

ACTT-4 Longitudinal Analysis Data Set – Data Dictionary

The ACTT-4 Longitudinal Analysis Data Set is an analysis data set of the parameters for time to recovery, clinical ordinal score, and mortality.

The table below provides a definition for each parameter available in the data set.

Label	Variable	Definition
Unique Subject ID	USUBJID	Unique Subject Identifier
Randomized Treatment	ARM	Treatment Randomized to Receive
Actual Treatment	ACTARM	Treatment Received
Baseline Severity – Actual Ordinal Scale	BCSOSN	Baseline Ordinal Scale Score at Time or Randomization
Time to Death (days) ¹	D29DTHE0	Date of Death – Date of Randomization
Time to Death Censor Time Point (days) ¹	D29DTHE1	Date of Last Visit – Date of Randomization
Time to Recovery (days) ^{1,2}	TTRECOV0	Date of Recovery – Date of Randomization
Time to Recovery Censor Time Point (days) ¹	TTRECOV1	Date of Last Visit – Date of Randomization
Ordinal Scale Score Assessment Day ¹	ADYC	Baseline=Last Observed Ordinal Score prior to Randomization ADYC="1" is ordinal score between Randomization and midnight on day of Randomization. ADYC="2", "3"... is Assessment Date – Randomization Date + 1
Ordinal Scale Score ²	ORDSCOR	See table below. This column does not include any imputations for missing data, other than death. Death was carried forward for Assessment Days 15, 22 and 29, if the death occurred prior to the visit.
Ordinal Scale Score Day 15	OR15SCOR	If a subject was missing Day 15 ordinal score, then the following imputations were used: <ul style="list-style-type: none"> • Subject was randomized but had no ordinal score data available for any timepoint (pre-or post-randomization): OR15SCOR="7". • Subject died on or prior to study day 15: OR15SCOR = "8" • Subject was discharged from the hospital not due to death or transfer to hospice/another hospital and did not return for the Day 15 visit: OR15SCOR = "2" • Subject was discharged from the hospital due to transfer to hospice: OR15SCOR = "7". • Subject was discharged from the hospital due to transfer to another hospital: OR15SCOR = last observed ORDSCOR.

Label	Variable	Definition
		<ul style="list-style-type: none"> • Subject was terminated from the study while hospitalized (termination not due to death) prior to Day 15 assessment: OR15SCOR = last observed ORDSCOR. • Subject was discharged and readmitted 2 or more days later to the hospital prior to Day 15 assessment and was still hospitalized at study day 15: OR15SCOR = “7”.
Age (years)	AGEC	Age at Time of Randomization. Note: Age is a character field as all subjects > 89 years of age are included with an age of >89 to help maintain data anonymity.
Sex	SEX	M=Male F=Female
Duration of Symptoms (days)	BDURSYMP	Subject Reported Duration of Symptoms at Time of Randomization
Comorbidities	COMORB1	<p>Any Comorbidities Reported at BaselineCategorized as:</p> <ul style="list-style-type: none"> • Any Comorbidities • No Comorbidities • Unknown <p>The following comorbidities are included:</p> <ul style="list-style-type: none"> • Baseline Hypertension • Baseline Coronary Artery Disease • Baseline Congestive Heart Failure • Baseline Chronic Respiratory Disease • Baseline Chronic Oxygen Requirement • Baseline Chronic Liver Disease • Baseline Chronic Kidney Disease • Baseline Diabetes I • Baseline Diabetes II • Baseline Obesity • Baseline Cancer • Baseline Immune Deficiency • Baseline Asthma

Label	Variable	Definition
Comorbidities	COMORB2	<p>Number of Comorbidities Reported at BaselineCategorized as:</p> <ul style="list-style-type: none"> • None • 1 Comorbidity • 2 or more Comorbidities <p>The following comorbidities are included:</p> <ul style="list-style-type: none"> • Baseline Hypertension • Baseline Coronary Artery Disease • Baseline Congestive Heart Failure • Baseline Chronic Respiratory Disease • Baseline Chronic Oxygen Requirement • Baseline Chronic Liver Disease • Baseline Chronic Kidney Disease • Baseline Diabetes I • Baseline Diabetes II • Baseline Obesity • Baseline Cancer • Baseline Immune Deficiency • Baseline Asthma
Race	RACE	<p>Reported Race, including:</p> <ul style="list-style-type: none"> • American Indian or Alaska Native • Asian • Native Hawaiian or Other Pacific Islander • Black or African American • White • Multiple • Unknown
Ethnicity	ETHNIC	<p>Reported Ethnicity, including:</p> <ul style="list-style-type: none"> • Not Hispanic or Latino • Hispanic or Latino • Not Reported • Unknown
BMI (kg/m2)	BMI	Defined as: $\text{Weight} / (\text{Height} / 100)^2$
Geographic Region 1	REGION1	<ul style="list-style-type: none"> • US Site • Non-US Site
Geographic Region 2	REGION2	<ul style="list-style-type: none"> • North America • Europe • Asia
Randomized Disease Severity Stratum (N)	STRATAR	<p>Disease Severity used for Randomization:</p> <ul style="list-style-type: none"> • Severe Disease • Moderate Disease

Label	Variable	Definition
Actual Disease Severity Stratum (N)	STRATAV	Actual Disease Severity at the Time of Randomization <ul style="list-style-type: none"> • Severe Disease • Moderate Disease
Baseline Hypertension Flag	HYPFL	Y, N, or null; subject reported hypertension at time of screening
Baseline Coronary Artery Disease Flag	CADFL	Y, N, or null; subject reported coronary artery disease at time of screening
Baseline Congestive Heart Failure Flag	CHFFL	Y, N, or null; subject reported congestive heart failure at time of screening
Baseline Chronic Resp Disease Flag	CRDFL	Y, N, or null; subject reported chronic respiratory disease at time of screening
Baseline Chronic Kidney Disease Flag	CKDFL	Y, N, or null; subject reported chronic kidney disease at time of screening
Baseline Diabetes I Flag	DIAB1FL	Y, N, or null; subject reported Diabetes I at time of screening
Baseline Diabetes II Flag	DIAB2FL	Y, N, or null; subject reported Diabetes II at time of screening
Baseline Obesity Flag	OBESIFL	Y, N, or null; subject reported obesity at time of screening
Baseline Immune Deficiency Flag	IMMDFL	Y, N, or null; subject reported immune deficiency at time of screening
Baseline Asthma Flag	ASTHMAFL	Y, N, or null; subject reported asthma at time of screening
Baseline Cancer Flag	CANCERFL	Y, N, or null; subject reported cancer at time of screening
Baseline Cardiac Valvular Disease Flag	CVDFL	Y, N, or null; subject reported cardiac valvular disease at time of screening
Baseline Coagulopathy Flag	COAGFL	Y, N, or null; subject reported coagulopathy at time of screening

Label	Variable	Definition
Baseline Nicotine Consumption Flag	NICFL	Y, N, or null; subject reported nicotine consumption at time of screening
Baseline Risk Factor for DVT or PE Flag	RFDVTFL	Y, N, or null; subject reported risk factor for DVT or PE at time of screening
Current or Prior Major Surgery Flag	SURGFL	Y, N, or null; subject reported current or prior major surgery at time of screening
Current or Prior Immobility Flag	IMMOFL	Y, N, or null; subject reported current or prior prolong immobility at time of screening
Current or Prior DVT or PE Flag	CPDVTFL	Y, N, or null; subject reported current or prior DVT or PE at time of screening
Current or Prior Delivery in 6 Weeks Flag	DELVFL	Y, N, or null; subject reported current or prior delivery within 6 weeks at time of screening
Baseline Depression Flag	DEPRFL	Y, N, or null; subject reported depression at time of screening
Baseline Epilepsy Flag	EPLYFL	Y, N, or null; subject reported epilepsy at time of screening
Baseline Lupus Flag	LUPSFL	Y, N, or null; subject reported lupus at time of screening
Baseline Autoimmune Hepatitis Flag	AIHPFL	Y, N, or null; subject reported autoimmune hepatitis at time of screening
Baseline Other Autoimmune Flag	OTAIFL	Y, N, or null; subject reported other autoimmune disease at time of screening
Baseline Thyroid Disease Flag	THYDFL	Y, N, or null; subject reported thyroid disease at time of screening
Baseline Cardiac Arrhythmia Flag	CARRFL	Y, N, or null; subject reported cardiac arrhythmia at time of screening
Baseline Vaccines to SARs-CoV-2 Flag	VAXFL	Y, N, or null; subject reported receipt of vaccines to SARs-CoV-2

¹Time to death and time to recovery fields will be one day less than the Ordinal Scale Score Assessment Day. The Assessment Day is the Study Day while the time to death or recovery is the days from randomization. For example, subjects are randomized on Day 1 and if a subject died on Day 3, the time to death would be 2 days.

²Time to recovery does not align with the first observed ordinal score of a 1, 2 or 3 in many cases. This is due to subjects being discharged from the hospital and the site then collects the next ordinal scale score at their next visit on Days 15, 22 or 29. Since they are discharged, the subject meets the definition of a 1 or 2 ordinal scale score once discharged and their time to recovery is the time to discharge.

The table below provides the ordinal scale definitions.

Ordinal Scale	Ordinal Scale Score
Death	8
Hospitalized, on invasive mechanical ventilation or ECMO	7
Hospitalized, on non-invasive ventilation or high flow oxygen devices	6
Hospitalized, requiring supplemental oxygen	5
Hospitalized, not requiring supplemental oxygen, requiring ongoing medical care	4
Hospitalized, not requiring supplemental oxygen, no longer requires ongoing medical care	3
Not hospitalized, limitation on activities and/or requiring home oxygen	2
Not hospitalized, no limitation on activities	1