



**December 2018**

Dear CiPA Community,

Welcome to the CiPA Quarterly Update!

We are happy to share news from the recent ICH face-to-face meeting held in November 2018. The ICH S7B/E14 Q&A concept paper and work plan have been approved! The ICH Assembly endorsed the establishment of an Implementation Working Group (IWG) to begin the process of developing a Q&A document. This IWG will build on work done by the former E14/S7B Discussion Group (DG) including work on the CiPA initiative.

The purpose of the IWG will be to provide guidance around the proposed nonclinical assays (*in vitro*, *in silico*, and *in vivo*). The current plan calls for a two-staged Q&A approach starting with S7B and then E14 guidance with the goal to have this be a more efficient process. Read more online including the concept paper and work plan:

**E14/S7B Questions & Answers: Clinical and non-Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential:**

<https://www.ich.org/products/guidelines/efficacy/article/efficacy-guidelines.html#13-3>

**Concept Paper:**

[https://www.ich.org/fileadmin/Public\\_Web\\_Site/ICH\\_Products/Guidelines/Efficacy/E14/E14S7BIWG\\_ConceptPaper\\_Final\\_2018\\_1122.pdf](https://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E14/E14S7BIWG_ConceptPaper_Final_2018_1122.pdf)

**Work Plan:**

[https://www.ich.org/fileadmin/Public\\_Web\\_Site/ICH\\_Products/Guidelines/Efficacy/E14/E14S7BIWG\\_WorkPlan\\_Final\\_2018\\_1122.pdf](https://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E14/E14S7BIWG_WorkPlan_Final_2018_1122.pdf)

Recent Publications:

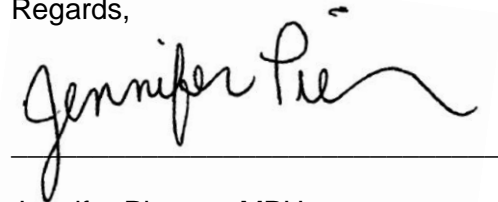
- Vicente J, Zusterzeel R, Johannesen L, Ochoa-Jimenez R, Mason JW, Sanabria C, Kemp S, Sager PT, Patel V, Matta MK, Liu J, Florian J, Garnett C, Stockbridge N, Strauss DG. (2018.) Assessment of Multi-Ion Channel Block in a Phase-1 Randomized Study Design: Results of the CiPA Phase 1 ECG Biomarker Validation Study. *Clin Pharmacol Ther.* 2018 Nov 17. [doi: 10.1002/cpt.1303](https://doi.org/10.1002/cpt.1303).
- Li Z., Ridder B. J., Han X., Wu W. W., Sheng J., Tran P. N., Wu M., Randolph A., Johnstone R. H., Mirams G. R., Kuryshv Y., Kramer J., Wu C., Crumb W. J., Strauss,

D. G. (2018). Assessment of an In Silico Mechanistic Model for Proarrhythmia Risk Prediction Under the CiPA Initiative. *Clinical Pharmacology and Therapeutics*. Available online August 27, 2018. [doi:10.1002/cpt.1184](https://doi.org/10.1002/cpt.1184)

- Blinova K., Dang Q., Millard D., Smith G., Pierson J., Liang G., Brock M., Lu H.R., Kraushaar U., Zeng H., Shi H., Zhang X., Sawada K., Osada T., Kanda Y., Sekino Y., Pang L., Feaster T.K., Kettenhofen R., Stockbridge N., Strauss D.G., Gintant G. (2018). International Multisite Study of Human Induced Pluripotent Stem Cell Derived Cardiomyocytes for Drug Proarrhythmic Potential Assessment. *Cell Reports*. Available online September 25, 2018. <https://doi.org/10.1016/j.celrep.2018.08.079>.

If you're interested in finding past Quarterly Updates, they are available online:  
<http://cipaproject.org/latest-news/>.

Regards,

A handwritten signature in black ink that reads "Jennifer Pierson". The signature is written in a cursive style and is positioned above a horizontal line.

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