

EnprEMA WG6: A framework for networks to interact with industry and regulators when implementation/conduct of clinical trials agreed in PIPs is no longer possible

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Remit

- What can networks offer to industry when they submit modifications of agreed PIPs because conduct of agreed studies no longer feasible (or never started?)?
- How can networks feedback to PDCO / regulators (national competent authorities) to help them assess the request for modification of an agreed PIP?
- What information are regulators looking for when considering requests for modification to PIPs?

A further additional point of action was agreed that was essential to consider in advance of those stated above:

- It suits neither industry, academics, regulators or ultimately patients or public to have non-feasible studies in the planning or conduct stage.
 - a) What information is required (and by whom) and
 - b) How can this information be provided by networks, academic experts and via public involvement.



Output

- Detailed paper draft for consultation by Steering committee and Enpr-EMA colleagues in first instance.



Output

- Need to try to define clear mechanism for review of both clinical need and proposed studies, accessible by industry, regulators and networks (as source of experts and public engagement), in form that is acceptable to regulator so that further “independent expert advice” is not required.
- Need to define:
 - How to provide expert, unbiased advice to Industry and PDCO before the PIP is approved while maintaining a clear(er) mechanism for avoiding conflicts of interest.
 - What to do when the PIP is not working (eg if assumptions change or field moves on)



Key need 1: provide clear, detailed, up to date and accurate conflicts of interest (Col) statements in the public arena for all experts or network members

- in the public arena (or at least visible to the stakeholders in this process) and regulators
- industry would need to be able to clearly identify who is able to act as expert for new drugs without risk of breach of confidentiality.
- Academic networks themselves need explicit transparency regarding funding sources for their organisation and for any collaborative work or trials conducted under the name of that organisation.

See paper for detailed description of why current system may not be fit for purpose



Potential solution: modernisation of all stakeholders conflict of interest handling process.

- Provide much clearer and easier individual expert Col submission process available in public domain
 - individuals to be able to produce one Col form for use across multiple agencies – employer, national organisations, European/international organisations/Government
- Requirement of EnprEMA-associated networks to have public clarity of funding sources including of supporting charitable Foundations
 - and for easily accessible clarity of funding sources for all individual studies conducted by the networks.

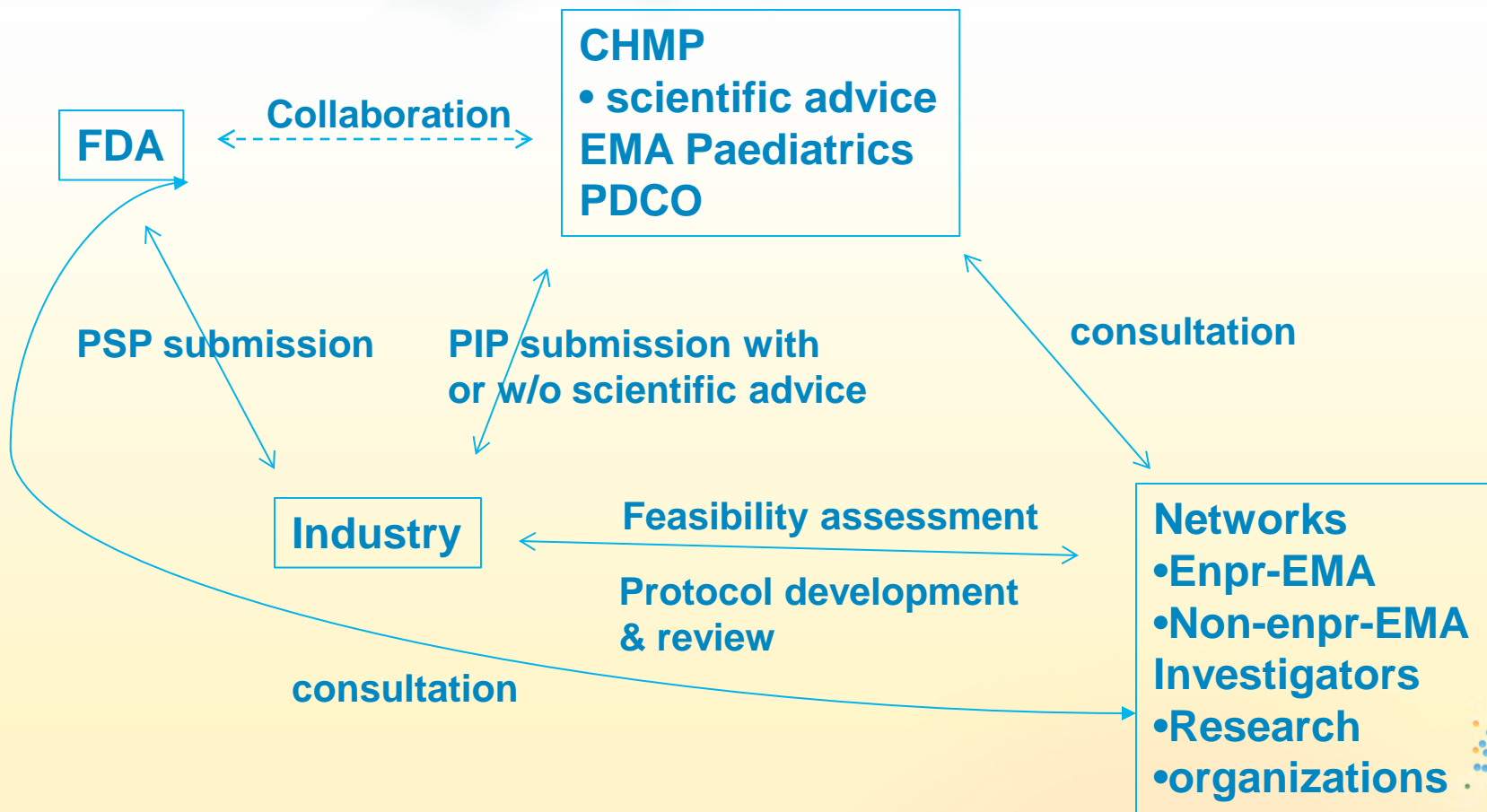


Key need 2: What to do when the PIP is not working

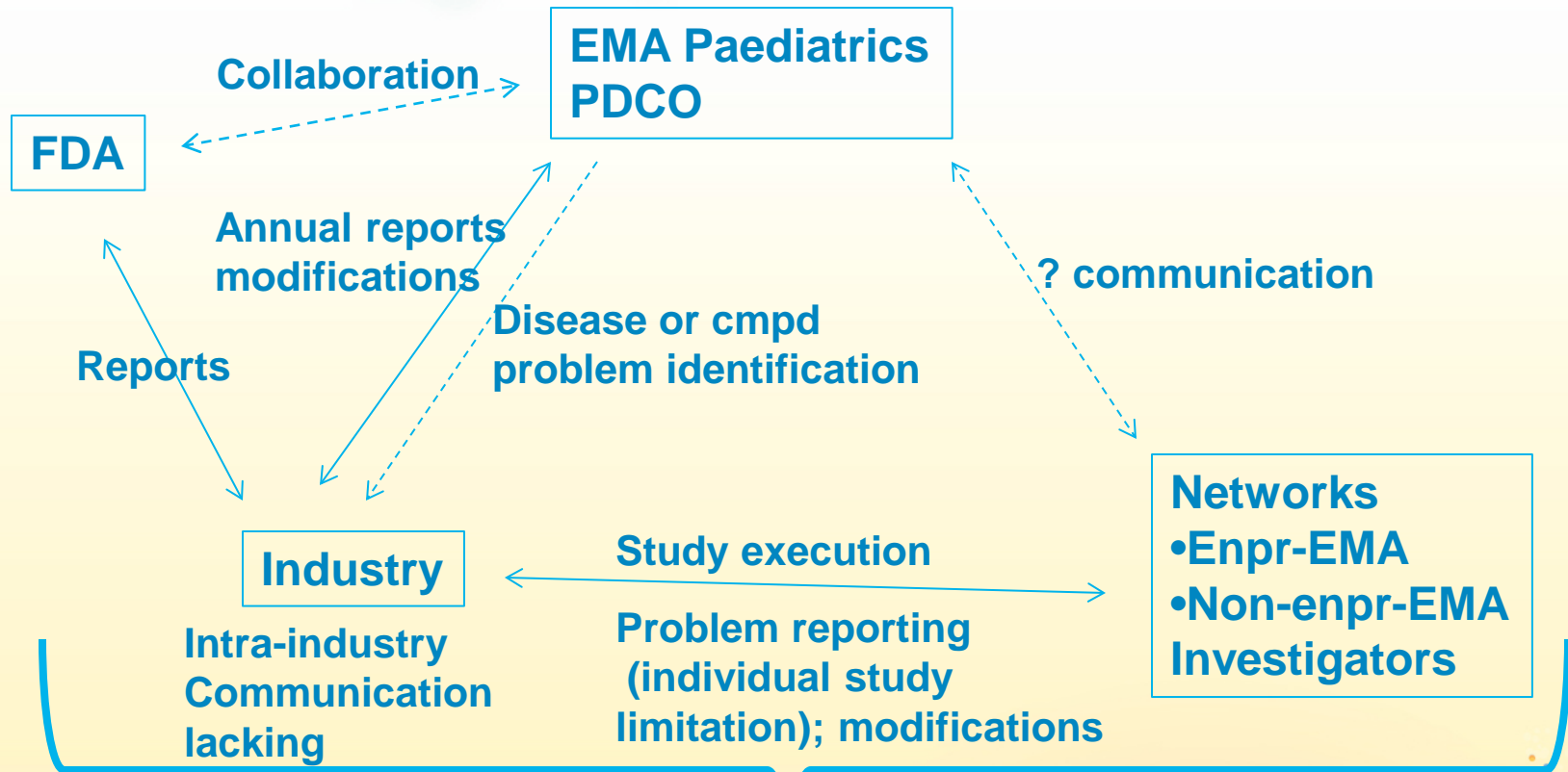
- Mechanisms to bring stakeholders together to design feasible trials (assuming Col issues resolved)
 - joint meetings, mechanisms to bring industry together to discuss same-class drug wide issues pre/during PIP development.
- Clear guidance should be available from the PDCO to industry regarding review mechanisms possible if signed off PIP subsequently found (by whatever means) to be unfeasible prior to paediatric study delivery
- need to provide detail and honest information on the reasons that a study is not been delivered and the actions undertaken to address the issues identified
 - use of stakeholder meetings to bring stakeholders together where problems are identified



PIP Process



PIP Progress



Once problem identified:
Multi-stake holder consensus conference



Thank you

