

Ion channel breakout session

- Large pharma – practical working ways for drug discovery already; this ion channel assay standardization is bringing extra complexity. Motivation requires clear regulatory use of the ion channel data – labeling, changes in PIII ECG monitoring, something that would motivate changes in current ways of doing things.
- Willingness depends on internal decision vs. regulatory decision; is there link between discovery and regulatory submission?
- Need clearer explanation of the benefit of Milne's protocol to get hERG kinetic data.
- FDA certifying CRO for CiPA package.
- What response companies would need to provide when they receive FDA letters for performing CiPA package.
- Share FDA data and protocol/methods of analysis in advance so management support can be requested.
- More physiological ways of acquiring ion channel data (ICaL)
- Cell line? FDA needs to test multiple protocols to get an idea about IC50.