Table 14.1.1.1
Participant Accountability and Study Disposition by eGFR, Dosing, and Age Group
Safety Population

	30 – 59 ml/min per 1.73m²			≥60 ml/min per 1.73m²			
	0.1 mg/kg/day (N=5)	0.2 mg/kg/day (N=3)	0.4 mg/kg/day (N=0)	0.1 mg/kg/day (N=8)	0.2 mg/kg/day (N=7)	0.4 mg/kg/day (N=3)	Total (N=26)
Enrolled and Dosed (Safety Population)							
Enrolled and Dosed Participants	5 (100.0%)	3 (100.0%)	0	8 (100.0%)	7 (100.0%)	3 (100.0%)	26 (100.0%)
Protocol Treatment Enrollments (IC1)	3 (60.0%)	1 (33.3%)	0	3 (37.5%)	5 (71.4%)	3 (100.0%)	15 (57.7%)
Standard of Care Enrollments (IC2)	2 (40.0%)	2 (66.7%)	0	5 (62.5%)	2 (28.6%)	0	11 (42.3%)
Full PK Analysis Population							
Protocol Treatment Enrollments (IC1)	2 (40.0%)	1 (33.3%)	0	3 (37.5%)	4 (57.1%)	2 (66.7%)	12 (46.2%)
Standard of Care Enrollments (IC2)	2 (40.0%)	2 (66.7%)	0	5 (62.5%)	1 (14.3%)	0	10 (38.5%)
Status of Participants							
Completed Study	5 (100.0%)	3 (100.0%)	0	8 (100.0%)	5 (71.4%)	2 (66.7%)	23 (88.5%)
Early Termination	0	0	0	0	2 (28.6%)	1 (33.3%)	3 (11.5%)
Reasons for Early Termination							
Lost to follow-up	0	0	0	0	1 (14.3%)	0	1 (3.8%)
Investigator decision	0	0	0	0	1 (14.3%)	0	1 (3.8%)
Termination of study or withdrawal of participant by sponsor	0	0	0	0	0	1 (33.3%)	1 (3.8%)

Note : Enrollment did not open in protocol-defined 2-6 year old age group.

Table 14.1.1.2
Participant Enrollment by Site and Enrollment Group
Safety Population

	30-59 ml/min per 1.73m		≥60 ml/min per 1.73m			
Site	**0.1 mg/kg/day (N=5)**	**0.2 mg/kg/day (N=3)**	**0.1 mg/kg/day (N=8)**	**0.2 mg/kg/day (N=7)**	**0.4 mg/kg/day (N=3)**	**Total (N=26)**
Cincinnati Children's Hospital Medical Center	0	0	0	1 (100.0%)	0	1 (100.0%)
Childrens Mercy Hospital	0	0	0	1 (50.0%)	1 (50.0%)	2 (100.0%)
Emory University	0	1 (11.1%)	4 (44.4%)	3 (33.3%)	1 (11.1%)	9 (100.0%)
New York University Medical Center	2 (50.0%)	0	1 (25.0%)	1 (25.0%)	0	4 (100.0%)
University of Alabama	1 (25.0%)	1 (25.0%)	2 (50.0%)	0	0	4 (100.0%)
University of Arkansas	0	1 (50.0%)	0	0	1 (50.0%)	2 (100.0%)
University of Michigan	2 (50.0%)	0	1 (25.0%)	1 (25.0%)	0	4 (100.0%)

Note: Denominator is the number of participants enrolled at each site.

Table 14.1.2.1.1
Demographic and Baseline Summary by Enrollment Group
Safety Population

	30-59 ml/min per 1.73m		≥60 ml/min per 1.73m			
	0.1 mg/kg/day (N=5)	0.2 mg/kg/day (N=3)	0.1 mg/kg/day (N=8)	0.2 mg/kg/day (N=7)	0.4 mg/kg/day (N=3)	Total (N=26)
Age at First Study Dose (Years)						
N	5	3	8	7	3	26
Mean (SD)	14.7 (1.6)	12.2 (3.1)	15.0 (2.6)	13.7 (3.0)	10.5 (3.0)	13.7 (2.8)
Median (Min,Max)	14.2 (13.1 , 16.9)	12.1 (9.1 , 15.4)	15.6 (11.0 , 17.7)	15.0 (9.6 , 16.5)	12.0 (7.0 , 12.4)	14.5 (7.0 , 17.7)
Height at Baseline (cm)						
N	5	3	8	7	3	26
Mean (SD)	151.0 (16.0)	139.4 (37.0)	147.8 (22.8)	147.7 (17.7)	126.7 (15.2)	145.0 (21.1)
Median (Min,Max)	151.0 (130.4 , 170.8)	155.6 (97.0 , 165.5)	148.0 (107.7 , 181.5)	157.1 (122.0 , 164.7)	125.6 (112.1 , 142.4)	148.0 (97.0 , 181.5)
Height at Baseline (Percentile)						
N	5	3	8	7	3	26
Mean (SD)	15.5 (19.8)	33.2 (40.0)	18.7 (27.4)	8.9 (7.7)	4.8 (5.8)	15.5 (22.0)
Median (Min,Max)	3.7 (<0.1 , 44.8)	22.1 (<0.1 , 77.7)	3.8 (<0.1 , 77.9)	5.5 (0.3 , 22.9)	3.2 (<0.1 , 11.2)	5.0 (<0.1 , 77.9)
Weight at Baseline (kg)						
N	5	3	8	7	3	26
Mean (SD)	65.1 (18.6)	57.0 (47.4)	50.7 (17.3)	50.2 (13.2)	26.4 (6.6)	51.3 (21.9)
Median (Min,Max)	56.9 (53.0 , 97.9)	47.2 (15.2 , 108.5)	50.4 (19.7 , 75.7)	53.9 (29.4 , 62.0)	24.8 (20.7 , 33.7)	53.2 (15.2 , 108.5)
Weight at Baseline (Percentile)						
N	5	3	8	7	3	26

Note: BMI categories- underweight is <5th percentile, healthy weight is between 5th and 85th percentile, overweight is between 85th and 95th percentile and obese is >95th percentile.
BMI is not evaluated in children <2 years of age.

Table 14.1.2.1.1
Demographic and Baseline Summary by Enrollment Group
Safety Population

	30-59 ml/min per 1.73m		≥60 ml/min per 1.73m			
	0.1 mg/kg/day (N=5)	0.2 mg/kg/day (N=3)	0.1 mg/kg/day (N=8)	0.2 mg/kg/day (N=7)	0.4 mg/kg/day (N=3)	Total (N=26)
Mean (SD)	76.4 (19.5)	58.2 (51.9)	43.0 (37.6)	51.3 (23.6)	10.3 (10.3)	49.6 (34.2)
Median (Min,Max)	82.7 (51.7 , 98.1)	74.7 (<0.1 , 99.8)	46.8 (<0.1 , 99.4)	55.9 (15.0 , 92.3)	10.3 (<0.1 , 20.6)	56.1 (<0.1 , 99.8)
BMI at Baseline (kg/m²)						
N	5	3	8	7	3	26
Mean (SD)	28.6 (6.4)	25.1 (12.7)	22.8 (5.8)	22.7 (3.2)	16.3 (0.5)	23.4 (6.6)
Median (Min,Max)	28.6 (21.4 , 36.4)	19.5 (16.2 , 39.6)	22.0 (17.0 , 35.8)	22.8 (18.5 , 28.1)	16.5 (15.7 , 16.6)	22.3 (15.7 , 39.6)
BMI at Baseline (Percentile)						
N	5	3	8	7	3	26
Mean (SD)	89.4 (15.1)	73.7 (25.4)	56.8 (35.9)	77.0 (22.1)	37.1 (30.9)	68.2 (30.3)
Median (Min,Max)	97.9 (64.0 , 99.3)	72.4 (48.9 , 99.6)	60.2 (3.1 , 99.5)	80.8 (31.9 , 98.1)	24.9 (14.2 , 72.3)	74.4 (3.1 , 99.6)
BMI at Baseline						
Underweight	0	0	1 (12.5%)	0	0	1 (3.8%)
Healthy Weight	1 (20.0%)	2 (66.7%)	5 (62.5%)	4 (57.1%)	3 (100.0%)	15 (57.7%)
Overweight	1 (20.0%)	0	0	1 (14.3%)	0	2 (7.7%)
Obese	3 (60.0%)	1 (33.3%)	2 (25.0%)	2 (28.6%)	0	8 (30.8%)
Number of Transplants						
N	5	3	8	7	3	26
Mean (SD)	1.0 (0.0)	1.0 (0.0)	1.0 (0.0)	1.0 (0.0)	1.0 (0.0)	1.0 (0.0)

Note: BMI categories- underweight is <5th percentile, healthy weight is between 5th and 85th percentile, overweight is between 85th and 95th percentile and obese is >95th percentile.
BMI is not evaluated in children <2 years of age.

Table 14.1.2.1.1
Demographic and Baseline Summary by Enrollment Group
Safety Population

	30-59 ml/min per 1.73m		≥60 ml/min per 1.73m			
	0.1 mg/kg/day (N=5)	**0.2 mg/kg/day (N=3)**	**0.1 mg/kg/day (N=8)**	**0.2 mg/kg/day (N=7)**	**0.4 mg/kg/day (N=3)**	**Total (N=26)**
Median (Min,Max)	1.0 (1.0 , 1.0)	1.0 (1.0 , 1.0)	1.0 (1.0 , 1.0)	1.0 (1.0 , 1.0)	1.0 (1.0 , 1.0)	1.0 (1.0 , 1.0)
Time from recent Transplant (Months)						
N	5	3	8	7	3	26
Mean (SD)	80.6 (73.4)	70.7 (51.8)	42.9 (34.5)	55.0 (42.0)	50.3 (69.0)	57.5 (49.2)
Median (Min,Max)	59.0 (7.0 , 175.0)	53.0 (30.0 , 129.0)	30.0 (11.0 , 111.0)	36.0 (11.0 , 109.0)	13.0 (8.0 , 130.0)	36.0 (7.0 , 175.0)
Screening eGFR						
N	5	3	8	7	3	26
Mean (SD)	41.4 (9.3)	44.6 (13.3)	82.4 (15.9)	77.3 (14.1)	91.9 (13.5)	69.9 (22.9)
Median (Min,Max)	38.8 (30.9 , 51.6)	52.0 (29.2 , 52.6)	81.3 (62.5 , 111.2)	74.7 (60.5 , 98.2)	94.9 (77.2 , 103.7)	72.1 (29.2 , 111.2)
Gender						
Male	3 (60.0%)	3 (100.0%)	5 (62.5%)	5 (71.4%)	2 (66.7%)	18 (69.2%)
Female	2 (40.0%)	0	3 (37.5%)	2 (28.6%)	1 (33.3%)	8 (30.8%)
Participant Ethnicity						
Hispanic or Latino	2 (40.0%)	1 (33.3%)	1 (12.5%)	1 (14.3%)	0	5 (19.2%)
Not Hispanic or Latino	3 (60.0%)	2 (66.7%)	7 (87.5%)	6 (85.7%)	3 (100.0%)	21 (80.8%)
Participant Race						

Note: BMI categories- underweight is <5th percentile, healthy weight is between 5th and 85th percentile, overweight is between 85th and 95th percentile and obese is >95th percentile.
BMI is not evaluated in children <2 years of age.

Table 14.1.2.1.1
Demographic and Baseline Summary by Enrollment Group
Safety Population

	30-59 ml/min per 1.73m		≥60 ml/min per 1.73m			
	0.1 mg/kg/day (N=5)	**0.2 mg/kg/day (N=3)**	**0.1 mg/kg/day (N=8)**	**0.2 mg/kg/day (N=7)**	**0.4 mg/kg/day (N=3)**	**Total (N=26)**
White or Caucasian	3 (60.0%)	1 (33.3%)	4 (50.0%)	2 (28.6%)	3 (100.0%)	13 (50.0%)
Black or African American	0	1 (33.3%)	3 (37.5%)	3 (42.9%)	0	7 (26.9%)
Asian	0	0	0	1 (14.3%)	0	1 (3.8%)
American Indian or Alaska Native	0	1 (33.3%)	0	0	0	1 (3.8%)
Not reported	2 (40.0%)	0	1 (12.5%)	1 (14.3%)	0	4 (15.4%)
Tanner Stage at Baseline						
Not Reported	2 (40.0%)	0	3 (37.5%)	0	0	5 (19.2%)
Stage I	0	1 (33.3%)	0	3 (42.9%)	2 (66.7%)	6 (23.1%)
Stage II	0	0	2 (25.0%)	0	1 (33.3%)	3 (11.5%)
Stage III	0	0	0	1 (14.3%)	0	1 (3.8%)
Stage IV	2 (40.0%)	1 (33.3%)	1 (12.5%)	2 (28.6%)	0	6 (23.1%)
Stage V	1 (20.0%)	1 (33.3%)	2 (25.0%)	1 (14.3%)	0	5 (19.2%)

Note: BMI categories- underweight is <5th percentile, healthy weight is between 5th and 85th percentile, overweight is between 85th and 95th percentile and obese is >95th percentile.
BMI is not evaluated in children <2 years of age.

Table 14.1.2.1.2.1
Demographic and Baseline Summary by Enrollment Group
Safety Population - IC1

	30-59 ml/min per 1.73m		≥60 ml/min per 1.73m			
	0.1 mg/kg/day (N=3)	0.2 mg/kg/day (N=1)	0.1 mg/kg/day (N=3)	0.2 mg/kg/day (N=5)	0.4 mg/kg/day (N=3)	Total (N=15)
Age at First Study Dose (Years)						
N	3	1	3	5	3	15
Mean (SD)	14.4 (1.1)	15.4	14.2 (2.7)	14.0 (2.6)	10.5 (3.0)	13.5 (2.7)
Median (Min,Max)	14.2 (13.5 , 15.6)	15.4	14.8 (11.2 , 16.6)	15.0 (10.3 , 16.4)	12.0 (7.0 , 12.4)	14.2 (7.0 , 16.6)
Height at Baseline (cm)						
N	3	1	3	5	3	15
Mean (SD)	147.6 (15.8)	165.5	147.0 (17.7)	149.4 (17.4)	126.7 (15.2)	145.1 (17.6)
Median (Min,Max)	151.0 (130.4 , 161.5)	165.5	145.0 (130.4 , 165.7)	157.1 (122.0 , 164.7)	125.6 (112.1 , 142.4)	145.0 (112.1 , 165.7)
Height at Baseline (Percentile)						
N	3	1	3	5	3	15
Mean (SD)	16.2 (24.9)	22.1	12.2 (19.3)	10.6 (8.7)	4.8 (5.8)	11.7 (13.8)
Median (Min,Max)	3.7 (<0.1 , 44.8)	22.1	2.0 (0.3 , 34.5)	9.8 (0.3 , 22.9)	3.2 (<0.1 , 11.2)	5.2 (<0.1 , 44.8)
Weight at Baseline (kg)						
N	3	1	3	5	3	15
Mean (SD)	56.9 (4.5)	108.5	45.8 (5.2)	52.1 (10.7)	26.4 (6.6)	50.4 (20.6)
Median (Min,Max)	55.9 (53.0 , 61.9)	108.5	44.4 (41.4 , 51.6)	53.9 (34.0 , 62.0)	24.8 (20.7 , 33.7)	53.0 (20.7 , 108.5)
Weight at Baseline (Percentile)						
N	3	1	3	5	3	15

Note: BMI categories- underweight is <5th percentile, healthy weight is between 5th and 85th percentile, overweight is between 85th and 95th percentile and obese is >95th percentile.
BMI is not evaluated in children <2 years of age.

Table 14.1.2.1.2.1
Demographic and Baseline Summary by Enrollment Group
Safety Population - IC1

	30-59 ml/min per 1.73m		≥60 ml/min per 1.73m			
	0.1 mg/kg/day (N=3)	0.2 mg/kg/day (N=1)	0.1 mg/kg/day (N=3)	0.2 mg/kg/day (N=5)	0.4 mg/kg/day (N=3)	Total (N=15)
Mean (SD)	67.1 (19.4)	99.8	35.6 (29.6)	55.4 (27.4)	10.3 (10.3)	47.7 (32.2)
Median (Min,Max)	60.6 (51.7 , 88.9)	99.8	35.3 (6.1 , 65.3)	56.2 (15.0 , 92.3)	10.3 (<0.1 , 20.6)	55.9 (<0.1 , 99.8)
BMI at Baseline (kg/m²)						
N	3	1	3	5	3	15
Mean (SD)	27.0 (8.2)	39.6	21.4 (2.8)	23.3 (3.1)	16.3 (0.5)	23.4 (6.8)
Median (Min,Max)	23.2 (21.4 , 36.4)	39.6	21.1 (18.8 , 24.3)	22.8 (19.6 , 28.1)	16.5 (15.7 , 16.6)	21.8 (15.7 , 39.6)
BMI at Baseline (Percentile)						
N	3	1	3	5	3	15
Mean (SD)	83.4 (17.9)	99.6	62.0 (30.2)	76.4 (27.0)	37.1 (30.9)	68.6 (29.7)
Median (Min,Max)	86.9 (64.0 , 99.3)	99.6	54.9 (36.0 , 95.0)	85.1 (31.9 , 98.1)	24.9 (14.2 , 72.3)	72.3 (14.2 , 99.6)
BMI at Baseline						
Healthy Weight	1 (33.3%)	0	2 (66.7%)	2 (40.0%)	3 (100.0%)	8 (53.3%)
Overweight	1 (33.3%)	0	0	1 (20.0%)	0	2 (13.3%)
Obese	1 (33.3%)	1 (100.0%)	1 (33.3%)	2 (40.0%)	0	5 (33.3%)
Number of Transplants						
N	3	1	3	5	3	15
Mean (SD)	1.0 (0.0)	1.0	1.0 (0.0)	1.0 (0.0)	1.0 (0.0)	1.0 (0.0)
Median (Min,Max)	1.0 (1.0 , 1.0)	1.0	1.0 (1.0 , 1.0)	1.0 (1.0 , 1.0)	1.0 (1.0 , 1.0)	1.0 (1.0 , 1.0)

Note: BMI categories- underweight is <5th percentile, healthy weight is between 5th and 85th percentile, overweight is between 85th and 95th percentile and obese is >95th percentile.
BMI is not evaluated in children <2 years of age.

Table 14.1.2.1.2.1
Demographic and Baseline Summary by Enrollment Group
Safety Population - IC1

	30-59 ml/min per 1.73m		≥60 ml/min per 1.73m			
	0.1 mg/kg/day (N=3)	0.2 mg/kg/day (N=1)	0.1 mg/kg/day (N=3)	0.2 mg/kg/day (N=5)	0.4 mg/kg/day (N=3)	Total (N=15)
Time from recent Transplant (Months)						
N	3	1	3	5	3	15
Mean (SD)	29.7 (26.6)	30.0	65.3 (48.7)	37.8 (36.0)	50.3 (69.0)	43.7 (40.9)
Median (Min,Max)	23.0 (7.0 , 59.0)	30.0	71.0 (14.0 , 111.0)	31.0 (11.0 , 99.0)	13.0 (8.0 , 130.0)	30.0 (7.0 , 130.0)
Screening eGFR						
N	3	1	3	5	3	15
Mean (SD)	38.9 (10.5)	52.6	79.5 (5.3)	82.2 (13.5)	91.9 (13.5)	73.0 (22.2)
Median (Min,Max)	35.1 (30.9 , 50.8)	52.6	76.9 (76.0 , 85.6)	84.0 (63.6 , 98.2)	94.9 (77.2 , 103.7)	76.9 (30.9 , 103.7)
Gender						
Male	1 (33.3%)	1 (100.0%)	1 (33.3%)	4 (80.0%)	2 (66.7%)	9 (60.0%)
Female	2 (66.7%)	0	2 (66.7%)	1 (20.0%)	1 (33.3%)	6 (40.0%)
Participant Ethnicity						
Hispanic or Latino	2 (66.7%)	0	0	0	0	2 (13.3%)
Not Hispanic or Latino	1 (33.3%)	1 (100.0%)	3 (100.0%)	5 (100.0%)	3 (100.0%)	13 (86.7%)
Participant Race						
White or Caucasian	1 (33.3%)	0	0	1 (20.0%)	3 (100.0%)	5 (33.3%)

Note: BMI categories- underweight is <5th percentile, healthy weight is between 5th and 85th percentile, overweight is between 85th and 95th percentile and obese is >95th percentile.
BMI is not evaluated in children <2 years of age.

Table 14.1.2.1.2.1
Demographic and Baseline Summary by Enrollment Group
Safety Population - IC1

	30-59 ml/min per 1.73m		≥60 ml/min per 1.73m			
	0.1 mg/kg/day (N=3)	0.2 mg/kg/day (N=1)	0.1 mg/kg/day (N=3)	0.2 mg/kg/day (N=5)	0.4 mg/kg/day (N=3)	Total (N=15)
Black or African American	0	1 (100.0%)	3 (100.0%)	3 (60.0%)	0	7 (46.7%)
Asian	0	0	0	1 (20.0%)	0	1 (6.7%)
Not reported	2 (66.7%)	0	0	0	0	2 (13.3%)
Tanner Stage at Baseline						
Not Reported	0	0	2 (66.7%)	0	0	2 (13.3%)
Stage I	0	0	0	2 (40.0%)	2 (66.7%)	4 (26.7%)
Stage II	0	0	0	0	1 (33.3%)	1 (6.7%)
Stage III	0	0	0	1 (20.0%)	0	1 (6.7%)
Stage IV	2 (66.7%)	0	0	1 (20.0%)	0	3 (20.0%)
Stage V	1 (33.3%)	1 (100.0%)	1 (33.3%)	1 (20.0%)	0	4 (26.7%)

Note: BMI categories- underweight is <5th percentile, healthy weight is between 5th and 85th percentile, overweight is between 85th and 95th percentile and obese is >95th percentile.
BMI is not evaluated in children <2 years of age.

Table 14.1.2.1.2.2
Demographic and Baseline Summary by Enrollment Group
Safety Population - IC2

	30-59 ml/min per 1.73m		≥60 ml/min per 1.73m		
	0.1 mg/kg/day (N=2)	0.2 mg/kg/day (N=2)	0.1 mg/kg/day (N=5)	0.2 mg/kg/day (N=2)	Total (N=11)
Age at First Study Dose (Years)					
N	2	2	5	2	11
Mean (SD)	15.0 (2.7)	10.6 (2.2)	15.4 (2.7)	13.0 (4.9)	14.0 (3.2)
Median (Min,Max)	15.0 (13.1 , 16.9)	10.6 (9.1 , 12.1)	16.3 (11.0 , 17.7)	13.0 (9.6 , 16.5)	14.9 (9.1 , 17.7)
Height at Baseline (cm)					
N	2	2	5	2	11
Mean (SD)	156.0 (21.0)	126.3 (41.4)	148.2 (27.4)	143.6 (24.9)	144.8 (26.0)
Median (Min,Max)	156.0 (141.1 , 170.8)	126.3 (97.0 , 155.6)	151.0 (107.7 , 181.5)	143.6 (126.0 , 161.2)	151.0 (97.0 , 181.5)
Height at Baseline (Percentile)					
N	2	2	5	2	11
Mean (SD)	14.5 (18.0)	38.8 (54.9)	22.7 (32.8)	4.7 (1.2)	20.9 (29.8)
Median (Min,Max)	14.5 (1.8 , 27.3)	38.8 (<0.1 , 77.7)	4.7 (<0.1 , 77.9)	4.7 (3.9 , 5.5)	4.7 (<0.1 , 77.9)
Weight at Baseline (kg)					
N	2	2	5	2	11
Mean (SD)	77.4 (29.0)	31.2 (22.6)	53.7 (21.9)	45.7 (23.1)	52.4 (24.6)
Median (Min,Max)	77.4 (56.9 , 97.9)	31.2 (15.2 , 47.2)	54.0 (19.7 , 75.7)	45.7 (29.4 , 62.0)	54.0 (15.2 , 97.9)
Weight at Baseline (Percentile)					
N	2	2	5	2	11

Note: BMI categories- underweight is <5th percentile, healthy weight is between 5th and 85th percentile, overweight is between 85th and 95th percentile and obese is >95th percentile.
BMI is not evaluated in children <2 years of age.

Table 14.1.2.1.2.2
Demographic and Baseline Summary by Enrollment Group
Safety Population - IC2

	30-59 ml/min per 1.73m		≥60 ml/min per 1.73m		
	0.1 mg/kg/day (N=2)	0.2 mg/kg/day (N=2)	0.1 mg/kg/day (N=5)	0.2 mg/kg/day (N=2)	Total (N=11)
Mean (SD)	90.4 (10.9)	37.4 (52.8)	47.5 (44.5)	41.2 (6.8)	52.3 (38.2)
Median (Min,Max)	90.4 (82.7 , 98.1)	37.4 (<0.1 , 74.7)	58.4 (<0.1 , 99.4)	41.2 (36.4 , 46.1)	58.4 (<0.1 , 99.4)
BMI at Baseline (kg/m²)					
N	2	2	5	2	11
Mean (SD)	31.1 (3.5)	17.8 (2.4)	23.7 (7.3)	21.2 (3.8)	23.5 (6.6)
Median (Min,Max)	31.1 (28.6 , 33.6)	17.8 (16.2 , 19.5)	23.0 (17.0 , 35.8)	21.2 (18.5 , 23.9)	23.0 (16.2 , 35.8)
BMI at Baseline (Percentile)					
N	2	2	5	2	11
Mean (SD)	98.4 (0.7)	60.7 (16.6)	53.7 (42.0)	78.6 (3.1)	67.6 (32.5)
Median (Min,Max)	98.4 (97.9 , 98.9)	60.7 (48.9 , 72.4)	65.5 (3.1 , 99.5)	78.6 (76.4 , 80.8)	76.4 (3.1 , 99.5)
BMI at Baseline					
Underweight	0	0	1 (20.0%)	0	1 (9.1%)
Healthy Weight	0	2 (100.0%)	3 (60.0%)	2 (100.0%)	7 (63.6%)
Obese	2 (100.0%)	0	1 (20.0%)	0	3 (27.3%)
Number of Transplants					
N	2	2	5	2	11
Mean (SD)	1.0 (0.0)	1.0 (0.0)	1.0 (0.0)	1.0 (0.0)	1.0 (0.0)
Median (Min,Max)	1.0 (1.0 , 1.0)	1.0 (1.0 , 1.0)	1.0 (1.0 , 1.0)	1.0 (1.0 , 1.0)	1.0 (1.0 , 1.0)

Note: BMI categories- underweight is <5th percentile, healthy weight is between 5th and 85th percentile, overweight is between 85th and 95th percentile and obese is >95th percentile.
BMI is not evaluated in children <2 years of age.

Table 14.1.2.1.2.2
Demographic and Baseline Summary by Enrollment Group
Safety Population - IC2

	30-59 ml/min per 1.73m		≥60 ml/min per 1.73m		
	0.1 mg/kg/day (N=2)	0.2 mg/kg/day (N=2)	0.1 mg/kg/day (N=5)	0.2 mg/kg/day (N=2)	Total (N=11)
Time from recent Transplant (Months)					
N	2	2	5	2	11
Mean (SD)	157.0 (25.5)	91.0 (53.7)	29.4 (16.9)	98.0 (15.6)	76.3 (55.1)
Median (Min,Max)	157.0 (139.0 , 175.0)	91.0 (53.0 , 129.0)	24.0 (11.0 , 55.0)	98.0 (87.0 , 109.0)	55.0 (11.0 , 175.0)
Screening eGFR					
N	2	2	5	2	11
Mean (SD)	45.2 (9.1)	40.6 (16.1)	84.2 (20.5)	65.0 (6.3)	65.7 (24.2)
Median (Min,Max)	45.2 (38.8 , 51.6)	40.6 (29.2 , 52.0)	87.4 (62.5 , 111.2)	65.0 (60.5 , 69.4)	62.5 (29.2 , 111.2)
Gender					
Male	2 (100.0%)	2 (100.0%)	4 (80.0%)	1 (50.0%)	9 (81.8%)
Female	0	0	1 (20.0%)	1 (50.0%)	2 (18.2%)
Participant Ethnicity					
Hispanic or Latino	0	1 (50.0%)	1 (20.0%)	1 (50.0%)	3 (27.3%)
Not Hispanic or Latino	2 (100.0%)	1 (50.0%)	4 (80.0%)	1 (50.0%)	8 (72.7%)
Participant Race					
White or Caucasian	2 (100.0%)	1 (50.0%)	4 (80.0%)	1 (50.0%)	8 (72.7%)

Note: BMI categories- underweight is <5th percentile, healthy weight is between 5th and 85th percentile, overweight is between 85th and 95th percentile and obese is >95th percentile.
BMI is not evaluated in children <2 years of age.

Table 14.1.2.1.2.2
Demographic and Baseline Summary by Enrollment Group
Safety Population - IC2

	30-59 ml/min per 1.73m		≥60 ml/min per 1.73m		
	0.1 mg/kg/day (N=2)	0.2 mg/kg/day (N=2)	0.1 mg/kg/day (N=5)	0.2 mg/kg/day (N=2)	Total (N=11)
American Indian or Alaska Native	0	1 (50.0%)	0	0	1 (9.1%)
Not reported	0	0	1 (20.0%)	1 (50.0%)	2 (18.2%)
Tanner Stage at Baseline					
Not Reported	2 (100.0%)	0	1 (20.0%)	0	3 (27.3%)
Stage I	0	1 (50.0%)	0	1 (50.0%)	2 (18.2%)
Stage II	0	0	2 (40.0%)	0	2 (18.2%)
Stage IV	0	1 (50.0%)	1 (20.0%)	1 (50.0%)	3 (27.3%)
Stage V	0	0	1 (20.0%)	0	1 (9.1%)
Months on Lisinopril at Screning Visit					
N	2	2	5	1	10
Mean (SD)	1.5 (0.7)	15.5 (13.4)	27.6 (30.5)	1.0	17.3 (24.0)
Median (Min,Max)	1.5 (1.0 , 2.0)	15.5 (6.0 , 25.0)	20.0 (1.0 , 80.0)	1.0	10.0 (1.0 , 80.0)

Note: BMI categories- underweight is <5th percentile, healthy weight is between 5th and 85th percentile, overweight is between 85th and 95th percentile and obese is >95th percentile.
BMI is not evaluated in children <2 years of age.

Table 14.1.2.2.1
Summary of Medical History by System Organ Class, Preferred Term and by Enrollment and IC Group
Safety Population - IC1

	30 – 59 ml/min per 1.73m²				≥ 60 ml/min per 1.73m²							
	0.1 mg/kg/day (N=3)		0.2 mg/kg/day (N=1)		0.1 mg/kg/day (N=3)		0.2 mg/kg/day (N=5)		0.4 mg/kg/day (N=3)		Total (N=15)	
System Organ Class Preferred Term	Participants With Medical History N (%)	Total Medical History N	Participants With Medical History N (%)	Total Medical History N	Participants With Medical History N (%)	Total Medical History N	Participants With Medical History N (%)	Total Medical History N	Participants With Medical History N (%)	Total Medical History N	Participants With Medical History N (%)	Total Medical History N
Blood and lymphatic system disorders	2 (66.7%)	4	1 (100%)	2	0	0	0	0	2 (66.7%)	3	5 (33.3%)	9
Anaemia	1 (33.3%)	1	1 (100%)	1	0	0	0	0	1 (33.3%)	1	3 (20%)	3
Coagulopathy	1 (33.3%)	1	0	0	0	0	0	0	0	0	1 (6.7%)	1
Haemolytic anaemia	0	0	0	0	0	0	0	0	1 (33.3%)	1	1 (6.7%)	1
Haemolytic uraemic syndrome	1 (33.3%)	1	0	0	0	0	0	0	0	0	1 (6.7%)	1
Methaemoglobinaemia	0	0	0	0	0	0	0	0	1 (33.3%)	1	1 (6.7%)	1
Neutropenia	1 (33.3%)	1	0	0	0	0	0	0	0	0	1 (6.7%)	1
Thrombocytopenia	0	0	1 (100%)	1	0	0	0	0	0	0	1 (6.7%)	1
Cardiac disorders	0	0	0	0	0	0	0	0	2 (66.7%)	2	2 (13.3%)	2
Cardiac aneurysm	0	0	0	0	0	0	0	0	1 (33.3%)	1	1 (6.7%)	1
Congestive cardiomyopathy	0	0	0	0	0	0	0	0	1 (33.3%)	1	1 (6.7%)	1
Congenital, familial and genetic disorders	1 (33.3%)	1	1 (100%)	2	2 (66.7%)	2	3 (60%)	5	3 (100%)	6	10 (66.7%)	16
Alagille syndrome	0	0	0	0	0	0	1 (20%)	1	0	0	1 (6.7%)	1
Alport's syndrome	0	0	0	0	1 (33.3%)	1	0	0	0	0	1 (6.7%)	1
Atrial septal defect	0	0	0	0	0	0	0	0	1 (33.3%)	2	1 (6.7%)	2

Note: The percentages are based on the total number of participants in each enrollment group or total.
Participants are counted once at each System Organ Class and Preferred Term levels.

Table 14.1.2.2.1
Summary of Medical History by System Organ Class, Preferred Term and by Enrollment and IC Group
Safety Population - IC1

	30 – 59 ml/min per 1.73m²				≥ 60 ml/min per 1.73m²							
	0.1 mg/kg/day (N=3)		0.2 mg/kg/day (N=1)		0.1 mg/kg/day (N=3)		0.2 mg/kg/day (N=5)		0.4 mg/kg/day (N=3)		Total (N=15)	
System Organ Class Preferred Term	Participants With Medical History N (%)	Total Medical History N	Participants With Medical History N (%)	Total Medical History N	Participants With Medical History N (%)	Total Medical History N	Participants With Medical History N (%)	Total Medical History N	Participants With Medical History N (%)	Total Medical History N	Participants With Medical History N (%)	Total Medical History N
Congenital absence of bile ducts	0	0	0	0	0	0	1 (20%)	1	0	0	1 (6.7%)	1
Congenital anomaly	0	0	1 (100%)	1	0	0	0	0	0	0	1 (6.7%)	1
Congenital urinary tract obstruction	0	0	0	0	1 (33.3%)	1	0	0	0	0	1 (6.7%)	1
Congenital uterine anomaly	1 (33.3%)	1	0	0	0	0	0	0	0	0	1 (6.7%)	1
Cystinosis	0	0	0	0	0	0	0	0	1 (33.3%)	1	1 (6.7%)	1
Eagle Barrett syndrome	0	0	0	0	0	0	0	0	1 (33.3%)	1	1 (6.7%)	1
Hypospadias	0	0	0	0	0	0	0	0	1 (33.3%)	1	1 (6.7%)	1
Pyloric stenosis	0	0	0	0	0	0	0	0	1 (33.3%)	1	1 (6.7%)	1
Renal dysplasia	0	0	1 (100%)	1	0	0	1 (20%)	1	0	0	2 (13.3%)	2
Urethral valves	0	0	0	0	0	0	1 (20%)	1	0	0	1 (6.7%)	1
Ventricular septal defect	0	0	0	0	0	0	1 (20%)	1	0	0	1 (6.7%)	1
Ear and labyrinth disorders	0	0	0	0	0	0	1 (20%)	1	0	0	1 (6.7%)	1
Tympanic membrane perforation	0	0	0	0	0	0	1 (20%)	1	0	0	1 (6.7%)	1
Endocrine disorders	1 (33.3%)	1	0	0	0	0	0	0	1 (33.3%)	1	2 (13.3%)	2
Hypothyroidism	0	0	0	0	0	0	0	0	1 (33.3%)	1	1 (6.7%)	1

Note: The percentages are based on the total number of participants in each enrollment group or total.
Participants are counted once at each System Organ Class and Preferred Term levels.

Table 14.1.2.2.1
Summary of Medical History by System Organ Class, Preferred Term and by Enrollment and IC Group
Safety Population - IC1

	30 – 59 ml/min per 1.73m²				≥ 60 ml/min per 1.73m²							
	0.1 mg/kg/day (N=3)		0.2 mg/kg/day (N=1)		0.1 mg/kg/day (N=3)		0.2 mg/kg/day (N=5)		0.4 mg/kg/day (N=3)		Total (N=15)	
System Organ Class Preferred Term	Participants With Medical History N (%)	Total Medical History N	Participants With Medical History N (%)	Total Medical History N	Participants With Medical History N (%)	Total Medical History N	Participants With Medical History N (%)	Total Medical History N	Participants With Medical History N (%)	Total Medical History N	Participants With Medical History N (%)	Total Medical History N
Precocious puberty	1 (33.3%)	1	0	0	0	0	0	0	0	0	1 (6.7%)	1
Eye disorders	0	0	0	0	0	0	0	0	1 (33.3%)	1	1 (6.7%)	1
Dacryostenosis acquired	0	0	0	0	0	0	0	0	1 (33.3%)	1	1 (6.7%)	1
Gastrointestinal disorders	0	0	0	0	0	0	1 (20%)	1	2 (66.7%)	5	3 (20%)	6
Constipation	0	0	0	0	0	0	0	0	1 (33.3%)	1	1 (6.7%)	1
Gastric fistula	0	0	0	0	0	0	0	0	1 (33.3%)	1	1 (6.7%)	1
Gastric perforation	0	0	0	0	0	0	0	0	1 (33.3%)	1	1 (6.7%)	1
Gastrooesophageal reflux disease	0	0	0	0	0	0	1 (20%)	1	1 (33.3%)	1	2 (13.3%)	2
Inguinal hernia	0	0	0	0	0	0	0	0	1 (33.3%)	1	1 (6.7%)	1
Hepatobiliary disorders	0	0	0	0	0	0	1 (20%)	1	1 (33.3%)	1	2 (13.3%)	2
Cholelithiasis	0	0	0	0	0	0	1 (20%)	1	0	0	1 (6.7%)	1
Hyperbilirubinaemia	0	0	0	0	0	0	0	0	1 (33.3%)	1	1 (6.7%)	1
Immune system disorders	1 (33.3%)	1	1 (100%)	2	3 (100%)	3	1 (20%)	1	1 (33.3%)	2	7 (46.7%)	9
Drug hypersensitivity	0	0	0	0	0	0	0	0	1 (33.3%)	1	1 (6.7%)	1

Note: The percentages are based on the total number of participants in each enrollment group or total.
Participants are counted once at each System Organ Class and Preferred Term levels.

Table 14.1.2.2.1
Summary of Medical History by System Organ Class, Preferred Term and by Enrollment and IC Group
Safety Population - IC1

	30 – 59 ml/min per 1.73m²				≥ 60 ml/min per 1.73m²							
	0.1 mg/kg/day (N=3)		0.2 mg/kg/day (N=1)		0.1 mg/kg/day (N=3)		0.2 mg/kg/day (N=5)		0.4 mg/kg/day (N=3)		Total (N=15)	
System Organ Class Preferred Term	Participants With Medical History N (%)	Total Medical History N	Participants With Medical History N (%)	Total Medical History N	Participants With Medical History N (%)	Total Medical History N	Participants With Medical History N (%)	Total Medical History N	Participants With Medical History N (%)	Total Medical History N	Participants With Medical History N (%)	Total Medical History N
Hypersensitivity	0	0	0	0	0	0	1 (20%)	1	0	0	1 (6.7%)	1
Hypogammaglobulinaemia	0	0	0	0	0	0	0	0	1 (33.3%)	1	1 (6.7%)	1
Immunodeficiency	0	0	0	0	2 (66.7%)	2	0	0	0	0	2 (13.3%)	2
Immunosuppression	0	0	0	0	1 (33.3%)	1	0	0	0	0	1 (6.7%)	1
Transplant rejection	1 (33.3%)	1	1 (100%)	2	0	0	0	0	0	0	2 (13.3%)	3
Infections and infestations	0	0	0	0	2 (66.7%)	4	1 (20%)	1	2 (66.7%)	2	5 (33.3%)	7
Cytomegalovirus infection	0	0	0	0	1 (33.3%)	1	0	0	0	0	1 (6.7%)	1
Rhinitis	0	0	0	0	0	0	0	0	1 (33.3%)	1	1 (6.7%)	1
Sepsis	0	0	0	0	0	0	0	0	1 (33.3%)	1	1 (6.7%)	1
Urinary tract infection	0	0	0	0	1 (33.3%)	1	1 (20%)	1	0	0	2 (13.3%)	2
Viraemia	0	0	0	0	2 (66.7%)	2	0	0	0	0	2 (13.3%)	2
Injury, poisoning and procedural complications	0	0	1 (100%)	1	0	0	0	0	1 (33.3%)	2	2 (13.3%)	3
Complications of transplanted kidney	0	0	1 (100%)	1	0	0	0	0	0	0	1 (6.7%)	1
Vascular injury	0	0	0	0	0	0	0	0	1 (33.3%)	1	1 (6.7%)	1
Vascular pseudoaneurysm	0	0	0	0	0	0	0	0	1 (33.3%)	1	1 (6.7%)	1

Note: The percentages are based on the total number of participants in each enrollment group or total.
Participants are counted once at each System Organ Class and Preferred Term levels.

Table 14.1.2.2.1
Summary of Medical History by System Organ Class, Preferred Term and by Enrollment and IC Group
Safety Population - IC1

	30 – 59 ml/min per 1.73m²				≥ 60 ml/min per 1.73m²							
	0.1 mg/kg/day (N=3)		0.2 mg/kg/day (N=1)		0.1 mg/kg/day (N=3)		0.2 mg/kg/day (N=5)		0.4 mg/kg/day (N=3)		Total (N=15)	
System Organ Class Preferred Term	Participants With Medical History N (%)	Total Medical History N	Participants With Medical History N (%)	Total Medical History N	Participants With Medical History N (%)	Total Medical History N	Participants With Medical History N (%)	Total Medical History N	Participants With Medical History N (%)	Total Medical History N	Participants With Medical History N (%)	Total Medical History N
Investigations	0	0	1 (100%)	1	0	0	1 (20%)	1	1 (33.3%)	1	3 (20%)	3
Body height below normal	0	0	0	0	0	0	1 (20%)	1	1 (33.3%)	1	2 (13.3%)	2
Drug level	0	0	1 (100%)	1	0	0	0	0	0	0	1 (6.7%)	1
Metabolism and nutrition disorders	1 (33.3%)	1	1 (100%)	2	1 (33.3%)	2	1 (20%)	1	1 (33.3%)	3	5 (33.3%)	9
Acidosis	0	0	1 (100%)	1	1 (33.3%)	1	0	0	0	0	2 (13.3%)	2
Dyslipidaemia	0	0	0	0	0	0	1 (20%)	1	0	0	1 (6.7%)	1
Hyperkalaemia	0	0	0	0	0	0	0	0	1 (33.3%)	1	1 (6.7%)	1
Hypertriglyceridaemia	0	0	0	0	0	0	0	0	1 (33.3%)	1	1 (6.7%)	1
Hypophosphataemia	0	0	1 (100%)	1	0	0	0	0	0	0	1 (6.7%)	1
Vitamin D deficiency	1 (33.3%)	1	0	0	1 (33.3%)	1	0	0	1 (33.3%)	1	3 (20%)	3
Musculoskeletal and connective tissue disorders	1 (33.3%)	1	0	0	0	0	0	0	0	0	1 (6.7%)	1
Osteodystrophy	1 (33.3%)	1	0	0	0	0	0	0	0	0	1 (6.7%)	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	0	0	0	0	0	0	0	1 (33.3%)	1	1 (6.7%)	1
Congenital cystic kidney disease	0	0	0	0	0	0	0	0	1 (33.3%)	1	1 (6.7%)	1

Note: The percentages are based on the total number of participants in each enrollment group or total.
Participants are counted once at each System Organ Class and Preferred Term levels.

Table 14.1.2.2.1
Summary of Medical History by System Organ Class, Preferred Term and by Enrollment and IC Group
Safety Population - IC1

	30 – 59 ml/min per 1.73m²				≥ 60 ml/min per 1.73m²							
	0.1 mg/kg/day (N=3)		0.2 mg/kg/day (N=1)		0.1 mg/kg/day (N=3)		0.2 mg/kg/day (N=5)		0.4 mg/kg/day (N=3)		Total (N=15)	
System Organ Class Preferred Term	Participants With Medical History N (%)	Total Medical History N	Participants With Medical History N (%)	Total Medical History N	Participants With Medical History N (%)	Total Medical History N	Participants With Medical History N (%)	Total Medical History N	Participants With Medical History N (%)	Total Medical History N	Participants With Medical History N (%)	Total Medical History N
Nervous system disorders	0	0	1 (100%)	2	0	0	1 (20%)	2	1 (33.3%)	1	3 (20%)	5
Altered state of consciousness	0	0	1 (100%)	1	0	0	0	0	0	0	1 (6.7%)	1
Convulsion	0	0	0	0	0	0	1 (20%)	1	0	0	1 (6.7%)	1
Headache	0	0	1 (100%)	1	0	0	0	0	0	0	1 (6.7%)	1
Hemiparesis	0	0	0	0	0	0	1 (20%)	1	0	0	1 (6.7%)	1
Migraine	0	0	0	0	0	0	0	0	1 (33.3%)	1	1 (6.7%)	1
Psychiatric disorders	0	0	0	0	0	0	0	0	1 (33.3%)	1	1 (6.7%)	1
Sleep disorder	0	0	0	0	0	0	0	0	1 (33.3%)	1	1 (6.7%)	1
Renal and urinary disorders	3 (100%)	3	1 (100%)	2	2 (66.7%)	4	4 (80%)	5	3 (100%)	7	13 (86.7%)	21
Focal segmental glomerulosclerosis	0	0	0	0	0	0	0	0	1 (33.3%)	1	1 (6.7%)	1
Glomerulonephritis membranous	0	0	0	0	0	0	1 (20%)	1	0	0	1 (6.7%)	1
Hydronephrosis	0	0	1 (100%)	1	0	0	0	0	1 (33.3%)	1	2 (13.3%)	2
Nephropathy	1 (33.3%)	1	0	0	0	0	0	0	0	0	1 (6.7%)	1
Nephrotic syndrome	0	0	0	0	0	0	0	0	1 (33.3%)	1	1 (6.7%)	1
Proteinuria	0	0	0	0	0	0	1 (20%)	1	0	0	1 (6.7%)	1

Note: The percentages are based on the total number of participants in each enrollment group or total.
Participants are counted once at each System Organ Class and Preferred Term levels.

Table 14.1.2.2.1
Summary of Medical History by System Organ Class, Preferred Term and by Enrollment and IC Group
Safety Population - IC1

	30 – 59 ml/min per 1.73m²				≥ 60 ml/min per 1.73m²							
	0.1 mg/kg/day (N=3)		0.2 mg/kg/day (N=1)		0.1 mg/kg/day (N=3)		0.2 mg/kg/day (N=5)		0.4 mg/kg/day (N=3)		Total (N=15)	
System Organ Class Preferred Term	Participants With Medical History N (%)	Total Medical History N	Participants With Medical History N (%)	Total Medical History N	Participants With Medical History N (%)	Total Medical History N	Participants With Medical History N (%)	Total Medical History N	Participants With Medical History N (%)	Total Medical History N	Participants With Medical History N (%)	Total Medical History N
Renal failure acute	0	0	0	0	1 (33.3%)	1	0	0	0	0	1 (6.7%)	1
Renal failure chronic	1 (33.3%)	1	1 (100%)	1	2 (66.7%)	2	3 (60%)	3	1 (33.3%)	1	8 (53.3%)	8
Renal hypertension	0	0	0	0	0	0	0	0	1 (33.3%)	1	1 (6.7%)	1
Renal tubular acidosis	0	0	0	0	0	0	0	0	1 (33.3%)	1	1 (6.7%)	1
Renal tubular necrosis	0	0	0	0	1 (33.3%)	1	0	0	0	0	1 (6.7%)	1
Ureteric obstruction	0	0	0	0	0	0	0	0	1 (33.3%)	1	1 (6.7%)	1
Urinary tract disorder	1 (33.3%)	1	0	0	0	0	0	0	0	0	1 (6.7%)	1
Respiratory, thoracic and mediastinal disorders	0	0	0	0	1 (33.3%)	1	2 (40%)	2	2 (66.7%)	6	5 (33.3%)	9
Adenoidal hypertrophy	0	0	0	0	0	0	0	0	1 (33.3%)	1	1 (6.7%)	1
Asthma	0	0	0	0	1 (33.3%)	1	1 (20%)	1	1 (33.3%)	1	3 (20%)	3
Cough	0	0	0	0	0	0	0	0	1 (33.3%)	1	1 (6.7%)	1
Diaphragmatic paralysis	0	0	0	0	0	0	0	0	1 (33.3%)	1	1 (6.7%)	1
Hypoxia	0	0	0	0	0	0	1 (20%)	1	0	0	1 (6.7%)	1
Nasal obstruction	0	0	0	0	0	0	0	0	1 (33.3%)	1	1 (6.7%)	1
Rhinorrhoea	0	0	0	0	0	0	0	0	1 (33.3%)	1	1 (6.7%)	1

Note: The percentages are based on the total number of participants in each enrollment group or total.
Participants are counted once at each System Organ Class and Preferred Term levels.

Table 14.1.2.2.1
Summary of Medical History by System Organ Class, Preferred Term and by Enrollment and IC Group
Safety Population - IC1

	30 – 59 ml/min per 1.73m²				≥ 60 ml/min per 1.73m²							
	0.1 mg/kg/day (N=3)		0.2 mg/kg/day (N=1)		0.1 mg/kg/day (N=3)		0.2 mg/kg/day (N=5)		0.4 mg/kg/day (N=3)		Total (N=15)	
System Organ Class Preferred Term	Participants With Medical History N (%)	Total Medical History N	Participants With Medical History N (%)	Total Medical History N	Participants With Medical History N (%)	Total Medical History N	Participants With Medical History N (%)	Total Medical History N	Participants With Medical History N (%)	Total Medical History N	Participants With Medical History N (%)	Total Medical History N
Skin and subcutaneous tissue disorders	1 (33.3%)	1	1 (100%)	1	1 (33.3%)	1	0	0	0	0	3 (20%)	3
Acanthosis nigricans	0	0	1 (100%)	1	0	0	0	0	0	0	1 (6.7%)	1
Acne	1 (33.3%)	1	0	0	1 (33.3%)	1	0	0	0	0	2 (13.3%)	2
Social circumstances	1 (33.3%)	1	0	0	0	0	0	0	0	0	1 (6.7%)	1
Disability	1 (33.3%)	1	0	0	0	0	0	0	0	0	1 (6.7%)	1
Surgical and medical procedures	1 (33.3%)	2	1 (100%)	1	1 (33.3%)	1	2 (40%)	4	1 (33.3%)	5	6 (40%)	13
Catheter placement	0	0	0	0	0	0	0	0	1 (33.3%)	1	1 (6.7%)	1
Gingivectomy	0	0	0	0	0	0	1 (20%)	1	0	0	1 (6.7%)	1
Immunisation	0	0	0	0	0	0	1 (20%)	1	0	0	1 (6.7%)	1
Immunosuppressant drug therapy	1 (33.3%)	1	0	0	0	0	0	0	0	0	1 (6.7%)	1
Inguinal hernia repair	0	0	0	0	0	0	0	0	1 (33.3%)	1	1 (6.7%)	1
Liver transplant	0	0	0	0	0	0	1 (20%)	1	0	0	1 (6.7%)	1
Nephrectomy	0	0	0	0	0	0	0	0	1 (33.3%)	1	1 (6.7%)	1
Omentectomy	0	0	0	0	0	0	0	0	1 (33.3%)	1	1 (6.7%)	1
Pulmonary valve repair	0	0	0	0	0	0	1 (20%)	1	0	0	1 (6.7%)	1

Note: The percentages are based on the total number of participants in each enrollment group or total.
Participants are counted once at each System Organ Class and Preferred Term levels.

Table 14.1.2.2.1
Summary of Medical History by System Organ Class, Preferred Term and by Enrollment and IC Group
Safety Population - IC1

	30 – 59 ml/min per 1.73m²				≥ 60 ml/min per 1.73m²							
	0.1 mg/kg/day (N=3)		0.2 mg/kg/day (N=1)		0.1 mg/kg/day (N=3)		0.2 mg/kg/day (N=5)		0.4 mg/kg/day (N=3)		Total (N=15)	
System Organ Class Preferred Term	Participants With Medical History N (%)	Total Medical History N	Participants With Medical History N (%)	Total Medical History N	Participants With Medical History N (%)	Total Medical History N	Participants With Medical History N (%)	Total Medical History N	Participants With Medical History N (%)	Total Medical History N	Participants With Medical History N (%)	Total Medical History N
Renal transplant	1 (33.3%)	1	1 (100%)	1	1 (33.3%)	1	0	0	0	0	3 (20%)	3
Shoulder operation	0	0	0	0	0	0	0	0	1 (33.3%)	1	1 (6.7%)	1
Vascular disorders	1 (33.3%)	1	1 (100%)	2	2 (66.7%)	2	4 (80%)	5	2 (66.7%)	2	10 (66.7%)	12
Arteriovenous fistula	0	0	0	0	0	0	0	0	1 (33.3%)	1	1 (6.7%)	1
Essential hypertension	0	0	0	0	1 (33.3%)	1	0	0	0	0	1 (6.7%)	1
Hypertension	1 (33.3%)	1	1 (100%)	2	1 (33.3%)	1	4 (80%)	4	1 (33.3%)	1	8 (53.3%)	9
Superior vena cava syndrome	0	0	0	0	0	0	1 (20%)	1	0	0	1 (6.7%)	1

Note: The percentages are based on the total number of participants in each enrollment group or total.
Participants are counted once at each System Organ Class and Preferred Term levels.

Table 14.1.2.2.2
Summary of Medical History by System Organ Class, Preferred Term and by Enrollment and IC Group
Safety Population - IC2

	30 – 59 ml/min per 1.73m²				≥ 60 ml/min per 1.73m²					
	0.1 mg/kg/day (N=2)		0.2 mg/kg/day (N=2)		0.1 mg/kg/day (N=5)		0.2 mg/kg/day (N=2)		Total (N=11)	
System Organ Class Preferred Term	Participants With Medical History N (%)	Total Medical History N	Participants With Medical History N (%)	Total Medical History N	Participants With Medical History N (%)	Total Medical History N	Participants With Medical History N (%)	Total Medical History N	Participants With Medical History N (%)	Total Medical History N
Blood and lymphatic system disorders	1 (50%)	1	0	0	1 (20%)	1	1 (50%)	1	3 (27.3%)	3
Anaemia	0	0	0	0	1 (20%)	1	1 (50%)	1	2 (18.2%)	2
Iron deficiency anaemia	1 (50%)	1	0	0	0	0	0	0	1 (9.1%)	1
Congenital, familial and genetic disorders	1 (50%)	1	2 (100%)	2	3 (60%)	3	1 (50%)	1	7 (63.6%)	7
Bicuspid aortic valve	0	0	1 (50%)	1	0	0	0	0	1 (9.1%)	1
Cerebral palsy	0	0	0	0	1 (20%)	1	0	0	1 (9.1%)	1
Congenital cystic kidney disease	0	0	0	0	1 (20%)	1	1 (50%)	1	2 (18.2%)	2
Renal hypoplasia	1 (50%)	1	0	0	0	0	0	0	1 (9.1%)	1
Urethral valves	0	0	1 (50%)	1	1 (20%)	1	0	0	2 (18.2%)	2
Endocrine disorders	0	0	1 (50%)	1	1 (20%)	1	1 (50%)	2	3 (27.3%)	4
Delayed puberty	0	0	0	0	0	0	1 (50%)	1	1 (9.1%)	1
Growth hormone deficiency	0	0	1 (50%)	1	0	0	0	0	1 (9.1%)	1
Hyperparathyroidism	0	0	0	0	1 (20%)	1	1 (50%)	1	2 (18.2%)	2
Gastrointestinal disorders	0	0	0	0	2 (40%)	3	0	0	2 (18.2%)	3

Note: The percentages are based on the total number of participants in each enrollment group or total.
Participants are counted once at each System Organ Class and Preferred Term levels.

Table 14.1.2.2.2
Summary of Medical History by System Organ Class, Preferred Term and by Enrollment and IC Group
Safety Population - IC2

	30 – 59 ml/min per 1.73m²				≥ 60 ml/min per 1.73m²					
	0.1 mg/kg/day (N=2)		0.2 mg/kg/day (N=2)		0.1 mg/kg/day (N=5)		0.2 mg/kg/day (N=2)		Total (N=11)	
System Organ Class Preferred Term	Participants With Medical History N (%)	Total Medical History N	Participants With Medical History N (%)	Total Medical History N	Participants With Medical History N (%)	Total Medical History N	Participants With Medical History N (%)	Total Medical History N	Participants With Medical History N (%)	Total Medical History N
Constipation	0	0	0	0	2 (40%)	2	0	0	2 (18.2%)	2
Vomiting	0	0	0	0	1 (20%)	1	0	0	1 (9.1%)	1
General disorders and administration site conditions	0	0	0	0	2 (40%)	2	0	0	2 (18.2%)	2
Adverse drug reaction	0	0	0	0	1 (20%)	1	0	0	1 (9.1%)	1
Fatigue	0	0	0	0	1 (20%)	1	0	0	1 (9.1%)	1
Immune system disorders	1 (50%)	1	0	0	1 (20%)	1	0	0	2 (18.2%)	2
Seasonal allergy	0	0	0	0	1 (20%)	1	0	0	1 (9.1%)	1
Transplant rejection	1 (50%)	1	0	0	0	0	0	0	1 (9.1%)	1
Infections and infestations	0	0	2 (100%)	2	3 (60%)	3	2 (100%)	3	7 (63.6%)	8
Cellulitis	0	0	0	0	1 (20%)	1	0	0	1 (9.1%)	1
Clostridium difficile colitis	0	0	0	0	0	0	1 (50%)	1	1 (9.1%)	1
Epstein-Barr virus infection	0	0	0	0	1 (20%)	1	1 (50%)	1	2 (18.2%)	2
Fungal oesophagitis	0	0	1 (50%)	1	0	0	0	0	1 (9.1%)	1
Sinusitis	0	0	0	0	0	0	1 (50%)	1	1 (9.1%)	1
Streptococcal abscess	0	0	0	0	1 (20%)	1	0	0	1 (9.1%)	1

Note: The percentages are based on the total number of participants in each enrollment group or total.
Participants are counted once at each System Organ Class and Preferred Term levels.

Table 14.1.2.2.2
Summary of Medical History by System Organ Class, Preferred Term and by Enrollment and IC Group
Safety Population - IC2

	30 – 59 ml/min per 1.73m²				≥ 60 ml/min per 1.73m²					
	0.1 mg/kg/day (N=2)		0.2 mg/kg/day (N=2)		0.1 mg/kg/day (N=5)		0.2 mg/kg/day (N=2)		Total (N=11)	
System Organ Class Preferred Term	Participants With Medical History N (%)	Total Medical History N	Participants With Medical History N (%)	Total Medical History N	Participants With Medical History N (%)	Total Medical History N	Participants With Medical History N (%)	Total Medical History N	Participants With Medical History N (%)	Total Medical History N
Urinary tract infection	0	0	1 (50%)	1	0	0	0	0	1 (9.1%)	1
Injury, poisoning and procedural complications	0	0	1 (50%)	1	0	0	0	0	1 (9.1%)	1
Wrist fracture	0	0	1 (50%)	1	0	0	0	0	1 (9.1%)	1
Investigations	2 (100%)	2	0	0	3 (60%)	3	1 (50%)	1	6 (54.5%)	6
Body height below normal	1 (50%)	1	0	0	2 (40%)	2	1 (50%)	1	4 (36.4%)	4
Drug level	0	0	0	0	1 (20%)	1	0	0	1 (9.1%)	1
Polyomavirus test positive	1 (50%)	1	0	0	0	0	0	0	1 (9.1%)	1
Metabolism and nutrition disorders	2 (100%)	2	0	0	4 (80%)	7	0	0	6 (54.5%)	9
Diabetes mellitus	0	0	0	0	1 (20%)	1	0	0	1 (9.1%)	1
Hypercholesterolaemia	0	0	0	0	1 (20%)	1	0	0	1 (9.1%)	1
Hypomagnesaemia	0	0	0	0	1 (20%)	1	0	0	1 (9.1%)	1
Hypophosphataemia	0	0	0	0	1 (20%)	1	0	0	1 (9.1%)	1
Metabolic disorder	0	0	0	0	1 (20%)	1	0	0	1 (9.1%)	1
Obesity	1 (50%)	1	0	0	1 (20%)	1	0	0	2 (18.2%)	2
Vitamin D deficiency	1 (50%)	1	0	0	1 (20%)	1	0	0	2 (18.2%)	2

Note: The percentages are based on the total number of participants in each enrollment group or total.
Participants are counted once at each System Organ Class and Preferred Term levels.

Table 14.1.2.2.2
Summary of Medical History by System Organ Class, Preferred Term and by Enrollment and IC Group
Safety Population - IC2

	30 – 59 ml/min per 1.73m²				≥ 60 ml/min per 1.73m²					
	0.1 mg/kg/day (N=2)		0.2 mg/kg/day (N=2)		0.1 mg/kg/day (N=5)		0.2 mg/kg/day (N=2)		Total (N=11)	
System Organ Class Preferred Term	Participants With Medical History N (%)	Total Medical History N	Participants With Medical History N (%)	Total Medical History N	Participants With Medical History N (%)	Total Medical History N	Participants With Medical History N (%)	Total Medical History N	Participants With Medical History N (%)	Total Medical History N
Musculoskeletal and connective tissue disorders	0	0	1 (50%)	2	0	0	0	0	1 (9.1%)	2
Growth retardation	0	0	1 (50%)	1	0	0	0	0	1 (9.1%)	1
Osteochondrosis	0	0	1 (50%)	1	0	0	0	0	1 (9.1%)	1
Psychiatric disorders	0	0	0	0	1 (20%)	1	0	0	1 (9.1%)	1
Depression	0	0	0	0	1 (20%)	1	0	0	1 (9.1%)	1
Renal and urinary disorders	2 (100%)	3	2 (100%)	6	3 (60%)	7	1 (50%)	2	8 (72.7%)	18
Bladder dysfunction	0	0	1 (50%)	1	0	0	0	0	1 (9.1%)	1
Bladder spasm	0	0	1 (50%)	1	0	0	0	0	1 (9.1%)	1
Focal segmental glomerulosclerosis	0	0	0	0	1 (20%)	1	0	0	1 (9.1%)	1
Hydroureter	0	0	1 (50%)	1	0	0	0	0	1 (9.1%)	1
Neurogenic bladder	0	0	1 (50%)	1	0	0	0	0	1 (9.1%)	1
Obstructive uropathy	1 (50%)	1	0	0	0	0	0	0	1 (9.1%)	1
Renal failure	0	0	0	0	1 (20%)	2	0	0	1 (9.1%)	2
Renal failure acute	0	0	0	0	1 (20%)	1	0	0	1 (9.1%)	1

Note: The percentages are based on the total number of participants in each enrollment group or total.
Participants are counted once at each System Organ Class and Preferred Term levels.

Table 14.1.2.2.2
Summary of Medical History by System Organ Class, Preferred Term and by Enrollment and IC Group
Safety Population - IC2

	30 – 59 ml/min per 1.73m²				≥ 60 ml/min per 1.73m²					
	0.1 mg/kg/day (N=2)		0.2 mg/kg/day (N=2)		0.1 mg/kg/day (N=5)		0.2 mg/kg/day (N=2)		Total (N=11)	
System Organ Class Preferred Term	Participants With Medical History N (%)	Total Medical History N	Participants With Medical History N (%)	Total Medical History N	Participants With Medical History N (%)	Total Medical History N	Participants With Medical History N (%)	Total Medical History N	Participants With Medical History N (%)	Total Medical History N
Renal failure chronic	1 (50%)	2	1 (50%)	1	2 (40%)	3	0	0	4 (36.4%)	6
Renal hypertension	0	0	0	0	0	0	1 (50%)	1	1 (9.1%)	1
Tubulointerstitial nephritis	0	0	0	0	0	0	1 (50%)	1	1 (9.1%)	1
Vesicoureteric reflux	0	0	1 (50%)	1	0	0	0	0	1 (9.1%)	1
Respiratory, thoracic and mediastinal disorders	0	0	1 (50%)	2	2 (40%)	2	0	0	3 (27.3%)	4
Asthma	0	0	1 (50%)	1	1 (20%)	1	0	0	2 (18.2%)	2
Dyspnoea	0	0	0	0	1 (20%)	1	0	0	1 (9.1%)	1
Rhinitis allergic	0	0	1 (50%)	1	0	0	0	0	1 (9.1%)	1
Skin and subcutaneous tissue disorders	0	0	1 (50%)	1	0	0	0	0	1 (9.1%)	1
Dermatitis contact	0	0	1 (50%)	1	0	0	0	0	1 (9.1%)	1
Social circumstances	0	0	1 (50%)	1	0	0	0	0	1 (9.1%)	1
Corrective lens user	0	0	1 (50%)	1	0	0	0	0	1 (9.1%)	1
Surgical and medical procedures	0	0	0	0	2 (40%)	3	0	0	2 (18.2%)	3

Note: The percentages are based on the total number of participants in each enrollment group or total.
Participants are counted once at each System Organ Class and Preferred Term levels.

Table 14.1.2.2.2
Summary of Medical History by System Organ Class, Preferred Term and by Enrollment and IC Group
Safety Population - IC2

	30 – 59 ml/min per 1.73m²				≥ 60 ml/min per 1.73m²					
	0.1 mg/kg/day (N=2)		0.2 mg/kg/day (N=2)		0.1 mg/kg/day (N=5)		0.2 mg/kg/day (N=2)		Total (N=11)	
System Organ Class Preferred Term	Participants With Medical History N (%)	Total Medical History N	Participants With Medical History N (%)	Total Medical History N	Participants With Medical History N (%)	Total Medical History N	Participants With Medical History N (%)	Total Medical History N	Participants With Medical History N (%)	Total Medical History N
Insertion of ambulatory peritoneal catheter	0	0	0	0	1 (20%)	1	0	0	1 (9.1%)	1
Renal transplant	0	0	0	0	1 (20%)	1	0	0	1 (9.1%)	1
Splenectomy	0	0	0	0	1 (20%)	1	0	0	1 (9.1%)	1
Vascular disorders	1 (50%)	1	1 (50%)	1	4 (80%)	6	1 (50%)	1	7 (63.6%)	9
Collateral circulation	0	0	0	0	1 (20%)	1	0	0	1 (9.1%)	1
Hypertension	1 (50%)	1	1 (50%)	1	4 (80%)	4	1 (50%)	1	7 (63.6%)	7
Phlebitis	0	0	0	0	1 (20%)	1	0	0	1 (9.1%)	1

Note: The percentages are based on the total number of participants in each enrollment group or total.
Participants are counted once at each System Organ Class and Preferred Term levels.

Table 14.1.2.3.1
Summary of Prior Medications by Drug Classification, Drug Name and Enrollment Group
Safety Population - IC1

	30 – 59 ml/min per 1.73m²				≥ 60 ml/min per 1.73m²							
	0.1 mg/kg/day (N=3)		0.2 mg/kg/day (N=1)		0.1 mg/kg/day (N=3)		0.2 mg/kg/day (N=5)		0.4 mg/kg/day (N=3)		Total (N=15)	
WHO Class Medication Name	Pts With Medn N (%)	Total Medns N	Pts With Medn N (%)	Total Medns N	Pts With Medn N (%)	Total Medns N	Pts With Medn N (%)	Total Medns N	Pts With Medn N (%)	Total Medns N	Pts With Medn N (%)	Total Medns N
ALIMENTARY TRACT AND METABOLISM	3 (100%)	4	1 (100%)	2	1 (33.3%)	1	2 (40%)	3	3 (100%)	4	10 (66.7%)	14
CALCIUM	1 (33.3%)	1	0	0	0	0	0	0	0	0	1 (6.7%)	1
CALCIUM CITRATE	1 (33.3%)	1	0	0	0	0	0	0	0	0	1 (6.7%)	1
LANSOPRAZOLE	0	0	0	0	0	0	1 (20%)	1	1 (33.3%)	1	2 (13.3%)	2
MACROGOL	1 (33.3%)	1	0	0	0	0	0	0	0	0	1 (6.7%)	1
MAGNESIUM OXIDE	1 (33.3%)	1	0	0	1 (33.3%)	1	0	0	0	0	2 (13.3%)	2
MERCAPTAMINE BITARTRATE	0	0	0	0	0	0	0	0	1 (33.3%)	1	1 (6.7%)	1
MULTIVITAMIN	0	0	0	0	0	0	0	0	1 (33.3%)	1	1 (6.7%)	1
MULTIVITAMIN MULTIMINERAL	0	0	0	0	0	0	1 (20%)	1	0	0	1 (6.7%)	1
OMEPRAZOLE	0	0	1 (100%)	1	0	0	0	0	0	0	1 (6.7%)	1
VITAMIN D NOS	0	0	1 (100%)	1	0	0	1 (20%)	1	1 (33.3%)	1	3 (20%)	3
ANTIINFECTIVES FOR SYSTEMIC USE	0	0	1 (100%)	2	1 (33.3%)	1	4 (80%)	4	2 (66.7%)	2	8 (53.3%)	9
BACTRIM	0	0	1 (100%)	1	1 (33.3%)	1	4 (80%)	4	2 (66.7%)	2	8 (53.3%)	8
VALGANCICLOVIR HYDROCHLORIDE	0	0	1 (100%)	1	0	0	0	0	0	0	1 (6.7%)	1
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	3 (100%)	6	1 (100%)	2	3 (100%)	6	5 (100%)	11	3 (100%)	6	15 (100%)	31

Note: The percentages are based on the total number of enrolled participants in each treatment group or total.
Participants are counted once for each medication before study dose.

Table 14.1.2.3.1
Summary of Prior Medications by Drug Classification, Drug Name and Enrollment Group
Safety Population - IC1

	30 – 59 ml/min per 1.73m²				≥ 60 ml/min per 1.73m²							
	0.1 mg/kg/day (N=3)		0.2 mg/kg/day (N=1)		0.1 mg/kg/day (N=3)		0.2 mg/kg/day (N=5)		0.4 mg/kg/day (N=3)		Total (N=15)	
WHO Class Medication Name	Pts With Medn N (%)	Total Medns N	Pts With Medn N (%)	Total Medns N	Pts With Medn N (%)	Total Medns N	Pts With Medn N (%)	Total Medns N	Pts With Medn N (%)	Total Medns N	Pts With Medn N (%)	Total Medns N
MYCOPHENOLATE MOFETIL	3 (100%)	3	1 (100%)	1	2 (66.7%)	2	5 (100%)	5	3 (100%)	3	14 (93.3%)	14
SIROLIMUS	1 (33.3%)	1	0	0	1 (33.3%)	1	3 (60%)	3	1 (33.3%)	1	6 (40%)	6
TACROLIMUS	2 (66.7%)	2	1 (100%)	1	3 (100%)	3	3 (60%)	3	2 (66.7%)	2	11 (73.3%)	11
ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS	0	0	0	0	0	0	0	0	1 (33.3%)	1	1 (6.7%)	1
ATOVAQUONE	0	0	0	0	0	0	0	0	1 (33.3%)	1	1 (6.7%)	1
BLOOD AND BLOOD FORMING ORGANS	2 (66.7%)	3	1 (100%)	1	0	0	0	0	1 (33.3%)	1	4 (26.7%)	5
ENOXAPARIN SODIUM	1 (33.3%)	1	0	0	0	0	0	0	0	0	1 (6.7%)	1
FERROUS SULFATE	0	0	0	0	0	0	0	0	1 (33.3%)	1	1 (6.7%)	1
SODIUM BICARBONATE	1 (33.3%)	1	1 (100%)	1	0	0	0	0	0	0	2 (13.3%)	2
VITAMIN B COMPLEX WITH IRON	1 (33.3%)	1	0	0	0	0	0	0	0	0	1 (6.7%)	1
CARDIOVASCULAR SYSTEM	2 (66.7%)	2	1 (100%)	1	2 (66.7%)	3	4 (80%)	5	3 (100%)	6	12 (80%)	17
AMLODIPINE	2 (66.7%)	2	1 (100%)	1	0	0	1 (20%)	1	1 (33.3%)	1	5 (33.3%)	5
AMLODIPINE BESILATE	0	0	0	0	2 (66.7%)	2	2 (40%)	2	1 (33.3%)	1	5 (33.3%)	5
ATENOLOL	0	0	0	0	1 (33.3%)	1	1 (20%)	1	1 (33.3%)	1	3 (20%)	3

Note: The percentages are based on the total number of enrolled participants in each treatment group or total.
Participants are counted once for each medication before study dose.

Table 14.1.2.3.1
Summary of Prior Medications by Drug Classification, Drug Name and Enrollment Group
Safety Population - IC1

	30 – 59 ml/min per 1.73m²				≥ 60 ml/min per 1.73m²							
	0.1 mg/kg/day (N=3)		0.2 mg/kg/day (N=1)		0.1 mg/kg/day (N=3)		0.2 mg/kg/day (N=5)		0.4 mg/kg/day (N=3)		Total (N=15)	
WHO Class Medication Name	Pts With Medn N (%)	Total Medns N	Pts With Medn N (%)	Total Medns N	Pts With Medn N (%)	Total Medns N	Pts With Medn N (%)	Total Medns N	Pts With Medn N (%)	Total Medns N	Pts With Medn N (%)	Total Medns N
CARVEDILOL	0	0	0	0	0	0	0	0	1 (33.3%)	1	1 (6.7%)	1
CLONIDINE	0	0	0	0	0	0	0	0	1 (33.3%)	1	1 (6.7%)	1
ISRADIPINE	0	0	0	0	0	0	0	0	1 (33.3%)	1	1 (6.7%)	1
NIFEDIPINE	0	0	0	0	0	0	1 (20%)	1	0	0	1 (6.7%)	1
DERMATOLOGICALS	1 (33.3%)	1	0	0	1 (33.3%)	1	0	0	0	0	2 (13.3%)	2
CLINDAMYCIN	1 (33.3%)	1	0	0	1 (33.3%)	1	0	0	0	0	2 (13.3%)	2
GENITO URINARY SYSTEM AND SEX HORMONES	2 (66.7%)	2	0	0	0	0	0	0	0	0	2 (13.3%)	2
BICITRA	1 (33.3%)	1	0	0	0	0	0	0	0	0	1 (6.7%)	1
MEDROXYPROGESTERONE	1 (33.3%)	1	0	0	0	0	0	0	0	0	1 (6.7%)	1
NERVOUS SYSTEM	1 (33.3%)	1	0	0	0	0	1 (20%)	1	1 (33.3%)	1	3 (20%)	3
MELATONIN	0	0	0	0	0	0	0	0	1 (33.3%)	1	1 (6.7%)	1
OXCARBAZEPINE	0	0	0	0	0	0	1 (20%)	1	0	0	1 (6.7%)	1
TYLENOL ULTRA RELIEF	1 (33.3%)	1	0	0	0	0	0	0	0	0	1 (6.7%)	1
RESPIRATORY SYSTEM	1 (33.3%)	1	0	0	1 (33.3%)	1	1 (20%)	4	2 (66.7%)	6	5 (33.3%)	12
BECLOMETASONE DIPROPIONATE	0	0	0	0	0	0	0	0	1 (33.3%)	1	1 (6.7%)	1

Note: The percentages are based on the total number of enrolled participants in each treatment group or total.
Participants are counted once for each medication before study dose.

Table 14.1.2.3.1
Summary of Prior Medications by Drug Classification, Drug Name and Enrollment Group
Safety Population - IC1

	30 – 59 ml/min per 1.73m²				≥ 60 ml/min per 1.73m²							
	0.1 mg/kg/day (N=3)		0.2 mg/kg/day (N=1)		0.1 mg/kg/day (N=3)		0.2 mg/kg/day (N=5)		0.4 mg/kg/day (N=3)		Total (N=15)	
WHO Class Medication Name	Pts With Medn N (%)	Total Medns N	Pts With Medn N (%)	Total Medns N	Pts With Medn N (%)	Total Medns N	Pts With Medn N (%)	Total Medns N	Pts With Medn N (%)	Total Medns N	Pts With Medn N (%)	Total Medns N
CETIRIZINE	0	0	0	0	0	0	0	0	1 (33.3%)	1	1 (6.7%)	1
FLUTICASONE PROPIONATE	0	0	0	0	0	0	1 (20%)	1	2 (66.7%)	2	3 (20%)	3
LORATADINE	0	0	0	0	0	0	1 (20%)	1	0	0	1 (6.7%)	1
MONTELUKAST SODIUM	1 (33.3%)	1	0	0	0	0	1 (20%)	1	1 (33.3%)	1	3 (20%)	3
SALBUTAMOL	0	0	0	0	1 (33.3%)	1	1 (20%)	1	1 (33.3%)	1	3 (20%)	3
SYSTEMIC HORMONAL PREP.,EXCL.SEX HORM.AND INSULIN	0	0	0	0	0	0	0	0	1 (33.3%)	1	1 (6.7%)	1
LEVOTHYROXINE SODIUM	0	0	0	0	0	0	0	0	1 (33.3%)	1	1 (6.7%)	1
SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS	3 (100%)	3	1 (100%)	1	3 (100%)	3	3 (60%)	3	3 (100%)	3	13 (86.7%)	13
PREDNISONE	3 (100%)	3	1 (100%)	1	3 (100%)	3	3 (60%)	3	3 (100%)	3	13 (86.7%)	13

Note: The percentages are based on the total number of enrolled participants in each treatment group or total.
Participants are counted once for each medication before study dose.

Table 14.1.2.3.2
Summary of Prior Medications by Drug Classification, Drug Name and Enrollment Group
Safety Population - IC2

	30 – 59 ml/min per 1.73m²				≥ 60 ml/min per 1.73m²					
	0.1 mg/kg/day (N=2)		0.2 mg/kg/day (N=2)		0.1 mg/kg/day (N=5)		0.2 mg/kg/day (N=2)		Total (N=11)	
WHO Class Medication Name	Pts With Medn N (%)	Total Medns N	Pts With Medn N (%)	Total Medns N	Pts With Medn N (%)	Total Medns N	Pts With Medn N (%)	Total Medns N	Pts With Medn N (%)	Total Medns N
ALIMENTARY TRACT AND METABOLISM	2 (100%)	4	2 (100%)	5	4 (80%)	7	1 (50%)	3	9 (81.8%)	19
CALCITRIOL	1 (50%)	1	1 (50%)	1	0	0	1 (50%)	1	3 (27.3%)	3
CALCIUM ACETATE	0	0	1 (50%)	1	0	0	0	0	1 (9.1%)	1
CALCIUM CARBONATE	0	0	0	0	0	0	1 (50%)	1	1 (9.1%)	1
COLECALCIFEROL	1 (50%)	1	0	0	0	0	0	0	1 (9.1%)	1
ERGOCALCIFEROL	0	0	0	0	1 (20%)	1	0	0	1 (9.1%)	1
INSULIN LISPRO	0	0	0	0	1 (20%)	1	0	0	1 (9.1%)	1
MACROGOL	0	0	0	0	2 (40%)	2	0	0	2 (18.2%)	2
MAGNESIUM CHLORIDE	1 (50%)	1	0	0	0	0	0	0	1 (9.1%)	1
MAGNESIUM OXIDE	0	0	0	0	1 (20%)	1	0	0	1 (9.1%)	1
MULTIVITAMIN	0	0	1 (50%)	1	1 (20%)	1	0	0	2 (18.2%)	2
RANITIDINE HYDROCHLORIDE	0	0	1 (50%)	1	1 (20%)	1	0	0	2 (18.2%)	2
TUMS	0	0	1 (50%)	1	0	0	0	0	1 (9.1%)	1
VITAMIN D NOS	1 (50%)	1	0	0	0	0	1 (50%)	1	2 (18.2%)	2
ANTIINFECTIVES FOR SYSTEMIC USE	0	0	1 (50%)	3	1 (20%)	2	1 (50%)	1	3 (27.3%)	6
BACTRIM	0	0	1 (50%)	1	1 (20%)	1	0	0	2 (18.2%)	2
BETA-LACTAM ANTIBACTERIALS, PENICILLINS	0	0	0	0	1 (20%)	1	0	0	1 (9.1%)	1

Note: The percentages are based on the total number of enrolled participants in each treatment group or total.
Participants are counted once for each medication before study dose.

Table 14.1.2.3.2
Summary of Prior Medications by Drug Classification, Drug Name and Enrollment Group
Safety Population - IC2

	30 – 59 ml/min per 1.73m²				≥ 60 ml/min per 1.73m²					
	0.1 mg/kg/day (N=2)		0.2 mg/kg/day (N=2)		0.1 mg/kg/day (N=5)		0.2 mg/kg/day (N=2)		Total (N=11)	
WHO Class Medication Name	Pts With Medn N (%)	Total Medns N	Pts With Medn N (%)	Total Medns N	Pts With Medn N (%)	Total Medns N	Pts With Medn N (%)	Total Medns N	Pts With Medn N (%)	Total Medns N
IMMUNOGLOBULINS, NORMAL HUMAN	0	0	1 (50%)	1	0	0	0	0	1 (9.1%)	1
METRONIDAZOLE	0	0	0	0	0	0	1 (50%)	1	1 (9.1%)	1
NITROFURANTOIN	0	0	1 (50%)	1	0	0	0	0	1 (9.1%)	1
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	2 (100%)	3	2 (100%)	4	5 (100%)	10	2 (100%)	3	11 (100%)	20
AZATHIOPRINE	0	0	1 (50%)	1	0	0	0	0	1 (9.1%)	1
MYCOPHENOLATE MOFETIL	0	0	1 (50%)	1	5 (100%)	5	1 (50%)	1	7 (63.6%)	7
MYCOPHENOLATE SODIUM	1 (50%)	1	0	0	0	0	0	0	1 (9.1%)	1
SIROLIMUS	0	0	1 (50%)	1	1 (20%)	1	0	0	2 (18.2%)	2
TACROLIMUS	2 (100%)	2	1 (50%)	1	4 (80%)	4	2 (100%)	2	9 (81.8%)	9
BLOOD AND BLOOD FORMING ORGANS	1 (50%)	1	1 (50%)	1	0	0	1 (50%)	1	3 (27.3%)	3
FERROUS SULFATE	0	0	1 (50%)	1	0	0	0	0	1 (9.1%)	1
IRON	1 (50%)	1	0	0	0	0	1 (50%)	1	2 (18.2%)	2
CARDIOVASCULAR SYSTEM	2 (100%)	3	2 (100%)	6	5 (100%)	10	2 (100%)	3	11 (100%)	22
AMLODIPINE	1 (50%)	1	0	0	2 (40%)	2	0	0	3 (27.3%)	3
AMLODIPINE BESILATE	0	0	2 (100%)	2	2 (40%)	2	1 (50%)	1	5 (45.5%)	5

Note: The percentages are based on the total number of enrolled participants in each treatment group or total.
Participants are counted once for each medication before study dose.

Table 14.1.2.3.2
Summary of Prior Medications by Drug Classification, Drug Name and Enrollment Group
Safety Population - IC2

	30 – 59 ml/min per 1.73m²				≥ 60 ml/min per 1.73m²					
	0.1 mg/kg/day (N=2)		0.2 mg/kg/day (N=2)		0.1 mg/kg/day (N=5)		0.2 mg/kg/day (N=2)		Total (N=11)	
WHO Class Medication Name	Pts With Medn N (%)	Total Medns N	Pts With Medn N (%)	Total Medns N	Pts With Medn N (%)	Total Medns N	Pts With Medn N (%)	Total Medns N	Pts With Medn N (%)	Total Medns N
ATORVASTATIN CALCIUM	0	0	1 (50%)	1	0	0	0	0	1 (9.1%)	1
CLONIDINE	0	0	1 (50%)	1	0	0	0	0	1 (9.1%)	1
ISRADIPINE	0	0	0	0	1 (20%)	1	0	0	1 (9.1%)	1
LISINOPRIL	2 (100%)	2	2 (100%)	2	5 (100%)	5	2 (100%)	2	11 (100%)	11
GENITO URINARY SYSTEM AND SEX HORMONES	0	0	2 (100%)	3	0	0	0	0	2 (18.2%)	3
BICITRA	0	0	1 (50%)	1	0	0	0	0	1 (9.1%)	1
POTASSIUM CITRATE	0	0	1 (50%)	1	0	0	0	0	1 (9.1%)	1
TROSPIUM CHLORIDE	0	0	1 (50%)	1	0	0	0	0	1 (9.1%)	1
NERVOUS SYSTEM	0	0	1 (50%)	1	1 (20%)	1	0	0	2 (18.2%)	2
CITALOPRAM	0	0	0	0	1 (20%)	1	0	0	1 (9.1%)	1
MELATONIN	0	0	1 (50%)	1	0	0	0	0	1 (9.1%)	1
RESPIRATORY SYSTEM	0	0	1 (50%)	5	1 (20%)	1	1 (50%)	1	3 (27.3%)	7
BUDESONIDE W/FORMOTEROL FUMARATE	0	0	1 (50%)	1	0	0	0	0	1 (9.1%)	1
CETIRIZINE HYDROCHLORIDE	0	0	1 (50%)	1	0	0	0	0	1 (9.1%)	1
FLUTICASONE PROPIONATE	0	0	1 (50%)	1	0	0	0	0	1 (9.1%)	1
IPRATROPIUM BROMIDE	0	0	1 (50%)	1	0	0	0	0	1 (9.1%)	1

Note: The percentages are based on the total number of enrolled participants in each treatment group or total.
Participants are counted once for each medication before study dose.

Table 14.1.2.3.2
Summary of Prior Medications by Drug Classification, Drug Name and Enrollment Group
Safety Population - IC2

	30 – 59 ml/min per 1.73m²				≥ 60 ml/min per 1.73m²					
	0.1 mg/kg/day (N=2)		0.2 mg/kg/day (N=2)		0.1 mg/kg/day (N=5)		0.2 mg/kg/day (N=2)		Total (N=11)	
WHO Class Medication Name	Pts With Medn N (%)	Total Medns N	Pts With Medn N (%)	Total Medns N	Pts With Medn N (%)	Total Medns N	Pts With Medn N (%)	Total Medns N	Pts With Medn N (%)	Total Medns N
LORATADINE	0	0	0	0	0	0	1 (50%)	1	1 (9.1%)	1
SALBUTAMOL	0	0	1 (50%)	1	1 (20%)	1	0	0	2 (18.2%)	2
SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS	2 (100%)	2	2 (100%)	3	5 (100%)	5	2 (100%)	2	11 (100%)	12
PREDNISOLONE	0	0	1 (50%)	1	0	0	1 (50%)	1	2 (18.2%)	2
PREDNISONE	2 (100%)	2	1 (50%)	1	5 (100%)	5	1 (50%)	1	9 (81.8%)	9
SOMATROPIN	0	0	1 (50%)	1	0	0	0	0	1 (9.1%)	1
VARIOUS	1 (50%)	1	0	0	0	0	0	0	1 (9.1%)	1
SEVELAMER CARBONATE	1 (50%)	1	0	0	0	0	0	0	1 (9.1%)	1

Note: The percentages are based on the total number of enrolled participants in each treatment group or total.
Participants are counted once for each medication before study dose.

Table 14.1.3.1
Summary of Protocol Deviations by Site
All Participants

	Informed Consent/ Assent		Eligibility/ Enrollment		Study Medication Administration		Protocol Procedure/ Assessment		Concomitant Treatment		Unreported AE		Other Classification		Total	
Site	Pts with PD N (%)	Total PDs N	Pts with PD N (%)	Total PDs N	Pts with PD N (%)	Total PDs N	Pts with PD N (%)	Total PDs N	Pts with PD N (%)	Total PDs N	Pts with PD N (%)	Total PDs N	Pts with PD N (%)	Total PDs N	Pts with PD N (%)	Total PDs N
Cincinnati Children's Hospital Medical Center	0	0	0	0	0	0	1 (33.3%)	8	0	0	0	0	1 (33.3%)	1	1 (33.3%)	9
Childrens Mercy Hospital	1 (50%)	1	0	0	1 (50%)	1	1 (50%)	1	0	0	1 (50%)	1	1 (50%)	1	2 (100%)	5
Emory University	0	0	2 (20%)	3	3 (30%)	3	9 (90%)	30	0	0	1 (10%)	1	1 (10%)	1	9 (90%)	38
New York University Medical Center	2 (50%)	2	0	0	1 (25%)	1	3 (75%)	6	0	0	0	0	2 (50%)	2	3 (75%)	11
University of Alabama	1 (25%)	1	1 (25%)	1	0	0	3 (75%)	6	0	0	0	0	0	0	3 (75%)	8
University of Arkansas	1 (50%)	1	0	0	0	0	2 (100%)	11	0	0	2 (100%)	5	0	0	2 (100%)	17
University of Michigan	0	0	0	0	0	0	4 (100%)	10	0	0	1 (25%)	1	0	0	4 (100%)	11
Total	5 (17.2%)	5	3 (10.3%)	4	5 (17.2%)	5	23 (79.3%)	72	0	0	5 (17.2%)	8	5 (17.2%)	5	24 (82.8%)	99

Note: Denominator is the number of participants at each site or total.
Pts=Participants; PD=Protocol Deviation;

Table 14.1.3.2
Protocol Deviation Classification by Reason for Deviation
All Participants

	Research Staff/ Clinic Error		Laboratory Error		PI Decision		Participant Unable to Comply		Participant Refusal		Other Reason		Total	
Deviation Classification	Pts with PD N	Total PDs N (%)	Pts with PD N	Total PDs N (%)	Pts with PD N	Total PDs N (%)	Pts with PD N	Total PDs N (%)	Pts with PD N	Total PDs N (%)	Pts with PD N	Total PDs N (%)	Pts with PD N	Total PDs N (%)
Informed consent/assent	4	4 (80%)	0	0	0	0	0	0	0	0	1	1 (20%)	5	5 (100%)
Eligibility/enrollment	2	2 (50%)	0	0	0	0	0	0	0	0	2	2 (50%)	3	4 (100%)
Study medication administration	2	2 (40%)	0	0	0	0	0	0	0	0	3	3 (60%)	5	5 (100%)
Protocol procedure/assessment	18	33 (45.8%)	5	7 (9.7%)	4	6 (8.3%)	4	5 (6.9%)	3	4 (5.6%)	11	17 (23.6%)	23	72 (100%)
Unreported AE	3	6 (75%)	0	0	1	1 (12.5%)	0	0	0	0	1	1 (12.5%)	5	8 (100%)
Other	0	0	0	0	3	3 (60%)	0	0	0	0	2	2 (40%)	5	5 (100%)
Total	20	47 (47.5%)	5	7 (7.1%)	7	10 (10.1%)	4	5 (5.1%)	3	4 (4%)	15	26 (26.3%)	24	99 (100%)

Note: Denominator is the number of Protocol Deviations in each Classification or total.
Pts=Participants; PD=Protocol Deviation;

Table 14.1.3.3
Summary of Site-Specific Protocol Deviations
All Sites

Site	Study Product	Research Specimens	Total
New York University Medical Center	1	1	2
University of Alabama	0	1	1