

PDCO FEEDBACK
HCPWP-PCWP meeting
15 March 2017

PDCO member
As HCPWP representative
Jan Taminiau

PDCO and HCPWP interrelations

Last meeting HCPWP-PDCO discussed building up pool of experts available for issues in Pediatric Investigation Plans (PIP's)

Enpr-EMA is currently through participating paediatric societies offering experts

HCPWP only European Association of Pediatric Societies is partner

From 2007 to 2017 gradually less expertise needed only in extremely rare treatment issues in rare conditions or adult disease extremely rare in children

1. Study details of available experts

2. Need for PCWP-HCPWP-Entr-EMA and industry experts in development of improving research for rare diseases in children, which is underperforming yet

Pediatric Disease Databases

Academic databases will in due time run industry's databases for safety follow up

Drug industry

Drug industry runs cohorts of disease specific drug databases

Cohorts cannot compare to national cancer registries

Overlap after frequent drug switch in biologicals

Academic databases

Children pass age of 18 years enter adult data bases

Pediatric databases lag behind development of European Disease based databases

Pediatric database ownerships (Horizon 20 projects) are posted at single countries

HCPWP-PCWP involvement

Enlarging Pediatric databases at some point will compete with industry cohorts

Full access to academic databases is mandatory for industry to join