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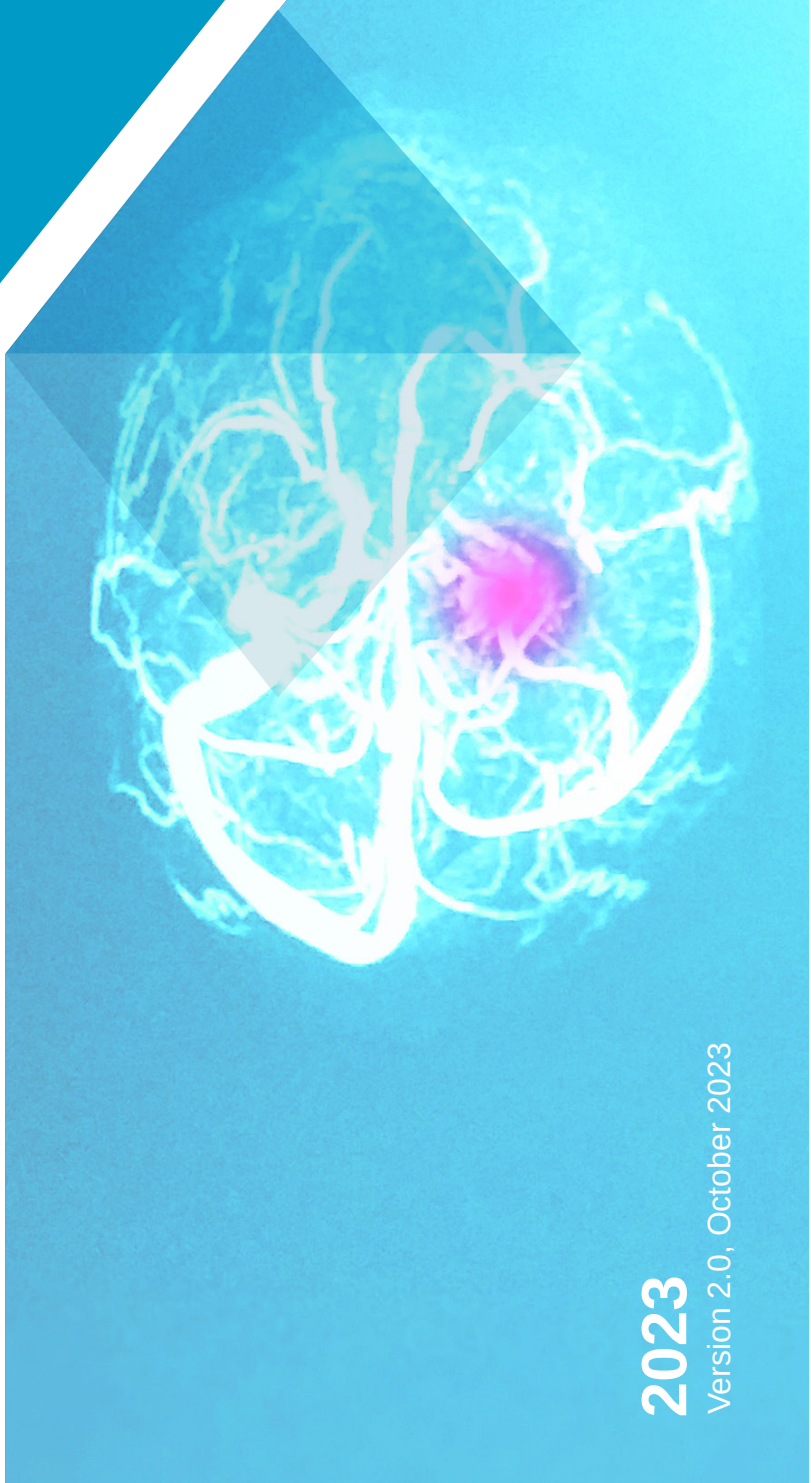
Case Study



OATS-I on ACQUIS Health

The OATS-I Study:

AcquisCT provides a secure, affordable collaboration platform for the OATS-I Global Ischaemic Stroke Observational Trial.

Optimal Antiplatelet Therapy in TIA and Ischaemic Stroke - International (OATS-I) Observational Study

2023
Version 2.0, October 2023

Case Study

What made the OATS-I Observational Trial Secure, Affordable and Efficient?

While many clinical trial cloud solutions have come to market to support global and decentralized clinical trials, they have been cost-prohibitive and focused on big pharma drug delivery trials.

Many grant-funded observational and clinical research studies continue to face the challenge of managing their trials using generic software applications like spreadsheets and email. Alternatively, the only other option is a mediocre yet expensive clinical trial software, which requires time-consuming setup, implementation, and management. The OATS-I team came to Acquis BI to address these technical barriers and cost factors to successfully set up and manage the OATS-I study. They needed an affordable cloud-based Electronic Data Capture (EDC) that provided integrated eCRF and EDC with secure global access, efficient, high-quality data collection, and advanced data security. Setup time and onboarding are significant cost-efficiency factors, so they also needed an intuitive, user-friendly design that could fast-track their study kickoff.

According to the World Health Organization, stroke is the second leading cause of death globally (pre-COVID-19)1 (Singh 2019). The Vascular Neurology Research Foundation (VNRF) was awarded a grant to fund a global, multi-center study across eight countries over three years to research the response of Antiplatelet Therapy in TIA Ischaemic Stroke. This study, "Optimal Antiplatelet Therapy in TIA and Ischaemic Stroke-International" (OATS-I), would identify patients who do and do not respond to antiplatelet therapies by collecting over 700 data points to ascertain which individuals are at most risk of recurrent vascular events.

The **AcquisHEALTH** team provided a fast-track setup, enabling researchers to **focus** on the study, **collaborate** with study teams, and focus on **patient engagement**.

Like many academics running multi-site or global trials, the OATS-I team found that solutions to manage data protection and access rights across study teams must be revised or exorbitantly expensive. Many low-cost solutions are not designed to manage private medical information, and many still lack the data security and privacy specifications needed to comply with study ethics, security compliance, and accountability standards.

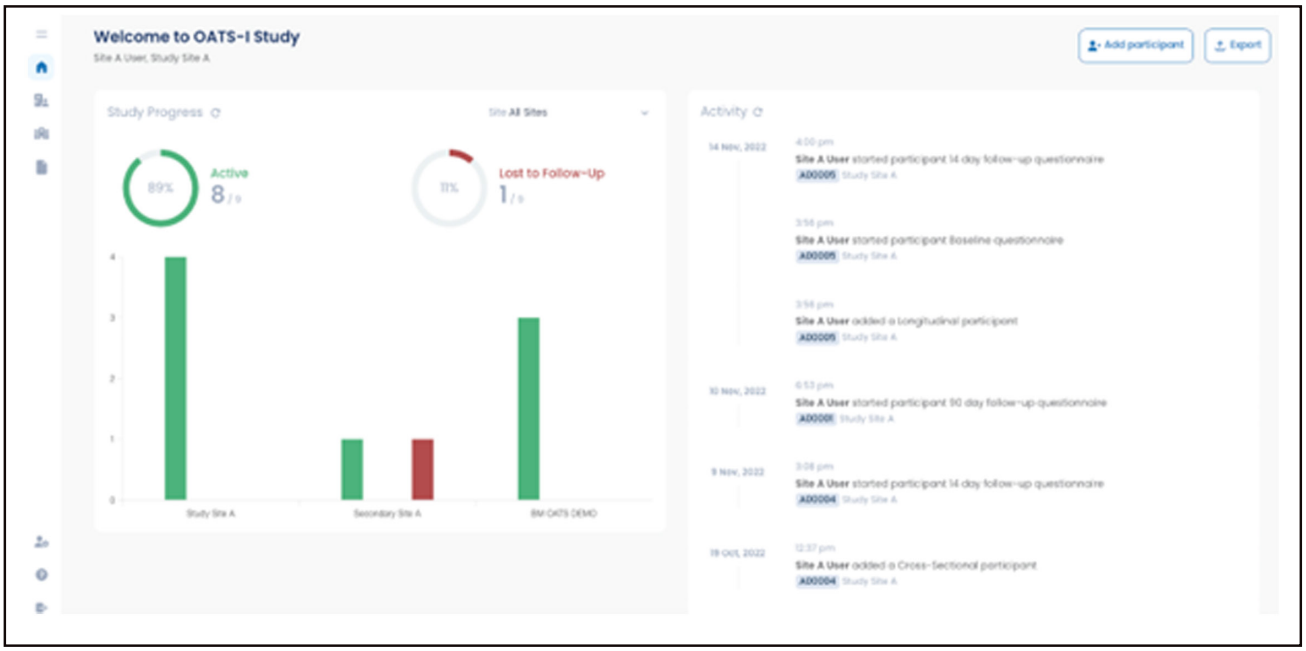
Acquis BI developed AcquisHEALTH, our integration healthcare platform, based on GDPR data protection requirements. Its entire framework, including AcquisCT, our clinical trial solution, was developed with advanced data security, secure role-based access, and user-focused design.

Fast Track Kickoff

Study designers need to become digital data experts with the advent of cloud-based eCRF and EDC solutions. They must consider not only which data to collect but also how to structure and format patient-reported outcomes to accurately output quality data for further analysis, often in other systems. This landmark study uses both novel and established laboratory tests while also performing individualized genetic testing in all participants following TIA/ischaemic stroke. The study captures hundreds of clinical data types (data points), for which the format and output are critical in its design. OATS-I needed to collaborate in electronically managing, capturing, and storing both novel and standard clinical data types (data points) while ensuring the structure and formats chosen would provide consistent data quality across all eight international study sites. The AcquisHEALTH team worked with study designers with IT and data management considerations. This helped users to decide where clinical data standards should be used and where novel data types could be best designed for further analysis and possible future integration.

The AcquisHEALTH team worked with Professor Dominick McCabe, the Principal Investigator and chairman of VNRF (Vascular Neurology Research Foundation) at Tallaght University Hospital (THU), and his team to develop an integrated cloud-based solution for OATS-I based on the AcquisHEALTH platform called AcquisCT. Within two months, we designed and developed this global collaboration solution to securely collect eCRF questionnaires and other collaboration and study management tools. Dashboards are a quick and effective management tool that gives the study managers a birds-eye view of the study status. Using a role-based identity management system, the PI can invite team members and assign restricted roles to individuals or groups to ensure both team and participant management and compliance.

The coordinating study team can **view data from all centers worldwide in real-time** to confirm data quality, use the analysis engine, and provide clinical research and technical support where necessary.



OATS-I and Beyond: Main Objectives

OATS -I is headed by Professor Dominick McCabe, Principal Investigator and chairman of the VNRF at Tallaght University Hospital (THU).

Prof. McCabe and a team of international collaborators worked with AcquisHEALTH to develop a cloud-based solution to capture and analyze data from the landmark, multi-center Optimal Antiplatelet Therapy in TIA and Ischaemic Stroke-International (OATS-I) Study. In addition to being the second leading cause of death, stroke is the most common cause of acquired physical disability in adults worldwide (GBD 2016 Stroke Collaborators, 2019) (Gorelick, 2019). All transient ischaemic attacks (TIAs) by definition and the majority (85%) of strokes (Kapila et al., 2019) are 'ischaemic' in origin and caused by reduced blood supply to the brain, eye, or spinal cord.

The AcquisHEALTH clinical trials Electronic Data Capture module for the OATS-I study can capture and store 700+ data points over multiple visits for each study participant.

700	Data Points
8	Global Sites
2000	Projected Participants

According to Prof. McCabe, platelets play a pivotal role in the formation of blood clots and are excessively activated or 'hyper-reactive' after a TIA or ischaemic stroke. Antiplatelet agents such as Aspirin, Clopidogrel, Dipyridamole, Ticagrelor, or specific combinations of these medications can reduce the risk of recurrent vascular events in patients who have had a TIA or ischaemic stroke. However, several studies by Prof McCabe's research group and others worldwide have shown that many people do not respond as expected to commonly prescribed doses of these antiplatelet medications in the laboratory and have 'high on-treatment platelet reactivity' (HTPR). The OATS-I researchers have preliminary data to suggest that HTPR may be associated with a higher risk of recurrent vascular events in the clinical setting following TIA or ischaemic stroke (Lim ST et al., 2020), so for this phase of the study, the goal was to prove what the preliminary data showed in a definitive multi-center study.

OATS will perform genetic testing in all participants following TIA/ischaemic stroke while assessing HTPR status using both novel and established laboratory tests. Using this data, predictive models will be developed to combine clinical, HTPR, and pharmacogenetics data. "We aim to identify patients with TIA/ischaemic stroke who are at higher risk of experiencing recurrent vascular events (TIA, stroke, heart attacks) on their prescribed antiplatelet regimen and who should benefit from 'personalized antiplatelet therapy' to optimize cost-effective secondary prevention. This is a critical step towards the conduct of a definitive trial of HTPR-tailored antiplatelet therapy in this patient population with ischaemic cerebrovascular disease (CVD)", said Prof. McCabe.

AcquisCT: Smart, Connected Clinical Trial Framework

- **Study set-up Wizard**
- **Unlimited Customizable Questionnaires**
- **Cloud EDC**
- **Advanced Cloud Security**
- **Multi-level Data Encryption**
- **ePRO patient collaboration**
- **Export functions**
- **Global and Decentralized Trial Management**
- **Role-based team and participant management tools**
- **Trial Monitoring Dashboards**

The Project

Onboarding a global team has its challenges for study designers and researchers. Ethics, compliance, and consent benefit cost and study integrity if integrated into the solution. OATS-I needed to have the ability to confirm consent and develop and monitor questionnaires while collecting over 700 clinical and non-clinical data points for further analysis.

Other solutions available to the team involved hidden costs and time-consuming technical setup that would have drained funding while not providing the levels of security supplied by AcquisCT, the AcquisHEALTH platform for clinical trials. Our user-friendly study setup features an interface design that gives PIs a bird's eye view of all studies, study teams, and study sites while maintaining local site access controls and user permissions, improving study integrity.

The Context and Challenge

The OATS-I researchers had commenced study data capture data in documents and spreadsheets stored locally on individual machines in their hospital, creating a myriad of access and security issues. In launching OATS-I, the team needed to enable eight international partners to collect data quickly and securely in a controlled manner, ensuring all data was consistent and verifiable across all study sites. They needed to ensure that all data was input and maintained in the same format and use consistent interoperable standards to enable study-wide analysis. They also needed to ensure that all data was secure regarding who could access which study site's data and data encryption to protect data privacy and security.

Future-proofing Clinical Trials

Finally, they wanted to future-proof their study and explore the possible need to share patient data with patients via their hospital EHR or directly. Secure data portability and interoperability using secure identity management and FHIR standards would be vital to achieving this goal. As Patient participants' rights to access and transparency have expanded with regulations like GDPR, it is more important than ever for research study directors to provide patients with access or copies of personal and sensitive clinical data gathered about them.

Patient rights hinge on **data security** and **data access**.

AcquisCT was founded by design on **GDPR**, **HIPPA**, and **FHIR**, providing the tools, support, and reassurance that **healthcare professionals** need.

Successful Integration, Collaboration and Communication

The innovative AcquisHEALTH cloud platform was designed from the ground up around both HL7/ FHIR interoperability health standards and GDPR data protection and security from its inception. AcquisCT inherits all the AcquisHEALTH platform benefits and standards. FHIR ensures that data formats and standards are consistent across multiple platforms, ensuring future integration and portability without compromising the data during transfer or migration to any other FHIR-compliant system.

The primary study site managers have complete control over all other sites, each of which can view, access, and manage only their own sites' data assets. The system allows the primary site to assign roles and access permissions within other sites. Immutable records can be configured to ensure that no data can be modified within the study once published. The AcquisHEALTH platform is a secure, shared care record (SCR) with access to the e-CRF limited to authorized, trained clinical researchers involved in the OATS-I study.

Integrated SMOMED CT and ICD-10 clinical terminology services further minimize data input errors, improve data entry speed and accuracy, and facilitate analysis and systems interoperability. Across all sites, clinical terminology will be consistent, improving data analysis and study speed and success.

With cyber security and privacy in mind, AcquisHEALTH uses multi-level encryption and novel pathways to ensure data security and identity management. If needed in the future, study managers will be able to efficiently and accurately comply with GDPR requirements, allow patients to receive copies of their personal data, anonymize their data to ensure study results are tamper-proof and never compromised, and ensure data privacy is assured using multiple levels of data encryption. AcquisCTMS give research directors the confidence to plan and execute their trial, focusing on what they do best: recruiting patients, designing trials and laboratory assessment, implementing the study protocols, and monitoring and managing patients and their data capture. AcquisCTS provides safe, reliable setup, storage, and security so clinical trials can save time and funds without compromising efficiency and security.

Setup Is Time and Money — and Cost Matters.

With the addition of study setup wizards and a little help from the Acquis BI onboarding team, researchers can get up and running with our onboarding advice and support with no hidden fees. AcquisCT is a low flat rate per patient record, so study team size does not matter. Our job is to secure and protect patients' data. The Acquis BI team worked closely with the OATS-I team to ensure their study design setup was correct and efficient, giving them the space to focus on the patients and the data.

Commenting on this innovation award, Prof. McCabe said: "One of the challenges in running large, investigator-led, multi-center clinical research studies such as OATS-I is access to a reliable and affordable software platform for standardized capture, monitoring, and analysis of study data at each site. In this clinically important multi-center study which we are coordinating from TCD/TUH, development of a 'bespoke' Electronic Case Report Form (E-CRF) in close collaboration with partners at Acquis BI is facilitating achievement of these goals via centralized entry of clinical translational research data from national and international centres on the AcquisHEALTH user-friendly software platform".

> *"Clinical Researchers are not IT people. Their cost and time should be spent with their patients and their data.*
>
> *AcquisCT is the most affordable and user-friendly solution available.*
>
> *The Acquis BI team knows how to fast-track clinical trial setup, so researchers can focus on what they do best while we focus on what we do best."*

Successful Conclusion with the Future Health of Patients in Mind

The Acquis/OATS-I Clinical Research Software Platform Project was launched successfully in 2021. All OATS-I research study data are entered into AcquisCT, allowing the research team to focus on recruitment and clinical and laboratory assessment. It also paved the way for the study participants' follow-up and to plan centralized data monitoring, analysis, and interpretation at pre-specified time points. This solution will help enhance our knowledge base and hopefully foster personalized care of patients with TIA and ischaemic stroke in the foreseeable future to improve individual patient outcomes by reducing the risk of recurrent vascular events and vascular dementia.

The Future of AcquisHEALTH OATS-I

The OATS-I team, supported by the successful partnership with Acquis BI, plans to use the data from this study to fine-tune the design of a definitive, multi-center interventional treatment trial in patients with HTPR. Planned future projects with OATS-I should enable the development of analysis engines to assist clinical in identifying patients who have HTPR and who could benefit from an alternative antiplatelet treatment in individual TIA/ischaemic stroke. This clinical decision support engine would integrate into a compatible electronic health platform accessible to designated healthcare providers and end-users.

AcquisCT: The Globally Secure and Affordable Option

AcquisCT is breaking the mold and creating a dynamic and affordable pricing structure that will give everyone from CROs to student researchers a reasonable patient record-based pricing model. AcquisCT allows users to create multiple studies and invite multiple global users to a study without hidden setup or user-based costs. This cost model will enable more global studies at a more affordable rate than similar services while ensuring data security and patient privacy are at the forefront.

With user-friendly setup wizards, users can set up a trial in days and develop unlimited, customizable questionnaires to capture data from multiple sites while adding unlimited studies and study team members at no extra cost. This clinical trial cloud-based solution enables primary sites to manage their trials remotely while collaborating and communicating with patients and research teams. With all the inherited capabilities of the AcquisHEALTH Platform, AcquisCT is fast, affordable, and secure.

About Us

Acquis BI is a specialist technology-focused company based in Silicon Valley, California, US, and Dublin, Ireland. The company has an exemplary history of developing innovative data management and integration technologies for large, complex cloud-based systems, specifically government, utility, and healthcare markets.

For almost two decades, the company's innovative platforms have been repeatedly used to support the national US decennial census programs. Acquis BI opened its healthcare technology hub in Ireland in 2014 and developed the AcquisHEALTH platform to provide safe and secure health data access across a patient's healthcare teams to a single, sharable, immutable patient record.

With security, interoperability, scalability, and performance at the forefront, Acquis BI's reputation for delivering solutions for the future is apparent from its past delivery of cutting-edge performant technology on time and within budget.

Contact

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Footnotes

[1.] World Health Organization, By Dr Poonam Khetrapal Singh, WHO Regional Director for South-East Asia 2019: World Stroke Day

For more information on, or to donate to the Vascular Research Foundation, please visit www.vnrf.ie/