

## DMC19 Registry Instructions 4\_17\_20

- 1) Please complete the below data collection form (DCF) in REDCap at the **time of discharge or death**. Data will appear in the DMC19 database once entry and verification are complete.
- 2) We aim to capture **inpatients** with a confirmed COVID-19 diagnosis, **regardless of whether they have digestive manifestations**. After prevalence is defined in hospitalized patients, and as the numbers grow, we may focus on patients who are known to have GI manifestations and/or include outpatients.
- 3) Please make all efforts to collect data on the **first 50-100 consecutive** patients at your hospital or health system.
- 4) Eligible patients can and should be identified by any means necessary, which may include, but is not limited to, institutional laboratory records, data warehouse queries, electronic health record research subject identification tools/dashboards, and discussions with the infectious disease or critical care services, etc. You may elect to use the emergency ICD-10 code of U07.1 – 2019-nCov acute respiratory disease – to help identify eligible patients.
- 5) Please **triple check** data for accuracy before submission. Although we are performing central data monitoring, we cannot verify incoming data against source documents, nor are we performing on-site monitoring visits. Therefore, the overall quality of the data is assured primarily at the site level.
- 6) Along the lines of #5, coordinators should confer with a clinician during data collection to ensure that clinical context is accounted for as much as possible in the interpretation of questions that involve an element of subjectivity.
- 7) All data fields should have affirmative, negative, and unknown options. Therefore, missing data will be assumed to be inadvertent and this will generate a query.
- 8) Please maintain a secure key at your site that allows patient identification on the basis of subject ID#. This may be used in the future for to collect data pertaining to long-term outcomes.

<b>Subject ID #</b>	
<b>Institution</b>	
<b>Email address</b> (of individual entering data)	

<b>Patient characteristics</b>	
Age (years)	
Sex	<input type="checkbox"/> Male <input type="checkbox"/> Female - Pregnant - Not pregnant - Unknown
Race (check all that apply)	<input type="checkbox"/> American Indian or Alaska Native <input type="checkbox"/> Asian <input type="checkbox"/> Black or African American <input type="checkbox"/> Native Hawaiian or other Pacific Islander <input type="checkbox"/> White <input type="checkbox"/> Unknown

Ethnicity	<input type="checkbox"/> Hispanic or Latino <input type="checkbox"/> Not Hispanic or Latino <input type="checkbox"/> Unknown
Body mass index at presentation (kg/m <sup>2</sup> ): available?	<input type="checkbox"/> Yes <input type="checkbox"/> Cannot calculate, but obesity documented <input type="checkbox"/> Cannot calculate
Body mass index at presentation (kg/m <sup>2</sup> )	
Is the patient a health care worker?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Cigarette smoking status	<input type="checkbox"/> Current smoker <input type="checkbox"/> Ex-smoker <input type="checkbox"/> Non-smoker <input type="checkbox"/> Unknown
Vaping status	<input type="checkbox"/> Current vaping <input type="checkbox"/> Prior vaping <input type="checkbox"/> Does not vape <input type="checkbox"/> Unknown
Alcoholism	<input type="checkbox"/> Yes, current <input type="checkbox"/> Prior <input type="checkbox"/> No <input type="checkbox"/> Unknown
Cannabis use	<input type="checkbox"/> Current user <input type="checkbox"/> Prior user <input type="checkbox"/> No <input type="checkbox"/> Unknown
Illicit drug use	<input type="checkbox"/> Current user <input type="checkbox"/> Prior user <input type="checkbox"/> No <input type="checkbox"/> Unknown
Comorbidities (select all that apply)	<input type="checkbox"/> Hypertension <input type="checkbox"/> Coronary artery disease/prior or current myocardial infarction (MI) <input type="checkbox"/> Congestive heart failure (CHF) <input type="checkbox"/> Chronic pulmonary obstructive disease (COPD) <input type="checkbox"/> Asthma <input type="checkbox"/> Obstructive sleep apnea (OSA) <input type="checkbox"/> Interstitial lung disease (ILD)/pulmonary fibrosis <input type="checkbox"/> Peripheral vascular disease (PVD) <input type="checkbox"/> Prior or current cerebrovascular accident (CVA) or transient ischemic attack (TIA) <input type="checkbox"/> Dementia <input type="checkbox"/> Collagen vascular/rheumatologic disease <input type="checkbox"/> Chronic liver disease - Alcoholic liver disease - Non-alcoholic fatty liver disease (NAFLD)

	<ul style="list-style-type: none"> <li>- Hepatitis C virus</li> <li>- Hepatitis B virus</li> <li>- Other, specify</li> </ul> <input type="checkbox"/> Cirrhosis If yes, MELD score prior to COVID-19 illness <input type="checkbox"/> Diabetes mellitus, uncomplicated <input type="checkbox"/> Diabetes mellitus with end-organ damage <input type="checkbox"/> Moderate to severe kidney disease (creatinine >3 mg/dL prior to admission, end stage renal disease [ESRD], dialysis) <input type="checkbox"/> Active/Current malignancy, excluding non-melanoma skin cancer If yes, specify <input type="checkbox"/> Prior malignancy <input type="checkbox"/> Human immunodeficiency virus (HIV)/Acquired Immunodeficiency Syndrome (AIDS) <input type="checkbox"/> Solid organ transplant recipient <input type="checkbox"/> Bone marrow transplant recipient <input type="checkbox"/> Irritable bowel syndrome <input type="checkbox"/> Chronic diarrhea <input type="checkbox"/> Chronic constipation <input type="checkbox"/> Celiac disease <input type="checkbox"/> Prior biliary disease, including cholelithiasis, cholecystitis, choledocholithiasis or cholangitis <input type="checkbox"/> Prior pancreatitis If yes: <input type="checkbox"/> Acute pancreatitis <input type="checkbox"/> Recurrent acute pancreatitis <input type="checkbox"/> Chronic pancreatitis <input type="checkbox"/> Unknown <input type="checkbox"/> Inflammatory bowel disease <input type="checkbox"/> None <input type="checkbox"/> Other, not fitting into an above category
If other, specify	
Recent (within 6 months) or current (at admission) immunosuppression or chemotherapy	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
If yes, specify	(medication, dose, route, duration)
Recent (within 1 month of admission) or current (at admission) ACE inhibitor use	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Recent (within 1 month of admission) or current (at admission) angiotensin receptor blocker (ARB) use	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Recent (within 1 month of admission) or current (at admission) NSAIDs use	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown

Recent (within 1 month of admission) or current (at admission) antibiotic use	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Recent (within 1 month of admission) or current (at admission) PPI use	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Recent (within 1 month of admission) or current (at admission) H2 blocker use	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown

COVID-19 parameters	
History of known contact with COVID-19 positive individual(s)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Highest level of care	<input type="checkbox"/> Inpatient ward <input type="checkbox"/> Intensive care unit (ICU)
Duration of symptoms prior to first seeking medical attention (days)	
Duration of symptoms prior to hospitalization (days)	
Duration of hospitalization (days)	
If admitted to ICU, duration of ICU stay (days)	
Required mechanical ventilation	<input type="checkbox"/> Yes <input type="checkbox"/> No
Required extracorporeal membrane oxygenation (ECMO)	<input type="checkbox"/> Yes <input type="checkbox"/> No
Required vasopressor support	<input type="checkbox"/> Yes <input type="checkbox"/> No
Final discharge disposition	<input type="checkbox"/> Recovered (or almost recovered) <input type="checkbox"/> Discharged to rehab or nursing facility <input type="checkbox"/> Deceased
COVID-specific treatments (select all that apply)	<input type="checkbox"/> Remdesivir <input type="checkbox"/> Hydroxychloroquine <input type="checkbox"/> Chloroquine <input type="checkbox"/> Azithromycin <input type="checkbox"/> Glucocorticoids <input type="checkbox"/> Interferon alpha <input type="checkbox"/> Intravenous immunoglobulin (IVIG) <input type="checkbox"/> Lopinavir/ritonavir <input type="checkbox"/> Oseltamivir <input type="checkbox"/> Tocilizumab <input type="checkbox"/> Convalescent plasma <input type="checkbox"/> None <input type="checkbox"/> Other

If other, specify	(medication, dose, route, duration)
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Symptomatology	
Respiratory or systemic symptoms (select all that apply)	<input type="checkbox"/> Fever (subjective or objective) <input type="checkbox"/> Chills/rigors <input type="checkbox"/> Fatigue or subjective weakness <input type="checkbox"/> Myalgia <input type="checkbox"/> Sore throat <input type="checkbox"/> Rhinorrhea (runny nose) <input type="checkbox"/> Cough <input type="checkbox"/> Sneezing <input type="checkbox"/> Sputum production <input type="checkbox"/> Shortness of breath - At rest - On exertion - Not specified <input type="checkbox"/> Chest tightness or pain <input type="checkbox"/> Headache <input type="checkbox"/> Confusion or altered mental status <input type="checkbox"/> Loss of smell <input type="checkbox"/> Loss of taste <input type="checkbox"/> None <input type="checkbox"/> Other
If other, specify	
Gastrointestinal symptoms or signs (select all that apply)	<input type="checkbox"/> Anorexia <input type="checkbox"/> Nausea <input type="checkbox"/> Vomiting <input type="checkbox"/> Abdominal pain (including cramps) - Diffuse - Periumbilical - Epigastric - Right upper quadrant (RUQ) - Left upper quadrant (LUQ) - Right lower quadrant (RLQ) - Left lower quadrant (LLQ) - Not specified <input type="checkbox"/> Diarrhea - Maximum number of bowel movements in a 24 hour period <input type="checkbox"/> Not documented <input type="checkbox"/> Bloody diarrhea - Maximum number of bowel movements in a 24 hour period <input type="checkbox"/> Not documented <input type="checkbox"/> Hematemesis <input type="checkbox"/> Melena <input type="checkbox"/> Hematochezia (inc. bright red blood per rectum)

	<input type="checkbox"/> Dysphagia <input type="checkbox"/> Odynophagia <input type="checkbox"/> Constipation <input type="checkbox"/> Hiccups <input type="checkbox"/> Jaundice <input type="checkbox"/> None <input type="checkbox"/> Other
If other, specify	
Timing of gastrointestinal symptoms (if any) relative to respiratory/systemic symptoms (if any)	<input type="checkbox"/> GI symptom(s) <b>preceded</b> other symptoms <input type="checkbox"/> GI symptom(s) <b>followed</b> other symptoms <input type="checkbox"/> GI symptom(s) <b>came on concurrently</b> with other symptoms <input type="checkbox"/> GI symptoms were the <b>only</b> manifestation <input type="checkbox"/> Can't tell from medical records review
Duration of gastrointestinal symptoms	<input type="checkbox"/> GI symptom(s) were present for a short portion (<25% of the duration) of the entire COVID-19 illness <input type="checkbox"/> GI symptom(s) were present for significant portion (25-75% of the duration) of the entire COVID-19 illness <input type="checkbox"/> GI symptom(s) were present for the entire/almost entire COVID-19 illness <input type="checkbox"/> Can't tell from medical records review
Did gastrointestinal symptoms remain after resolution of other COVID-19 symptoms?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
If yes, how long (days)	
Prominence of gastrointestinal symptoms	<input type="checkbox"/> GI symptoms were less prominent than other symptoms related to COVID-19 <input type="checkbox"/> GI symptoms were equally prominent to other symptoms related to COVID-19 <input type="checkbox"/> GI symptoms were more prominent than other symptoms related to COVID-19 <input type="checkbox"/> Can't tell from medical records review
Were digestive manifestations (gastrointestinal or hepatic) specifically addressed in the Assessment/Plan section of any progress notes for <b>3 or more days</b> during the hospitalization?	<input type="checkbox"/> Yes, GI symptoms <input type="checkbox"/> Yes, LFT abnormalities <input type="checkbox"/> Yes, both <input type="checkbox"/> No
Did the gastroenterology or hepatology service consult on the patient during the hospitalization, as evidenced by consult notes?	<input type="checkbox"/> Yes, GI (including pancreaticobiliary) <input type="checkbox"/> Yes, hepatology/liver <input type="checkbox"/> Yes, both <input type="checkbox"/> No
Were stool studies other than FOBT (fecal occult blood test) obtained during the hospitalization?	<input type="checkbox"/> Yes <input type="checkbox"/> No

Gastrointestinal diagnoses established shortly before, during, or shortly after COVID-19 illness (select all that apply)	<input type="checkbox"/> Esophagitis/esophageal ulcers <input type="checkbox"/> Gastritis <input type="checkbox"/> Peptic ulcer disease (stomach or duodenum) <input type="checkbox"/> New enteritis <input type="checkbox"/> New colitis <input type="checkbox"/> Biliary disease, including cholelithiasis, cholecystitis, choledocholithiasis or cholangitis <input type="checkbox"/> Hepatitis <input type="checkbox"/> Pancreatitis <input type="checkbox"/> None <input type="checkbox"/> Other
If other, specify	
Was COVID-specific treatment prescribed specifically for digestive manifestations?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown

<b>Imaging and endoscopy</b>	
Was abdominal computed tomography (CT) <b>performed and abnormal</b> shortly before, during, or shortly after COVID-19 illness?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
If yes, list abnormal findings in the impression section of the most concerning CT report	
Was abdominal magnetic resonance imaging (MRI) <b>performed and abnormal</b> shortly before, during, or shortly after COVID-19 illness?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
If yes, list abnormal findings in the impression section of the most concerning MRI report	
Was abdominal ultrasound (US) <b>performed and abnormal</b> shortly before, during, or shortly after COVID-19 illness?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
If yes, list abnormal findings in the impression section of the most concerning US report	
Was endoscopy performed during COVID-19 illness? (select all that apply)	<input type="checkbox"/> Yes – upper endoscopy (EGD) <input type="checkbox"/> Yes – colonoscopy or flexible sigmoidoscopy <input type="checkbox"/> Yes – enteroscopy (balloon or push) <input type="checkbox"/> Yes – capsule endoscopy <input type="checkbox"/> Yes – ERCP <input type="checkbox"/> Yes – endoscopic ultrasound (EUS) <input type="checkbox"/> No <input type="checkbox"/> Unknown

If performed, how many total endoscopic sessions did the patient undergo? (EGD+colonoscopy or EUS+ERCP at the same time is considered 1 session)	
If performed, did the patient require respiratory support <b>BEFORE</b> their first procedure? (select all that apply)	<input type="checkbox"/> Yes – nasal cannula <input type="checkbox"/> Yes – high-flow oxygen <input type="checkbox"/> Yes – non-invasive positive pressure ventilation <input type="checkbox"/> Yes – mechanical ventilation <input type="checkbox"/> Yes – mechanical ventilation, prone <input type="checkbox"/> Yes – extracorporeal membrane oxygenation (ECMO) <input type="checkbox"/> No <input type="checkbox"/> Unknown
If performed, what kind of anesthesia did the patient receive <b>DURING</b> their first procedure? (select all that apply)	<input type="checkbox"/> Conscious sedation <input type="checkbox"/> Deep sedation/monitored anesthesia care (MAC) <input type="checkbox"/> General endotracheal anesthesia <input type="checkbox"/> No sedation <input type="checkbox"/> Unknown
If performed, did the patient experience an adverse cardiopulmonary event related to any of the endoscopic procedures? (select all that apply)	<input type="checkbox"/> Yes – Mild to moderate respiratory compromise <input type="checkbox"/> Yes – Severe respiratory compromise <input type="checkbox"/> Yes – Congestive heart failure/cardiomyopathy <input type="checkbox"/> Yes – Myocardial infarction <input type="checkbox"/> No <input type="checkbox"/> Unknown
Endoscopic findings (please list abnormal findings in impression section of endoscopy report(s))	
Histologic findings (please list abnormal findings in impression section of pathology report(s))	

Laboratory data and other hepatologic considerations	
<i>Prior to COVID-19, ideally when patient was healthy:</i> White blood cells (WBC) Hemoglobin Platelets Aspartate aminotransferase (AST) Alanine aminotransferase (ALT) Alkaline phosphatase (ALK-phos) Total bilirubin International normalized ratio (INR) Albumin Factor V level Lipase	



Creatinine	
<i>At time of hospital admission:</i> White blood cells (WBC) Hemoglobin Platelets Aspartate aminotransferase (AST) Alanine aminotransferase (ALT) Alkaline phosphatase (ALK-phos) Gamma-Glutamyl Transferase (highest) U/L Total bilirubin Direct bilirubin International normalized ratio (INR) Albumin Factor V level Lipase - What is the upper limit of normal Amylase - What is the upper limit of normal Creatinine	
<i>Highest or lowest level during illness:</i> WBC (highest and lowest) Hemoglobin (lowest) Platelets (lowest) AST (highest) ALT (highest) ALK-phos (highest) Gamma-Glutamyl Transferase (highest) U/L Total Bilirubin (highest) Direct Bilirubin (highest) INR (highest) Albumin (lowest) Factor 5 (lowest) Lipase (highest) - What is the upper limit of normal Amylase (highest) - What is the upper limit of normal Creatinine (highest) Absolute lymphocyte count (lowest) C-Reactive Protein (CRP) (highest) Procalcitonin (highest) Troponin (highest) Ferritin (highest) ng/mL or ug/L Interleukin-6 (highest) pg/mL	

Duration between first onset of symptoms and highest AST (days)	
Duration between first onset of symptoms and highest ALT (days)	
Duration between first onset of symptoms and highest total bilirubin (days)	
Duration between first hospital day and highest AST (days)	
Duration between first hospital day and highest ALT (days)	
Duration between first hospital day and highest total bilirubin (days)	
Abnormal LFTs were	<input type="checkbox"/> Still close to max at discharge/death <input type="checkbox"/> Improved but not resolved at discharge/death <input type="checkbox"/> Resolved or close to resolved at discharge/death <input type="checkbox"/> Not applicable
Were the increased LFTs suspected to be due to a drug reaction (based on review of progress/consult notes)?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unclear based on records
If yes, which medication(s) were suspected	(medication, dose, route, duration)
If yes, was this a COVID-specific treatment that was believed to increase LFTs (based on review of progress/consult notes)?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unclear based on records
Anti-HAV IgM	<input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Not checked
Anti-HCV	<input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Not checked
HCV RNA	<input type="checkbox"/> Positive -Level (in IU/L) <input type="checkbox"/> Negative <input type="checkbox"/> Not checked
HBsAg	<input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Not checked
Anti-HBc	<input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Not checked
Anti-HBc IgM	<input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Not checked
Anti-HBs	<input type="checkbox"/> Positive <input type="checkbox"/> Negative

	<input type="checkbox"/> Not checked
Epstein-Barr Virus antibody IgM (Anti-EBV IgM)	<input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Not checked
Cytomegalovirus antibody IgM (Anti-CMV IgM)	<input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Not checked
Anti-nuclear antibody (ANA)	<input type="checkbox"/> Positive -Level (titer) <input type="checkbox"/> Negative <input type="checkbox"/> Not checked
Anti-smooth muscle antibody (ASMA)	<input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Not checked
Anti-mitochondrial antibody (AMA)	<input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Not checked
Did the patient develop evidence of decompensated liver disease during or shortly after COVID-19 illness? (select all that apply)	<input type="checkbox"/> Yes – hepatic encephalopathy <input type="checkbox"/> Yes – ascites <input type="checkbox"/> Yes – variceal hemorrhage <input type="checkbox"/> Yes – hepatorenal syndrome <input type="checkbox"/> No
Was a liver biopsy performed during the COVID-19 hospitalization?	<input type="checkbox"/> Yes <input type="checkbox"/> No
If yes, histologic findings (please list abnormal findings in impression section of pathology report(s)).	