Thorough QT/TQT Study – in the Hands of Professionals

Competence in Clinical Development

Since the ICH E14 Note for Guidance, CRS has been conducting TQT trials at two of their Phase I Research clinics. CRS’ staff is well experienced in handling the theoretical and practical aspects and challenges of TQT trials in a CRO surrounding.

More than 2000 subjects have been treated in TQT related trial designs in a total of more than 20 trials in different subject populations and therapeutic areas. All leading techniques in Holter recording and stationary triple ECG assessment have been utilized. CRS has been cooperating with major ECG labs and is experienced in handling various techniques of data transfer.

Some of the conducted trials have been successfully submitted to the European and the US authorities.
TQT Setup

CRS run their TQT studies in specially arranged clinic surroundings separated from the main clinic activities. This enables a quiet, controlled conduct without external sources of disturbance, physically or mentally, that might cause variability in ECG data. Large numbers of subjects can be guided through the study with a maximum of 2 groups of 10 – 15 subjects per profile day.

Consultancy

CRS customize TQT Study designs according to the client’s needs and guidance requires. Consultancy comprises discussion of crossover designs, blinding procedures, double dummy approaches, dosages, practical technical settings, recording equipments, data transfer and implementation of simultaneous safety ECGs in real time.

Trial Teams

Dedicated clinical teams with specialization and experience in ECG and TQT trials are available. Technical handling of device and management of study subjects is optimised. Regular internal and external training for physicians, study nurses and QA staff is mandatory.

Special Populations and Designs

Additional to healthy young volunteers special patient populations and elderly, middle aged volunteers and postmenopausal women were enrolled in TQT trials over the last years. The database of CRS comprises more than 22,000 subjects distributed over all age classes and is balanced in the gender ratio. Additionally CRS has experience in long-term hospitalisation of subjects in TQT trials of up to 46 days.

Also the handling of complex designs (5-way cross over), mixed (ambulatory & hospital) procedures, treatment schedules from oral to intravenous, simulation of maximum inhibition of metabolizing enzyme or transporters by DDI is part of our experience. Among others we have published an article in the EPC journal describing the CRS approach to designing and conduct of trials following the E14.

CRS’ ECG Device Experience

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<td>Bluetooth interface enables online observation via PC display</td>
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