

Clinical Guidelines

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HINWEIS: Dieses Dokument soll der ersten Orientierung dienen und wurde von uns mit größtmöglicher Sorgfalt erstellt. Wir erheben jedoch keinen Anspruch auf Vollständigkeit und Aktualität (jährliches Update). Weiterführende Informationen finden Sie auf der EMA Website: <http://www.ema.europa.eu/ema/>. Dieses Dokument enthält Links zu externen Webseiten Dritter, auf deren Inhalte wir keinen Einfluss haben. Deshalb können wir für diese fremden Inhalte keine Gewähr übernehmen.

	Pharmaceuticals	Biological and Biotechnological Products
General Information	<ul style="list-style-type: none"> • Note for guidance on good clinical practice (ICH E6) CPMP/ICH/135/95 • Note for guidance on general considerations for clinical trials (ICH E8) CPMP/ICH/291/95 • Note for guidance on statistical principles for clinical trials (ICH E9) CPMP/ICH/363/96 • Note for guidance on choice of control group in clinical trials (ICH E10) CPMP/ICH/364/96 • Guideline on the choice of the non-inferiority margin EMA/CPMP/EWP/2158/99 Rev • Guideline on clinical development of fixed combination medicinal products EMA/CHMP/281825/2015 • Note for Guidance on the clinical requirements for locally applied, locally acting products containing known constituents CPMP/EWP/239/95 final (NOTE: Currently under revision: EMA/CHMP/558326/2013) • Guideline on the investigation of drug interactions CPMP/EWP/560/95/Rev. 1 Corr. 2** • The extent of population exposure to assess clinical safety for drugs intended for long-term treatment of non-life-threatening conditions (ICH E1) 	

	Pharmaceuticals	Biological and Biotechnological Products
General Information	<ul style="list-style-type: none"> • Points to consider on application with 1. Meta-analyses; 2. One pivotal study CPMP/EWP/2330/99 • Points to consider on multiplicity issues in clinical trials CPMP/EWP/908/99 • Guideline on the evaluation of the pharmacokinetics of medicinal products in patients with decreased renal function EMA/CHMP/83874/2014 	
Treatment of bacterial infections	<ul style="list-style-type: none"> • Guideline on the evaluation of medicinal products indicated for treatment of bacterial infections CPMP/EWP/558/95 Rev 2 • Addendum to the guideline on the evaluation of medicinal products indicated for treatment of bacterial infections EMA/CHMP/351889/2013 • Guideline on the use of pharmacokinetics (PK) and pharmacodynamics (PD) in the development of antimicrobial medicinal products EMA/CHMP/594085/2015 • Addendum on agents to treat <i>Mycobacterium tuberculosis</i> EMA/CHMP/EWP/14377/2008 (NOTE: Currently under revision: EMA/CHMP/EWP/14377/2008 Rev 1 2016) • Guideline on the clinical development of medicinal products for the treatment of cystic fibrosis EMA/CHMP/EWP/9147/2008-corr* (NOTE: Currently under revision: EMA/CHMP/259918/2016) • Guideline on clinical investigations of medicinal products for the treatment of sepsis CHMP/EWP/4713/03 	
Treatment of HIV	<ul style="list-style-type: none"> • Guideline on the clinical development of medicinal products for HIV infection EMA/CPMP/EWP/633/02 Rev 3 	
Hepatitis	<ul style="list-style-type: none"> • Guideline on the clinical evaluation of direct acting antivirals for the treatment of chronic hepatitis C EMA/CHMP/EWP/30039/2008 (NOTE: Currently under revision: EMA/CHMP/EWP/30039/2008 Rev 1) • Clinical evaluation of medicinal products intended for treatment of hepatitis B CPMP/EWP/6172/03 	