

Acronis



CASE STUDY

Proud Innovations Leverages
Acronis Cyber Notary
to Provide GxP Compliance
to Pharmaceutical Industry

Bringing Data
Integrity and
Authenticity to
Quality Assurance
Departments

Background

Proud Innovations is a Dutch IT consulting firm with a unique niche. It consults to pharmaceutical companies about data integrity and assurance, ultimately advising on GxP compliance (e.g. Good Manufacturing Practice, Good Laboratory Practice, Good Documentation Practice, and Good Clinical Practice) and IT at the same time. Proud Innovations consults primarily with Quality Assurance (QA) departments in multi-national pharmaceutical firms, helping these departments – who control GxP environments – ensure data assurance for everything coming out of their labs. The firm is three years old, has seven full time staff, and is run by president and founder, Steven Trommel.

KEY CHALLENGES

- Modernize the backup and recovery solutions in GxP-compliant environments
- Ensure data integrity and authenticity
- Reduce client burden when responding to 60+ annual audits

KEY REQUIREMENTS

- Provide a backup and digital data integrity solution that is GxP compliant

KEY BENEFITS

- Migrate away from paper archives
- Improve access and searchability of backups
- Drastically reduce the time spent responding to audits



The Challenge and Opportunity

A few years ago, Trommel started to notice that Pharma QA departments were finally starting to move GxP environments into the digital age. Traditional legacy environments had been historically “paper and pencil” operations when it came to files, let alone backups, and those that were working with digital files used traditional backup approaches to CD/DVD and hard drives. GxP rules required paper storage to be housed for 20 years, which led to significant warehousing costs and logistic challenges, not to mention limited access and file searchability. It also left these original paper files vulnerable to any sort of natural disaster. There was a significant opportunity to modernize these environments with digital data integrity solutions.

However, GxP is focused on compliance and auditing. Everything needs to be traceable. If there is a problem, it must be traced, its root cause identified, and new procedures created to solve the issue next time. Proud Innovations’ clients can have upwards of 60 audits per

year and, not surprisingly, data integrity is a key topic.

Additionally, for the QA departments of pharmaceutical firms that deal with tightly controlled clinical trial data, data tampering is a top concern. Scientists are under pressure to develop critical new drugs and patents. Falsifying research outcomes, however, could lead to dangerous or ineffective drugs hitting the market and billions of dollars in lost revenue and potential law suits. According to Trommel, “Pharmaceutical companies have been struggling for years as to how to determine whether data has been improperly modified.”

So, while a big market opportunity existed any technical solution needed to squarely address the compliance, auditing, and data integrity and authenticity issues required by GxP environments. Enter Acronis Cyber Notary, digital notarization technology incorporated into Acronis Cyber Backup.



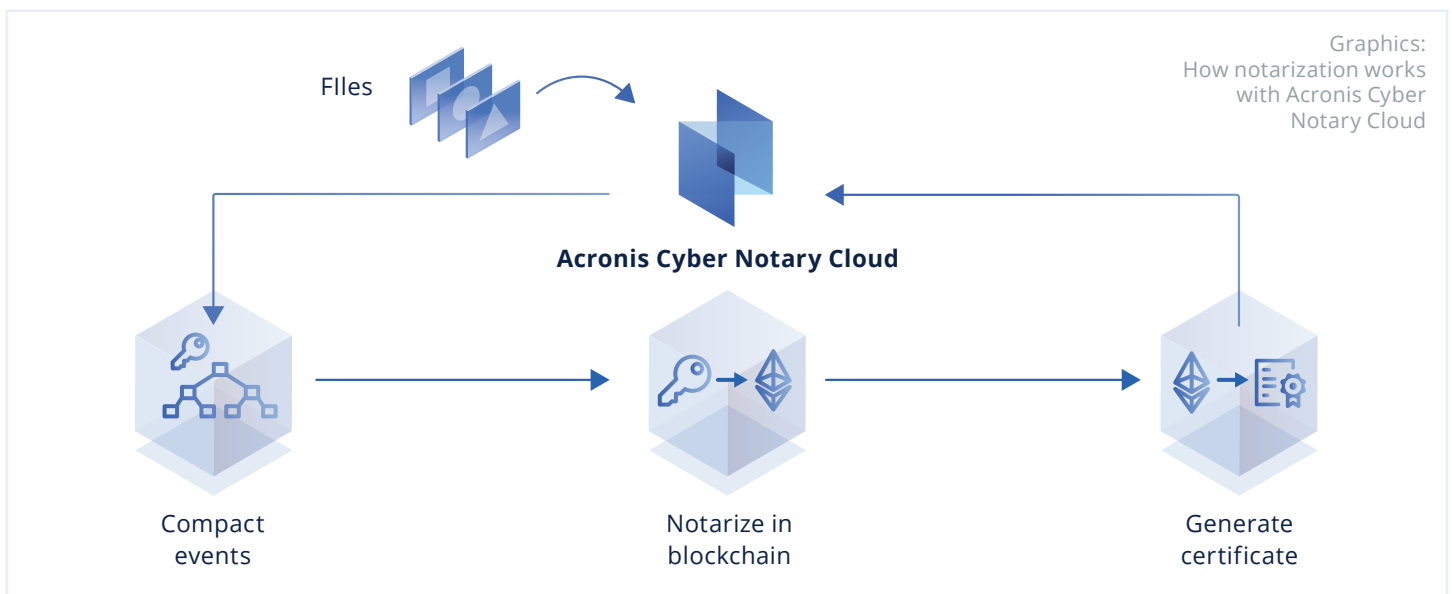
The Solution – Acronis Cyber Backup with Acronis Cyber Notary

Acronis Cyber Notary is a new technology that allows file notarization, proving data authenticity via blockchain. Incorporated into Acronis Cyber Backup, it creates a digital cryptographic hash, or “fingerprint”, that is unique for each file. This hash is an algorithm that produces the same output when given the exact same input file, enabling the verification of the file’s authenticity. This is because any change in the input file, however slight, results in a dramatically different fingerprint. Furthermore, the hash algorithm is designed to work only in one direction, it is impossible to determine the original file inputs from the output alone – making the process tamper-proof.

Acronis Cyber Notary then takes the hash and stores it in a public blockchain ledger and then outputs a digital

certificate, which enables independent validation of its authenticity and proof it existed at a specified date and time. Upon recovering a specific file from an archive, a new certificate can be created and then compared to its original certificate that was created when it was put into storage, thereby ensuring an identical bit-for-bit match. If the hashes don’t match, the document has been tampered with. Every record in the blockchain ledger is time-stamped, immutable, and independently verifiable.

Acronis Cyber Notary ensures the authenticity of digital files. For the purposes of regulatory compliance and auditing, it offers mathematical proof that a file previously archived or backed up has remained unchanged and is authentic.



The Benefits

Acronis Cyber Notary addresses all of the data integrity and authenticity requirements presented by the European Commission in its governance of GxP environments.

This has enabled Proud Innovations to help QA departments within the pharmaceutical industry as they modernize their backup strategies to be GxP-compliant. According to Trommel, "When our clients create new files, the policy we implement is to immediately back up and notarize the file so we know we have the original and can therefore determine if it was ever modified or tampered with."

The benefits of Acronis Cyber Notary to Proud Innovations are most evident by the company's growth from being a "one man shop" found by Trommel to a

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Steven Trommel,
President and Owner

staff of seven with continued growth on the horizon. Trommel makes this point quite clearly when he says, "Data authenticity is an issue that is incredibly important to GxP environments. Showing that we have a blockchain-based data authenticity solution is THE most important part of my sales pitch because the amount of time it reduces in responding to audits is just incredible."

He also notes that blockchain is an increasingly interesting technology for the pharmaceutical industry, which makes Acronis Cyber Notary particularly attractive. According to Trommel, "Last year the FDA was talking about blockchain as a standard by 2022. We are ahead of the curve. My customers and prospects don't have to worry about potentially new compliance issues that will be coming over the next few years."

ABOUT ACRONIS

Acronis leads the world in [cyber protection](#) – solving safety, accessibility, privacy, authenticity, and security (SAPAS) challenges with innovative [backup](#), [security](#), [disaster recovery](#), and [enterprise file sync and share solutions](#). Enhanced by [AI technologies](#) and [blockchain-based authentication](#), Acronis protects all data in any environment: physical, virtual, cloud, mobile workloads, and applications.

With dual headquarters in Switzerland and Singapore, Acronis is a global organization that is trusted by 100% of Fortune 1000 companies. Learn more at [acronis.com](https://www.acronis.com)

