

SUMMARY OF REAL-WORLD DATA FOR PATIENTS HOSPITALIZED WITH CORONAVIRUS DISEASE 2019 (COVID-19)

MULTI-CENTER, LONGITUDINAL, CLINICAL REAL-WORLD STUDY TO EVALUATE MORTALITY AND CLINICAL OUTCOMES IN HOSPITALIZED ADULTS WITH COVID-19 INFECTION IN THE UNITED STATES

GS-US-540-5835

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CONFIDENTIAL AND PROPRIETARY INFORMATION

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ALT	alanine aminotransferase
AST	aspartate aminotransferase
BiPAP	bi-level pressure
CDC	Center for Disease Control and Prevention
CKD-EPI	Chronic Kidney Disease Epidemiology Collaboration equation
СМ	Clinical Modification
COVID-19	Coronavirus Disease 2019
CoVs	Coronavirus
CPAP	continuous positive airway pressure
CPT	Current Procedural Terminology
EBOV	Ebola Virus
ECMO	extracorporeal membrane oxygenation
eGFR	estimated glomerular filtration rate
EHR	electronic health record
EMR	electronic medical record
HCOs	healthcare organizations
HCPCS	Healthcare Common Procedure Coding System
HHS	United States Department of Health and Human Services
ICD	International Classification of Diseases
MARV	Marburg virus
MERS	Middle East respiratory syndrome (MERS-CoV)
NIPPV	nasal intermittent positive airway pressure
PCR	polymerase chain reaction
PCS	Procedure Coding System
Q1	the 25 th percentile, or the first quartile
Q3	the 75 th percentile, or the third quartile
RDV	Remdesivir (GS-5734 TM)
RNA	ribonucleic acid
RSV	respiratory syncytial virus
RWD	Real-World Data
SARS	Severe Acute Respiratory Syndrome
US	United States
WBC	white blood cells
WHO	World Health Organization

1. INTRODUCTION

In December 2019, a cluster of patients with pneumonia of unknown cause was reported and linked to a seafood wholesale market in Wuhan, Hubei province, China {Chen 2020, Zhu 2020}. By 07 January 2020, a novel coronavirus, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2; previously known as 2019-nCoV), was isolated from these patients with virus-infected pneumonia, which was later designated coronavirus disease 2019 (COVID-19) in February 2020, by the World Health organization (WHO) {Zhou 2020}.

Since then, the COVID-19 outbreak has continued to spread rapidly around the world. On 30 January 2020, the WHO declared the outbreak a Public Health Emergency of International Concern {World Health Organization (WHO) 2020c}. With increasing numbers of cases of COVID-19 globally and in the United States, the US Department of Health and Human Services (HHS) declared a national public health emergency on 31 January 2020 {Gostin 2020}. On 11 March 2020, the WHO declared COVID-19 outbreak a pandemic {World Health Organization (WHO) 2020b}.

Globally, as of 06 April 2020, 1,210,956 cases and 67,594 deaths from COVID-19 have been confirmed worldwide {World Health Organization (WHO) 2020a}. Among these, 655,339 cases and 49,479 deaths were reported in the European region, and 352,592 cases and 9,680 deaths were reported in regions of the Americas. In the US, there have been 8,358 death reports so far. Table 1 summarizes the number of cases and deaths in the countries with the highest number of cases.

Country	Number of Cases	Number of Deaths
US	307,318	8,358
Spain	130,759	12,418
Italy	128,948	15,889
Germany	95,391	1,434
China	83,005	3,340
France	69,607	8,064

Table 1.COVID-19 Number of Cases and Deaths by Country with the Highest
Number of Cases as of 06 April 2020

Source: World Health Organization (WHO) 2020a}

Note: This information is last updated as of 06 April 2020 but may not represent the latest totals of each country. Due to differences in reporting methods and data cutoff times, there may exist a discrepancy in the number of confirmed cases and deaths.

Remdesivir (RDV, GS-5734TM) is an antiviral drug under evaluation as a potential treatment for COVID-19. Remdesivir is a nucleotide prodrug that is intracellularly metabolized into an analog of adenosine triphosphate that inhibits viral RNA polymerases and has broad spectrum activity against members of the filoviruses (e.g., Ebola virus [EBOV], Marburg virus [MARV]), CoVs (e.g., SARS-CoV, Middle East respiratory syndrome [MERS]-CoV), and paramyxoviruses (e.g., respiratory syncytial virus [RSV], Nipah virus, and Hendra virus).

Beginning on 25 January 2020, Gilead received compassionate use requests for RDV for treatment of COVID-19 and has since provided RDV to hundreds of patients with severe COVID-19 under the compassionate use program.

To investigate the efficacy of RDV used for the treatment of COVID-19, a synthetic comparative arm was developed from real-world data (RWD). This synthetic comparative arm is being compared to a cohort of patients with confirmed COVID-19 infection treated with RDV under compassionate use program.

This report describes this multi-center, longitudinal, clinical RWD study to evaluate the mortality and clinical outcomes in hospitalized adults with COVID-19 infection in the US.

Results from the comparison analysis will not be described in the current report.

2. METHODS FOR REAL-WORLD COVID-19 DATA COLLECTION AND ANALYSIS

2.1. Analysis Objectives

- The primary objectives of the analysis were as follows:
- To estimate the mortality rate in hospitalized adults aged ≥ 18 years with COVID-19 in the US using RWD;
- To compare the mortality rate of hospitalized patients from the RWD clinical setting to patients participating in the compassionate use study of RDV.

The secondary objectives of the analysis were as follows:

- To describe the health status of adult patients with COVID-19 at baseline, defined as time of initial hospitalization, in the US;
- To describe the changes in health status in the hospitalized patients with COVID-19 using a 6-point ordinal scale at baseline and at end of follow-up.

2.2. Selection of Analysis Population

2.2.1. Data Source

Real-world data for patients diagnosed with COVID-19 in the US were licensed by Gilead from TriNetX, which has built a global network of healthcare organizations (HCOs) that allows the interrogation of the HCO's data for clinical research purposes. TriNetX has integrated a wide array of data from major healthcare institutions worldwide, including academic medical centers, specialty hospitals, specialty physician practices, and community hospitals. The available data include deidentified patient demographics, diagnosis history, medications administered and prescribed, procedures performed, laboratory results, and vital signs.

The RWD are commonly sourced from the HCO's intermediate data warehouse, not directly from their online electronic health record (EHR) system, which allows TriNetX to capture data from any available electronic medical record (EMR). Direct identifiers are removed, and a blinded identifier is assigned to each patient. The data were then mapped to a common set of standard clinical terminology.

Data for 13 participating HCOs in the US provided EHR data to TriNetX. A cohort was developed that included adult patients (\geq 18 years of age) hospitalized with COVID-19 on or after 20 January 2020, who did not participate in a clinical trial during this period. The study period described in this report includes patient-level data from 20 January 2020 to 30 March 2020.

2.2.2. Inclusion and Exclusion Criteria

The criteria for inclusion in the TriNetX cohort were as follows:

- Male or female patients aged 18 years and older.
- Patients diagnosed with the following International Classification of Diseases ICD-10 codes:

B97.29 (other coronavirus as the causes of diseases classified elsewhere),

B34.2 (coronavirus infection, unspecified), and

U07.1 (2019-nCoV acute respiratory disease [WHO])

• Patients hospitalized after the first COVID-19 index patient was diagnosed in the US on 20 January 2020.

The criteria for exclusion in the TriNetX cohort were as follows:

• Patients diagnosed with the following ICD-9 code:

079.89 (other specific viral infections)

• Patients who were enrolled in a clinical trial on or after 20 January 2020

2.3. Analysis Sets

Data were presented for the overall data set and according to the following subgroups based on oxygen support status at baseline (ie, the first date of hospitalization or Day 0):

• Invasive Oxygen Support

Extracorporeal membrane oxygenation (ECMO)

Invasive mechanical ventilation

• Non-Invasive Oxygen Support

Non-invasive mechanical ventilation

Oxygen flow (e.g., either high- or low-flow supplemental oxygen)

Room air

Oxygen support status at baseline and during hospitalization was defined by associated ICD-9/-10 Procedure Coding System (PCS) Clinical Modification (CM), Current Procedural Terminology (CPT), and Healthcare Common Procedure Coding System (HCPCS) codes and was categorized as follows:

- Extracorporeal membrane oxygenation or ECMO) (ie, initiation, daily management, and/or insertion or reposition of central/peripheral cannula [by sternotomy/thoracotomy]).
- Invasive mechanical ventilation (i.e., respiratory ventilation, continuous assistance with respiratory filtration, dependence on an aspirator or respirator, ventilator assistance and management [with pressure or volume preset ventilators for assisted or controlled breathing in a hospital inpatient setting and/or used with invasive interfaces (eg, tracheostomy tubes)], and direct measurements of oxygen saturation, excluding pulse oximetry).

Also included in the classification were records of procedures related to intubations on the trachea/larynx and tracheostomies.

- Non-invasive mechanical ventilation (ie, non-mechanical respiratory ventilation, continuous positive airway pressure [CPAP], nasal intermittent positive airway pressure [NIPPV], bi-level pressure [BiPAP], continuous/intermittent negative airway pressure, and non-invasive interfaces [eg, oral/nasal masks and the associated device components]).
- Oxygen (supplementation) flow (i.e., supplemental oxygen dependence/enrichment, use of non-invasive ear or pulse oximetry and their related components for oxygen saturation, [non-] pressurized inhalation treatment or therapeutic substances introduced into the respiratory tract, use of oxygen gas/liquid systems).

Also included in the classification were records of (the initial use of) tracheostomy masks to indicate the improvement in oxygen status from invasive mechanical ventilation to the less invasive administration of oxygen supplementation.

• Room air (defined as the absence of ECMO, either type of mechanical ventilation, and oxygen supplementation procedure codes during hospitalization).

3. SUMMARY OF COVID-19 REAL-WORLD DATA

3.1. Demographics and Baseline Characteristics

As of 30 March 2020, a total of 236 patients were included in the TriNetX cohort; of these, 153 (64.8%) were hospitalized with COVID-19. Demographics for the 153 patients are summarized in Table 2, along with information on the clinical status of the patient on the day of hospitalization. Patients included were from 13 HCOs in the US. The RWD does not contain the duration of signs/symptoms or the results of confirmatory testing for COVID-19 (e.g., polymerase chain reaction (PCR) testing).

Median (Q1, Q3) age was 62.0 (51.0, 72.0) years overall. The median (Q1, Q3) ages were similar for the invasive oxygen support (62.0 [50.5, 75.5] years) and non-invasive oxygen support groups (62.0 [51.0, 72.0] years). The proportion of older patients (\geq 60 years) was similar in the invasive oxygen support group (15 of 24 patients [62.5%]) relative to the non-invasive oxygen support group (69 of 129 patients [53.5%]). Overall, 49.7% (76 of 153 patients) were male, with higher percentages of male patients in the invasive oxygen support group relative to the non-invasive oxygen support group (58.3% and 48.1% respectively).

Overall, the majority of patients hospitalized were white (81 of 153 patients [52.9%]). Black or African Americans accounted for 55 of 153 patients (35.9%).

	Invasive (N = 24)	Non-Invasive (N = 129)	Total (N = 153)
Age (years), median (Q1, Q3)	62.0 (50.5, 75.5)	62.0 (51.0, 72.0)	62.0 (51.0, 72.0)
Age categories			
< 50 years, n (%)	5 (20.8%)	27 (20.9%)	32 (20.9%)
\geq 50 years to < 60 years, n (%)	4 (16.7%)	33 (25.6%)	37 (24.2%)
\geq 60 years to < 70 years, n (%)	7 (29.2%)	32 (24.8%)	39 (25.5%)
≥ 70 years, n (%)	8 (33.3%)	37 (28.7%)	45 (29.4%)
Gender			
Male, n (%)	14 (58.3%)	62 (48.1%)	76 (49.7%)
Race/Ethnicity			
White, n (%)	13 (54.2%)	68 (52.7%)	81 (52.9%)
Black or African American, n (%)	9 (37.5%)	46 (35.7%)	55 (35.9%)
Hispanic or Latino, n (%)	0	5 (3.9%)	5 (3.3%)
Asian, n (%)	0	3 (2.3%)	3 (2.0%)
Unknown, n (%)	2 (8.3%)	7 (5.4%)	9 (5.9%)

Table 2.Demographic Characteristics by Baseline Oxygen Support Status and
Total: All Hospitalized Patients

Baseline oxygen support status was defined as the oxygen status on the first day of hospitalization. Invasive oxygen support includes ECMO and invasive mechanical ventilation.

Non invasive oxygen support includes non invasive ventilation, oxygen therapy, and room air. Source: Tables 2.1, 2.2

In the invasive oxygen support group, all 24 patients were on mechanical ventilation. No patients were on ECMO. Of the 129 patients in the non-invasive oxygen support group, 5 (3.3%) were on non-invasive ventilation, 46 (30.1%) were on oxygen support, and 78 (51.0%) were on room air.

3.2. Baseline Disease Characteristics

3.2.1. Medical History

Medical history data were only available for 62 of 153 (40.5%) patients (Table 3). A higher proportion of patients on invasive oxygen support at time of hospital admission had a history of pulmonary diseases (eg, asthma or chronic obstructive pulmonary disease) or diabetes mellitus than patients on non-invasive oxygen support.

Medical History	Invasive (N = 24)	Non-Invasive (N = 129)	Total (N = 153)
Number of Patients with Medical History, n (%)	11 (45.8%)	51 (39.5%)	62 (40.5%)
Asthma, n (%)	4 (16.7%)	11 (8.5%)	15 (9.8%)
Cancer, n (%)	3 (12.5%)	10 (7.8%)	13 (8.5%)
Chronic Liver Disease, n (%)	1 (4.2%)	1 (0.8%)	2 (1.3%)
Chronic Obstructive Pulmonary Disease, n (%)	6 (25.0%)	10 (7.8%)	16 (10.5%)
Cardiovascular Disease, n (%)	8 (33.3%)	28 (21.7%)	36 (23.5%)
Diabetes Mellitus, n (%)	7 (29.2%)	15 (11.6%)	22 (14.4%)
HIV/AIDS, n (%)	0	5 (3.9%)	5 (3.3%)
Inflammatory Bowel Disease, n (%)	0	3 (2.3%)	3 (2.0%)
Rheumatoid Arthritis, n (%)	0	2 (1.6%)	2 (1.3%)
Renal Insufficiency, n (%)	4 (16.7%)	18 (14.0%)	22 (14.4%)

Table 3. Medical History by Baseline Oxygen Support Status

Source: Table 6

3.2.2. Duration of Hospitalization

The median (Q1, Q3) duration of hospitalization was 7 (3, 14) days overall (Table 4). The median durations of hospitalization were similar for the invasive and non-invasive oxygen support groups. A higher proportion of patients on invasive oxygen support at baseline were hospitalized for more than 10 days, as compared with patients on non-invasive oxygen support (11 of 24 (45.8%) vs. 45 of 129 (34.9%), respectively).

	Invasive (N = 24)	Non-Invasive (N = 129)	Total (N = 153)
Median (Q1, Q3) Duration (Days)	7.5 (4.5, 17.5)	7.0 (3.0, 14.0)	7.0 (3.0, 14.0)
Duration categories			
<5 days, n (%)	6 (25.0%)	44 (34.1%)	50 (32.7%)
5 – 9 days, n (%)	7 (29.2%)	40 (31.0%)	47 (30.7%)
≥ 10 days, n (%)	11 (45.8%)	45 (34.9%)	56 (36.6%)

Table 4.Duration of Hospitalization by Baseline Oxygen Support Status

Source: Tables 3.1, 3.2

3.3. Clinical Outcomes

Clinical outcomes are summarized by baseline oxygen support status (Table 5). A total of 39 of 153 (25.5%) patients were discharged. A total of 26 of 153 (17.0%) of patients overall continued to be hospitalized. A total of 11 of 153 (7.2%) of patients died overall, including deaths that occurred after hospital discharge based on available medical records. During hospitalization, 6 of 153 (3.9%) patients died. Outcome status was unknown or pending for 77 of 153 (50.3%) patients due to having \leq 1 day of follow-up or hospital status was unknown or pending in the medical records.

Table 5.Clinical Outcomes by Baseline Oxygen Support Status

Outcome	Invasive (N = 24)	Non-Invasive (N = 129)	Total (N = 153)
Discharge, n (%)	5 (20.8%)	34 (26.4%)	39 (25.5%)
Hospitalization ongoing, n (%)	2 (8.3%)	24 (18.6%)	26 (17.0%)
Death during follow-up (overall), n (%)	6 (25.0%)	5 (3.9%)	11 (7.2%)
Death during hospitalization, n (%)	3 (12.5%)	3 (2.3%)	6 (3.9%)
Death after hospitalization, n (%)	3 (12.5%)	2 (1.6%)	5 (3.3%)
Unknown/Pending status, n (%)	11 (45.8%)	66 (51.2%)	77 (50.3%)

Hospitalization ongoing includes patients who were alive and remained in the hospital at the data cut off (30 March 2020). Source: Table 4

The total duration of follow-up for all patients was 2,718 days. A total of 11 of 153 (7.2%) patients died, and the mortality rate was 0.40 (95% CI 0.20, 0.72) per 100 days follow-up. The overall survival is presented in Figure 1. The mortality rates for male and female patients and the mortality rates for patients in the invasive and non-invasive oxygen support groups are presented in Table 6.

Outcome Group	Number of Deaths (N)	Total Number of Days	Mortality Rate per 100 days (95% CI)
All Patients	11	2718	0.40 (0.20, 0.72)
Invasive Oxygen Support Patients	6	431	1.39 (0.51, 3.03)
Non-Invasive Oxygen Support Patients	5	2287	0.22 (0.07, 0.51)
Male Patients	9	1395	0.65 (0.30, 1.22)
Female Patients	2	1323	0.15 (0.02, 0.55)

Table 6.	Mortality Ra	es by Sex and	Baseline Oxygen	Support State
Table U.	Mortanty Na	to by ber anu	Daschine Oxygen	Support Sta

Source: Tables 7.1 7.8

Figure 1.





Product-Limit Survival Estimate With Number of Subjects at Risk A comparison of survival over time by baseline oxygen support status is presented in Figure 2. Patients in the invasive oxygen support group had a statistical significantly higher mortality rate than patients in the non-invasive oxygen support group $(p \quad 0.0003)$ based on univariate log-rank test. The median survival was not reached for either group.





A comparison of survival over time by gender is presented in Figure 3. Male patients had a statistical significantly higher mortality rate than female patients $(p \quad 0.046)$ based on univariate log-rank test. The median survival was not reached for either group.





Patients on invasive oxygen support at baseline had a higher mortality rate than patients on non-invasive oxygen support; the mortality rate ratio was 6.37 (95% CI: 1.94, 20.86; Table 7). The mortality rate ratio for males compared to females was 4.27 (95% CI 0.92, 19.75). The mortality rate ratio was 3.87 (95% CI%: 0.84, 17.92) for patients \geq 60 years of age compared to those who were < 60 years of age.

Table 7.	Mortality Rate 1	Ratios

Comparison Group	Mortality Rate Ratio (95% CI)
Invasive and Non-Invasive Oxygen Support Patients	6.37 (1.94, 20.86)
Male and Female Patients	4.27 (0.92, 19.75)
Age ≥ 60 years and < 60 years	3.87 (0.84, 17.92)

Source: Tables 7.6 7.8

3.3.1. 2-Point Clinical Improvement from Baseline

A summary of the clinical outcome on the last day of follow-up (ie, last day of available data) by baseline oxygen support status is presented in Table 8. Clinical improvement was assessed using a 6-point ordinal scale.

Overall, 41 of 153 (26.8%) had a 2-point clinical improvement from baseline. The proportion of patients with a 2-point clinical improvement was similar for the invasive oxygen support status and the non-invasive oxygen support status groups. A total of 35 of 153 (22.9%) patients did not have a 2-point clinical improvement. Clinical outcome could not be determined for 77 of 153 (50.3%) patients because either there was only clinical data with ≤ 1 day of follow-up or it was not possible to determine hospitalization status with the existing medical records.

Table 8.Clinical Improvement on the Last Day of Follow-up by Baseline
Oxygen Support Status

	Invasive (N = 24)	Non-Invasive (N = 129)	Total (N = 153)
≥ 2 Point Clinical Improvement from Baseline, n (%)	7 (29.2%)	34 (26.4%)	41 (26.8%)
No Clinical Improvement, n (%)	6 (25.0%)	29 (22.5%)	35 (22.9%)
Unknown/Pending status	11 (45.8%)	66 (51.2%)	77 (50.3%)

Source: Table 8.1

Change in oxygen support status from baseline to the last day of follow-up is presented in Table 9.

Table 9.Shift in Oxygen Support Status from Baseline (Invasive vs.
Non-Invasive)

	Invasive (N = 24)	Non-Invasive (N = 129)	Total (N = 153)
Vent status on Last Day of Follow-up, n (%)			
Death	6 (25.0%)	5 (3.9%)	11 (7.2%)
Invasive Mechanical Ventilation	0	1 (0.8%)	1 (0.7%)
ECMO	0	0	0
Non-Invasive Mechanical Ventilation	0	0	0
Oxygen	0	5 (3.9%)	5 (3.3%)
Room Air	2 (8.3%)	18 (14.0%)	20 (13.1%)
Discharge	5 (20.8%)	34 (26.4%)	39 (25.5%)
Unknown/Pending Status	11 (45.8%)	66 (51.2%)	77 (50.3%)

Source: Table 8.2

3.4. Clinical Laboratory Assessments

3.4.1. Liver-Related Laboratory Parameters

Tables showing Median (Q1, Q3) alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase, and total bilirubin over time are provided in Table 10, Table 11, Table 12, and Table 13, respectively.

Table 10.Median (Q1, Q3) Alanine Aminotransferase (ALT) Over Time

	Baseline	Day 7	Day 14	Day 28
Number of Patients with Lab Data	101	33	16	3
Median (Q1, Q3) (IU/L)	27 (16, 43)	36 (29, 72)	27 (15.5, 44)	14 (13, 40)

Baseline is the date of initial hospitalization after COVID 19 diagnosis. Source: Table 5.1

Table 11.Median (Q1, Q3) Aspartate Aminotransferase (AST) Over Time

	Baseline	Day 7	Day 14	Day 28
Number of Patients with Lab Data	101	33	16	3
Median (Q1, Q3) (IU/L)	33 (22, 48)	37 (25, 60)	30 (18.5, 55.5)	18 (15, 73)

Baseline is the date of initial hospitalization after COVID 19 diagnosis. Source: Table 5.2

Table 12.Median (Q1, Q3) Alkaline Phosphatase Over Time

	Baseline	Day 7	Day 14	Day 28
Number of Patients with Lab Data	101	32	16	3
Median (Q1, Q3) (U/L)	84 (67, 130)	91 (71, 137.5)	89.5 (70, 195.5)	156 (64, 183)

Baseline is the date of initial hospitalization after COVID 19 diagnosis. Source: Table 5.3

	Baseline	Day 7	Day 14	Day 28
Number of Patients with Lab Data	101	28	13	2
Median (Q1, Q3) (mg/dL)	0.5 (0.3, 0.9)	0.7 (0.4, 1.4)	0.5 (0.5, 1.3)	0.5 (0.4, 0.5)

Table 13.Median (Q1, Q3) Total Bilirubin Over Time

Baseline is the date of initial hospitalization after COVID 19 diagnosis. Source: Table 5.4

3.4.2. Renal-Related Laboratory Parameters

Median (Q1, Q3) serum creatinine and estimated glomerular filtration rate (eGFR) over time are provided in Table 14 and Table 15, respectively. The eGFR was calculated using the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equation.

Table 14.Median (Q1, Q3) Serum Creatinine Over Time

	Baseline	Day 7	Day 14	Day 28
Number of Patients with Lab Data	122	56	27	8
Median (Q1, Q3) (mg/dL)	1.0 (0.8, 1.5)	1.0 (0.8, 1.5)	1.0 (0.8, 1.6)	1.2 (0.8, 1.8)

Baseline is the date of initial hospitalization after COVID 19 diagnosis. Source: Table 5.5

Table 15.Median (Q1, Q3) CKD-EPI Estimated Glomerular Filtration Rate
(eGFR)

	Baseline	Day 7	Day 14	Day 28
Number of Patients with Lab Data	105	48	23	8
Median (Q1, Q3) (ml/min/1.73m ²)	70.5 (42.2, 101.7)	71.6 (46.6, 102.9)	74.6 (42.4, 91.6)	69.2 (37.0, 88.0)

Baseline is the date of initial hospitalization after COVID 19 diagnosis. Source: Table 5.6

3.4.3. Hematology-Related Laboratory Parameters

Median (Q1, Q3) white blood cells (WBC), lymphocytes, and platelets over time are provided in Table 16, Table 17, and Table 18 respectively.

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	Baseline	Day 7	Day 14	Day 28
Number of Patients with Lab Data	121	54	24	8
Median (Q1, Q3) (x10 ⁹ /L)	8.6 (5.5, 13.4)	7.5 (4.6, 10.8)	7.6 (4.5, 11.0)	9.8 (5.7, 13.6)

Table 16.Median (Q1, Q3) White Blood Cells (WBC) Over Time

Baseline is the date of initial hospitalization after COVID 19 diagnosis. Source: Table 5.7

Table 17.Median (Q1, Q3) Lymphocytes Over Time

	Baseline	Day 7	Day 14	Day 28
Number of Patients with Lab Data	77	20	17	4
Median (Q1, Q3) (x10 ⁹ /L)	1.3 (0.8, 2.4)	1.2 (0.5, 2.3)	0.8 (0.6, 1.4)	1.1 (0.9, 1.4)

Baseline is the date of initial hospitalization after COVID 19 diagnosis. Source: Table 5.8

Table 18.Median (Q1, Q3) Platelets Over Time

	Baseline	Day 7	Day 14	Day 28
Number of Patients with Lab Data	121	54	24	8
Median (Q1, Q3) (x10 ⁹ /L)	202 (152, 270)	199.5 (133, 264)	184 (144, 300.5)	262 (175.5, 333)

Baseline is the date of initial hospitalization after COVID 19 diagnosis. Source: Table 5.9

4. SUMMARY OF RESULTS

This report summarizes available RWD from 13 HCOs in the US that provided EHR data for 153 patients who had been hospitalized for COVID-19. To be included, patients needed to have been diagnosed with COVID-19 (as determined by ICD-10 codes) and not participating in a clinical study at the time of enrollment. The study period included patient data from 20 January2020 to the data cut-off date of 30 March 2020.

At baseline, 15.7% of patients had invasive oxygen support (ie, invasive mechanical ventilation) and 84.3% of patients had non-invasive oxygen support (including non-invasive ventilation, oxygen, or room air).

The median (Q1, Q3) duration of hospitalization was 7 days (3.0, 14.0). Overall, 25.5% of patients were discharged and 17.0% of patients remained hospitalized through the data cut-off date. A total of 11 patients (7.2%) died, and the overall mortality rate was 0.4 (95% CI 0.20, 0.72) per 100 days of follow-up. Patients on invasive oxygen support at time of hospital admission had a higher mortality rate than patients on non-invasive oxygen support; the mortality rate ratio was 6.37 (95% CI 1.94, 20.86). The mortality rate ratio for males compared to females was 4.27 (95% CI 0.92, 19.75). The mortality rate ratio was 3.87 (95% CI%: 0.84, 17.92) for patients aged \geq 60 years of age compared to those who were < 60 years of age.

Overall, 26.8% (41 of 153 patients) had a 2-point clinical improvement from baseline. The proportion of patients with a 2-point clinical improvement was similar for the invasive and the non-invasive oxygen support status groups (29.2% and 26.4%, respectively, respectively).

Clinical laboratory assessments were done for selected liver-, renal-, and hematology-related laboratory tests. Available data was insufficient to assess changes over time.

This RWD study provides a unique perspective on patients hospitalized for the treatment of COVID-19 at the early stages of the pandemic in the US. The EHR data are from 13 different HCOs across the US and enables a multi-center, longitudinal analysis. The initial data available for analysis, however, did not yet include PCR testing confirmatory results for COVID-19. Patients may have been hospitalized prior to the release of CDC recommended diagnostic codes and thus some patients might not have been identified for inclusion into the analysis set. Also, although all hospitalization records were provided in a timely manner, patient data may be incomplete and may be updated with time.

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Table 3.1: Duration of Hospitalization by Baseline Oxygen Support Status (Overall) Patients in the Analysis Set

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Figure 2: Kaplan-Meier Plot by Oxygen Support Patients in the Analysis Set

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Table 1. Factent Disposition			
	Total (N=236)		
Patients with Data Received	236 (100.0%)		
Number of Hospitalized Patients	153 (64.8%)		

Table 1: Patient Disposition

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Gilead Sciences, Inc Study GS-US-540-5835

(TriNetX EHR data)

	Total (N=153)
Age Categories (years) ¹	
< 50	32 (20.9%)
> 50 - < 60	37 (24.2%)
> 60 - < 70	39 (25.5%)
> 70	45 (29.4%)
Age (years) ¹	
Ν	153
Mean (SD)	60.7 (16.2)
Median	62.0
Q1, Q3	51.0, 72.0
Min, Max	22.0, 90.0
Gender	
Male	76 (49.7%)
Female	77 (50.3%)
Race/Ethnicity	
White, non-Hispanic	81 (52.9%)
Black or African American	55 (35.9%)

Table 2.1: Baseline Characteristics Patients in the Analysis Set

The TriNetX analysis set is defined as hospitalized adult (> 18 years) patients from US health care organizations with a COVID-19 diagnosis that occurred on or after January 20, 2020 and before March 30, 2020 (inclusive)

No patients with missing oxygen support status

 1 Patients' age > 90 years was rounded by TriNetX to 90 years in order to protect patient privacy, the number of patients with age > 90 is 4.

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	(1	Total N=153)
Hispanic or Latino	5	(3.3%)
Asian	3	(2.0%)
Unknown	9	(5.9%)
Oxygen Support Status		
Invasive	24	(15.7%)
Invasive Mechanical Ventilation	24	(15.7%)
ECMO	0	(0.0%)
Non-Invasive	129	(84.3%)
Non-Invasive Ventilation	5	(3.3%)
Oxygen	46	(30.1%)
Room Air	78	(51.0%)

Table 2.1: Baseline Characteristics Patients in the Analysis Set

The TriNetX analysis set is defined as hospitalized adult (> 18 years) patients from US health care organizations with a COVID-19 diagnosis that occurred on or after January 20, 2020 and before March 30, 2020 (inclusive)

No patients with missing oxygen support status

 1 Patients' age > 90 years was rounded by TriNetX to 90 years in order to protect patient privacy, the number of patients with age > 90 is 4.

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Table 2.2: Baseline Characteristics by Baseline Oxygen Support Status Patients in the Analysis Set

	Invasive (N=24)	Non-Invasive (N=129)	Total (N=153)
Age Categories ¹			
< 50	5 (20.8%)	27 (20.9%)	32 (20.9%)
> 50 - < 60	4 (16.7%)	33 (25.6%)	37 (24.2%)
> 60 - < 70	7 (29.2%)	32 (24.8%)	39 (25.5%)
> 70	8 (33.3%)	37 (28.7%)	45 (29.4%)
Age (years) ¹			
Ν	24	129	153
Mean (SD)	62.7 (15.9)	60.3 (16.3)	60.7 (16.2)
Median	62.0	62.0	62.0
Q1, Q3	50.5, 75.5	51.0, 72.0	51.0, 72.0
Min, Max	35.0, 90.0	22.0, 90.0	22.0, 90.0
Gender			
Male	14 (58.3%)	62 (48.1%)	76 (49.7%)
Female	10 (41.7%)	67 (51.9%)	77 (50.3%)
Race/Ethnicity			
White, non-Hispanic	13 (54.2%)	68 (52.7%)	81 (52.9%)

The TriNetX analysis set is defined as hospitalized adult (> 18 years) patients from US health care organizations with a COVID-19 diagnosis that occurred on or after January 20, 2020 and before March 30, 2020 (inclusive).

A logistic regression model was applied for lab tests adjusting for age and sex, no significant difference was found for baseline invasive and non-invasive groups.

¹ Patients' age >90 years was rounded by TriNetX to 90 years in order to protect patient privacy, the number of patients with age > 90 is 4.

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Table 2.2: Baseline Characteristics by Baseline Oxygen Support Status Patients in the Analysis Set

	Invasive (N=24)	Non-Invasive (N=129)	Total (N=153)
Black or African American	9 (37.5%)	46 (35.7%)	55 (35.9%)
Hispanic or Latino	0	5 (3.9%)	5 (3.3%)
Asian	0	3 (2.3%)	3 (2.0%)
Unknown	2 (8.3%)	7 (5.4%)	9 (5.9%)
AST Categories (IU/L)			
< 40	9 (56.3%)	52 (61.2%)	61 (60.4%)
> 40	7 (43.8%)	33 (38.8%)	40 (39.6%)
AST (IU/L)			
Ν	16	85	101
Mean (SD)	46.4 (34.1)	44.4 (48.4)	44.7 (46.3)
Median	35.5	33.0	33.0
Q1, Q3	21.0, 70.0	22.0, 46.0	22.0, 48.0
Min, Max	10.0, 134.0	7.0, 412.0	7.0, 412.0
ALT Categories (IU/L)			
< 50	14 (87.5%)	68 (80.0%)	82 (81.2%)
> 50	2 (12.5%)	17 (20.0%)	19 (18.8%)

The TriNetX analysis set is defined as hospitalized adult (> 18 years) patients from US health care organizations with a COVID-19 diagnosis that occurred on or after January 20, 2020 and before March 30, 2020 (inclusive).

A logistic regression model was applied for lab tests adjusting for age and sex, no significant difference was found for baseline invasive and non-invasive groups.

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Table 2.2: Baseline Characteristics by Baseline Oxygen Support Status Patients in the Analysis Set

	Invasive (N=24)	Non-Invasive (N=129)	Total (N=153)
ALT (IU/L)			
Ν	16	85	101
Mean (SD)	28.2 (26.7)	40.8 (41.6)	38.8 (39.8)
Median	19.0	28.0	27.0
Q1, Q3	14.0, 32.0	17.0, 46.0	16.0, 43.0
Min, Max	5.0, 113.0	5.0, 248.0	5.0, 248.0
Alkaline Phosphatase (x10^9/L)			
Ν	16	85	101
Mean (SD)	153.2 (122.3)	109.3 (79.8)	116.2 (88.6)
Median	124.5	84.0	84.0
Q1, Q3	71.5, 161.5	62.0, 112.0	67.0, 130.0
Min, Max	54.0, 533.0	31.0, 481.0	31.0, 533.0
Bilirubin Categories(mg/dL)			
< 1.5	14 (87.5%)	74 (87.1%)	88 (87.1%)
> 1.5	2 (12.5%)	11 (12.9%)	13 (12.9%)

The TriNetX analysis set is defined as hospitalized adult (> 18 years) patients from US health care organizations with a COVID-19 diagnosis that occurred on or after January 20, 2020 and before March 30, 2020 (inclusive).

A logistic regression model was applied for lab tests adjusting for age and sex, no significant difference was found for baseline invasive and non-invasive groups.

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Table 2.2: Baseline Characteristics by Baseline Oxygen Support Status Patients in the Analysis Set

	Invasive (N=24)	Non-Invasive (N=129)	Total (N=153)
Bilirubin (mg/dL)			
Ν	16	85	101
Mean (SD)	0.8 (0.6)	1.0 (1.5)	0.9 (1.4)
Median	0.6	0.5	0.5
Q1, Q3	0.4, 1.1	0.3, 0.8	0.3, 0.9
Min, Max	0.2, 2.1	0.1, 9.3	0.1, 9.3
Creatinine Categories (mg/dL)			
< 1.5	15 (75.0%)	72 (70.6%)	87 (71.3%)
> 1.5	5 (25.0%)	30 (29.4%)	35 (28.7%)
Creatinine (mg/dL)			
Ν	20	102	122
Mean (SD)	1.3 (0.7)	1.6 (2.1)	1.6 (2.0)
Median	1.1	1.0	1.0
Q1, Q3	0.8, 1.4	0.8, 1.5	0.8, 1.5
Min, Max	0.6, 3.2	0.5, 16.8	0.5, 16.8

The TriNetX analysis set is defined as hospitalized adult (> 18 years) patients from US health care organizations with a COVID-19 diagnosis that occurred on or after January 20, 2020 and before March 30, 2020 (inclusive).

A logistic regression model was applied for lab tests adjusting for age and sex, no significant difference was found for baseline invasive and non-invasive groups.

¹ Patients' age >90 years was rounded by TriNetX to 90 years in order to protect patient privacy, the number of patients with age > 90 is 4.

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Table 2.2: Baseline Characteristics by Baseline Oxygen Support Status Patients in the Analysis Set

	Invasive (N=24)	Non-Invasive (N=129)	Total (N=153)
eGFR categories(ml/min/1.73m ²)			
< 50	4 (23.5%)	29 (33.0%)	33 (31.4%)
> 50	13 (76.5%)	59 (67.0%)	72 (68.6%)
eGFR (ml/min/1.73m ²)			
Ν	17	88	105
Mean (SD)	69.8 (33.7)	71.8 (38.8)	71.5 (37.9)
Median	68.8	70.6	70.5
Q1, Q3	51.9, 97.6	42.2, 101.8	42.2, 101.7
Min, Max	15.3, 118.9	3.7, 159.2	3.7, 159.2
Platelets Categories (x10^9/L)			
< 100	3 (15.0%)	13 (12.9%)	16 (13.2%)
> 100	17 (85.0%)	88 (87.1%)	105 (86.8%)
Platelets (x10^9/L)			
Ν	20	101	121
Mean (SD)	214.7 (131.6)	212.9 (101.4)	213.2 (106.3)
Median	189.5	206.0	202.0

The TriNetX analysis set is defined as hospitalized adult (> 18 years) patients from US health care organizations with a COVID-19 diagnosis that occurred on or after January 20, 2020 and before March 30, 2020 (inclusive).

A logistic regression model was applied for lab tests adjusting for age and sex, no significant difference was found for baseline invasive and non-invasive groups.

¹ Patients' age >90 years was rounded by TriNetX to 90 years in order to protect patient privacy, the number of patients with age > 90 is 4.

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Table 2.2: Baseline Characteristics by Baseline Oxygen Support Status Patients in the Analysis Set

	Invasive (N=24)	Non-Invasive (N=129)	Total (N=153)
Q1, Q3	148.5, 296.5	152.0, 268.0	152.0, 270.0
Min, Max	7.0, 539.0	9.0, 592.0	7.0, 592.0
Lymphocytes Categories (x10^9/L)			
< 1	7 (43.8%)	19 (31.1%)	26 (33.8%)
> 1	9 (56.3%)	42 (68.9%)	51 (66.2%)
Lymphocytes (x10^9/L)			
Ν	16	61	77
Mean (SD)	2.1 (3.8)	4.2 (7.4)	3.8 (6.8)
Median	1.2	1.4	1.3
Q1, Q3	0.4, 1.7	0.8, 2.6	0.8, 2.4
Min, Max	0.2, 15.9	0.1, 33.3	0.1, 33.3
WBC Categories(x10^9/L)			
< 4	4 (20.0%)	10 (9.9%)	14 (11.6%)
> 4	16 (80.0%)	91 (90.1%)	107 (88.4%)
WBC (x10^9/L)			
Ν	20	101	121

The TriNetX analysis set is defined as hospitalized adult (> 18 years) patients from US health care organizations with a COVID-19 diagnosis that occurred on or after January 20, 2020 and before March 30, 2020 (inclusive).

A logistic regression model was applied for lab tests adjusting for age and sex, no significant difference was found for baseline invasive and non-invasive groups.

¹ Patients' age >90 years was rounded by TriNetX to 90 years in order to protect patient privacy, the number of patients with age > 90 is 4.

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Table 2.2: Baseline Characteristics by Baseline Oxygen Support Status Patients in the Analysis Set

	Invasive (N=24)	Non-Invasive (N=129)	Total (N=153)
Mean (SD)	11.0 (6.3)	9.8 (6.0)	10.0 (6.1)
Median	10.2	8.2	8.6
Q1, Q3	7.3, 14.7	5.3, 12.3	5.5, 13.4
Min, Max	0.8, 24.8	0.3, 27.4	0.3, 27.4

The TriNetX analysis set is defined as hospitalized adult (> 18 years) patients from US health care organizations with a COVID-19 diagnosis that occurred on or after January 20, 2020 and before March 30, 2020 (inclusive).

A logistic regression model was applied for lab tests adjusting for age and sex, no significant difference was found for baseline invasive and non-invasive groups.

¹ Patients' age >90 years was rounded by TriNetX to 90 years in order to protect patient privacy, the number of patients with age > 90 is 4.

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Gilead Sciences, Inc Study GS-US-540-5835 (TriNetX EHR data)

Invasive (N=24)	Non-Invasive (N=129)	Total (N=153)	
(⁰ / ₀)			
6 (25.0%)	44 (34.1%)	50 (32.7%)	
7 (29.2%)	40 (31.0%)	47 (30.7%)	
11 (45.8%)	45 (34.9%)	56 (36.6%)	
vs)			
24	129	129 153	
13.4 (15.0)	10.7 (11.2)	11.1 (11.8)	
7.5	7.0	7.0	
4.5, 17.5	3.0, 14.0	3.0, 14.0	
1.0, 55.0	1.0, 53.0	1.0, 55.0	
	Invasive (N=24) %) 6 (25.0%) 7 (29.2%) 11 (45.8%) rs) 24 13.4 (15.0) 7.5 4.5, 17.5 1.0, 55.0	Invasive $(N=24)$ Non-Invasive $(N=129)$ %)6 (25.0%)44 (34.1%)7 (29.2%)40 (31.0%)11 (45.8%)45 (34.9%) rs)2412913.4 (15.0)10.7 (11.2)7.57.04.5, 17.53.0, 14.01.0, 55.01.0, 53.0	

Table 3.1: Duration of Hospitalization by Baseline Oxygen Support Status (Overall) Patients in the Analysis Set

Duration of hospitalization is defined as `last day of hospitalization first day of initial hospitalization +1'. Source: t hosp char.sas 07APR2020 11:25

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Gilead Sciences, Inc Study GS-US-540-5835 (TriNetX EHR data)

Table 3.2: Duration of Hospitalization by Baseline Oxygen Support Status (Invasive vs. Non-Invasive) Patients in the Analysis Set

	Invasive			Non-Invasive		
	ECMO (N=0)	Invasive Mechanical Ventilation (N=24)	Non-Invasive Ventilation (N=5)	Oxygen (N=46)	Room Air (N=78)	Total (N=153)
Duration of Hospitalization, n (%)						
< 5 Days		6 (25.0%)	5 (100.0%)	11 (23.9%)	28 (35.9%)	50 (32.7%)
5 - 9 Days		7 (29.2%)		18 (39.1%)	22 (28.2%)	47 (30.7%)
> 10 Days		11 (45.8%)		17 (37.0%)	28 (35.9%)	56 (36.6%)
Duration of Hospitalization (Days)						
Ν	0	24	5	46	78	153
Mean (SD)		13.4 (15.0)	1.2 (0.4)	12.3 (11.9)	10.3 (10.8)	11.1 (11.8)
Median		7.5	1.0	8.0	6.0	7.0
Q1, Q3		4.5, 17.5	1.0, 1.0	5.0, 17.0	3.0, 14.0	3.0, 14.0
Min, Max		1.0, 55.0	1.0, 2.0	1.0, 43.0	1.0, 53.0	1.0, 55.0

Duration of hospitalization is defined as `last day of hospitalization first day of initial hospitalization +1'. Source: t hosp char split.sas 07APR2020 11:25

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Study GS-US-540-5835 (TriNetX EHR data)

Table 4: Clinical Outcomes by Baseline Oxygen Support Status Patients in the Analysis Set

	Invasive (N=24)	Non-Invasive (N=129)	Missing/Unknown (N=0)	Total (N=153)
Discharged (Patient is alive until the end of follow-up), n (%)	5 (20.8%)	34 (26.4%)	0	39 (25.5%)
Hospitalization ongoing (Patient is alive and remains in hospital), n (%)	2 (8.3%)	24 (18.6%)	0	26 (17.0%)
Death (overall), n (%)	6 (25.0%)	5 (3.9%)	0	11 (7.2%)
Death during hospitalization, n (%)	3 (12.5%)	3 (2.3%)	0	6 (3.9%)
Death after discharge, n (%)	3 (12.5%)	2 (1.6%)	0	5 (3.3%)
Unknown/Pending status, n (%)	11 (45.8%)	66 (51.2%)	0	77 (50.3%)

Hospital discharge is defined as discharge from hospital (valid discharge record).

Hospitalization ongoing is defined as patient has not been discharged.

Unknown and pending status patients included those with < 1 day of follow-up or had a hospitalization status that was unknown or pending in the medical records.

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	Invasive (N=24)	Non-Invasive (N=129)	Missing/Unknown (N=0)	Total (N=153)
Baseline				
Ν	16	85	0	101
Mean (SD)	28.2 (26.7)	40.8 (41.6)		38.8 (39.8)
Median	19	28		27
Q1, Q3	14, 32	17, 46		16, 43
Min, Max	5, 113	5, 248		5, 248
t Day 7				
Ν	3	30	0	33
Mean (SD)	46 (45.4)	67.1 (71.9)		65.2 (69.7)
Median	26	41		36
Q1, Q3	14, 98	29, 72		29, 72
Min, Max	14, 98	10, 312		10, 312
t Day 14				
Ν	3	13	0	16
Mean (SD)	23.3 (10.2)	38.8 (31.4)		35.9 (29)
Median	19	28		27
Q1, Q3	16, 35	15, 51		15.5, 44

Table 5.1: Liver-Related: ALT (IU/L) and Change from Baseline by Baseline Oxygen Support Status Patients in the Analysis Set

	Invasive (N=24)	Non-Invasive (N=129)	Missing/Unknown (N=0)	Total (N=153)
Min, Max	16, 35	10, 108		10, 108
At Day 28				
Ν	1	2	0	3
Mean (SD)	40	13.5 (0.7)		22.3 (15.3)
Median	40	13.5		14
Q1, Q3	40, 40	13, 14		13, 40
Min, Max	40, 40	13, 14		13, 40
hange at Day 7				
Ν	3	30	0	33
Mean (SD)	-4 (81.5)	15.1 (48.4)		13.4 (50.7)
Median	-1	3		3
Q1, Q3	-87, 76	-12, 26		-12, 26
Min, Max	-87, 76	-34, 216		-87, 216
hange at Day 14				
Ν	3	13	0	16
Mean (SD)	-24 (63.8)	-7.2 (26)		-10.3 (33.6)
Median	4	-5		-5

Table 5.1: Liver-Related: ALT (IU/L) and Change from Baseline by Baseline Oxygen Support Status Patients in the Analysis Set

	Invasive (N=24)	Non-Invasive (N=129)	Missing/Unknown (N=0)	Total (N=153)
Q1, Q3	-97, 21	-17, 4		-24.5, 5
Min, Max	-97, 21	-49, 58		-97, 58
Change at Day 28				
Ν	1	2	0	3
Mean (SD)	6	-20.5 (2.1)		-11.7 (15.4)
Median	6	-20.5		-19
Q1, Q3	6, 6	-22, -19		-22, 6
Min, Max	6, 6	-22, -19		-22, 6

Table 5.1: Liver-Related: ALT (IU/L) and Change from Baseline by Baseline Oxygen Support Status Patients in the Analysis Set

Baseline (Day 0) is the date of initial hospitalization after COVID-19 diagnosis. Day 7 is the date of hospitalization plus 7 days (+/- 1 day). Day 14 is the date of hospitalization plus 14 days (+/- 1 day). Day 28 is the date of hospitalization plus 28 days (+/- 2 days). Source: t labs.sas 08APR2020 15:28

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	Invasive (N=24)	Non-Invasive (N=129)	Missing/Unknown (N=0)	Total (N=153)
Baseline				
Ν	16	85	0	101
Mean (SD)	46.4 (34.1)	44.4 (48.4)		44.7 (46.3)
Median	35.5	33		33
Q1, Q3	21, 70	22, 46		22, 48
Min, Max	10, 134	7, 412		7, 412
t Day 7				
Ν	3	30	0	33
Mean (SD)	96.7 (103.4)	71.6 (153.7)		73.9 (148.8)
Median	57	36.5		37
Q1, Q3	19, 214	25, 60		25, 60
Min, Max	19, 214	11, 867		11, 867
t Day 14				
Ν	3	13	0	16
Mean (SD)	63 (24.9)	30.6 (19.5)		36.7 (23.6)
Median	68	24		30
Q1, Q3	36, 85	15, 40		18.5, 55.5

Table 5.2: Liver-Related: AST (IU/L) and Change from Baseline by Baseline Oxygen Support Status Patients in the Analysis Set

	Invasive (N=24)	Non-Invasive (N=129)	Missing/Unknown (N=0)	Total (N=153)
Min, Max	36, 85	10, 69		10, 85
At Day 28				
Ν	1	2	0	3
Mean (SD)	73	16.5 (2.1)		35.3 (32.7)
Median	73	16.5		18
Q1, Q3	73, 73	15, 18		15, 73
Min, Max	73, 73	15, 18		15, 73
hange at Day 7				
Ν	3	30	0	33
Mean (SD)	10.7 (145.5)	14.9 (89.8)		14.5 (92.9)
Median	-23	-1.5		-2
Q1, Q3	-115, 170	-10, 6		-14, 6
Min, Max	-115, 170	-76, 455		-115, 455
hange at Day 14				
Ν	3	13	0	16
Mean (SD)	-23.3 (69.7)	-5.5 (18.6)		-8.8 (31.2)
Median	-12	-5		-5

Table 5.2: Liver-Related: AST (IU/L) and Change from Baseline by Baseline Oxygen Support Status Patients in the Analysis Set

Baseline (Day 0) is the date of initial hospitalization after COVID-19 diagnosis. Day 7 is the date of hospitalization plus 7 days (+/- 1 day). Day 14 is the date of hospitalization plus 14 days (+/- 1 day). Day 28 is the date of hospitalization plus 28 days (+/- 2 days). Source: t labs.sas 08APR2020 15:28

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	Invasive (N=24)	Non-Invasive (N=129)	Missing/Unknown (N=0)	Total (N=153)
Q1, Q3	-98, 40	-8, -1		-10.5, 2.5
Min, Max	-98, 40	-42, 32		-98, 40
Change at Day 28				
Ν	1	2	0	3
Mean (SD)	5	-9.5 (2.1)		-4.7 (8.5)
Median	5	-9.5		-8
Q1, Q3	5, 5	-11, -8		-11, 5
Min, Max	5, 5	-11, -8		-11, 5

Table 5.2: Liver-Related: AST (IU/L) and Change from Baseline by Baseline Oxygen Support Status Patients in the Analysis Set

Table 5.3: Liver-Related: Alkaline Phosphatase (U/L) and Change from Baseline by Baseline Oxygen Support Status Patients in the Analysis Set

	Invasive (N=24)	Non-Invasive (N=129)	Missing/Unknown (N=0)	Total (N=153)
Baseline				
Ν	16	85	0	101
Mean (SD)	153.2 (122.3)	109.3 (79.8)		116.2 (88.6)
Median	124.5	84		84
Q1, Q3	71.5, 161.5	62, 112		67, 130
Min, Max	54, 533	31, 481		31, 533
t Day 7				
Ν	3	29	0	32
Mean (SD)	137 (14.7)	127.8 (100.9)		128.7 (96)
Median	145	84		91
Q1, Q3	120, 146	69, 130		71, 137.5
Min, Max	120, 146	48, 390		48, 390
t Day 14				
Ν	3	13	0	16
Mean (SD)	240.7 (183.2)	125.8 (89.1)		147.4 (113.9)
Median	186	85		89.5
Q1, Q3	91, 445	66, 181		70, 195.5

Baseline (Day 0) is the date of initial hospitalization after COVID-19 diagnosis. Day 7 is the date of hospitalization plus 7 days (+/- 1 day). Day 14 is the date of hospitalization plus 14 days (+/- 1 day). Day 28 is the date of hospitalization plus 28 days (+/- 2 days). Source: t labs.sas 08APR2020 15:28

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Table 5.3: Liver-Related: Alkaline Phosphatase (U/L) and Change from Baseline by Baseline Oxygen Support Status Patients in the Analysis Set

	Invasive (N=24)	Non-Invasive (N=129)	Missing/Unknown (N=0)	Total (N=153)
Min, Max	91, 445	48, 327		48, 445
At Day 28				
Ν	1	2	0	3
Mean (SD)	183	110 (65.1)		134.3 (62.4)
Median	183	110		156
Q1, Q3	183, 183	64, 156		64, 183
Min, Max	183, 183	64, 156		64, 183
hange at Day 7				
Ν	3	29	0	32
Mean (SD)	-116 (241.8)	14.7 (55.2)		2.5 (89.5)
Median	-37	2		0
Q1, Q3	-387, 77	-12, 14		-14.5, 15.5
Min, Max	-387, 77	-111, 182		-387, 182
Change at Day 14				
Ν	3	13	0	16
Mean (SD)	-68.3 (335.8)	2.8 (35.1)		-10.6 (129.8)
Median	29	2		3

Baseline (Day 0) is the date of initial hospitalization after COVID-19 diagnosis. Day 7 is the date of hospitalization plus 7 days (+/- 1 day). Day 14 is the date of hospitalization plus 14 days (+/- 1 day). Day 28 is the date of hospitalization plus 28 days (+/- 2 days). Source: t labs.sas 08APR2020 15:28

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Table 5.3: Liver-Related: Alkaline Phosphatase (U/L) and Change from Baseline by Baseline Oxygen Support Status Patients in the Analysis Set

	Invasive (N=24)	Non-Invasive (N=129)	Missing/Unknown (N=0)	Total (N=153)
Q1, Q3	-442, 208	-12, 14		-13, 23
Min, Max	-442, 208	-56, 84		-442, 208
Change at Day 28				
Ν	1	2	0	3
Mean (SD)	-127	-5 (75)		-45.7 (88.1)
Median	-127	-5		-58
Q1, Q3	-127, -127	-58, 48		-127, 48
Min, Max	-127, -127	-58, 48		-127, 48

Baseline (Day 0) is the date of initial hospitalization after COVID-19 diagnosis. Day 7 is the date of hospitalization plus 7 days (+/- 1 day). Day 14 is the date of hospitalization plus 14 days (+/- 1 day). Day 28 is the date of hospitalization plus 28 days (+/- 2 days). Source: t labs.sas 08APR2020 15:28

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Table 5.4: Liver-Related: Total Bilirubin (mg/dL) and Change from Baseline by Baseline Oxygen Support Status Patients in the Analysis Set

	Invasive (N=24)	Non-Invasive (N=129)	Missing/Unknown (N=0)	Total (N=153)
Baseline				
Ν	16	85	0	101
Mean (SD)	0.8 (0.6)	1 (1.5)		0.9 (1.4)
Median	0.6	0.5		0.5
Q1, Q3	0.4, 1.1	0.3, 0.8		0.3, 0.9
Min, Max	0.2, 2.1	0.1, 9.3		0.1, 9.3
t Day 7				
Ν	3	25	0	28
Mean (SD)	0.4 (0.2)	1.7 (3.1)		1.6 (2.9)
Median	0.4	0.7		0.7
Q1, Q3	0.3, 0.6	0.4, 1.4		0.4, 1.4
Min, Max	0.3, 0.6	0.2, 13.1		0.2, 13.1
t Day 14				
Ν	3	10	0	13
Mean (SD)	3 (3.9)	0.9 (0.8)		1.4 (2)
Median	1	0.5		0.5
Q1, Q3	0.4, 7.5	0.5, 1.3		0.5, 1.3

Baseline (Day 0) is the date of initial hospitalization after COVID-19 diagnosis. Day 7 is the date of hospitalization plus 7 days (+/- 1 day). Day 14 is the date of hospitalization plus 14 days (+/- 1 day). Day 28 is the date of hospitalization plus 28 days (+/- 2 days). Source: t labs.sas 08APR2020 15:28

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Table 5.4: Liver-Related: Total Bilirubin (mg/dL) and Change from Baseline by Baseline Oxygen Support Status Patients in the Analysis Set

	Invasive (N=24)	Non-Invasive (N=129)	Missing/Unknown (N=0)	Total (N=153)
Min, Max	0.4, 7.5	0.2, 2.4		0.2, 7.5
At Day 28				
Ν	1	1	0	2
Mean (SD)	0.5	0.4		0.5 (0.1)
Median	0.5	0.4		0.5
Q1, Q3	0.5, 0.5	0.4, 0.4		0.4, 0.5
Min, Max	0.5, 0.5	0.4, 0.4		0.4, 0.5
hange at Day 7				
Ν	3	25	0	28
Mean (SD)	-0.5 (0.2)	0.4 (1.6)		0.3 (1.5)
Median	-0.6	0		0
Q1, Q3	-0.7, -0.3	-0.2, 0.5		-0.2, 0.5
Min, Max	-0.7, -0.3	-3.2, 5.2		-3.2, 5.2
hange at Day 14				
Ν	3	10	0	13
Mean (SD)	1.6 (3.5)	0 (0.7)		0.4 (1.7)
Median	-0.3	-0.2		-0.2

Baseline (Day 0) is the date of initial hospitalization after COVID-19 diagnosis. Day 7 is the date of hospitalization plus 7 days (+/- 1 day). Day 14 is the date of hospitalization plus 14 days (+/- 1 day). Day 28 is the date of hospitalization plus 28 days (+/- 2 days). Source: t labs.sas 08APR2020 15:28

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Table 5.4: Liver-Related: Total Bilirubin (mg/dL) and Change from Baseline by Baseline Oxygen Support Status Patients in the Analysis Set

	Invasive (N=24)	Non-Invasive (N=129)	Missing/Unknown (N=0)	Total (N=153)
Q1, Q3	-0.5, 5.7	-0.3, 0		-0.3, 0
Min, Max	-0.5, 5.7	-0.5, 1.9		-0.5, 5.7
Change at Day 28				
Ν	1	1	0	2
Mean (SD)	-1.6	-0.6		-1.1 (0.7)
Median	-1.6	-0.6		-1.1
Q1, Q3	-1.6, -1.6	-0.6, -0.6		-1.6, -0.6
Min, Max	-1.6, -1.6	-0.6, -0.6		-1.6, -0.6

Baseline (Day 0) is the date of initial hospitalization after COVID-19 diagnosis. Day 7 is the date of hospitalization plus 7 days (+/- 1 day). Day 14 is the date of hospitalization plus 14 days (+/- 1 day). Day 28 is the date of hospitalization plus 28 days (+/- 2 days). Source: t labs.sas 08APR2020 15:28

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Table 5.5: Renal-Related: Creatinine (mg/dL) and Change from Baseline by Baseline Oxygen Support Status Patients in the Analysis Set

	Invasive (N=24)	Non-Invasive (N=129)	Missing/Unknown (N=0)	Total (N=153)
Baseline				
Ν	20	102	0	122
Mean (SD)	1.3 (0.7)	1.6 (2.1)		1.6 (2)
Median	1.1	1.0		1.0
Q1, Q3	0.8, 1.4	0.8, 1.5		0.8, 1.5
Min, Max	0.6, 3.2	0.5, 16.8		0.5, 16.8
t Day 7				
Ν	11	45	0	56
Mean (SD)	1 (0.5)	1.6 (1.5)		1.5 (1.4)
Median	0.9	1		1
Q1, Q3	0.7, 1.1	0.8, 1.6		0.8, 1.5
Min, Max	0.6, 2.5	0.4, 7.9		0.4, 7.9
t Day 14				
Ν	6	21	0	27
Mean (SD)	1 (0.4)	1.7 (1.9)		1.5 (1.7)
Median	1.0	1.0		1
Q1, Q3	0.9, 1.0	0.8, 1.6		0.8, 1.6

Baseline (Day 0) is the date of initial hospitalization after COVID-19 diagnosis. Day 7 is the date of hospitalization plus 7 days (+/- 1 day). Day 14 is the date of hospitalization plus 14 days (+/- 1 day). Day 28 is the date of hospitalization plus 28 days (+/- 2 days). Source: t labs.sas 08APR2020 15:28

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Table 5.5: Renal-Related: Creatinine (mg/dL) and Change from Baseline by Baseline Oxygen Support Status Patients in the Analysis Set

	Invasive (N=24)	Non-Invasive (N=129)	Missing/Unknown (N=0)	Total (N=153)
Min, Max	0.5, 1.7	0.3, 9		0.3, 9
At Day 28				
Ν	4	4	0	8
Mean (SD)	1 (0.4)	3.3 (3.7)		2.1 (2.7)
Median	0.9	1.7		1.2
Q1, Q3	0.7, 1.3	1.1, 5.5		0.8, 1.8
Min, Max	0.7, 1.5	0.9, 8.7		0.7, 8.7
hange at Day 7				
Ν	11	45	0	56
Mean (SD)	-0.2 (0.2)	0.2 (1.3)		0.2 (1.2)
Median	-0.2	-0.1		-0.1
Q1, Q3	-0.3, 0.0	-0.2, 0.1		-0.2, 0.1
Min, Max	-0.6, 0.1	-1.0, 7.1		-1.0, 7.1
hange at Day 14				
Ν	6	21	0	27
Mean (SD)	0 (0.5)	0.2 (0.9)		0.2 (0.8)
Median	-0.1	0		0

Baseline (Day 0) is the date of initial hospitalization after COVID-19 diagnosis. Day 7 is the date of hospitalization plus 7 days (+/- 1 day). Day 14 is the date of hospitalization plus 14 days (+/- 1 day). Day 28 is the date of hospitalization plus 28 days (+/- 2 days). Source: t labs.sas 08APR2020 15:28

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Table 5.5: Renal-Related: Creatinine (mg/dL) and Change from Baseline by Baseline Oxygen Support Status Patients in the Analysis Set

	Invasive (N=24)	Non-Invasive (N=129)	Missing/Unknown (N=0)	Total (N=153)
Q1, Q3	-0.3, 0.2	-0.2, 0.3		-0.2, 0.3
Min, Max	-0.4, 0.9	-0.8, 3.6		-0.8, 3.6
Change at Day 28				
Ν	4	4	0	8
Mean (SD)	0.1 (0.4)	1 (1.6)		0.5 (1.2)
Median	-0.1	0.3		0.1
Q1, Q3	-0.2, 0.3	0.0, 1.9		-0.1, 0.6
Min, Max	-0.2, 0.6	-0.1, 3.3		-0.2, 3.3

Baseline (Day 0) is the date of initial hospitalization after COVID-19 diagnosis. Day 7 is the date of hospitalization plus 7 days (+/- 1 day). Day 14 is the date of hospitalization plus 14 days (+/- 1 day). Day 28 is the date of hospitalization plus 28 days (+/- 2 days). Source: t labs.sas 08APR2020 15:28

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Table 5.6: Renal-Related: eGFR (ml/min/1.73m²) and Change from Baseline by Baseline Oxygen Support Status Patients in the Analysis Set

	Invasive (N=24)	Non-Invasive (N=129)	Missing/Unknown (N=0)	Total (N=153)
Baseline				
Ν	17	88	0	105
Mean (SD)	69.8 (33.7)	71.8 (38.8)		71.5 (37.9)
Median	68.8	70.6		70.5
Q1, Q3	51.9, 97.6	42.2, 101.8		42.2, 101.7
Min, Max	15.3, 118.9	3.7, 159.2		3.7, 159.2
t Day 7				
Ν	10	38	0	48
Mean (SD)	80.7 (28.1)	73.2 (39.7)		74.8 (37.4)
Median	80.7	71.3		71.6
Q1, Q3	63.5, 105.6	45.2, 100.3		46.6, 102.9
Min, Max	25.1, 115.1	6.6, 162.5		6.6, 162.5
t Day 14				
Ν	5	18	0	23
Mean (SD)	79.6 (15.5)	65.4 (35.8)		68.5 (32.7)
Median	75.5	71.7		74.6
Q1, Q3	69.5, 91.9	37.0, 88.9		42.4, 91.9

Baseline (Day 0) is the date of initial hospitalization after COVID-19 diagnosis. Day 7 is the date of hospitalization plus 7 days (+/- 1 day). Day 14 is the date of hospitalization plus 14 days (+/- 1 day). Day 28 is the date of hospitalization plus 28 days (+/- 2 days). Source: t labs.sas 08APR2020 15:28

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Table 5.6: Renal-Related: eGFR (ml/min/1.73m²) and Change from Baseline by Baseline Oxygen Support Status Patients in the Analysis Set

	Invasive (N=24)	Non-Invasive (N=129)	Missing/Unknown (N=0)	Total (N=153)
Min, Max	61.9, 99.1	5.8, 133.3		5.8, 133.3
at Day 28				
Ν	4	4	0	8
Mean (SD)	79.6 (32.1)	48.5 (37.5)		64 (36.3)
Median	80.7	46.7		69.2
Q1, Q3	59.5, 99.6	20.4, 76.5		37.0, 88.0
Min, Max	39.1, 117.6	6.0, 94.5		6.0, 117.6
hange at Day 7				
Ν	10	38	0	48
Mean (SD)	11.1 (14)	1.9 (25)		3.8 (23.3)
Median	10.9	6.1		6.5
Q1, Q3	-2.5, 20.9	-7.5, 15.7		-4.7, 15.8
Min, Max	-5.5, 32.7	-98.8, 56.6		-98.8, 56.6
hange at Day 14				
Ν	5	18	0	23
Mean (SD)	10.8 (15.8)	4.3 (16.8)		5.7 (16.5)
Median	10.6	0		0

Baseline (Day 0) is the date of initial hospitalization after COVID-19 diagnosis. Day 7 is the date of hospitalization plus 7 days (+/- 1 day). Day 14 is the date of hospitalization plus 14 days (+/- 1 day). Day 28 is the date of hospitalization plus 28 days (+/- 2 days). Source: t labs.sas 08APR2020 15:28

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Table 5.6: Renal-Related: eGFR (ml/min/1.73m²) and Change from Baseline by Baseline Oxygen Support Status Patients in the Analysis Set

	Invasive (N=24)	Non-Invasive (N=129)	Missing/Unknown (N=0)	Total (N=153)
Q1, Q3	6.7, 22.6	-9.9, 13.7		-9.9, 21.6
Min, Max	-13.1, 27.4	-16.9, 36.7		-16.9, 36.7
hange at Day 28				
N	4	4	0	8
Mean (SD)	-3.9 (22.3)	-4.7 (11.3)		-4.3 (16.4)
Median	2.5	-8.7		-2.3
Q1, Q3	-17.9, 10.2	-12.7, 3.3		-12.7, 8.2
Min, Max	-35.9, 15.3	-12.8, 11.3		-35.9, 15.3

Baseline (Day 0) is the date of initial hospitalization after COVID-19 diagnosis. Day 7 is the date of hospitalization plus 7 days (+/- 1 day). Day 14 is the date of hospitalization plus 14 days (+/- 1 day). Day 28 is the date of hospitalization plus 28 days (+/- 2 days). Source: t labs.sas 08APR2020 15:28

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	Invasive (N=24)	Non-Invasive (N=129)	Missing/Unknown (N=0)	Total (N=153)
Baseline				
Ν	20	101	0	121
Mean (SD)	11 (6.3)	9.8 (6)		10 (6.1)
Median	10.2	8.2		8.6
Q1, Q3	7.3, 14.7	5.3, 12.3		5.5, 13.4
Min, Max	0.8, 24.8	0.3, 27.4		0.3, 27.4
At Day 7				
Ν	11	43	0	54
Mean (SD)	8.9 (8)	8.4 (4.9)		8.5 (5.6)
Median	7.3	7.6		7.5
Q1, Q3	4.5, 8.1	4.6, 10.9		4.6, 10.8
Min, Max	1.9, 31.7	0.2, 19.4		0.2, 31.7
At Day 14				
Ν	5	19	0	24
Mean (SD)	11.4 (7.1)	8.4 (6.9)		9 (6.9)
Median	8.2	7.1		7.6
Q1, Q3	7.4, 12.8	3.4, 10.8		4.5, 11.0

Table 5.7: Hematology: WBC (x10^9/L) and Change from Baseline by Baseline Oxygen Support Status Patients in the Analysis Set

	Invasive (N=24)	Non-Invasive (N=129)	Missing/Unknown (N=0)	Total (N=153)
Min, Max	5.4, 23.1	1.3, 29.7		1.3, 29.7
at Day 28				
Ν	4	4	0	8
Mean (SD)	10.5 (4.5)	11.9 (11.8)		11.2 (8.3)
Median	11.0	8.1		9.8
Q1, Q3	7.5, 13.6	4.6, 19.2		5.7, 13.6
Min, Max	4.6, 15.5	2.3, 29.1		2.3, 29.1
nange at Day 7				
Ν	11	43	0	54
Mean (SD)	-1.5 (9.9)	-0.8 (6.1)		-0.9 (6.9)
Median	-1.8	-0.6		-0.8
Q1, Q3	-7.7, 1.8	-3.6, 2.3		-3.6, 1.8
Min, Max	-17, 21.6	-12.7, 14.6		-17, 21.6
hange at Day 14				
Ν	5	19	0	24
Mean (SD)	-4.5 (4.4)	0.2 (6.7)		-0.8 (6.5)
Median	-2.4	-0.6		-1.4

Table 5.7: Hematology: WBC (x10^9/L) and Change from Baseline by Baseline Oxygen Support Status Patients in the Analysis Set

	Invasive (N=24)	Non-Invasive (N=129)	Missing/Unknown (N=0)	Total (N=153)
Q1, Q3	-7.6, -1.7	-4.0, 2.7		-4.3, 0.2
Min, Max	-10.6, -0.1	-8.4, 22.2		-10.6, 22.2
Change at Day 28				
Ν	4	4	0	8
Mean (SD)	-0.5 (1.5)	5.7 (10.8)		2.6 (7.9)
Median	-0.4	0.5		0.1
Q1, Q3	-1.7, 0.8	-0.3, 11.6		-0.8, 1.2
Min, Max	-2.1, 1	-0.3, 21.9		-2.1, 21.9

Table 5.7: Hematology: WBC (x10^9/L) and Change from Baseline by Baseline Oxygen Support Status Patients in the Analysis Set

Table 5.8: Hematology: Lymphocytes (x10^9/L) and Change from Baseline by Baseline Oxygen Support Status Patients in the Analysis Set

	Invasive (N=24)	Non-Invasive (N=129)	Missing/Unknown (N=0)	Total (N=153)
Baseline				
Ν	16	61	0	77
Mean (SD)	2.1 (3.8)	4.2 (7.4)		3.8 (6.8)
Median	1.2	1.4		1.3
Q1, Q3	0.4, 1.7	0.8, 2.6		0.8, 2.4
Min, Max	0.2, 15.9	0.1, 33.3		0.1, 33.3
At Day 7				
Ν	4	16	0	20
Mean (SD)	5.4 (8.5)	2.8 (4.6)		3.3 (5.4)
Median	1.4	1.2		1.2
Q1, Q3	0.8, 10.1	0.3, 2		0.5, 2.3
Min, Max	0.7, 18.2	0.1, 16.1		0.1, 18.2
At Day 14				
Ν	5	12	0	17
Mean (SD)	0.7 (0.3)	2.4 (4.5)		1.9 (3.8)
Median	0.8	1		0.8
Q1, Q3	0.7, 0.8	0.6, 1.9		0.6, 1.4

Baseline (Day 0) is the date of initial hospitalization after COVID-19 diagnosis. Day 7 is the date of hospitalization plus 7 days (+/- 1 day). Day 14 is the date of hospitalization plus 14 days (+/- 1 day). Day 28 is the date of hospitalization plus 28 days (+/- 2 days). Source: t labs.sas 08APR2020 15:28

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Table 5.8: Hematology: Lymphocytes (x10^9/L) and Change from Baseline by Baseline Oxygen Support Status Patients in the Analysis Set

	Invasive (N=24)	Non-Invasive (N=129)	Missing/Unknown (N=0)	Total (N=153)
Min, Max	0.2, 0.9	0.1, 16.3		0.1, 16.3
t Day 28				
Ν	3	1	0	4
Mean (SD)	1 (0.2)	1.6		1.1 (0.3)
Median	1	1.6		1.1
Q1, Q3	0.8, 1.1	1.6, 1.6		0.9, 1.4
Min, Max	0.8, 1.1	1.6, 1.6		0.8, 1.6
hange at Day 7				
Ν	4	16	0	20
Mean (SD)	0.5 (1.3)	-4.9 (11)		-3.8 (10)
Median	0.4	-0.2		-0.1
Q1, Q3	-0.4, 1.4	-10.9, 0.1		-4.0, 0.4
Min, Max	-0.9, 2.3	-25.8, 15.0		-25.8, 15.0
hange at Day 14				
Ν	5	12	0	17
Mean (SD)	-0.2 (0.5)	-0.4 (6.9)		-0.4 (5.7)
Median	-0.1	-0.1		-0.1

Baseline (Day 0) is the date of initial hospitalization after COVID-19 diagnosis. Day 7 is the date of hospitalization plus 7 days (+/- 1 day). Day 14 is the date of hospitalization plus 14 days (+/- 1 day). Day 28 is the date of hospitalization plus 28 days (+/- 2 days). Source: t labs.sas 08APR2020 15:28

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Table 5.8: Hematology: Lymphocytes (x10^9/L) and Change from Baseline by Baseline Oxygen Support Status Patients in the Analysis Set

	Invasive (N=24)	Non-Invasive (N=129)	Missing/Unknown (N=0)	Total (N=153)
Q1, Q3	-0.3, 0.2	-1.0, 0.4		-0.6, 0.3
Min, Max	-1, 0.3	-17.4, 14.5		-17.4, 14.5
Change at Day 28				
Ν	3	1	0	4
Mean (SD)	-0.1 (0.5)	-15.9		-4.1 (7.9)
Median	-0.1	-15.9		-0.4
Q1, Q3	-0.6, 0.4	-15.9, -15.9		-8.3, 0.2
Min, Max	-0.6, 0.4	-15.9, -15.9		-15.9, 0.4

Baseline (Day 0) is the date of initial hospitalization after COVID-19 diagnosis. Day 7 is the date of hospitalization plus 7 days (+/- 1 day). Day 14 is the date of hospitalization plus 14 days (+/- 1 day). Day 28 is the date of hospitalization plus 28 days (+/- 2 days). Source: t labs.sas 08APR2020 15:28

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Table 5.9: Hematology: Platelets (x10^9/L) and Change from Baseline by Baseline Oxygen Support Status Patients in the Analysis Set

	Invasive (N=24)	Non-Invasive (N=129)	Missing/Unknown (N=0)	Total (N=153)
Baseline				
Ν	20	101	0	121
Mean (SD)	214.7 (131.6)	212.9 (101.4)		213.2 (106.3)
Median	189.5	206		202
Q1, Q3	148.5, 296.5	152, 268		152, 270
Min, Max	7, 539	9, 592		7, 592
at Day 7				
Ν	11	43	0	54
Mean (SD)	207.7 (152.4)	210 (109.5)		209.6 (117.8)
Median	153	205		199.5
Q1, Q3	106, 310	153, 260		133, 264
Min, Max	16, 498	9, 545		9, 545
at Day 14				
Ν	5	19	0	24
Mean (SD)	269.4 (134.5)	194.9 (115.7)		210.4 (120.8)
Median	183	185		184
Q1, Q3	176, 404	111, 290		144, 300.5

Baseline (Day 0) is the date of initial hospitalization after COVID-19 diagnosis. Day 7 is the date of hospitalization plus 7 days (+/- 1 day). Day 14 is the date of hospitalization plus 14 days (+/- 1 day). Day 28 is the date of hospitalization plus 28 days (+/- 2 days). Source: t labs.sas 08APR2020 15:28

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Table 5.9: Hematology: Platelets (x10^9/L) and Change from Baseline by Baseline Oxygen Support Status Patients in the Analysis Set

	Invasive (N=24)	Non-Invasive (N=129)	Missing/Unknown (N=0)	Total (N=153)
Min, Max	156, 428	12, 382		12, 428
at Day 28				
Ν	4	4	0	8
Mean (SD)	312.8 (140.9)	203.8 (92.2)		258.3 (124.7)
Median	333	236.5		262
Q1, Q3	207.5, 418	145.5, 262		175.5, 333
Min, Max	129, 456	69, 273		69, 456
hange at Day 7				
Ν	11	43	0	54
Mean (SD)	33.8 (103.5)	11.7 (83.7)		16.2 (87.5)
Median	0	-1		-0.5
Q1, Q3	-37, 78	-34, 69		-34, 69
Min, Max	-65, 309	-219, 175		-219, 309
hange at Day 14				
Ν	5	19	0	24
Mean (SD)	41.6 (84.2)	17.1 (110.1)		22.2 (104.1)
Median	18	13		15.5

Baseline (Day 0) is the date of initial hospitalization after COVID-19 diagnosis. Day 7 is the date of hospitalization plus 7 days (+/- 1 day). Day 14 is the date of hospitalization plus 14 days (+/- 1 day). Day 28 is the date of hospitalization plus 28 days (+/- 2 days). Source: t labs.sas 08APR2020 15:28

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Table 5.9: Hematology: Platelets (x10^9/L) and Change from Baseline by Baseline Oxygen Support Status Patients in the Analysis Set

	Invasive (N=24)	Non-Invasive (N=129)	Missing/Unknown (N=0)	Total (N=153)
Q1, Q3	-5, 60	-45, 127		-33.5, 93.5
Min, Max	-42, 177	-195, 185		-195, 185
Change at Day 28				
Ν	4	4	0	8
Mean (SD)	61.3 (70.9)	-11.3 (116.1)		25 (97.1)
Median	67.5	18.5		49.5
Q1, Q3	2, 120.5	-102, 79		-29, 97
Min, Max	-19, 129	-164, 82		-164, 129

Baseline (Day 0) is the date of initial hospitalization after COVID-19 diagnosis. Day 7 is the date of hospitalization plus 7 days (+/- 1 day). Day 14 is the date of hospitalization plus 14 days (+/- 1 day). Day 28 is the date of hospitalization plus 28 days (+/- 2 days). Source: t labs.sas 08APR2020 15:28

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Study GS-US-540-5835 Gilead Sciences, Inc (TriNetX EHR data)

	Invasive (N=24)	Non-Invasive (N=129)	Total (N=153)
Number of Patients With Medical History	11 (45.8%)	51 (39.5%)	62 (40.5%)
Number of Patients With Medical History by the Following Clinical Conditions:			
Asthma	4 (16.7%)	11 (8.5%)	15 (9.8%)
Cancer	3 (12.5%)	10 (7.8%)	13 (8.5%)
Chronic Liver Disease	1 (4.2%)	1 (0.8%)	2 (1.3%)
Chronic Obstructive Pulmonary Disease	6 (25.0%)	10 (7.8%)	16 (10.5%)
Cardiovascular Disease	8 (33.3%)	28 (21.7%)	36 (23.5%)
Diabetes Mellitus	7 (29.2%)	15 (11.6%)	22 (14.4%)
HIV/AIDS	0	5 (3.9%)	5 (3.3%)
Inflammatory Bowel Disease	0	3 (2.3%)	3 (2.0%)
Rheumatoid Arthritis	0	2 (1.6%)	2 (1.3%)
Renal Insufficiency	4 (16.7%)	18 (14.0%)	22 (14.4%)

Table 6: Medical History Patients in the Analysis Set

The TriNetX analysis set is defined as hospitalized adult (> 18 years) patients from US health care organizations with a COVID-19 diagnosis that occurred on or after January 20, 2020 and before March 30, 2020 (inclusive). Source: t bl medical history.sas 06APR2020 13:28 page 1 of 1

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Table 7.	1: Moi	ctality Ra	te
Patients	in the	Analysis	Set

Death Cases Days per 100 Days Confidence Interval 11 2718 0.40 0.20 - 0.72	Number of	Total Number of	Mortality Rate	95%
11 2718 0.40 0.20 - 0.72	Death Cases	Days	per 100 Days	Confidence Interval
	11	2718	0.40	0.20 - 0.72

Table 7.2: Mortality Rate for Male Patients Patients in the Analysis Set

Number of	Total Number of	Mortality Rate	95%
Death Cases	Days	per 100 Days	Confidence Interval
9	1395	0.65	0.30 - 1.22

Patients in the Analysis Set				
Number of Death Cases	Total Number of Days	Mortality Rate per 100 Days	95% Confidence Interval	
2	1323	0.15	0.02 - 0.55	

Table 7.3: Mortality Rate for Female Patients Patients in the Analysis Set

Table 7.4: Mortality Rate for Invasive Patients Patients in the Analysis Set

Number of	Total Number of	Mortality Rate	95%
Death Cases	Days	per 100 Days	Confidence Interval
6	431	1.39	0.51 - 3.03

Table 7.5: Mortality Rate for Non-Invasive Patients Patients in the Analysis Set

Number of	Total Number of	Mortality Rate	95%
Death Cases	Days	per 100 Days	Confidence Interval
5	2287	0.22	0.07 - 0.51

Table 7.6: Mortality Rate Ratio Invasive and Non-Invasive Patients Patients in the Analysis Set

	95%
Mortality Rate Ratio	Confidence Interval
6.44	1.96 - 21.10

Table 7.7: Mortality Rate Ratio Male and Female Patients Patients in the Analysis Set

	95%
Mortality Rate Ratio	Confidence Interval
4.93	1.06 - 22.80
Table 7.8: Mortality Rate Ratio Age >= 60 and < 60 Patients Patients in the Analysis Set

	95 %		
Mortality Rate Ratio	Confidence Interval		
3.50	0.76 - 16.23		

Table 8.1: Clinical Improvement on the Last Day of Follow-up from Baseline (Invasive vs. Non-Invasive) Patients in the Analysis Set

	Baseline Oxyge	Baseline Oxygen Support Status		
	Invasive (N=24)	Non-Invasive (N=129)	Total (N=153)	
Any 2-pt Improvement in the Ordinal Scale by the Last Follow-up Visit, n (%)				
Yes	7 (29.2%)	34 (26.4%)	41 (26.8%)	
No	6 (25.0%)	29 (22.5%)	35 (22.9%)	
Unknown/Pending Status ¹	11 (45.8%)	66 (51.2%)	77 (50.3%)	

¹Unknown and pending status patients included those with < 1 day of follow-up or had a hospitalization status that was unknown or pending in the medical records. Source: t clin improve.sas 07APR2020 10:42 page 1 of 1

Table 8.2: Shift in Oxygen Support Status from Baseline (Invasive vs. Non-Invasive) Patients in the Analysis Set

	Invasive (N=24)	Non-Invasive (N=129)	Total (N=153)
Last Visit, n (%)			
Death	6 (25.0%)	5 (3.9%)	11 (7.2%)
Invasive Mechanical Ventilation	0	1 (0.8%)	1 (0.7%)
ECMO	0	0	0
Oxygen	0	5 (3.9%)	5 (3.3%)
Non-invasive Mechanical Ventilation	0	0	0
Room Air	2 (8.3%)	18 (14.0%)	20 (13.1%)
Discharge	5 (20.8%)	34 (26.4%)	39 (25.5%)
Unknown/Pending status	11 (45.8%)	66 (51.2%)	77 (50.3%)

Unknown and pending status patients included those with < 1 day of follow-up or had a hospitalization status that was unknown or pending in the medical records. Source: t O2 shift.sas 07APR2020 10:42

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Figure 2: Kaplan-Meier Plot by Oxygen Support Patients in the Analysis Set Gilead Sciences, Inc Study GS-US-540-5835 (TriNetX EHR data)



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Product-Limit Survival Estimates With Number of Subjects at Risk 1.0 -----0.8 Survival Probability 0.6 -0.4 0.2 + Censored Logrank p=0.0466 0.0 Male 76 35 19 12 1 Female 77 34 18 7 1 Т 28 42 14 56 0 Survival Time (Days) Gender Male Female

Figure 3: Kaplan-Meier Plot by Gender

Patients in the Analysis Set

Gilead Sciences, Inc Study GS-US-540-5835 (TriNetX EHR data)

Source:f km.sas 05APR20:13:43

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