

At PhinC Development, 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 Development 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 DEVELOPMENT, 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.

Creation and study design FDA/EMA acceptance criteria.



ECG analysis & interpretation by trained cardiologists

Upload of ECG to FDA warehouse Secured data transfert ECG database to PhinC for analysis

SAP/MAP (Statistical/Modeling Analysis Plan)



- 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

Derive analysis dataset from the source data provided by Banook

- TFL\*IUT\*C-R\* Modeling
- C-R\* Modeling

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TFL: Tables, Figures and Listings IUT: Interaction-Union Test

Cardiac Safety Report

*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-of-the-art and regulation compliant TQT studies.





## CONTACT US TODAY TO GET A QUALIFICATION APPOINTMENT

