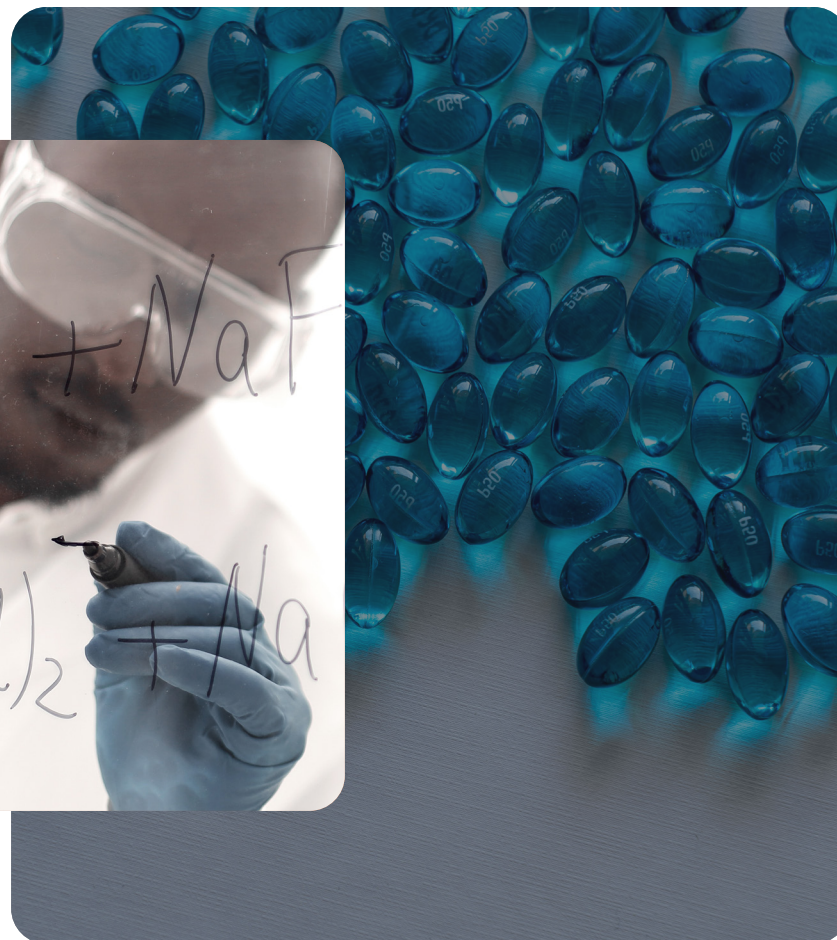
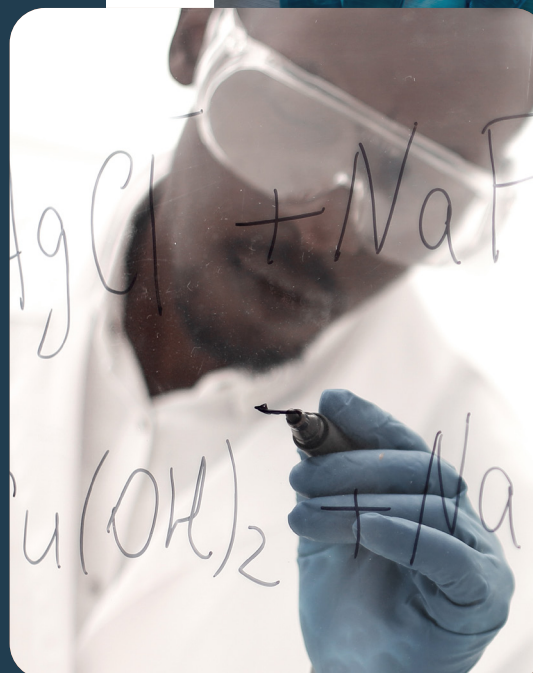




CUSTOMER SPOTLIGHT

Journey to an R-based FDA submission



SUMMARY:

Novo Nordisk is a leading global healthcare company, founded in 1923 and headquartered in Denmark. The company is driven by a singular purpose: to defeat serious chronic diseases, including diabetes, obesity, and rare blood and endocrine disorders.

ABOUT:

Founded in 1923, Novo Nordisk is a Denmark-based healthcare leader dedicated to defeating chronic conditions such as diabetes, obesity, and rare endocrine disorders.

INDUSTRY:

Life Science & Healthcare

SIZE:

64,000 employees
worldwide

TECHNOLOGY USED:

Posit Connect, Posit Workbench,
Posit Package Manager



The Challenge:

Modernizing Clinical Submissions

For decades, the pharmaceutical industry relied on proprietary, legacy systems for FDA submissions. Novo Nordisk aimed to break this cycle by proving that open-source tools could meet the rigorous regulatory standards required for clinical trial reporting.

- **OVERCOMING INDUSTRY INERTIA:**
The team faced the monumental task of shifting a global organization away from established legacy workflows toward a code-first, open-source environment that regulators would trust.
- **ENSURING REGULATORY COMPLIANCE:**
The primary hurdle was ensuring that an R-based submission could provide the same level of reproducibility, security, and validation as traditional proprietary software.



The Solution:

An R-Based Submission Pipeline

By leveraging Posit Team, Novo Nordisk built a robust statistical computing environment that supports both R and Python, allowing for greater innovation in clinical data-science.

- **ACHIEVING THE FIRST R-ONLY FDA PACKAGE:**
The team successfully delivered a clinical trial submission package to the FDA where the data outputs were written entirely in R, proving the viability of open source for high-stakes regulatory work.
- **STANDARDIZING THE COMPUTING ENVIRONMENT:**
Using Posit Workbench and Posit Package Manager, the team established a centralized, validated platform that allows hundreds of programmers to collaborate securely while maintaining strict version control.

Learn more at posit.co > | [Read the full story](#) >