

## ICH M7(R1) EWG Work Plan 31 August 2017

**Topic Adopted:** June 2017

**Last Face-to-Face Meeting:** Fukuoka, Japan – June 2014

### 1. Anticipated Milestones

Completion Date	Deliverable
2018	<i>Step 2</i>

### 2. Timelines

Date	Task / Activity	Details
December 2017	EWG 1 <sup>st</sup> WebEx / Discussion of the 2 <sup>nd</sup> addendum work plan	<ul style="list-style-type: none"> <li>➤ The detailed work plan for 2<sup>nd</sup> addendum will be discussed.</li> <li>➤ A new list of compounds will be made.</li> </ul>
2018	EWG 2 <sup>nd</sup> WebEx / Discussion of monographs for compounds	<ul style="list-style-type: none"> <li>➤ The EWG safety group will discuss about alternative ways to calculate AIs or PDEs (<i>eg.</i>, extrapolation from BMDL) for approval.</li> <li>➤ The EWG safety group will review the compounds in the list to move forward to the 2<sup>nd</sup> addendum.</li> </ul>
2018	Final (3 <sup>rd</sup> ) EWG WebEx before <i>Step 2</i>	<ul style="list-style-type: none"> <li>➤ Continue discussion to reach <i>Step 2</i></li> </ul>
2018	Reached <i>Step 2</i>	<ul style="list-style-type: none"> <li>➤ Document open for Public comment period.</li> </ul>