Deloitte.

MyPath™ for Clinical

Accelerating next-generation patient experience and therapy management

What is MyPath?

COVID-19 has impacted the industry's ability to conduct trials with broad travel restrictions, concerns about investigative site capacity, and most importantly patient safety considerations. US and international regulatory bodies have moved quickly to encourage the adoption of remote data capture and telemedicine capabilities with patient and investigator safety as paramount concerns.[1]

MyPath for Clinical is a cloud-based digital platform designed to accelerate the execution of digital clinical trials. It brings digital engagement, telemedicine via virtual consults, and the ability for remote data collection and compliance monitoring, to allow trial processes to proceed remotely during COVID-19, and help enhance the productivity and patient experience of trials once the pandemic is behind us. MyPath can improve engagement among patients, investigators, and clinical research associates (CRAs) through real-time data access, a convenient and effective user experience, and more digital direct-to-patient data collection and sharing. It can be used globally and tailored across study phases while supporting various therapeutic areas.

Why now?

As of March 2020, biopharma companies were conducting more than 9,000 ongoing studies.[2] Many of these trials require frequent visits to investigational sites for patient monitoring and data collection throughout the study. Potential disruption in trial operations due to COVID-19 is anticipated, with an accelerated shift to more virtual and remote trials. This is in addition to some of the traditional challenges with study conduct and participation, including:

- **Patient recruitment:** Clinical trials typically require many visits to the investigative sites which could create a time and travel-related burden on patients. This is one of the key reasons patient focus groups cite as an impediment to joining clinical trials. But some clinical trial activities can be done by the patient at home. Remote trial activities could help reduce the burden on the patient and may encourage more patients to enroll in future trials.
- **Patient engagement to drive retention:** Patient dropout remains one of the greatest challenges for clinical trials. Leveraging trends such as remote visits, direct data capture, connected medical devices, and behavorial nudges or gamification is becoming increasingly important to to help minimize common barriers to retention and effectively engage target patients.
- **Protocol compliance:** Poor medication adherence and lack of protocol compliance negatively impacts patient and trial outcomes, significantly delaying a therapy's time to market. Focusing on medication alerts and nudges can help strengthen patient engagement and increase protocol compliance to produce better, higher-quality data.

[1] Guidance on the management of clinical trials during the COVID-19 (Coronavirus) pandemic, version 3 28/04/2020, European Medicines Agency, Commission européenne/Europese Commissie, https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-10/guidanceclinicaltrials_covid19_n.pdf
[2] March 2020 data from https://clinicaltrials.gov/, U.S. National Library of Medicine, U.S. National Institutes of Health.

What are the potential benefits of MyPath for Clinical?

- Provides one platform to create a seamless user experience for remote patient direct data collection that help drives consistency and efficiency across disease areas and programs
- Enables better communication and stronger engagement between patient and investigator and investigators and sponsor study teams
- Helps improve recruitment, simplifies site engagement, and enhances patient engagement
- Enables increased patient adherence, protocol compliance, and outcomes
- Supports direct connectivity and organizes patient data into helpful dashboards
- Enables innovative digital/hybrid and virtual clinical trial designs

Modular functionality

MyPath provides a modular platform that guides patients and investigators through the clinical trial process and allows patients to collect patient direct data capture as part of a remote clinical trial visit. This foundation of core modular functionality is designed to help accelerate the digital clinical trial journey.

	Patients	Investigator/Site	CRA/Sponsor
Dashboards and analytics	Patient profile Personal data visualization, trends, and analytics Custom reminders for protocol activities Gamification / nudges	Investigator profile Patient trends and analytics Site performance Custom reminders Gamification / nudges	CRA profile Study data trends and analytics Study operations dashboard Study and site performance Custom reminders Gamification / nudges
Functionality	Electronic informed consent (eConsent) EHR connectivity ePRO data collection Biometric data collection via wearables Patient-reported symptom tracking	Medication management and reminders Patient education and resources Study tips and resources Data sharing with HCP / Care Team Social platform and community integration	Clinical trial matching and notifications Gamification / behavioral nudges Visit and site support Patient / HCP / Caregiver communication Data privacy and security
Data sources	Patients' wearables and IoT devices	Sponsors' investigator sites CROs / specialty labs regulators	Patient advocacy groups Social and peer networks Clinical trial matching services

Case studies

Case study

A leading life sciences company wanted to develop a patient engagement platform for patients with a rare cancer and launch a digital clinical trial. The platform was intended to help patients better manage their disease on a daily basis, including symptom management and activity tracking. Not only was the platform meant to enable patient-to-patient connections, it also provided the opportunity for patients to receive tailored content about their disease and connected them to patient communities and advocacy groups.

Deloitte used MyPath for Clinical to help this organization develop a patient-facing engagement app with the following capabilities:

- Electronic Informed Consent (eConsent)
- EHR connectivity
- ePRO data collection
- Biometric data collection via wearables
- Patient reported symptom tracking
- Social platform forums and community
- Integration
- Personal data visualization, trends, and analytics
- Custom reminders
- Gamification/nudges
- Patient education resources and study tips

Additionally, the project sponsor gained capabilities including study data trends and analytics, data insights from ePRO and other patient data, and patient and cohort dashboards for treatment pathways, symptoms, and risks.

Case study

A global life sciences company wanted to develop a patient-centric clinical platform that would enhance its ability to conduct digital clinical trials by engaging patients, create patient communities, improve recruitment rates, reduce dropout rates, and support patients throughout the trial to drive protocol compliance. Specifically, the organization wanted to decrease recruitment time and collect 70 percent of clinical trial data remotely by 2023; decrease clinical trial dropout rates by 5 percent; and decrease protocol deviations by 30 percent.

The MyPath for Clinical platform helped this organization advance their vision by creating a **combined web and mobile experience** that helps provide unique engagement opportunities for patients, investigators, and CRAs.

- It provides the ability to **digitize a clinical trial protocol** with capabilities to collect data remotely, including social communities, clinical trial matching, eConsent, EHR connectivity, ePROs/eCOAs/surveys, patient medication management, patient scheduling, workflow-driven appointment and task tracking, and IoT-connected medical device data collection.
- It offers **guided workflows to assist with protocol compliance and dashboard analytics** to share information designed to improve trial outcomes.
- The solution will enable **multiple trials to be run from a single application** experience.

Why ConvergeHEALTH?

ConvergeHEALTH creates new health ecosystems to enable the future of health by combining next-generation platforms, deep industry experience, and novel collaboration models. We move with the agility of a health startup, backed by a network of global member firms, to design and offer platforms and services that empower the shift to value-based personalized health care. We do this by connecting an ecosystem of digital health and analytics platforms and industry collaborations, and leading advisory and technology services at a global scale, all to put patients at the center of health care.

Start the conversation

Visit www.deloitte.com/us/mypath-clinical for more information.

Chris Zant
Principal
Life Sciences
Deloitte Consulting LLP
czant@deloitte.com
+1 484 431 8492

Dawn Anderson
Managing Director
R&D Life Sciences Consulting
Deloitte Consulting LLP
dawanderson@deloitte.com
+1 973 602 4453