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FACT SHEET RAVE OMICS

Rave Omics

As the oncology community has demonstrated, genomic and other 'omic data is crucial for understanding disease risk, prognosis, and treatment efficacy. With technologies like Next-Generation Sequencing increasing data value and decreasing costs, life science companies are expanding their 'omic data collection efforts in clinical trials. Such data have the near-term potential to identify actionable insights that improve the safety and efficacy of treatments, and increase the likelihood of successful drug development.

However, many organizations, particularly those centered around clinical development, are not equipped to handle the new genomics processes that are required for trials: integrating genomic data with traditional clinical trial data, standardizing data across trials, and applying analytical methods that are robust, reproducible, and high-throughput. Medidata's Rave Omics helps turn the ad-hoc process of genomic analysis in clinical trials into an efficient, streamlined pain-free step in clinical development and accelerates biomarker discovery.

Accelerate Timelines to Genomics-Driven Safety and Efficacy Insights

Rave Omics is part of the Medidata platform and works seamlessly with Rave Electronic Data Capture within the Medidata cloud infrastructure to address the challenges of including genomic data in clinical trials. It is designed to identify actionable hypotheses for both closed and ongoing studies and to power future genomics-based scientific findings across studies as a path to precision medicine.



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Rave Omics Streamlines the Integration of Multi-Omic Data into Your Clinical Trial and Prevents Costly Mistakes

Latest Analyses						Expression (5) Mutat	tutation (5) Samples identied for review				
Name	Uploaded By	Date	Subjects	Samples	Ð	Identified for Review (5)	Excluded from Analysis (0)	Included in Analysis (95) All Sample	es (100)	Q. Search for a thin	
Expression_Analysis	John Doe	17 Feb 2017	4	23	٩	SampleID	SubjectID A	Duplicate Check	Sex Check	Outlier Check	Status
Jutation_Analysis	Steven Carter	21 Feb 2017	2	4	Q	✓ A1	ABC123	Failed	Passed	Passed	N/A
re_Mutation_Analysis	Nancy Smith	02 Feb 2017	6	12	٢	✓ A2	DEF456	Passed	Failed	Failed	N/A
Post_Mutation_Analysis	Abe Ryan	19 Jan 2017	9	32		▲ A2	DEP450	Passed	Failed	Palled	N/A
Pre_Expression_Analysis	Michelle McDonald	08 Feb 2017	3	14	T	✓ A3	GHI789	Failed	Passed	Passed	N/A
	See all analyses					✓ A4	JKL012	Passed	Failed	Failed	N/A
Overview						A5	MNO345	Passed	Failed	Failed	N/A
						Remove from Analysis Duplicate Check	Include in Analy	sis			
/ariable Distributions					-	Sex Check					
Desse effects Asses have	non han	even falsen				Outlier Check Lorem ipsum dolor sit am vestibulum at eros. Nullan 28	et, consectetur adipisc a quis risus eget urna r JRD-16		porta gravida at eget metu JRD-16	JRD-1	

Scalable cloud storage and processing within the Medidata platform enables trial sites and vendors to upload genomic data asynchronously and securely into a single source of truth. Data management dashboards help track collection of genomic data and it's integration with clinical patient data and enable data managers to manage the entire genomic data lifecycle.

Automated detection of quality issues in 'omic data during the trial reduces risk and saves money by excluding erroneous data and allowing for the possibility of re-collecting, or re-assaying problematic samples.

Rave Omics can identify samples that are:

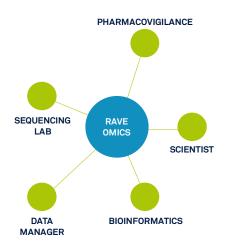
- Duplicate samples assigned to different subject
- Mismatched between the clinical data sex of a subject and the genomic sex of the samples
- Outlier samples

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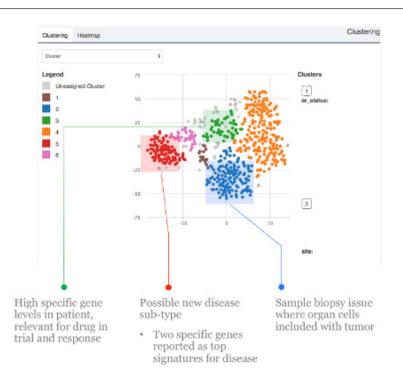
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Rave Omics Breaks Down Silos

An easy-to-use interface and robust, reproducible analytics complements your biomarker discovery team and breaks down traditional barriers between computational and scientific staff viewing these data.Customizable user roles and permissions maintains data access controls and security while allowing for a single-source of data.



Rave Omics Drives Scientific Insights and Accelerates Biomarker Discovery



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User-friendly analytics tools assist in identifying patients who will best respond to a therapeutic agent or those who are more likely to suffer from adverse events, enabling first-line analysis as soon as the data is available.

Efficient access to well-established tools for biomarker discovery increases analysis throughput and leads to reproducible discoveries:

- **Unsupervised clustering:** Cluster samples using gene expression or proteomic data and detect associations to clinical variables.
- **Regression and tests of association:** Explore your clinical and omic data and identify the strongest associations between clinical and 'omic variables.
- **Regression trees:** Identify clinical or genomic variables that predict time to event (e.g., survival time) or that interact with treatment effect.

About Medidata Solutions

Medidata's unified platform, pioneering analytics, and unrivaled expertise power the development of new therapies for over 1,000 pharmaceutical companies, biotech, medical device firms, academic medical centers and contract research organizations around the world. The Medidata Clinical Cloud® connects patients, physicians and life sciences professionals. Companies on the Medidata platform are individually and collaboratively reinventing the way research is done to create smarter, more precise treatments.

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