GRAIL3 – Ganciclovir to Prevent Reactivation of CMV in Patients with Acute Respiratory Failure and Sepsis
Atlas Open Report – Data as of May 23, 2026

Table O1 – Screen–out Summary by Site

	Brigham and Womens	Cleveland Clinic Main	Duke U	Henry Ford	Intermountain	Johns Hopkins Bayview
Participants Screened[1]	80	22	23	80	494	1070
Participants Enrolled[2]	0 (0%)	5 (23%)	0 (0%)	7 (9%)	22 (4%)	33 (3%)
Participants not Enrolled[2]	80 (100%)	17 (77%)	23 (100%)	73 (91%)	472 (96%)	1037 (97%)
Participant did not complete all screening procedures[3]	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Participant is eligible but declined enrollment[3]	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Reason participant not enrolled is missing (Incomplete screening)[3]	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Participant not eligible[3,4]	80 (100%)	17 (100%)	23 (100%)	73 (100%)	472 (100%)	1037 (100%)
No subject/next of kin informed consent	5 (6%)	1 (6%)	9 (39%)	4 (5%)	132 (28%)	39 (4%)
Age < 18 years	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Not CMV IgG seropositive by LFA or standard serologic methods	1 (1%)	7 (41%)	1 (4%)	6 (8%)	198 (42%)	171 (16%)
Not Intubated or does not require mechanical positive pressure ventilation	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Does not meet protocol–defined criteria for sepsis within a 24–hour time period	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
On day of randomization eligible for SBT (Spontaneous Breathing Trial)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
On day of randomization, did not fail SBT	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
HIV +	0 (0%)	1 (6%)	0 (0%)	2 (3%)	0 (0%)	26 (3%)
Stem cell transplantation within specified time	2 (3%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Solid organ transplantation with receipt of systemic immunosuppression	6 (8%)	2 (12%)	0 (0%)	10 (14%)	0 (0%)	19 (2%)
Cytotoxic anti–cancer chemotherapy within the past three months	12 (15%)	0 (0%)	2 (9%)	5 (7%)	3 (1%)	49 (5%)
Congenital immunodeficiency requiring antimicrobial prophylaxis	1 (1%)	0 (0%)	0 (0%)	2 (3%)	1 (<1%)	2 (<1%)
Receipt of immunosuppressive agents associated with CMV reactivation	11 (14%)	0 (0%)	0 (0%)	0 (0%)	3 (1%)	7 (1%)
Expected to survive < 72 hours or not committed to full intensive care support	1 (1%)	1 (6%)	3 (13%)	4 (5%)	17 (4%)	101 (10%)
Unable to receive first dose of study drug within 120 hours after hospitalization	0 (0%)	3 (18%)	0 (0%)	16 (22%)	20 (4%)	402 (39%)
Currently pregnant or breastfeeding	1 (1%)	0 (0%)	0 (0%)	0 (0%)	1 (<1%)	2 (<1%)
Absolute neutrophil count < 1,000/mm3	1 (1%)	0 (0%)	0 (0%)	2 (3%)	0 (0%)	2 (<1%)
Use of anti–CMV drugs within seven days of randomization	2 (3%)	0 (0%)	0 (0%)	0 (0%)	1 (<1%)	2 (<1%)
Currently enrolled in an interventional trial of an anti–CMV therapeutic agent	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (<1%)	1 (<1%)
Has both a tracheostomy and been on continuous mechanical ventilation	8 (10%)	1 (6%)	0 (0%)	5 (7%)	3 (1%)	35 (3%)
Child Class C Cirrhosis	5 (6%)	1 (6%)	1 (4%)	4 (5%)	1 (<1%)	32 (3%)
Severe pre–existing interstitial lung disease	13 (16%)	0 (0%)	4 (17%)	10 (14%)	9 (2%)	7 (1%)
Allergy to ganciclovir	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Incarcerated	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (<1%)	3 (<1%)
Other exclusion reason	2 (3%)	0 (0%)	3 (13%)	2 (3%)	80 (17%)	125 (12%)

[1] Number of participants screened is based on the Inclusion Exclusion Criteria eCRF.
[2]Percentage of participants screened within each study site.
[3]Percentage of participants not enrolled within each study site.
[4]Participants may be ineligible for more than one reason.

Source: SCHARP (Zhuoran) – /trials/infect/grail3/analysis/atlas/code/open/t_screening_summary.sas, SAS Version 9.4 (24MAY2026,6:50)

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Table O1 – Screen–out Summary by Site

	Johns Hopkins Hosp.	Medical U South Carolina	Montefiore Moses	Montefiore Weiler	Ohio State U	U of Cincinnati
Participants Screened[1]	2282	228	202	195	924	46
Participants Enrolled[2]	32 (1%)	7 (3%)	6 (3%)	1 (1%)	13 (1%)	25 (54%)
Participants not Enrolled[2]	2250 (99%)	221 (97%)	196 (97%)	194 (99%)	911 (99%)	21 (46%)
Participant did not complete all screening procedures[3]	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Participant is eligible but declined enrollment[3]	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Reason participant not enrolled is missing (Incomplete screening)[3]	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Participant not eligible[3,4]	2250 (100%)	221 (100%)	196 (100%)	194 (100%)	911 (100%)	21 (100%)
No subject/next of kin informed consent	37 (2%)	22 (10%)	23 (12%)	47 (24%)	7 (1%)	0 (0%)
Age < 18 years	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Not CMV IgG seropositive by LFA or standard serologic methods	136 (6%)	27 (12%)	48 (24%)	56 (29%)	23 (3%)	7 (33%)
Not Intubated or does not require mechanical positive pressure ventilation	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Does not meet protocol–defined criteria for sepsis within a 24–hour time period	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
On day of randomization eligible for SBT (Spontaneous Breathing Trial)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
On day of randomization, did not fail SBT	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
HIV +	63 (3%)	5 (2%)	8 (4%)	5 (3%)	12 (1%)	0 (0%)
Stem cell transplantation within specified time	1 (<1%)	1 (<1%)	1 (1%)	0 (0%)	5 (1%)	0 (0%)
Solid organ transplantation with receipt of systemic immunosuppression	124 (6%)	11 (5%)	22 (11%)	3 (2%)	67 (7%)	0 (0%)
Cytotoxic anti–cancer chemotherapy within the past three months	81 (4%)	46 (21%)	15 (8%)	12 (6%)	243 (27%)	1 (5%)
Congenital immunodeficiency requiring antimicrobial prophylaxis	3 (<1%)	1 (<1%)	0 (0%)	0 (0%)	2 (<1%)	0 (0%)
Receipt of immunosuppressive agents associated with CMV reactivation	25 (1%)	8 (4%)	5 (3%)	0 (0%)	18 (2%)	0 (0%)
Expected to survive < 72 hours or not committed to full intensive care support	122 (5%)	12 (5%)	6 (3%)	19 (10%)	49 (5%)	0 (0%)
Unable to receive first dose of study drug within 120 hours after hospitalization	1187 (53%)	31 (14%)	3 (2%)	2 (1%)	433 (48%)	1 (5%)
Currently pregnant or breastfeeding	15 (1%)	1 (<1%)	0 (0%)	1 (1%)	1 (<1%)	0 (0%)
Absolute neutrophil count < 1,000/mm3	4 (<1%)	3 (1%)	5 (3%)	0 (0%)	18 (2%)	1 (5%)
Use of anti–CMV drugs within seven days of randomization	6 (<1%)	1 (<1%)	3 (2%)	2 (1%)	0 (0%)	0 (0%)
Currently enrolled in an interventional trial of an anti–CMV therapeutic agent	1 (<1%)	1 (<1%)	0 (0%)	0 (0%)	4 (<1%)	0 (0%)
Has both a tracheostomy and been on continuous mechanical ventilation	57 (3%)	5 (2%)	5 (3%)	6 (3%)	52 (6%)	3 (14%)
Child Class C Cirrhosis	51 (2%)	19 (9%)	38 (19%)	14 (7%)	50 (5%)	7 (33%)
Severe pre–existing interstitial lung disease	44 (2%)	13 (6%)	3 (2%)	2 (1%)	53 (6%)	0 (0%)
Allergy to ganciclovir	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Incarcerated	7 (<1%)	1 (<1%)	0 (0%)	0 (0%)	35 (4%)	0 (0%)
Other exclusion reason	236 (10%)	6 (3%)	11 (6%)	9 (5%)	16 (2%)	0 (0%)

[1] Number of participants screened is based on the Inclusion Exclusion Criteria eCRF.
[2]Percentage of participants screened within each study site.
[3]Percentage of participants not enrolled within each study site.
[4]Participants may be ineligible for more than one reason.

Source: SCHARP (Zhuoran) – /trials/infect/grail3/analysis/atlas/code/open/t_screening_summary.sas, SAS Version 9.4 (24MAY2026,6:50)

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Table O1 – Screen–out Summary by Site

	U of Colorado Denver	U of Michigan	U of Pittsburgh	U of Vermont	U of Wash. Harborview	U of Washington
Participants Screened[1]	282	106	96	299	63	70
Participants Enrolled[2]	20 (7%)	1 (1%)	1 (1%)	2 (1%)	9 (14%)	4 (6%)
Participants not Enrolled[2]	262 (93%)	105 (99%)	95 (99%)	297 (99%)	54 (86%)	66 (94%)
Participant did not complete all screening procedures[3]	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Participant is eligible but declined enrollment[3]	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Reason participant not enrolled is missing (Incomplete screening)[3]	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Participant not eligible[3,4]	262 (100%)	105 (100%)	95 (100%)	297 (100%)	54 (100%)	66 (100%)
No subject/next of kin informed consent	18 (7%)	2 (2%)	4 (4%)	14 (5%)	3 (6%)	4 (6%)
Age < 18 years	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Not CMV IgG seropositive by LFA or standard serologic methods	34 (13%)	2 (2%)	7 (7%)	47 (16%)	17 (31%)	21 (32%)
Not Intubated or does not require mechanical positive pressure ventilation	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Does not meet protocol–defined criteria for sepsis within a 24–hour time period	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
On day of randomization eligible for SBT (Spontaneous Breathing Trial)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
On day of randomization, did not fail SBT	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
HIV +	5 (2%)	1 (1%)	2 (2%)	0 (0%)	1 (2%)	0 (0%)
Stem cell transplantation within specified time	1 (<1%)	8 (8%)	0 (0%)	1 (<1%)	0 (0%)	0 (0%)
Solid organ transplantation with receipt of systemic immunosuppression	10 (4%)	9 (9%)	9 (9%)	6 (2%)	0 (0%)	0 (0%)
Cytotoxic anti–cancer chemotherapy within the past three months	21 (8%)	16 (15%)	1 (1%)	28 (9%)	2 (4%)	5 (8%)
Congenital immunodeficiency requiring antimicrobial prophylaxis	0 (0%)	3 (3%)	2 (2%)	3 (1%)	0 (0%)	0 (0%)
Receipt of immunosuppressive agents associated with CMV reactivation	14 (5%)	10 (10%)	0 (0%)	4 (1%)	0 (0%)	1 (2%)
Expected to survive < 72 hours or not committed to full intensive care support	42 (16%)	11 (10%)	16 (17%)	23 (8%)	2 (4%)	5 (8%)
Unable to receive first dose of study drug within 120 hours after hospitalization	28 (11%)	47 (45%)	36 (38%)	41 (14%)	17 (31%)	15 (23%)
Currently pregnant or breastfeeding	4 (2%)	0 (0%)	0 (0%)	2 (1%)	0 (0%)	1 (2%)
Absolute neutrophil count < 1,000/mm3	3 (1%)	3 (3%)	0 (0%)	1 (<1%)	0 (0%)	0 (0%)
Use of anti–CMV drugs within seven days of randomization	5 (2%)	4 (4%)	1 (1%)	2 (1%)	0 (0%)	0 (0%)
Currently enrolled in an interventional trial of an anti–CMV therapeutic agent	4 (2%)	0 (0%)	1 (1%)	0 (0%)	1 (2%)	0 (0%)
Has both a tracheostomy and been on continuous mechanical ventilation	15 (6%)	1 (1%)	4 (4%)	6 (2%)	0 (0%)	0 (0%)
Child Class C Cirrhosis	29 (11%)	6 (6%)	7 (7%)	13 (4%)	3 (6%)	6 (9%)
Severe pre–existing interstitial lung disease	10 (4%)	27 (26%)	0 (0%)	3 (1%)	0 (0%)	1 (2%)
Allergy to ganciclovir	0 (0%)	0 (0%)	0 (0%)	1 (<1%)	0 (0%)	0 (0%)
Incarcerated	2 (1%)	1 (1%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Other exclusion reason	31 (12%)	0 (0%)	18 (19%)	14 (5%)	8 (15%)	4 (6%)

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[2]Percentage of participants screened within each study site.
[3]Percentage of participants not enrolled within each study site.
[4]Participants may be ineligible for more than one reason.

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Table O1 – Screen–out Summary by Site

	U of Wisconsin	Vanderbilt U	Wake Forest	Washington U St Louis	All Sites
Participants Screened[1]	12	419	263	72	7328
Participants Enrolled[2]	0 (0%)	8 (2%)	8 (3%)	9 (13%)	213 (3%)
Participants not Enrolled[2]	12 (100%)	411 (98%)	255 (97%)	63 (88%)	7115 (97%)
Participant did not complete all screening procedures[3]	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Participant is eligible but declined enrollment[3]	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Reason participant not enrolled is missing (Incomplete screening)[3]	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Participant not eligible[3,4]	12 (100%)	411 (100%)	255 (100%)	63 (100%)	7115 (100%)
No subject/next of kin informed consent	5 (42%)	13 (3%)	48 (19%)	15 (24%)	452 (6%)
Age < 18 years	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Not CMV IgG seropositive by LFA or standard serologic methods	3 (25%)	16 (4%)	15 (6%)	24 (38%)	867 (12%)
Not Intubated or does not require mechanical positive pressure ventilation	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Does not meet protocol–defined criteria for sepsis within a 24–hour time period	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
On day of randomization eligible for SBT (Spontaneous Breathing Trial)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
On day of randomization, did not fail SBT	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
HIV +	0 (0%)	11 (3%)	5 (2%)	0 (0%)	147 (2%)
Stem cell transplantation within specified time	0 (0%)	6 (1%)	0 (0%)	0 (0%)	26 (<1%)
Solid organ transplantation with receipt of systemic immunosuppression	0 (0%)	49 (12%)	9 (4%)	7 (11%)	363 (5%)
Cytotoxic anti–cancer chemotherapy within the past three months	0 (0%)	62 (15%)	21 (8%)	0 (0%)	625 (9%)
Congenital immunodeficiency requiring antimicrobial prophylaxis	0 (0%)	1 (<1%)	0 (0%)	0 (0%)	21 (<1%)
Receipt of immunosuppressive agents associated with CMV reactivation	0 (0%)	9 (2%)	4 (2%)	0 (0%)	119 (2%)
Expected to survive < 72 hours or not committed to full intensive care support	1 (8%)	50 (12%)	63 (25%)	3 (5%)	551 (8%)
Unable to receive first dose of study drug within 120 hours after hospitalization	0 (0%)	96 (23%)	29 (11%)	7 (11%)	2414 (34%)
Currently pregnant or breastfeeding	0 (0%)	2 (<1%)	0 (0%)	0 (0%)	31 (<1%)
Absolute neutrophil count < 1,000/mm3	0 (0%)	4 (1%)	5 (2%)	1 (2%)	53 (1%)
Use of anti–CMV drugs within seven days of randomization	0 (0%)	1 (<1%)	0 (0%)	1 (2%)	31 (<1%)
Currently enrolled in an interventional trial of an anti–CMV therapeutic agent	0 (0%)	1 (<1%)	0 (0%)	0 (0%)	15 (<1%)
Has both a tracheostomy and been on continuous mechanical ventilation	0 (0%)	11 (3%)	10 (4%)	1 (2%)	228 (3%)
Child Class C Cirrhosis	1 (8%)	31 (8%)	18 (7%)	3 (5%)	340 (5%)
Severe pre–existing interstitial lung disease	0 (0%)	41 (10%)	18 (7%)	2 (3%)	260 (4%)
Allergy to ganciclovir	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (<1%)
Incarcerated	1 (8%)	4 (1%)	0 (0%)	0 (0%)	55 (1%)
Other exclusion reason	1 (8%)	0 (0%)	8 (3%)	5 (8%)	579 (8%)

[1] Number of participants screened is based on the Inclusion Exclusion Criteria eCRF.
[2]Percentage of participants screened within each study site.
[3]Percentage of participants not enrolled within each study site.
[4]Participants may be ineligible for more than one reason.

Source: SCHARP (Zhuoran) – /trials/infect/grail3/analysis/atlas/code/open/t_screening_summary.sas, SAS Version 9.4 (24MAY2026,6:50)