



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Topic Group Academia, Learned Societies and HCP organisations proposals (or how to move forward)

Presented by Rosa Giuliani/Sergio Bonini
Topic Group Chairpersons



HCPWP, 15 June 2016

An agency of the European Union





General objectives of the Topic Group

- **Reflect on the need to review the EMA framework of interactions with HCPs**
- **Support the development of the EMA framework for collaboration with Academia**
- **Identify current practice with involvement in regulatory activities**
- **Discuss areas for improvement and foreseeable changes**



Topic Group Members

Chairpersons : Sergio Bonini (EMA), Rosa Giuliani (ESMO)

- **Angeles Alonso Garcia (ESC)**
- **Jamie Wilkinson (PGEU)**
- **Gonzalo Calvo (EACPT)**
- **Michel Delvaux (UEG)**
- **Riccardo Riccardi (PDCO)**
- **Lorenzo Dagna (EFIM)**
- **Olivier Clement (ESR)**
- **Roberto Frontini (EAHP)**
- **Karin Plass (EAU)**
- **Marianne de Visser (EAN)**

Activity progress since June 4,2015

- **A Kick-off teleconference was held on June 29 to define actions, responsibilities, deadlines and milestones**
- **Nomination of chairpersons : Sergio Bonini (EMA) and Rosa Giuliani (ESMO)**
- **Interaction through TCs and mini-meeting during HCPWP meetings**
- **Preparation of internal (topic group) survey (Monica Ensini)**
- **Preparation of a questionnaire for Academia, Learned Societies and HCP organizations (Monica Ensini)**



Key areas of the internal survey

Does the current EMA framework of interaction with HCPs need to be reviewed?

http://www.ema.europa.eu/docs/en_GB/document_library/Other/2011/12/WC500119625.pdf

Which **initiatives** can be suggested to develop **closer relationship** with Academia?

Areas deserving **special consideration** (from a general point of view and more specifically to each organization)



Summary of the comments received

Review of the HCP framework document

- **The 2011 Framework document should be up-dated to adapt to a more relevant role of HCPs in drug development and monitoring**
- **HCPs should significantly contribute to the drafting of an updated version**



Which initiatives to enhance relationships with Academia ?

- **More active involvement in regulatory policy initiatives**
- **Increased representation in EMA Committees**
- **Early involvement in the authorization process of medicines**
- **Joint workshops on specialized topics**
- **Cross-learning programs and reciprocal participation in scientific events**
- **Involvement in drafting of documents and guidelines**



SWOT Analysis of the current situation

Strengths

Existence of the framework

Bilateral willingness and commitment for a closer collaboration

Transparency & intensive dialogue
Organisation & support

Opportunities

Each partner can bring an unique complementary contribution

Feedback on relevant documents / communications

Weakness

Priorisation

Short deadlines

HCP umbrella of different societies:

Uncertainty on deliverables

Threats

Inefficiency in finding common denominators

Theoretical discussions, deviation from daily practice

Economical support

Prioritization for bodies with a very busy agenda

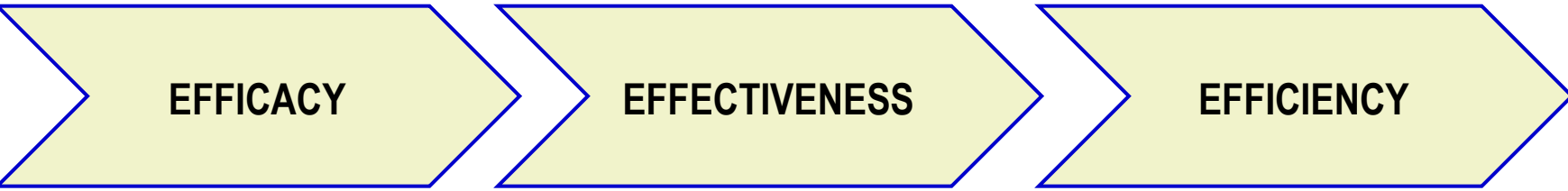


Conclusions (survey) and future activities of the Topic Group

- ✓ **The HCP framework** document could be reviewed with the contribution of HCP
- ✓ **Relationships with HCP/Academia and EMA should be enhanced:**
 - A more active involvement of HCP/Academia in EMA activities
 - Enhancement of educational programs and reciprocal participation in scientific events
 - Collaboration in research projects
- ✓ **Future activities**
 - Discussion within the Topic Group of issues emerged
 - Launch and analysis of the Academia/HCP Survey



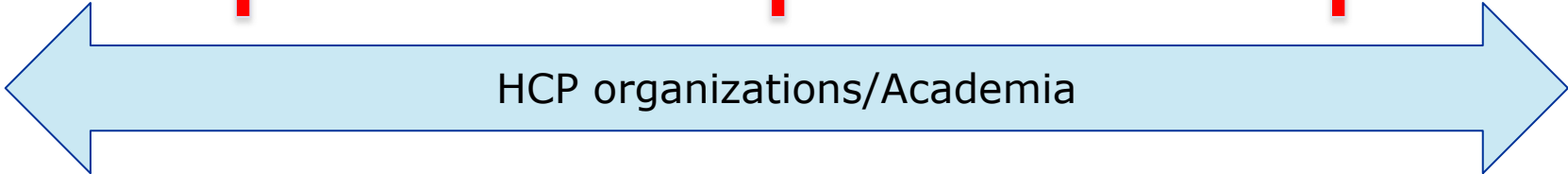
1. Active involvement



**Does it work
in clinical TRIALS?**

**Does it work
in clinical PRACTICE?**

**Does it contribute to more
efficient use of resources?**



**B/R
EMA**

**HTA assessment
National → HTAN**

Real-world data
(registries, post-A S&E studies,
observational trials...)



2. Education & Research



EDUCATION

- Workshops on specific topics of reciprocal and pragmatcal interest (to be discussed by HCPWP?)
- Educational program in Regulatory Science (Uni/masterclass, et cet...)
- Facilitating "permeation"

RESEARCH

- Calls for topics of interest
- Eg: -how to use Real world data
- biomarkers
- how to structure a EU collaboraive Research
- Interaction with EUnetHTA/HTAN

COMMUNICATION

- Improved in time, still suboptimal (confusion or lack of knowledge on EMA activities)
- Research on communication:** how do HCPs/Academia organization receive information?

HCP organizations/Academia



Publication

In the societies Journal (eg "contents" from **this workshop!**)

Regular updates on websites (both EMA and Academia) and journals

Intersection with other topic groups (social media)





- Membership
- Guidelines
- Conferences
- Career Development
- Research
- Patients
- Policy
- Science & Education on OncologyPRO

ESMO congress
 COPENHAGEN 2016
7-11 OCTOBER 2016
 COPENHAGEN, DENMARK

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ESMO 2016

Register today and join us in Copenhagen, Denmark for the annual ESMO congress! Early registration deadline: 30 June

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Video

E. Smit elaborates the results of the clinical study of **nab-Paclitaxel plus carboplatin** in advanced squamous NSCLC with a focus on elderly patients. [View video](#)

Latest News

- 08 JUN 2016**
Immune Modulation in Colorectal and Anal Cancers
 Highlights from ASCO 2016 Annual Meeting
- 07 JUN 2016**
EMA Recommends Extension of Therapeutic Indications for Brentuximab Vedotin
 A new indication concerns adult patients with CD30-positive Hodgkin lymphoma at increased risk of relapse or progression following ASCT
- 07 JUN 2016**
ESMO Workshop: Cancer Patient Advocacy Networks Driving Research
 View the slide presentations and download the report from the workshop for cancer patient advocates
- 06 JUN 2016**
FDA Approves New Diagnostic Imaging Agent to Detect Rare Neuroendocrine Tumours
 The uptake of Ga 68 dotatate reflects the level of somatostatin receptor density

Communication & Dissemination of information



Awareness of regulatory activities is suboptimal on both side of the ocean...

Letters

RESEARCH LETTER

Physicians' Knowledge About FDA Approval Standards and Perceptions of the "Breakthrough Therapy" Designation

Kesselheim et al

JAMA April 12, 2016 Volume 315, Number 14



Table 1. Physicians' Perceptions of US Food and Drug Administration (FDA) Approval and Breakthrough Therapy Designations

	No. of Responses/ Total Respondents ^a	% (95% CI) ^b
3 Questions on the FDA Approval Process		
1. FDA approval typically means that a drug is as effective as other drugs approved to treat the same condition.		
True	495/682	73 (69-76)
False ^c	187/682	27 (24-31)
2. FDA approval typically means that a drug has benefits that outweigh its harms.		
True ^c	585/686	85 (82-88)
False	101/686	15 (12-18)
3. In order for a drug to get FDA approval, it has to have...		
A statistically significant result	90/687	13 (11-16)
A clinically important result	76/687	11 (9-14)
Both results	480/687	70 (66-73)
Neither of the results ^c	41/687	6 (4-8)
Physicians with number of correct answers		
0	67/675	10 (8-12)
1	423/675	63 (59-66)
2	176/675	26 (23-30)
3	9/675	1 (1-3)



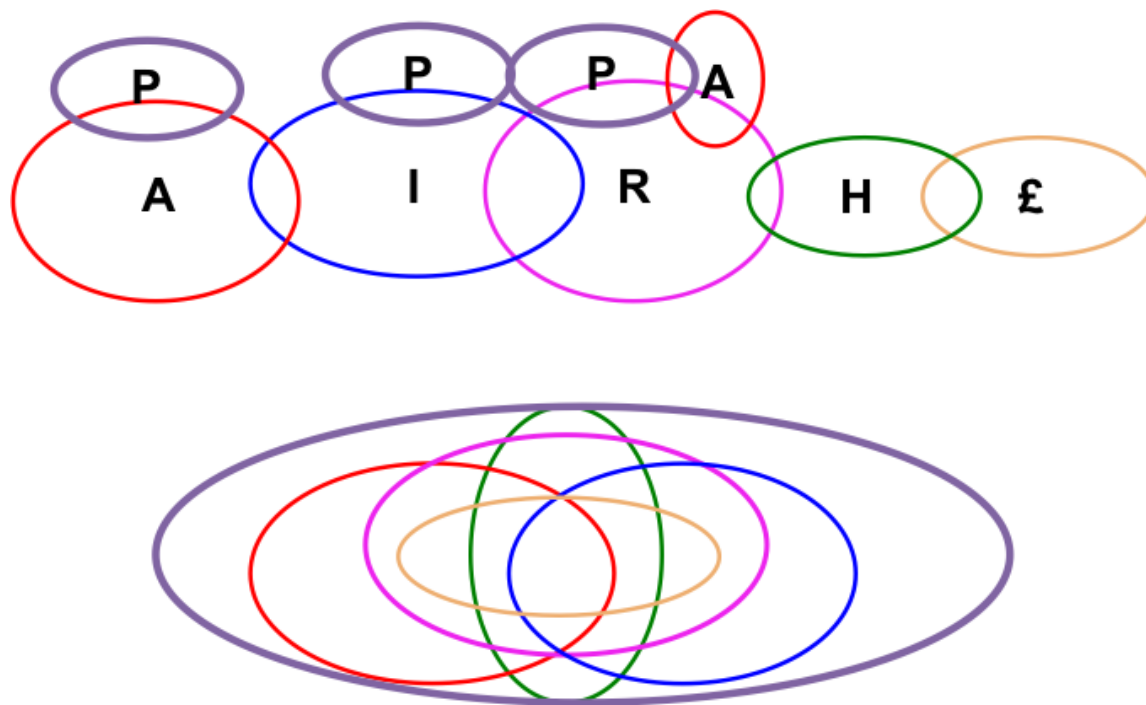
EMA-ACADEMIA workshop

Workshops

e.g. Biomarkers 2005, 2006; Pharmacogenomics 2008;
Personalised Medicine 2012; Immunotherapies 2016



Rare cancers
Shift in biology:
precise medicine → a lot of
smaller biologic entities:
How do we collect data to
speed up innovation?



Promotion of platforms/forums for interaction and collaboration



Thank you for your attention

Further information

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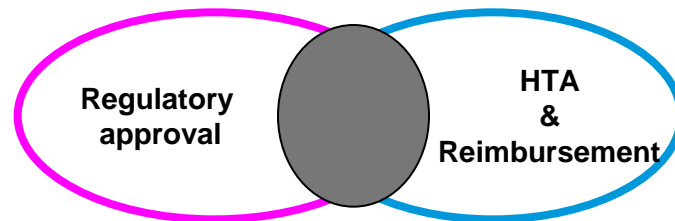
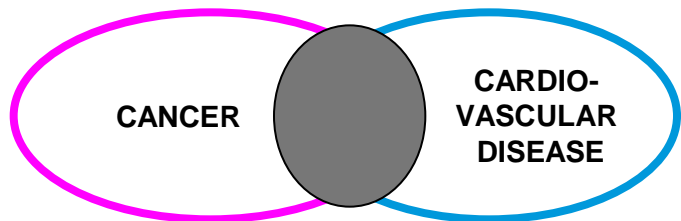
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Send a question via our website www.ema.europa.eu/contact

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>>>> 50 Shades of grey....



HCPs/Academia organizations may contribute to clear grey areas (sometimes we create them..)

