

Clinical Guidelines

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| | Pharmaceuticals | Biological and Biotechnological Products |
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| General Information | <ul style="list-style-type: none"> Guideline for good clinical practice (ICH E6 (R2)) EMA/CHMP/ICH/135/1995 General considerations for clinical trials (ICH E8) CPMP/ICH/291/95 Statistical principles for clinical trials (ICH E9) CPMP/ICH/363/96 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 Guideline on clinical development of fixed combination medicinal products EMA/CHMP/158268/2017 Note for Guidance on the clinical requirements for locally applied, locally acting products containing known constituents CPMP/EWP/239/95 (NOTE: Currently under revision: CPMP/EWP/239/95 Rev. 1) 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) CPMP/ICH/375/95 Points to consider on application with 1. Meta-analyses; 2. One pivotal study CPMP/EWP/2330/99 | |

| | Pharmaceuticals | Biological and Biotechnological Products |
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| | <ul style="list-style-type: none"> Points to consider on multiplicity issues in clinical trials CPMP/EWP/908/99 (NOTE: Currently under revision: EMA/CHMP/44762/2017) 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 (NOTE: Currently under revision: EMA/CHMP/75653/2018) Addendum to the guideline on the evaluation of medicinal products indicated for treatment of bacterial infections EMA/CHMP/351889/2013 Addendum to the guideline on the evaluation of medicinal products indicated for treatment of bacterial infections to address the clinical development of new agents to treat pulmonary disease due to <i>Mycobacterium tuberculosis</i> EMA/CHMP/EWP/14377/2008 Rev. 1 Draft: Addendum to the guideline on the evaluation of medicinal products indicated for treatment of bacterial infections to address paediatric-specific clinical data requirements EMA/CHMP/187859/2017 Guideline on the use of pharmacokinetics (PK) and pharmacodynamics (PD) in the development of antimicrobial medicinal products EMA/CHMP/594085/2015 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 | |
| Treatment of Hepatitis | <ul style="list-style-type: none"> Guideline on the clinical evaluation of direct acting antivirals for the treatment of chronic hepatitis 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 | |