



# STARS

STRENGTHENING  
REGULATORY  
SCIENCE

## Breakout Session 2 Outcomes

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This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 825881

Classified as internal/staff & contractors by the European Medicines Agency



Please rank from most to least important

11



- |    |  |                        |      |
|----|--|------------------------|------|
| 1. | #2 Appropriate media channels                                | <div><div></div></div> | 3.82 |
| 2. | #10 Optimize engagement and collaboration of academia.       | <div><div></div></div> | 3.64 |
| 3. | #6 Support in the preparation of scientific advice           | <div><div></div></div> | 3.18 |
| 4. | #18 Early contact and dialogue                               | <div><div></div></div> | 3.09 |
| 5. | #14 Monitoring compliance with regulatory affairs (Eudra CT) | <div><div></div></div> | 1.27 |

## Recommendation #2

⇒ Strategic Area 1: Regulatory authorities in Europe

### Use of appropriate media channels to reach out to academia

- High quality and reliability of the presented data
  - compliance with regulations, NCA / EMA website based data
  - Easy access, personal and informal contact
  - Constant evaluation of the dissemination efficacy is important (tools needed)
- 
- Videos (animated)
  - decision tree approach
  - chat box
  - Information board (see pilot II)
  - Q&A pages (search function)
  - → ask for more ideas the consumer (crowd-sourcing)

## Recommendation #10

➡ Strategic Area 2: Academic Researchers and Institutions

### Optimize engagement and collaboration of academia

- Mindset change in sharing information
  - Avoidance of same hurdles over and over again
- Strengthen awareness for regulatory key competences
  - Building a business case
  - pitching for a grant
- Incentives needed to motivate academics for networking
  - networks that involve different stakeholders could provide regulatory support
- Incentives needed like certifications and diplomas, scholarships to motivate scientists to complete on-line regulatory courses (= career building)

## Recommendation #6

⇒ Strategic Area 1: Regulatory authorities in Europe

### Support in the preparation of scientific advice for academia

- Informal, personal, timely contact to a innovation unit at the NCA or TTO/innovation offices at the university could facilitate the quality of SA documentation and thereby the outcome of SA
- Caveat: personal resources at NCAs and local innovation offices / TTOs are limited

☰ Active poll

10 

## Regulatory support for academia is important

on national level



on local level



on EU level



## Recommendation #18

⇒ Strategic Area 4: Industry

**The early contact and dialogue between academic researchers/institutions and start-ups, small medium enterprises and industry should be fostered reciprocal**

- Sufficient regulatory feasibility and proven compliance of a new, innovative medicinal product makes it more appealing for the industry and increases the monetary value of academic innovations
- Early contact to experienced partners, can pave the way, eliminating hurdles, anticipating problems beforehand and readjust accordingly to aim for the next steps of the innovation on the way to the patient

## Recommendation #14

⇒ Strategic Area 3: European Commission, Ministries and Funders

### Monitoring compliance with regulatory affairs during the project

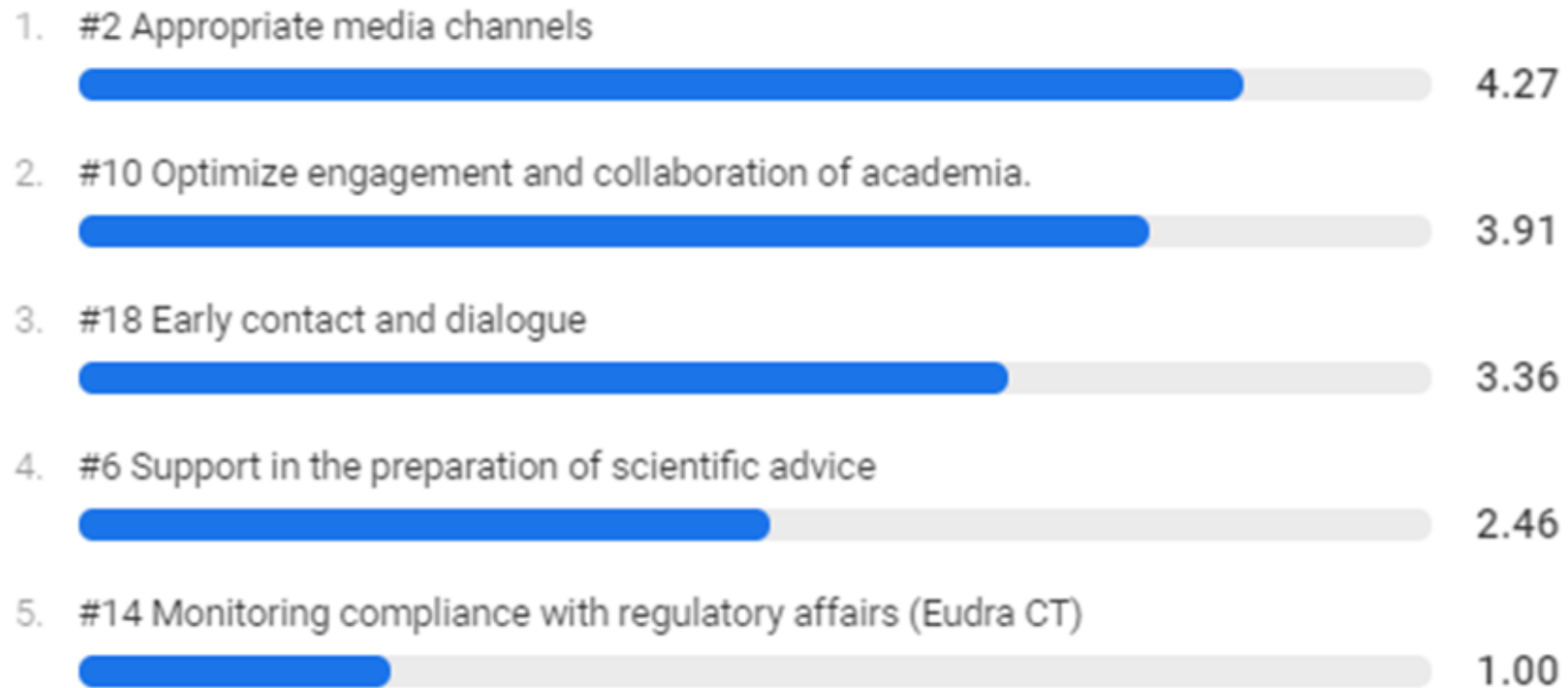
- Keeping track on overall regulatory preparedness might facilitate the overall development process and avoid being stuck in the translational valley of death
- Facilitation of the monitoring can be challenging for all stakeholders
- Focus of the recommendation should not necessarily be reporting at the EudraCT





Please rank from most to least important

11  ...



**What are important aspects when it comes to regulatory support for academia? (Free text, multiple answers allowed)**

