

General

- [FDA](#)
- [EMA](#)
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- [PMDA](#)
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FDA

EMA

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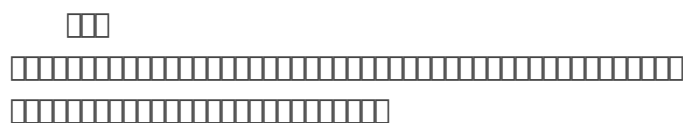
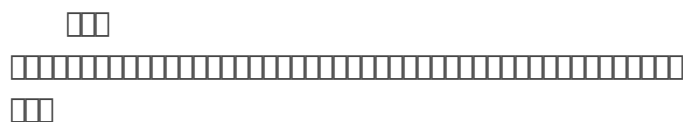
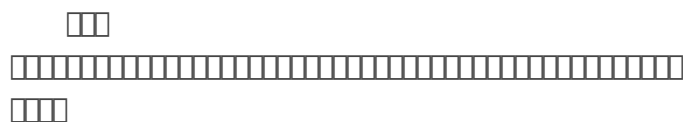
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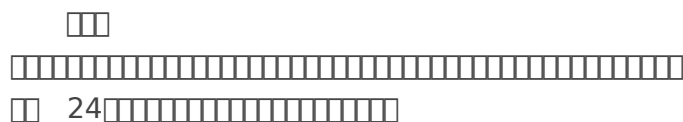
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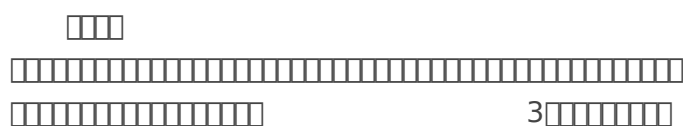
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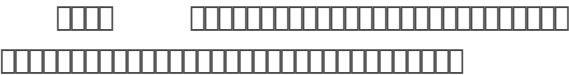
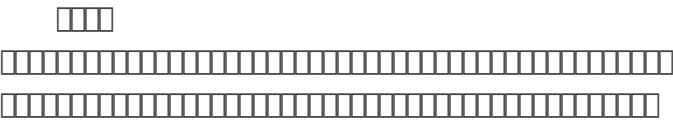
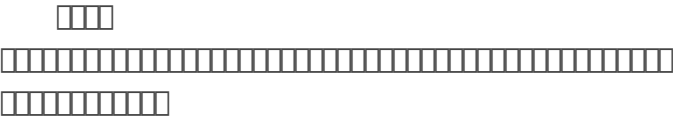


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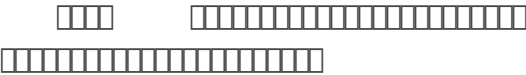
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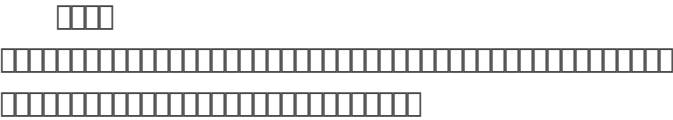
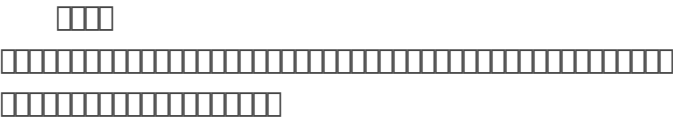
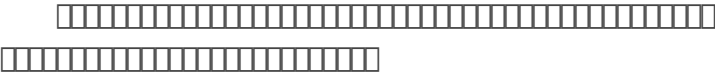
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NMPA

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ICH GCP

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2018 □ 52

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1. ????????

Age Group	Number of People
10	100
20	90
30	80
40	70
50	60
60	50
70	40
80	30
90	20

2. ???????????

GCP

3. ?????????????

/ BA/BE
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 PK/PD ICH E5 E17
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PK / PD
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PK PD PK/PD

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44

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NDA

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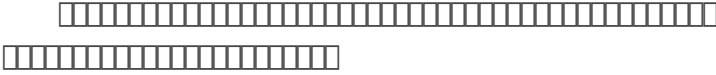
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4. ????????



ICH E6

DSUR

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- [1] U.S.FOOD And DRUG ADMINISTRATION . Guidance for Industry Expedited Programs for Serious Conditions – Drugs and Biologics.
- [2] Beaver JA, Howie LJ, Pelosof L, et al. A 25-Year Experience of US Food and Drug Administration Accelerated Approval of Malignant Hematology and Oncology Drugs and Biologics: A Review. JAMA Oncol, 2018, 4(6):849-856.
- [3] European Medicines Agency . Guideline on the scientific application and the practical arrangements necessary to implement Commission Regulation (EC) No 507/2006 on the conditional marketing authorisation for medicinal products for human use falling within the scope of Regulation (EC) No 726/2004.

NMPA

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locally applied, locally acting products LALAP

ICH

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1. ???

Diagram illustrating the iterative step of the merge sort algorithm. It shows two sorted arrays, labeled 1 and 2, being merged into a new array. The arrays are represented as horizontal bars divided into segments. Array 1 has 10 segments, and Array 2 has 10 segments. The new array is shown below them, with segments being copied from the input arrays. The process is labeled "Merge" and "Sort".

A diagram showing seven horizontal bars of different lengths, each composed of small squares. The bars are arranged in descending order of length from top to bottom. The lengths are 25, 20, 10, 20, 20, 20, and 5 squares respectively.

2. ?????

A diagram consisting of 10 rows of 10 small squares each, totaling 100 squares. The first row is shaded gray, representing 10% of the total.

2.1 ?????????????????????

PK □ PD

2.2 ?? ??????

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2.3 ??????

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3. ?????????????

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A diagram illustrating 10% of a total. It consists of 10 rows, each containing 10 small squares. The first row is shaded gray, representing 10% of the total 100 squares.

4.????

4.1 ?????????????????????

A diagram consisting of 10 rows of small squares. The first row is shaded gray and contains 10 squares. The remaining 9 rows are white and each contains 10 squares, for a total of 100 squares.

4.2 ?????????????????????

5. ?????

PK

PD

skin blanching study

PK

PK

PK /

PD

skin blanching study

PD

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1.  2021.
2.  2005.
3.  2020.
4. ICH, E8 General Considerations for Clinical Trials,1997.
5. EMA  Note for guidance on the clinical requirements for locally applied, locally acting products containing known constituents (CPMP/EWP/239/95),1995.
6. EMA, Requirements for clinical documentation for orally inhaled products (OIP) including the requirements for demonstration of therapeutic equivalence between two inhaled products for use in the treatment of Asthma and Chronic Obstructive Pulmonary Disease (COPD) in adults and for use in the treatment of asthma in children and adolescents,2009.
7. FDA  Guidance on Topical Dermatologic Corticosteroids: in vivo bioequivalence, 1995.

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Age Group	Count
15-20	10
20-25	10
25-30	10
30-35	10
35-40	10

PK PD

I

4.

ICH E5 R1

PK PD -

ICH E5

PK PD -

1.

II

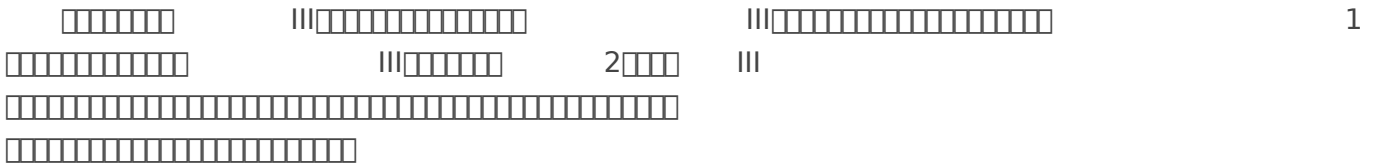
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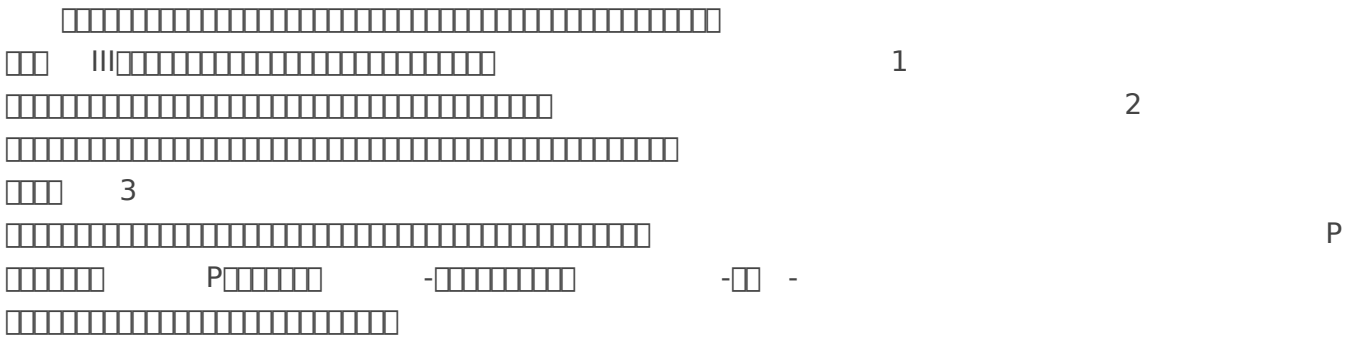
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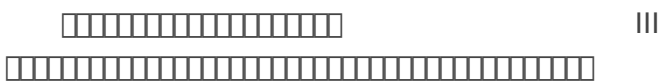
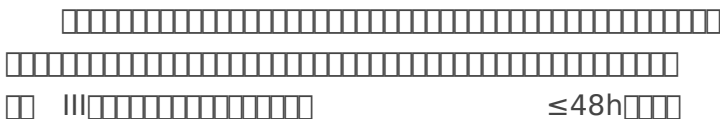
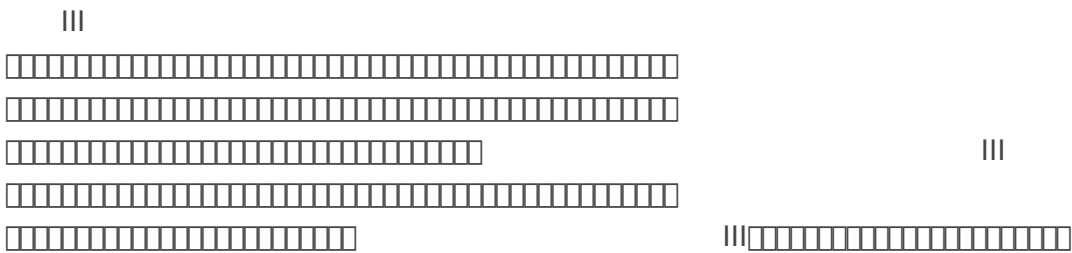
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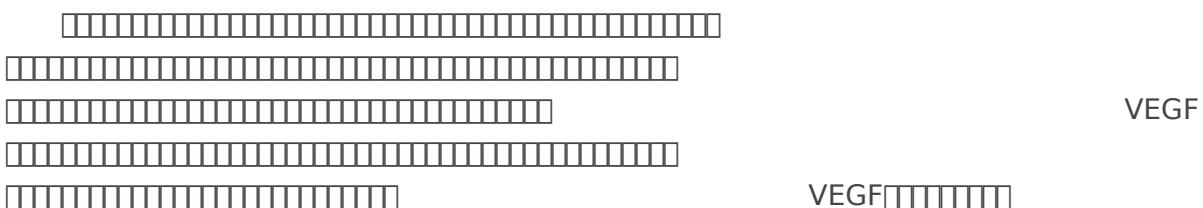
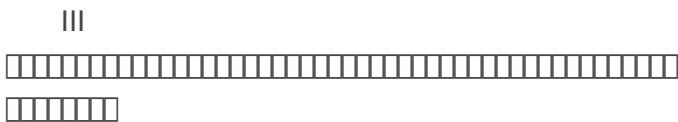
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2. III????????????



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4. ?????????????

5. ?????????????

III

PASI 75

sPGA

75%

0/1

0

1

PASI 100

PASI 90

PASI 50

PASI 75

48

96

PASI

DLQI

IL-17, IL-23, TNF- α

PASI 75/90/100

sPGA 0/1

III

A handwriting practice sheet with ten rows of boxes. Each row contains 26 boxes, one for each letter of the alphabet. The first row is pre-filled with the letters A through Z. The remaining nine rows are empty for practice.

E1

ICH

III

ICH E9

ICH E9□

ICH

A diagram showing a large 100x100 grid. A smaller 10x10 grid is highlighted in the top-left corner of the larger grid. The number '1' is placed in the center of this 10x10 subgrid.

3



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1. ?????|?||?||????????????????????????????????







2. ?????????????

3.??

[illegible]

2

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[2] [ICH. E5\(R1\): Ethnic Factors in the Acceptability of Foreign Clinical Data](#) [EB/OL]. Feb 1998.

[3] [ICH. E8\(R1\): General Considerations for Clinical Trials](#) [EB/OL]. Oct 2021.

[4] ICH. E9: Statistical Principles for Clinical Trials [EB/OL]. Feb 1998.

<https://www.cde.org.cn/ichWeb/guidelch/toGuidelch/3/0>

[5] ICH. E10: Choice of Control Group and Related Issues in Clinical Trials [EB/OL]. July

2000. <https://www.cde.org.cn/ichWeb/guidelch/toGuidelch/3/0>

[6] ICH. E17: General principle on planning and Designing Multi-Regional Clinical Trials [EB/OL]. Nov

2017. <https://www.cde.org.cn/ichWeb/guidelch/toGuidelch/3/0>

[7] ICH. E19 A Selective Approach To Safety Data Collection In Specific Late-Stage Pre-approval Or Post-Approval Clinical Trials [EB/OL]. Sep 2022.

<https://www.cde.org.cn/ichWeb/guidelch/toGuidelch/3/0>

[8] [国家药品监督管理局](#) . [国家药品监督管理局](#) [EB/OL] 2017 1 .

<https://www.cde.org.cn/zdyz/domesticinfopage?zdyzldCODE=b32eaabf2c4cc56570c23c19f9608076>

[9] [国家药品监督管理局](#) . [国家药品监督管理局](#) [EB/OL] 2022 5 .

[10] [国家药品监督管理局](#) . [国家药品监督管理局](#)

2020 82 [EB/OL] 2020 7 .

<https://www.nmpa.gov.cn/xxgk/fgwj/xzhgfxwj/20200708151701834.html>

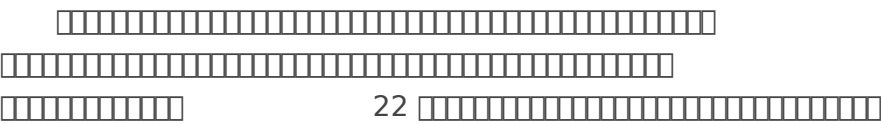
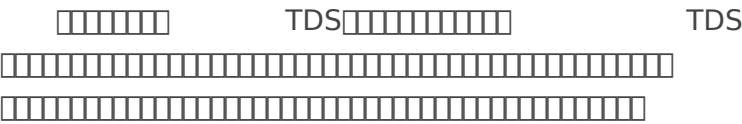
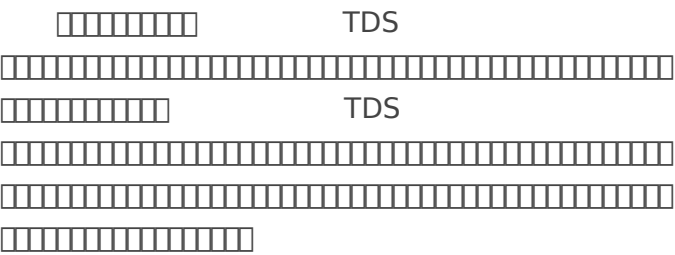
[11] [国家药品监督管理局](#) . [国家药品监督管理局](#) [EB/OL] 2020 12 .

<https://www.cde.org.cn/zdyz/domesticinfopage?zdyzldCODE=35d77016fdcd7dc0be456d8cf17ae238>

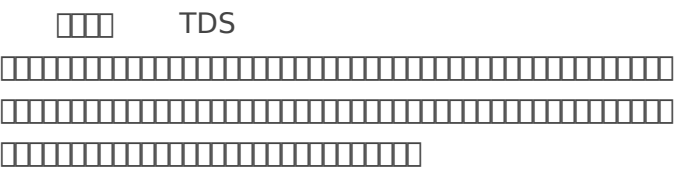
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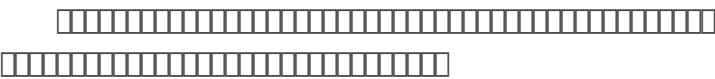
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- 1. []

API

TDS

RLD

3

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TDS

1

階級	達成率	評価
0	≥ 90%	TDS 4段階
1	≥ 75% < 90%	5段階

Diagram illustrating a memory layout with four rows of 1000 words each. The layout is as follows:

- Row 1: I/S (10 words), TDS (10 words), RLD (10 words)
- Row 2: TDS (10 words)
- Row 3: TDS (10 words)
- Row 4: I/S (10 words)

Diagram illustrating the instruction format (32 bits):

- Instruction fields (from left to right):
 - 16 bits: I/S
 - 4 bits: "TDS"
 - 4 bits: 21
 - 4 bits: 14
 - 4 bits: 17
 - 4 bits: TDS
 - 4 bits: I/S

Diagram illustrating four different data access patterns between a client and a server:

- Pattern 1:** Client requests 10 blocks, server responds with 10 blocks.
- Pattern 2:** Client requests 10 blocks, server responds with 10 blocks, then client requests 21 blocks, server responds with 2 blocks, and finally client requests 1 block, server responds with 1 block.
- Pattern 3:** Client requests 10 blocks, server responds with 10 blocks, then client requests 1 block, server responds with 1 block, and finally client requests 10 blocks, server responds with 10 blocks.
- Pattern 4:** Client requests 10 blocks, server responds with 10 blocks, then client requests 1 block, server responds with 1 block, and finally client requests 10 blocks, server responds with 10 blocks.































[illegible]

4.

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TDS []
TDS []

TDS []

[] I/S []
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TDS
TDS [] TDS
TDS []

5. []

[] 0 7
[] A-H []

[] 2 []

[]	[]
0	[]
1	[]
2	[]
3	[]
4	[]
5	[]
6	[]
7	[]

[] 3 []

[]	[]
A [] 0 []	[]
B [] 1 []	[]
C [] 2 []	[]
F [] 3 []	[]
G [] 3 []	[] TDS []
H [] 3 []	[]

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[] 1 [] “ [] ” []
[] “ [] ” [] 0 7 [] “ [] ” []
A-H
0/1/2/3 []

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48

[illegible]

TDS

TDS

TDS □ 48□

 $1 \square 2$ [illegible]

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縮略語	略称	略称
TDS	Transdermal and Topical Delivery Systems	透皮経皮薬物送達システム
GCP	Good Clinical Practice	良好臨床試験の実施基準
ICH	International Conference on Harmonization	国際調和会議
API	Active Pharmaceutical Ingredient	有効成分
PPS	Per-Protocol Set	試験計画に従った群
I/S	Irritation and Sensitization	刺激と感作試験
RLD	Reference Listed Drug	参照製剤
MIS	Mean Stimulus Score	平均刺激スコア
MAS	Mean Adhesion Score	平均接着スコア
LOCF	Last Observation Carried Forward	最終観察値を繰り越す

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[1] FDA. Assessing Adhesion With Transdermal and Topical Delivery Systems for ANDAs Draft Guidance for Industry [EB/OL]. Apr 2023. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/assessing-adhesion-transdermal-and-topical-delivery-systems-andas-draft-guidance-industry>.

[2] FDA. Assessing the Irritation and Sensitization Potential of Generic Transdermal and Topical Delivery Systems for ANDAs Draft Guidance for Industry [EB/OL]. Apr 2023.
<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/assessing-irritation-and-sensitization-potential-transdermal-and-topical-delivery-systems-andas>.

[3] EMA. Guideline on the pharmacokinetic and clinical evaluation of modified release 279 dosage forms [EB/OL]. Nov 2014. <https://www.ema.europa.eu/en/pharmacokinetic-clinical-evaluation-modified-release-dosage-forms-scientific-guideline>

[4] [\[10\]](#) . [\[11\]](#) [EB/OL]. 2022 [5
[1] .

[5] [\[12\]](#) . [\[13\]](#) IVRT [\[14\]](#) IVPT
[\[15\]](#) [EB/OL]. 2025 [6 [1] .

[6] FDA. Assessment of Adhesion for Topical and Transdermal Systems Submitted in New Drug Applications [EB/OL]. Jul 2021. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/assessment-adhesion-topical-and-transdermal-systems-submitted-new-drug-applications>.

NMPA

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Figure 1: Schematic representation of the study design. The diagram shows a flow from 1000 patients to 1000 samples, which are then divided into 1000 Tumor-Agnostic and 1000 Pan-tumor samples. The Tumor-Agnostic samples are further divided into 1000 Tumor-Agnostic and 1000 Pan-tumor samples. The Pan-tumor samples are further divided into 1000 Tumor-Agnostic and 1000 Pan-tumor samples. The diagram illustrates the process of sample collection and analysis for Tumor-Agnostic and Pan-tumor samples.

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cell and gene therapy, CGT

good clinical practice GCP

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use, ICH

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A diagram consisting of 10 rows of 10 small squares each, totaling 100 squares. The first row is shaded gray, representing 10% of the total.

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1 [REDACTED] [EB/OL].2023 3
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[EB/OL].2020 12 . https://www.cde.org.cn/main/news/viewInfoCommon/2a6d7894c0ee2aaa37fd1ca8e941cdab

3 [REDACTED]
[EB/OL].20 20 12 . https://www.cde.org.cn/main/news/viewInfoCommon/e303bd3deb01db072c7b37cd46195a67

4 [REDACTED] [EB/OL].2021 11 .
https://www.cde.org.cn/main/news/viewInfoCommon/ef7bfde96c769308ad080bb7 ab2f538e

5 [REDACTED] [EB/OL].2021 12
. https://www.cde.org.cn/main/news/viewInfoCommon/321 ca 4648 e 2 e 2 d f c8 ac 05 e 9 ba 28 d 6 de 4

6 [REDACTED] [EB/OL].2023 3 .
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RCT [|||||]

Diagram illustrating the instruction format (32 bits total):

- Opcode (8 bits): SAT
- Source Register Index (8 bits): R1
- Destination Register Index (8 bits): R2
- Immediate Value (8 bits): IMM

SAT

/|||||

SAT

????????RCT???

Diagram illustrating the RCT (Randomized Controlled Trial) design. The process starts with a population of 1000 individuals, which is divided into two groups of 500 each. The RCT group is then compared to the control group, showing a higher SAT score for the RCT group.



 tumor  NTRK  "  " Pan-

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 RCT

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The diagram illustrates two rows of blocks. The top row is labeled "SAT" and contains 20 blocks. The bottom row is labeled "SAT" and contains 10 blocks followed by 10 blocks.

Study Type	Number of Studies
RCT	22
meta	10
other	10

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Diagram illustrating a 3D memory layout with three rows of memory blocks:

- Top row: 16 blocks, labeled SAT on the right.
- Middle row: 32 blocks, labeled SAT on the left and SAT on the right.
- Bottom row: 8 blocks, labeled SAT on the right.

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SAT

SAT /

[illegible]

2 SAT

Diagram illustrating the structure of a Composite SAT and its components:

- SAT** (Total length 8 blocks)
- Composite SATs mode** (2 blocks)
- CSM** (1 block)
- SAT** (3 blocks)
- Sole SAT mode** (1 block)
- SSM** (1 block)

SAT

SAT

CSM [] / [] SAT [] SAT
[] / [] SAT
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?????SAT???????




[illegible][illegible]

Diagram illustrating a 12-bit bus system. The bus is represented by a horizontal line with a '12' indicating its width. Four registers are connected to the bus:

- Register A (top right): 12 bits wide.
- Register B (top left): 8 bits wide.
- Register A (bottom right): 4 bits wide.
- Register B (bottom left): 8 bits wide.

The diagram illustrates the process of DNA replication. The top part shows a replication fork where the double-stranded DNA is being unwound. The leading strand is synthesized continuously towards the fork, while the lagging strand is synthesized discontinuously away from the fork as Okazaki fragments. The bottom part shows the completion of the replication bubble, resulting in two identical daughter DNA molecules, each composed of one parental strand and one newly synthesized strand.

A grid consisting of 4 rows and 20 columns of empty boxes, intended for writing the answer to Question 1.

SAT

SAT

A 10x10 grid of squares. The top row is shaded gray. The first two columns are shaded gray.

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RCT

RCT

☐ SAT

SAT

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13 6 [EB/OL].2021-4 .
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PMDA

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