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single arm trial SAT

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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

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SAT SAT

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4 [redacted]

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<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>

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