

Accepted Manuscript

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PII: S1056-8719(18)30690-7
DOI: [doi:10.1016/j.vascn.2018.09.002](https://doi.org/10.1016/j.vascn.2018.09.002)
Reference: JPM 6541

To appear in: *Journal of Pharmacological and Toxicological Methods*

Received date: 22 June 2018
Revised date: 19 September 2018
Accepted date: 21 September 2018

Please cite this article as: Bernard Fermini, Kevin P. Coyne, Shawn T. Coyne , Challenges in Designing and Executing Clinical Trials in a Dish Studies. Jpm (2018), doi:[10.1016/j.vascn.2018.09.002](https://doi.org/10.1016/j.vascn.2018.09.002)

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Challenges in Designing and Executing Clinical Trials in a Dish Studies**Bernard Fermini^a, Kevin P. Coyne^a, and Shawn T. Coyne^a****^aCoyne Scientific, 1899 Powers Ferry Road SE, Atlanta, GA, USA 30339****Kevin P. Coyne: kcoyne@coynesci.com****Shawn T. Coyne: scoyne@coynesci.com****Corresponding Author:**

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Abstract

The ever-increasing cost of drug discovery and development represents a significant challenge for the pharmaceutical industry and new strategies to bridge studies between preclinical testing and clinical trials are needed to reduce the knowledge gap prior to first human exposures, and to allow earlier decisions to be made on the further development of drugs.

A number of studies have demonstrated that various cell types differentiated from human induced pluripotent stem cells (iPSCs) do not just respond similarly to human tissues in general, but rather recapitulate the drug response of their *specific* donor's, when exposed to the same drug

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