

Catalysing the integration of science and technology in development

- Catalysis – strengthened support to industry welcome
 - But it will only be used/effective (& reduce need for animal studies) if commercial sensitivity is respected
- Avoid blocking
 - don't set out detailed rules/standards in law
 - ensure adaptable dynamic frameworks
 - don't apply rules developed for human medicines without considering applicability
 - ensure science prevails over politics
 - help public to have confidence in authorised novel technologies
 - cater for novel approaches to manufacture
- International dimension key – global development projects
 - develop capability on novel therapies with Regulators outside EU;
 - learn together and define requirements together – aim for international guidance (even VICH ultimately)
 - divergence = additional (animal) studies
- 3Rs – first question the need for animal studies
 - mutual recognition of clinical (and safety) trial data
 - best use of available data including modelling
 - address countries still insisting on a batch release test in animals

