

????????????????????????????????????????

?

????

single arm trial SAT

randomized controlled

SAT RCT SAT

randomized controlled

SAT SAT SAT

SAT SAT

RCT RCT

RCT

SAT SAT

" "

SAT SAT

SAT SAT

SAT SAT

"

" "

cell and gene therapy, CGT

good clinical practice GCP

good clinical practice GCP

International Council for Harmonisation of Technical Requirements

for Pharmaceuticals for Human Use, ICH

????????????????????????????????????????

SAT SAT

SAT SAT

SAT

SAT SAT

SAT









4 [redacted]

[EB/OL].2021 11 .

<https://www.cde.org.cn/main/news/viewInfoCommon/ef7bfde96c769308ad080bb7ab2f538e>

5 [redacted]

[EB/OL].2023 2 .

<https://www.cde.org.cn/main/news/viewInfoCommon/14aac16a4fc5b5841bc2529988a611cc>

13 6 [redacted]

[EB/OL].2021 4 .

<https://www.cde.org.cn/main/news/viewInfoCommon/2a1c437ed54e7b838a7e86f4ac21c539>

---

Revision #3

Created 2026-01-09 16:49:31 UTC by Colin Wang

Updated 2026-01-09 16:59:03 UTC by Colin Wang