

Considerations from a Japanese regulatory viewpoint

- The purpose is to improve the proarrhythmic risk assessment
- An expanded non-clinical assessment will still require high-confidence clinical ECG assessment
- ICH S7B and E14 guidelines have provided a high level of safety assurance. A novel approach must retain the same threshold of safety assurance
- CIPA is a promising initiative with parts that we clearly support, such as looking at more cardiac ion channels than hERG and an increased role of stem cell derived cardiomyocytes.
- Without more data, it is not possible to state anything firmly about the future role of CIPA or the relative contributions of each element in CIPA
- A new approach should be harmonized across regions, i.e. discussed and agreed on within ICH, before implementation.