

Infant Enrollment Report: IDCRC21-0004
Data Through: 30NOV2023
Report Run: 01DEC2023
Total Infant Enrollment: 571
Table 1: Enrollment Progress

				Enrollment During Week Beginning On								
				31JUL22	07AUG22	14AUG22	21AUG22					
Site		First Enrollment Date	Enrollment Through 30JUL22					Total Weeks	Total Enrollment	Average Per Week	Slots	Slots Available
All Sites	Group 3 - Infants of Pregnant participants	22JUL21	314	0	0	0	0	37	314	8.5	750	436
	Group 4 - Infants of Postpartum participants	30JUL21	54	0	0	0	0	23	54	2.3	250	196
	Group 6 - Infants of Pregnant participants with Boost	18NOV21	202	0	0	0	1	32	203	6.3	750	547
BCM VTEU	Group 3 - Infants of Pregnant participants	29JUL21	30	0	0	0	0	16	30	1.9	50	20
	Group 4 - Infants of Postpartum participants	02AUG21	9	0	0	0	0	6	9	1.5	12	3
	Group 6 - Infants of Pregnant participants with Boost	25DEC21	15	0	0	0	0	12	15	1.3		
CHOP - Vanderbilt VTEU sub	Group 3 - Infants of Pregnant participants		0								100	100
	Group 4 - Infants of Postpartum participants	28SEP21	5	0	0	0	0	5	5	1.0	35	30
	Group 6 - Infants of Pregnant participants with Boost	26JAN22	13	0	0	0	0	9	13	1.4		
Cincinnati VTEU	Group 3 - Infants of Pregnant participants	04NOV21	6	0	0	0	0	5	6	1.2	50	44
	Group 4 - Infants of Postpartum participants		0								12	12
	Group 6 - Infants of Pregnant participants with Boost	02DEC21	22	0	0	0	0	17	22	1.3		
Emory VTEU	Group 3 - Infants of Pregnant participants	22JUL21	86	0	0	0	0	30	86	2.9	100	14
	Group 4 - Infants of Postpartum participants	30JUL21	13	0	0	0	0	9	13	1.4	35	22
	Group 6 - Infants of Pregnant participants with Boost	03DEC21	26	0	0	0	0	17	26	1.5		
NYU VTEU - Brooklyn	Group 3 - Infants of Pregnant participants	03SEP21	32	0	0	0	0	18	32	1.8	50	18
	Group 4 - Infants of Postpartum participants		0								17	17
	Group 6 - Infants of Pregnant participants with Boost	02JAN22	7	0	0	0	0	5	7	1.4		
New York - VTEU	Group 3 - Infants of Pregnant participants	27AUG21	25	0	0	0	0	15	25	1.7	50	25
	Group 4 - Infants of Postpartum participants	24SEP21	1	0	0	0	0	1	1	1.0	18	17
	Group 6 - Infants of Pregnant participants with Boost	18NOV21	27	0	0	0	0	15	27	1.8		
Rochester VTEU	Group 3 - Infants of Pregnant participants	27AUG21	26	0	0	0	0	17	26	1.5	100	74
	Group 4 - Infants of Postpartum participants	21SEP21	9	0	0	0	0	7	9	1.3	35	26
	Group 6 - Infants of Pregnant participants with Boost	09DEC21	54	0	0	0	1	27	55	2.0		
Seattle Children's - UW VTEU sub	Group 3 - Infants of Pregnant participants		0								100	100
	Group 4 - Infants of Postpartum participants		0								35	35

Enrollment is defined as submission of Enrollment eCRF. 14 enrolled mothers were determined to be ineligible and have been excluded.

Enrollment is capped at 200 per vaccine type for Group 3 - Infants of Pregnant Participants
Enrollment is capped at 65 per vaccine type for Group 4 - Infants of Postpartum Participants

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	Group 6 - Infants of Pregnant participants with Boost		0									
UIC - SLU VTEU sub	Group 3 - Infants of Pregnant participants	29AUG21	23	0	0	0	0	15	23	1.5	50	27
	Group 4 - Infants of Postpartum participants	15AUG21	9	0	0	0	0	7	9	1.3	16	7
	Group 6 - Infants of Pregnant participants with Boost	18NOV21	17	0	0	0	0	13	17	1.3		
UPMC Magee - UMB VTEU sub	Group 3 - Infants of Pregnant participants	05AUG21	86	0	0	0	0	19	86	4.5	100	14
	Group 4 - Infants of Postpartum participants	19AUG21	8	0	0	0	0	5	8	1.6	35	27
	Group 6 - Infants of Pregnant participants with Boost	11DEC21	21	0	0	0	0	16	21	1.3		

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Table 2: Enrollment of Infant by Race

	Race																Total	
	American Indian/Alaskan Native		Asian		Black or African American		Native Hawaiian/Pacific Islander		White		Other		Multiracial		Unknown			
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	N	%
BCM VTEU	0	0.0	4	7.4	4	7.4	0	0.0	40	74.1	1	1.9	5	9.3	0	0.0	54	9.5
CHOP - Vanderbilt VTEU sub	0	0.0	0	0.0	5	27.8	0	0.0	13	72.2	0	0.0	0	0.0	0	0.0	18	3.2
Cincinnati VTEU	0	0.0	1	3.6	0	0.0	0	0.0	25	89.3	0	0.0	2	7.1	0	0.0	28	4.9
Emory VTEU	0	0.0	5	4.0	39	31.2	0	0.0	65	52.0	4	3.2	12	9.6	0	0.0	125	21.9
NYU VTEU - Brooklyn	0	0.0	5	12.8	1	2.6	2	5.1	15	38.5	16	41.0	0	0.0	0	0.0	39	6.8
New York - VTEU	0	0.0	4	7.5	0	0.0	0	0.0	29	54.7	18	34.0	2	3.8	0	0.0	53	9.3
Rochester VTEU	0	0.0	3	3.3	8	8.9	0	0.0	78	86.7	0	0.0	1	1.1	0	0.0	90	15.8
Seattle Children's - UW VTEU sub	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0
UIC - SLU VTEU sub	0	0.0	2	4.1	16	32.7	0	0.0	29	59.2	2	4.1	0	0.0	0	0.0	49	8.6
UPMC Magee - UMB VTEU sub	0	0.0	4	3.5	3	2.6	0	0.0	98	85.2	3	2.6	7	6.1	0	0.0	115	20.1
All Sites	0	0.0	28	4.9	76	13.3	2	0.4	392	68.7	44	7.7	29	5.1	0	0.0	571	100

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Table 3: Enrollment of Infant by Ethnicity

	Ethnicity								Total	
	Hispanic or Latino		Not Hispanic or Latino		Not reported		Unknown			
	n	%	n	%	n	%	n	%	N	%
BCM VTEU	13	24.1	41	75.9	0	0.0	0	0.0	54	9.5
CHOP - Vanderbilt VTEU sub	0	0.0	18	100	0	0.0	0	0.0	18	3.2
Cincinnati VTEU	2	7.1	26	92.9	0	0.0	0	0.0	28	4.9
Emory VTEU	14	11.2	103	82.4	5	4.0	3	2.4	125	21.9
NYU VTEU - Brooklyn	16	41.0	11	28.2	2	5.1	10	25.6	39	6.8
New York - VTEU	2	3.8	31	58.5	6	11.3	14	26.4	53	9.3
Rochester VTEU	2	2.2	56	62.2	29	32.2	3	3.3	90	15.8
Seattle Children's - UW VTEU sub	0	0	0	0	0	0	0	0	0	0.0
UIC - SLU VTEU sub	18	36.7	31	63.3	0	0.0	0	0.0	49	8.6
UPMC Magee - UMB VTEU sub	5	4.3	110	95.7	0	0.0	0	0.0	115	20.1
All Sites	72	12.6	427	74.8	42	7.4	30	5.3	571	100

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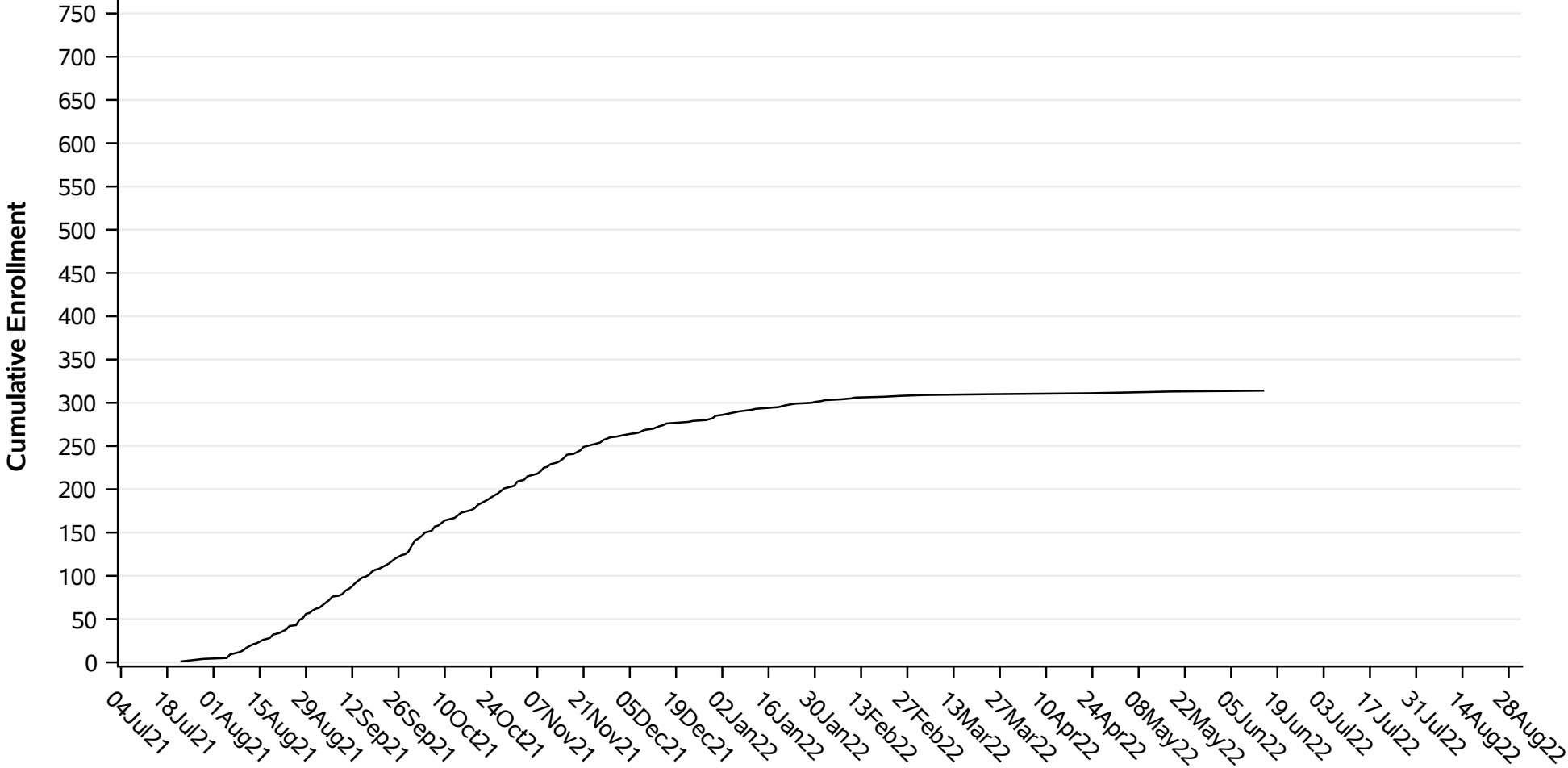
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Table 4: Enrollment of Infant by Group

	Group						Total	
	Group 3 - Infants of Pregnant participants		Group 4 - Infants of Postpartum participants		Group 6 - Infants of Pregnant participants with Boost			
	n	%	n	%	n	%	N	%
BCM VTEU	30	55.6	9	16.7	15	27.8	54	9.5
CHOP - Vanderbilt VTEU sub	0	0.0	5	27.8	13	72.2	18	3.2
Cincinnati VTEU	6	21.4	0	0.0	22	78.6	28	4.9
Emory VTEU	86	68.8	13	10.4	26	20.8	125	21.9
NYU VTEU - Brooklyn	32	82.1	0	0.0	7	17.9	39	6.8
New York - VTEU	25	47.2	1	1.9	27	50.9	53	9.3
Rochester VTEU	26	28.9	9	10.0	55	61.1	90	15.8
Seattle Children's - UW VTEU sub	0	0	0	0	0	0	0	0.0
UIC - SLU VTEU sub	23	46.9	9	18.4	17	34.7	49	8.6
UPMC Magee - UMB VTEU sub	86	74.8	8	7.0	21	18.3	115	20.1
All Sites	314	55.0	54	9.5	203	35.6	571	100

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Figure 1: IDCRC21-0004 Group 3 - Infants of Pregnant Participants Enrollment by Week

Target Enrollment: 750 Total Enrollment: 314
First Enrollment: 22JUL2021 Last Enrollment: 15JUN2022
Report created 01DEC2023 on data entered 30NOV2023



SOURCE: SCHARP (craig) /trials/idcrc/p002/reporting/progress/code/idc002_enrollment_report.sas (SAS 9.4) 01DEC2023 09:35

Figure 2: IDCRC21-0004 Group 4 - Infants of Postpartum Participants Enrollment by Week

Target Enrollment: 250 Total Enrollment: 54
First Enrollment: 30JUL2021 Last Enrollment: 31JAN2022
Report created 01DEC2023 on data entered 30NOV2023

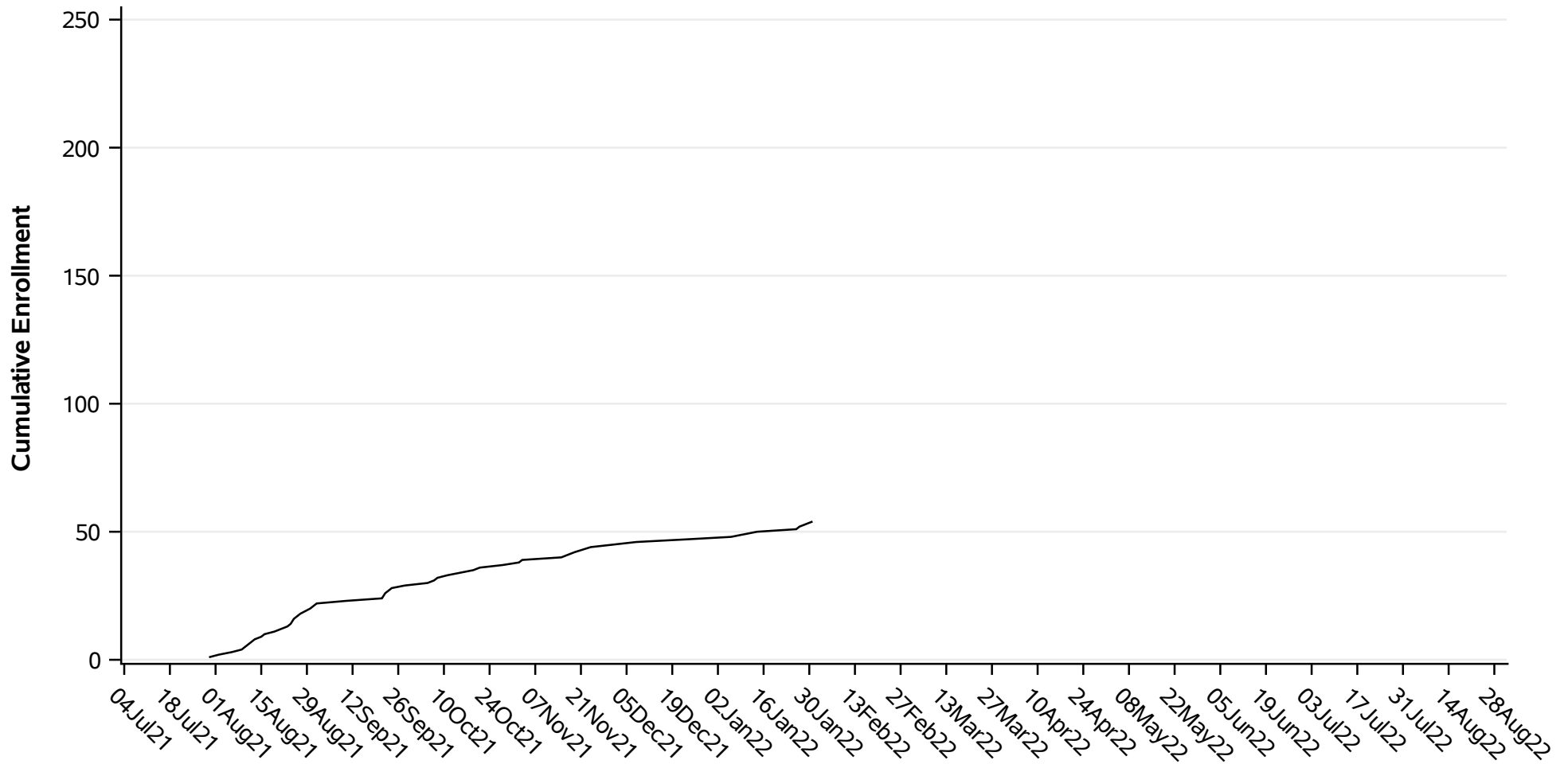


Figure 3: IDCRC21-0004 Group 6 - Infants of Pregnant Participants with Boost Enrollment by Week

Target Enrollment: 750 Total Enrollment: 203
First Enrollment: 18NOV2021 Last Enrollment: 26AUG2022
Report created 01DEC2023 on data entered 30NOV2023

