

myMedidata — Medidata's Patient Portal

Background

In the last 50 years, technology advancements have improved efficiencies across a variety of industries. Yet with over 330,000 clinical trials conducted annually — addressing some of the most daunting medical challenges, not much has changed in the way clinical trials are conducted. Some of the bigger challenges in running a clinical trial are recruiting enough patients (in part due to lack of awareness or understanding of clinical trials by potential participants), retaining those patients once recruited and enrolled, and ensuring they remain compliant throughout the completion of the study. Almost 80% of sites fail to meet enrollment rates¹, prolonging new treatments for those affected by life-threatening and debilitating diseases such as cancer, heart disease, Alzheimer's Disease, and diabetes. By incorporating the use of technology, data capture will no longer be restricted to physical site visits - increasing patient participation.

Patient-related Challenges and Their Impact on Traditional Clinical Trials

One of the biggest components to clinical research is the patient's ability to participate. By making research more patient-centric and giving patients the ability to virtually access and actively engage in their trials, we lower the patient burden, which in return increases engagement and retention rates. Traditional trial processes need to be disrupted and simplified to create a more seamless patient experience. Virtual clinical trial visits allow sponsors and researchers to directly collect symptoms from research participants who may not otherwise be able to continue with traditional site visits. In addition, sponsors can virtually screen patients and review medical records, enlarging the number of potential trial subjects, which ultimately increases recruitment and enrollment rates. The following statistics demonstrate the impact of patient-related challenges on clinical studies.

23%

of patients are dissatisfied with site location²

58%

increase in number of investigative sites due to increasing trial complexity³

30%

of trials are cancelled due to insufficient participation⁴

30%

patient drop out before the study ends⁵

4 of 5

sites fail to enroll to targets⁶

80%

drop in enrollment from COVID-19⁷

¹ 2012 Clinical trial delays: America's patient recruitment dilemma ² 2017 CISCPR Perceptions & Insights Study

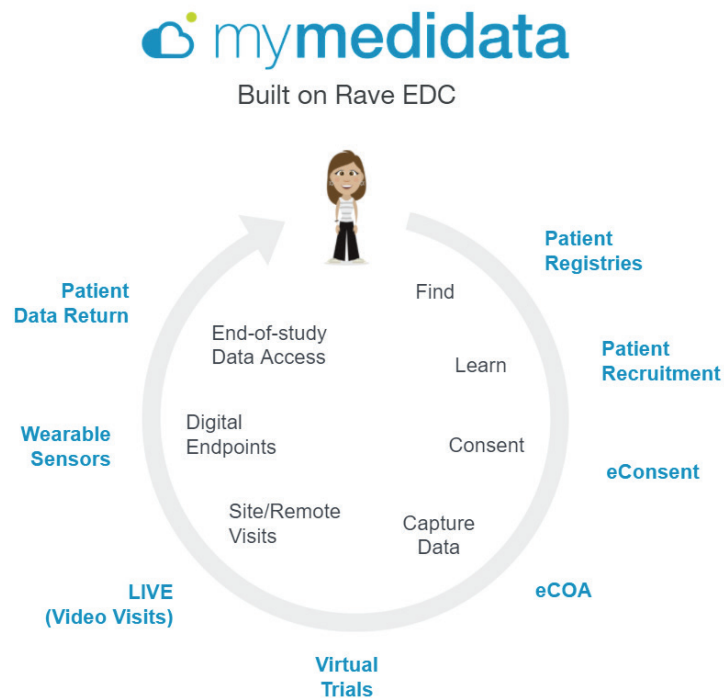
³ 2015 Tufts: The Cost of Clinical Trial Delays ⁴ 2015 Why Clinical Trials Are Terminated

⁵ National Academy of Sciences . The Prevention and Treatment of Missing Data in Clinical Trials. Washington, D.C.: National Academies Press; 2010. Available at: www.nap.org

⁶ 2012 Clinical trial delays: America's patient recruitment dilemma ⁷ Covid-19 & Clinical Trials — The Medidata Perspective

Medidata’s Patient Portal — myMedidata

myMedidata, a single-destination patient portal, enables patients to virtually enroll and participate in clinical trial activities. Built directly on the industry's leading Rave EDC platform, myMedidata extends all of the capabilities of Medidata’s patient-facing solutions for electronic patient consent and clinical outcomes assessment (eCOA), collection of critical data through wearable and other biosensors, COVID-19 symptom tracking, live video investigator/patient visits, and enablement of hybrid and virtual trials through a web-based portal. Using myMedidata, patients can easily complete forms, participate in video visits with their study team, receive reminders and notifications for study-related tasks, and access their results, using any device with an internet connection.



myMedidata was developed using insights Medidata’s Patient Centricity by Design framework, where patient advocates regularly engage and provide direct input into the myMedidata software design and development life cycle. myMedidata allows patients to view their own clinical data (current and historical). Patients’ engagement with their study teams are enhanced via friendly reminders, progress tracking, and continued support throughout their studies. By providing a better overall study experience, patients are more likely to actively participate in and remain on their clinical trial.

myMedidata — Web-Based eConsent

To virtually enroll in a new study, patients are invited to create their myMedidata account, then are guided through an electronic consenting process, also known as eConsent. Through myMedidata eConsent, patients watch the study's eConsent video and review all relevant consent documents. Upon confirming full understanding of the consent, patients virtually sign their web-based eConsent.

myMedidata LIVE — Video Visits

During the COVID-19 pandemic, many clinical trials were paused in part due to patients' inability to travel to the trial site for scheduled visits. myMedidata LIVE is a web-based, live video conferencing capability connecting patients with their clinical trial study staff. myMedidata LIVE video visits between patients and sites can replace a scheduled site-based appointments and allow the study teams to complete their data entry in Rave EDC while patients remain engaged offsite through myMedidata.

myMedidata — Web-Based eCOA

Throughout the trial life cycle, patients access their myMedidata accounts to virtually complete any necessary electronic clinical outcome assessment. Study teams configure all patient data forms needed and patients log into myMedidata to complete their web-based forms.

COVID-19 Symptom Tracker

A new feature of myMedidata includes the complimentary COVID-19 Symptom Tracker-enabling patients on any active clinical study (regardless of therapeutic focus) to monitor and track their COVID-19 symptoms in order to better track their progression, remain active in any current clinical trials while providing more accurate trial data. The COVID-19 Symptom Tracker is also available to non-Medidata users upon signing a customer agreement. Working with the sponsor, site study teams identify appropriate patients and offer them the opportunity to participate. Patients who decide to “opt in” receive a “Golden Ticket” or unique identifier that provides secure access to myMedidata. Patients virtually access myMedidata, enroll and virtually enter their symptoms throughout the study. The COVID-19 Symptom Tracker is available in US-English, French, Spanish (European and Latin American), Mandarin, Japanese and Korean.

COVID-19 Symptom Tracker How it Works



- 1 Participating sites distribute golden ticket codes for each patient. Codes are pre-mapped to the Rave subject IDs for each patient
- 2 Patient opts-in
- 3 Patient creates an account and tracks symptoms the first time
- 4 a If no symptoms are flagged, the patient is reminded to repeat weekly
- 4 b If symptoms are flagged, the patient is reminded to repeat daily
- 5 Data can be integrated with study information to provide value for scientific research and other use cases

myMedidata — Trial Virtualization

myMedidata offers Sponsors and CROs a streamlined and trusted approach to virtualizing clinical trials. Recognizing that all trials will not be 100% virtual, Medidata’s “Trial Dial” functionality allows sponsors to strike the right balance between traditional and virtual visits (hybrid trial) to deliver a true patient-centric study with more engaged and dynamic patient participation. Since myMedidata can be used for any Medidata study whether traditional or remote, the need for integrating disparate solutions and reconciling data is reduced. The number of vendors required to provide virtualization and/or patient engagement offerings is also minimized, streamlining the operations and reducing the costs of setting up and maintaining multiple systems. Risk is mitigated when virtualizing any aspect of a clinical trial, since the unified Medidata Rave Clinical Cloud™, used for patient data capture at the site, is the same platform used to capture patient data from myMedidata.

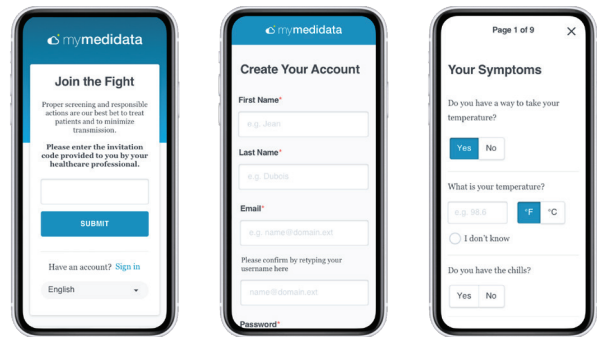
The key benefits of myMedidata are:

- Unified dashboard for patients to access their clinical trial data (current or past)
- Web-based eConsent
- myMedidata LIVE video visits with study staff
- Web-based eCOAs throughout the study
- Notifications/reminders sent to patients - improving protocol adherence
- COVID-19 Symptom Tracker available on all studies
- Enablement of virtualization of clinical trials

The Future of myMedidata

New functionality will be added to myMedidata throughout 2020 and 2021 beginning with additional support for trial virtualization. Future functionality on myMedidata will include:

- Patient engagement via community access to resources and other community members
- Patients view of their trial data
- Patient access to alternative clinical trials for participation
- Long-term follow up
- Viewing and tracking of mobile nurses
- Direct to Patient drug shipments



About Medidata

Medidata is leading the digital transformation of life sciences, creating hope for millions of patients. Medidata helps generate the evidence and insights to help pharmaceutical, biotech, medical device and diagnostics companies, and academic researchers accelerate value, minimize risk, and optimize outcomes. More than one million registered users across 1,500 customers and partners access the world's most-used platform for clinical development, commercial, and real-world data.

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Cloud-based clinical research solutions | Innovative technology | Data-driven analytics
Reduced costs | Improved time to market | Faster decisions | Minimized risk