

myMedidata and the COVID-19 Symptom Tracker

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 subjects), 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 to Traditional Clinical Trials

One of the biggest components to clinical research is the patient’s ability to participate. Without the patient we wouldn’t have successful trials. By making research more patient-centric and giving patients the ability to virtually access and actively engage in their trials, we remove the patient burden which in return increases engagement and retention rates. Traditional trial processes will need to be disrupted and simplified to create a more seamless patient experience. Virtual clinical trial visits will allow sponsors and researchers the ability to collect symptoms directly from research participants who may not otherwise be able to continue with traditional site visits.

23%

of patients unhappy with site location¹

72%

studies run >1 month behind schedule²

30%

trials are canceled due to insufficient participation³

30%

patient drop out before the study ends⁴

4 of 5

sites fail to enroll to targets⁵

80%

drop in enrollment from COVID-19⁶

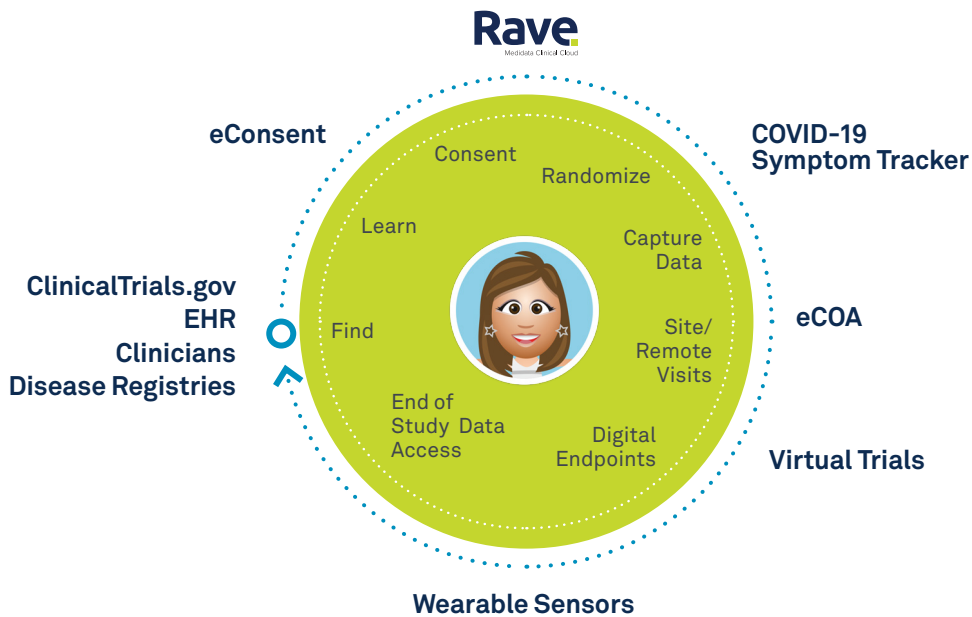
¹ [2017 CISCRP Perceptions & Insights Study](#) ² 2005 Cutting Edge Information: Clinical trial delays cost pharmaceutical companies

³ [2015 Why Clinical Trials Are Terminated](#) ⁴ 2006 Impact Report — Tufts CSDD 8(5) ⁵ [2012 Clinical trial delays: America’s patient recruitment dilemma](#)

⁶ [Covid-19 & Clinical Trials — The Medidata Perspective](#)

Medidata’s Patient Portal — myMedidata

Medidata’s patient portal — myMedidata — is a single-destination intuitive platform enabling patients to enroll and participate in clinical trial activities on a Rave Study. This platform is the industry’s single most comprehensive tool set for all aspects of site and remote based clinical research. myMedidata encompasses all of the capabilities of Medidata’s patient-facing solutions such as the COVID-19 Symptom Tracker, eConsent, eCOA, wearable and other biosensors, and enablement of hybrid and virtual trials. Patients will also be able to use myMedidata to identify other trials and registries that can support them in disease treatment options. myMedidata now presents the results from these patient-centric applications on one dashboard for ease of viewing creating a single platform experience for all patients.

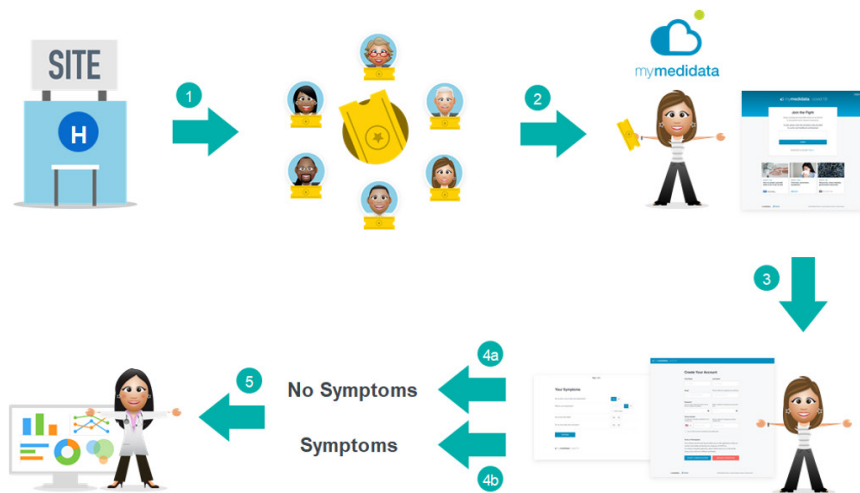


myMedidata was built using insights generated by the company’s Patient Centricity by Design framework, where patient advocates regularly engage as a part of the Medidata software design and development life cycle. The new portal provides patients the opportunity to view their own clinical data (current and historical) thereby increasing their engagement with the study team. With this new approach to engaging patients in a study supported by Medidata technology, patients have a better experience and are more likely to participate and remain on a clinical trial, all while using the same industry-leading Rave technology and solutions used by clinical sites.

COVID-19 Symptom Tracker

The first release of myMedidata includes the complimentary COVID-19 Symptom Tracker that enables patients on any active study supported by Medidata technology to participate in research about COVID-19. 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.

How the myMedidata COVID-19 Symptom Tracker Works



Process

- 1 Participating sites generate golden tickets for each patient
- 2 Patient opts-in
- 3 Patient creates an account and tracks symptoms
- 4a If no symptoms are reported, the patient is reminded to repeat weekly
- 4b If symptoms are reported, the patient is reminded to repeat daily for 14 days
- 5 Data provides value to scientific research and other use cases

THE COVID-19 SYMPTOM TRACKER:

- Is a web-based BYOD patient engagement platform available through computers and mobile smart devices
- Is accessed by patients via unique, credentials provided to them by the study team
- Tracks and reports symptoms of COVID-19 for patients on a study supported by Medidata technology
- Provides the opportunity for patients to contribute to ongoing COVID-19 research about the impact of COVID-19 on their clinical trials as well as the course of the disease based on patients’ demographics and clinical profiles
- Allows sponsors to identify patients in active trials with COVID-19 symptoms, so they can be identified in the future for pharmacovigilance activities

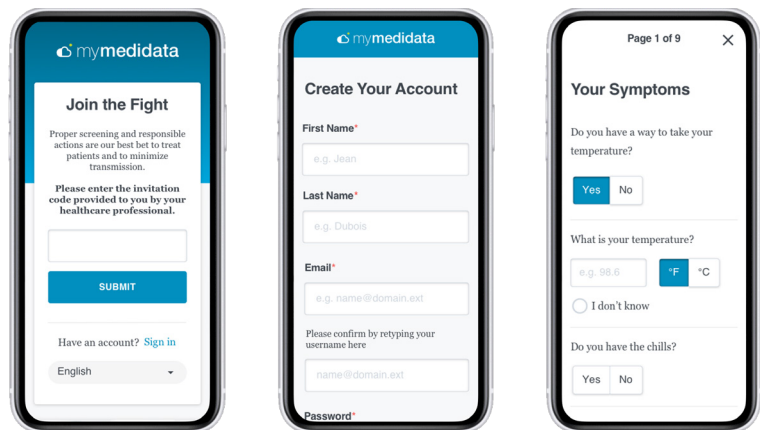
myMedidata offers Sponsors and CROs a streamlined and trusted approach to Virtualizing clinical trials. Since myMedidata can be used for any Rave study (whether traditional or remote), the need for integrating disparate solutions and reconciliation of data is reduced. The number of vendors required to provide virtualization and/or patient engagement offerings is reduced, streamlining the operations and reducing the costs of setting up and maintaining multiple systems. Risk is also mitigated when virtualizing any aspect of a clinical trial, since the Rave platform used for patient data capture at the site is the same platform used to capture patient data from myMedidata.

Therapeutics and vaccines cannot be tested without the most critical components in clinical research: The patients, and their ability to participate. myMedidata makes participating in clinical trials more patient-centric, giving patients the ability to virtually access and actively engage in their own health care needs.

The Future of myMedidata

New functionality will be added to myMedidata throughout 2020 and 2021 beginning with additional support for virtual trials, remote eConsent and web-based eCOA/ePRO - all of which are planned for 2020. Future functionality on myMedidata will include:

- Telemedicine
- Patient view of trial data
- Clinical trial recruitment
- Long term follow up



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 1,400 customers and partners access the world's most-used platform for clinical development, commercial, and real-world data.

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