Zentrum für Klinische Studien der MHH

marvin

DIGIT-HF 10 Years Powered by Marvin

A long-running, multi-country clinical trial transformed by stable eCRF performance, streamlined endpoint workflows, and rapid adaptability even through COVID-19

Background

The DIGIT-HF Study (Digitoxin to Improve Outcomes in Patients with Advanced Chronic Heart Failure) was a large-scale, long-term, phase-4 clinical trial designed to evaluate the efficacy and safety of digitoxin in patients with chronic heart failure and reduced ejection fraction (HFrEF). The study aimed to determine whether low-dose digitoxin, added to modern standard therapies, could reduce all-cause mortality and hospitalizations for worsening heart failure.

Led by the Center for Clinical Studies (ZKS) at the Hannover Medical School (MHH), the project involved extensive trial management, monitoring, biometrics, pharmacovigilance, and data handling throughout a remarkable 10-year duration.

Originally planned for 36 months of recruitment and 49 months total, DIGIT-HF ultimately spanned over a decade, due to expanded enrollment, international collaboration, and challenges such as the COVID-19 pandemic. Marvin, introduced early in the process, became the backbone of data capture, adjudication workflows, and multilingual expansion

How Marvin Enabled a Decade of High-Quality Data for Europe's Landmark Heart Failure Study

From study launch to final database lock, Marvin enabled reliable data capture, complex endpoint adjudication, and international expansion for this study.

DIGIT-HF was an ambitious clinical trial with a large planned patient population of originally 2,190 participants and study sites spanning multiple countries, including Germany, Austria, and Serbia. It featured a complex endpoint structure involving both mortality and hospitalizations, and its design was rigorously double-blind, randomized, and placebo-controlled. The study also required remote workflows during the COVID-19 pandemic, as well as external randomization and highly structured adjudication processes. With the recruitment period ultimately extending to 104 months instead of the planned 36, robust systems were essential to maintain data quality and ensure continuity throughout the trial.

Requirements and Challenges

Marvin was implemented as the Central eCRF Platform.The study was launched in 2014 on MHH servers and later upgraded and migrated to our data centers. Regular updates ensured stability and new features throughout the trial.

Supporting Randomization
Although randomization was performed externally through the IWRS at MHH biometrics:

- IWRS imports were manually integrated into Marvin daily
- IMP package numbers were cross-checked between IWRS and eCRF
- Central monitoring ensured full consistency of treatment allocation data

Comprehensive Endpoint Adjudication
Marvin supported a robust adjudication process:

- Unique Event IDs were generated across all patients
- Events were tracked with linked discharge letters and certificates
- Committee members had individual assessment forms
- Automated logic flagged discrepancies for follow-up meetings

International Expansion
When Serbia joined the study:

- All eCRF question texts, help texts, codelists, and messages were translated
- Reports were provided in both German and English
- Training and data entry materials were localized

Adaptation during COVID-19
The pandemic required immediate protocol and system changes:

- Introduction of telephone visit forms
- New COVID-related data collection (PCR tests, vaccinations, infections)
- Recruitment continued uninterrupted

Supporting DIGIT-HF over ten years was both complex and deeply rewarding. A study of this scale requires more than just a reliable system, it requires a strong partnership."

Anita Popp, Project Data Manager Marvin Team Munich

DIGIT-HF in Numbers

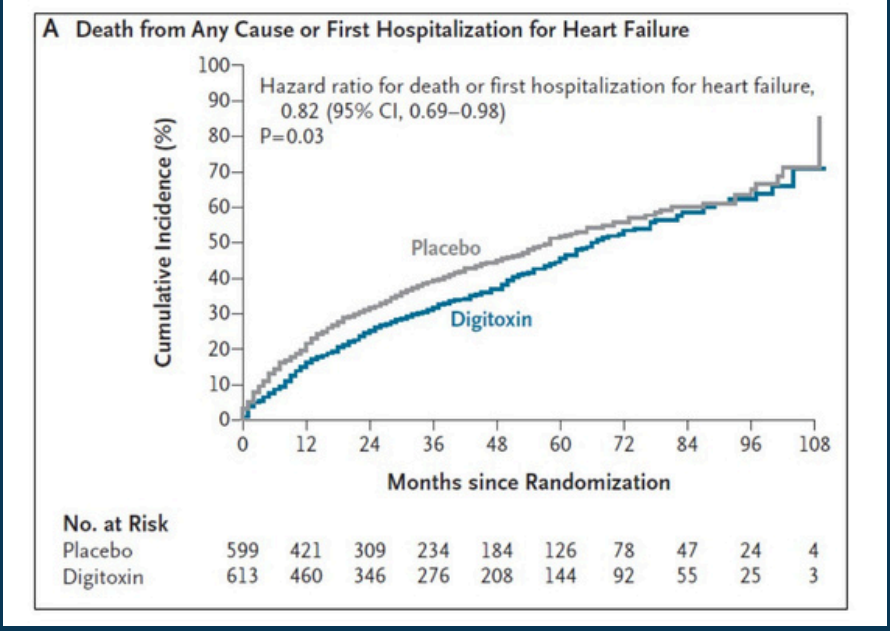
1240 patients **59 study centers**

10,244 study visits **29,856 queries**
3,837 adjudicated hospitalizations and deaths
61 eCRF change requests 542 programmed actions
19 metadata versions (MDVs)

These numbers emphasize the operational scale and the data management complexity over the decade.

Study Outcome

The results were significant:
Digitoxin, as adjunctive therapy, reduced mortality and hospitalizations in patients with advanced HFrEF. This outcome confirms digitoxin's modern relevance in heart failure therapy and underscores the importance of long-term, high-quality data capture and adjudication.



The DIGIT-HF study demonstrates how a modern EDC system like Marvin can support a complex, long-term, multi-country clinical trial. From initial launch through international expansion and COVID-19 adaptations, Marvin enabled high-quality data capture, endpoint adjudication, and regulatory readiness. The successful study outcomes further highlight the value of robust digital infrastructure in clinical research.

Benefits

With thousands of events to review, Marvin's automated workflows ensured:

- **Unique event tracking**
- **Centralized documentation**
- **Discrepancy detection**
- **Smooth committee processing**

This allowed adjudication to remain efficient and fully traceable.

Fast Adaptation During COVID-19:
Recruitment continued despite the pandemic thanks to Marvin's rapid configurability:

- **Telephone visit forms**
- **New COVID-related data modules**
- **Safe, remote-friendly workflows**

International Expansion Made Easy:
Adding Serbian sites required complete English translations of the eCRF, reports, and training materials. Marvin's multilingual capabilities enabled a fast, clean rollout across borders.

Trusted Data Quality to the Final Lock
With 19 metadata versions and continuous upgrades, Marvin delivered high-quality data all the way to database lock in February 2025, supporting successful publication-grade results.

> *Across more than ten years of data collection, thousands of events, and the extraordinary challenges of COVID-19, Marvin provided the stability and flexibility we needed.*

Barbara Neuhaus, Data Manager, Center for Clinical Studies at the Medizinische Hochschule Hannover, Germany

Contact us to learn more about this.

marvin

We are a leading provider of modern eClinical solutions designed specifically for experts in clinical research.

Our eClinical software, Marvin, is an effective **CDISC-certified** EDC system that includes numerous modules such as randomization, patient-reported outcomes (ePRO), IWRS, CDISC tabulation, reporting, medical coding, and more.

www.marvin.now | info@marvin.now | +49 89 4522775-000