REDCAP CLOUD

Simplifying Collaboration for Patients, Sites, and Sponsors

> "REDCap Cloud has helped us to provide effective solutions to novel challenges faced by our studies, enabling us to adjust to new parameters."

CATHIE SPINO
ScD, Director, SABER Research Professor

Overview

The University of Michigan's **Statistical Analysis of Biomedical and Educational Research Group (SABER)** unit of the Department of Biostatistics provides expertise in the design, conduct, and analysis of multi-center clinical trials and multi-disciplinary research. SABER applies its resources to deliver time-effective design and quality-based output to meet investigational needs, whether they be statistical, methodological, or operational.

SABER supports clinical research in a variety of different disease states for investigators inside and outside of the university, ranging from single-center clinical trials that span a few dozen patients to international studies targeting thousands of participants. That includes trials of new therapies, as well as observational natural history registries, and research consortia brought together to develop new studies, in areas including pulmonary, nephrology, diabetes, cardiology, and many others.

Among the projects supported by REDCap Cloud, DEPTH (Doxycycline for Emphysema in People Living with HIV) is a phase 2, multicenter, randomized, double-blinded, placebo-controlled clinical trial. Sponsored by the **National Heart, Lung, and Blood Institute** (NHLBI), the study aims to determine if doxycycline reduces progression of emphysema relative to placebo as measured by rate of decline (slope) of present predicted diffusing capacity for carbon monoxide corrected for hemoglobin, carboxyhemoglobin, and barometric pressure over the 72-week treatment period. SABER is the data coordinating center for this project and will provide project management, data management, clinical monitoring, software development and statistical analysis for the clinical trial.

PRODUCTS USED

REDCap Cloud EDC
Collect and manage all clinical research data within our next-generation data capture solution
Learn More

myREDCap Cloud
Enable patients to learn about and participate in clinical trials from any location at any time
Learn More

REDCap Cloud eConsent
Enable patients to consent onsite or remotely via the myREDCap Cloud portal
Learn More

REDCap Cloud Advanced Reporting
Provide study teams with real-time monitoring of individual and aggregate performance metrics
Learn More

SABER Group and REDCap Cloud

SABER Group selected the REDCap Cloud platform as its electronic data capture (EDC) system for all of the new studies it's launching, after searching for a **21 CFR Part 11-compliant EDC system** to replace one being sunset by the university. REDCap Cloud's robust functionality, ease of use by non-programmer staff, and patient portal enabling direct participant feedback were all factors in the selection.

Business Impact

Easier deployment and maintenance of clinical studies

Offers a robust base for traditional studies, while facilitating decentralized and hybrid clinical trial models

Patient portal option enables trials that weren't feasible under the prior EDC system

Dashboard for clinical trial sponsors enables real-time data monitoring without the need for additional reports

Robust and secure data management solutions, with the flexibility to be tailored to individual study needs

> SABER takes great pride in being a flexible and adaptable research partner. No two studies have exactly the same needs, and the ability for any system, in particular a data capture system, to allow for multiple approaches is essential to a project's success."

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