



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

03 September 2013
EMA/543324/2013

Minutes – Enpr-EMA members meeting

27 June 2013

Item		Summary of discussion	Action
1	Welcome to new members: SwissPedNet and RED SAMID	<ul style="list-style-type: none">SwissPedNet (CH) joined Enpr-EMA as Category 3 member in Q1 2013RED SAMID (ES) joined Enpr-EMA as Category 3 member in Q2 2012 and is being upgraded to Category 2	N/A
2	Pediatric research network based on the children's hospitals in Japan recently launched.	Presentation - New paediatric clinical trials network in Japan (Nao Tsuchida)	N/A
3	Update on status of emerging networks	<ul style="list-style-type: none">Cardiology Network: Presentation - Cardiology Network (Sylvie DI FILIPPO)Gastro-enterology NetworkDiabetes/endocrinology Network: Presentation - Diabetes and endocrinology European research network (David Dunger)	N/A
4	Advocacy for need of infrastructure/ funding of networks on European level: - Corporate Enpr-EMA response to 5-year report on paediatric regulation - Meeting with members of European Parliament	<p>This topic was discussed during the Enpr-EMA open meeting with Networks, Industry Representatives and Patient's organisations. Please refer to the Enpr-EMA 5th annual workshop report (Report on annual workshop of the European Network of Paediatric Research at the European Medicines Agency, 27-28 June 2013) and slides from Peter Helms: Report from Coordinating Group_peter helms: https://docs.eudra.org/webtop/drl/objectId/090142b2822cee83</p> <p>It was proposed that Enpr-EMA should elaborate a "business model case" for core funding, to provide estimate on overall costs, staff resources (in full time equivalents), etc. This would help networks as basis for negotiation with potential funding sources.</p>	MT to set up discussion group
5	Feedback from networks: - Experience with being a member of Enpr-EMA - Involvement in PIP related clinical trials - Proposals for future activities	<ul style="list-style-type: none">It was suggested that pharmaceutical companies should approach the individual Networks ahead of PIP application submission to the RegulatorsThe approach from a disease/condition point of view should be taken into consideration when preparing for standard PIPsThe Networks should liaise with PDCO about list of priority drugs where there is a therapeutic need in the paediatric population	Networks



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6	Involvement of young people / family in Enpr-EMA networks: - Update on survey result publication - Outlines of involvement strategies at 1 network - Practical tips and training on involvement strategies for other Enpr-EMA networks	<ul style="list-style-type: none"> An outline of the results of the survey on involvement of young people and family members in Enpr-EMA networks was presented: Presentation - Involvement of young people and families in Enpr-EMA networks (Benjamin Pelle, Peter Helms and Jenny Newman) Practical tips and training on children involvement strategies at the UK MCRN were presented: Presentation - Involvement of young people in Enpr-EMA networks (Jennifer Preston & Dr Pamela Dicks). UK MCRN to develop a business case for involvement of young people and family members in Enpr-EMA networks 	UK MCRN
7	Next steps	To develop business case for sustainable funding of networks in Europe	
8.	A.O.B	FINPEDMED has helped establishment of a new network of paediatric clinical centres in Norway	