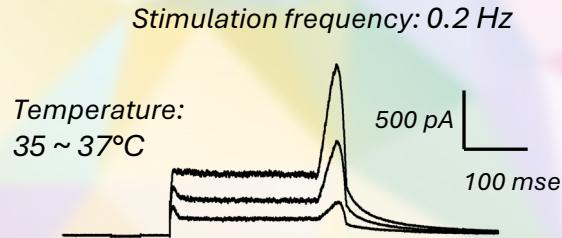
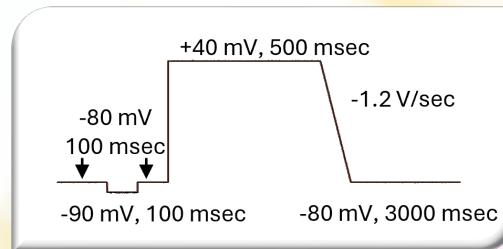


## What is Best Practice?

- ❖ 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



▲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](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

✓ **Ca<sup>2+</sup> channel**



✓ **Na<sup>+</sup> channel (Peak)**

Na<sup>+</sup> 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!