



EHR INTEGRATION & DATA SECURITY

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ABSTRACT

The U.S. healthcare market presents significant challenges for startups, with failure rates that exceed those of other industries. The digital healthcare startup failure rate stands at a staggering 98%, compared to the broader startup failure rate of 90%.

Alarmingly, 51% of digital healthcare startups do not survive beyond their first two years, while 75% of *U.S.-based* medical device startups fail to gain traction. These sobering statistics highlight the complexities of entering a market with stringent regulations, limited opportunities to pivot, and intense competition.

One of the primary reasons startups fail is poor market fit—an issue cited by 42% of failed businesses, according to CB Insights. Even the most innovative solutions will struggle to succeed if they fail to address a genuine and widespread problem. Simply put, if a startup develops a product that does not meet an unmet need, it will struggle to attract customers and sustain growth. In the healthcare sector, where compliance, security, and interoperability are non-negotiable, EHR integration and data security play a critical role in determining whether a startup thrives or becomes part of the failure statistic.

This white paper provides a comprehensive guide to navigating the complexities of EHR integration and data security. By understanding these essential elements, startups can enhance their market fit, align with provider needs, and ensure compliance with U.S. regulations. The strategies, integration approaches, and security measures outlined in this paper are designed to help digital health startups build solutions that not only work but are also indispensable to healthcare providers and patients alike.

PART 1: THE IMPORTANCE OF EHR INTEGRATION

EHR systems serve as the digital foundation of modern U.S. healthcare operations. These systems consolidate patient health information into a centralized, real-time digital record that authorized providers can securely access. By integrating effectively with EHR platforms, startups can improve data exchange, streamline healthcare workflows, and enhance decision-making processes. More than just a technical requirement, EHR integration is fundamental for digital health solutions to gain traction and credibility within the U.S. healthcare ecosystem.

A well-executed EHR integration strategy provides multiple benefits. It significantly enhances efficiency and productivity by reducing administrative burdens and optimizing healthcare operations. Seamless interoperability between systems enables better data exchange, which in turn improves clinical decision-making and patient outcomes. Establishing robust integration also strengthens market access and helps startups develop sustainable partnerships with healthcare providers. Furthermore, compliance with regulatory standards such as HIPAA and HITECH is essential to ensure data security and build trust within the industry.

WHY IS EHR INTEGRATION IMPORTANT FOR US MARKET ENTRY?

Enhanced Efficiency & Productivity

EHR integration streamlines workflows, reduces administrative tasks, and improves efficiency.

Interoperability & Data Exchange

More data means better solutions. EHR integration and data exchange allow for a more informed purpose.

Market Access & Sustained Partnerships

Expand market reach and customer base while creating a “stickiness” to your solution that makes it less likely to be abandoned.

Regulatory Adherence & Compliance

Aligning your solution to regulatory or compliance requirements can make it a priority for healthcare organizations.

PART 2: CORE ELEMENTS OF A SUCCESSFUL EHR INTEGRATION STRATEGY

A structured and well-planned approach is essential for successful EHR integration. Five core elements define an effective strategy, each playing a vital role in ensuring that security, functionality, and regulatory requirements are met.

Security and compliance are at the core of EHR integration, as healthcare data is highly sensitive and subject to stringent regulatory standards. In the U.S., adherence to the Health Insurance Portability and Accountability Act (HIPAA) is mandatory for any entity handling protected health information (PHI). Additionally, the Health Information Technology for Economic and Clinical Health (HITECH) Act enforces stricter rules on data security and breach notifications. For startups aiming to enter this market, achieving SOC 2 certification is often recommended as a foundational security measure. Other certifications, such as HITRUST and ISO 27001, can further enhance credibility and ensure robust security practices, depending on the business needs and target healthcare partners.

COMPLIANCE REQUIREMENTS

HIPAA

Federal Law to protect sensitive patient health information from being disclosed without patient consent or knowledge

HITECH

Provides financial incentives for EHR adoption increasing penalties for HIPAA violations and more stringent requirements for breach notifications

SECURITY CERTIFICATIONS

SOC2

A voluntary compliance standard by the American Institute of CPAs, ensuring security, availability, processing integrity, confidentiality, and privacy.
*Gold standard for new market entrants

ISO 9001/ ISO 13485

Quality management system standard for general businesses/medical devices

HITRUST

Framework that offers a comprehensive approach to risk management, aligning with HIPAA, ISO 27001, NIST, GDPR, etc.

ISO 27001

Certification that demonstrates the people, processes, and technology are in place to protect the organization's data
*Good for 3 years, subject to annual audits

DATA COLLECTION

A well-defined data collection strategy is fundamental to successful integration. Startups must determine what data elements they will collect, how they will structure them, and how these elements align with industry standards. Ensuring standardized data formats is critical for interoperability, as variations in data capture methods can hinder seamless exchange between different EHR systems. Additionally, it is crucial to assign clear ownership for data accuracy and compliance monitoring, establishing protocols to maintain consistency and reliability in data entry and management.

KEY QUESTIONS

- Are the data elements custom or mapped to standards?
- Is the data captured through free text or discrete fields?
- Are there multiple fields for the same data element and how to differentiate?
- Is there a product owner of the data field and clear definitions of the data entered?
- Have there been recent changes to the data fields?
- Is the data documented in multiple different systems?
- Does someone monitor the compliance of these data elements?

DATA STORAGE & OWNERSHIP

Determining how and where data is stored is another critical aspect of integration. Startups must decide between cloud-based and on-premise storage solutions, both of which come with their own security implications and regulatory requirements. Compliance with established security standards ensures the protection of sensitive patient information while defining ownership of data within the organization helps maintain accountability. By carefully structuring data storage and access protocols, startups can build a secure and scalable foundation for their digital health solutions.

MUST HAVES

HIPAA

Mandates safeguards to protect electronic protected health information (ePHI).

HITECH

Introduces breach notification rules, requiring entities to report data breaches to affected individuals and HHS

RECCOMENDED

ISO 9001/ 13485/27001

Quality, information security, and medical device quality management

SOC2

Assesses security controls of organizations, ensuring they protect customer data

HITRUST

Helps manage risks associated with protecting sensitive information

DATA TRANSFER

The ability to securely and efficiently transfer data between systems is a fundamental requirement for EHR integration. Startups must select the most appropriate transport standards based on their specific needs. Fast Healthcare Interoperability Resources (FHIR) is widely regarded as the gold standard for modern healthcare data exchange, providing a web-based framework for seamless interoperability. Other commonly used transport protocols include HL7, APIs, and secure direct messaging solutions. Ensuring adherence to these standards allows for smoother integration with healthcare providers' existing systems while maintaining compliance with industry regulations.

DATA ANALYSIS & REPORTING

Beyond simply storing and exchanging data, an effective EHR integration strategy should leverage data analytics to drive meaningful insights. The ability to analyze patient records, track key performance indicators, and generate actionable reports enhances the overall value proposition of a digital health solution. Furthermore, compliance with reporting requirements ensures that organizations meet regulatory expectations while optimizing healthcare delivery through data-driven decision-making.

PART 3: APPROACHES TO EHR INTEGRATION

There are multiple approaches to EHR integration, each with its own advantages and challenges. Startups should carefully assess their resources, business objectives, and target healthcare environments before selecting the most suitable method.

DATA ANALYSIS & REPORTING

As an entry-level approach, manual workarounds involve methods such as e-faxing, secure file transfer protocol (SFTP) exchanges, and manual data entry. While these processes are labor-intensive and less scalable, they can be effective for early-stage validation and pilot programs with minimal financial investment. Many startups initially adopt these workarounds to test their solutions within healthcare settings before committing to more advanced integration methods.

THIRD-PARTY INTEGRATION

For startups seeking a more efficient integration process without extensive in-house development, third-party integration platforms offer a practical solution. Companies such as Redox and Particle Health act as intermediaries, providing pre-built integration capabilities with major EHR vendors. This approach significantly reduces development time and accelerates the integration timeline by leveraging existing infrastructure and expertise. However, relying on external platforms also introduces dependencies that must be managed strategically, including ensuring continued compliance with evolving regulations and maintaining seamless system interoperability.

A successful example of third-party integration is HealthSnap, a digital health startup that has rapidly expanded by integrating with major EHR systems to support chronic disease management. By leveraging interoperability platforms, HealthSnap was able to streamline its data exchange processes, scale its operations to serve over 150 medical groups, and demonstrate improved clinical outcomes. This strategic integration enabled the company to expand its footprint and attract investment, highlighting the potential benefits for startups that effectively incorporate third-party solutions into their growth strategy.

HealthSnap

Case Study

Year founded: 2015

Funding: \$49M

Area of focus: Remote patient monitoring & Chronic care management (e.g., hypertension, obesity, heart failure, type II diabetes)

SOLUTION OFFERING

- EHR-integrated virtual care platform for monitoring chronic conditions supported by connected devices
- Services and features including monitoring patients' physiological data, customized alert and risk triaging, patient education, billing, etc.
- Offer care management services by its clinical team (LPNs & RNs) to provide monitoring, consultations, education, and care coordination

INTEGRATION DETAILS

- **Integration partner:** Rather than building an in-house integration team, HealthSnap partnered with Redox to integrate with major EHR players (e.g., Epic, Allscripts, Athena, NextGen, Meditech, Cerner, etc.)
- **Timeline:** On average, integration takes 4-6 weeks to complete
- **Compliance & Security:** HIPAA compliant & HITRUST certified



EXAMPLE OF HOW BI-DIRECTIONAL COMMUNICATION OCCUR

- HealthSnap works together with the health system to customize escalation metrics and the alerts can reach to providers through Epic In-basket messaging
- Monthly summary reports, trends, and symptom-tracking graphs for patients can be attached to their charts in the EHR
- HealthSnap compiles documentation on patient encounters and billing eligibility reports and sends them to the EHR

On experience with partnering a 3rd party vendor: Data sharing and roles and responsibilities depends on the scope of services and where we can land in their platform - e.g., "...we had a cardiovascular company partner who only wanted discrete data pushing, so they are the medical service provider while we push the data to their platforms"

FULL INTEGRATION VIA APIs OR HL7

A fully integrated approach involves direct access to EHR systems using APIs or HL7 messaging protocols. This method provides the most seamless data exchange experience, allowing real-time interoperability between healthcare systems. While full integration offers significant long-term benefits, it requires substantial resources, technical expertise, and compliance with strict security and privacy regulations.



KEY DIFFERENCES IN HEALTHCARE DATA EXCHANGE

HL7: Legacy standard for institutional data exchange; requires persistent connections and transmits large datasets.

API: Enables on-demand data retrieval with enhanced security and user authentication.

FHIR: Modern standard combining API flexibility with structured healthcare data, ensuring better interoperability.

PART 4: IMPLEMENTATION PHASES

A phased approach to EHR integration helps ensure a structured and effective execution.

The process typically begins with planning and initiation, where business goals are defined, and key stakeholders are aligned. The design and development phase follows, during which workflows are mapped, and technical infrastructure is built. Training and execution play a vital role in ensuring users are well-equipped to navigate the system, followed by the go-live and optimization phase, where feedback is collected, and refinements are made.

01

STAKEHOLDER
ALIGNMENT

PROJECT
PLANNING

PLANNING AND INITIATION

- Identify and engage with key stakeholders to be included in the integration
- Align on integration / program goals, scope and outcomes
- Create project plan and timeline
- Schedule and facilitate a kick-off meeting

02

SOLUTION DESIGN

SOLUTION
DEVELOPMENT

DESIGN AND DEVELOPMENT

- Conduct workshops to understand current care pathways, EHR configuration and billing/revenue cycle workflows
- Design program requirements such as selection criteria, workflow and technical integrations
- Finalize referral pathway workflows, clinical care, escalation and communication protocols
- Configure EHR documentation, referral pathways, and report
- Align on performance metrics for evaluation and collection process

03

TRAINING

EXECUTION

TRAINING AND EXECUTION

- Communicate and socialize program across key staff
- Onboard relevant staff and provide training
- Communicate the reasons behind implementing EHR integration
- Communicate measurement of success
- Develop a detailed go-live plan with contingencies
- Share internal marketing materials

04

GO-LIVE

SOLUTION
OPTIMIZATION

GO-LIVE AND OPTIMIZATION

- Perform a pilot
- Share marketing /promotional materials
- Report out baseline performance included in the evaluation framework
- Refine workflows & processes over 2-4 weeks
- Identify post-implementation stakeholders and schedule regular touchpoints

CONCLUSION

For startups entering the U.S. healthcare market, EHR integration and data security are not just technical necessities; they are critical determinants of success. In an industry where venture funding for digital health startups reached \$10.1 billion across 497 deals last year—following an additional \$1.8 billion raised in Q4 alone—investors and stakeholders are increasingly looking for companies with strong regulatory adherence, seamless technology integration, and clear market fit. Simply having an innovative solution is no longer enough; startups must ensure that their offerings align with the interoperability needs of healthcare providers while maintaining the highest standards of data security.

By adopting a strategic approach to EHR integration, startups can position themselves for long-term success. This involves selecting the right integration method, whether through manual workarounds, third-party platforms, or full API-based solutions, and ensuring strict adherence to compliance frameworks such as HIPAA and HITECH. A well-planned integration not only enhances workflow efficiency but also helps build credibility with healthcare institutions, making solutions more attractive to potential investors and partners.

Furthermore, as healthcare organizations continue to prioritize interoperability and data-driven decision-making, startups that offer seamless EHR integration will gain a competitive advantage. Successful integration fosters trust among providers, accelerates adoption, and creates long-term opportunities for scaling within the market. By focusing on regulatory compliance, security, and provider needs, startups can build solutions that not only survive but thrive, ensuring sustainable growth in the highly competitive U.S. healthcare landscape.

The opportunity is vast, and with the right approach, your startup can become an essential part of the evolving healthcare ecosystem. The time to act is now—position your company for sustainable growth and impact!

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READY TO NAVIGATE THE US HEALTHCARE MARKET?

EHR integration is just one piece of the complex puzzle of entering the US healthcare market. If you seek expert guidance to ensure a successful entry, consider joining Decimal.health's **US Market Entry Program for International Digital Health Startups**.

OUR PROGRAM PROVIDES:

- **In-depth US healthcare insights:** Understand the landscape, from regulations to business models.
- **Proven go-to-market frameworks:** Develop a tailored strategy to reach providers, payers, and other key stakeholders.
- **EHR & billing integration support:** Navigate technical and compliance challenges with expert guidance.
- **Hands-on workshops & mentorship:** Learn directly from insiders and validate your approach with decision-makers.
- **Market validation & connections:** Build relationships with credible US organizations and secure your first US customers.

COURSE CATALOG

Intro to US Healthcare

Understanding Key Incentives

Pt. 1- Care Finance

Pt. 2- Care Delivery

Pt. 3- Problem-Solution Fit

Revenue and Operating Models

Regulatory Requirements

Data Security & EHR Integrations

Assessing US Market Fit

LEARNING SERIES INCLUDES:

- **US Healthcare 101:** Gain essential industry knowledge.
- **Medical Device & Digital Health Regulations:** Ensure compliance with US laws.
- **Business Models in Digital Health:** Understand revenue opportunities and value-based care.

Don't let EHR integration challenges delay your US market entry. Join Decimal.health's program and gain the strategic insights, mentorship, and market connections needed for a successful launch in the US.

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