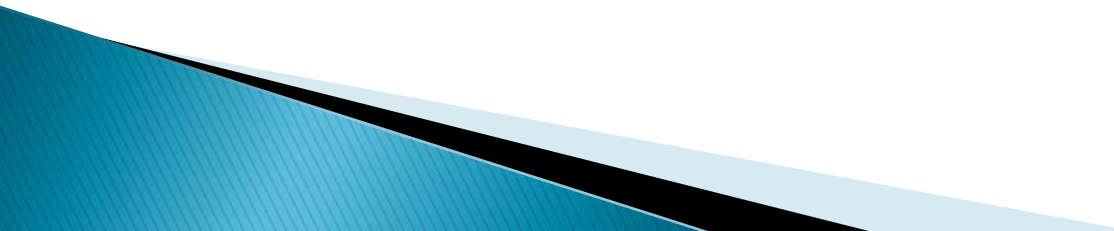


Enpr-EMA WG6: A framework for networks to interact with industry and regulators when implementation/conduct of clinical trials agreed in PIPs is no longer possible

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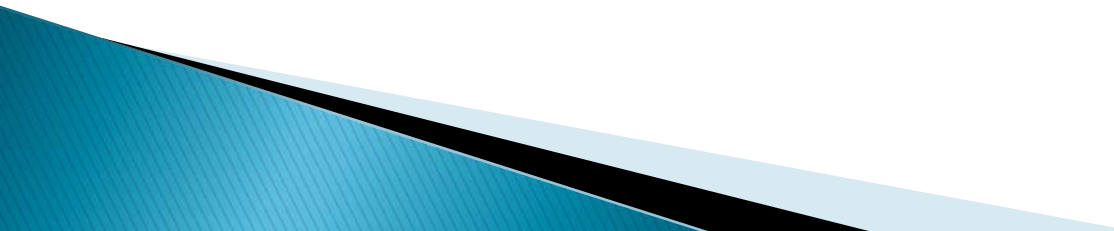
28th May 2015

Summary from 2014

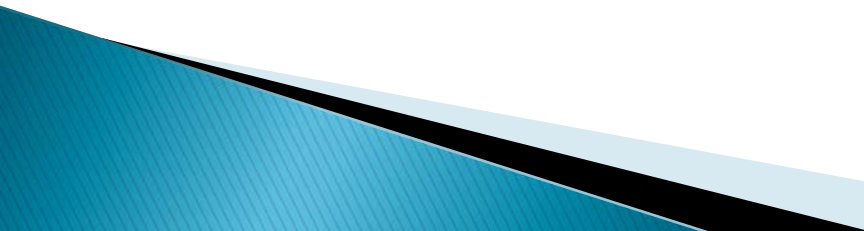
- ▶ Need for all stakeholders (industry, academic networks, regulators) to both anticipate potential problems and identify problems if they occur.
 - ▶ Need to establish mechanism(s) to resolve problems, in set up/feasibility and for studies in progress.
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Q1: Anticipation of potential problems

Who has the knowledge?

- ▶ Industry not knowledgeable – information not necessarily available to industry re how many compounds are being looked at for the same diseases
 - ▶ Regulars have the knowledge (no. of studies), investigators/networks to a lesser extent.
 - ▶ Networks know whether the patients are out there or not.
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Q2: Identification of problems in existing studies

- ▶ Industry finds unanticipated problem, unaware of others experiencing similar issues.
 - ▶ Academic networks identify unanticipated problem, unable to breach confidentiality for individual studies.
 - ▶ Problems could be
 - too many studies
 - another study better designed;
 - or another IMP or drug already considered “better”?
- 

A: Networks have this information (or could do) as they have been asked to participate in multiple studies – eg investigators went to EMA for diabetes discussions.

Outstanding questions:

EU-wide need to collect patients enrolled/time or other standard metrics

- ▶ Where is the information at present? (some national networks eg CRN in UK) – Is there benchmarking at the EMA or data in annual reports?
- ▶ Is it possible to have a system of automatic metrics reporting from already collected data?

Proposal: EU needs a mechanism for detailed feasibility and information sharing

- ▶ Need SOP for Enpr–EMA to gather and disseminate info
 - eg if 3 companies submit simultaneous PIPs need mechanism for how Enpr–EMA and regulator can help bring people together for discussion

Outstanding questions:

- ▶ Who has the authority to notify everyone?
 - is this the regulator or could this be a function of EnprEMA?
- ▶ How do we deliver such an SOP in 2015?

Q: If there is an issue, what steps can be taken to address them?

Proposal: set up mechanism for Enpr-EMA to host generic issue consensus meeting.

Outstanding question:

- ▶ Can Enpr-EMA hold the funding, contributed to equally by all industry stakeholders involved, and use this to convene a meeting?

Q: Stakeholder meetings

Scope: any stakeholder can raise an issue

- ▶ Regulator – flags via automated metrics
- ▶ Networks – via collected metrics (e.g. UK +/- others?)
- ▶ Industry – to Enpr-EMA to ask if others have similar issues

Opinion sought from networks/specialist society network members and individuals with appropriate declarations of interest in place, focus on generic issues not compound-specific.

Output to be distributable through stakeholders.

Summary – 2 SOPs/mechanisms required

- ▶ For Enpr-EMA to gather and disseminate information on behalf of regulator, stakeholders and networks
- ▶ For Enpr-EMA to host generic issue stakeholder meetings jointly funded by industry stakeholders