EUPATI: Preparing guidance for interaction

Interactive session at DIA Europe 2015

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Guidance for interaction – Why?

- Patients & PO involved more widely
- EMA has developed a mature framework over time
- However, overarching guidance on meaningful and ethical interaction missing in many areas
- PO-industry code by some PCWP members did not cover drug development
- EUPATI aims to come up with guidance, covering four areas:
  - Industry
  - Ethics committees
  - Health Technology Assessment (HTA)
  - Regulators
- EMA framework used as guiding principle

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- **Industry led R & D**
  - Clear & robust guidance most needed in this area (WS July 2014)
  - Building on best practice & established examples (EATG, Eurordis)
  - Current codes focus on market, post approval
  - Not everybody is ready for meaningful interaction (on both sides)
  - Need to cover interaction opportunities within process of drug development
  - Consider guiding principles developed by Lifetrain http://www.emtrain.org/index.php/lifetrain2
  - Clarify framework coverage (formalised / ad hoc; individual experts / organisations).
  - Legal obstacles in some countries
  - Matchmaking discussion: how much can we do within EUPATI? PO alignment necessary.
  - Implementation is a process!

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- **Ethics committees**
  - Challenging area – EC are under national jurisdiction
  - Big differences within Europe, patients not mentioned in some regulations
  - New CT Regulation gives some, but not enough leverage
  - Patients could be included in different positions and tasks
    - External reviewer
    - General advisor
    - Regular EC member
  - Key areas for patient input:
    - Assessing study risk/burden/benefit
    - Informed consent documents
  - Need to clarify prerequisites & criteria for patients joining committees
  - Likely: recommendations including call for better European legislation in this area

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HTA

- Patient inclusion in HTA: well documented area
- Few implemented examples to draw on, national jurisdiction prevailing
- 2010 survey: 52% of responding agencies involve patients in process, 22% provide trainings & 19% evaluate involvement
- Barriers for better involvement well known
  - Time, cost
  - Enthusiasm of staff
  - Concern about bias etc
- Capacity building the biggest single issue
- No single model to build on around; case studies needed for better input
- EC collaborative committee on HTA, Eurordis & EPF participating
- ISPOR & EUNet HTA sources

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Regulatory bodies

- Mature EMA framework to draw on
- Dialogue with patients started in 1996 with HIV patients
- Patient's Working Group from 2003; PCWP formally established 2006. Legal basis since 2004 (Art 78 Regulation EC 726/2004)
- Interaction covers areas of common interests with clearly defined objectives
  - Facilitate participation in benefit/risk evaluation
  - Ensure that patients, consumers and their organisations are listened to and involved in developing plans and policies
  - Enhance organisation understanding of EMA role within EU regulatory network re development, evaluation, monitoring & provision of information on medicines
  - Optimise communication tools to support their role in the safe & rational use

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Regulatory bodies

- EMA framework relies on 5 critical elements
  1. Network of European PCO
  2. EMA Working Party as forum of exchange
  3. Pool of patients acting as experts
  4. Interaction with EU regulatory network
  5. Capacity building
- Yearly report on interaction; satisfaction survey every 2 years
- 3 categories of patient participation
  1. Member, alternate or observer
  2. Individual patient expert
  3. Representative of an organisation
- EMA framework easily adaptable at national level, efforts in different countries ongoing

DIA guidances session Apr 15

- Very useful session, good feedback
- Guidance documents much awaited for
- Grid and guidance elements more clear
- Need to address implementation and updating guidances

Next steps

- First draft due Jul 7 2015
- Report on guidance due to IMI Jan 2016
- External consultations in 2016 (EFPIA, EMA PCWP, EC)