

Involvement of externally-funded research projects with regulatory scientists

Use of regulatory support services

Regulatory services for medicine development and also for tools of drug development, protocols and novel methodologies

ITF or Academia Briefing

Scientific Advice

Qualification Advice and Opinion

Ad hoc interactions

Ad hoc regulator participation in event

Workshop or public event of work package or consortium

Regulator can speak to specific topics and join panel discussion

Regulator may provide insights based on public information and recommend using regulatory services

Regulator in advisory role to consortium

Relevant for regulators to timely influence activities

Regulatory scientists from EMA and NCAs (National competent authorities)

EMA contact has cross-functional internal network

Regulator as consortium partner

For specific contribution to tasks or work packages, such as dedicated syntheses, consolidated views

Proactive internal support

Typically decided once winning consortium is identified (no support letter; published EMA interests to be referenced in application)

Consortia present opportunities for creating solutions for regulatory science issues and innovations to advance public health

Collaboration management meeting via regulatory.science@ema.europa.eu, also see https://www.ema.europa.eu/en/documents/other/european-medicines-agency-process-engaging-externally-funded-regulatory-sciences-and-process-improvement-research-activities-public-and-animal-health_en.pdf and <https://www.hma.eu/about-hma/working-groups/eu-innovation-network-eu-in.html#ui-id-5>