BioTech Breakthrough Awards Names Medidata's Synthetic Control Arm® "RWE Solution of the Year" for Transforming Patient Equity in Clinical Trials

Game-changing technology makes it possible for more patients in clinical trials to receive the promising investigational therapies they need

NEW YORK – November 10, 2026 – Medidata, a Dassault Systèmes brand and leading provider of clinical trial solutions, today announced that its **Medidata Synthetic Control Arm® has been named the "Real World Evidence (RWE) Solution of the Year" in the 6th annual BioTech Breakthrough Awards**. Selected from among 1,500 entries across life sciences and biotechnology, this award recognizes Medidata's groundbreaking work in reshaping clinical trial design and creating more patient-centric research models.

Medidata Synthetic Control Arm is an External Control Arm (ECA) that is redefining how clinical trials are designed by giving sponsors an alternative to the traditional randomized controlled trial. Medidata's ECA is powered by AI intelligence that makes them scalable, accurate and scientifically rigorous. In a clinical trial, a control group is essential for understanding whether a treatment is effective. But enrolling patients into a placebo or standard-of-care arm can be challenging, particularly in rare disease studies and others where patients have limited treatment options.

Medidata's ECA addresses this challenge by replacing or augmenting traditional control arms with a tailored external control group. The control group leverages aggregated, anonymized patient-level data from more than 42,000 clinical trials and 13 million patients and applies advanced propensity score modeling to closely match the demographics and disease characteristics of the study population.

"By putting existing clinical trial data to work in a new way, Medidata Synthetic Control Arm has the potential to make trials more efficient, reduce the burden on participants, and help sponsors make faster, evidence-based decisions about promising therapies," said Bryan Vaughn, Managing Director, BioTech Breakthrough. "That's why we are recognizing Medidata with the 'RWE Solution of the Year' award."

Value and Impact
Two recent pivotal studies highlight the game-changing impact of Medidata Synthetic Control Arm:

- In partnership with immunotherapy company Medicenna, Medidata successfully negotiated a hybrid ECA design with the FDA that reduced the required randomized control arm in a Phase 3 trial by 66%, saving significant time and resources. Beyond increased efficiency, this innovative design allowed for a greater proportion of enrolled patients to receive the investigational therapy.

- Working with CAR T-cell therapy company Autolus, Medidata contextualized a single-arm Phase 2 trial testing Aucatzyl in B-cell precursor acute lymphoblastic leukemia with Medidata's ECA, contributing to a more complete evaluation of Aucatzyl, alongside the pivotal trial results. The EMA granted conditional marketing authorization of Aucatzyl in mid-2025.

"Winning this year's Biotech Breakthrough Award spotlights the profound value of reimagining trial design through bold thinking and AI advancement," said Anthony Costello, CEO of Medidata. "Medidata Synthetic Control Arm efficiently and effectively generates scientifically rigorous evidence that might not otherwise be available, reduces burden for patients and sites, and successfully supports regulatory approvals, bringing the hope of new life-saving therapies to more patients like never before."

About the BioTech Breakthrough Awards
Sponsored by Tech Breakthrough, the BioTech Breakthrough Awards provide a platform for public recognition of achievements by breakthrough biotechnology companies and products in categories including therapeutics, diagnostics, research, and data. For more information, visit BioTechBreakthrough.com.

The BioTech Breakthrough Awards are evaluated by an independent panel of industry experts and recognize the world's most innovative biotechnology companies, products, and services. Medidata joins an elite community of past breakthrough winners, including BostonGene, Caris Life Science, Thermo Fisher Scientific, and Waters.

About Medidata
Medidata has been powering smarter treatments and healthier people by supporting clinical trials through groundbreaking technological innovations for over 25 years. Medidata is a leader in AI-powered solutions across the entire trial lifecycle to accelerate clinical breakthroughs, reduce patient and site burden, and bring new therapies to market faster. Supported by one of the largest clinical datasets in the industry of more than 42,000 trials and 13 million patients, Medidata's Study, Patient, and Data Experiences are trusted by more than 1 million registered users across approximately 2,300 customers. A Dassault Systèmes brand (Euronext Paris: FR0014003TT8, DSY.PA), Medidata is headquartered in New York City and is recognized as a leader by Everest Group and IDC. Discover more at www.medidata.com**.** Listen to our latest podcast, *from Dreamers to Disruptors*, and follow us at @medidata-solutions on LinkedIn.

About Dassault Systèmes
Dassault Systèmes is a catalyst for human progress. Since 1981, the company has pioneered virtual worlds to improve real life for consumers, patients and citizens. Through the 3DEXPERIENCE agentic platform, AI-powered, science-based virtual twins help 390,000 customers of all sizes, in all industries, collaborate, imagine and create sustainable innovations that drive meaningful impact. For more information, visit: www.3ds.com

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