# Medidata Virtual Trials and Trial Dial™

Typically clinical trials are designed around a study protocol, which includes the identification and use of multiple contracted research sites that recruit patients to participate in the trial. Many times the patient burden in trial participation, including accessibility to research sites, is not considered.

With advancements in mobile technology, the clinical research community has made significant progress in becoming more patient-centric in clinical trials. By designing the clinical trial around the patient and incorporating the use of technology, patient data capture can happen outside of the traditional trial site, that is, virtually. Virtual Trials remove the patients' burden of travel, allowing them to more easily participate while going about their day-to-day lives. This type of study design allows for remote gathering of novel endpoints in real-time.

One of the big challenges sites face in meeting trial timelines is patient recruitment. Almost 80% of sites fail to meet patient enrollment rates,[1] despite more than 74% of patients showed interest in discussing participation in clinical research.[2] Traditional clinical trials restrict patient recruitment to those who live close to trial sites. By removing the geographic limitations and opening up access to virtual participation, more patients can join more trials, speeding up the process of treatments from research to market.

Additionally, patients' inability to travel to sites due to age, sickness, and/or income has been a contributing factor to the lack of diversity in many clinical studies. Last year the FDA included the use of virtual trials in its guidance on increasing patient diversity. By opening up access to virtual trial participation, those patients previously unable to participate in traditional site-based only studies can now participate. An increase in the demographic diversity of trial subjects ultimately leads to better quality data.[3]

## Virtualization Benefits

- Patients are a stakeholder and a valued partner in the trial
- Increased access to clinical trials by removing geographic limitations in visiting sites
- Increased diversity in trial recruitment, leading to better quality data
- Reduced number of clinical sites and faster enrollment rates, decreasing total trial time
- Improved patient engagement and retention through patient-centric design

## Study Conduct

- Future collection of patient data will increasingly be done outside of the site through smart devices and sensors
- Increased use of hybrid studies, which are partially done at sites and partially done at the patient's home
- The FDA supports inclusion of virtual technologies in running research studies

[1] https://www.clinicaltrialsarena.com/analysis/featureclinical-trial-patient-recruitment/

[2] https://www.ciscrp.org/wp-content/uploads/2019/06/2017-CISCRP-Perceptions-and-Insights-Study-Decision-Making-Process.pdf

[3] https://www.fda.gov/media/127712/download



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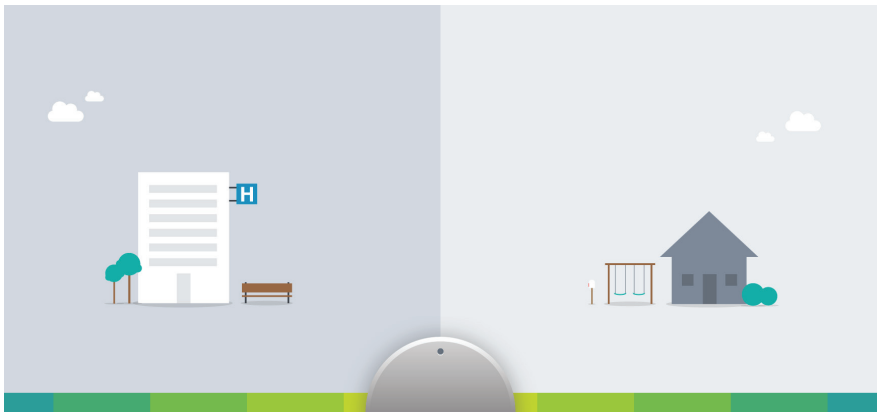
# "Turning the Trial Dial"

An alternative to a complete virtual trial model is Medidata's "Trial Dial". Trial Dial is a way for rare disease sponsors to partner with Medidata and conduct anywhere between 100% site-based studies to 100% virtual studies.




Recognizing that all trials will not be 100% virtual, Medidata's "Trial Dial" helps sponsors strike the right balance of site-based and virtual visits to deliver a true patient-centric clinical trial with more engaging and dynamic patient participation. Ideally, sponsors can customize the design of the trial to reflect the best mix of onsite/virtual touch points for a seamless experience for the patient. Driven by the increased focus on lowering the amount of patient burden associated with trials, the industry is interested in turning the "Trial Dial" to introduce some level of virtualization on more trials. This might include, for example, remote electronic consent, followed by a site visit, followed by the remote use of eCOA tools by the patient before returning to the site for lab tests or treatment. In some studies there is a dramatic reduction in site visits with assessments being provided remotely.

Medidata believes the future of most clinical research will consist of some level of virtualization and continues to develop innovative products and solutions to support that virtual trial reality.

## 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.

Medidata, a Dassault Systèmes company (Euronext Paris: #13065, DSY.PA), is headquartered in New York City and has offices around the world to meet the needs of its customers. Discover more at **www.medidata.com** and follow us **@medidata**, The Operating System for Life Sciences™.

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