October 2018

Dear CiPA Community,

Welcome to the CiPA Quarterly Update!

Recent publications from the CiPA workstreams are listed below. Visit the CiPA website to see all publications: http://cipaproject.org/publications/:

- Strauss D.G., Gintant G, Li Z, Wu W, Blinova K, Vicente J, Turner J.R., Sager P.T. (2018). Comprehensive In Vitro Proarrhythmia Assay (CiPA) Update from a Cardiac Safety Research Consortium / Health and Environmental Sciences Institute / FDA Meeting. *Therapeutic Innovation & Regulatory Science*. First Published August 29, 2018. doi.org/10.1177/2168479018795117

- 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., Kuryshev 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 Therapuetics*. Available online August 27, 2018. doi: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). (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.

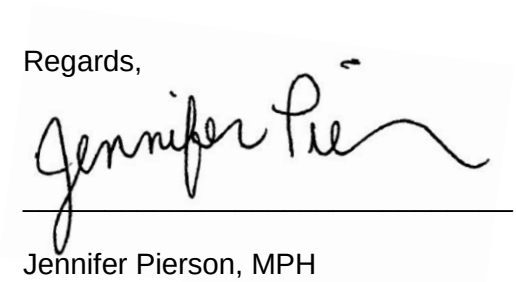
Open Data Formatting:
A subteam including volunteers from industry and FDA is currently working on an open data format specification for manual and automated patch clamp data. The open format will be manufacturer independent and will meet CiPA in vitro and in silico needs. The format will be also eCTD compliant.

Best Practices Papers:
The CiPA Work Streams continue to make progress on additional manuscripts including one from each group that will detail some of the discussions and recommendations that came out of the recent May 2018 CiPA Meeting. These publications will cover topics such as quality

standards necessary for regulatory submissions to best practices and recommendations. The hope is to help provide some further clarity around expectations around the differences in early drug development screening tools and data that will be submitted as part of a regulatory submission package.

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

Regards,



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