Medidata Announces New Research Published at American Society for Clinical Oncology Annual Meeting

Advances demonstrated in combining omic and clinical data, using real-world data and pooled clinical trial data, and applying synthetic control arms

NEW YORK, NY – May 27, 2020 – Medidata, the global leader in creating end-to-end solutions to support the entire clinical trial process, and a Dassault Systèmes company, announced the online publication of four abstracts at the ASCO 2020 Annual Meeting, being held virtually May 29 - 31.

Acorn AI, by Medidata, and its partners - Friends of Cancer Research, Guardian Research Network, Donald and Barbara Zucker School of Medicine of Hofstra/Northwell, Memorial Sloan Kettering Cancer Center, New York-Presbyterian/Weill Cornell Medical Center and Weill Cornell Medicine, and New York Medical College - collaborated on research studies that highlight the importance of integrating multiple sources of data to provide insights into clinical oncology.

“Our research findings demonstrate the value of generating new clinical insights by collecting, combining, and analyzing data in innovative ways,” said Glen de Vries, co-founder and co-CEO, Medidata. “We are proud to be working with outstanding research partners, who help bring meaningful contributions to the field and hope to millions of patients.”

The published abstracts include use cases that combine omic and clinical data, use real-world data and pooled clinical trial data, and that expand on Medidata’s pioneering work in synthetic control arms. The following are a summary of these abstracts:

- ***Exploring the validity of a synthetic control arm (SCA) for augmentation or replacement of a randomized control in difficult-to-study indications – a case study in relapsed or refractory multiple myeloma (R/R MM)*** (Abstract e20521)
    - The study demonstrated that the treatment effect based on a synthetic control arm can mimic the treatment effect from a randomized clinical trial in a study involving patients with relapsed or refractory multiple myeloma; this may have significant implications in speeding drug development and reducing patient burden

- ***Evaluating progression free survival in black and white women with triple negative breast cancer in pooled clinical trials from a Synthetic Control Database™ (SCD) and real-world electronic medical records (EMR)*** (Abstract e13102)
    - A representative pool of cross trial triple negative breast cancer patients demonstrated lower progression free survival in Black patients compared to their non-Black counterparts by using a Synthetic Control Database and real-world EMR data, underscoring the necessity of diversity in clinical trials

- ***Assessing the relationship in relapsed-refractory multiple myeloma between response, progression, and survival between pooled clinical trial subjects and a real-world electronic medical record data source*** (Abstract e20525)
    - The study revealed that using pooled clinical trial analyses, together with real-world data, can overcome individual trial sample size limitations and biases; this can expand the range of populations and allow a more comprehensive understanding of the complex oncology treatment landscape

- ***Error-free, automated data integration of exosome cargo protein data with extensive clinical data in an ongoing, multi-omic translational research study*** (Abstract e16743)
    - The automatic, efficient, and reliable integration of clinical and omic data was demonstrated in a clinical trial for pancreatic ductal adenocarcinoma (PDAC), an aggressive, difficult to treat malignancy; much-needed diagnostic biomarkers for early detection may now be found in a more expedited, less-resource intensive manner

The Acorn AI/Medidata team invites the oncology community to learn more about these studies at the ASCO Industry Expert Theater, which are available starting May 29. This is an opportunity to dive deeper into how the company is bringing data, expertise and technology to the frontlines of decision-making in clinical oncology:

- ***Making Precision Medicine a Reality in Clinical Development, Discovery and Beyond*** with Bryant Fields, Senior Director, Integrated Evidence Commercial Lead, Acorn AI
- ***Clinical Trial Data meets the Real World: Bridging the Experimental and Post-Launch Worlds*** with Aaron Galaznik, Head, Acorn AI Labs Boston, Real-World Evidence (RWE)

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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™.

About Acorn AI

Acorn AI, by Medidata, a Dassault Systèmes company, combines data, technology, and deep expertise to help life sciences companies deliver actionable insights across the entire continuum of clinical development. Acorn AI's advanced analytics answers the most important questions in R&D and commercialization including accelerating breakthrough innovation, optimizing study execution and commercial success, and demonstrating the value of therapies. Built upon the Medidata platform comprising 20,000+ trials and more than six million patients, Acorn AI products feature the industry's largest structured, standardized clinical trial data repository connected with real world, translational, and other datasets. For more information, please visit www.medidata.com/acornai.

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