

At PhinC Modeling, we help you identify, mitigate and overcome all the challenges you may face during your drug development process

QT / QTC ANALYSIS (TQT) FOR CARDIAC SAFETY

PhInc. Modeling has been a pioneer in the use of the concentration-response modeling approach to document QT-liability through intensive ECG monitoring from first-in-human studies to ICH E14 dedicated TQT study.

Since its revision in 2015, the ICH E14 guideline now accepts the use of C-R (Concentration-Response) approach applied to first-in-human studies as a possible alternative to the TQT study.



PHINC. MODELING, A PIONEER IN EXPLORING CARDIAC SAFETY IN EARLY PHASE

As for all PhInc' services, the C-QTc analysis is performed within a reproducible analysis and reporting environment. This allows for a highly effective and efficient workflow with submission ready reports being available in a timely manner.

Upload of ECG

to FDA

warehouse

Creation and study design FDA/EMA acceptance criteria.

Collection, management & processing of digital ECG

SAP/MAP (Statistical/Modeling Analysis Plan)

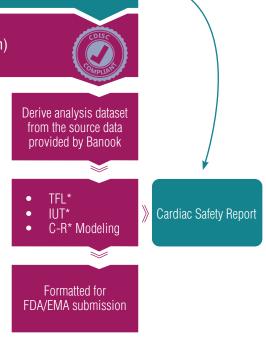
ECG analysis

& interpretation

by trained

cardiologists

- Use of C-R* models through intensive ECG from FIH to ICH E14 TQT studies
- According to ICH E14 guideline revision in 2015
- Advantage: C-R analysis consider all the ECG collected simultaneously with systemic exposure to the drug
- Use preliminary C-R models, predict QT-interval prolongation and adapt regulatory ECG studies if necessary
- Approach sufficiently powerful and suitable in FIH



Secured data transfert

ECG database to PhinC

for analysis

TFL: Tables, Figures and Listings IUT: Interaction-Union Test C-R: Concentration-Response

Cardiabase-Banook, a partner of choice for TQT studies

Cardiabase-Banook Group is the best cardiac core lab in Europe. It specializes in data acquisition, processing, analysis, reporting and archiving for digital and paper ECG as well as holter monitoring. Working with Banook experts ensures that you achieve state-ofthe-art and regulation compliant TQT studies.





CONTACT US TODAY TO GET A QUALIFICATION APPOINTMENT



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