STARS
STRENGTHENING
REGULATORY
SCIENCE

Breakout Session 1 Outcomes

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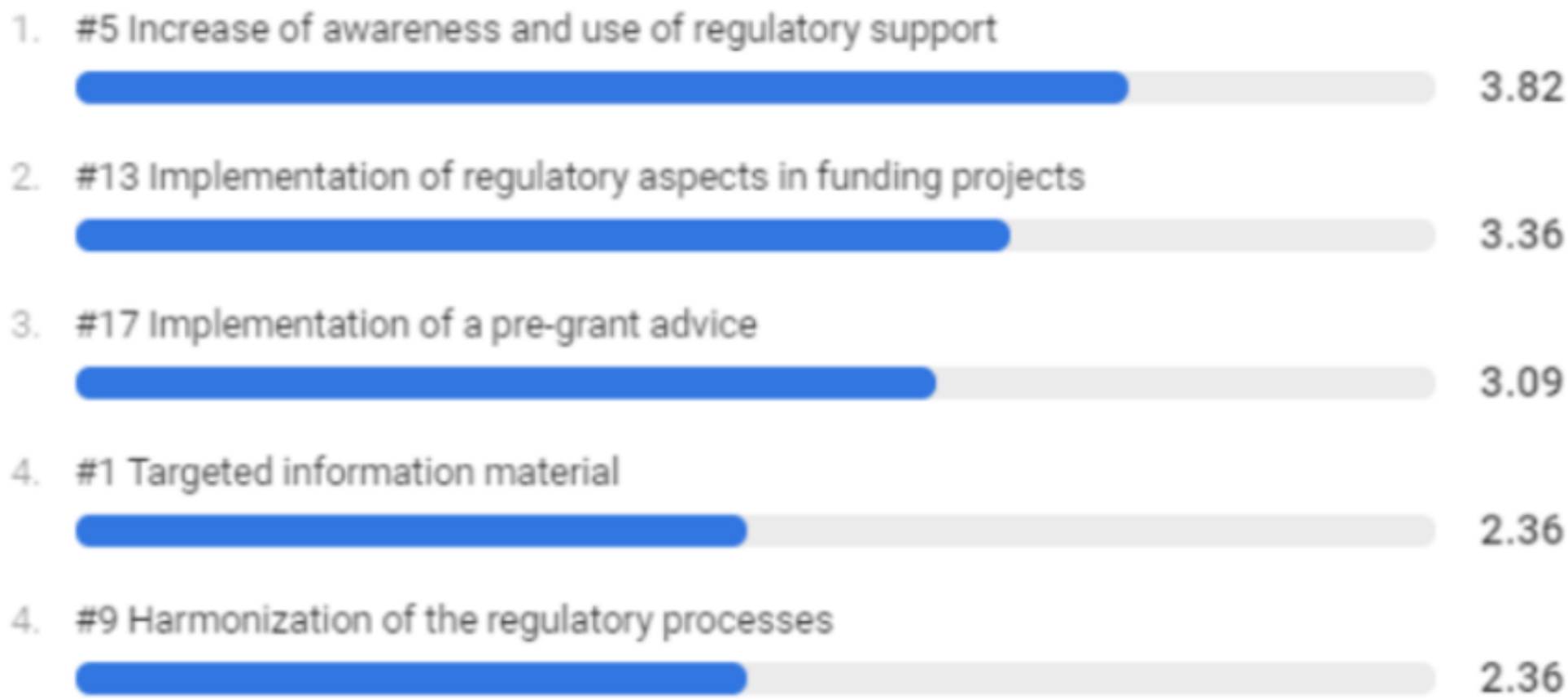
Breakout Session 1 - Polls



Recommendations

Provision and regular update of targeted information material about the regulatory framework and legal approval procedures in place

- Expand the introductory information on Regulatory affairs - e.g. EMA's SME userguide
- Survey on the landscape – whom to approach and get material
- Support correct categorization of research activities
- Sign-posting - Communication between funding bodies and the NCAs
- New regulation at EU level not just local
- Support "regulatory readiness"

Recommendations

Increase of awareness and use of regulatory support tools which are already offered

- Key individuals – ‘train the trainer’ – refer the researchers to the RAs for their research
- Effective use of social media – use hashtags, involve high profile researchers, organisations, linkedin etc.
- One-stop-shop – regulatory information accessible online
- Allow informal discussions e.g Innovation office form (HPRA) – general regulatory advice
- Case studies to overcome hesitancy – successful outcome of scientific advice

Recommendations

Harmonization of the regulatory processes between the member states

- Harmonisation of the regulatory processes between the member states is expected to be beneficial for all stakeholders, including the academics. The harmonisation should include adapted and standardised forms and processes as well as mutual online service platforms.
- Receive scientific advice from NCAs in other member states using tools such as Simultaneous National Scientific Advice (SNSA)
- Encourage more applications from academia across member states

Introduction and implementation of regulatory needs and aspects for funded biomedical research projects

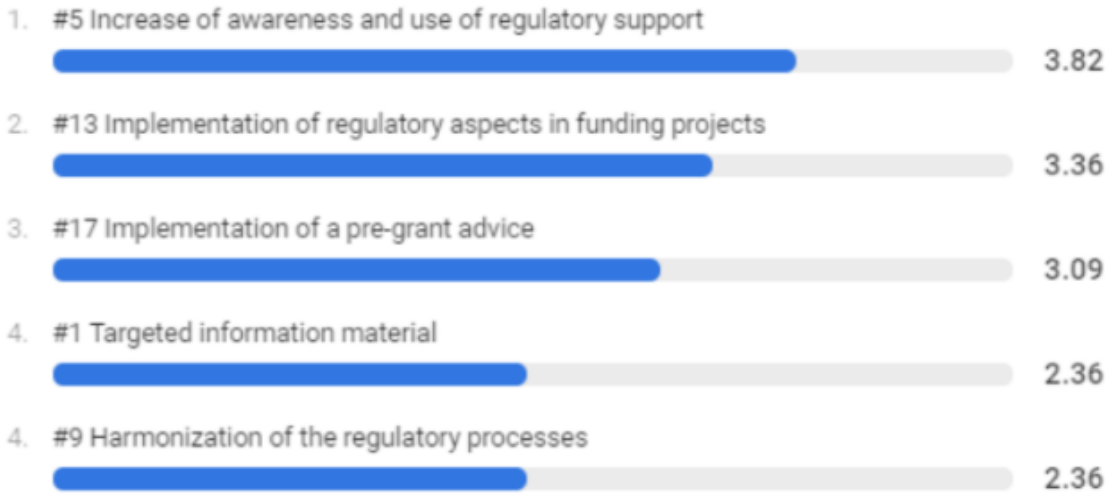
- An increased emphasis on regulatory aspects as part of the funding process.
- Ensure incorporation of potential regulatory costs as part of grant approval process, avoid missed “hidden” additional charges.
- Funder has undertaken due diligence on regulatory aspects such as document preparation (IMPD, labels etc) and appropriate training.
- Reimbursing fees and regulatory training of researchers
- Important that funding that is granted is channelled into the regulatory aspects

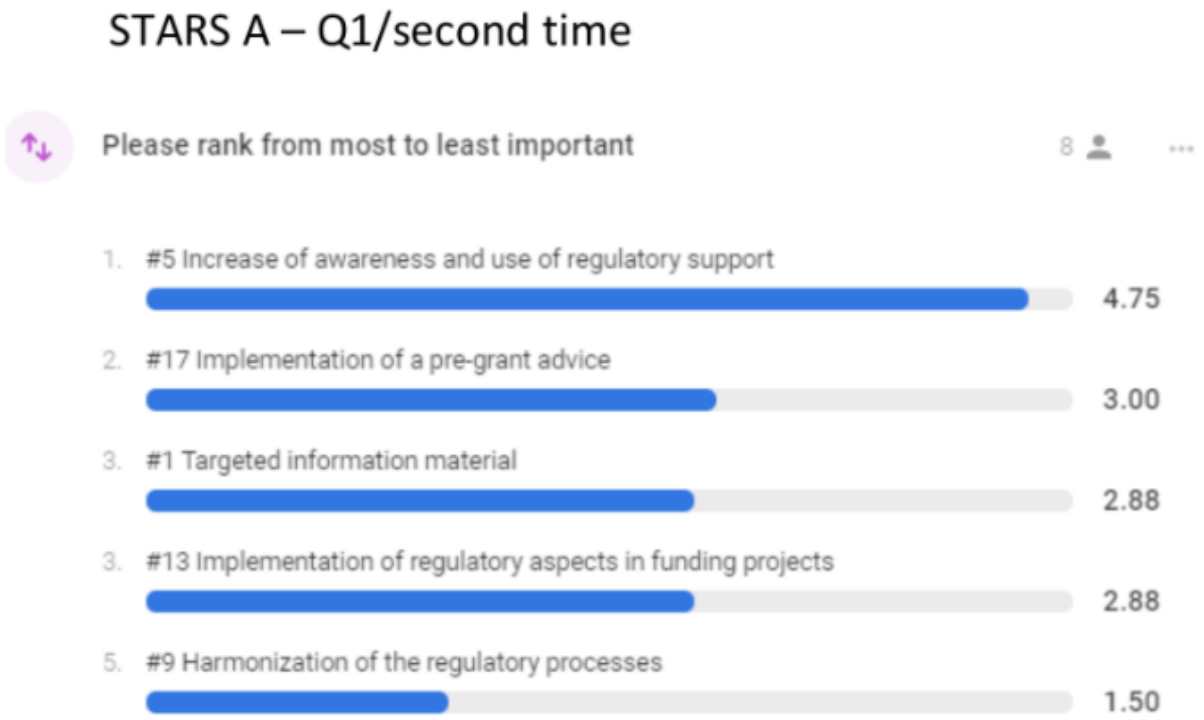
Recommendations

Implementation of a pre-grant advice

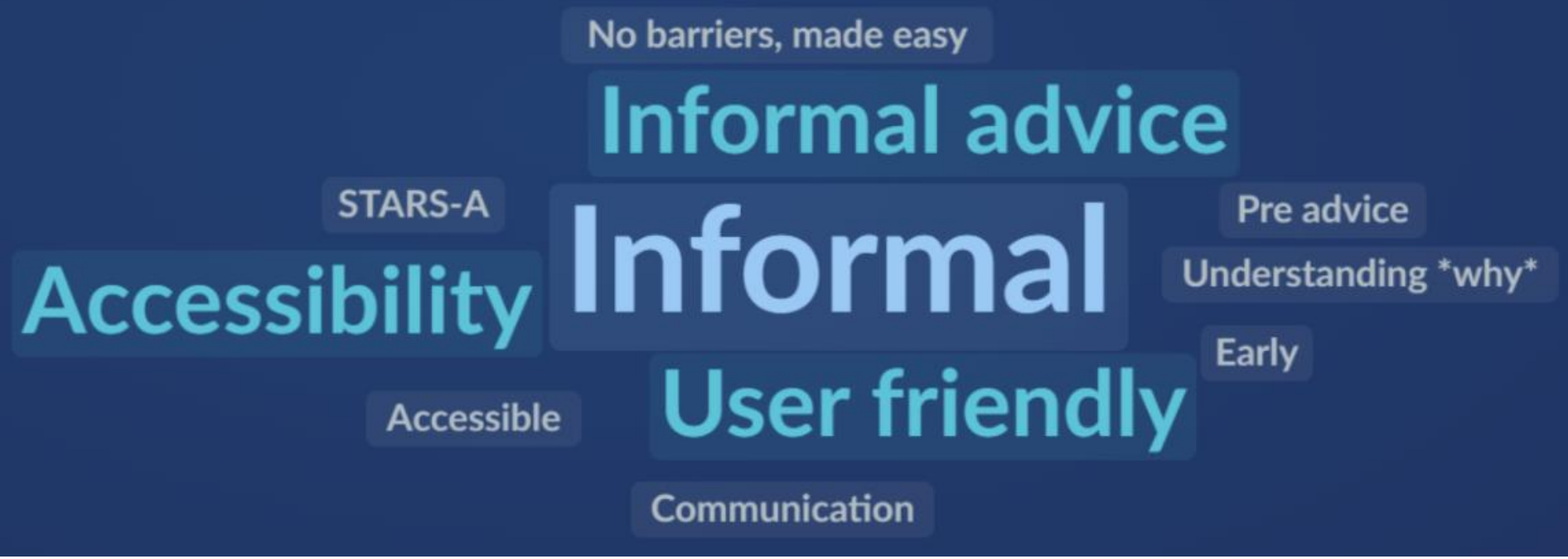
- Integrating the pre-grant advice format into funding programs as a standardized tool and active interplay between funders, developers and regulators would be an early mechanism to ensure that appropriate considerations are given to regulatory aspects to further improve regulatory science.
- Informal consultations – pre-grant advice involving key stakeholders (Funding body & applicant)
- Early interaction is beneficial
- Before the grant application call, it would be better and more necessary to consult with regulators, and then include the corresponding costs in the budget and activities into work plan
- Adapting on a case-by-case basis - mechanism for deciding which research activities would warrant scientific advice
- Maintaining impartiality by the regulatory authority is very important.

Breakout Session 1 - Polls





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



Recommendations

Additional points discussed:

- Incorporate patient involvement and focus
- Adapt as we see the implementation of the new regulation Clinical Trials Regulation 536/2014
- Communication of the outcome of STARS – plan around dissemination of strategy, curricula, inventory etc.
- Networking and collaborating

Thank you