

574 **Supplementary Appendix**

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607 **APPENDIX A: CCC-19 Quality Scores**

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609 The CCC-19 uses a quality scoring system to determine the suitability of records for inclusion in analyses. A score greater
610 than 5 was considered insufficient for inclusion in the analysis presented. Scores are tabulated as follows:

611

Minor problems (+1 points per problem)

ADT missing/unknown (prostate cancers only)
Biomarkers missing/unknown (breast cancers only)
ICU admission missing/unknown
Hospitalization missing/unknown
Mechanical ventilation missing/unknown
O2 ever needed missing/unknown
Days to death missing/unknown
Cancer status unknown
ECOG PS unknown
Missing cancer drug names for patients on systemic anti-cancer treatment
Missing or unknown categorical lab values if labs were drawn

Moderate problems (+3 points per problem)

Cancer status missing
ECOG PS missing
Death status missing/unknown
Baseline COVID-19 severity missing/unknown
Should have 30-day follow-up but doesn't

Major problems (+5 points per problem)

High levels of missingness
High levels of unknowns

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626 **APPENDIX B: Breast Cancer Disparities Statistical Analysis Plan:**

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628 Approved Project Title: **Racial and Ethnic Disparities among Patients with Breast Cancer and COVID-19 in CCC19**
629 **Cohort**

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631

632 Project Team Leads: Gayathri Nagaraj, Melissa Accordini, Maryam Lustberg, Dimpy Shah

633

634 Name of the investigator completing this survey: Gayathri Nagaraj and Melissa Accordini

635

636 Proposed milestone deadline for this manuscript:

637 • Abstract submission for ASCO 2021, deadline February 17 completed.

638 • ASCO abstract accepted for oral presentation. Deadlines for prelim slide upload May 7, and final deadline for
639 uploading slides May 14.

640 • Manuscript preparation simultaneously, deadline and journal TBD

641 Do you have local statistical support: No

642

643 Name and emails of (at most) 2 additional project team members who would like to be part of the analysis team for the
644 project:

645 Melissa Accordini, Email: mkg2134@cumc.columbia.edu

646 Maryam Lustberg, Email: Maryam.Lustberg@osumc.edu

647 Dimpy Shah, Email: shahdp@uthscsa.edu

648

649 Initial draft of the Statistical Analysis Plan (SAP), following STROBE guidelines, for our review and input. Please complete
650 sections 1 and 3-11 (and 12 if you have local statistical support)

651

652 **1 (a) Manuscript Title:** **Racial and Ethnic Disparities among Patients with Breast Cancer and COVID-19 in CCC19**
653 **Cohort**

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655 **1 (b) Provide in the abstract an informative and balanced summary of what was done and what will be found.**

656

657 Racial and Ethnic minority subgroups are at a disproportionately increased risk of contracting COVID-19 or experiencing
658 severe illness regardless of age. Racial and Ethnic disparities also affect breast cancer incidence and mortality. The impact of
659 COVID-19 on patients with breast cancer is largely unknown but is currently under investigation. Outcomes of COVID-19
660 specifically in racial and ethnic minority patients with active or prior history of breast cancer is currently unknown.

661 **3. Objectives**

662 State specific objectives, including any prespecified hypotheses:

663

664 **The overarching goal** of this study is to evaluate the racial and ethnic disparities related to COVID-19 outcomes, in patients
665 with active or previous history of breast cancer. To evaluate this, the following specific aims are proposed:

666

- 667 • **Specific Aim 1: To compare the distribution of major clinical, sociodemographic, and breast cancer risk**
668 **factors among racial and ethnic subgroups of women with active or previous history of single primary**
669 **invasive breast cancer diagnosed with COVID-19.**

670 We *hypothesize* that racial and ethnic minority women with breast cancer are more likely to have active comorbid
671 conditions, such as diabetes mellitus, obesity, smoking history, and a baseline lower performance status compared to
672 non-Hispanic white (NHW) women with active or previous history of breast cancer diagnosed with COVID-19.
673 Other variables of interest are age, month/year of COVID-19 diagnosis, area of patient residence, geographic region,
674 insurance type, treatment center characteristics, receipt of anti-COVID-19 treatment along with tumor characteristics
675 including breast cancer biologic subtype, cancer status, treatment intent, timing of anti-cancer treatment and
676 modality of anti-cancer treatment.

677

- 678 • **Specific Aim 2: To compare COVID-19 clinical outcomes on a five-level ordinal scale based on patient's most**
679 **severe reported outcomes: no complications (uncomplicated); hospital admission, intensive care unit (ICU)**
680 **admission, mechanical ventilation; or death from any cause in racial and ethnic minority subgroups of**
681 **women with previous or active history of breast cancer compared to NHW adjusted for baseline**
682 **characteristics. We also plan to evaluate the death within 30 days of COVID-19 diagnosis among racial and**
683 **ethnic subgroups of women with previous or active history of breast cancer compared to NHW adjusted for**
684 **baseline characteristics.**

685 We *hypothesize* that there will be higher rates of severe COVID-19 related outcomes in the racial and ethnic
686 minority subgroups compared to non-Hispanic white (NHW) patients with active or previous history of breast
687 cancer.

688

- 689 • **Exploratory aims:**

690

- 691 1. To evaluate the frequency of hospitalization, supplemental oxygen use, ICU admission and use of
692 mechanical ventilation in the various racial ethnic groups.
693 2. To describe the distribution of major clinical, sociodemographic, breast cancer risk factors and outcomes in
694 men with active or previous history of breast cancer diagnosed with COVID-19.
695 3. Assess the rate of major clinical complications such as cardiovascular, pulmonary, gastrointestinal,
696 superimposed infection, vascular thrombosis and others among various racial and ethnic groups of women
697 with active or previous history of breast cancer.
698

699 **4. Study Design**

700 Study Design:

701 Present key elements of study design early in the paper

702 This is a retrospective cohort study using de-identified data from the COVID-19 and Cancer Consortium (CCC19) database
703 which is a centralized multi-institution registry of patients with current or past history of cancer diagnosed with COVID-19.
704 Study data are collected and managed using REDCap software hosted at Vanderbilt University Medical Center.

705

706

707 **5. Setting**

708 **Setting**

709 Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection.

710 The CCC19 international registry consists of de-identified data on adult patients (18 years and older) with a current or past
711 history of hematologic malignancy or invasive solid tumor who either have laboratory-confirmed SARS-CoV-2 infection or
712 presumptive diagnosis of COVID-19. The CCC19 registry includes patients with either active cancer or a history of cancer
713 and contains variables related to patient demographics, cancer history, and COVID-19 clinical course including receipt of
714 COVID-19 related therapeutics along with follow-up data. The member institutions of the consortium report data through the
715 online REDCap data collection survey developed by CCC19. Data collection period is ongoing, for the purpose of this
716 analysis, the data collected from March 17, 2020 to February 9 2021 will be used.

717 **6. Participants**

718 (a) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up:

719

720 Patients with active or previous history of invasive breast cancer with evaluable self-reported race/ethnicity data, and with
721 laboratory confirmed COVID-19 will be our study population. While the primary analysis will be restricted to women with
722 active or previous history of breast cancer and descriptive data on men with active or previous history of breast cancer will be
723 provided separately as part of the exploratory analysis given the small numbers. We will restrict our analysis to patients
724 diagnosed in the United States of America since the racial and ethnic disparities of interest have been previously described in
725 United States. We will also exclude patients who have multiple malignancies including a history of bilateral breast cancer
726 with the exception of contralateral DCIS only. Further, patients who are not evaluable for the primary ordinal outcome or
727 with a data quality score >4 will be excluded. For this analysis, the unknown/Not reported category of race and ethnicity will
728 be excluded.

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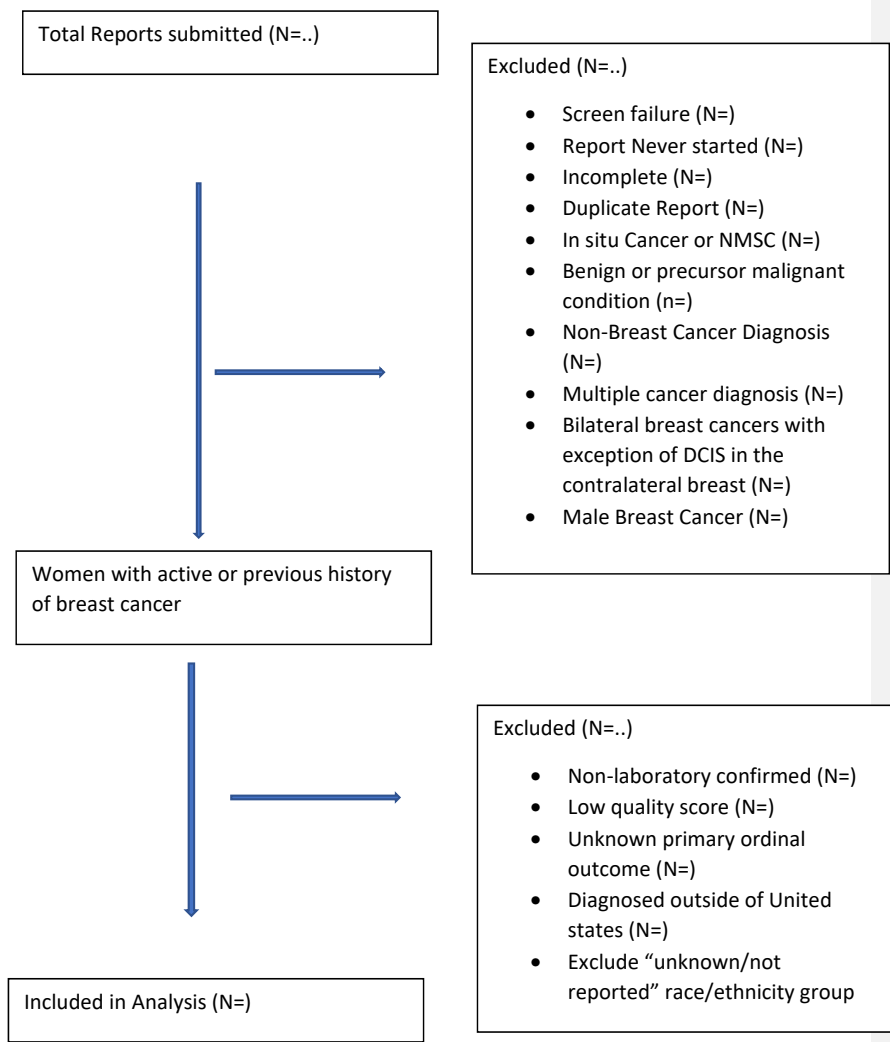
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CONSORT flow diagram



775 (b) For matched studies, give matching criteria and number of exposed and unexposed:

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777 Not applicable as the CCC19 registry does not carry data for cancer patients who are not exposed to Covid-19.

778

779 **7. Variables (Clearly define all variables)**

780 **Outcomes:**

- 781 • Primary: COVID-19 severity outcome defined on a five-level ordinal scale based on patient's most severe reported
- 782 outcomes: No complications (uncomplicated); hospital admission; intensive care unit admission, mechanical
- 783 ventilation; or death from any cause.
- 784 • Secondary: 30-day all-cause mortality
- 785 • Exploratory/Descriptive:
- 786 ○ Rates of hospitalization; oxygen requirements; ICU admission; mechanical ventilation.
- 787 ○ Major clinical complications (cardiovascular, pulmonary, gastrointestinal, AKI, MOF, superimposed
- 788 infection, sepsis, any bleeding, DIC, Thrombosis).
- 789 ○ Descriptive statistics for men with breast cancer diagnosed with COVID-19.

790

791 **Exposures**

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793 **Predictors**

- 793 1) Self-reported race
- 794 2) Self-reported ethnicity

795

796 **Potential confounders**

797

798 **Higher priority**

- 797 1) Age in years
- 798 2) Obesity (obese, not obese)
- 799 3) Co-morbidities (pulmonary, cardiovascular, renal, diabetes mellitus)
- 800 4) ECOG PS (0, 1, ≥ 2 , unknown)
- 801 5) Receptor status (Hormone receptor positive, HER2 positive, dual positive, Triple negative)
- 802 6) Cancer status (remission < 5 years, remission > 5 years, active stable, active responding, active progressing,
- 803 unknown)
- 804 7) Timing of anti-cancer treatment (never treated, 0-4 weeks, 1-3 months, >3 months)
- 805 8) Modality of recent anti-cancer treatment (none, cytotoxic chemotherapy, targeted therapy, endocrine therapy,
- 806 immunotherapy, locoregional therapy, other)
- 807 9) Period of COVID-19 diagnosis (Jan-April 2020, May-August 2020, Sep-Nov 2020, Dec 2020-Feb 2021)

808

809 **Lower priority**

- 810 10) Smoking (ever, never)
- 811 11) US region of patient residence (NE, MW, South, West)
- 812 12) Area of patient residence (urban, suburban, rural)
- 813 13) Insurance status (Not insured, private insurance, Medicaid/Medicare, other government, missing/unknown)
- 814 14) Treatment center characteristics academic (university, tertiary and NCI designated comprehensive cancer centers),
- 815 community (practice and hospital), other.

816

817 **Effect modifiers**

818 **None**

819

820 Diagnostic criteria (if applicable)

821 8. Data Sources / Measurement

822 For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe
823 comparability of assessment methods if there is more than one group.

824

825 9. Bias

826 Describe any efforts to address potential sources of bias

827 Multivariable regression models will be used to adjust for known confounding variables.

828

829 10. Study size

830 Explain how the study size was arrived at

831 Study size is based on the number of breast cancer cases reported in the registry at the time of Analysis. Breast cancer is the
832 single largest solid tumor cohort within the CCC19 registry accounting for roughly 21% of cases. The numbers are expected
833 to rise given the steep accrual rate.

834

835 11. Quantitative variables

836 Explain how quantitative variables will be handled in the analyses. If applicable, describe which groupings will be chosen
837 and why

838

839 12. Statistical methods

840 (a) Describe all statistical methods, including those to be used to control for confounding

841

842 *Primary analysis among women:*

843 Standard descriptive statistics will summarize major clinical, demographic, and breast cancer prognostic factors; clinical
844 complications during hospitalization; and rates of 30-day mortality, hospitalization, oxygen requirement, ICU admission, and
845 mechanical ventilation among racial and ethnic subgroups. Multivariable ordinal and binary logistic regression models will
846 estimate differences in adjusted odds of COVID-19 severity and 30-day mortality, respectively, between racial and ethnic
847 subgroups. Because the ordinal outcome is assessed over patient's total follow-up period, the model will include an offset for
848 (log) follow-up time. Adjustment covariates will be selected first from the "higher priority" confounders listed above,
849 followed by those listed as "lower priority." Coefficients and standard errors from models with different levels of adjustment,
850 variance inflation factors, and clinical judgement will be used to assess model stability.

851

852 *Descriptive analysis among men:*

853 We will calculate standard descriptive statistics for major clinical, demographic, and breast cancer prognostic factors and
854 clinical complications during hospitalization; rates of 30-day mortality, hospitalization, oxygen requirement, ICU admission,
855 and mechanical ventilation among men with active or previous history of breast cancer.

856

857
858 (b) Describe any methods that will be used to examine subgroups and interactions

859 None included.

860

861 (c) Explain how missing data will be addressed

862 Multiple imputation will be used to impute missing and unknown data for all variables included in the analysis, with some
863 exceptions: unknown ECOG performance score and unknown cancer status will not be imputed and treated as a separate
864 category in analyses. Imputation will be performed on the largest dataset possible (that is, after removing test cases and other
865 manual exclusions, but before applying specific exclusion criteria). At least 10 imputed datasets will be used.

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867 (d) If applicable, explain how loss to follow-up will be addressed

868 All observed outcomes will be used with models adjusted for duration of follow-up.

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870 (e) Describe any sensitivity analyses

871 None.

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894 **APPENDIX C: CCC19 Approved Project Variables**

895 *Primary Outcome (Table III)*

| Outcome description | Outcome variable name | Outcome values |
|---|------------------------|--|
| Custom ordinal outcome with death at any time | <i>der_ordinal_v1a</i> | 0 = not hospitalized; 1 = hospitalized; 2 = ICU; 3 = mechanical ventilation; 4 = death at any time |
| Follow-up in days, with some estimation for intervals | <i>der_days_fu</i> | Integer (days) |

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897 *Secondary Outcome (Table II)*

| Outcome description | Outcome variable name | Outcome values | Additional Details |
|--|---|-------------------------------|--|
| Derived dead/alive variable | <i>der_deadbinary</i> | 0 = No; 1 = Yes; 99 = Unknown | |
| Derived variable indicating whether patient has died within 30 days of COVID-19 diagnosis (default = No) | <i>der_dead30</i> | 0 = No; 1 = Yes; 99 = Unknown | |
| Derived variable indicating whether patients required mechanical ventilation | <i>der_mv</i> | 0 = No; 1 = Yes; 99 = Unknown | |
| Derived variable indicating time in ICU | <i>der_ICU</i> | 0 = No; 1 = Yes; 99 = Unknown | |
| Derived hospitalized/not hospitalized variable | <i>der_hosp</i> | 0 = No; 1 = Yes; 99 = Unknown | |
| Derived cardiovascular complication variable (see additional details) | <i>der_CV_event_v2</i> (<i>der_any_CV</i> is the variable name in R script) | 0 = No; 1 = Yes; 99=Unknown. | <p>Derived with the following derived variables:</p> <ul style="list-style-type: none"> <i>der_hotn_comp</i>, <i>der_MI_comp</i>, <i>der_card_isch_comp</i>, <i>der_AFib_comp</i>, <i>der_VF_comp</i>, <i>der_arry_oth_comp</i>, <i>der_CMY_comp</i>, <i>der_CHF_comp</i>, <i>der_PE_comp</i>, <i>der_DVT_comp</i>, <i>der_stroke_comp</i>, <i>der_thrombosis_NOS_comp</i> <p>Coded as 1 if any of these variables is 1; coded as 0 if all these variables are 0; coded as 99 if any of variables is 99 and <i>der_CV_event_v2</i> is missing;</p> |

| | | | |
|--|---|-------------------------------|--|
| | | | otherwise, NA For all listed variable here: 0=No, 1=Yes, 99=Unknown |
| Derived pulmonary complication variable (see additional details) | der_pulm_event (der_any_Pulm is the variable name in R script) | 0 = No; 1 = Yes; 99=Unknown. | Derived with the following derived variables: der_resp_failure_comp, der_pneumonitis_comp, der_pneumonia_comp, der_ARDS_comp, der_PE_comp, der_pleural_eff_comp, der_empyema_comp Coded as 1 if any of these variables is 1; coded as 0 if all these variables are 0; coded as 99 if any of variables is 99 and der_pulm_event is missing; otherwise, NA For all listed variable here: 0=No, 1=Yes, 99=Unknown |
| Derived gastrointestinal complication variable (see additional details) | der_GI_event (der_any_Gast is the variable name in R script) | 0 = No; 1 = Yes; 99=Unknown. | Derived with the following derived variables: der_AHI_comp, der_ascites_comp, der_BO_comp, der_bowelPerf_comp, der_ileus_comp, der_peritonitis_comp Coded as 1 if any of these variables is 1; coded as 0 if all these variables are 0; coded as 99 if any of variables is 99 and der_GI_event is missing; otherwise, NA For all listed variable here: 0=No, 1=Yes, 99=Unknown |
| Acute kidney injury (checkbox only) | der_AKI_comp | 0 = No; 1 = Yes; 99 = Unknown | |
| Multisystem organ failure | der_MOF_comp | 0 = No; 1 = Yes; 99 = Unknown | |
| Any co-infection within +/- 2 weeks of COVID-19 dx | der_coinfection_any | 0 = No; 1 = Yes; 99 = Unknown | |
| Sepsis | der_sepsis_comp | 0 = No; 1 = Yes; 99 = Unknown | |
| Bleeding | der_bleeding_comp | 0 = No; 1 = Yes; 99 = Unknown | |
| DIC (without modifier of | der_DIC_comp | 0 = No; 1 = Yes; 99 = | |

| | | | |
|--|---------------------|-------------------------------|--|
| definite/probable/possible) | | Unknown | |
| Remdesivir as treatment for COVID-19 ever | der_rem | 0 = No; 1 = Yes; 99 = Unknown | |
| Hydroxychloroquine as COVID-19 treatment ever | der_hcq | 0 = No; 1 = Yes; 99 = Unknown | |
| Steroids as COVID-19 treatment ever | der_steroids_c19 | 0 = No; 1 = Yes; 99 = Unknown | |
| COVID-19 treatments other than HCQ, steroids, remdesivir | der_other_tx_c19_v2 | 0 = No; 1 = Yes; 99 = Unknown | |
| Indicates whether patient has ever had supplemental o2 | der_o2_ever | 0 = No; 1 = Yes; 99 = Unknown | |

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| Covariate description | Variable name | Covariate values | Additional Details |
|--|---------------|--|--------------------|
| Race/ethnicity including Asian | der_race_v2 | Hispanic; Non-Hispanic AAPI; Non-Hispanic Black; Non-Hispanic White; Other | |
| Age with imputation for categoricals | der_age_trunc | Years (continuous 18-89; patients noted to be greater than 89 are set to be age = 90) | |
| Insurance type | der_insurance | Medicaid alone; Medicare alone; Medicare/Medicaid +/- other; Other government +/- other; Private +/- other; Uninsured; Unknown | |
| Derived variable for smoking status collapsing the current/former smoker variables | der_smoking2 | Never; Current or Former; Unknown | |
| Binary obesity (BMI \geq 30 or checkbox checked) indicator | der_obesity | 0 = No; 1 = Yes; 99 = Unknown | |
| Cardiovascular comorbidity (CAD, CHF, Afib, arrhythmia NOS, PVD, CVA, cardiac disease NOS) | der_card | 0 = No; 1 = Yes; 99 = Unknown | |
| Derived variable indicating whether patient has pulmonary comorbidities | der_pulm | 0 = No; 1 = Yes; 99 = Unknown | |
| Renal comorbidities | der_renal | 0 = No; 1 = Yes; 99 = | |

| | | | |
|---|-------------------------|---|---|
| | | Unknown | |
| Derived variable indicating whether patient has diabetes mellitus | der_dm2 | 0 = No; 1 = Yes; 99 = Unknown | |
| Performance Status | der_ecogcat2 | ECOG 0, 1, or 2+ | |
| Breast biomarkers combined variable | der_breast_biomarkers | 1 = ER+; 2 = ER+/HER2+; 3 = HER2+; 4 = triple negative; 99 = Unknown | |
| Derived variable indicating cancer status (Splits remission/NED by cancer timing) | der_cancer_status_v4 | 0 - Remission/NED, remote; 1 - Remission/NED, recent; 2 - Active, responding; 3 - Active, stable; 4 - Active, progressing; 99 - Unknown | |
| Timing of cancer treatment relative to COVID-19, collapsed | der_cancer_tx_timing_v2 | 0 = more than 3 months; 1 = 0-4 weeks; 2 = 1-3 months (*); 88 = never or after COVID-19 diagnosis; 99 = unknown | |
| No cancer treatment in the 3 months prior to COVID-19 | der_cancertr_none | 0=No; 1=Yes; 99=Unknown | Derived with the following covariates: der_any_cyto, der_any_targeted, der_any_endo, der_any_immuno, der_any_local, der_any_other Coded as 1 if all these variables are 0; coded as 0 if any of these variables is 1; coded as 99 if any of these variables is 99; otherwise, NA |
| Any cytotoxic cancer treatment in the 3 months prior to COVID-19 | der_any_cyto | 0 = No; 1 = Yes; 99 = Unknown | |
| Any targeted therapy in the 3 months prior to COVID-19 | der_any_targeted | 0 = No; 1 = Yes; 99 = Unknown | |
| Any targeted therapy includes an anti-HER2 therapy in the 3 months prior to COVID-19 | der_her2_3m | 0 = No; 1 = Yes | Derived with der_her2, der_any_targeted. Coded as 1 if der_any_targeted is 1 and der_her2 is 1 Coded as 0 if: a. der_any_targeted is 1 and der_her2 is 0 b. der_any_targeted is 1 Otherwise, NA |

| | | | |
|---|----------------|---|--|
| | | | <p>der_her2: 0 = No; 1 = Yes</p> |
| <p>Any targeted therapy includes a CDK4/6 inhibitor therapy in the 3 months prior to COVID-19</p> | der_cdk46i_3m | 0 = No; 1 = Yes | <p>Derived with der_cdk46i, der_any_targeted.</p> <p>Coded as 1 if der_any_targeted is 1 and der_cdk46i is 1</p> <p>Coded as 0 if: a. der_any_targeted is 1 and der_cdk46i is 0 b. der_any_targeted is 1</p> <p>Otherwise, NA</p> <p>der_cdk46i: 0 = No; 1 = Yes</p> |
| <p>Any other targeted therapy (Not anti-HER2 / CDK4/6 inhibitor) in the 3 months prior to COVID-19</p> | der_other_3m | 0 = No; 1 = Yes | <p>Derived with der_targeted_not_her2_cdk46i, der_any_targeted.</p> <p>Coded as 1 if der_any_targeted is 1 and der_targeted_not_her2_cdk46i is 1</p> <p>Coded as 0 if: a. der_any_targeted is 1 and der_targeted_not_her2_cdk46i is 0 b. der_any_targeted is 1</p> <p>Otherwise, NA</p> <p>der_targeted_not_her2_cdk46i: 0 = No; 1 = Yes</p> |
| <p>Any endocrine therapy in the 3 months prior to COVID-19</p> | der_any_endo | 0 = No; 1 = Yes; 99 = Unknown | |
| <p>Any immunotherapy in the 3 months prior to COVID-19</p> | der_any_immuno | 0 = No; 1 = Yes; 99 = Unknown | |
| <p>Any local therapy (surgery or RT) within 3 months</p> | der_any_local | 0 = No; 1 = Yes; 99 = Unknown | |
| <p>Any other cancer therapy in the 3 months prior to COVID-19</p> | der_any_other | 0 = No; 1 = Yes; 99 = Unknown | |
| <p>Region of patient residence with ex-US collapsed</p> | der_region_v2 | Non-US; Other; Undesignated US; US Midwest; US Northeast; US South; US West | |
| <p>Trimester and year of</p> | der_tri_rt_dx | T1 2020; T2 2020; T3 | |

| | | | |
|--|--------------------------------------|---|--|
| diagnosis, using the most recent side of the interval as anchor | | 2020; T1 2021 | |
| What type of area does the patient primarily reside in? | urban_rural ¹ | 1, Urban (city) 2, Suburban (town, suburbs) 3, Rural (country) 88, Other 99, Unknown | |
| The type of health care center providing the patient's data | der_site_type | AMC = academic medical center; CP = community practice; TCC = tertiary care center | |
| Initial Severity and Course of Illness | severity_of_covid_19_v2 ¹ | 1, Mild (no hospitalization required) 2, Moderate (hospitalization indicated) 3, Severe (ICU admission indicated) 99, Unknown | |
| Derived treatment intent | der_tr_intent | Unknown Treatment; Not on Treatment; Palliative; Curative; Missing Unknown Treatment and Missing were collapsed for analysis | Derived with der_anytx and treatment_intent: Coded as "Unknown Treatment" if der_anytx is NA or 99; Coded as "Not on Treatment" if der_anytx is 0 Coded as "Palliative" if der_anytx is 1 and treatment_intent is 2 Coded as "Curative" if der_anytx is 1 and treatment_intent is 1 Otherwise, Missing der_anytx: 0 = No; 1 = Yes; 99 = Unknown Treatment_intent: 1, Curative 2, Palliative 99, Unclear or unknown |
| Most recent line of cancer treatment, including systemic and non-systemic therapies | der_txline | Untreated in last 12 months; Curative NOS; First line; Non-curative NOS; Other; Second line or greater; Unknown | |
| Hematologic malignancy indicator | der_heme | 0 = No; 1 = Yes | |

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| Other covariate related to cohort selection for analysis | Variable name | Covariate values | Covariate description |
|--|---------------|------------------|-----------------------|
| Sex (Recode other/prefer not to | der_sex | Male, Female | |

| | | | |
|--|----------------------------|------------------------------------|--|
| say gender --> missing) | | | |
| Breast cancer | der_Breast | 0 = No; 1 = Yes | |
| Cancer type of second malignancy. If the patient has more than two malignancies, please select the second-most recently diagnosed cancer type. If unknown or unclear, please specify in the free text box below | cancer_type_2 ¹ | ** indicates no second malignancy. | |
| Region of patient residence with US and ex-US collapsed | der_region_v3 | Non-US; Other; US | |

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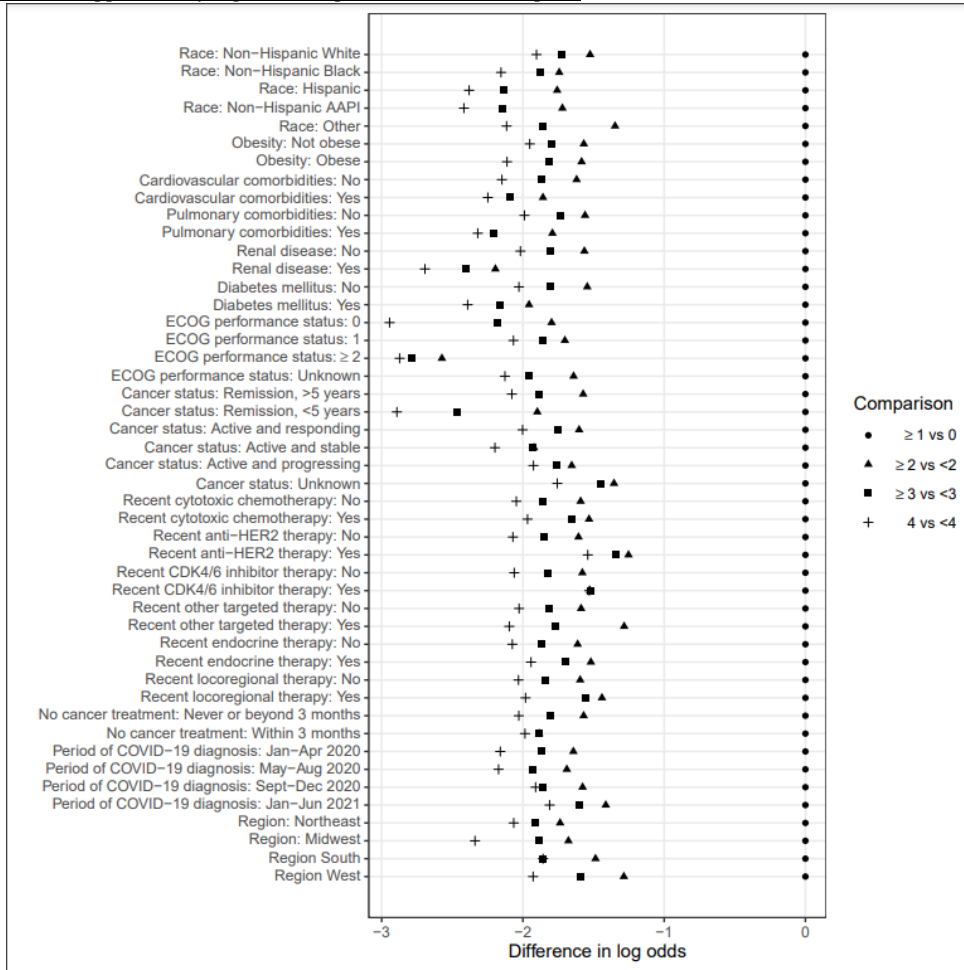
903 New covariate request – 2-5-22

| New covariate | Variable name | Covariate values | Covariate description |
|------------------------|-----------------|-------------------------------|---|
| MBC vs non-MBC | der_metastatic | 0 = No; 1 = Yes; 99 = Unknown | Metastatic cancer status (only applicable to solid tumors/lymphoma) |
| MBC site of metastasis | der_met_bone | 0 = No; 1 = Yes; 99 = Unknown | Metastatic to bone |
| MBC site of metastasis | der_met_liver | 0 = No; 1 = Yes; 99 = Unknown | Metastatic to liver |
| MBC site of metastasis | der_met_lung_v2 | 0 = No; 1 = Yes; 99 = Unknown | Metastatic to lung |

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906 **APPENDIX D: Supplementary Figure I - Proportional Odds Assumption**



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915 **APPENDIX E**

| Supplement Table 1. Unadjusted rates of outcomes after COVID-19 diagnosis by cancer status | | | | | | | |
|---|---------------------------|---------------------------|--------------------------------------|----------------------------------|---------------------------------------|-----------------------------|--------------------------|
| | NED>5 Years | NED<5 Years | Active and Responding | Active and Stable | Active and Progressing | Missing/ Unknown | Total |
| | n^a (%) | n^a (%) | n^a (%) | n^a (%) | n^a (%) | n^a (%) | n^a (%) |
| Outcomes | | | | | | | |
| Total all-cause mortality ^b | 40 (11) | 12 (3) | 12 (7) | 11 (7) | 37 (38) | 11 (9) | 123 (9) |
| 30-day all-cause mortality ^c | 29 (8) | 10 (2) | 10 (6) | 4 (2) | 27 (28) | 9 (7) | 89 (6) |
| Received mechanical ventilation ^b | 20 (5) | 13 (3) | 9 (5) | 7 (4) | 12 (12) | 8 (7) | 69 (5) |
| Admitted to an intensive care unit ^b | 35 (10) | 25 (6) | 13 (8) | 8 (5) | 18 (19) | 12 (10) | 111 (8) |
| Admitted to the hospital ^b | 163 (43) | 129 (29) | 54 (31) | 57 (34) | 70 (72) | 39 (32) | 512 (37) |
| ^a N is based on non-missing data | | | | | | | |
| ^b Included in primary ordinal COVID-19 severity outcome. | | | | | | | |
| ^c Secondary outcome. | | | | | | | |

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936 **APPENDIX F**

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| Supplementary Table IIA: Baseline characteristics of female patients with MBC | |
|--|-------------------|
| MBC (N=233) | |
| Age, years^a | |
| Median [IQR] | 58.0 [49.8, 68.3] |
| Race/Ethnicity | |
| Non-Hispanic White | 107 (46%) |
| Non-Hispanic Black | 56 (24%) |
| Hispanic | 50 (21%) |
| Non-Hispanic AAPI | 10 (4%) |
| Other | 10 (4%) |
| Smoking Status | |
| Never | 162 (70%) |
| Current or Former | 66 (28%) |
| Missing/unknown | 5 (2%) |
| Obesity | |
| No | 139 (60%) |
| Yes | 93 (40%) |
| Comorbidities^b | |
| Cardiovascular | 42 (18%) |
| Pulmonary | 37 (16%) |
| Renal Disease | 16 (7%) |
| Diabetes mellitus | 52 (22%) |
| Missing/unknown | 3 (1%) |
| ECOG Performance Status | |
| 0 | 63 (27%) |
| 1 | 84 (36%) |
| 2+ | 42 (18%) |
| Unknown | 44 (19%) |
| Missing | 0 (0%) |
| Receptor status | |
| HR+/HER2- | 98 (42%) |
| HR+/HER2+ | 53 (23%) |
| HR-/HER2+ | 26 (11%) |
| Triple Negative | 33 (14%) |
| Missing/unknown | 23 (10%) |
| Cancer Status | |

| | |
|---|-----------|
| Active and responding | 55 (24%) |
| Active and stable | 78 (33%) |
| Active and progressing | 74 (32%) |
| Unknown | 25 (11%) |
| Missing | 0 (0%) |
| Metastatic sites (MBC) | |
| Lung | 65 (28%) |
| Bone | 135 (58%) |
| Liver | 61 (26%) |
| Missing/unknown | 19 (8%) |
| Timing of anti-cancer therapy | |
| Never/After COVID-19 | X* |
| 0-4 weeks | 189 (81%) |
| 1-3 months | 14 (6%) |
| >3 months | 19 (8%) |
| Missing/unknown | 11 (5%)* |
| Modality of active anti-cancer therapy^{b,c} | |
| None | 24 (10%) |
| Cytotoxic Chemotherapy | 114 (49%) |
| Targeted Therapy | 115 (49%) |
| Endocrine Therapy | 98 (42%) |
| Immunotherapy | 17 (7%) |
| Local (Surgery/Radiation) | 27 (12%) |
| Other | 6 (3%) |
| Missing/unknown | 6 (3%) |
| Region | |
| Northeast | 97 (42%) |
| Midwest | 44 (19%) |
| South | 34 (15%) |
| West | 56 (24%) |
| Undesignated | 2 (1%) |
| Period of COVID-19 diagnosis | |
| Jan-Apr 2020 | 33 (14%) |
| May-Aug 2020 | 101 (43%) |
| Sept-Dec 2020 | 52 (22%) |
| Jan-Aug 2021 | 45 (19%) |
| Missing/unknown | 2 (1%) |
| Area of patient residence | |
| Urban | 103 (44%) |
| Suburban | 80 (34%) |
| Rural | 12 (5%) |
| Missing/unknown | 38 (16%) |
| Treatment center characteristics | |

| | |
|--|-----------|
| Academic Medical Center | 43 (18%) |
| Community Practice | 63 (27%) |
| Tertiary Care Center | 127 (55%) |
| Missing/unknown | 0 (0%) |
| Severity of COVID19 | |
| Mild | 126 (54%) |
| Moderate | 93 (40%) |
| Severe | 13 (6%) |
| Missing/Unknown | 1 (<1%) |
| *Cells combined to mask N<5 according to CCC19 low count policy | |
| ^a Age was truncated at 90 years. | |
| ^b Percentages could sum to >100% because categories are not mutually exclusive. | |
| ^c Within 3 months of COVID-19 diagnosis. | |

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Supplement Table IIB: Unadjusted rates of outcomes after COVID-19 diagnosis in females with MBC

| | n ^f (%) |
|--|--------------------|
| Outcomes | |
| Total all-cause mortality ^a | 45 (19) |
| 30-day all-cause mortality ^b | 28 (12) |
| Received mechanical ventilation ^a | 20 (9) |
| Admitted to an intensive care unit ^a | 29 (12) |
| Admitted to the hospital ^a | 124 (53) |
| Clinical Complications | |
| Any cardiovascular complication ^c | 48 (21) |
| Any pulmonary complication ^d | 86 (37) |
| Any gastrointestinal complication ^e | 13 (6) |
| Acute kidney injury | 32 (14) |
| Multisystem organ failure | 12 (5) |
| Superimposed infection | 32 (14) |
| Sepsis | 28 (12) |
| Any bleeding | 8 (3) |
| Interventions | |
| Remdesivir | 35 (15) |
| Hydroxychloroquine | 25 (11) |
| Corticosteroids | 65 (29) |
| Covid Other | 45 (20) |
| Supplemental oxygen | 84 (37) |
| ^a Included in primary ordinal COVID-19 severity outcome | |
| ^b Secondary outcome | |
| ^c Cardiovascular complication includes hypotension, myocardial infarction, other cardiac ischemia, atrial fibrillation, ventricular fibrillation, other cardiac arrhythmia, cardiomyopathy, congestive heart failure, pulmonary embolism (PE), deep vein thrombosis (DVT), stroke, thrombosis NOS complication. | |
| ^d Pulmonary complication includes respiratory failure, pneumonitis, pneumonia, acute respiratory distress syndrome (ARDS), PE, pleural effusion, empyema. | |
| ^e Gastrointestinal complication includes acute hepatic injury, ascites, bowel obstruction, bowel perforation, ileus, peritonitis | |
| ^f N is based on non-missing data | |

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APPENDIX G

| Supplement Table III: Adjusted Associations of Race Factors with COVID-19 Severity Outcome. | | | |
|--|-------------------|--------------------------------------|-----------------------------------|
| Race (Ref: NHW) | COVID-19 severity | | |
| | OR (95% CI) | Point Value E estimates ^a | Lower bound E values ^a |
| Black | 1.74 (1.24- 2.45) | 1.97 | 1.47 |
| Hispanic | 1.38 (0.93- 2.05) | 1.63 | 1.00 |
| AAPI | 3.40 (1.70- 6.79) | 3.09 | 1.93 |
| Other | 2.97 (1.71- 5.17) | 2.84 | 1.94 |

^aThese values were calculated based on the formula for logistic regression

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969 **APPENDIX H:**

| Supplement Table IVA: Male patients with breast cancer and COVID-19: Baseline Characteristics | |
|--|------------------|
| Total | 25 (100%) |
| Age, years^a | |
| Median [IQR] | 67.0 [60 - 75] |
| Race/Ethnicity | |
| NHW | 13 (52%) |
| Black | 8 (32%) |
| Hispanic | <5 (<20%) |
| AAPI | 0 (0%) |
| Other | <5 (<20%) |
| Smoking Status | |
| Never | 18 (72%) |
| Current or Former | 7 (28%) |
| Obesity | |
| No | 12 (48%) |
| Yes | 13 (52%) |
| Comorbidities^b | |
| Cardiovascular | 6 (24%) |
| Pulmonary | 5 (20%) |
| Renal Disease | <5 (<20%) |
| Diabetes mellitus | 11 (44%) |
| ECOG Performance Status | |
| 0 | 5 (20%) |
| 1 | 10 (40%) |
| 2+ | X* |
| Unknown | 10 (40%)* |
| Receptor status | |
| HR+/HER2- | 18 (72%) |
| HR+/HER2+ | 5 (20%) |
| HR+/HER2+ | X* |
| Triple Negative | 0 (0%) |
| Missing/unknown | 2 (8%)* |
| Cancer Status | |
| Remission or NED, >5 years | <5 (<20%) |
| Remission or NED, <5 years | 6 (24%) |
| Active and responding | <5 (<20%) |
| Active and stable | <5 (<20%) |
| Active and progressing | 5 (20%) |

| | |
|---|-----------|
| Unknown | 3 (12%) |
| Timing of anti-cancer therapy | |
| Never/After COVID-19 | <5 (<20%) |
| 0-4 weeks | 17 (68%) |
| 1-3 months | 0 (0%) |
| >3 months | <5 (<20%) |
| Missing/unknown | 1 (4%) |
| Modality of active anti-cancer therapy ^{b,c} | |
| None | 7 (28%) |
| Chemotherapy | 6 (24%) |
| Targeted Therapy | 6 (24%) |
| Endocrine Therapy | 10 (40%) |
| Immunotherapy | 0 (0%) |
| Local (Surgery/Radiation) | <5 (<20%) |
| Other | 0 (0%) |
| Missing/unknown | 1 (4%) |
| Region | |
| Northeast | 11 (44%) |
| Midwest | <5 (<20%) |
| South | <5 (<20%) |
| West | 7 (28%) |
| Undesignated | 0 (0%) |
| Period of COVID-19 diagnosis | |
| Jan-Apr 2020 | 10 (40%) |
| May-Aug 2020 | 9 (36%) |
| Sept-Dec 2020 | 5 (20%) |
| Area of patient residence | |
| Urban | 9 (36%) |
| Suburban | 8 (32%) |
| Rural | 0 (0%) |
| Missing/unknown | 8 (32%) |
| Severity of COVID19 | |
| Mild | 11 (44%) |
| Moderate/Severe | 14 (56%) |
| *Cells combined to mask N<5 according to CCC19 low count policy | |
| ^a Age was truncated at 90 years. | |
| ^b Percentages could sum to >100% because categories are not mutually exclusive. | |
| ^c Within 3 months of COVID-19 diagnosis. | |
| Variable Categories with one to five cases are masked by replacing with N < 5 according to CCC19 policy | |

| Suppl Table IVB: Unadjusted rates of outcomes after COVID-19 diagnosis among males with BC | |
|--|-----------|
| Outcomes | |
| Total all-cause mortality | 5 (20) |
| 30-day all-cause mortality | 5 (20) |
| Received mechanical ventilation | <5 (<20%) |
| Admitted to an intensive care unit | <5 (<20%) |
| Admitted to the hospital | 15 (60) |
| Clinical Complications | |
| Any cardiovascular complication ^a | <5 (<20%) |
| Any pulmonary complication ^b | 12 (48) |
| Any gastrointestinal complication ^c | 0 (0%) |
| Acute kidney injury | <5 (<20%) |
| Multisystem organ failure | <5 (<20%) |
| Superimposed infection | <5 (<20%) |
| Sepsis | <5 (<20%) |
| Any bleeding | <5 (<20%) |
| Interventions | |
| Remdesivir | <5 (<20%) |
| Hydroxychloroquine | 7 (28) |
| Corticosteroids | <5 (<20%) |
| Other | 9 (36) |
| Supplemental oxygen | 12 (48) |
| Variable Categories with one to five cases are masked by replacing with N < 5 according to CCC19 policy | |
| ^a Cardiovascular complication includes hypotension, myocardial infarction, other cardiac ischemia, atrial fibrillation, ventricular fibrillation, other cardiac arrhythmia, cardiomyopathy, congestive heart failure, pulmonary embolism (PE), deep vein thrombosis (DVT), stroke, thrombosis NOS complication. | |
| ^b Pulmonary complication includes respiratory failure, pneumonitis, pneumonia, acute respiratory distress syndrome (ARDS), PE, pleural effusion, empyema. | |
| ^c Gastrointestinal complication includes acute hepatic injury, ascites, bowel obstruction, bowel perforation, ileus, peritonitis | |

972 **APPENDIX I:**

973 **List of Participants by Institution**

974 Alphabetical list of participants by institution that contributed at least one record to the analysis.

975 **Bolded** = site PI/co-PIs; site co-investigators are listed alphabetically by last name.

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1116 MSc BS; Benjamin French, PhD; Erin A. Gillaspie, MD, MPH; Daniel Hausrath, MD; Cassandra Hennessy, MS;
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