Supplementary Table: Opportunities, Challenges and Actions arising from plenary discussion

Opportunities with M&S	Challenges with M&S	Actions / Next Steps
Increase efficiency of drug development by integrative data analysis and design optimisation	Communication gap between modelling scientists and other disciplines both within Industry and between Industry and Regulators	Establish a more standardised and quantitative framework for extrapolation
Integration of new technologies (e.g. Omics) in the development and evaluation of medicinal products	Mis-perception that dose-response characterization and dose regimen selection are determined solely at the company's risk	Strengthen model and data sharing initiatives
Support extrapolation of clinical data across different populations	Lack of standardisation of methods for data generation, analysis and reporting	Debate an update to the current regulatory guidance on dose ranging/finding
Increase the robustness of both Regulatory and Industry decision-making	Heterogeneity and inconsistency in practice of M&S approaches within Industry	Agree on common good practices, standardisation of methods and reporting
Better use of resources by prioritising more promising drug	Use of model based approaches to make inferential statements around efficacy and safety	Development of standards on when and how longitudinal analysis can be used for inference in a similar way to landmark analysis
Better informed benefit risk decisions and labelling of medicinal products	Difficulties in sharing data in a competitive environment	Establish communication strategy utilizing existing regulatory pathways
	Variable readiness and capacity of the regulatory system to evaluate M&S approaches	Organise further workshops to continue to share experiences
	eCTD structure does not lend itself to detailed reporting of MBDD activities	To integrate and expand the influence of M&S competence in the EU regulatory network