STARS
STRENGTHENING
REGULATORY
SCIENCE

Breakout Session 3 Outcomes

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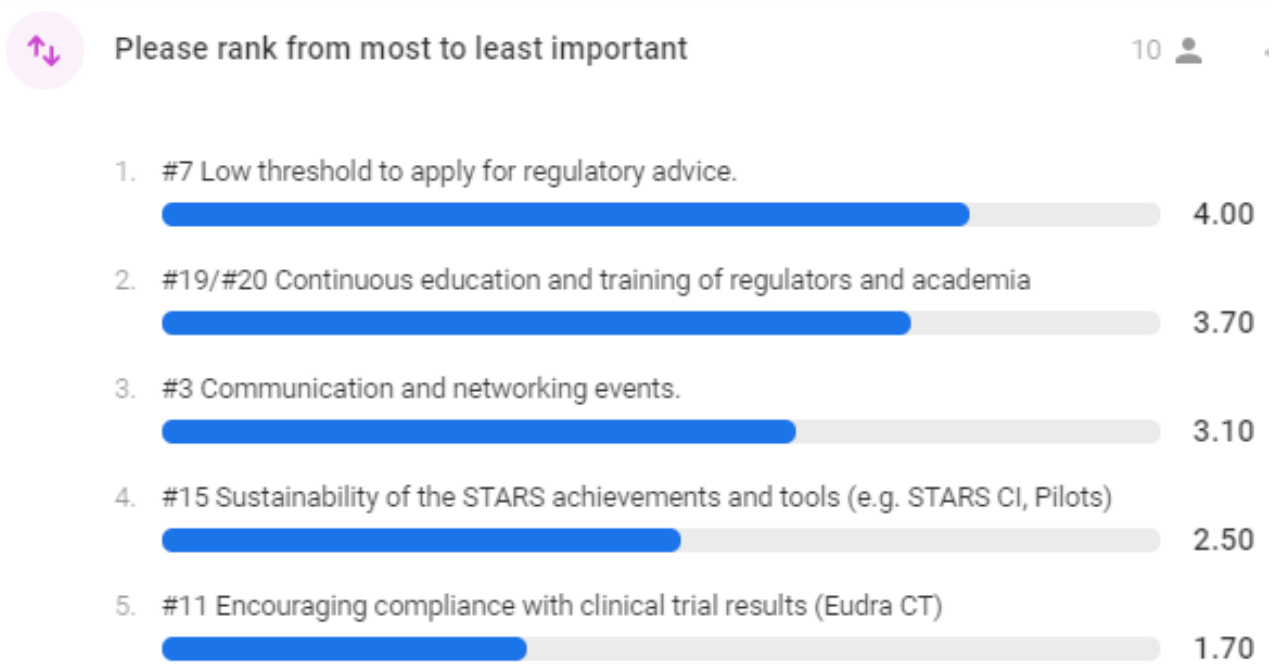
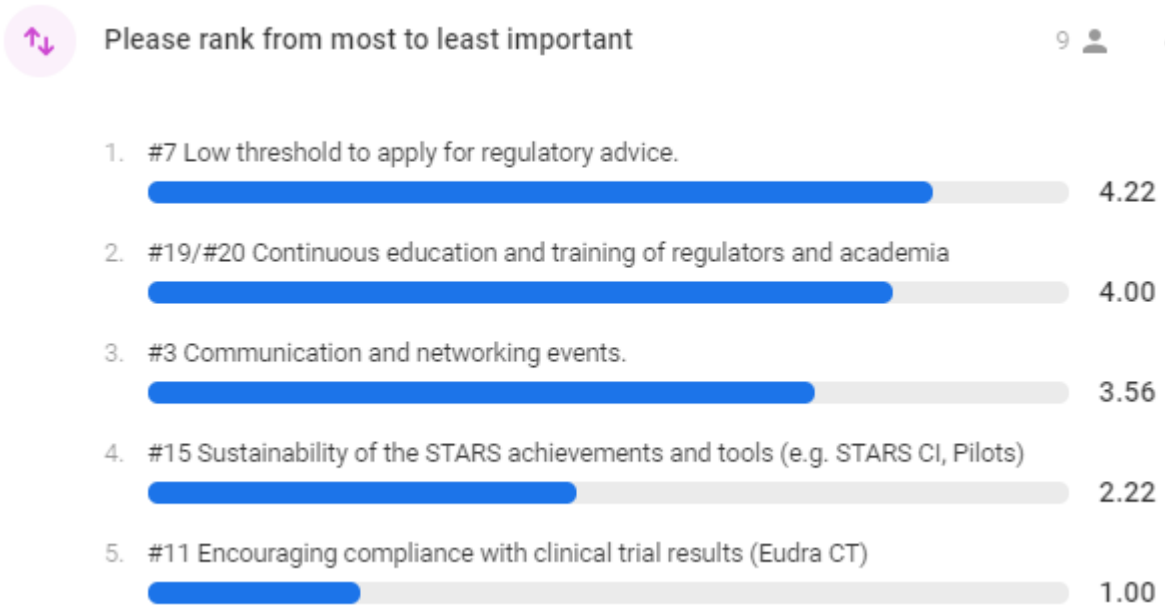
STARS C – Q1/first time

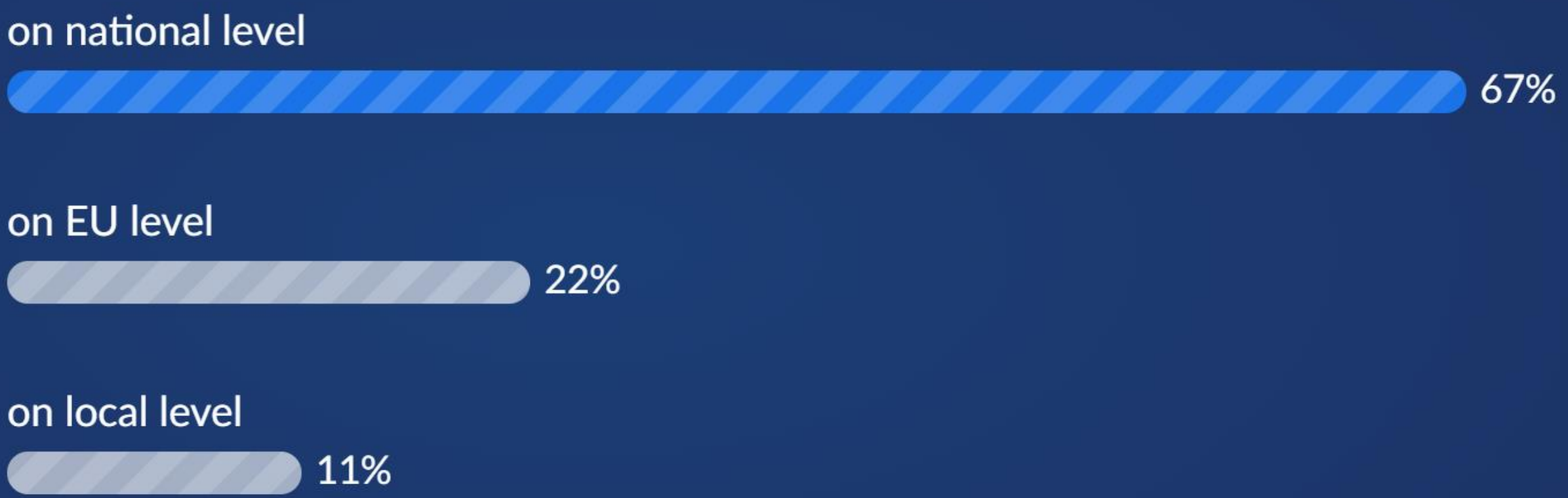


STARS C – Q1/second time



Active poll 9

Regulatory support for academia is important



Active poll 9

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

#7 Low threshold to apply for regulatory advice

Next to a low threshold communication and contact point, academia has to consider financial aspects. Reduction of costs or fee waivers need to be considered

- Pre-grant advice very useful for researchers
- Some agencies offer free of charge (e..g Spain)
- Would be useful to have informal contact possibility (build relationship)
- Need better profiling of existing opportunities and services
- Local expert centres could handle general questions
- Continuous process starting light (already happens so)

#19/20 Continuous education and training of regulators

Education of regulators, such as visiting conferences, doing courses and training such as in the EU Network Training Centre (EU NTC) in order to ensure up-to-date decision making standards

- Funders might ask the researchers to complete courses as part of funding.
- Mandatory courses may create pushback of busy researchers – how to encourage?
- Support after clinical trial?
- Support for understanding preclinical pathway needed
- Lack of inexpensive training on product development – not only reg aspects

#3 Communication and networking events

Interactive events, like local open house days, roadshows or innovation days organized by regulatory authorities will encourage academia, NCAs and funding bodies to exchange about relevant topics, needs and developments. Interactive sessions can contribute and stimulate collaboration between academia, NCAs, funding bodies and where suitable industry and other stakeholders....

- The NCAs and Funding bodies should advertise as much as possible the courses given by them and by others.
- The NCAs or EMA could make a summary of resources available for the funders to give to the researchers when they come to ask for funding.
- Work with National or European Societies
- Newsletters could be used. Having an efficient communication is a must for full awareness within eco-system

#15 Sustainability of the STARS achievements and tools (e.g. STARS CI, Pilots)

Sustainability of the work done by STARS and the implementation of the recommendations going forward.
Sustain the STARS comprehensive inventory.
Consideration of Pilot I, Pilot II and STARS curricula for future developments.

- Can the inventory also give information about quality of service and competences – difficult to make statements
- There are tools and websites to include this comprehensive inventory, e.g. Rare Diseases EJP
- Improve the awareness of this kind of projects
- Look to new partnerships e.g. IHI and Rare Diseases

#11 Encouraging compliance with clinical trial results reporting (Eudra CT)

It should be an obligation to publish clinical trial results on EudraCT.
In this connection the agreement and implementation of minimum standards for promoting academic sponsors to report in EudraCT should be developed.

- Lots of work and lots of reporting
- It would be helpful if the data base is up to date.
- The researchers see that it's a burden but they need to see also the advantages of fill this data bases
- Some funders make it part of funding – can we do this widely?
- Will CTIS make compliance higher?

Recommendations

- **Raise awareness** on what are the best routes to address needs – **lots available**
- Need of **good coordination for the pre-grant advice**, especially with funders – very valuable service
- E&T: **Train the researchers but not overload them**. Look what it is there and where are the gaps; modularity for differing needs
- Communication: is key and it should be focused on **raising awareness on the activities given by NCAs and EMA** and have some information to be shared with funders. **Use aggregation points** like funders and publishers
- **Reporting clinical trials very important**: burden for the researchers - need to **show advantages** of having this data bases up to date
- **Look to new partnerships** e.g. IHI and Rare Diseases for supporting **sustainability** of STARS outputs