

Clinical type II variations

Latest process improvements to improve quality of submissions

Presented by Iordanis Gravanis Head of Service C (Clinical type II variations); Procedure Management Department; European Medicines Agency





Topics to be covered

- Simplification of RMP variations
- Clarification of submission requirements for type II variations
- Publication of validation checklist
- Second monthly linguistic review for variations on weekly and alternative monthly timetables



Updates to post-authorisation guidance in 2016

Post-authorisation guidance updates (June 2016)

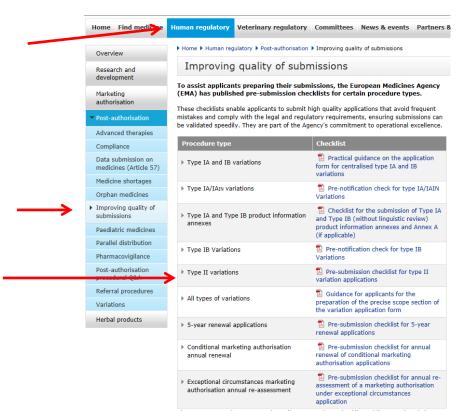
- RMP
- Type II variations (focus on submission requirements)
- Classification of changes

Period	Q1-2 2016	Q1-2 2017	
Dataset	338 (non-)clinical	234 (non-)clinical	
	variations started	variations started	
Validation issues	420/ of submissions	279/ of submissions	
Validation issues	42% of submissions Mainly on scope	37% of submissions Mainly RMP, Clinical	
	I wanting our scope	Overview, incorrect	
		number of scopes and	
		incorrect classification	
Cultural and an	A fa 500/	A fa 400/	
Submission components with validation issues	App form: >50%	App form: 48%	
	Expert statement: 26%	Clin trials statement: 24%	
	RMP: 20%	Expert statement: 22%	
		RMP: 10%	
Extensions of	23 extensions of	19 extensions of	
indication	indication started	indication started	
Validation issues	16 (70%)	9 (47%)	
with extensions of			
indication			
	i e	i e	



Publication of type II variation validation checklist

- The type II variation validation checklist was published on June 26th on the webpage for quality of submissions
- Stakeholder feedback on the checklist would be highly appreciated



Proposal for second monthly linguistic review

- A second linguistic review in the month could expedite implementation of variations on weekly and alternative monthly timetables
- 2 pilots run in May-June 2016 and April-June 2017
- The number of eligible procedures was ultimately small (<5/mo in 2016 and <10/mo in 2017)
- The administrative and technical complexity to implement the 2nd linguistic review at EMA and NCAs was finally considered to outweigh the benefits from having the possibility to implement PI changes slightly earlier
- The proposal was finally abandoned

Possible points for discussion

- Industry experience with the updated RMP and type II variation guidance
- Preliminary experience with updated GVP mod V and leaner RMP template
- Feedback on the published checklist would be highly appreciated at the next platform meeting
- Feedback on the introduction of the 'rolling' PRAC variations
- Other proposals for the Agency's consideration?



Thank you for your attention

Further information

Iordanis.Gravanis@ema.europa.eu

European Medicines Agency

30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom

Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555

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Back-up slide



Introduction of alternative monthly timetables for variations

involving the PRAC

	Procedure starts	Procedure outcomes	
Weekly TT	29%*	23%*	
+ alternative monthly TT	61%**	39%**	
*Based on 2016 data **Based on Jan-May 2017 data			

