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Appropriate Dose Selection How To Optimize Clinical Drug

Selection of the Appropriate Package Type Terms and Recommendations for Labeling Injectable Medical Products Packaged in Multiple-Dose, Single-Dose, and Single-Patient-Use Containers for Human Use

Selection of the Appropriate Package Type Terms and

Dose Selection in Drug Development and Regulation: Possible Future Direction Richard Lalonde and Donald Stanski Pfizer and AstraZeneca . 2 EMA 2014 Overview What is the problem and how did we get here Examples of the challenge ... Importance of Appropriate Dose Selection

Dose Selection in Drug Development and Regulation

Optimal dose individualization has become more important in improving clinical efficacy and safety, given the variability in drug response, e.g., due to concurrent illnesses or co-medications. Therefore, the role of optimal dose finding in early clinical drug development so as to maximize successful clinical use is emphasized.

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Critical decisions such as candidate selection, early proof of concept/principle, dose ranging, development risks, and patient stratification are based on the appropriate measurements of biomarkers that are biologically and/or clinically validated.

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combination. The average dose injected by patients using prostaglandin E1 was 5.58 µg. (95% confidence interval 4.83 to 6.34 µg.). Patients using the combination injected an average dose of 0.40 ml. (95% confidence interval 0.342 to 0.457 ml., 0.40 ml. of the combination equals 4.8 mg. papaverine, 0.4 mg. phentolamine and 3.6 µg.

Intracavernous Pharmacotherapy for Impotence Selection of

sions such as candidate selection, early proof of concept/principle, dose ranging, development risks, and patient stratification are based on the appropriate measurements of biomarkers that are biologically and/or

clinically validated.

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Dose selection for biopharmaceuticals is also out of the scope of this document. 6 | Guidance on dose level selection. ... Medicines with appropriate characteristics will require the standard preclinical safety assessment package prior to further clinical trials.

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