

Rave Study Feasibility

Leverage objective site performance data to optimize site and country feasibility and predict trial performance

Rave Study Feasibility adds certainty to an uncertain site identification process

Conventional Site Selection

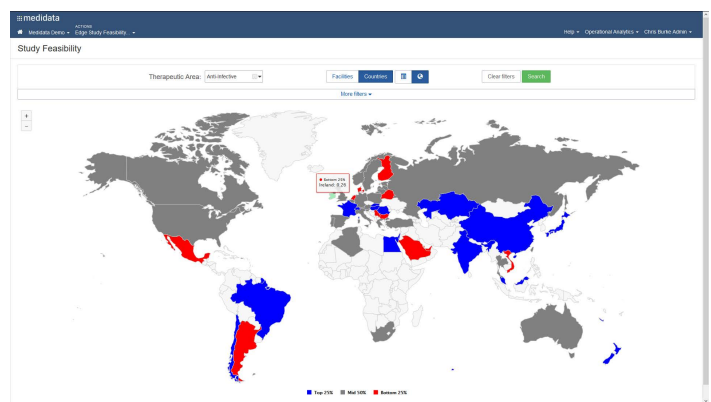
Poor Performing Sites

- ~%30 of study sites in Rave EDC never enroll a single patient
- On average, studies in Rave EDC have ~%25 non-enrolling sites
- High enrolling sites take significantly less time to enroll their first patient. On average, high enrolling sites take ~%40 fewer days to enroll their first patient.

- limited historical performance metrics for sites
- subjective assessment based on experience & relationships

Robust Data: Study Feasibility leverages industry-wide, historical, operational performance data to make more informed site decisions

Site	Site Name	City	Country	Enrollment Rate (Patients/Year)	Enrollment Months %	Enrollment Months (Months)	Site Opened (Y)	Site Lay Down (Y)	Screen Failure Rate (%)	Site Closures (N)	Site Closures (%)	Total Patients	Patients Lost
1	Site 1	Site 1	Site 1	10	100	12	Y	N	5%	0	0%	100	0
2	Site 2	Site 2	Site 2	5	50	6	Y	N	10%	1	20%	50	10
3	Site 3	Site 3	Site 3	15	100	12	Y	N	2%	0	0%	150	0
4	Site 4	Site 4	Site 4	8	80	10	Y	N	8%	2	25%	80	10
5	Site 5	Site 5	Site 5	12	100	12	Y	N	3%	0	0%	120	0
6	Site 6	Site 6	Site 6	6	60	6	Y	N	12%	1	17%	60	10
7	Site 7	Site 7	Site 7	9	90	10	Y	N	7%	1	11%	90	10
8	Site 8	Site 8	Site 8	11	110	12	Y	N	4%	0	0%	110	0
9	Site 9	Site 9	Site 9	7	70	8	Y	N	9%	1	14%	70	10
10	Site 10	Site 10	Site 10	13	130	12	Y	N	1%	0	0%	130	0
11	Site 11	Site 11	Site 11	4	40	4	Y	N	15%	2	50%	40	10
12	Site 12	Site 12	Site 12	14	140	12	Y	N	0%	0	0%	140	0



- Cross-industry performance data that is current, standardized, and consistently refreshed
- Compare and filter by site, country, disease area and other study characteristics

User Friendly: Make identifying optimal sites easier

Country	Enrollment Rate (Patients / Month)	Enrollment Percentile (%)	CTMS Cycle Time (External)	Site Create to FPI (Days)	Data Lag (Visit to Entry) (Days)	Data Correction Rate (%)	Total Enrolled Subjects (#)	Total Studies (#)	Previously Used	Outpatient Visits (External RWE2) (#)	Inpatient Visits (External RWE1) (#)
Germany	2.1	91	1,004	25	4	N/A	4	1	Yes	23,513	1,554
United Kingdom	1.9	87	964	53	6	N/A	11	1	Yes	24,586	1,495
China	1.8	81	768	62	7	N/A	7	1	Yes	24,146	1,383
China	1.8	85	53	85	18	N/A	8	1	Yes	24,203	697
Netherlands	1.7	87	973	22	12	N/A	23	1	Yes	15,870	1,984
United Kingdom	1.6	83	802	25	25	N/A	7	1	Yes	24,282	1,008
Japan	1.5	95	963	5	0	5.9	20	1	Yes	25,426	441
Italy	1.4	80	1,169	17	3	N/A	6	1	Yes	21,226	1,717
Thailand	1.4	77	972	30	17	N/A	3	1	Yes	30,409	1,054
United States	1.3	84	61	26	5	N/A	8	1	Yes	28,189	1,616
Site 53-488-059	1.3	86	651	40	0	N/A	5	1	Yes	16,673	858
Site 53-487-894	1.3	97	561	52	25	4.5	5	1	Yes	17,225	1,041
Site 53-491-018	1.3	88	345	27	2	N/A	6	1	Yes	15,968	1,072

1. Ability to integrate external data sources (customer CTMS, RWE sources)
2. Intuitive user experience with customized drill-down capability
3. Multivariate ranking based on sponsor priorities

Generate Enrollment Forecasts: Save time and money with more efficient patient enrollment

1. Provide Study Characteristics

- Phase
- Disease area (indication)
- Subject population (healthy / patient)
- Study duration
- Country and/or site activation schedule

2. Medidata leverages industry-wide site performance data and runs predictive model

Rank	Site Name	Site	Country	Enrollment Rate (Patients / Month)	Enrollment Percentile (%)	CTMS Cycle Time (External)	Site Create to FPI (Days)	Data Lag (Visit to Entry) (Days)	Data Correction Rate (%)	Total Enrolled Subjects (#)	Total Studies (#)	Previously Used	Outpatient Visits (External RWE2) (#)	Inpatient Visits (External RWE1) (#)
1	Healthcare Facility 03-001-860	Madison	United States	2.8	99	814	2	1.6	84	1	Yes	26,480	1,880	
2	Healthcare Facility 03-001-857	Washington	United States	2.8	97	15	28	6	6.2	7	1	Yes	71,270	2,289
3	Healthcare Facility 03-001-856	Madison	United States	2.4	95	880	18	16	5.9	21	1	Yes	16,847	1,064
4	Healthcare Facility 03-001-855	Phase III 2	Madison	2.2	93	384	27	2	2.9	128	3	Yes	45,638	2,023
5	Healthcare Facility 03-001-842	Washington	United States	2.8	96	854	38	2	3	112	4	Yes	14,238	1,087
6	Healthcare Facility 03-001-854	Washington	United States	2.4	97	1,252	8	1	2.5	8	1	Yes	85,191	2,024
7	Healthcare Facility 03-001-858	Washington	United States	2.2	97	216	188	4	2.1	38	3	Yes	100,280	2,288

3. Medidata Provides Enrollment Predictions

Enrolled Subjects

Month 0 2 4 6 8 10 12 14 16 18 20 22 24 26 28 30 32 34 36

Target Enrollment

- Predict future enrollment performance accurately for selected sites
- Reach target enrollment faster by selecting high-performing sites
 - Reduce cost by using fewer non-enrolling sites

The Platform of Choice for Clinical Research

The Medidata's Rave Clinical Cloud is the cutting-edge platform that transforms the clinical trial experience for patients, sponsors, CROs, and research sites. Designed with a unified data platform, the Rave Clinical Cloud creates a single source of truth for all study-related data. Simply put, enter data once and let the platform master and populate it throughout the end-to-end suite of Rave applications. Optimize operational execution, decrease the data entry and maintenance burden, and reduce the number of clinical systems across your study teams. Throw away your list of passwords and excel sheets, you are now on a truly unified platform.

About Medidata

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Medidata Rave Clinical Cloud

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