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SCIENCE MEDICINES HEALTH

Regulatory Perspective on Post-licensing Evidence Generation (PLEG) & Real World Evidence (RWE)

ADAPT SMART closing meeting

Presented by Francesca Cerreta on 21 March 2018

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Regulatory guidance on PLEG

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- Scientific guidance on Post-Authorisation Efficacy Studies PAES

•**Categories** of uncertainties, data source, study design (e.g. Registries can allow variety of observational study design options)

•**Data quality crucial**. Measures include common terminologies, quality control and standards, Limitations acknowledged

•**Other guidance:** PASS, CMA report, pregnancy, ATMP, EMA registries initiative; recent workshops (Big data)

high quality timely data and methods (control of chance, bias and confounding)

to address remaining uncertainties at MA and for strengthened life cycle approach

Toolbox for cooperation in PLEG

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Estimated 4% of Scientific advices with RWE proposals

Parallel consultations involving other stakeholders in planning Post Launch Evidence Generation: product / not product specific

- Qualification Advice (Confidential) on protocols and method development
- Qualification Opinion (public) acceptability of a specific method (e.g. biomarker) in drug development based on assessment of submitted data; Public consultation
  - Registry - kinds of regulatory studies that could be conducted
  - Subsequent protocol interaction with regulators still preferred
- Public workshop - potentially wider face to face inputs, complementary to Committee assessment procedures as above

Regulatory use of PLEG: Conclusions

- PLEG > Real world evidence/non randomised studies
- Existing regulatory guidance -strengths, limitations, role of PLEG/RWE
- PLEG complements Pivotal RCT data - some remaining uncertainties
- Gap workability of registries; scope - improvement quality /timeliness
- To progress - need PLEG and RWE discussions on specific proposals
- How to best have cooperative discussions?
  - EMA EUnetHTA bilateral, EMA PLEG focus group Industry + EUnethTA

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Thank you for your attention

Further information

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