

CTSC Standard Operating Procedure (SOP) Related to Research Use of TriNetX Platform

September 8, 2026

1. Introduction

The Clinical and Translational Science Collaborative (CTSC) of Northern Ohio catalyzes clinical and translational science and transformative research across Case Western Reserve University (CWRU) and its affiliated partner institutions, including Cleveland Clinic, MetroHealth, University Hospitals, VA Northeast Ohio Healthcare System, University of Toledo, and Northeast Ohio Medical University. In carrying out this mission, the CTSC is responsible for ensuring that research conducted with CTSC-supported resources meets applicable standards for scientific rigor, transparency, reproducibility, and responsible stewardship of data.

Recently, TriNetX™, a CTSC-supported research network and data platform, has come under scrutiny (Joelving, 2026; Rhodes, 2026; Lin et al., 2026). This Standard Operating Procedure (SOP) outlines the rules for using TriNetX™ data correctly so the CTSC can serve the public, make the most of its research, and meet NIH and HHS guidelines for data accuracy and sharing. This document ensures every TriNetX™-enabled finding disseminated under CTSC support is reproducible, trustworthy, and suitable to represent the CTSC. This SOP governs the use of TriNetX™-derived research data in research dissemination materials and applies throughout the lifecycle of a TriNetX™-enabled project, beginning at project initiation.

2. SOP Purpose:

1. Support appropriate project development, statistical and reproducibility planning so that TriNetX™-enabled studies are designed from the outset to meet standards for rigor, transparency, and responsible data stewardship.
2. Provide oversight through statisticians and data scientists before public or professional dissemination, and enable review and, when warranted, independent reproduction of primary findings.
3. If any project is CTSC supported through funding, consultations, or other assistance, establish clear citation expectations by requiring that no manuscript, abstract, poster, presentation, preprint, report, or other covered dissemination product may cite or acknowledge the NIH CTSA award UM1TR004528 until the required verification process has been successfully completed and data scientist/statistician confirmation has been issued.

3. Scope

This SOP applies to all TriNetX™ research activities that result in, or are reasonably expected to result in, manuscripts, abstracts, posters, oral presentations, slide presentations, preprints, reports, or other public or professional communications using TriNetX™-derived data, analyses, or findings (collectively, “research dissemination materials”)

4. Responsible Use of TriNetX™

The CTSC affirms that platforms such as TriNetX™ are valuable tools for clinical and translational research. Investigators using these resources responsibly are advancing an important public mission. Researchers are encouraged to:

1. design projects with reproducibility in mind from the outset;
2. seek statistical and methodological support early, especially when using complex cohort definitions or analytic methods;
3. document key decisions regarding cohort construction, variable derivation, exclusions, and analytic assumptions;
4. ensure that students and trainees using TriNetX™ are appropriately trained, supervised, and mentored;
5. use downloaded datasets and external analytic workflows when required to ensure reproducibility and independent verification;
6. engage statisticians and data scientists with experience in Big Data, before dissemination deadlines; and
7. view verification as a scientific quality support process that strengthens the resulting work.

5. Policy

5.1. TriNetX Training

Any investigator or student wishing to use TriNetX should receive proper training in order to use the platform effectively and judiciously. Training is available directly through the TriNetX Training Center on the platform through an institutional account. Contact the research office at your institution to determine your log in ability. If you are affiliated with CWRU or University Hospitals, training can be obtained through the CTSC [SPARC](#) platform>TriNetX request.

5.2. Data Preparation

With the assistance of an expert statistician/data scientist, investigators would submit a request for TriNetX to download a dataset that is:

- a. De-identified and compliant with all IRB, HIPAA, and TriNetX governance requirements.
- b. Sufficiently annotated (with codebooks, variable definitions, and analytic scripts) to allow independent reproduction of all tables, figures, and statistical results.
- c. The dataset must be downloaded (e.g., CSV, RData, SAS, or similar format) and must include all code/scripts used for data cleaning and analysis (e.g., R, Python, SAS, or SQL).

5.3 Data Submission and verification

Prior to manuscript submission or public presentation, the investigator must share their TriNetX online analytics session with a collaborating statistician/data scientist to allow a dataset to be downloaded and retained in the repository of the CTSC-affiliated health system that provided access to TriNetX.

The statistician/data scientist will:

- d. Review investigator materials (abstract, manuscript, etc.) for accuracy in the statistics methodology section and ensure methodology is in alignment with platform capabilities.
- e. Download and retain a copy of the online analytics session dataset
- f. The downloaded dataset and code will be reviewed for accuracy.
 - i. Independently reproduce all primary findings (main tables/figures) as reported in the manuscript.
 - ii. Document any discrepancies or issues and communicate them to the investigator for resolution.

Before submission or posting of research dissemination materials the investigator must provide the required dataset and documentation to the UHHS CRC statisticians for independent verification.

- a. The verification process must be confirmed as completed before manuscript submission to any journal or public forum.

5.3. Approval to Cite CTSA Grant

Upon successful sign off by an experienced statistician/data scientist, the research dissemination materials should cite the NIH CTSA grant number (UM1TR004528).

6. Compliance And Consequences

Non-compliance with this SOP will result in:

- a. Withholding of CTSC support and resources.
- b. Notification to institutional leadership and/or the NIH as required by 42 CFR Part 93 and NOT-OD-21-013.

References:

Joelving F. "Rise in papers using powerful medical research tool raises concern," Science. 2026 Jun 25;392(6805):1330-1331. doi: 10.1126/science.aej9810. Epub 2026 Jun 25. PMID: 42348699.

Rhodes S, Schumacher FR, Shoag JE. Guest post: The uncomfortable truth an explosion of papers reveals about authors' access to data. Retraction Watch. August 25, 2026. Available at: <https://retractionwatch.com/2026/08/25/guest-post-trinetx-data-accountability-statement/>

Lin Y-J, Tsai K-W, Lu K-C, et al. "On the reported methodology in published TriNetX-based studies: an analysis of impossible index event designs." European Journal of Epidemiology. Published 21 Feb 2026.

