Clinical Guidelines

NOTE: This document should only be used as a first orientation and was created with utmost caution and great care. However, we do neither claim completeness nor timeliness of data published (yearly update). For further information visit the EMA website: http://www.ema.europa.eu/ema/. This document contains links to external websites no liability for any content of any external site is taken. The content of external sites belongs to the sphere of responsibility of its respective publisher.


<table>
<thead>
<tr>
<th>Pharmaceuticals</th>
<th>Biological and Biotechnological Products</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>General Information</strong></td>
<td><strong>Guideline for good clinical practice (ICH E6 (R2))</strong> EMA/CHMP/ICH/135/1995</td>
</tr>
<tr>
<td></td>
<td><strong>Guideline for good clinical practice (ICH E6 (R2))</strong> EMA/CHMP/ICH/135/1995</td>
</tr>
<tr>
<td></td>
<td><strong>General considerations for clinical trials (ICH E8)</strong> CPMP/ICH/291/95</td>
</tr>
<tr>
<td></td>
<td><strong>Statistical principles for clinical trials (ICH E9)</strong> CPMP/ICH/363/96</td>
</tr>
<tr>
<td></td>
<td><strong>Choice of control group in clinical trials (ICH E10)</strong> CPMP/ICH/364/96</td>
</tr>
<tr>
<td></td>
<td><strong>Guideline on the choice of the non-inferiority margin</strong> EMEA/CPMP/EWP/2158/99</td>
</tr>
<tr>
<td></td>
<td><strong>Guideline on clinical development of fixed combination medicinal products</strong> EMA/CHMP/158268/2017</td>
</tr>
<tr>
<td></td>
<td><strong>Note for Guidance on the clinical requirements for locally applied, locally acting products containing known constituents</strong> CPMP/EWP/239/95 (NOTE: Currently under revision: CPMP/EWP/239/95 Rev. 1)</td>
</tr>
<tr>
<td></td>
<td><strong>Guideline on the investigation of drug interactions</strong> CPMP/EWP/560/95/Rev. 1 Corr. 2**</td>
</tr>
<tr>
<td></td>
<td><strong>The extent of population exposure to assess clinical safety for drugs intended for long-term treatment of non-life-threatening conditions (ICH E1)</strong> CPMP/ICH/375/95</td>
</tr>
<tr>
<td></td>
<td><strong>Points to consider on application with 1. Meta-analyses; 2. One pivotal study</strong> CPMP/EWP/2330/99</td>
</tr>
<tr>
<td>Pharmaceuticals</td>
<td>Biological and Biotechnological Products</td>
</tr>
<tr>
<td>------------------</td>
<td>------------------------------------------</td>
</tr>
<tr>
<td>• Points to consider on multiplicity issues in clinical trials CPMP/EWP/908/99 (NOTE: Currently under revision: EMA/CHMP/44762/2017)</td>
<td></td>
</tr>
<tr>
<td>• Guideline on the evaluation of the pharmacokinetics of medicinal products in patients with decreased renal function EMA/CHMP/83874/2014</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Addendum to the guideline on the evaluation of medicinal products indicated for treatment of bacterial infections EMA/CHMP/351889/2013</td>
</tr>
<tr>
<td></td>
<td>• 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 <em>Mycobacterium tuberculosis</em> EMA/CHMP/EWP/14377/2008 Rev. 1</td>
</tr>
<tr>
<td></td>
<td>• 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</td>
</tr>
<tr>
<td></td>
<td>• Guideline on the use of pharmacokinetics (PK) and pharmacodynamics (PD) in the development of antimicrobial medicinal products EMA/CHMP/594085/2015</td>
</tr>
<tr>
<td></td>
<td>• Guideline on clinical investigations of medicinal products for the treatment of sepsis CHMP/EWP/4713/03</td>
</tr>
<tr>
<td>Treatment of HIV</td>
<td>• Guideline on the clinical development of medicinal products for HIV infection EMEA/CPMP/EWP/633/02 Rev. 3</td>
</tr>
<tr>
<td></td>
<td>• Clinical evaluation of medicinal products intended for treatment of hepatitis B CPMP/EWP/6172/03</td>
</tr>
</tbody>
</table>