中国新药注册临床试验[redacted]

（2022

2023 9

除 1.5%

1974 2021 2022

2033 *vs.* 1974

2. 药物类型和品种

50% 40%

2022 46

3. 试验分类与申办者

BE 2022

57.9% BE 42.1% 2021

2022 60.5% vs. 57.9%

并 2022 88.5%

4. 目标适应症与临床试验分期

2022

胞 胞

2022 2021

43.0% 胞

2021 胞

64 *vs.* 61

68 *vs.* 43

2021 胞

5. 临床试验地域分布分析

2022 , ,

0 ,

胞

6. 临床试验实施效率分析

2022 胞 6 并

除 55.8%

56.7% 59.1% 1

并 21.2% 2021 4.4%

T 胞 ,

,

2021 2022

并 3.3 2021

3.8 6 91.5%

2021 85.7%

7. 年度上市新药分析

2022 21

76.2%

52.4% 11

保 1

2022 - 除

3410 2021 ½

57.9% *vs.* 60.5%

并

除

54.4% 45.7% 21/46

5% 2/46 39 胞

4

BE 116 vs. 67 1

BE 25.9% vs.

79.1% 2022 除 6

并 55.8% 2022

胞 6 并 91.5% 2022

胞 5 50%

并

3、罕见疾病药物临床试验.....

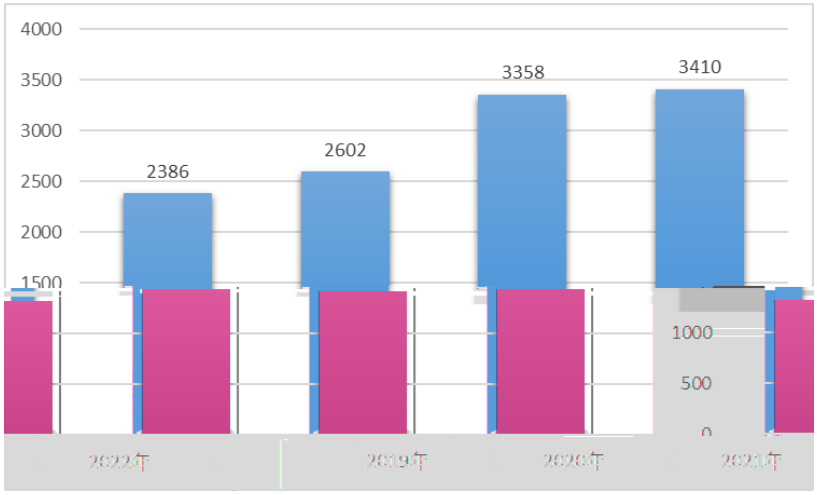
DMC

.....

2022 3410 CTR

2021 1.5%

1974 BE 1436



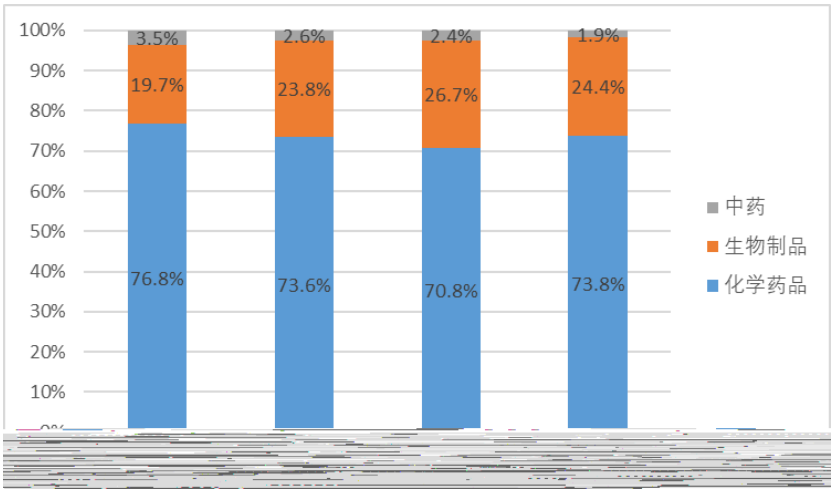
2019-2022 除 CTR

2022

73.8%

24.4% 1.9%

!



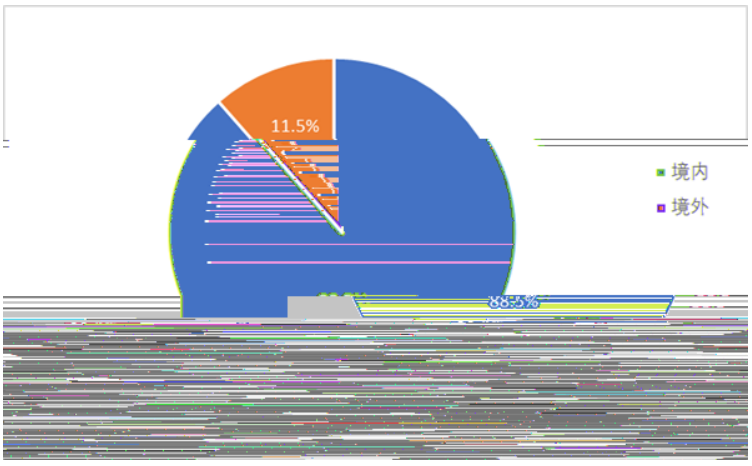
除 2019-2022

并

J 并 并 2022

并 88.5%

3018 2021 并 10%

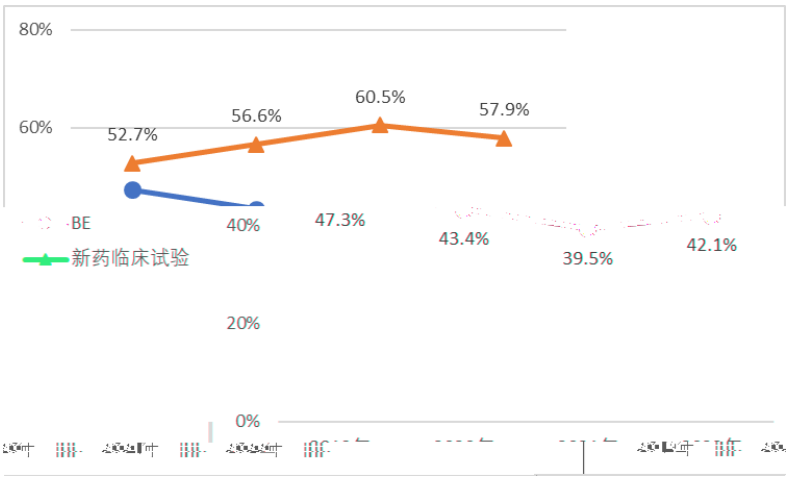


2022 并

BE

2022 1974

57.9% ,BE 1436 42.1% 2021



2019-2022

2022

1083 54. 9% 829 42. 0%

62 3. 1%

50%

40%

2019-2022

1、新药临床试验

77 除 7.1% 77/1083

SHR8554 S086

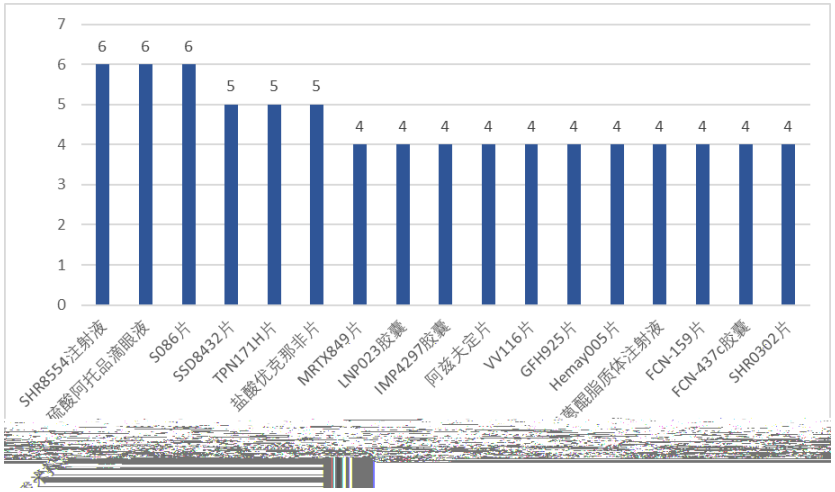
6 10，

21 6

3

2021 10，

SHR0302



2022 10，

2022 10，

86 除 10.4% 86/829

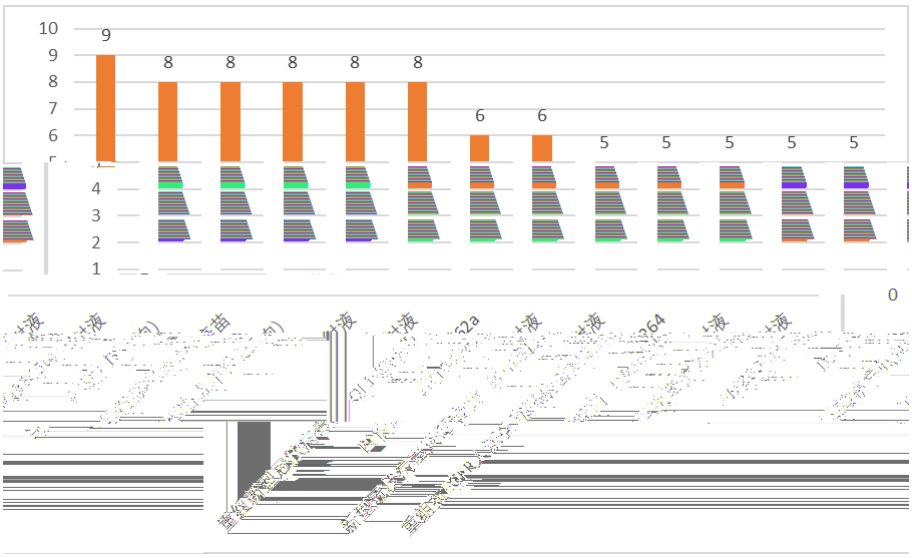
10 62

72.1% 3 24 27.9%

47 54.7% 47/86 7

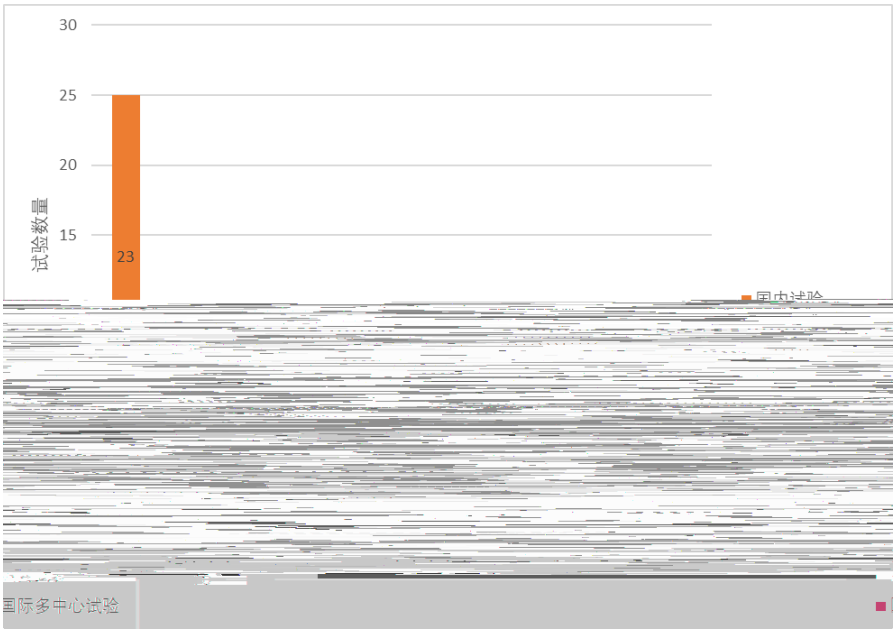
QL1706

9

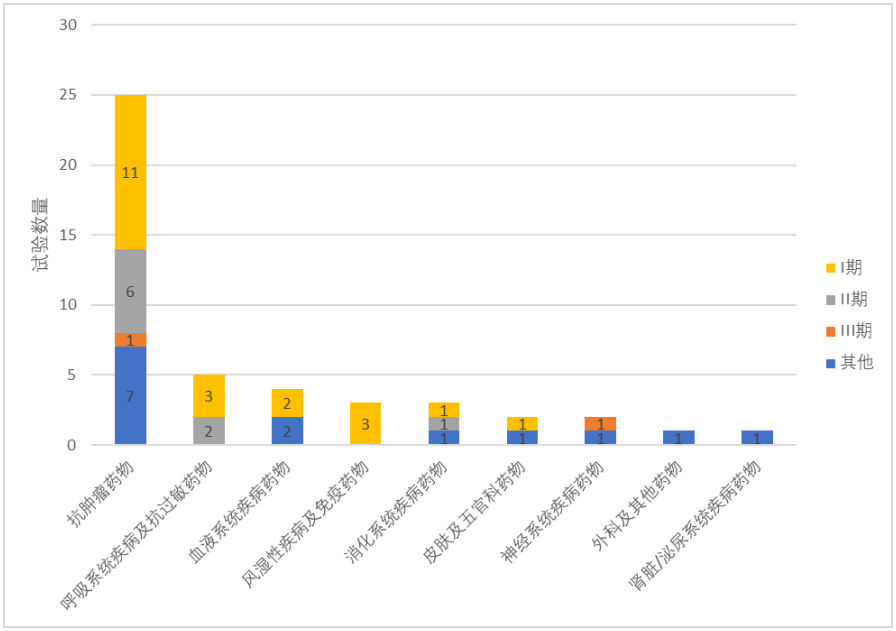


2022 10，

2、细胞和基因治疗品种

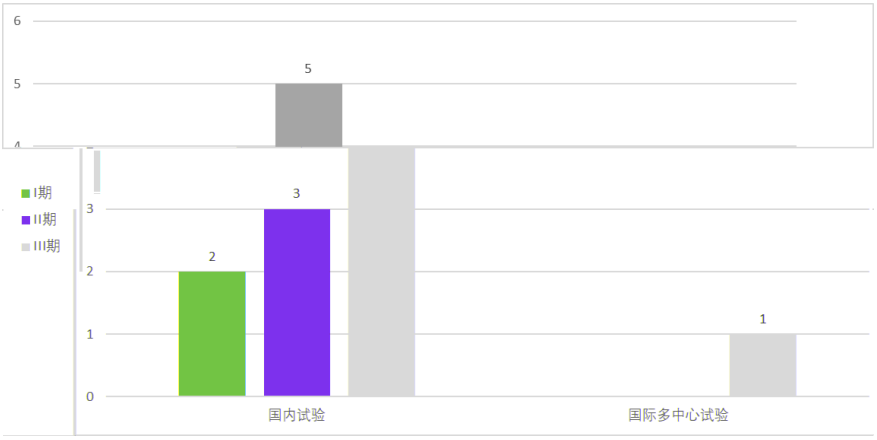


2022



2022

3、医学影像学品种



2022

2019

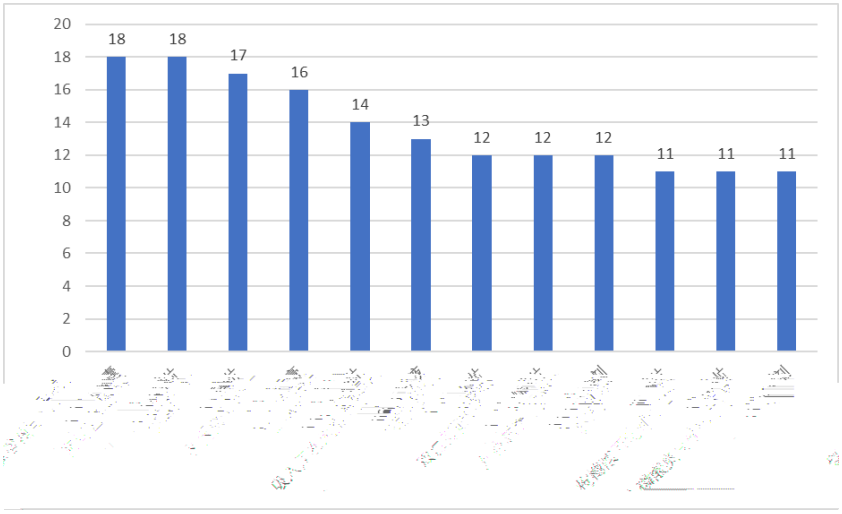
除 2019

2021 0 5 8

4、生物等效性试验品种

2022 BE 10，

18



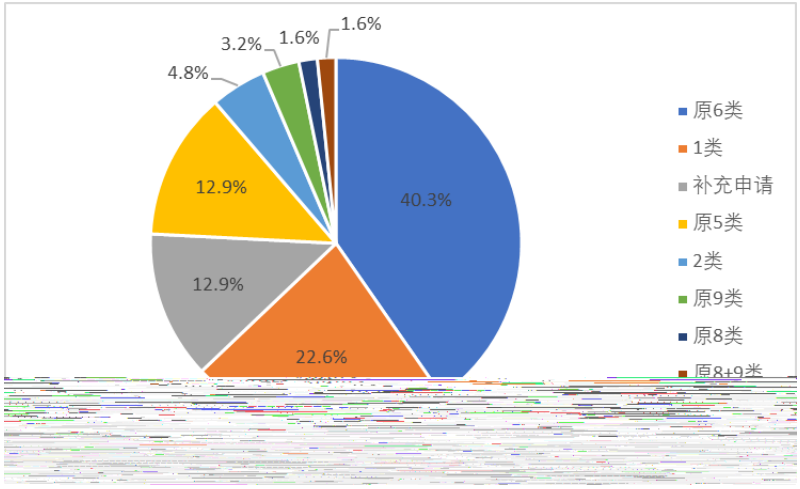
2022 BE 10，

2021 10， 3

3，

2022 62

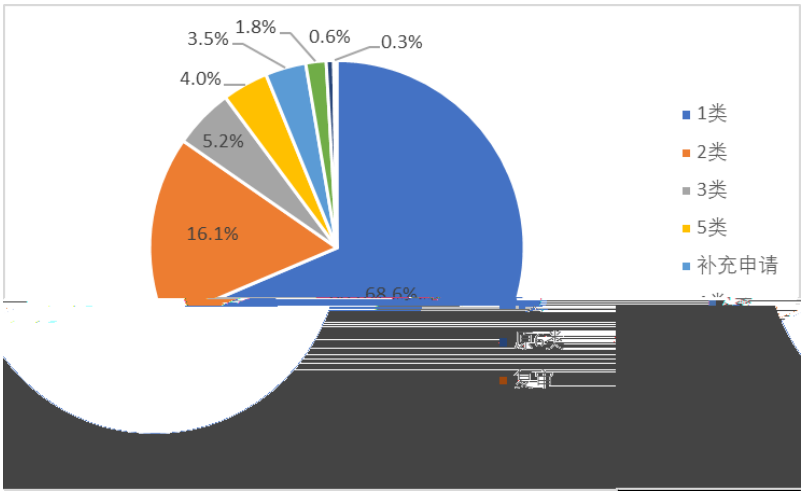
6 40.3% 1 22.6%



2022

1 68.6% 2

16.1%

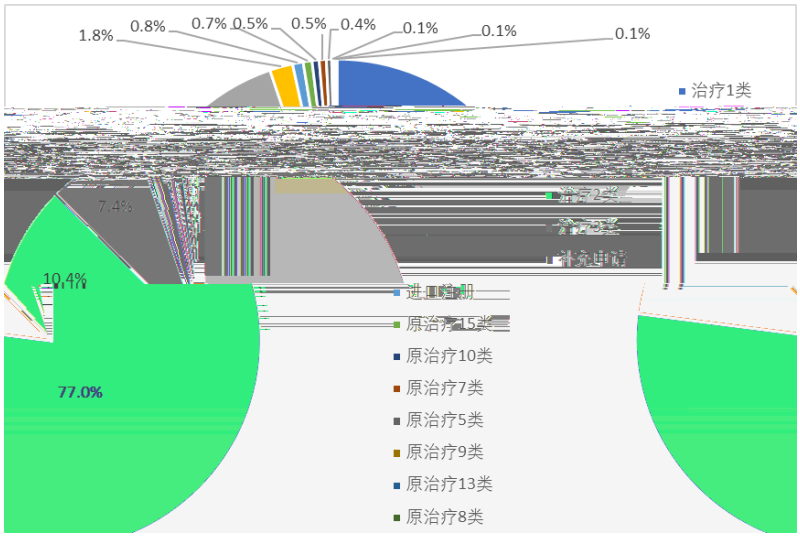


2022

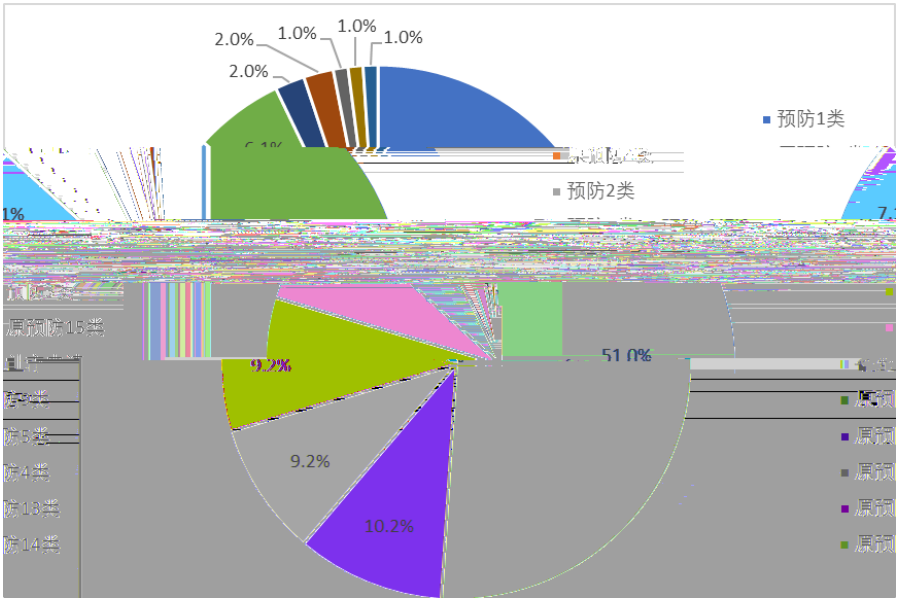
2022 1 2

77.0% 10.4%

1 6 51. 0% 10.2%



2022

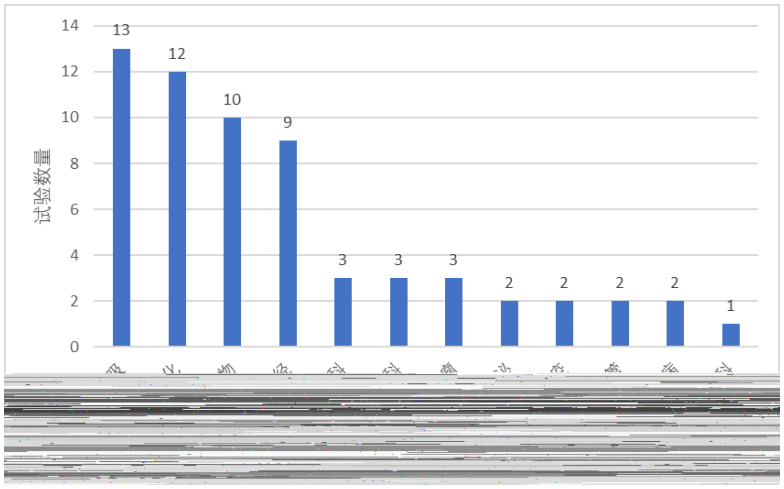


2022

2022 胞

5

除 75. 8% 21.0%



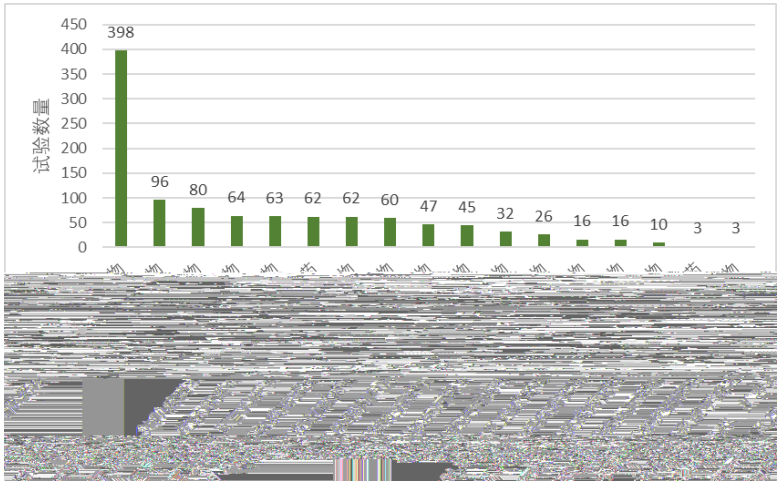
2022

2022

除 36.7%

8.9％ 7.4％

5.9％ 5.8％



2022

2022

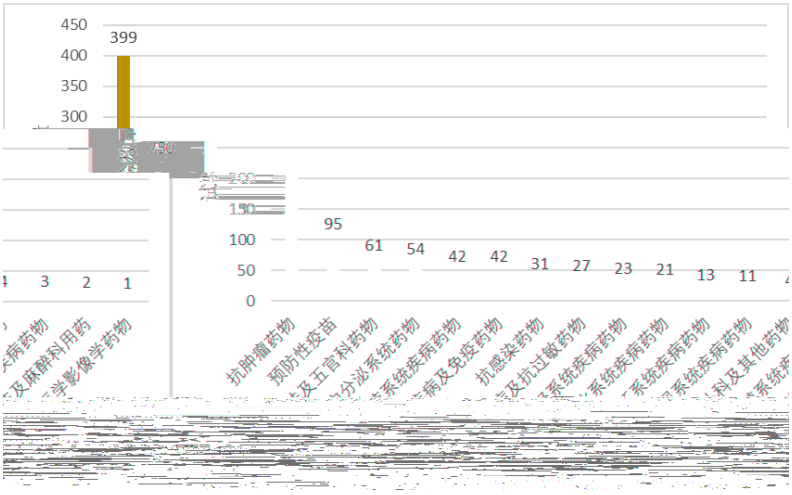
除 48.1％

11.5％ 7.4％ 6.5％

5.1％

39 41.1％

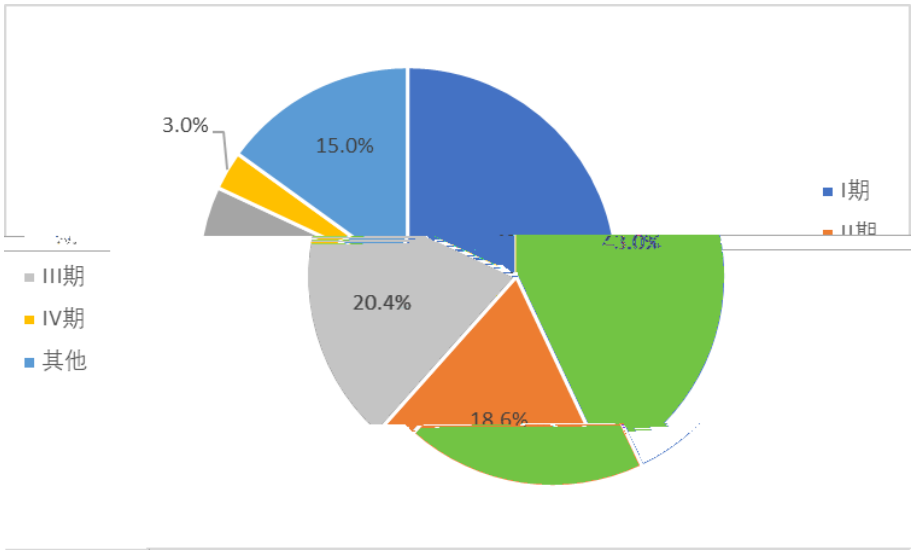
39/95



2022

除

2021



2022

2022

1878 349.2

	42.3	191.6	390.3	1700.0	252.0
	49.6	112.7	272.5	3011.0	114.4
	75.5	151.3	805.2	7348.3	186.6

2022

，　　1

，　　，

621　　除

1/5　24.7%

，

胞

0　　2022　　24.7%　18.8%　9.6%　6.5%

，　　2，　　2021

，　　2019-2022

2022

，39427 1 ，

，

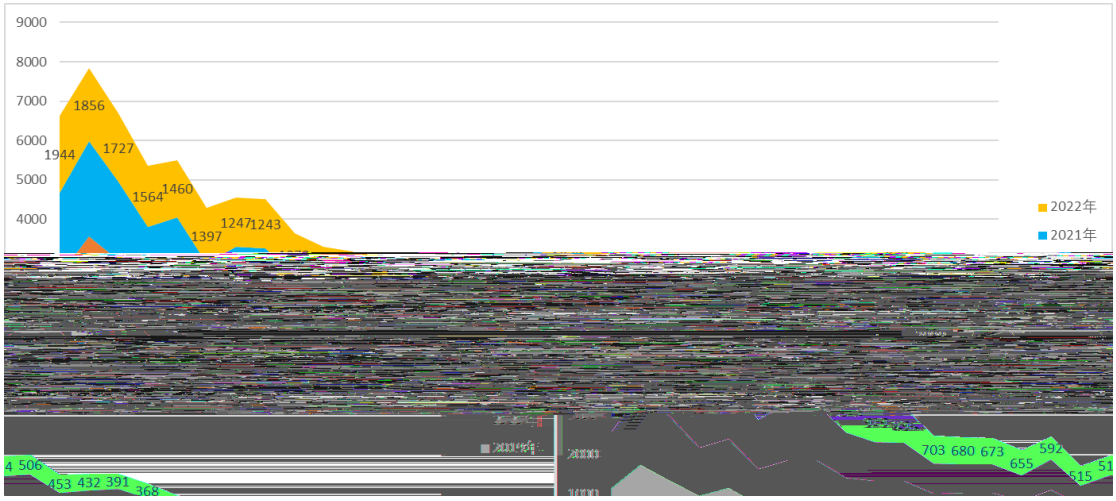
，23262

2021

2022 ，1500 4

0

，



，2019-2022

2022 41.0%

2021 36.1% 2020 43.4%

2019-2022

/

?1 1

2、儿童人群药物临床试验

2022 并

164 胞 8.3% 164

vs. 1974 114

胞 64 胞

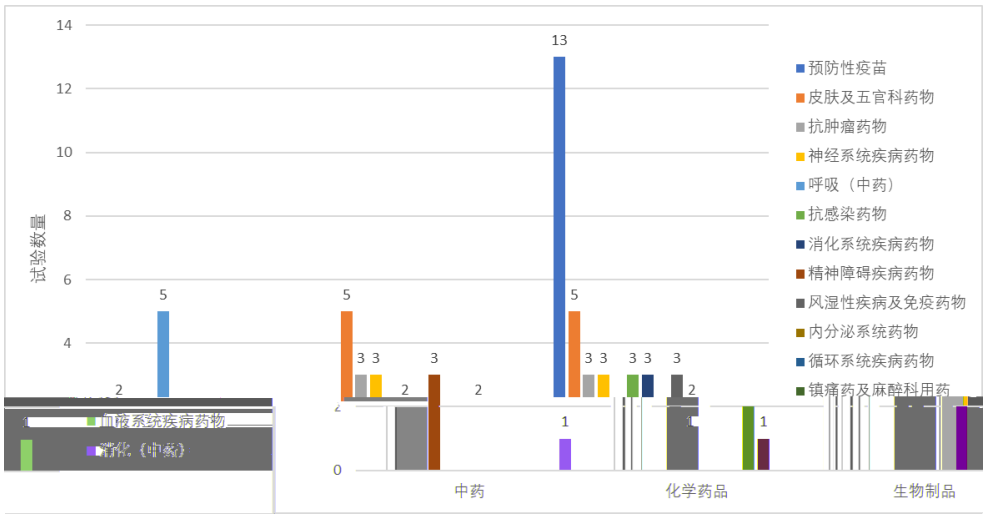
3.2% 64 *vs.* 1974

13

36 20

8

除 36.1%

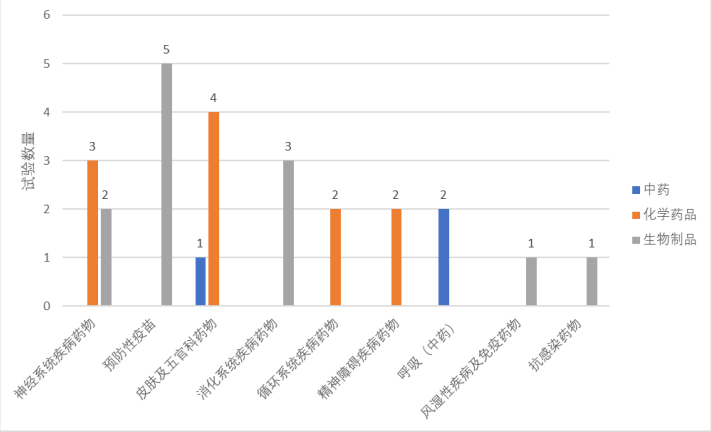


2022 胞

胞 64

40.6% 26 *vs.* 64 胞 26

，　　，



2022 胞

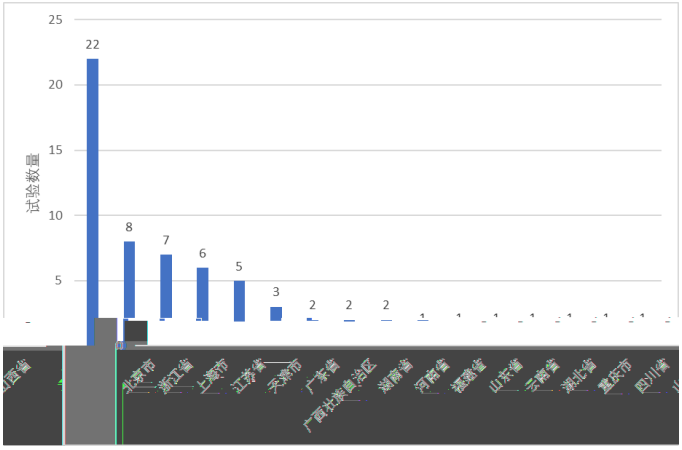
胞 ，

64 ， 16

，

22

1 ，

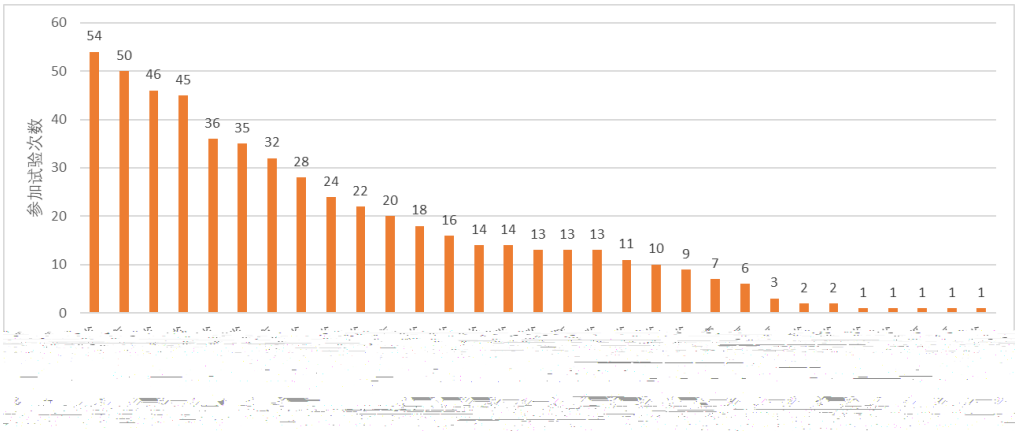


2022 ，

，　　64　　，

31　　548

50



2022　　，

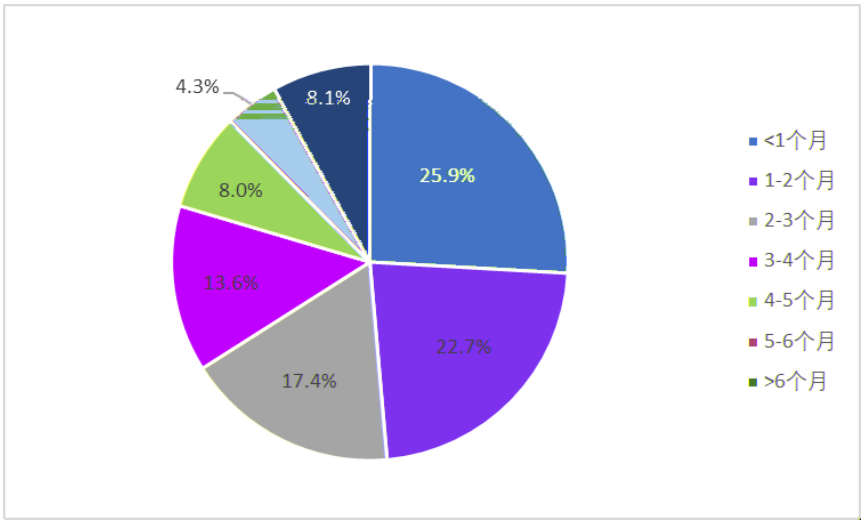
3、罕见疾病药物临床试验

2022

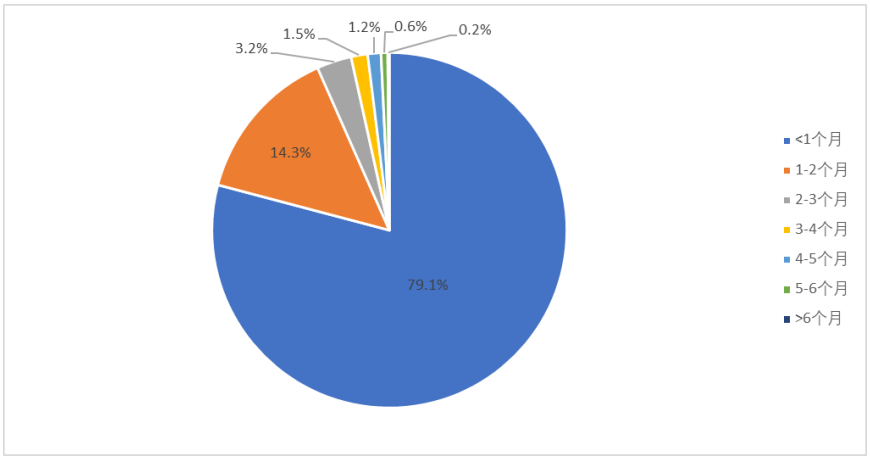
68

33　　35

2019-2022



2022



2022 BE

2022

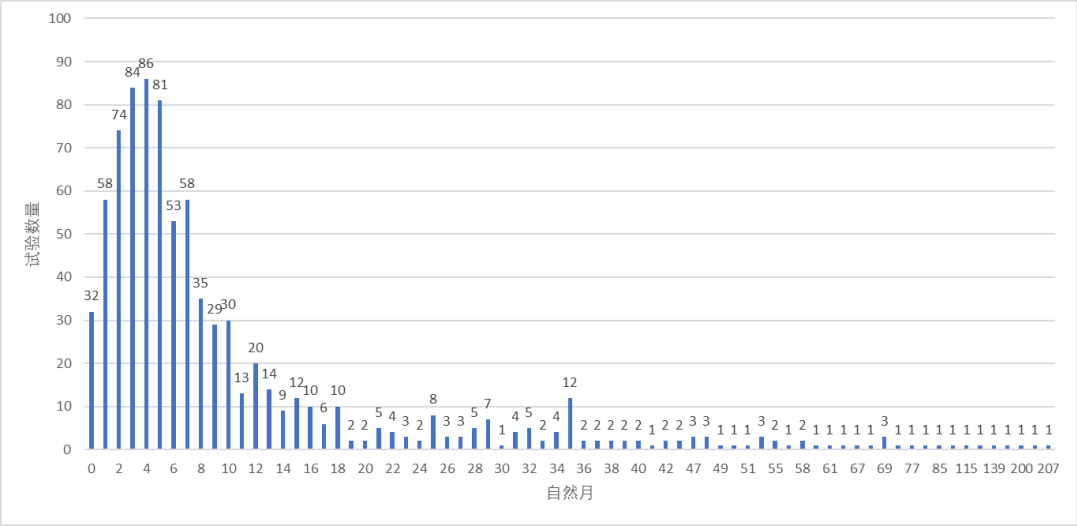
并 ICF

2022 胞 2022

846 ICF

1 207

48



2022

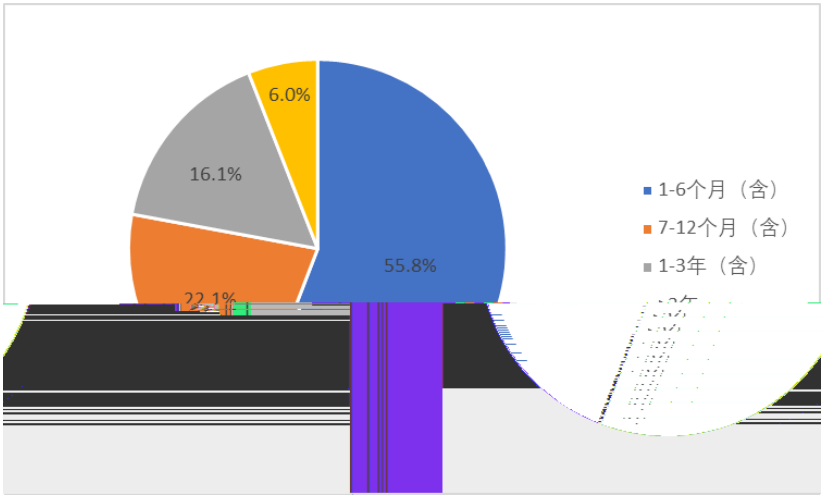
除 55. 8% 胞 6 并

2021 51.4%

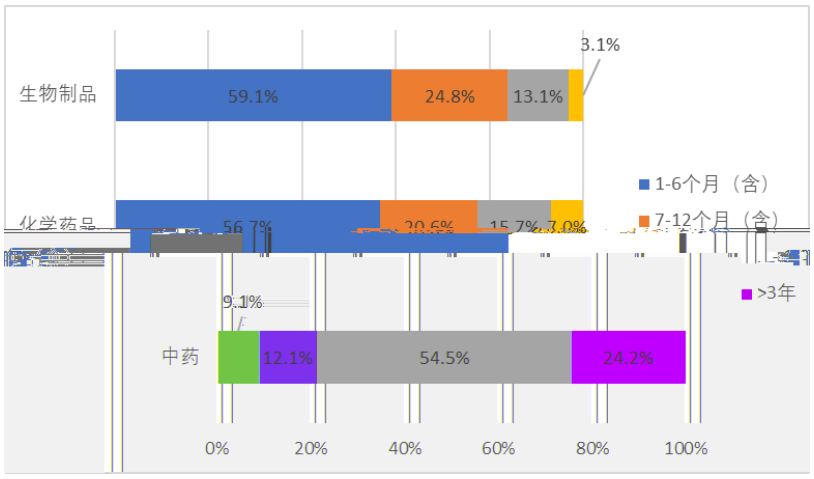
胞 6 并

56.7% 59.1% 1 并

21.2% 2021 4.4%



2022 除



2022

T 胞

，

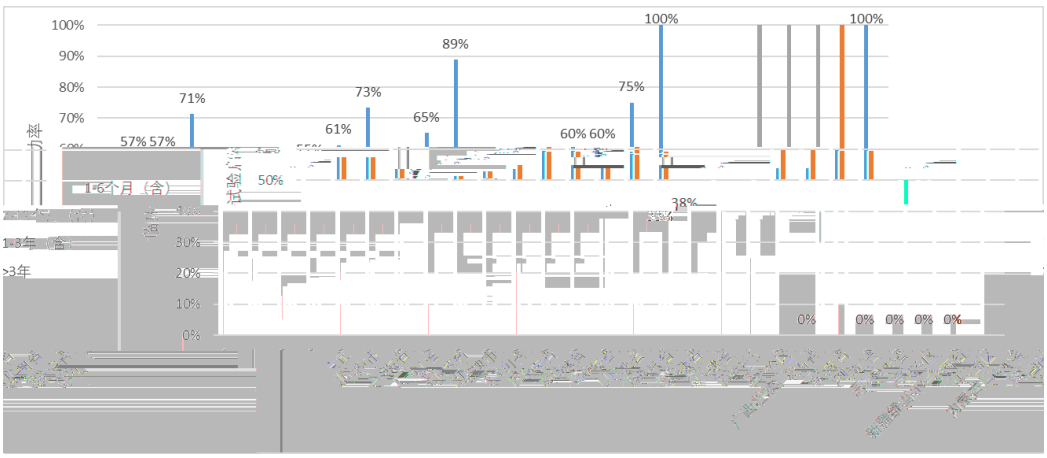
2022

5 6 并

70% 6

并 70% 胞 6

100%



2022

并

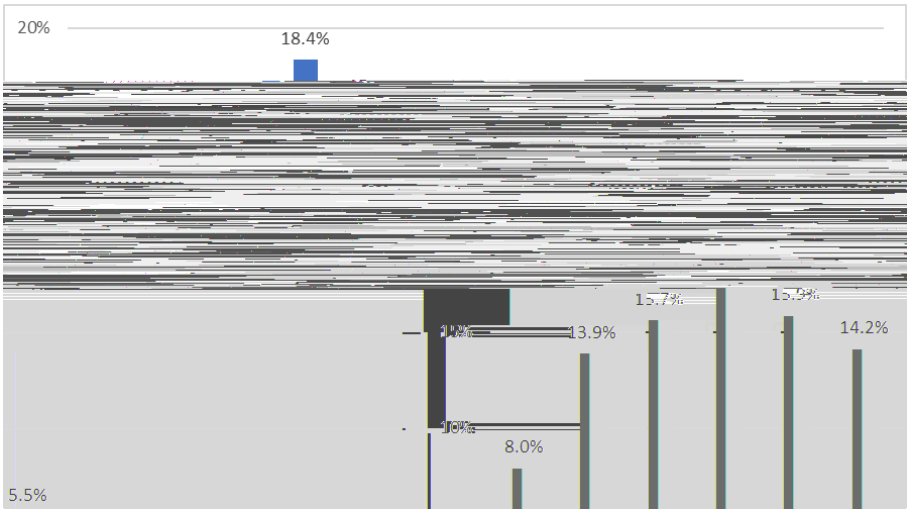
2022

402 1 11 3.3

6 91.5% 2021

2021 3.8 6

2021 85.7%



2022

DMC

2022 1974

DMC 294 14.9%

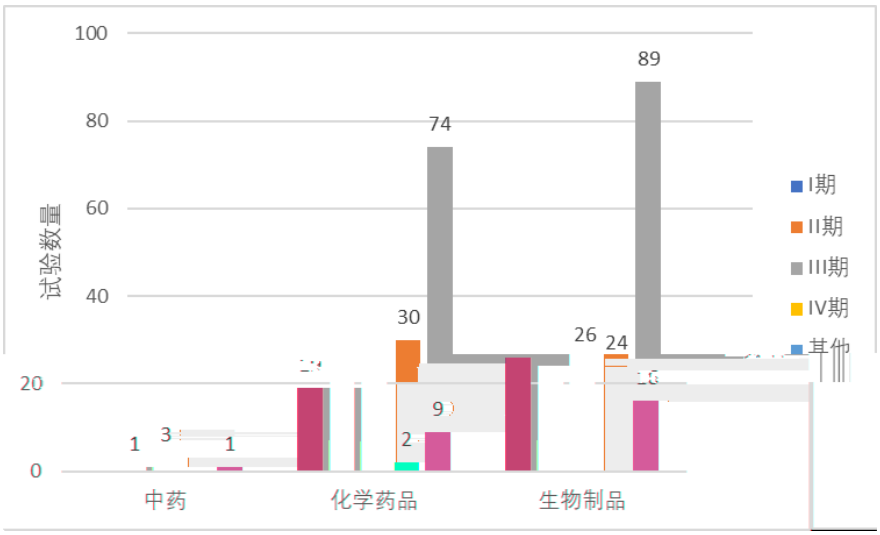
DMC 52.7%

155/ 294 45.6% 134/294

DMC 56.5%

0.7% DMC

15.3% 18.7%



2022 DMC

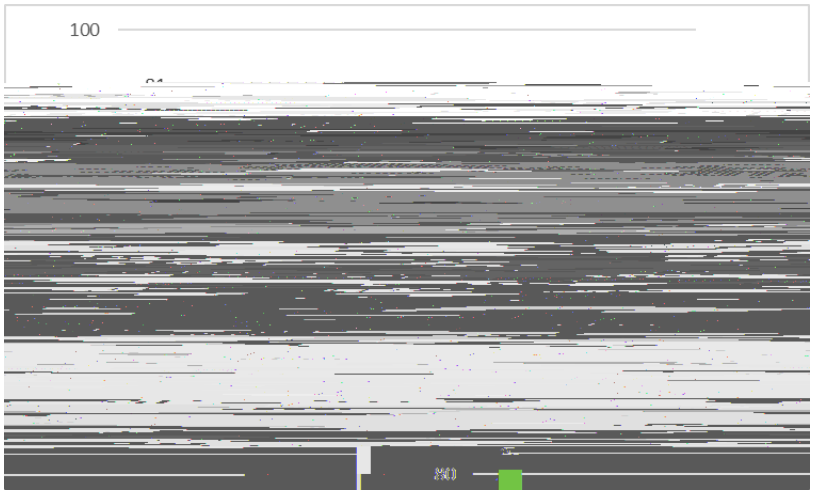
2022 1974

胞 2022 129

94 72.9 %

114 88. 4% 2

14



2022

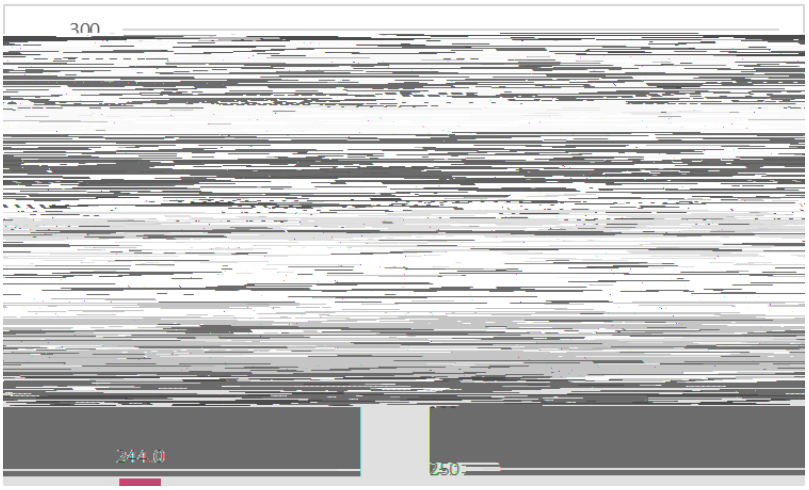
ICF

11 258

76.7

71.9

244



2022

2022 9

3 4 2 16

10 5 1

1

	2	1	-	1) ; 1 2) ; 1 3) ; 1
	3	10	-	1) ; 1

				2) ; 1 3) 1 4) 2 5) 7 6) 1
	4	5	1	1) 2 2) 1 3) 1 4) 3 5) 2 6) 1
	9	16	1	

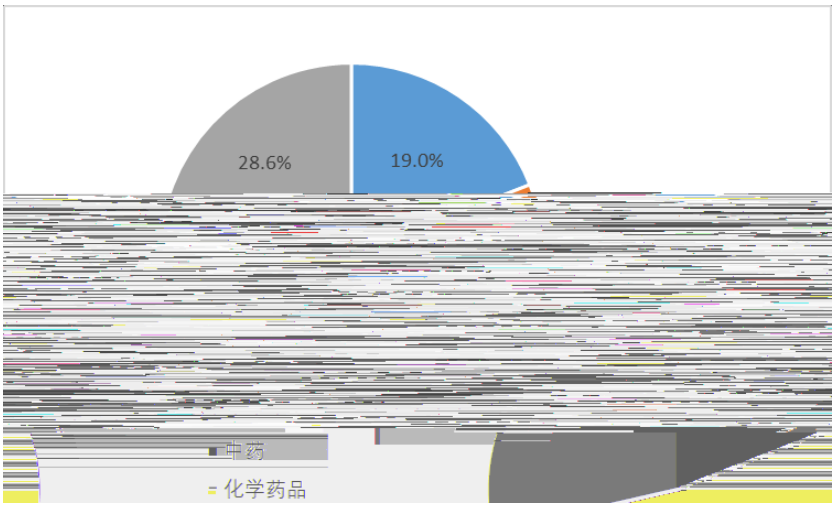
2022

21

11 52.4%

6 4

76. 2%



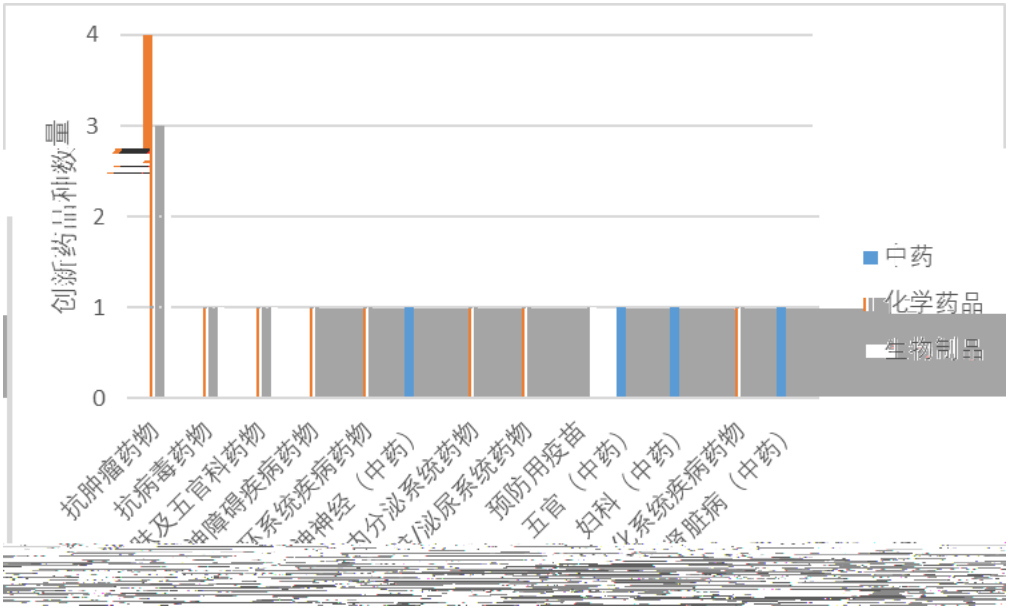
2022

除 2022

7 33.3% 4

2

保 1



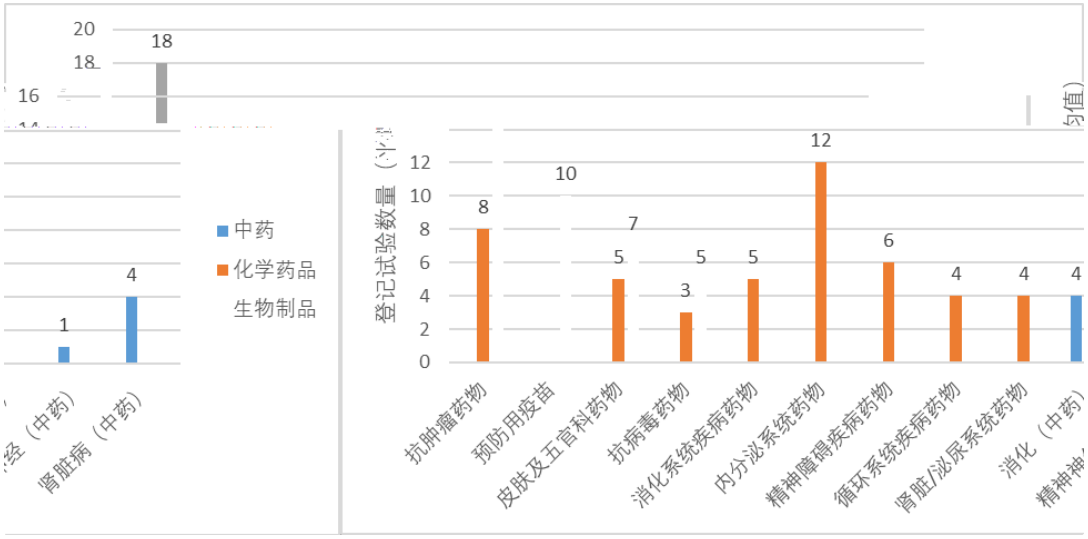
2022

CTR 2022

1 21 7.3

11.6 6.5 3

10



2022

1

2 胞 2012

，

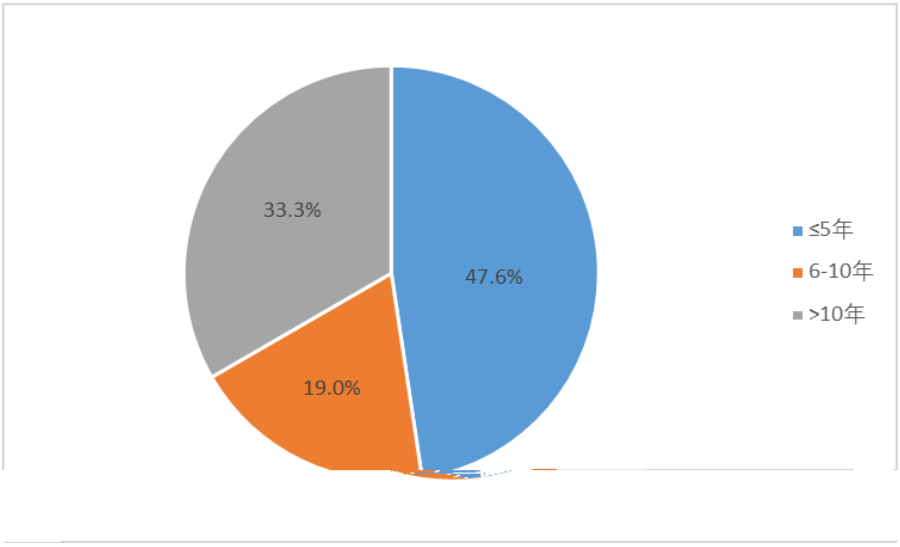
T 2022

2022 T

2022 胞 5

10 除 47.6% 4 除

19. 0%



2022

附件：编制说明

1.

胞 2022 1 1

2022 12 31

CTR 胞

2.

除

除

3. [

]

4. <18

并 65 并

5. 2018 5 11 5