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ICH - Clinical Safety E1 - E2F

ICH-E1 The Extent of Population Exposure to Assess Clinical Safety for Drugs Intended for Long-term Treatment of Non-Life-Threatening Conditions

ICH-E2A Clinical Safety Data Management: Definitions and Standards for Expedited Reporting ICH-E2B(R2) Clinical Safety Data Management: Data Elements for Transmission of Individual Case Safety

Reports

ICH-E2C(R2) Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs

ICH-E2D Post-Approval Safety Data Management: Definitions and Standards for Expedited Reporting

ICH-E2E Pharmacovigilance Planning

ICH-E2F Development Safety Update Report

Samples of DSURS

European Directive 2001/20/EC

European Directive 2005/28/EC



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