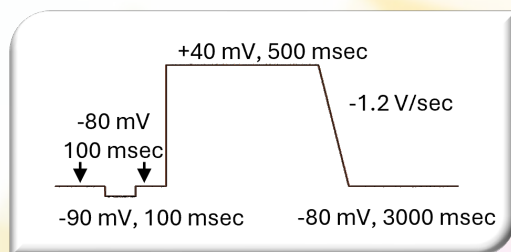


? What is Best Practice?

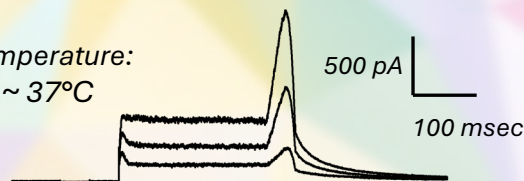
- ❖ Best practices enable reliable cardiac risk assessment through high-quality assays.
- ❖ We approach follows the **best practice recommendations** outlined in **ICH S7B Q&A 2.1**.

- ✓ Use of CiPA-recommended protocols
- ✓ Measurement of concentration-response relationships
- ✓ Inclusion of positive and negative reference compounds



Stimulation frequency: 0.2 Hz

Temperature:
35 ~ 37°C



▲ CiPA-Recommended Voltage Protocol and Current Waveform for hERG Currents

CiPA. Voltage protocols for drug-cardiac ion channel studies [Internet]. 2021. Available from: <https://www.fda.gov/media/151418/download>

? Why hERG Best Practice?

Traditionally...

Thorough QT (TQT) studies have been required to assess QT prolongation risk in clinical development.

Recent...

ICH E14/S7B Q&A supports early QT risk assessment using high quality non-clinical data.

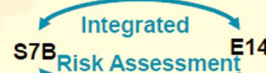
Integrated non-clinical strategies

- best practices for hERG assays
- in vivo QT evaluations

→ Reduce: need for TQT studies

E14 and S7B Q&As

How to apply the integrated risk assessment in clinical development



- To decrease the need for clinical Thorough QT (TQT) studies (E14 Q&A 5.1)
- To inform regulatory decision making when a TQT (or equivalent) can't be performed (E14 Q&A 6.1)

ICH. E14/S7B Q&A [Internet]. 2022. Available from: https://database.ich.org/sites/default/files/ICH_E14-S7B_TrainingMaterial_2022_0407.pdf

→ Support: safe & efficient

First-in-Human transition

Support

better decisions in drug development

hERG best practices

Enhance

clinical predictivity

? Why Our hERG Assay is the Preferred Choice?

- ✓ Pioneered hERG assay
- ✓ High Quality and Reproducible results
- ✓ A track record of **40+** GLP-compliant studies

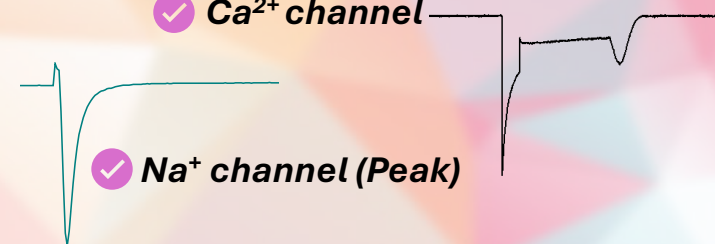
No.1



- ✓ Only participant from Asia in the HESI/FDA project
- ✓ Flexible prompt and Courteous response

Other ion channels

✓ Ca²⁺ channel



✓ Na⁺ channel (Peak)

Na⁺ channel (Late)
Under Development – Stay Tuned!!

hERG Best Practice Assay

Drug Safety Testing Center Co., Ltd.

sales@dstc.co.jp

<https://www.dstc.jp>



Check it out now!