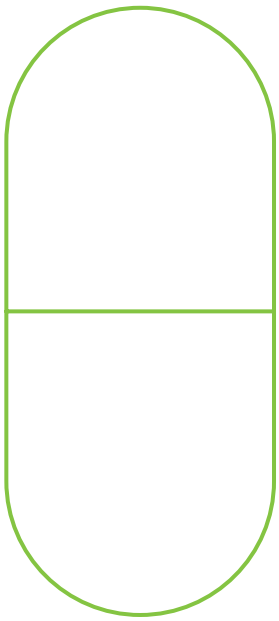
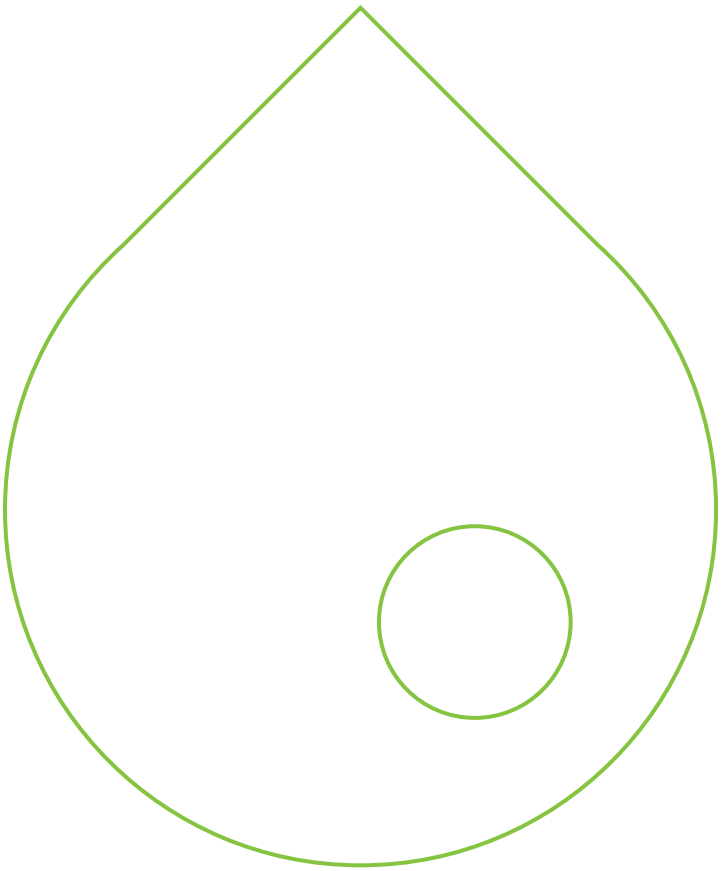
The Case for Data Integration at the Intersection of Healthcare and Biopharma — and How to Make It Happen





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Abstract

Complex healthcare data leads to equally complex data integration issues. This eBook explores how biopharma and healthcare organizations can benefit by integrating data from disparate sources to generate valuable insights by addressing the issues of data fragmentation and low interoperability.

1. How unifying patient data expedites precision treatment development
2. How to bridge the disconnect between digital health and other data platforms
3. How to unlock greater value from real-world data
4. How a data activation platform improves the connection between healthcare and biopharma

Healthcare is a hot button issue in the U.S. public sector, given that 19.7% ($4.1 trillion) of the U.S. gross domestic product is spent on it, according to the CMS.[1]

19.7%

Yet, the U.S. healthcare system is one of the most complex in the world. There are thousands of hospitals, clinics, and individual physicians supported by life sciences organizations (LSOs).
The diverse nature of this complex environment leads to data fragmentation. Additional forms of data are generated from the increasing consumerism and digitization of healthcare and mushrooming use of wearables and smart devices like continuous blood sugar monitors, activity trackers, and myriad digital health apps. Increased use leads to challenges in the ability to understand patient needs and histories, to innovate for their care, and to scale and popularize the innovations.

Some healthcare data sources integrate easily, especially if they are in interoperable software. A great deal more need specialized processing in a HIPAA-compliant manner.

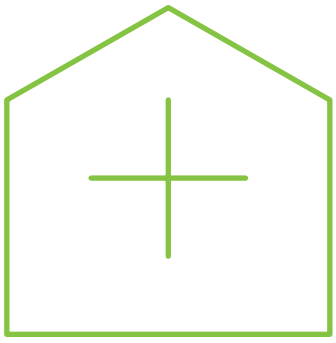
However:

- If there is the ability to integrate data within the healthcare ecosystem
- And when this integration is enabled at its interface with stakeholders like biopharma organizations
- Then it can expand collaboration opportunities for better clinical research, elevated patient outcomes, and improved patient and provider experiences

In this eBook, we:

- Examine the nature of data fragmentation in healthcare and biopharma
- List three areas where data integration benefits stakeholders
- Discuss remediation solutions to help move the industry towards better data integration

What is the Cost of Isolated Data?

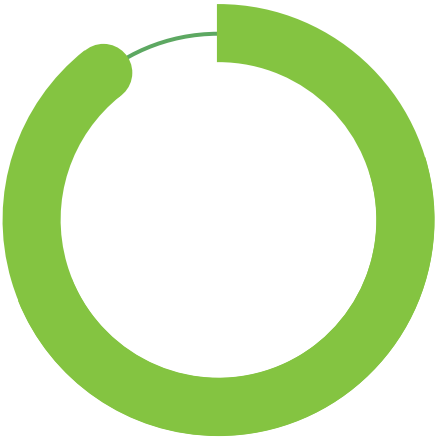


$600,000+

The cost per day of trial delays[3]

$564 Billion

Revenue lost annually due to medication non-adherence[4]



80%

Clinical trials fail to meet enrollment timelines[2]

11,000+

Digital health start-ups leading to data explosion & more data silos[16]

Why is Health Data so Fragmented?

The digitization process that began in the 1980s, in a decentralized healthcare system, has meant that most organizations have followed their own standards and technology, without a referential North Star, or a commonly agreed standard.

Here are four examples of how that plays out:

Operating systems: Most medical devices use custom-built Real Time Operating Systems (RTOS) rather than general purpose OSs. Wearables rely on proprietary operating systems. Such data often needs a change of format before integrating with the EHR.

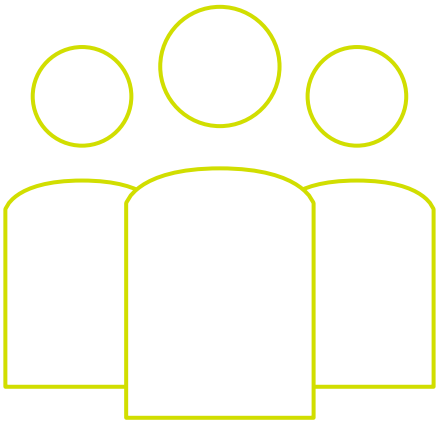
Mode of data generation: Some data, like prescriptions or prognosis notes, are collected by hand. Such unstructured data is harder to catalog and organize than structured data. Healthcare providers also rely on a wide variety of inputs that do not easily talk to each other, such as X-rays, CT scans, or ultrasound. Other sources of medical and biological information use distinct and incompatible formats.

Intent of use: Data is collected differentially based on the intent of use. Standards for integration of clinical trial data, such as CDISC-SDTM5 or OMOP Common Data Model 6, are not interoperable with the HL7 FHIR standard prescribed for integration of healthcare data.[7]

New data sources: At the intersection of industry, patients, and healthcare providers, digital health produces a range of medical device automation, device virtualization, big data, telemedicine platforms, targeted apps, and wearables that aim to deliver patient data for the management of chronic conditions. The rising number of digital health apps adds to the volume of data healthcare workers have to process. It also adds data silos.

The Cost of Data Fragmentation

The consequence of this fragmentation is that only a few healthcare practitioners have a complete picture of the patient's medical history. Further, epidemiological studies that need large data sets can be delayed and put on hold, as we saw during the COVID-19 pandemic. **The UK, where medical records are integrated in the NHS, was able to study 17 million patient EHRs to determine COVID-19 risk factors.**[9]



17 Million patients

If we can unlock the value stored within the massive volumes of data on each patient, we can...

1. Enable healthcare providers to have a 360° view of their patient for more contextualized care.
2. Improve outcomes through better remote monitoring and increased medication adherence. However, the industry must first move from fragmentation to integration.

Biopharma and healthcare can work together to facilitate data integration, creating a rich and holistic view of target patient populations. It requires a common enterprise data platform that lives in the cloud **where it's secure, accessible, and actionable from any device, anywhere.**

The Benefits of Data Integration

With healthcare becoming more patient-centric and digitally enabled, data integration is the next step in improving outcomes. Data integration also enables improved communication and collaboration between biopharma and healthcare organizations.

Data integration benefits patients:

Having all the data gives patients the power to grant or withhold consent over the use of their integrated data set for research.

Integration helps patients avoid duplication of diagnostic tests, saving time and money.

Integration of patient health data with insurance records allows savings on expensive co-pays.

Patients can be more easily found and considered for clinical trials when approved options are not available. (Clinical Research as a Care Option[10] — aka Expanded Access Programs)

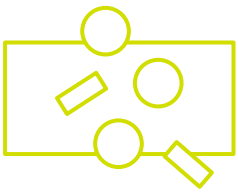
Data integration benefits providers:

Better input for decisions by caregivers: Data integration leads to clearer patient diagnoses which can help avoid misdiagnoses and reduce some of the costs and risk to reputation.

Avoiding unproductive diagnostic procedures and duplication: A 2010 study of 85 patients with EHRs fragmented across Health Care Organizations showed that 20% of all clinical tests were unnecessarily duplicated[11]. The cost of this duplication was estimated in 2018 at around $200 billion per annum.[11]

The ability to target medicine better: Healthcare providers may mis-prescribe because they do not have the full medical history of the patient, including allergies and counter-indications recorded in prior health interventions. Data integration would help prevent this scenario.

The Case for Data Integration



1 Precision medicine progress

Precision medicine, aka personalized medicine, is an approach that targets treatment—which may include medication—to a specific sub-group of patients based on their genetic or molecular profile. One of the obstacles faced by biopharma companies in developing precision medicine for a rare condition is to identify sufficient patients to enrol in clinical trials, leading to delays in drug development.

> In 2020, 39% of new drugs approved by the FDA were personalized medicines.[12] Examples include cancer patients with a specific genetic mutation or children with a rare disease for which no other treatment exists.

Identifying patients who may fit the criteria for a precision medicine clinical trial requires extensive communication with patient organizations, patient registries, and physicians. While clinical trial sponsors and/or CROs use a range of tactics to find and engage with participants, integration with EHR data—with collaborating health systems, post patient consent and consistent with HIPAA regulations—would give them a way to engage with physicians at the point of diagnosis.

With access to integrated data, physicians would have information at hand with which to educate patients about relevant clinical trials, paving the way to easier patient recruitment while offering research as a care option.

2 Richer real-world evidence

Real-world evidence (RWE) that integrates data from a wide variety of sources is now becoming the applicable industrial standard.[13] One of the promises of using integrated RWE is the improvement in drug approvals by the FDA.

However, to unlock the real value of real-world data (RWD) that sits within the health systems' EHRs is difficult. Most pharma companies currently rely on commercial sources acquired from data aggregators which do not allow for a complete view of the patient/whole-person. Additionally, much of the RWD within health information systems is fragmented and not of value on its own. A data platform that extracts, curates, and aggregates healthcare data in near-real time can resolve the data fragmentation and quality issues that hold back RWE generation.

With unified patient records based on high-quality data, integrated from healthcare sources, biopharma organizations would gain the following:

A

Demonstrate economic value of the treatment to payers by enabling outcomes-based pricing and innovative value-based contracting (VBC) programs

B

Improve outcomes by targeting the right patient sub-groups– underdiagnosed patients, super-responders, patients likely to switch or discontinue

C

Label expansion of already approved drugs without the need for additional Randomized Controlled Trials (RCTs)

All in all, integration of RWD with clinical research on a data platform leads to stronger and more targeted development and commercialization strategies—a win-win for biopharma.

3 Drive digital health

Digital health traverses healthcare, technology, life sciences, and biopharma. It connects patients, providers, and the industry. The umbrella term includes regulated and unregulated apps, telehealth platforms, and wearables, among other devices.

To bring consensus in the industry about what digital health really means, HIMSS created a definition.[15]

> Digital health connects and empowers people and populations to manage health and wellness, augmented by accessible and supportive provider teams working within flexible, integrated, interoperable, and digitally enabled care environments that strategically leverage digital tools, technologies, and services to transform care delivery.

Digital health holds the promise for delivery of patient-centric care, and also value-based care, as these technology tools focus on wellness over illness. However, many digital health devices do not connect with EHRs and/or other healthcare data systems, making it difficult for patients to share data or communicate with care teams through these devices.[15]

The healthcare industry is working towards the goal of integration between digital health and healthcare to help move the industry from a business of disease to a business of wellness. With data integrated in a user-friendly interface that works within the EHR, physicians would have easy access to digital health data and a more complete picture of the patient's health. This allows physicians to make more informed treatment decisions and provide recommendations to further improve the patient's health.

The Innovaccer Advantage

Innovaccer is a healthcare technology company with a mission to connect and curate the world's healthcare information to make it accessible and useful. The Innovaccer platform is the ideal partner to enable collaboration across various healthcare stakeholders. Our platform applies FHIR data standards on the provider-facing side, and fit-for-purpose data models on the biopharma-facing side, and helps protect each organizations' data privacy interests while also providing a mechanism that can foster collaboration.

Specifically, our platform enables and supports different data privacy and data use controls for the data controller and data processor such that the data processor can access only the data they need, in accordance with their data use agreement with the data controller.

1

The Innovaccer Data Activation Platform (DAP) offers flexibility and structure

The DAP is deployable across all major cloud platforms, leveraging a modern cloud lakehouse architecture that combines the flexibility of a data lake with the rigor of early-binding source data to a unified data model. This dramatically lowers the total cost of ownership, time to value, and promotes transferable reuse of business value across DAP deployments.

2

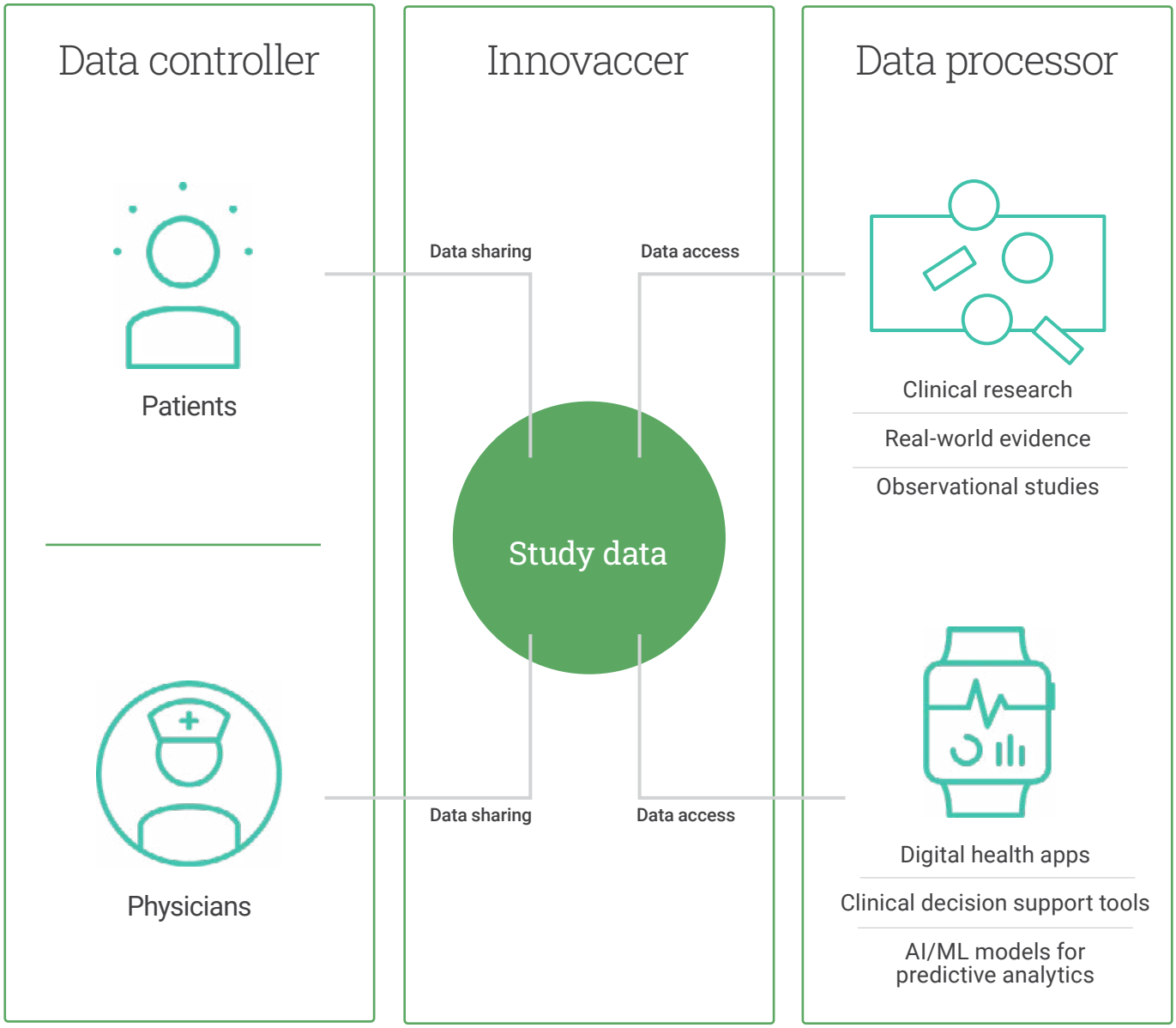
Best in KLAS recognition

Innovaccer's DAP received the 2022 Best in KLAS award from KLAS Research in the new Data and Analytics Platforms category. Innovaccer earned that top ranking based on high marks for customer satisfaction, product quality, and product value scores.

3

Scalable architecture that helps organizations accelerate innovation

The Innovaccer advantage helps organizations start at step 7 by extending well after data integration. Its value continues with building scalability for innovation in digital products and services, such as digital disease management ecosystems. One of the immediate rewards is the ability to standardize data collection across the organization. The third advantage is the ability to achieve scale through automation. This has often been the key challenge for taking an innovation from alpha to beta stage, and finally to market release.



DAP provides the foundation for a variety of use cases.

The Innovaccer Advantage

Innovaccer's modular architecture-based platform for data integration offers the healthcare and biopharma industry a universe of possibilities, the required infrastructure and mechanism to collaborate, based on a foundation of large integrated data sets. While the digital transformation to an integrated era of healthcare– from clinic to clinical trial and back to the clinic– is perceived to be expensive, the opportunity costs are more than matched by the resulting reduction in procedural hurdles, greater scalability of healthcare solutions, and improvement in clinical outcomes.

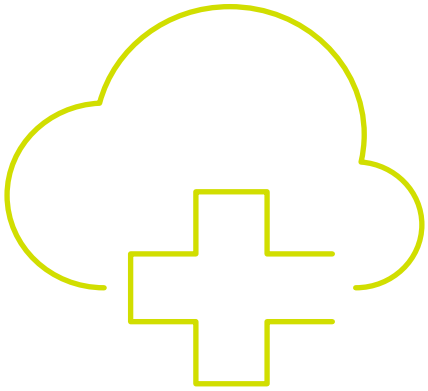
Begin with the end in mind

Moving from data fragmentation to integration requires the following action steps:

Set up the physical infrastructure to **digitize data and integrate it meaningfully, prioritizing privacy, security, and compliance.** Plan the infrastructure for integration with other stakeholder data sets to prepare for the future.

Make effective use of the integrated data through **automation, scalable analytics, and human expertise.**

Ensure the infrastructure is future-ready and able **to adapt to emerging technologies, changes in regulatory guidance, and new approaches to data analytics.**



The Innovaccer® Health Cloud enables healthcare and biopharma to apply and use large data sets previously locked in silos. As patients move between the clinic and clinical trials, these organizations can capture and unify patient data onto a common enterprise platform, securely accessible in the cloud. With holistic patient views, drug development and commercialization have the potential to reach new levels of success.

References

1. National Health Expenditure Data, Historical. CMS.gov https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical

2. Mitchell, Aaron et al. Is data science the treatment for inefficiencies in operations? ZS white paper. https://www.zs.com/insights/is-data-science-the-treatment-for-inefficiencies-in-clinical-trial-operations

3. Accelerating Study Start-Up: The Key to Avoiding Trial Delays. ACRP Clinical Researcher, Feb. 1, 2017.. https://acrpnet.org/2017/02/01/accelerating-study-start-up-the-key-to-avoiding-trial-delays/

4. Forissier, Thomas; Firlik, Katrina MD. Estimated Annual Pharmaceutical Revenue Loss Due to Medication Non-Adherence. Capgemini Consulting, 2012. https://www.capgemini.com/wp-content/uploads/2017/07/Estimated_Annual_Pharmaceutical_Revenue_Loss_Due_to_Medication_Non-Adherence.pdf

5. Technology Q&A. HCL Technologies, https://www.hcltech.com/technology-qa/what-cdisc-and-sdtm

6. Data Standardization. Observational Health Data Sciences and Informatics, https://ohdsi.org/data-standardization/

7. What is FHIR? Office of the National Coordinator for Health Information Technology, https://www.healthit.gov/sites/default/files/2019-08/ONCFHIRFSWhatIsFHIR.pdf

8. Bauer, M & Kirchner, J, 2020. Implementation science: What is it and why should I care? Psychiatry Research 283: 112376. Accessed online 16 February 2022: https://www.sciencedirect.com/science/article/pii/S016517811930602X#bib0023

9. Lovell, Tammy. Researchers analyze 17.4 million NHS patient EHRs in the world's largest study to date on COVID-19 deaths. Healthcare IT News, May 12, 2020. https://www.healthcareitnews.com/news/emea/researchers-analyse-174-million-nhs-patient-ehrs-world-s-largest-study-date-covid-19

10. de Beek, HV, 2019. Clinical Research as a Care Option: Optimizing Approaches. Applied Clinical Trials 28 (6). Accessed online 14 February 2022: https://www.appliedclinicaltrialsonline.com/view/clinical-research-care-option-optimizing-approaches

11. Stewart, BA et al, 2010. A preliminary look at duplicate testing associated with lack of electronic health record interoperability for transferred patients. J Am Med Inform Assoc. 17(3): 341–344. Accessed online 14 February 2022: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2995707/

12. Personalized Medicines Top One-Third of All New Drug Approvals in 2020 for Third Time in Last Four Years. Personalized Medicine Coalition press release, Feb. 11, 2021. https://www.prnewswire.com/news-releases/personalized-medicines-top-one-third-of-all-new-drug-approvals-in-2020-for-third-time-in-last-four-years-301226356.html

13. Examples of Real-World Evidence (RWE) Used in Medical Device Regulatory Decisions. U.S. FDA Center for Devices and Radiological Health. March 16, 2021. https://www.fda.gov/news-events/fda-voices/leveraging-real-world-evidence-regulatory-submissions-medical-devices

14. https://innovaccer.com/roche-clinical-decision-support/

15. Snowdon, Anne RN. HIMSS Defines Digital Health for the Global Healthcare Industry. himss.org. March 2, 2020. https://www.himss.org/news/himss-defines-digital-health-global-healthcare-industry

16. The Top Digital Health Companies Of 2021 https://www.cbinsights.com/research/report/digital-health-startups-redefining-healthcare/

Innovaccer Inc., the Health Cloud company, is a leading San Francisco-based healthcare technology company committed to accelerating innovation in healthcare. The Innovaccer® Health Cloud unifies patient data across systems and settings, and empowers healthcare organizations to rapidly develop scalable, modern applications that improve clinical, operational, and financial outcomes. Innovaccer's solutions have been deployed across more than 1,000 care settings in the U.S., enabling more than 37,000 providers to transform care delivery and work collaboratively with payers and life sciences companies. Innovaccer has helped organizations unify health records for more than 24 million people and generate more than $600 million in savings. Innovaccer is the #1 rated Data and Analytics Platform by KLAS, and the #1 rated population health technology platform by Black Book. For more information, please visit innovaccer.com.