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QTc evaluation in drug development: QTc prolongation and concern for Torsades des pointes risk in modern drug development

Assessing the cardiovascular safety of novel compounds is an important clinical drug development objective for drugs with preclinical cardiovascular safety signals and agents for which a cardiovascular class effect is suspected. Consequently for most compounds, regulatory authorities still expect to see a Thorough QT (TQT) study according to FDA guideline ICH-E14. Evaluation of ECG's during these early clinical studies typically involves the assessment of clinically significant, abnormal ECG's only. If statistical analysis is performed, traditionally it has been limited to descriptive statistics of ECG parameters. Combined with Concentration Effect Modelling (CEM), precise estimates of QTc effect may substantially improve the ability to detect QTc prolongation early in the development process. For both small and large molecules, a rigorous assessment of the ECG during early clinical studies can turn out to be an excellent long-term investment. Assessing effects of your drug on ECG parameters requires experience and the right study design, study assessments and data analysis methods. For any TQT study or an early clinical study, the right experience and expertise in study design and execution is needed. Procedures and methods to deliver will be discussed.

Biography

Jan Leendert Pouwel Brouwer completed his MD training and internships at the University of Groningen, Netherlands. There he also worked at the department of hematology as a coagulation specialist. He obtained his PhD thesis at the same University. Dr Brouwer is a board certified cardiologist and was trained at the Radboud University in Nijmegen, Netherlands. He has published more than 25 papers in international peer reviewed journals. Currently he is working as a cardiologist and medical director at a CRO and a thrombosis service center.