

Status, Challenges and Opportunities for Regulatory Advice for Academia (STARS) – regulatory perspective

- Support drug development process early (rec. #4)
- Improve understanding of the roles and objectives of regulators and academia (rec. # 5)
 - Provide guidance on opportunities and limitations of scientific advices for academia AND regulators
- Establish specialised project management units (rec. #5-8)
 - Establish units specialized to give translational support (from bench to bedside)
 - Provide funding for project management units / consultancy
- Allocate sufficient time & resources for scientific advice preparation (rec. #6)
- Ensure continuous regulatory advice of projects in all stages (incl. pre-grant phase) (rec. #17)