

Baseline Characteristics: Study Design Examples

Results Database Train-the-Trainer Workshop
August 2021

Crossover

Per-sequence arms/groups:

- Show how evenly participants were distributed when they were randomized
- Avoid double counting the unit of analysis (participants)

Baseline Measures Overview

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Edit		Arm/Group Title	Hypertena, Then Placebo	Placebo, Then Hypertena	Total
		▼ Arm/Group Description	Participants first received Hypertena 20 mg tablet each morning in a fasting state for 2 weeks. After a washout period of 2 weeks, they then received Placebo tablet (matching Hypertena 20 mg) in a fasting state each morning for 2 weeks.	Participants first received Placebo tablet (matching Hypertena 20 mg) in a fasting state each morning for 2 weeks. After a washout period of 2 weeks, they then received Hypertena 20 mg in a fasting state each morning for 2 weeks.	
Edit		Overall Number of Baseline Participants	65	65	130
		► Baseline Analysis Population Description			
Edit		Age, Continuous	65 participants	65 participants	130 participants
Delete		Mean (Standard Deviation)			
		Unit of measure: years	40.5 (5.3)	40.1 (5.9)	40.3 (5.6)
Edit		Sex: Female, Male	65 participants	65 participants	130 participants
Delete		Measure Type: Count of Participants			
		Unit of measure: participants			
		Female	31 47.69%	29 44.62%	60 46.15%
		Male	34 52.31%	36 55.38%	70 53.85%
Edit		Ethnicity (NIH/OMB)	65 participants	65 participants	130 participants
Delete		Measure Type: Count of Participants			
		Unit of measure: participants			
		Hispanic or Latino	13 20%	12 18.46%	25 19.23%
		Not Hispanic or Latino	52 80%	53 81.54%	105 80.77%
		Unknown or Not Reported	0 0%	0 0%	0 0%

Data for each arm/group and for the overall population are required.

Crossover

Percentages are automatically calculated when "Count of Participants" is the Measure Type. Displaying them is optional.

Edit Delete	Race (NIH/OMB) Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	65 participants	65 participants	130 participants
		American Indian or Alaska Native	0 0%	0 0%	0 0%
		Asian	0 0%	0 0%	0 0%
		Native Hawaiian or Other Pacific Islander	0 0%	0 0%	0 0%
		Black or African American	10 15.38%	9 13.85%	19 14.62%
		White	55 84.62%	56 86.15%	111 85.38%
		More than one race	0 0%	0 0%	0 0%
		Unknown or Not Reported	0 0%	0 0%	0 0%
Edit Delete	Region of Enrollment Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	65 participants	65 participants	130 participants
	United States		65 100%	65 100%	130 100%
Edit Delete	Weight Mean (Standard Deviation) Unit of measure: kg	Number Analyzed	65 participants	65 participants	130 participants
			63.9 (8.9)	66.1 (13.0)	65.0 (11.2)
Edit Delete	Sitting Systolic Blood Pressure (SBP) Mean (Standard Deviation) Unit of measure: mmHg	Number Analyzed	65 participants	65 participants	130 participants
			143.9 (15.5)	149.9 (23.1)	146.9 (19.9)
Edit Delete	Sitting Diastolic Blood Pressure (DBP) Mean (Standard Deviation) Unit of measure: mmHg	Number Analyzed	65 participants	65 participants	130 participants
			89.9 (8.6)	93.7 (9.6)	91.8 (9.3)

Dose Escalation

Baseline Measures Overview

Participants are presented according to dose level to inform analyses comparing dose levels.

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Edit		Arm/Group Title	Ender-G 100 mg/m ²	Ender-G 125 mg/m ²	Ender-G 150 mg/m ²	Total
		▼ Arm/Group Description	Cohort 1: Participants were administered 100 mg/m ² of Ender-G twice a day, via intravenous catheter (IV), for 4 weeks, with 4 weeks of follow-up after the last dose was administered.	Cohort 2: Participants were administered 125 mg/m ² of Ender-G twice a day, via intravenous catheter (IV), for 4 weeks, with 4 weeks of follow-up after the last dose was administered.	Cohort 3: Participants were administered 150 mg/m ² of Ender-G twice a day, via intravenous catheter (IV), for 4 weeks, with 4 weeks of follow-up after the last dose was administered.	
Edit		Overall Number of Baseline Participants	3	6	6	15
		► Baseline Analysis Population Description				
Edit		Age, Continuous Median (Full Range)	3 participants	6 participants	6 participants	15 participants
Delete		Unit of measure: years				
			67 (43 to 72)	63 (36 to 74)	62.5 (42 to 82)	67 (36 to 82)
Edit		Sex: Female, Male	3 participants	6 participants	6 participants	15 participants
Delete		Measure Type: Count of Participants				
		Unit of measure: participants				
		Female	2 66.67%	3 50%	2 33.33%	7 46.67%
		Male	1 33.33%	3 50%	4 66.67%	8 53.33%
Edit		Race (NIH/OMB)	3 participants	6 participants	6 participants	15 participants
Delete		Measure Type: Count of Participants				
		Unit of measure: participants				
		American Indian or Alaska Native	0 0%	0 0%	0 0%	0 0%
		Asian	0 0%	0 0%	0 0%	0 0%
		Native Hawaiian or Other Pacific Islander	0 0%	0 0%	0 0%	0 0%
		Black or African American	1 33.33%	2 33.33%	1 16.67%	4 26.67%
		White	2 66.67%	4 66.67%	5 83.33%	11 73.33%
		More than one race	0 0%	0 0%	0 0%	0 0%
		Unknown or Not Reported	0 0%	0 0%	0 0%	0 0%

Data for each arm/group and for the overall population are required.

Dose Escalation

Edit Delete	Region of Enrollment Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	3 participants	6 participants	6 participants	15 participants
	United States		3 100%	6 100%	6 100%	15 100%
Edit Delete	WHO Performance Status [1] Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	3 participants	6 participants	6 participants	15 participants
	0 (Asymptomatic)		1 33.33%	2 33.33%	2 33.33%	5 33.33%
	1 (Symptomatic, but ambulatory)		1 33.33%	3 50%	3 50%	7 46.67%
	2 (Symptomatic, <50% in bed)		1 33.33%	1 16.67%	1 16.67%	3 20%
	<p>[1] Measure Description: World Health Organization (WHO) performance status:</p> <ul style="list-style-type: none"> • 0 = Asymptomatic (Fully active, able to carry out predisease activities without restriction) • 1 = Symptomatic, but ambulatory (only physically strenuous activity restricted) • 2 = Symptomatic, <50% in bed (Ambulatory, capable of all self care, unable to carry out any work activities. Up and about >50% of waking hours) • 3 = Symptomatic, >50% in bed, but not bedbound (only limited self-care, confined to bed or chair >50% of waking hours) • 4 = Bedbound (Completely disabled, no self-care, Totally confined to bed or chair) • 5 = Death 					
Edit Delete	Tumor Type Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	3 participants	6 participants	6 participants	15 participants
	Non-small-cell lung carcinoma (NSCLC)		1 33.33%	2 33.33%	2 33.33%	5 33.33%
	Prostate		1 33.33%	2 33.33%	2 33.33%	5 33.33%
	Ovarian		1 33.33%	2 33.33%	2 33.33%	5 33.33%
Edit Delete	Number of Prior Chemotherapy Regimens Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	3 participants	6 participants	6 participants	15 participants
	1		1 33.33%	1 16.67%	2 33.33%	4 26.67%
	2		0 0%	1 16.67%	1 16.67%	2 13.33%
	3		1 33.33%	1 16.67%	0 0%	2 13.33%
	≥ 4		1 33.33%	3 50%	3 50%	7 46.67%

Category Titles briefly describe each stage or grade.

The Baseline Measure Description fully describes all stages or grades, from best to worst outcome.

Percentages are automatically calculated when "Count of Participants" is the Measure Type. Displaying them is optional.

When categories and the Measure Type "Count of Participants" are both used, system validations can check that the sum of participants per arm/group equals the number analyzed.

Units Other Than Participants

Baseline Measures Overview

Arms/groups represent the randomization of units (implants) and show how well the units were distributed.

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Edit	Arm/Group Title	Ghostsply® Implants	Crestene® Implants	Total
	▼ Arm/Group Description Titanium Ghostsply® implants were randomly assigned to the left or the right mandible side in a split-mouth randomized design.		Ceramic Crestene® implants were randomly assigned to the left or the right mandible side in a split-mouth randomized design.	
Edit	Overall Number of Baseline Participants	26	26	26
	Overall Number of Units Analyzed Type of Units Analyzed: implants ▼ Baseline Analysis Population Description [Not specified]	48	42	90
Edit	Age, Continuous Median (Full Range) Unit of measure: years	26 participants	26 participants	26 participants
Delete		55 (21 to 75)	55 (21 to 75)	55 (21 to 75)
Edit	Age, Customized Measure Type: Number Unit of measure: participants	26 participants	26 participants	26 participants
Delete	<= 18 years	0	0	0
	Between 18 and 65 years	25	25	25
	>= 65 years	1	1	1

A row is added to the Baseline Characteristics table to:

- Display the Type of Units Analyzed and the number analyzed per arm/group
- Allow the selection of “implants” as the analysis population in the baseline measures

Data for each arm/group and for the overall population are required.

Units Other Than Participants

Edit	Sex/Gender, Customized Measure Type: Number Unit of measure: participants	Number Analyzed	26 participants		26 participants		26 participants		
Delete			Female	9	9	9	17	17	
			Male	17	17	17	17	17	
Delete	Race and Ethnicity Not Collected [1] Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	0 participants		0 participants		0 participants		
				---	---	0			
			[1] Measure Analysis Population Description: Race and Ethnicity were not collected from any participant.						
Edit	Region of Enrollment Measure Type: Number Unit of measure: participants	Number Analyzed	26 participants		26 participants		26 participants		
Delete			United States	26	26	26			
Edit	Implantation Site Type Measure Type: Count of Units Unit of measure: implants	Number Analyzed	48 implants		42 implants		90 implants		
Delete			Prior Edentulism (missing tooth)	19	39.58%	16	38.1%	35	38.89%
			Extraction	29	60.42%	26	61.9%	55	61.11%

Customized measures and the Measure Type "Number" are used to allow the adjustment of the Total values across rows of participants. This avoids the double counting of participants.

The Number Analyzed row displays the number of implants analyzed per arm/group when "Count of Units" is selected as the Measure Type.

When categories and the Measure Type "Count of Units" are both used, system validations can check that the sum of units per arm/group equals the number analyzed.

Percentages are automatically calculated when "Count of Units" is the Measure Type. Displaying them is optional.

Cluster Randomized

- A row is added to the Baseline Characteristics table to:
- Display the Type of Units Analyzed and the number analyzed per arm/group
 - Allow the selection of “Intensive Care Units” as the analysis population in the baseline measures

Baseline Measures Overview

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Edit		Arm/Group Title	Group 1: Standard Care	Group 2: Targeted Decolonization Plus Standard Care	Group 3: Enhanced Room Disinfection Plus Standard Care	Total
		▼ Arm/Group Description	Patients were screened for <i>Poissomonosis davriiarum</i> (PD) infection on intensive care unit (ICU) admission. Each enrolled ICU took transmission-based precautions, based on guidance from the Centers for Disease Control and Prevention (CDC).	As in Group 1, patients were screened for PD infection on ICU admission and each enrolled ICU took transmission-based precautions, based on guidance from the CDC. In addition, PD-positive patients received a 5-day decolonization regimen of twice daily intranasal 2% No Bug cream and daily bathing with 4% No-Scrub sanitizing cloths.	As in Groups 1 and 2, patients were screened for PD infection on ICU admission and each enrolled ICU took transmission-based precautions, based on guidance from the CDC. In addition, rooms from which PD patients were discharged were disinfected with a solution containing hypochlorite (bleach) plus a disinfecting ultraviolet light (UV-C) device.	
Edit		Overall Number of Baseline Participants	78,653	80,685	77,593	236,931
		Overall Number of Units Analyzed	23	22	29	74
		Type of Units Analyzed: Intensive Care Units				
		► Baseline Analysis Population Description				
Edit		Age, Continuous [1] Median (Inter-Quartile Range)				
Details		Unit of measure: years				
		Baseline Period	39,530 participants	41,229 participants	38,804 participants	119,563 participants
			63 (51 to 76)	66 (54 to 78)	67 (55 to 79)	65 (52 to 77)
		Intervention Period	39,123 participants	39,456 participants	38,789 participants	117,368 participants
			64 (52 to 77)	65 (53 to 77)	66 (54 to 78)	65 (52 to 77)
		[1] Measure Analysis Population Description: Participants assessed for age in the baseline and intervention periods				
Edit		Sex: Female, Male [1] Measure Type: Count of Participants				
Details		Unit of measure: participants				
		Baseline Period	39,530 participants	41,229 participants	38,804 participants	119,563 participants
		Female	19,014 48.1%	20,367 49.4%	20,100 51.8%	59,481 49.75%
		Male	20,516 51.9%	20,862 50.6%	18,704 48.2%	60,082 50.25%
		Intervention Period	39,123 participants	39,456 participants	38,789 participants	117,368 participants
		Female	18,427 47.1%	19,412 49.2%	18,929 48.8%	56,768 48.37%
		Male	20,696 52.9%	20,044 50.8%	19,860 51.2%	60,600 51.63%
		[1] Measure Analysis Population Description: Participants assessed for sex in the baseline and intervention periods				

Data for each arm/group and for the overall population are required.

Cluster Randomized

Separate rows are used to present data for the two periods of the study.

Analysis populations are adjusted from the Overall Number of Participants Analyzed values to reflect participation in each period, and an explanation is provided in the Measure Analysis Population Description.

Edit		Ethnicity (NIH/OMB) [1]									
Details		Measure Type: Count of Participants									
		Unit of measure: participants									
Baseline Period	Number Analyzed	39,530 participants		41,229 participants		38,804 participants		119,563 participants			
	Hispanic or Latino	910	2.3%	985	2.39%	1,501	3.87%	3,396	2.84%		
	Not Hispanic or Latino	38,620	97.7%	40,244	97.61%	37,303	96.13%	116,167	97.16%		
	Unknown or Not Reported	0	0%	0	0%	0	0%	0	0%		
Intervention Period	Number Analyzed	39,123 participants		39,456 participants		38,789 participants		117,368 participants			
	Hispanic or Latino	896	2.29%	963	2.44%	1,479	3.81%	3,338	2.84%		
	Not Hispanic or Latino	38,227	97.71%	38,493	97.56%	37,310	96.19%	114,030	97.16%		
	Unknown or Not Reported	0	0%	0	0%	0	0%	0	0%		
[1] Measure Analysis Population Description: Participants assessed for ethnicity in the baseline and intervention periods											
Edit		Race (NIH/OMB) [1]									
Details		Measure Type: Count of Participants									
		Unit of measure: participants									
Baseline Period	Number Analyzed	39,530 participants		41,229 participants		38,804 participants		119,563 participants			
	American Indian or Alaska Native	420	1.06%	859	2.08%	560	1.44%	1,839	1.54%		
	Asian	1,962	4.98%	1,209	2.93%	2,737	7.05%	5,908	4.94%		
	Native Hawaiian or Other Pacific Islander	131	0.33%	244	0.59%	169	0.44%	544	0.45%		
	Black or African American	8,386	21.21%	9,882	23.97%	9,821	25.31%	28,089	23.49%		
	White	28,631	72.43%	29,035	70.42%	25,517	65.76%	83,183	69.57%		
	More than one race	0	0%	0	0%	0	0%	0	0%		
	Unknown or Not Reported	0	0%	0	0%	0	0%	0	0%		
Intervention Period	Number Analyzed	39,123 participants		39,456 participants		38,789 participants		117,368 participants			
	American Indian or Alaska Native	391	1%	659	1.67%	581	1.5%	1,631	1.39%		
	Asian	1,956	5%	1,009	2.56%	2,715	7%	5,680	4.84%		
	Native Hawaiian or Other Pacific Islander	129	0.33%	158	0.4%	171	0.44%	458	0.39%		
	Black or African American	8,215	21%	9,182	23.27%	9,697	25%	27,084	23.08%		
	White	28,432	72.67%	28,448	72.1%	25,625	66.06%	82,505	70.3%		
	More than one race	0	0%	0	0%	0	0%	0	0%		
	Unknown or Not Reported	0	0%	0	0%	0	0%	0	0%		
[1] Measure Analysis Population Description: Participants assessed for race in the baseline and intervention periods											

Cluster Randomized

Edit	Region of Enrollment	Number Analyzed	78,653 participants		80,685 participants		77,593 participants		236,931 participants	
Delete	Measure Type: Count of Participants									
	Unit of measure: participants									
	United States		78,653	100%	80,685	100%	77,593	100%	236,931	100%
Edit	Intensive Care Unit Type [1]									
Delete	Measure Type: Count of Units									
	Unit of measure: Intensive Care Units									
	Baseline Period :	Number Analyzed	23 [2] Intensive Care Units		22 [3] Intensive Care Units		29 [4] Intensive Care Units		74 [5] Intensive Care Units	
	Medical only		3	13.04%	3	13.64%	2	6.9%	8	10.81%
	Baseline Period :	Number Analyzed	23 [2] Intensive Care Units		22 [3] Intensive Care Units		29 [4] Intensive Care Units		74 [5] Intensive Care Units	
	Surgical only		2	8.7%	4	18.18%	3	10.34%	9	12.16%
	Baseline Period :	Number Analyzed	23 [2] Intensive Care Units		22 [3] Intensive Care Units		29 [4] Intensive Care Units		74 [5] Intensive Care Units	
	Medical and Surgical		18	78.26%	15	68.18%	24	82.76%	57	77.03%
	Intervention Period :	Number Analyzed	23 [6] Intensive Care Units		20 [7] Intensive Care Units		29 [8] Intensive Care Units		72 [9] Intensive Care Units	
	Medical only		3	13.04%	1	5%	2	6.9%	6	8.33%
	Intervention Period :	Number Analyzed	23 [6] Intensive Care Units		20 [7] Intensive Care Units		29 [8] Intensive Care Units		72 [9] Intensive Care Units	
	Surgical only		2	8.7%	4	20%	3	10.34%	9	12.5%
	Intervention Period :	Number Analyzed	23 [6] Intensive Care Units		20 [7] Intensive Care Units		29 [8] Intensive Care Units		72 [9] Intensive Care Units	
	Medical and Surgical		18	78.26%	15	75%	24	82.76%	57	79.17%
			[1] Measure Analysis Population Description: Data not available for the two ICUs in Group 2 that withdrew during the intervention period [2] 39,530 participants [3] 41,229 participants [4] 38,804 participants [5] 119,563 participants [6] 39,123 participants [7] 39,456 participants [8] 38,789 participants [9] 117,368 participants							
Edit	Number of Participants with Prior PD Infection [1, 2]									
Delete	Measure Type: Count of Participants									
	Unit of measure: participants									
	Baseline Period	Number Analyzed	39,530 participants		41,229 participants		38,804 participants		119,563 participants	
			3,826	9.68%	4,025	9.76%	3,911	10.08%	11,762	9.84%
	Intervention Period	Number Analyzed	39,123 participants		39,456 participants		38,789 participants		117,368 participants	
			4,951	12.65%	4,783	12.12%	4,112	10.6%	13,846	11.8%
			[1] Measure Description: Prior infections were those that occurred 1 year prior to admission through day 2 of the ICU stay for the baseline or intervention period. [2] Measure Analysis Population Description: Participants assessed for prior PD infection in the baseline and intervention periods							

When categories and the Measure Type "Count of Units" are both used, system validations can check that the sum of units per arm/group equals the number analyzed.

The Number Analyzed row displays the number of Intensive Care Units analyzed per arm/group when "Count of Units" is selected as the Measure Type.

Percentages are automatically calculated when "Count of Units" is the Measure Type. Displaying them is optional.

The Number of Baseline Participants for each arm/group is displayed as a footnote when "Count of Units" is the Measure Type and the value differs from the Overall Number of Participants Analyzed.

An analysis population is adjusted from the Overall Number of Units Analyzed value to reflect participation in the intervention period, and an explanation is provided in the Measure Analysis Population Description.

The Baseline Measure Description provides additional information about the analysis.

Fractional Factorial

Edit	Race (NIH/OMB) Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	50 participants	50 participants	50 participants	50 participants	50 participants	50 participants	50 participants	50 participants	400 participants
Delete		American Indian or Alaska Native	0 0%	1 2%	0 0%	0 0%	0 0%	0 0%	1 2%	0 0%	2 0.5%
		Asian	3 6%	4 8%	2 4%	1 2%	5 10%	6 12%	4 8%	0 0%	25 6.25%
		Native Hawaiian or Other Pacific Islander	0 0%	0 0%	1 2%	0 0%	0 0%	1 2%	0 0%	0 0%	2 0.5%
		Black or African American	10 20%	15 30%	12 24%	16 32%	13 26%	14 28%	20 40%	11 22%	111 27.75%
		White	37 74%	30 60%	35 70%	33 66%	32 64%	29 58%	25 50%	39 78%	260 65%
		More than one race	0 0%	0 0%	0 0%	0 0%	0 0%	0 0%	0 0%	0 0%	0 0%
		Unknown or Not Reported	0 0%	0 0%	0 0%	0 0%	0 0%	0 0%	0 0%	0 0%	0 0%
Edit		Region of Enrollment Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	50 participants	50 participants	50 participants	50 participants	50 participants	50 participants	50 participants	50 participants
Delete	United States		50 100%	50 100%	50 100%	50 100%	50 100%	50 100%	50 100%	50 100%	400 100%
Edit	Previous In-School Suspensions Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	50 participants	50 participants	50 participants	50 participants	50 participants	50 participants	50 participants	50 participants	400 participants
Delete			9 18%	2 4%	7 14%	6 12%	8 16%	4 8%	2 4%	7 14%	45 11.25%
Edit	Repeated a Grade Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	50 participants	50 participants	50 participants	50 participants	50 participants	50 participants	50 participants	50 participants	400 participants
Delete			1 2%	3 6%	1 2%	2 4%	1 2%	3 6%	4 8%	3 6%	18 4.5%

Percentages are automatically calculated when "Count of Participants" is the Measure Type. Displaying them is optional.

SMART

Baseline Measures Overview

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Arms/groups are presented according to the randomization of participants in stage 1 and show how evenly participants were distributed when they were randomized.

Arm/Group Title		Stage 1: Usual Post-Adoption Follow-up (UF)	Stage 1: Adoption-Specific Family Counseling (ASFC)	Total	
Edit	Arm/Group Description ▼ Arm/Group Description	The adoption caseworker provided 12 weekly post adoption visits to record information about the adolescent's nutrition and growth, activities, and adjustment to school and the new family. The caseworker provided educational materials to the parents and general advice about adolescent development and parenting techniques for adolescents.	A licensed clinical social worker provided 12 weekly trauma-informed adoption counseling sessions for the adopted adolescent with his or her new parents and new siblings if applicable. Counseling aimed to educate parents about the best parenting practices for healing traumatized adolescents and the best ways to handle their behavioral issues.		
Edit	Overall Number of Baseline Participants	138	138	276	
	► Baseline Analysis Population Description	Includes all participants who started stage 1			
Edit Delete	Age, Continuous Mean (Standard Deviation) Unit of measure: years	138 participants 13.9 (1.9)	138 participants 14.2 (2.5)	276 participants 14.1 (2.2)	
Edit Delete	Sex: Female, Male Measure Type: Count of Participants Unit of measure: participants	138 participants	138 participants	276 participants	
	Female	76 55.07%	68 49.28%	144 52.17%	
	Male	62 44.93%	70 50.72%	132 47.83%	
Edit Delete	Ethnicity (NIH/OMB) Measure Type: Count of Participants Unit of measure: participants	138 participants	138 participants	276 participants	
	Hispanic or Latino	0 0%	0 0%	0 0%	
	Not Hispanic or Latino	138 100%	138 100%	276 100%	
	Unknown or Not Reported	0 0%	0 0%	0 0%	
Edit Delete	Race (NIH/OMB) Measure Type: Count of Participants Unit of measure: participants	138 participants	138 participants	276 participants	
	American Indian or Alaska Native	1 0.72%	0 0%	1 0.36%	
	Asian	88 63.77%	91 65.94%	179 64.86%	
	Native Hawaiian or Other Pacific Islander	0 0%	0 0%	0 0%	
	Black or African American	43 31.16%	40 28.99%	83 30.07%	
	White	6 4.35%	7 5.07%	13 4.71%	

Data for each arm/group and for the overall population are required.

Percentages are automatically calculated when "Count of Participants" is the Measure Type. Displaying them is optional.

SMART

Edit	Region of Enrollment	Number Analyzed	138 participants	138 participants	276 participants
Delete	Measure Type: Count of Participants				
	Unit of measure: participants				
	United States		138 100%	138 100%	276 100%
Edit	Friends and Family Interview (FFI) Attachment Classification [1, 2]				
Delete	Measure Type: Number				
	Unit of measure: Percentage of Participants				
	Number Analyzed		100 participants	100 participants	200 participants
			35	38	36.5
		[1] Measure Description: The FFI is a semi-structured interview used to classify adolescent attachment to adoptive parents as secure (best), insecure/ambivalent, insecure/avoidant, or disorganized (worst). The percentage of participants with either secure or insecure ordered (insecure/ambivalent or insecure/avoidant) attachment is reported.			
		[2] Measure Analysis Population Description: This assessment is reported for participants who completed stage 2 (outcome measure analysis population).			
Edit	Child Behavior Checklist (CBCL) Score [1, 2]				
Delete	Mean (Standard Deviation)				
	Unit of measure: units on a scale				
	Externalizing Behavior	Number Analyzed	100 participants	100 participants	200 participants
			12.68 (5.30)	11.22 (4.58)	11.95 (5.01)
	Internalizing Behavior	Number Analyzed	100 participants	100 participants	200 participants
			13.61 (5.38)	13.32 (5.14)	13.47 (5.26)
		[1] Measure Description: The Child Behavior Checklist/6-18 (CBCL) was used to assess adolescent behavior. The school-age CBCL is designed for children and adolescents ages 6-18 and includes eight syndrome scales. Three syndrome scales, Anxious/Depressed, Withdrawn/Depressed, and Somatic Complaints, are summed to produce an Internalizing Behavior subscale score ranging from 0 to 64, while two others, Rule Breaking Behavior and Aggressive Behavior, are summed to produce an Externalizing Behavior subscale score ranging from 0 to 70. Higher scores on both subscales indicate more numerous and frequent behavioral problems.			
		[2] Measure Analysis Population Description: This assessment is reported for participants who completed stage 2 (outcome measure analysis population).			

Baseline data relevant to the primary and secondary outcome measures are reported.

The Baseline Measure Description provides the range and directionality of each scale or subscale score.

Analysis populations are adjusted from the Overall Number of Participants Analyzed values to reflect the population used for the related outcome measures, and an explanation is provided in the Measure Analysis Population Description.