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Medidata Rave Virtual Trials and Trial Dial™

The clinical research community has matured significantly in recent years, recognizing the value of more effective patient engagement in clinical trials. By designing technologies that lower the patient burden—allowing them to more easily participate and simultaneously live their day-to-day lives—they become more willing to share information with us. Additionally, challenges around patient recruitment continue to grow as more and more studies are proposed for research while the traditional patient pool remains relatively the same.

Most clinical research, up until a few years ago, has been conducted almost entirely at the study site. Because of patient-centricity and patient engagement, along with the exponential progress made in mobile technology over the last 10-15 years, sponsors are looking for ways to move data capture outside of the site.

Sponsors can also achieve much more efficient study design by allowing some of the data to be captured on site and some outside.

"Turning the Trial Dial"

Medidata's **"Trial Dial"** is a way for sponsors to partner with Medidata and be able to conduct 100% site-based studies, 100% virtual studies, and to help with the majority of studies somewhere in the middle of those two extremes. There are no other vendors that can accommodate this hybrid type of study design.



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Virtualization Benefits

- Patients are a stakeholder and a valued partner in the trial
- Allows patients that might otherwise not participate in clinical trials due to geographic restrictions
- Allows sponsors to reduce the number of clinical sites, or eliminate sites all together
- Economic benefit by reducing costs for both the sponsor and patient
- Improves patient engagement and retention

Study Conduct

- Future data collection will increasingly be done outside of the site and with patients and/or sensors directly.
- Increased use of hybrid studies that are partially done at sites and partially at home.

We know that there are a percentage of clinical trials that can be run as truly "virtual" and also know that there are some studies that may remain 100% site and/or paper-based. The industry is interested in turning the "Trial Dial" to introduce some level of virtualization on most trials. This might include remote electronic consent, followed by a site visit, followed by the use of eCOA tools for the patient to share data from home before returning to the site for a physical, lab tests, or treatment. In some studies we are seeing a dramatic reduction in site visits with assessments being provided remotely.

Medidata believes the future of clinical research will be comprised by some level of virtualization. Contact us to learn more.

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.

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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