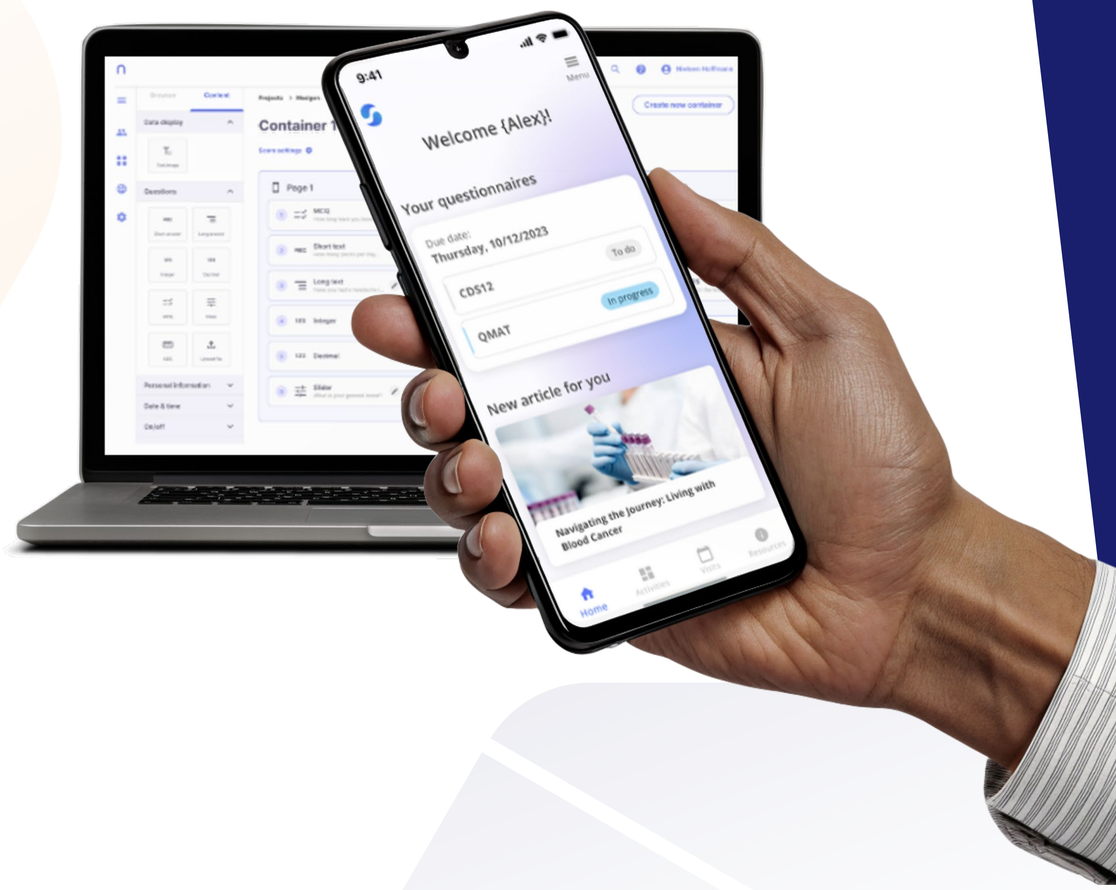
AliraHealth

SpherePX™

Patients at the Heart of Decision-Making

**Real-world evidence,
grounded in real patient lives.**



Today’s Studies Need to Be Faster, Smarter—and Human

Payers, regulators, and providers want compliance – and context.

What defines high-impact post-market studies

- Patient engagement that improves retention and data quality
- Evidence grounded in real-world clinical practice
- Insights that span care settings and diverse populations
- Flexibility to support PASS, LTFU, CER, registries, and hybrid designs

Bridging the Real-World Evidence Gap

Even with better platforms and regulatory openness, most post-market studies still fall short.

- Fragmented **data** across settings and systems
- Low **patient engagement** and **retention**
- Evidence that **lacks regulatory** and **payer-grade rigor**

The opportunity isn’t more data—it's the **right data:** connected, contextual, and patient-centered.

Introducing SpherePX

The patient-enabled platform for real-world evidence.

A flexible, modular solution, SpherePX streamlines the design, launch, and execution of post-market studies—delivering meaningful, real-time evidence grounded in patient experience.

Key Differentiators

- Designed around patient experience
- Regulatory-grade data
- Fully interoperable

Platform Benefits

- Reduced operational complexity
- Accelerated deployment
- Higher-quality insights

One Platform. Flexible Across Study Models.

Ready in weeks, not months.

SpherePX adapts to your evidence strategy—supporting standalone, hybrid, or longitudinal designs across all phases of the product lifecycle.

Study Types Supported

- Regulatory-grade registries
- Post-Authorization Safety Studies (PASS)
- Long-Term Follow-Up (LTFU)
- Comparative Effectiveness Research (CER)
- Hybrid studies for feasibility, value, and access
- Label expansion and reimbursement support

SpherePX Captures Evidence Where it Matters

In environments where patients live and care happens.

Approachable Design	Flexible and Multi-Setting	Scalable and Submission-Ready
Mobile-first, multilingual, literacy-aware	Modular design fits study needs and geographies	Designed for rapid localization and high-volume enrollment
Seamless and intuitive onboarding	Works across clinic, home, long-term care, and virtual care	Aligned with global regulatory submission standards
Patient- and provider-facing tools	Dynamic workflow and content builder (CMS)	Supports access, medical affairs, and regulatory use

Most platforms ask patients to adapt.
SpherePX adapts to them.

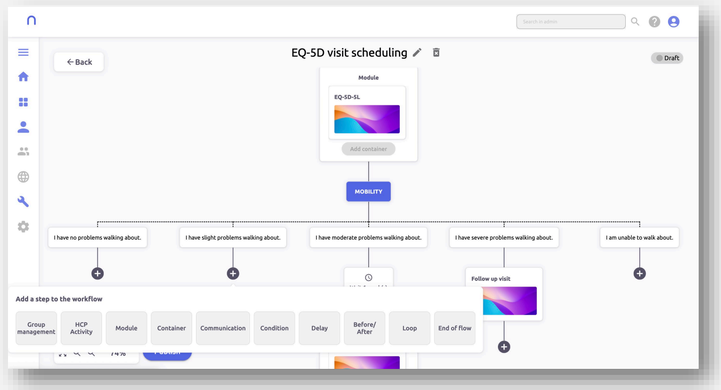
SpherePX Feature Highlights

Connecting sponsors, sites, and patients.

Management	Monitoring	Patient Experience
✓ Workflow builder	✓ Patient lists	✓ Custom onboarding flows
✓ Content builder	✓ Eligibility scoring	✓ Adaptive questionnaires
✓ Site and user management	✓ Pathway assignment	✓ eConsent/eSignature
✓ Localization tools	✓ Data entry and modification	✓ Behavior-based notifications
✓ eConsent and legal management	✓ Patient profile and visit management	✓ Integrated support and education hub
✓ Safety alerts for adverse events	✓ Personalized disease management plan	✓ Patient compensation
	✓ Monitoring tools	✓ EMR integration
		✓ Dynamic home page

Management Capabilities

Configure Studies Quickly, With Customization



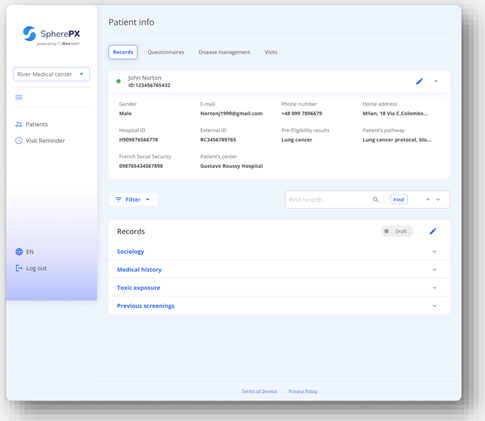
- **Reduce complexity**
  Use intuitive tools that let teams focus on what matters most
- **Accelerate set-up and deployment**
  Launch quickly with a flexible, no-code platform—even mid-study
- **Scale with confidence**
  Grow across studies, sites, and geographies without disruption

Core Features

- ✓ **Workflow Builder**
  Automate study steps and logic-based actions
- ✓ **Content Builder**
  Configure eCRFs, ePROs, educational modules, and more
- ✓ **Site and User Management**
  Assign roles, set permissions, and manage configurations
- ✓ **eConsent and Legal Management**
  Customize study-specific consent workflows
- ✓ **Localization**
  Deliver translated content across all modules
- ✓ **Safety Alerts for Adverse Events**
  Monitor safety through built-in pharmacovigilance tools

Monitoring Capabilities

Real-Time Oversight to Keep Studies on Track



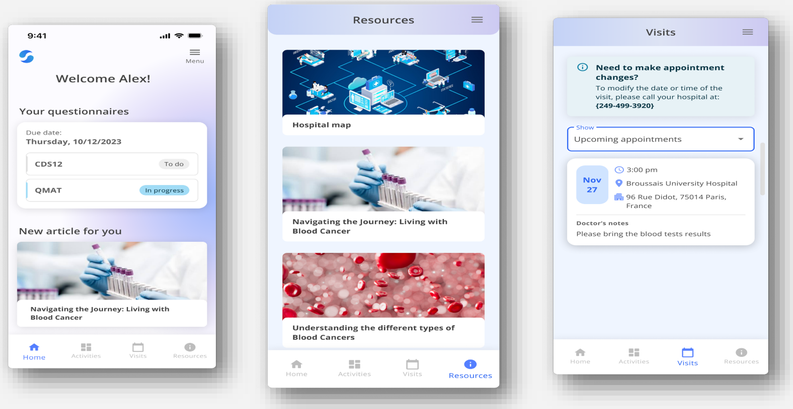
- **Reduce administrative burden**
  Automate documentation and workflows so teams can focus on care
- **Streamline patient management**
  Automate documentation and workflows so teams can focus on care
- **Access real-time data**
  Monitor study performance and patient input as it’s captured

Core Features

- ✓ **Patient lists**
  View patient status at-a-glance
- ✓ **Eligibility scoring and pathway assignments**
  Assign patients to tailored pathways using automated logic
- ✓ **Data entry and modification**
  Edit, manage, and review eClinROs, eCRFs, and ePROs
- ✓ **Patient Profile and Visit Management**
  Access complete patient records and visit history in one place
- ✓ **Personalized Disease Management Plan**
  Create and update custom management plans directly in the app
- ✓ **Monitoring Tools**
  Build dashboards, set alerts, and generate custom reports

Patient Experience Capabilities

Built for Engagement and Retention



- **Personalized for every patient**
  Tailored to the needs of each study and population
- **Intuitive for all users**
  Designed for any level of digital experience or literacy
- **Empowering patients through insight**
  Supports informed decisions with built-in education modules

Core Features

- ✓ **Custom Onboarding Flows**
  Guide patients through setup with AI-driven support to reduce drop-off
- ✓ **Adaptive Questionnaires**
  Capture study-specific input through tailored ePROs and eDiaries
- ✓ **eConsent/ eSignature**
  Enable secure, remote document signing through digital workflows
- ✓ **Behavior-Based Notifications**
  Deliver personalized reminders based on individual activity
- ✓ **Integrated Support and Education Hub**
  Provide AI-guided help, condition-specific content, and legal info
- ✓ **Patient Compensation**
  Offer incentives to increase study participation and engagement
- ✓ **EMR Integration**
  Allow patients to link and share medical records securely
- ✓ **Dynamic Home Page**
  Prioritize next steps to reduce cognitive burden

An AI Assistant Feature Suite for All Users

Transform how you capture, manage, and act on study data using AI you build to fit your workflows with our integrated AI Assistant Creator

For Study Administrators

- **Build Custom AI Assistants**
  Quickly create AI assistants using tailored prompts and uploaded study documents.

- **Targeted AI deployment**
  Decide exactly where and how each assistant functions.
  - Attach a specific assistant to an individual question, entire questionnaire, or place an informational chatbot on the study landing page.

- **Smart Access to Study Insights**
  Enable real-time answers to queries about your study or participants pulled from pre-defined fields in your study database or connected systems.

For Patients and Clinicians

- **Conversational Study Support**
  Give users instant answers about the study through a conversational chat interface with an AI assistant trained on your protocol.

- **AI-enhanced questionnaires**
  Attach an AI assistant that listens to dictation, transcribes the output, interprets the meaning using your AI model, and maps the output directly to structured eCRF fields.

- **Automated data extraction**
  Pre-populate forms with data extracted from medical records .

Proven Market Expertise

Trusted across studies, geographies, and populations.

60+
Clinical Studies

150K+
Patients Engaged

50+
Therapeutic Areas

20+
Countries

15+
Languages

Built on real-world needs and real results.

Case Study

Prospective, Multi-Center Colorectal Study

Description and Objectives

Design and **deploy** a **Virtual Site** to compare a stool DNA test for colorectal cancer (CRC) to colonoscopy. This study was a prospective, cross-sectional, multi-center study and expected to enroll approximately 12,500 patients to ensure at least 60 pathologically confirmed CRC cases with a valid stool DNA test.

With the following objectives to:

1. Provide a Virtual Site that supported all stages of the trial
2. EDC data integration
3. Improve patient-centricity by offering a more flexible and convenient option to patients through our digital solution - making retention, data collection and study-related communication much easier

Project Scope

TA
Colorectal Cancer

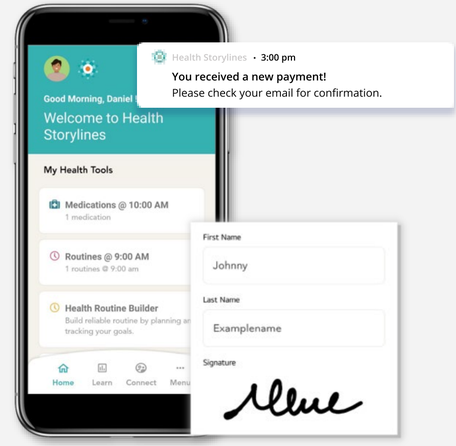
Project Status
Completed

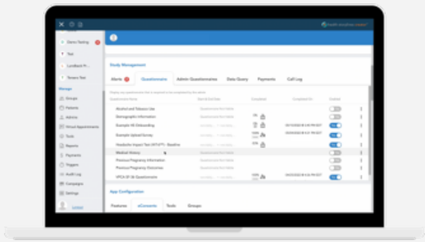
Industry
Pharma

Countries
US

Location
Decentralized

App





Key Activities

Solution Scoping, Design and Development
Launch virtual arm of clinical trial

- Patient app: study enrollment/onboarding, eConsent, data collection, patient engagement and retention, study closeout
- Real-time study management platform: patient monitoring dashboards, alerts, AE monitoring, IP delivery setup, data transfer

Key Facts and Results

- **Sole virtual site** deployed
- **5000+ app downloads** (pre-screening leads)
- **1200+** successfully **enrolled** patients
- **2nd highest** contributing site to the discovery of confirmed CRC cases

Successfully launched a virtual site to enroll patients for the clinical validation of a stool DNA test for Colorectal Cancer (CRC) screening. This decentralized approach enabled the expansion of patient recruitment and remote collection of blood, stool, and colonoscopy results from thousands of community physicians across the US.

Case Study

Migraine Pregnancy Registry

Description and Objectives

The primary objective of this registry is to compare the frequency of major congenital malformations (MCMs) among prospectively enrolled women with migraine exposed to the Sponsor's drugs during pregnancy with 2 unexposed comparator groups: prospectively enrolled women with migraine (treated or untreated), and women without migraine.

A secondary objective of the study is to assess the treatment decision-making process of physicians, and their understanding of the patient experience.

Project Scope

TA
Migraine

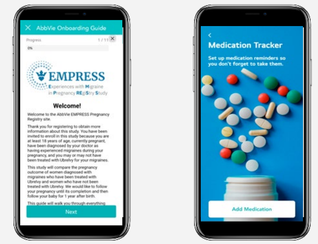
Project Status
Ongoing
(began March 2023)

Industry
Pharma

Countries
US, Canada

Location
Decentralized Virtual Sites

App



Key Activities

Solution Scoping, Design and Development

- Protocol development
- Recruitment, digital screening, enrollment, engagement
- Structured data collection through ePROs
- Data management, data reporting

>270 patients enrolled (to date)

Key Facts and Results

- This study will provide critical data to satisfy FDA post-marketing requirements and guide safe usage recommendations
- The registry will collect and analyze data on the effects of the sponsor's drugs during pregnancy, contributing to a deeper understanding of its safety profile
- Insights from the study will support healthcare providers in making informed decisions about migraine treatment during pregnancy, potentially improving maternal and infant health outcomes

Key Success Factors

The factors driving success include building on the success of past registries to rapidly implement study template, allowing for faster start-up and launch; patient compensation to drive engagement as we steadily recruit and onboard new patients; and with strong communication and sponsor support, driving mid study updates managed in due time and planned budget, following FDA regulations.

Source: Everest 2021

Case Study

Real-World Impact: A Global Study on Lupus Treatment Effectiveness

Description and Objectives

Evaluate the real-world effectiveness of adding the sponsor's drug to standard SLE* care, focusing on clinical outcomes and skin manifestations. The project captures unique data on medication use through standardized assessments and patient diaries, enabling valuable insights for stakeholders.

Project Scope

TA
Lupus

Patients
500pts

Sites
80

Timeline
18-month enrolment + 36 month follow up = 54 months per country

Key Activities

Use a conversational app to make data collection more engaging and approachable, with an adaptive language tree that changes based on the user's motivation and persona.

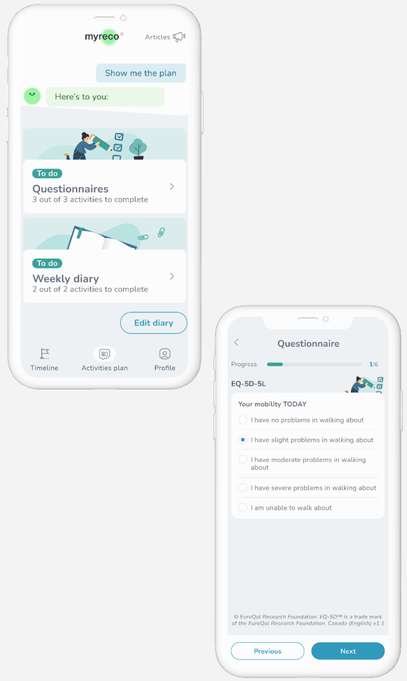
Key Facts and Results

- 97% of patients activated from screening
- 74% of patients completed ePROs as required by protocol

Key Success Factors

The factors driving success include a user-friendly application—reducing decision fatigue, promoting adherence, and delivered in multiple languages across nine countries; and strong partner support, dedicated to monitoring by leveraging our real-time dashboards.

App



*SLE: Systemic Lupus Erythematosus

Case Study

Disease Management in Cancer

Description and Objectives

Partnering with a hospital in France to develop personalized prevention in people at high risk of cancer. Cancer interception relies on a combination of early detection and prevention/ treatment to eradicate cancers before their clinical phase.

The objective of the program is to reduce the risk of stage 2 or higher (or equivalent) malignant tumors by 30% over 5 years in participants, by identifying people at increased risk of cancer as early as possible, and offering them a personalized course of screening and prevention of the disease.

Project Scope

TA
Cancer

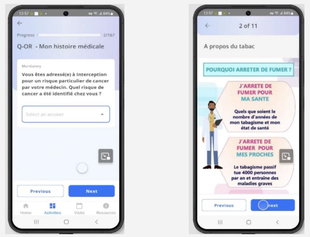
Project Status
Ongoing
(began February 2023)

Industry
Disease Management

Countries
France

Location
Hospitals/Centers

App



Key Activities

Solution Scoping, Design and Development

- Co-design the solution with the Hospital experts (app and web-based)
- Patient Pathways: Personalized risk-based pathways, care-plans, appointment booking, follow-up, etc.
- Algorithms (scores) and interoperability with EMR/EHR (upcoming)

Key Facts and Results

- Target Population: **2,000 patients per year** and per center, in **30 centers** covering the French territory
- To date: 7 centers onboarded, 132 HCPs, 780 patients

Key Success Factors

The 2 main factors contributing to success are: 1) focusing on what was previously unable to be done effectively, i.e. follow up with the participant after the visit by providing them with a prevention plan and personalized follow-up and 2) dramatically reducing administrative burden on HCPs by providing a single unified platform, where previously multiple systems and paper documentation was being utilized.

To date, **60%** of patients who have showed interest in participating were screened or enrolled.

Source: Everest 2021

Enterprise-Ready and Globally Compliant

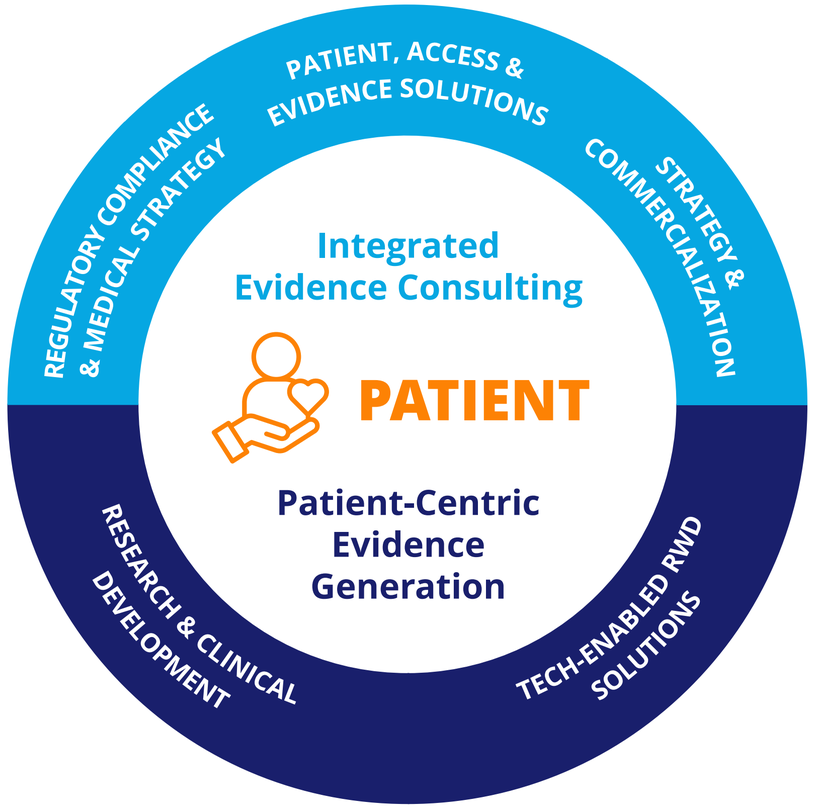
SpherePX meets the highest standards for data protection, interoperability, and multi-market execution.

- ✓ Multi-country and multi-language support
- ✓ Role-based access controls and audit trail tracking
- ✓ HL7 FHIR-compatible for EMR integration
- ✓ ISO 27001-aligned hosting infrastructure
- ✓ 21 CFR 11 and GDPR compliant
- ✓ Built-in localization for patients, investigators, and sponsors
- ✓ IEC 62304: framework for medical device software life cycle processes
- ✓ ISO 13485: targeted by end-2025/early-2026
- ✓ Cyber-security and Pen-Testing
- ✓ Alira Health's global internal QMS

More Than a Platform. A Strategic Partner.

SpherePX is embedded within Alira Health's evidence ecosystem—where strategy, science, and software work together.

- Evidence generation strategy
- Regulatory and payer engagement
- End-to-end data management and reporting



Beyond the platform—you're gaining a partner who understands the science, the strategy, and the people behind every study.

Start Your Journey With SpherePX

- Request a live demo
- Explore pilot use cases
- Align your post-market strategy with patient-enabled evidence

Learn More at:
alirahealth.com/spherepx

AliraHealth
Patient-Enabled Solutions™

Thank You

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