

Nonclinical Guidelines

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	Pharmaceuticals	Biological and Biotechnological Products
General Information	<ul style="list-style-type: none"> Guideline on strategies to identify and mitigate risk for first-in-human clinical trials with investigational medicinal products EMA/CHMP/SWP/28367/07 (NOTE: Currently under revision, draft guideline published: 15.11.16) Guideline on non-clinical safety studies for the conducts of human clinical trials and marketing authorisation for pharmaceuticals (ICH M3(R2)) EMA/CPMP/ICH/286/1995 Questions and answers to ICH guideline (M3(R2) Q&A) EMA/CHMP/ICH/507008/2011 	<ul style="list-style-type: none"> Preclinical safety evaluation of biotechnology-derived pharmaceuticals (ICH S6(R1)) EMA/CHMP/ICH/731268/1998
Drug Interaction	<ul style="list-style-type: none"> Guideline on the investigation of drug interaction CPMP/EWP/560/95/Rev. 1 Corr. 2 	

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Toxicology	<ul style="list-style-type: none"> Note for guidance on toxicokinetics: Assessment of systemic exposure in toxicity studies (ICH S3A) CPMP/ICH/384/95 Guideline on the evaluation of control samples for non-clinical safety studies: Checking for contamination with the test substance CPMP/SWP/1094/04 Note for guidance on pharmacokinetics: repeated dose tissue distribution studies (ICH S3B) CPMP/ICH/385/95 Guideline on repeated dose toxicity CPMP/SWP/1042/99 Rev 1 Corr 	
Genotoxicity and Carcinogenicity	<ul style="list-style-type: none"> Guideline on genotoxicity testing and data interpretation for pharmaceuticals intended for human use (ICH S2 (R1)) EMA/CHMP/ICH/126642/2008 Note for guidance on the need for carcinogenicity studies of pharmaceuticals (ICH S1A) CPMP/ICH/140/95 Carcinogenicity: Testing for Carcinogenicity of Pharmaceuticals (ICH S1B) EMA/ICH/299/95 Dose selection for carcinogenicity studies of pharmaceuticals (ICH S1C(R2)) EMA/CHMP/ICH/383/1995 Assessment and control of DNA reactive (mutagenic) impurities in pharmaceuticals to limit potential carcinogenic risk (ICH M7) EMA/CHMP/ICH/83812/2013 	<ul style="list-style-type: none"> Preclinical safety evaluations of biotechnology-derived pharmaceuticals S6(R1)
Pharmacology and Safety Pharmacology	<ul style="list-style-type: none"> Safety pharmacology studies for human pharmaceuticals (ICH S7A) CPMP/ICH/539/00 The nonclinical evaluation of the potential for delayed ventricular repolarization (QT interval prolongation) by human pharmaceuticals (ICH S7B) CPMP/ICH/423/02 	

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Other Toxicological Studies	<ul style="list-style-type: none"> Guideline on non-clinical local tolerance testing of medicinal products EMA/CHMP/SWP/2145/2000 Rev. 1, Corr. 1 Detection of toxicity to reproduction for medicinal products and toxicity to male fertility (ICH S5 (R2)) CPMP/ICH/386/95 Guideline on the need for non-clinical testing in juvenile animals on human pharmaceuticals for pediatric indications EMA/CHMP/SWP/169215/2005 Guideline on risk assessment of medicinal products on human reproduction and lactation: from data to labelling EMA/CHMP/203927/2005 Guidance on photosafety evaluation of pharmaceuticals (ICH S10) EMA/CHMP/ICH/752211/2012 	
	<ul style="list-style-type: none"> Note for guidance on duration of chronic toxicity testing in animals (rodents and non-rodent toxicity testing) (ICH S4) CPMP/ICH/300/95 Note for guidance on immunotoxicity studies for human pharmaceuticals (ICH S8) CHMP/167235/2004 	
Environmental Risk Assessment	<ul style="list-style-type: none"> Guideline on the environmental risk assessment of medicinal products for human use EMA/CHMP/SWP/4447/00 corr 2 	
		<ul style="list-style-type: none"> Guideline on environmental risk assessments for medicinal products consisting of, or containing, genetically modified organisms (GMOs) EMA/CHMP/BWP/473191/2006 - corr

Additional Guidelines

ATMPs

- Non-clinical studies required before first clinical use of gene therapy medicinal products [EMA/CHMP/GTWP/125459/06](#)
- Non-clinical testing for inadvertent germline transmission of gene transfer vectors [EMA/273974/05](#)
- Scientific requirements for the environmental risk assessment of gene-therapy medicinal products [EMA/CHMP/GTWP/125491/06](#)