePP resources database and EU PAS Register.			2nd wave upgrade of EU PAS Register according to prioritised business requirements	Subject to technical feasibility and EMA IT budget	*July 2017: release of new functionality 'transfer of ownership' *further change requests remain pending for the time being. *new release Sept2018: publication of revised landing pages (reference to registries); technical fix; update to webpage footer	ongoing	Subject to technical feasibility and EMA IT budget
				Release of technical upgrade of ENCePP resources database based on defined business requirements endorsed by SG	Subject to technical feasibility and EMA IT budget	*Log of issues prioritised and submitted to IT (May 2018)	ongoing	Subject to technical feasibility and EMA IT budget
	Increase study registration and status of the EU PAS Register	WG3	Gianluca Trifiro	Publication on EU PAS Register	Q3 2018 Q3 2020		pending	Defer to 2020
				Communication with ISPE to increase awareness of EU PAS Register	Q3 2018 Q3 2020		pending	Defer to 2020
Implement ENCePP Communications Plan	Evaluation of achievements of 10 years of ENCePP (2007 to 2017).	EMA/SG	Tom MacDonald (S. Perez-Gutthann)	Publication of revised 'key messages for communication on ENCePP'	Q3 2019	*Presentation to plenary on achievements and areas for improvement on the occasion of 10 year anniversary of ENCePP (Nov 2017)	pending	For discussion at SG meeting 19/09/2018; update before end September 2018 Agree internally Q4 2018 and send to SG in Q3 2019.
	Strengthen tools of communication with ENCePP partners	EMA/SG	Tom MacDonald	Draft proposal to SG	Q3 2018	*SG informed that Jforum will be removed from website in near future; potential replacement under review (May 2018)	ongoing	Defer to 2020