Hello Everyone,

As announced in late December, the IQ-CSRC Study Waveform Sharing Program is now in place and interested ECG laboratories are encouraged to submit their request for data before January 25, 2016. Below is a detailed description of the program and attached are a slide set providing further details, as well as the IQ-CSRC main study publication and project submission form.
The IQ-CSRC Study Waveform Data Sharing Program allows interested ECG core laboratories to access this validation dataset to test their ability to accurately characterize QT effects in a manner consistent with this alternative approach to the TQT.

- Just like with the original conduct of the IQ-CSRC study, each participating core lab will be blinded to treatment information, and the statistical analysis based on the ECG measurements done by each core lab will be conducted by a neutral 3rd party (Cindy Green, PhD – CSRC Data Warehouse Statistician).
- The statistical analysis will be based on an exposure response analysis of the data and follow an almost identical statistical analysis plan (SAP) as the original IQ-CSRC study. The SAP will be shared with participating core labs.
- Since the goal of this validation exercise is to foster understanding and confidence among sponsors in the use of this new approach, results from each participating core lab will be shared with the CSRC Scientific Oversight Committee.

The following are the steps for participating in this Program:

1) Complete the attached CSRC Project Submission form to obtain the documents necessary to participate in the Waveform Sharing Program
2) Review and sign the IQ-CSRC Study Waveform Sharing Program Agreement;
3) Review and sign the THEW Data Use Agreement;
3) Make payment to the THEW in the amount of $5,000 U.S. for support and access to the blinded ECG waveforms and blinded subject information;
4) Make payment to the CSRC in the amount of $5,000 U.S. for the statistical review and reporting related to participation in the Program.

Once the steps above are completed, the following steps will be followed by the Participant to complete the Program (full details are given in Program Agreement):

1) The Participant will be given secured access (online or via hard drive) to the raw ISHNE and annotation files from the IQ-CSRC study, as well as to the Study Protocol, relevant subject demographic data, and dosing time information (collectively the "Study Data") by the THEW. Access to the Study Data will be provided to Participant on February 1, 2016.
2) Once Study Data is released to a Participant, that Participant must complete analysis of such Study Data and submit the results, per the specifications of this Agreement, to the CSRC within six (6) weeks; in other words, a Participant must submit results by March 14, 2016.
3) The Participant will submit timepoint-level interval measurements for QT, QTcF, RR, PR and QRS, as well as a general, non-confidential description of its analysis methodology, which shall, at minimum, describe how many replicates were analyzed per timepoint and whether such analysis was done in a manual, semi-automated or fully automated manner (the interval measurement data and methodology description being collectively referred to herein as "Participant Analysis Results") to the CSRC in the format structure set forth by the CSRC. If the Participant does not submit the final Participant Analysis Results within the allotted 6-week timeline, then those results will not be analyzed by the CSRC and the Participant will not be provided another opportunity to submit the Participant Analysis Results or to further participate in the Program; further, the Participant will not be eligible for a refund of amounts paid to the THEW or to the CSRC hereunder.

4) Once the Participant has submitted the Participant Study Results, the CSRC statistician will perform statistical analysis on the timepoint-level data as outlined in the approved analysis plan agreed to by the CSRC ECG Data Warehouse Committee.
5) The CSRC statistician will provide applicable statistical results as detailed in the SAP to the Participant within an agreed-upon timeframe. It is acknowledged by the Participant, that it shall at no time receive a randomization code from CSRC or iCardiac that would enable the Participant to know which drugs subjects were administered.
6) In addition to providing statistical results to the Participant, the CSRC statistician shall provide such full statistical results to the CSRC Scientific Oversight Committee. By agreeing to participate in this Program, and in fairness to other participants and for the general benefit of the clinical trials industry, each Participant acknowledges and agrees that full statistical results relating to the Participant Analysis Results will be provided to all members of the CSRC Scientific Oversight Committee. If Participant initiates involvement in this Program by receiving Study Data but does not complete and submit its results in a timely manner, then in fairness to other participants it shall be noted to the CSRC Scientific Oversight Committee that the Participant voluntarily discontinued its efforts to analyze Study Data.
7) While it is not mandatory or a condition of participation in the Program that Participant actively take part in the drafting and review of a joint publication based on the results submitted by all participants, it is encouraged that each participating company do so. If a Participant takes part in such a publication, it may assign one person to collaborate on the joint publication and to be listed as a co-author.
8) The Participant may voluntarily choose to submit results from more than one methodology that the Participant used to analyze Study Data. However, the Participant agrees that each methodology shall be treated as a separate submission hereunder, meaning that for each submission Participant must: pay a $5,000 analysis fee to the CSRC and describe the analysis methodology that was used. However, the Participant shall be provided only one 6-week period from its initial receipt of Study Data during which to complete and submit all analyses, no matter how many different methodologies each Participant wishes to use hereunder. All and each Participant Analysis Results submitted as part of the Program may be published or publicly reported about as further outlined herein.

- In order to participate in this program, core labs need to indicate their interest to Cindy Green (email: cindy.green@duke.edu) and complete the needed paperwork, which outlines terms under which they are receiving the data, by **January 25, 2016**.
- The dataset will then be made available to all participating core labs on **February 1, 2016**.
- Each core lab will have 6 weeks to complete the process, so their data needs to be submitted to DCRI on or before **March 14, 2016**.

If your lab is interested in participating in this exciting opportunity, please let me know as soon as possible, and I will provide the full program agreement for your organization's review.

Click here for the CSRC Project Submission Form | IQ- CSRC Waveform Sharing Program PowerPoint |
Darpo et al 2015 Clinical Pharmacology & Therapeutics-Results From the IQ-CSRC Prospective Study