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digital platform

# The shifting landscape of virtual clinical trials
## Global events compel consideration of cloud-based clinical studies

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There has been a paradigm shift in how pharmaceutical trials are conducted and the current worldwide COVID-19 pandemic serves as the unintended catalyst for change.

**Life science organizations find they must adapt their traditional trial structures to meet new distancing requirements based on guidance from governing agencies such as the FDA, NIH and EMA. As indicated by the FDA, "Robust efforts by sponsors, investigators, and IRBs/IECs to maintain the safety of trial participants and study data integrity are expected, and such efforts should be documented. The FDA recognizes that protocol modifications may be required, including unavoidable protocol deviations due to COVID-19 illness and/or COVID-19 control measures[1]."**
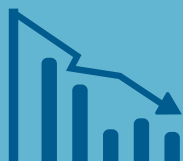
While the concept of decentralized virtual trials has been considered viable for several years, COVID-19 shines fresh light on the capabilities of the latest cloud-based solutions. Not every element of a clinical study can be conducted remotely, however a truly interoperable, fully secure and accessible cloud-based platform can offer valuable options for data collection and analysis.

The Philips HealthSuite digital platform (HSDP) is a cloud-based service which provides a comprehensive set of tools to support organizations seeking to build innovative solutions to support more flexible clinical trials. Examples of solutions include telehealth, remote monitoring, and predictive analytics, to name a few.

**Escalating costs**

**Low success rates**

**1 in 13**
patients have data compromised [4]

**80%** of studies fail to finish on time [2]

**Plethora of unleveraged data**

**30%** avg patient dropout [3]

## Trials and tribulations

Challenges exist at every turn during clinical trials – this is not new. Sponsors and investigators struggle with everything from escalating costs to participant dropout. The ability to navigate the clinical development process requires dedication to innovation and flexibility. COVID-19 is the latest disruptor that highlights the need to leverage the right technology in order to achieve success.

## Key considerations for investing in a cloud platform

Creating a patient-centric solution involves getting feedback from patients themselves and making decisions based on their needs and perspectives[5]. Patient centricity requires maximizing the potential of data from devices and other sources with standardized protocols and open, scalable platforms. It requires flexible scheduling (for participants), reduced complexity, and ease of engagement. Key to success is the ability to address these various concerns with an adaptable approach that can change with the needs of the patient.

Moving to a cloud-based clinical trial environment may be the answer. A nimble cloud infrastructure helps to encourage accelerated product development, improve data storage stability, and offers a cost-effective approach to trial management.

Benefits of a cloud platform (HSDP):
· **Security** – multi-layered security hierarchy designed specifically to mitigate breaches
· **Compliance** – ongoing and up-to-date adherence to a set of controls and regulatory requirements, i.e. HIPAA, ASIST, HITRUST, GDPR
· **Interoperability** – capacity to acquire, store, manage and analyze data from a widely diverse set of medical/consumer devices
· **Development** – versatile, cloud-native application development environment with rapid prototyping, testing, and deployment capabilities
· **Adaptive intelligence/Machine learning** – data science platform for the development and deployment of AI models to support data analysis/insights
· **Accessibility** – 24/7 data access with robust recovery/redundancy profile and improved patient/professional point-of-use access

· **Scalability** – virtually unlimited scalability with 'on demand' – 'pay for what you need' server structure
· **Cost control** – lower cost of ownership and better control through reduction in required in-house hardware, software, staffing expenditures

## A versatile cloud solution

HSDP offers organizations a diverse set of capabilities for ingesting data from multiple sources – electronic health records (EHRs), radiology information systems, consumer devices (i.e. Bluetooth enabled blood pressure monitors, weight scales, activity trackers, and autoinjectors), medical devices, imaging modalities, genomics, digital pathology, patient monitors, and more. Data is collected wirelessly from each device, with no patient data entry required, then routed directly to the cloud. Data is stored and managed in the cloud, then filtered to give meaning to the combined data streams. The data can then be shared and analyzed in a highly secure cloud environment conducive to algorithm and predictive model development.

Collection of digital biomarkers from home-based participants encourages trial retention and triggers an exponential growth in data volume. Furthermore, the cloud environment can support changes to patient sub-groups on the fly before the end of a trial phase, whether it's a reaction to how sub-populations are responding to different treatments, or monitoring the comparative effectiveness and safety of the trial drug itself. Data analysis capabilities can be created through customized algorithms and AI/ML applications can even predict prospective adverse events or anomalies before they occur.

AI can also help assess appropriate trial protocol design through rapid simulation, offer insights on optimal patient cohorts, and identify suitable trial locations geographically (i.e. COVID-19 hotspots).

**Building blocks to success**

HSDP offers services, capabilities, and tools built natively on Amazon Web Services (AWS). This HITRUST certified cloud infrastructure is HIPAA, ASIST, and GDPR compliant, which puts it in good standing when compared to the cost and time required to develop a similar environment locally. Running HSDP on AWS provides the reliability, performance, and scalability that the platform needs to help protect patient data as it continues to increase in scale. With AWS and HSDP, organizations have the tools necessary to conduct a significant portion of their clinical studies via the cloud. Now information is manageable, accessible, able to be processed in rapid fashion for intelligent insight, and stored in a way that's secure, convenient, and economical.

Services of HSDP can be selected a la carte and storage space is scaled on an as needed basis. Features such as consent based access control, standardized APIs, and AI workbench, make HSDP an ideal solution for the evolution of virtual clinical trials. Life science and pharmaceutical organizations who have had to pause their research or find the need to begin anew can be confident that Philips has a tested option at the ready.

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**Invest in a trusted cloud platform**

# Philips HealthSuite Digital Platform

· Connect devices and data
· Aggregate clinical and consumer data
· Store and share data securely
· Support analysis
· Create solutions that make data actionable

**PHILIPS HSDP**™

| Connect | Share | Store | Autorize | Host | Analyze |

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[1] FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency | Guidance for Industry, Investigators, and Institutional Review Boards, March 2020, (updated June 3, 2020) U.S. Food & Drug Administration, https://www.fda.gov/media/136238/download, accessed online, page 8, 06/18/2020.

[2] https://www.clinicalleader.com/doc/considerations-for-improving-patient-0001

[3] https://www.clinicalleader.com/doc/considerations-for-improving-patient-0001

[4] https://www.accenture.com/t20171221T005341Z__w__/us-en/_acnmedia/PDF-54/Accenture-Health-Cybersecurity-300-Billion-at-Risk.pdf#zoom=50

[5] Ryerson, Nancy, What is Patient Centricity in Clinical Trials, https://www.antidote.me/blog/what-is-patient-centricity, antidote, September 29, 2019, accessed January 22, 2020.

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**About the Philips HealthSuite digital platform (HSDP)**

HealthSuite digital platform gives healthcare and life science organizations the cloud expertise and capabilities to connect devices, collect electronic health data, aggregate and store data securely, analyze data, and create solutions in the cloud.

For more information visit: **www.philips.com/healthsuite**

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