ICH International Conference on harmonisation of technical requirements for registration of pharmaceuticals for human use

Revision of ICH M3 – Non-Clinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorisation for Pharmaceuticals.

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Original M3 Document Approved 1995 and Revised in 2000.

6 Pages of Text

Current Revision Started October 2006

Step 2 Reached June 2008

Current Version 23 Pages of Text!!

New Sections on:

Estimation of the First Dose in Humans
Exploratory Clinical Studies
Clinical Trials In Paediatric Populations
Immunotoxicology
Phototoxicity
Nonclinical Abuse Liability
Fixed Combination Drug Nonclinical Testing

Revised document more harmonised that previous, especially regarding inclusion of Women of Child Bearing Potential.

The 3 Rs taken into account, especially with regards to Acute Toxicology, Exploratory Clinical Trials, Duration of Repeated Dose Toxicity Studies and Timings for Reproduction Toxicity Studies

Many pages of comments received following release of Step 2 Document.

Progress in responding to comments has been slower than hoped.

Still plan to reach step 4 in Japan in June 2009.