Appendix1-DAY21 IL-21
Two-Sample T-Tests Allowing Unequal Variance

Numeric Results for Two-Sample T-Test Allowing Unequal Variance
Alternative Hypothesis: H1: δ = μ1 - μ2 ≠ 0

Target Power	Actual Power	N1	N2	N	μ1	μ2	δ	σ1	σ2	Alpha
0.90	0.99986	3	3	6	146.4	243.9	-97.6	16.3	12.9	0.050

References
Julious, S. A. 2010. Sample Sizes for Clinical Trials. Chapman & Hall/CRC. Boca Raton, FL.
Chow, S. C., Shao, J., and Wang, H. 2008. Sample Size Calculations in Clinical Research (Second Edition). Chapman & Hall/CRC. Boca Raton, FL.
Machin, D., Campbell, M., Fayers, P., and Pinol, A. 1997. Sample Size Tables for Clinical Studies, 2nd Edition. Blackwell Science. Malden, MA.
Zar, Jerrold H. 1984. Biostatistical Analysis (Second Edition). Prentice-Hall. Englewood Cliffs, New Jersey.

Report Definitions
Target Power is the desired power value (or values) entered in the procedure. Power is the probability of rejecting a false null hypothesis.
Actual Power is the power obtained in this scenario. Because N1 and N2 are discrete, this value is often (slightly) larger than the target power.
N1 and N2 are the number of items sampled from each population.
N is the total sample size, N1 + N2.
μ1 and μ2 are the assumed population means.
δ = μ1 - μ2 is the difference between population means at which power and sample size calculations are made.
σ1 and σ2 are the assumed population standard deviations for groups 1 and 2, respectively.
Alpha is the probability of rejecting a true null hypothesis.

Summary Statements
Group sample sizes of 3 and 3 achieve 99.986% power to reject the null hypothesis of equal means when the population mean difference is μ1 - μ2 = 146.4 - 243.9 = -97.6 with standard deviations of 16.3 for group 1 and 12.9 for group 2, and with a significance level (alpha) of 0.050 using a two-sided two-sample unequal-variance t-test.

Dropout-Inflated Sample Size

	Sample Size			Dropout-Inflated Enrollment Sample Size			Expected Number of Dropouts		
Dropout Rate	N1	N2	N	N1'	N2'	N'	D1	D2	D
20%	3	3	6	4	4	8	1	1	2

Definitions
Dropout Rate (DR) is the percentage of subjects (or items) that are expected to be lost at random during the course of the study and for whom no response data will be collected (i.e. will be treated as "missing").
N1, N2, and N are the evaluable sample sizes at which power is computed. If N1 and N2 subjects are evaluated out of the N1' and N2' subjects that are enrolled in the study, the design will achieve the stated power.
N1', N2', and N' are the number of subjects that should be enrolled in the study in order to end up with N1, N2, and N evaluable subjects, based on the assumed dropout rate. After solving for N1 and N2, N1' and N2' are calculated by inflating N1 and N2 using the formulas N1' = N1 / (1 - DR) and N2' = N2 / (1 - DR), with N1' and N2' always rounded up. (See Julious, S.A. (2010) pages 52-53, or Chow, S.C., Shao, J., and Wang, H. (2008) pages 39-40.)
D1, D2, and D are the expected number of dropouts. D1 = N1' - N1, D2 = N2' - N2, and D = D1 + D2.

Two-Sample T-Tests Allowing Unequal Variance

Procedure Input Settings

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Design Tab

Solve For:	Sample Size
Alternative Hypothesis:	Two-Sided
Power:	0.90
Alpha:	0.05
Group Allocation:	Equal (N1 = N2)
Input Type:	Means
μ1:	146.36
μ2:	243.91
σ1:	16.28
σ2:	12.86

Appendix2-DAY21 IgG4
Two-Sample T-Tests Allowing Unequal Variance

Numeric Results for Two-Sample T-Test Allowing Unequal Variance
Alternative Hypothesis: H1: δ = μ1 - μ2 ≠ 0

Target Power	Actual Power	N1	N2	N	μ1	μ2	δ	σ1	σ2	Alpha
0.90	0.92207	5	5	10	220.9	258.6	-37.8	9.5	18.4	0.050

References
Julious, S. A. 2010. Sample Sizes for Clinical Trials. Chapman & Hall/CRC. Boca Raton, FL.
Chow, S. C., Shao, J., and Wang, H. 2008. Sample Size Calculations in Clinical Research (Second Edition). Chapman & Hall/CRC. Boca Raton, FL.
Machin, D., Campbell, M., Fayers, P., and Pinol, A. 1997. Sample Size Tables for Clinical Studies, 2nd Edition. Blackwell Science. Malden, MA.
Zar, Jerrold H. 1984. Biostatistical Analysis (Second Edition). Prentice-Hall. Englewood Cliffs, New Jersey.

Report Definitions
Target Power is the desired power value (or values) entered in the procedure. Power is the probability of rejecting a false null hypothesis.
Actual Power is the power obtained in this scenario. Because N1 and N2 are discrete, this value is often (slightly) larger than the target power.
N1 and N2 are the number of items sampled from each population.
N is the total sample size, N1 + N2.
μ1 and μ2 are the assumed population means.
δ = μ1 - μ2 is the difference between population means at which power and sample size calculations are made.
σ1 and σ2 are the assumed population standard deviations for groups 1 and 2, respectively.
Alpha is the probability of rejecting a true null hypothesis.

Summary Statements
Group sample sizes of 5 and 5 achieve 92.207% power to reject the null hypothesis of equal means when the population mean difference is μ1 - μ2 = 220.9 - 258.6 = -37.8 with standard deviations of 9.5 for group 1 and 18.4 for group 2, and with a significance level (alpha) of 0.050 using a two-sided two-sample unequal-variance t-test.

Dropout-Inflated Sample Size

	Sample Size			Dropout-Inflated Enrollment Sample Size			Expected Number of Dropouts		
Dropout Rate	N1	N2	N	N1'	N2'	N'	D1	D2	D
20%	5	5	10	7	7	14	2	2	4

Definitions
Dropout Rate (DR) is the percentage of subjects (or items) that are expected to be lost at random during the course of the study and for whom no response data will be collected (i.e. will be treated as "missing").
N1, N2, and N are the evaluable sample sizes at which power is computed. If N1 and N2 subjects are evaluated out of the N1' and N2' subjects that are enrolled in the study, the design will achieve the stated power.
N1', N2', and N' are the number of subjects that should be enrolled in the study in order to end up with N1, N2, and N evaluable subjects, based on the assumed dropout rate. After solving for N1 and N2, N1' and N2' are calculated by inflating N1 and N2 using the formulas N1' = N1 / (1 - DR) and N2' = N2 / (1 - DR), with N1' and N2' always rounded up. (See Julious, S.A. (2010) pages 52-53, or Chow, S.C., Shao, J., and Wang, H. (2008) pages 39-40.)
D1, D2, and D are the expected number of dropouts. D1 = N1' - N1, D2 = N2' - N2, and D = D1 + D2.

Two-Sample T-Tests Allowing Unequal Variance

Procedure Input Settings

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Design Tab

Solve For:	Sample Size
Alternative Hypothesis:	Two-Sided
Power:	0.90
Alpha:	0.05
Group Allocation:	Equal (N1 = N2)
Input Type:	Means
μ1:	220.87
μ2:	258.62
σ1:	9.47
σ2:	18.36

Appendix3-DAY35 IL-21

Two-Sample T-Tests Allowing Unequal Variance

Numeric Results for Two-Sample T-Test Allowing Unequal Variance

Alternative Hypothesis: H1: $\delta = \mu1 - \mu2 \neq 0$

Target Power	Actual Power	N1	N2	N	μ1	μ2	δ	σ1	σ2	Alpha
0.90	0.95219	5	5	10	217.7	156.1	61.6	21.2	25.2	0.050

References

Julious, S. A. 2010. Sample Sizes for Clinical Trials. Chapman & Hall/CRC. Boca Raton, FL.

Chow, S. C., Shao, J., and Wang, H. 2008. Sample Size Calculations in Clinical Research (Second Edition). Chapman & Hall/CRC. Boca Raton, FL.

Machin, D., Campbell, M., Fayers, P., and Pinol, A. 1997. Sample Size Tables for Clinical Studies, 2nd Edition. Blackwell Science. Malden, MA.

Zar, Jerrold H. 1984. Biostatistical Analysis (Second Edition). Prentice-Hall. Englewood Cliffs, New Jersey.

Report Definitions

Target Power is the desired power value (or values) entered in the procedure. Power is the probability of rejecting a false null hypothesis.

Actual Power is the power obtained in this scenario. Because N1 and N2 are discrete, this value is often (slightly) larger than the target power.

N1 and N2 are the number of items sampled from each population.

N is the total sample size, N1 + N2.

μ1 and μ2 are the assumed population means.

δ = μ1 - μ2 is the difference between population means at which power and sample size calculations are made.

σ1 and σ2 are the assumed population standard deviations for groups 1 and 2, respectively.

Alpha is the probability of rejecting a true null hypothesis.

Summary Statements

Group sample sizes of 5 and 5 achieve 95.219% power to reject the null hypothesis of equal means when the population mean difference is μ1 - μ2 = 217.7 - 156.1 = 61.6 with standard deviations of 21.2 for group 1 and 25.2 for group 2, and with a significance level (alpha) of 0.050 using a two-sided two-sample unequal-variance t-test.

Dropout-Inflated Sample Size

	Sample Size			Dropout-Inflated Enrollment Sample Size			Expected Number of Dropouts		
Dropout Rate	N1	N2	N	N1'	N2'	N'	D1	D2	D
20%	5	5	10	7	7	14	2	2	4

Definitions

Dropout Rate (DR) is the percentage of subjects (or items) that are expected to be lost at random during the course of the study and for whom no response data will be collected (i.e. will be treated as "missing").

N1, N2, and N are the evaluable sample sizes at which power is computed. If N1 and N2 subjects are evaluated out of the N1' and N2' subjects that are enrolled in the study, the design will achieve the stated power.

N1', N2', and N' are the number of subjects that should be enrolled in the study in order to end up with N1, N2, and N evaluable subjects, based on the assumed dropout rate. After solving for N1 and N2, N1' and N2' are calculated by inflating N1 and N2 using the formulas N1' = N1 / (1 - DR) and N2' = N2 / (1 - DR), with N1' and N2' always rounded up. (See Julious, S.A. (2010) pages 52-53, or Chow, S.C., Shao, J., and Wang, H. (2008) pages 39-40.)

D1, D2, and D are the expected number of dropouts. D1 = N1' - N1, D2 = N2' - N2, and D = D1 + D2.

Two-Sample T-Tests Allowing Unequal Variance

Procedure Input Settings

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Design Tab

Solve For:	Sample Size
Alternative Hypothesis:	Two-Sided
Power:	0.90
Alpha:	0.05
Group Allocation:	Equal (N1 = N2)
Input Type:	Means
μ1:	217.72
μ2:	156.14
σ1:	21.16
σ2:	25.23

Appendix4-DAY35 IgG4
Two-Sample T-Tests Allowing Unequal Variance

Numeric Results for Two-Sample T-Test Allowing Unequal Variance
Alternative Hypothesis: H1: δ = μ1 - μ2 ≠ 0

Target Power	Actual Power	N1	N2	N	μ1	μ2	δ	σ1	σ2	Alpha
0.90	0.96326	4	4	8	271.0	170.5	100.5	34.7	26.1	0.050

References
Julious, S. A. 2010. Sample Sizes for Clinical Trials. Chapman & Hall/CRC. Boca Raton, FL.
Chow, S. C., Shao, J., and Wang, H. 2008. Sample Size Calculations in Clinical Research (Second Edition). Chapman & Hall/CRC. Boca Raton, FL.
Machin, D., Campbell, M., Fayers, P., and Pinol, A. 1997. Sample Size Tables for Clinical Studies, 2nd Edition. Blackwell Science. Malden, MA.
Zar, Jerrold H. 1984. Biostatistical Analysis (Second Edition). Prentice-Hall. Englewood Cliffs, New Jersey.

Report Definitions
Target Power is the desired power value (or values) entered in the procedure. Power is the probability of rejecting a false null hypothesis.
Actual Power is the power obtained in this scenario. Because N1 and N2 are discrete, this value is often (slightly) larger than the target power.
N1 and N2 are the number of items sampled from each population.
N is the total sample size, N1 + N2.
μ1 and μ2 are the assumed population means.
δ = μ1 - μ2 is the difference between population means at which power and sample size calculations are made.
σ1 and σ2 are the assumed population standard deviations for groups 1 and 2, respectively.
Alpha is the probability of rejecting a true null hypothesis.

Summary Statements
Group sample sizes of 4 and 4 achieve 96.326% power to reject the null hypothesis of equal means when the population mean difference is μ1 - μ2 = 271.0 - 170.5 = 100.5 with standard deviations of 34.7 for group 1 and 26.1 for group 2, and with a significance level (alpha) of 0.050 using a two-sided two-sample unequal-variance t-test.

Dropout-Inflated Sample Size

	Sample Size			Dropout-Inflated Enrollment Sample Size			Expected Number of Dropouts		
Dropout Rate	N1	N2	N	N1'	N2'	N'	D1	D2	D
20%	4	4	8	5	5	10	1	1	2

Definitions
Dropout Rate (DR) is the percentage of subjects (or items) that are expected to be lost at random during the course of the study and for whom no response data will be collected (i.e. will be treated as "missing").
N1, N2, and N are the evaluable sample sizes at which power is computed. If N1 and N2 subjects are evaluated out of the N1' and N2' subjects that are enrolled in the study, the design will achieve the stated power.
N1', N2', and N' are the number of subjects that should be enrolled in the study in order to end up with N1, N2, and N evaluable subjects, based on the assumed dropout rate. After solving for N1 and N2, N1' and N2' are calculated by inflating N1 and N2 using the formulas N1' = N1 / (1 - DR) and N2' = N2 / (1 - DR), with N1' and N2' always rounded up. (See Julious, S.A. (2010) pages 52-53, or Chow, S.C., Shao, J., and Wang, H. (2008) pages 39-40.)
D1, D2, and D are the expected number of dropouts. D1 = N1' - N1, D2 = N2' - N2, and D = D1 + D2.

Two-Sample T-Tests Allowing Unequal Variance

Procedure Input Settings

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Design Tab

Solve For:	Sample Size
Alternative Hypothesis:	Two-Sided
Power:	0.90
Alpha:	0.05
Group Allocation:	Equal (N1 = N2)
Input Type:	Means
μ1:	270.97
μ2:	170.47
σ1:	34.71
σ2:	26.06