

American Heart Association (AHA) - COVID-19 CVD Registry Powered by Get With The Guidelines Research Publication Author Reference

This summary provides guidance to authors in preparation of research abstracts and manuscripts using the American Heart Association's (AHA) COVID-19 CVD Registry Powered by Get With The Guidelines, a voluntary, national registry and performance improvement program.

Overall Process

- 1) Approved Research Proposals
 - a) Proposals that meet scoring criteria and are accepted are considered final and only minimal changes will be allowed at time of development. The approved proposal is included as an exhibit in the NDA DUA for the project. No additional analyses are allowed without prior approval by the Research and Publications Committee (R&P).
- 2) Development of Research Question
 - a) For AHA Data Analysis Team projects, a Statistical Analysis Plan (SAP) is developed based on the approved proposal and changes/increases to scope will only be minimal to ensure the key questions of the proposal are answered and a solid manuscript can be developed. See NDA DUA page six for detailed description of projects and costs managed by the AHA Data Analysis Team.
 - b) Investigator led analysis will be conducted on the AHA Precision Medicine Platform (PMP). Once a workspace has been provisioned on the PMP, the research teams will have two weeks to conduct their analysis.
 - c) Prepare draft of manuscript for Writing Group review (6 weeks). The manuscript should include analyses only conducted within the scope of the approved project. Project lead authors may be reassigned if timing expectations are not met.
- AHA Reviews
 - a) Once the entire Writing Group has reviewed and approved the final manuscript draft, it must be submitted to AHA for final approval before submitted to peer-reviewed journal. Manuscripts should be submitted to qualityresearch@heart.org
 - b) Manuscript drafts are reviewed separately by the COVID-19 Research & Publications Committee and AHA Science. Each manuscript review period is two weeks (10 business days).
 - c) A summary of committee feedback and/or approval is sent to the primary author within 14 days of manuscript submission.
- 4) Final Manuscript/Publication in Peer Review Journal
 - a) Final manuscript/abstract draft is submitted to the journal of choice by primary author or other designee
 - b) Journal decision, online release date and print release date are to be communicated back to the AHA by primary author or designee to ensure timely promotion.
 - c) Final PDF of publication should be sent to AHA Staff after publication.

Acknowledgement and Methods Section Manuscript Requirements

Include the following information in the Acknowledgement and Methods sections of the manuscript:

The Get With The Guidelines® programs are provided by the American Heart Association.

The American Heart Association Precision Medicine Platform (https://precision.heart.org/) was used for data analysis.

IQVIA (Parsippany, New Jersey) serves as the data collection and coordination center.

GWTG Sponsorship

Include the following information in the Sources of Funding section of the manuscript:

AHA's suite of Registries is funded by multiple industry sponsors. AHA's COVID-19 CVD Registry is partially supported by The Gordon and Betty Moore Foundation.

Additional Information

1) Sites

<u>Heart.org/qualityresearch</u> – Main Page <u>Heart.org/qipublications</u> – Online Publications Library <u>Heart.org/COVIDregistry</u> – COVID-19 CVD Registry program information

If you have any questions regarding the publication process or GWTG publications in general, please contact QualityResearch@heart.org.

2) Data Source

The Get With The Guidelines® (GWTG) Quality Programs were launched by the American Heart Association® (AHA) and the American Stroke Association to support continuous quality improvement within hospital systems of care for patients. The AHA's COVID-19 CVD Registry powered by Get With The Guidelines® (GWTG) builds on 20 years of successful hospital quality improvement efforts.

AHA collects millions of patient records in the GWTG Quality Programs, creating vast national level databases for advancing scientific research. Data is collected at the patient level in hospitals participating in AHA Quality programs. Patients entered in the database are from U.S. hospitals only. Data is patient- and hospital-de-identified at an aggregate level.

All participating institutions were required to comply with local regulatory and privacy guidelines and, if required, to secure institutional review board (IRB) approval. Since this database is predominantly used at the local site for quality improvement purposes, sites were granted a waiver of informed consent under the common rule.

Hospitals participating in the registry submit clinical information regarding the medical history, hospital care, and outcomes of consecutive patients hospitalized for coronary artery disease, stroke, or heart failure using an online, interactive case report form in the Patient Management Tool™ (PMT™) which is powered by IQVIA (Parsippany, New Jersey).

Trained clinical personnel populate registry data using standardized definitions for patient demographic characteristics, clinical comorbidities, inpatient laboratory data, treatment therapies at admission and discharge, and in-hospital outcomes. This process allows for information to be more reliably collected in a similar fashion across hospitals.