ACTT-3 Longitudinal Analysis Data Set – Data Dictionary

DMID Protocol: 20-0006 (ACTT-3)

The ACTT-3 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	BCSOSN	Baseline Ordinal Scale Score at Time or	
Ordinal Scale		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	ADYC	Baseline=Last Observed Ordinal Score prior	
Assessment Day ¹		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	
		includeany 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:	
		•Subject was randomized but had no ordinal	
		score data available for any timepoint (pre-	
		orpost-randomization): OR15SCOR="7".	
		Subject died on or prior to study day	
		15:OR15SCOR = "8"	
		Subject was discharged from the hospital	
		notdue 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 totransfer to hospice: OR15SCOR = "7".	
		Subject was discharged from the hospital due	
		totransfer to another hospital:	
		OR15SCOR = last observed ORDSCOR.	

Comorbidities COMORB1 Any Comorbidities Reported at BaselineCategorized as: • Any Comorbidities • No Comorbidities • Unknown The following comorbidities are included: • Baseline Hypertension • Baseline Coronary Artery Disease • Baseline Chronic Respiratory Disease • Baseline Chronic Oxygen Requirement • Baseline Chronic Liver Disease • Baseline Chronic Kidney Disease • Baseline Diabetes I	Label	Variable	Definition
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 COMORBI Any Comorbidities Reported at BaselineCategorized as: • Any Comorbidities • No Comorbidities • No Comorbidities • Unknown The following comorbidities are included: • Baseline Hypertension • Baseline Coronary Artery Disease • Baseline Chronic Respiratory Disease • Baseline Chronic Caygen Requirement • Baseline Chronic Caygen Requirement • Baseline Chronic Kidney Disease • Baseline Chronic Kidney Disease • Baseline Chronic Kidney Disease			· · · · · · · · · · · · · · · · · · ·
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Baseline Cancer Describe Learners Deficiency			
Baseline Immune Deficiency Baseline Asthma			•

Label	Variable	Definition 50 Aug 2021
Comorbidities	COMORB2	Number of Comorbidities Reported at
		BaselineCategorized as:
		• None
		• 1 Comorbidity
		2 or more Comorbidities
		The following comorbidities are included: 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	Reported Race, including:
		 American Indian or Alaska Native Asian Native Hawaiian or Other Pacific Islander Black or African American White Multiple Unknown
Ethnicity	ETHNIC	Reported Ethnicity, including:
		Not Hispanic or LatinoHispanic or LatinoNot ReportedUnknown
BMI (kg/m2)	BMI	Defined as: Weight / (Height / 100)^2
Geographic Region 1	REGION1	US Site Non-US Site
Geographic Region 2	REGION2	North America Europe Asia
Randomized Disease Severity Stratum (N)	STRATAR	Disease Severity used for Randomization: • Severe Disease • Moderate Disease

Label	Variable	Definition
Actual Disease Severity	STRATAV	Actual Disease Severity at the Time of
Stratum (N)		Randomization
		Severe Disease
		Moderate Disease
Baseline Hypertension Flag	HYPFL	Y, N, or null; subject reported hypertension at
		time of screening
Baseline Coronary Artery	CADFL	Y, N, or null; subject reported coronary artery
Disease Flag	CADIL	disease at time of screening
Disease Flag		disease at time of screening
Baseline Congestive Heart	CHFFL	Y, N, or null; subject reported congestive
Failure Flag		heart failure at time of screening
Baseline Chronic Resp Disease	CRDFL	Y, N, or null; subject reported chronic
Flag		respiratory disease at time of screening
Baseline Chronic Oxygen	CORFL	Y, N, or null; subject reported chronic oxygen
Requirement Flag		requirement at time of screening
Baseline Chronic Liver Disease	CLDFL	Y, N, or null; subject reported chronic liver
Flag		disease at time of screening
Baseline Chronic Kidney	CKDFL	Y, N, or null; subject reported chronic kidney
Disease Flag		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
		C
Baseline Cancer Flag	CANCERFL	Y, N, or null; subject reported cancer at time
		of screening
Daratina Immuni Difficion	IMMDEL	V N annull subject was at all annual a
Baseline Immune Deficiency Flag	IMMDFL	Y, N, or null; subject reported immune
1 lag		deficiency at time of screening
Baseline Asthma Flag	ASTHMAFL	Y, N, or null; subject reported asthma at time
	110111111111111111111111111111111111111	of screening
		or servening

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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