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

????

□□□

□□□

□□□

□□□□□□□□□□□□

????????

□□□□□□□□□□□□

□□□□□□□□□□□□□□□□□□

2. ??

□□□□□□□□□□□□□□□□□□

□□□

□□□

□□□□

??????

□□□□

□□□□□□□□□□□□□□□□□□□□□□□□ 3
□□□□□□□□□□□□□□□□□□□

□□□

/

α

IDMC

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

IDMC Data And Safety Monitoring Board DSMB Data Monitoring Committee DMC

IDMC

IDMC

IDMC IDMC IDMC 1 2 3 4 5 6

IDMC 1 IDMC 2 IDMC 3

IDMC□□□□□□□□□□□□□□□□□□□□□□□□ IDMC□□□□□□□□□□□□ IDMC□□□□□□□□□□□□
IDMC□□□□□□□□□□□□□□□□□ IDMC□□□□□□□□□□□□□□□□□□□□□□ IDMC
□□□□□□□□□□□□□□□□□□□

□□□

□□□

□□□

□□□

????

□□	□□
□□□□ Safety Set□ SS□	□□□□

□□□□□ Full Analysis Set□ FAS□	□□□□□

[3]. CCTS□□□□□□□□□□□□□□□□□□□□□□□□□□□□□ 2012□ 29□ 2□□ 270-274

[4]. CCTS□□□□□□□□□□□□□□□□□□□□□□□□□□□□□ 2012□ 29□ 3□□ 1-6

[5]. ICH E9□ Statistical Principles for Clinical Trials 1998

[6]. ICH E8□ General Considerations for Clinical Trials 1997

[7]. FDA□ Adaptive Design Clinical Trials for Drugs and Biologics(Draft Guidance) 2010

Revision #3
Created 2025-12-02 13:01:30 UTC by Colin Wang
Updated 2025-12-02 15:32:19 UTC by Colin Wang