

# ICH E9 ????????????

**English Version**

[ICH E9 Statistical Principles for Clinical Trials](#)

## 1. ??

### 1.1 ??????

ICH 1996 5 1 “

GCP “ ICH E6 ICH E6

CPMP

1994 12

1992 3

1998 7

ICH

- E1A: [ ]
- E2A: [ ]
- E2B: [ ]
- E2C: [ ]
- E3: [ ]
- E4: [ ]
- E5: [ ]
- E6: [ ]
- E7: [ ]
- E8: [ ]
- E10: [ ]
- M1: [ ]
- M3: [ ]

[Redacted text block]

## 1.2 ?????

[Redacted text block]

ICH

[Redacted text block]

ICH E6

[Redacted text block]

[Redacted text block]

[Redacted text block]

“ ”

[Redacted text block]

P

[Redacted text block]

/

## 2. ???????????





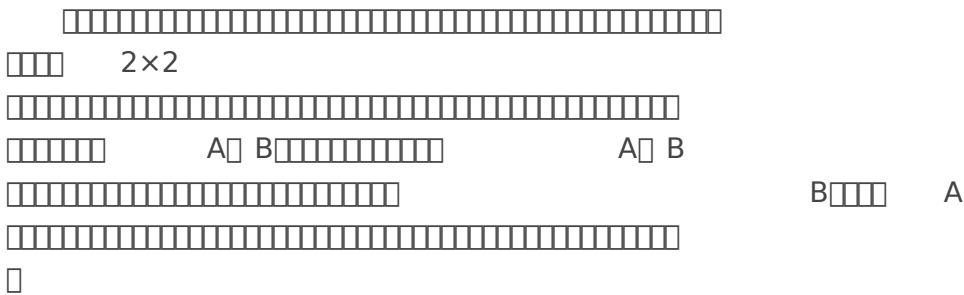
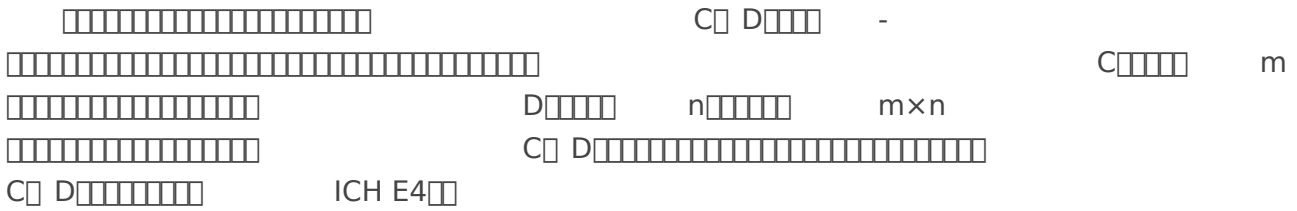
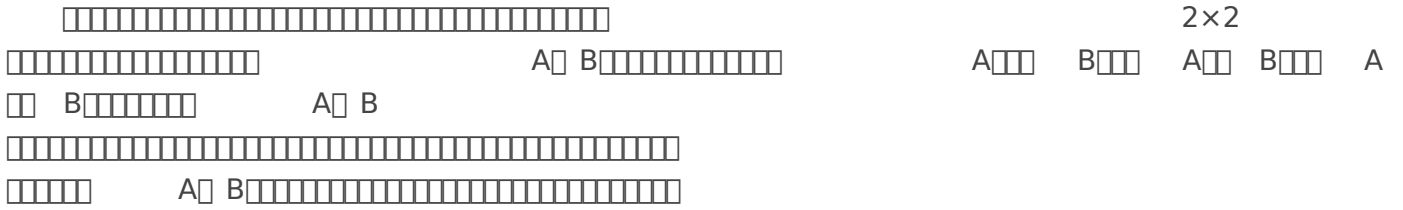




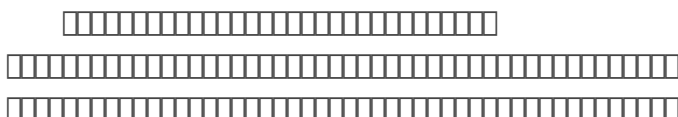
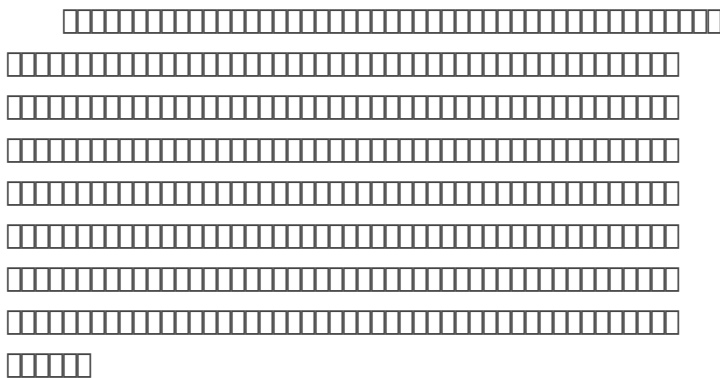
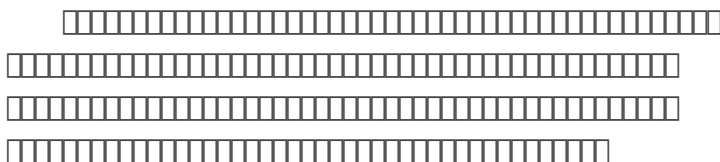
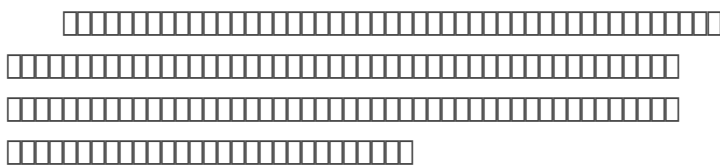




### 3.1.3 ?????



### 3.2 ??????



“ ”

[Redacted]  
 [Redacted]  
 [Redacted] ICH E6  
 [Redacted]  
 [Redacted]  
 [Redacted]

[Redacted]  
 [Redacted]  
 [Redacted]

[Redacted]  
 [Redacted]  
 [Redacted]  
 [Redacted]

[Redacted]  
 [Redacted]  
 [Redacted]  
 [Redacted]

[Redacted]  
 [Redacted]  
 [Redacted]  
 [Redacted]  
 [Redacted]

[Redacted]  
 [Redacted]

### 3.3 ?????

#### 3.3.1 ?????

[Redacted]  
 [Redacted] " [Redacted] "  
 [Redacted]

[Redacted]  
 [Redacted]

#### 3.3.2 ????????????

[Redacted]  
 [Redacted] " [Redacted] " [Redacted]

[Redacted text block]

[Redacted text block]

[Redacted text block]

[Redacted text block]

[Redacted text block]

[Redacted text block]

[Redacted text block]

[Redacted text block]

3.3.3 ??-???????

[Redacted text block]

5.5

I

I

3.5 [Redacted]

5.2.3 [Redacted]

ICH

-



























