

Digitisation of clinical records helps Almirall break into new markets, allowing more patients to benefit

“This major digitisation project, the first of its kind, has allowed us to break into new markets. We have accelerated global product rollouts, while at the same time complying with local country legal frameworks.”

Minerva Casas Ventura, research and development archivist and trial master file specialist, Almirall



Opening
new markets



More
patients have access to treatment benefits



Faster
market entry and product rollout



Efficient
records management in line with industry standards



Challenge

To commercialise medicines in new markets, Almirall needed to provide simple, speedy and secure access to all drug documentation and clinical results, to secure approval from local governing authorities.

Solution

Iron Mountain® helped Almirall develop a holistic digital strategy based on a digitisation solution for centralising and digitising records, with secure full chain of custody throughout. All the files are available 24/7 through an Iron Mountain Connect™ portal that can be accessed from anywhere, with role-based permissions.

Results

More patients can benefit from this medical treatment, improving the quality of lives. At the same time, Almirall has gained new routes to market and accelerated global product launches.



Aligning digital strategy to improve business efficiency and growth

“Iron Mountain has held our hand throughout our digitisation process and we are now really seeing tangible benefits in our results.”

Minerva Casas Ventura, research and development archivist and trial master file specialist, Almirall

Achieving two goals with one investment

Innovation partners in digital transformation

Present in 21 countries with 2,000 employees, Almirall is a global pharmaceutical company dedicated to dermatology and improving patients' lives. Digitisation and flexible workplace transformation are integral to this mission as Almirall looks to drive efficiency and access new international markets.

“We outsourced our archiving to Iron Mountain more than a decade ago and have been innovation partners ever since,” says Minerva Casas Ventura. “The joint focus has been on advancing our international expansion with a unified digital strategy.”

Part of Almirall's digital strategy involved minimising the use of paper documents through a project called Digital Workplace Transformation. Within this project, Almirall looked to Iron Mountain as a trusted expert partner to help address any ongoing requirements.

Fast entry to new markets

Alongside the Digital Workplace Transformation project there was a need to take an EU-approved product into the Chinese market. This led to the digitisation of all the documentation and clinical results associated with the medicine. The project involved a large number of documents that needed to be digitised in a short space of time, and which needed to be accessed easily and securely.

“We needed to urgently provide a distributor with quick and easy access to all the documentation and clinical results for a drug,” says Casas. “The medicine had been approved in the EU for some time, but we had to satisfy regulatory requirements from authorities in China and other countries.”



Iron Mountain gathered, sorted, and digitised the content of more than 4,000 boxes





Full end-to-end managed solution

“Creating digital content that we can share in real time with our supply chain and governing bodies is the future. And we are there now.”

Minerva Casas Ventura, research and development archivist and trial master file specialist, Almirall

Seamless digitisation, delivered on time with no business disruption

Full records access

Iron Mountain specialists worked with Almirall onsite and remotely, lifting the lids on 4,000 boxes, reviewing, cataloguing, and digitising their contents.

“Iron Mountain ensured we retained full access and traceability for every record throughout the project and even built that requirement into our SLA,” notes Casas. “So, if we needed to get to files at any time, we could do so via a cloud-based repository without risk of information security breaches.”

Pharma industry-standard taxonomy

That all important preparatory work included correctly classifying all documentation to comply with standardised taxonomy and metadata as endorsed by the Drug Information Association (DIA) and set out in the Trial Master File (TMF) Reference Model based on European Medicines Agency requirements.

“As well as enabling quicker searches, the TMF model means we only need to hold the minimum documentation to demonstrate regulatory compliance and good clinical practice,” says Casas.

Once digitised, Iron Mountain uploaded the PDF files to a secure, confidential private cloud platform where the Almirall supply chain partner could access them easily.



1.7 million pages of text digitised and stored in the cloud

Extending the frontiers of pharma treatments, with more patients having access to the benefits of treatment

“We are particularly proud of this project because it has allowed more patients to get access to the benefits of treatment with this drug, improving their quality of life.”

Minerva Casas Ventura, research and development archivist and trial master file specialist, Almirall

Spreading healthcare benefits

Crucially, the digitisation project's success has meant more patients could be treated for breathing problems and benefit from medication that they would otherwise not have had access to.

“It simply would not have been possible to deliver the 1.7 million pages of paper, 4,000 records, that the health authorities needed in the short time we had,” says Casas. “Creating digital content that we can share in real time with our supply chain and governing bodies is the future. And we are there now.”

Greater market access and accelerated product rollouts

Going forward, Almirall is better placed to meet pharmaceutical industry regulations. It can ensure all relevant documents are stored sensitively in a secure location, with restricted access. Documentation relating to the clinical trials of every drug it markets must be stored for 15 years or the product's entire life, whichever comes first, while retention time for electronic files is a minimum of 25 years after a drug ceases to be sold.

By moving to digital records Almirall has achieved first mover advantage. “This major digitisation project, the first of its kind, has allowed us to break into new markets. We have accelerated global product rollouts, while at the same time complying with local country legal frameworks,” concludes Casas.



Breaking into new markets



First mover advantage due to digitisation



Improved patient access to drugs and their benefits



Efficient document management in compliance with industry standards

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About Iron Mountain

Iron Mountain Incorporated (NYSE:IRM), founded in 1951, is the global leader for storage and information management services. Trusted by more than 220,000 organisations around the world, and with a real estate network of more than 85 million square feet across more than 1,400 facilities in over 50 countries, Iron Mountain stores and protects billions of information assets, including critical business information, highly sensitive data, and cultural and historical artifacts. Providing solutions that include secure storage, information management, digital transformation, secure destruction, as well as data centres, art storage and logistics, and cloud services, Iron Mountain helps organisations to lower cost and risk, comply with regulations, recover from disaster, and enable a more digital way of working. Visit www.ironmountain.com/en-gb for more information.

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