



QRS Prolongation, Thorough QT (TQT) Drug Trial Question: Why can't you include hERG ion channel assessment via molecular investigation or simulation automatically in investigational new drug (IND) submission ?



By **Randall BARDWELL**  Life Sciences Industry Team 2020-02-26 - Edited

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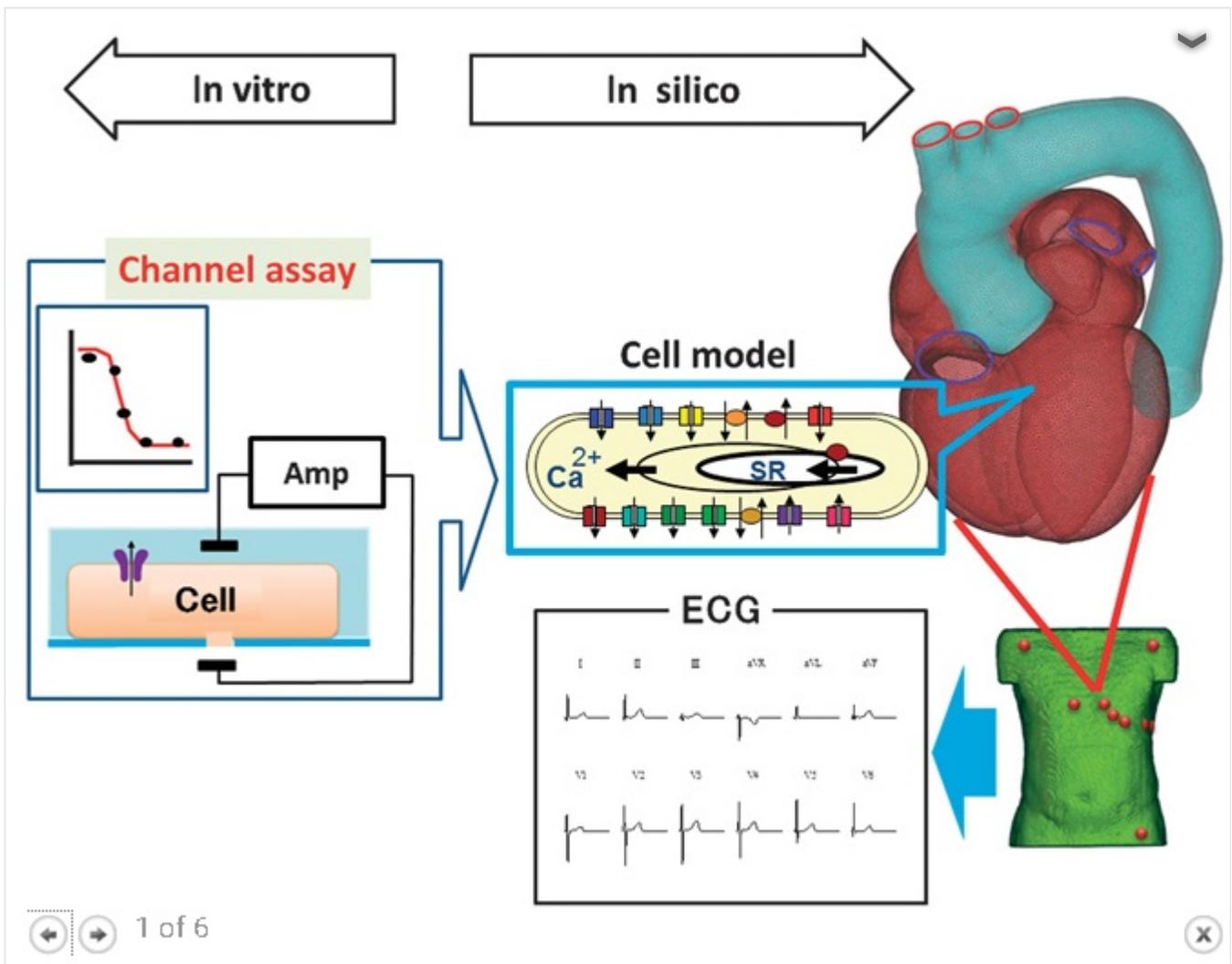
Thorough QT or TQT Studies were a pretty big market last time I was associated with them (FDA ECG Warehouse), and a question I've had since I've been here and surrounded by all of these biology/biopharma experts:

If you can predict that a drug will have a QRS prolongation effect via hERG potassium ion channel effect why not include that in a process that could simulate hERG potassium ion channel interaction and notify you ahead of the definition process? Maybe they do and my question is moot.

The TQT CRO process involves 12 lead ECG devices and the ability to forward HL7 aECG (annotated ECG files with P wave onset/offset and T wave onset/offset denoted) to the FDA ECG Warehouse. I would be curious as to the extent of existing Medidata work in the TQT field.

There have been papers that have suggested exactly that, and the last I heard was that the FDA was granting waivers for TQT studies in certain situations that might lessen the market size a bit, but the TQT/cardiac safety services market is estimated to be ~\$752M USD with 11.2% CAGR Growth

I have also seen companies such as Nova Research focus on services for GLP ion channel and analytical support so apparently there is still plenty of interest up to and including an article on exactly that point: cardiac simulation of the hERG ion channel for cardiac toxicity. Maybe not eliminate the TQT process but rather enhance it...



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Jiang YAO - 2020-02-26

Stanford and our team collaborated on this topic and published several papers: <http://biomechanics.stanford.edu/paper/CMAME19.pdf>, <https://www.biorxiv.org/content/biorxiv/early/2019/02/10/545863.full.pdf>

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Randall BARDWELL - 2020-02-26

I had a feeling that someone here could answer my question :) I look forward to reading the data. Thanks @Jiang YAO!

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Randall BARDWELL - 2020-02-29

Interesting papers, so its not such a crazy idea after all...thanks again!

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