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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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.

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.

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

<u>Outstanding questions:</u>

- 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.

<u>Outstanding question:</u>

- 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