

Edge Study Feasibility with MEDS

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

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

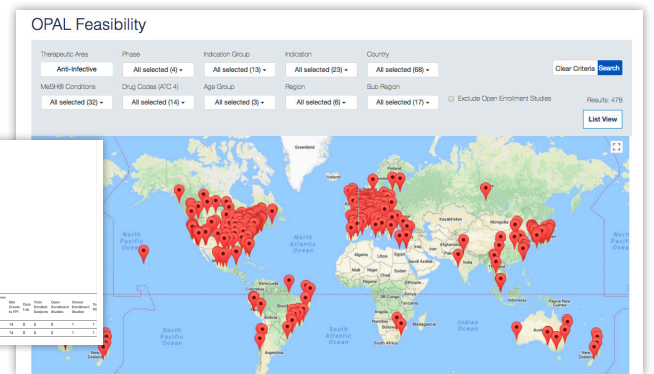
OPAL Feasibility

Therapeutic Area: Oncology | Phase: All selected (4) | Indication Group: All selected (11) | Indication: All selected (21) | Country: All selected (66)

Line of Therapy: MeSH Conditions | Drug Codes (ATC 4) | Age Group | Region | Sub-Region

Exclude Open Enrollment Studies

Rank	Site Name	City	Country	Enrollment Rate (Patients / Month)	Enrollment Percentile (%)	Enrollment Variability	CTMS Cycle Time (Days)	Site Check (Days)	Data Lag (Days)	Screen Failure Rate (%)	Data Correction Rate (%)	Total Enrolled Subjects (N)	Total Studies (Y)	Previously Used
1	Healthcare Facility 53-487-406	Washington	United States	1.9	94	high	390	16	11	75.0	N/A	2	1	Yes
2	Healthcare Facility 53-486-544	Washington	United States	1.5	83	high	1,150	35	12	73.0	6.3	5	1	Yes
2	Healthcare Facility 53-487-948	Tokyo	Japan	1.5	95	high	963	5	0	N/A	5.9	20	1	Yes
2	Healthcare Facility 53-487-436	Washington	United States	1.5	97	high	560	14	0	1.0	5.9	5	1	Yes
3	Healthcare Facility 53-490-095	Barcelona	Spain	1.4	75	low	911	70	22	0.0	7.8	35	7	Yes
3	Healthcare Facility 53-495-705	Barcelona	Spain	1.4	99	high	308	19	70	0.0	3.5	3	1	Yes
3	Healthcare Facility 53-494-857	Ottawa	Canada	1.4	98	high	894	119	19	86.0	N/A	4	1	Yes
3	Healthcare Facility 53-500-038	Bratislava Stare Mesto	Slovakia	1.4	96	high	574	16	5	58.0	9.5	2	1	Yes
4	Healthcare Facility 53-496-729	Bangkok	Thailand	1.3	89	low	930	104	18	71.7	6.0	46	3	Yes



- 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

The screenshot shows a web interface for site ranking. On the left, a 'Multivariate Ranking' panel allows users to assign weights (LOW, MED, HIGH) to various metrics. The main table displays a list of sites with columns for Country, Enrollment Rate, Enrollment Percentile, CTMS Cycle Time, Site Create to FPI, Data Lag, Data Correction Rate, Total Enrolled Subjects, Total Studies, Previously Used, Outpatient Visits, and Inpatient Visits. Red boxes and numbers 1, 2, and 3 highlight specific features: 1 points to the CTMS Cycle Time column, 2 points to the 'Hide Previously Used' checkbox, and 3 points to the 'Multivariate Ranking' tab.

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

The diagram illustrates a three-step process for generating enrollment forecasts. Step 1, 'Provide Study Characteristics', lists inputs such as Phase, Disease area, Subject population, Study duration, and Country/site activation schedule. Step 2, 'Medidata leverages industry-wide site performance data and runs predictive model', shows a table of site performance metrics. Step 3, 'Medidata Provides Enrollment Predictions', is a line graph showing the number of enrolled subjects over 36 months for two site lists, with a target enrollment line at 800.

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 03-488-860	Madison	United States	2.8	99	814	2	1.6	84	1	Yes	26,480	1,880	
2	Healthcare Facility 03-487-857	Washington	United States	2.8	97	15	28	8	6.2	7	1	Yes	71,270	2,289
3	Healthcare Facility 03-487-856	Madison	United States	2.4	85	880	106	15	5.6	21	1	Yes	16,847	1,084
4	Healthcare Facility 03-488-035	Phase III 2	Madison	2.2	85	384	27	2	2.8	126	3	Yes	45,638	2,023
5	Healthcare Facility 03-487-842	Washington	United States	2.8	86	854	88	2	2	112	4	Yes	14,236	1,087
6	Healthcare Facility 03-488-861	Washington	United States	2.4	87	1,252	8	1	2.5	8	1	Yes	85,191	2,244
7	Healthcare Facility 03-487-858	Washington	United States	2.2	87	216	100	2	2.1	28	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

Edge Trial Planning and Management

Pioneering Analytics Accelerates Clinical Operations

Edge Trial Planning and Management is a product suite that increases patient enrollment, retention, and study execution. Medidata Edge Design Optimization, Site Feasibility, Site Grants, and Payment solutions use historical benchmarks and automation from MEDS to reduce patient burden and site feasibility as well as site grants and payments. This has been proven to increase patient recruitment and retention rates.

Medidata also solves many of the biggest challenges in trial management. Medidata Strategic Monitoring and CTMS holistically address regulatory requirements for RBM by combining anomaly detection with intelligent workflows to enable sponsors, CROs, and sites to confidently move away from 100% SDV. Medidata master data management means that up to 76% of an eTMF's artifacts can be pre-populated from other sources.

About Us

Medidata is reinventing global drug and medical device development by creating the industry's leading cloud-based solutions for clinical research. Through our advanced applications and intelligent data analytics, Medidata helps advance the scientific goals of life sciences customers worldwide, including over 950 global pharmaceutical companies, biotech, diagnostic and device firms, leading academic medical centers, and contract research organizations.

The Medidata Clinical Cloud® brings a new level of quality and efficiency to clinical trials that empower our customers to make more informed decisions earlier and faster. Our unparalleled clinical trial data assets provide deep insights that pave the way for future growth. The Medidata Clinical Cloud® is the primary technology solution powering clinical trials for 18 of the world's top 25 global pharmaceutical companies and is used by 18 of the top 25 medical device developers—from study design and planning through execution, management and reporting.

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