

Most relevant STARS recommendations

How can Industry help to bridge the regulatory knowledge gap?

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

- Provide regulatory **knowledge** and **share experiences** of drug development in the EU and globally
 - Platforms such as public-private partnerships e.g. Innovative Medicines Initiative (IMI) and others
- Value and further develop the excellent **relationship** and cooperation between Regulatory decision makers and stakeholders.
 - Recognize academia a stakeholder for drug development
- Make use of **Network** and provide contact to **other relevant stakeholders** e.g. Patient and Consumer organisations, Health Care Professionals, HTA bodies
 - Joint working and focus groups e.g. European Network of Paediatric Research at the European Medicines Agency (Enpr-EMA)

Further considerations

- **Bridge the perceptual gap** between academic and industry.
 - Focus on common goal: **Patients early access** to safe innovative medicines
 - Build mutual **confidence** between the parties.
 - Consider regulatory requirements **not as a hurdle** but rather the foundation for safe medicines
- Build and maintain a **strong and trustful working relationship** between Regulators, academics and researchers, industry and other stakeholders
 - beyond the EMA academia stakeholder database.
- **Early** interactions
 - „Pipeline meeting approach“ for Academia and SMEs complementing early interaction options such as Scientific Advice (SA) meetings, Qualification of novel methodologies, Innovation Task Force (ITF) meetings, etc.



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