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SOP

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Data And Safety Monitoring

Board [Redacted] DSMB [Redacted] Data Monitoring Committee [Redacted] DMC

IDMC

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IDMC [Redacted] 1 [Redacted] IDMC

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QMS
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[redacted] CDISC [redacted] Clinical Data Interchange Standards Consortium
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[redacted] Statistical Analysis Plan [redacted] SAP
[redacted]
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Full Analysis Set [FAS]	
Global Assessment Variable	
Randomization Code Release	
Trial Statistician	
Double-Dummy	A B A B A B
Surrogate Variable	
Statistical Analysis Plan [SAP]	
Dropout	
Intention-To-Treat Principle	
Superiority Trial	
Confidence Interval [CI]	(1-α)
Centralized Randomization System	IVRS [Interactive Voice Response System] IWRS [Interactive Web Response System]

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[1]. SFDA []

GCP 2003

[2]. CDE []

2016

- [3]. CCTS [REDACTED] 2012 29 2 270-274
 - [4]. CCTS [REDACTED] 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 FDA Adaptive Design Clinical Trials for Drugs and Biologics(Draft Guidance) 2010
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