Realizing the promise of digital medicine

ZS Digital Medicine

How pharma, medtech and healthtech can use digital medicine to improve patient outcomes and transform care

Applying clinical rigor to digital solutions can leverage low-cost mobile devices, internet connectivity, connected devices, patient data portability, AI and machine learning, and other innovations to help diagnose and treat patients. This represents a tremendous opportunity to deliver better outcomes at a scale never before possible.

Delivering on this promise, however, is challenging as it requires both building great solutions and achieving commercial scale.

Building a great digital medicine solution starts with selecting the right medical challenge to address, as well as designing and building a solution that:

- Provides a demonstrable clinical benefit while delighting users

- Will be adopted by clinical opinion leaders
- Generates regulator-required clinical data on safety and efficacy
- Abides by other regulatory requirements
- Demonstrates financial value
- Does all the above across multiple countries with different clinical workflows, patient behaviors and regulatory regimes

Achieving commercial scale includes:

- Building the solution in an efficient and timely manner
- Generating the additional, even ongoing, evidence, required by the market's various stakeholders
- Navigating the currently fragmented, immature landscape to find a viable path for distribution, payment and adoption

By embracing innovative strategies to address these requirements, companies have an opportunity to transform healthcare.

Impact where it matters.®

CREATING REAL-WORLD IMPACT

We help deliver on the potential of digital medicine—wherever clients are on their journey. We help clients with such things as:

- Upfront strategic planning

- Product discovery and concepts

- Design and development

- Evidence planning and execution

- Go-to-market planning and deployment

- Ongoing quality and data management BPO

500+

Digital health and digital medicine projects delivered since 2012

130+

Clients in biopharma, medtech, retail health and more

210%

Increase in digital patient engagement in chronic programs

+15M

Lives managed in largest engagement program

Top 20 pharma

ZS helped design a digital therapy (DTx) for COPD patients, incorporating behavioral change techniques. We built a prototype used for observational studies in two geographies (indicating a 50% readmission reduction potential).

Medical devices

ZS helped a client evaluate their consumer technology for cardiac arrhythmia screening through clinical support, market and regulatory research and quality management.

Providers

ZS developed a software as medical device (SaMD) to better manage COVID-19 patients post-discharge, leveraging our HITRUST-certified Connected Health Platform for compliant data management.

Our approach

ZS understands the challenges to design and build digital medicine solutions that delight patients, improve clinical outcomes and achieve widespread adoption and reimbursement. In 2022 alone, we worked with more than 70 clients on their digital missions.

The complexity and rigor of digital medicine often requires taking a best-of-breed approach, leveraging not only ZS's capabilities but those of other ecosystem players, including ZS's portfolio of pre-qualified partners.

ZS provides end-to-end support across the life cycle, including:

- **Strategic advisory:** We have a dedicated team of experts focused on digital medicine. Whether you're looking to make, buy or partner, build foundational capabilities, create market opportunities, manage your product or commercialize an asset, our team can provide key experience-based expertise.

- **Product design and development:** Our product managers, UX researchers and designers, and technology architects and engineers can build a range of custom solutions and integrate them with third-party systems. Through the ZS SaMD Factory, an affiliate of ZS, and its ISO 13485-certified quality management system (QMS), we can execute your SaMD's design and development.

- **Solution modularization:** Many digital medicine solutions involve two types of components: non-SaMD (designed and built in a fully agile manner) and SaMD (subject to design control and validation). Our modularization strategies reflect both initial product constraints and future roadmaps.

- **Compliant technology platform:** We leverage our engagement and data platform to accelerate development of novel digital medicine solutions.

- **Healthcare partnership network:** We leverage ecosystem and technology partners to augment development, evidence generation and last-mile deployment—not only for one market solution but also localized versions for multiple markets.

- **Embedded regulatory, quality and compliance SME:** Whether helping clients establish their own SaMD-specific QMS and software development life cycle or

incorporating regulatory strategy into product definitions and rollout plans, our subject matter experts (SMEs) can support responsible innovation throughout the process.

- **Digital-centric study planning and evidence generation:** Our offerings can be used for various purposes across the life cycle, from concept testing to human factors and regulatory clearance to clinician adoption and pricing negotiations. We specialize in planning and execution of "digital-first" decentralized or hybrid studies best suited for many digital solutions—providing speed, higher participation and representativeness.

- **Commercial launch support:** We help pilot, integrate, partner and scale, leveraging the decades of experience and relationships that ZS has in healthcare ecosystem.

Our clients can leverage our experience, best practices and accelerators in a range of modalities:

- **Consulting:** Supporting your internal teams with experience, insight, creativity and rigorous analysis.

- **Outsourcing:** Taking on product development and operational responsibilities, before or after launch.

- **Capability building:** Helping plan, resource and train internal teams for clients who want to use our consulting or outsourcing only on an interim basis.

EXPERTISE AREAS

ZS SaMD Factory: We help clients master the combination of agility and regulated design controls.

Clinical decision support: We help clients productize algorithms built in-house; by third parties; or by ZS's AI, data science and analytics group.

DTx: We design, develop, validate and deploy DTxs targeted at improving patient outcomes.

Make, buy and partner: We help clients assess the roles and capabilities core to their business versus those that can leverage others' expertise or market penetration.

SaMD-specific foundational capabilities: We help clients set up their first ISO 13485 capabilities as well as help medical device veterans to develop SaMD-specific QMSs and SDLCs.

Connected devices and systems: We support development of connected drug delivery devices and their companion experiences to ensure engagement, data analytic and commercial success.

Behavior change: Our ZS cognitive and behavioral science team can help design digital solutions that impact patient behavior for improved adherence and clinical outcomes.

Last-mile integrations: Leveraging a variety of partnerships, we ensure solutions can integrate with the electronic health records (EHR), picture archiving and communication systems (PACS)/radiology information systems (RIS) or other systems needed for data acquisition and end-user adoption.

Why ZS

End-to-end support

From strategy through design, development, launch and scaling, ZS can support digital medicine initiatives across the entire life cycle.

ZS SaMD Factory

Via our ISO 13485-certified SaMD Factory, we can design and develop regulated SaMD's as a contract manufacturer, leveraging our agile, purpose-built QMS.

QMS accelerators and BPO

We offer pre-audited templates and tools to help clients stand-up their own QMS rapidly, and also an outsourced quality team to help manage the QMS, pre- or post-market.

Flexible and collaborative partner

Whether as advisor, subcontractor, manufacturer, operations support or platform provider, we understand different clients have different in-house capabilities, legacy vendors and future plans that require us to play different roles in different situations.

Connected Health Platform

Our Connected Health Platform optimizes development and deployment of innovative, scalable digital medicine solutions through a common stack of configurable solution accelerators and compliant digital core.

Best-of-breed approach

While ZS does offer a platform and various accelerators, our experience is that the rigor of digital medicine requires a best-of-breed approach for the given clinical scenario. We are comfortable collaborating with our network of partners as well as those of our clients.

Strong partner network

We bring together a broad suite of partners, including:

- Healthcare ecosystem partners to accelerate evidence generation and validation of solutions

- Technology partners to leverage tech innovations to augment client programs

- Compliance and certification partners to ensure trust-based engagements with patients, HCPs, payers and regulators

The most complete offering set

In collaboration with our clients and ecosystem partners, the ZS SaMD Factory helps ensure an integrated, end-to-end approach to get the right SaMD designed, built, validated and deployed rapidly.

Learn more: www.zs.com

About ZS

ZS is a management consulting and technology firm focused on transforming global healthcare and beyond. We leverage our leading-edge analytics, plus the power of data, science and products, to help our clients make more intelligent decisions, deliver innovative solutions and improve outcomes for all. Founded in 1983, ZS has more than 12,000 employees in 35 offices worldwide.