

CLINICAL STRATEGY

Community

Members are from Industry, CRO, and Academia.

Under the key words “strategy” and “tactics”, we have a meeting and share methods and ideas to address daily work issues.

Past and Present
1997 – 2017

Local to global development

- S: ICH-E5
 - ✓ Extrapolate Global data into J-NDA data
- Q: GCP implementation
 - ✓ 100% sampling to Risk Based Monitoring
- O: Global development model
 - ✓ Check applicability in Japan or not one by one
 - ✓ TransCelerate initiative

Future
2018 –

More streamlined model

- S: ICH-E17
 - ✓ Focus totality of the data
- Q: GCP renovation (ICH-E6 R2)
 - ✓ Quality by design and QMS
 - ✓ Real World Data/Evidence
- O: More efficient model
 - ✓ Patient centricity
 - ✓ Advanced technologies; HTA (value oriented), open innovation/partnering, AI/m-health, registry, IICT/CRC etc.

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Feel free to join us!

DIA