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[illegible]
[illegible] “[illegible]”（Tumor-Agnostic）“[illegible]”（Pan-tumor）[illegible] “[illegible]”
[illegible]

[illegible] “[illegible]”
[illegible]

[illegible]（cell and gene therapy, CGT）[illegible]
[illegible]
good clinical practice， GCP）[illegible] InternationalCouncil for Harmonisation of Technical Requirements forPharmaceuticals for Human Use, ICH
[illegible]

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[illegible]

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[illegible]

[illegible]

pharmacokinetics PK pharmacodynamics PD

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PK/PD

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NTRK

RET

randomized controlled trial RCT

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

PK PD

MSI-H/dMMR

[illegible]

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[illegible] RCT [illegible] single arm trial[illegible] SAT [illegible] SAT [illegible] SAT[illegible]
SAT
[illegible]

[illegible]

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[illegible]

[illegible]

[illegible] Cut-off [illegible] CMDE [illegible]

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[illegible]

[illegible]

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[illegible]

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[illegible]	[illegible]	[illegible]
[illegible]	Pan-tumor	[illegible] “[illegible]” (Tumor-Agnostic) [illegible]
[illegible]	Pan-tumor drug	[illegible]
[illegible]	Pharmacokinetics (PK)	[illegible]
[illegible]	Pharmacodynamics (PD)	[illegible]
[illegible]	Randomized Controlled Trial (RCT)	[illegible]
[illegible]	Single Arm Trial (SAT)	[illegible]
[illegible]	Companion Diagnostic	[illegible]
[illegible]	Biomarker	[illegible]
[illegible]	Good Clinical Practice (GCP)	[illegible]
[illegible]	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)	[illegible]

中文术语	英文术语	说明
细胞和基因治疗	Cell and Gene Therapy (CGT)	利用活细胞或基因作为治疗手段的一类新型疗法。

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1、国家药品监督管理局《单臂试验支持抗肿瘤药上市申请的适用性技术指导原则》[EB/OL].2023年 3月.https://www.cde.org.cn/main/news/viewInfoCommon/9f0c25dee6ba6781af80 9b36cf682eb6

2、国家药品监督管理局《单臂试验支持注册的抗肿瘤创新药进入关键试验前临床方面沟通交流技术指导原则》[EB/OL].2020年 12月 . https://www.cde.org.cn/main/news/viewInfoCommon/2a6d7894c0ee2aaa37fd1ca8e941cdab

3、国家药品监督管理局《单臂试验支持注册的抗肿瘤创新药申请上市前临床方面沟通交流技术指导原则》[EB/OL].20 20年 12月 . https://www.cde.or g.cn/main/news/viewInfoCommon/e303bd3deb01db072c7b37cd46195a67

4、国家药品监督管理局《以临床价值为导向的抗肿瘤药物临床研发指导原则》[EB/OL].2021年 11月 . https://www.cde.org.cn/main/news/viewInfoCommon/ef7bfde96c769308ad080bb7 ab2f538e

5、国家药品监督管理局《生物标志物在抗肿瘤药物临床研发中应用的技术指导原则》[EB/OL].2021年 12月 . htt ps://www . cde . o r g .c n/main/n ews / v i ew Inf oCo mm o n/321 ca 4648 e 2 e 2 d f c8 ac 05 e 9 ba 28 d 6 de 4

6、国家药品监督管理局《儿童抗肿瘤药物临床研发技术指导原则》[EB/OL].2023年 3月 . https://www.cde.org.cn/main/news/viewInfoCommon/ee059ce189bfd770522ebbb8b5b78023

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