



## **Syneos Health and ConcertAI Announce Strategic Collaboration to Accelerate the Use of Real World Evidence and AI to Advance Oncology Research**

December 3, 2020

### **Combination Offers Customers Access to Largest U.S. Oncology Real World Data Source and Best-in-Class Product Development Expertise for Faster, Smarter and More Patient-Centric Clinical Trials**

BOSTON and MORRISVILLE, N.C., Dec. 03, 2020 (GLOBE NEWSWIRE) -- Syneos Health (Nasdaq:SYNH), the only fully integrated biopharmaceutical solutions organization and ConcertAI, the leader in oncology real world evidence (RWE) and patient outcomes solutions for the biopharmaceutical and healthcare industries, today announced a strategic collaboration to accelerate and streamline the implementation of novel oncology clinical trial research and study designs.

The companies will initially focus on providing biopharmaceutical organizations with the ability to incorporate external control arms into oncology studies with custom, regulatory-grade data abstraction and advanced technologies to speed drug approvals and reduce research costs. In a first-of-its kind CRO collaboration, ConcertAI will bring its deep experience in RWE generation, innovative RWE technologies and regulatory-grade oncology and urology real world data (RWD). Syneos Health will provide customers with end-to-end product development expertise, including deep oncology and rare disease insights, and leading real world, late phase and regulatory consulting solutions.

"With COVID-19 delaying oncology trials, it's critical that we look to deliver novel study designs, such as external control arms, that speed life-saving therapies to market and reduce site and patient burden," said Alistair Macdonald, Chief Executive Officer, Syneos Health. "By collaborating with ConcertAI, together we can bring customers innovative oncology trial solutions by defining the tools, data and scientific expertise required to navigate the regulatory process of designing and submitting successful external control arms."

Over recent years, the U.S. Food and Drug Administration has offered increased flexibility around RWE to help speed drug development. This trend was recently reinforced on October 8<sup>th</sup> in an FDA-authored viewpoint article in the Journal of the American Medical Association (JAMA). Instead of recruiting patients to a control arm, external control arm patients can be sourced from retrospective patient data according to the current standard of care. These external controls are tightly matched to specifications comparable to an internal control arm. This novel design has high relevance in rare cancers where current standard of care therapies have relatively poor outcomes, providing a more ethical, cost effective and accelerated path to approval. External control arms also satisfy market requirements for fast-tracked breakthrough applications or newly approved treatments with only a single treatment arm and no comparative data.

"Oncology trial recruitment has always been challenging and COVID-19 has exacerbated this trend. The moral imperative to rapidly advance new medicines for the hardest to treat cancers requires that we responsibly challenge legacy ways of conducting studies," said Jeff Elton, PhD, Chief Executive Officer, ConcertAI. "We believe this industry-first collaboration means that biopharma innovators and cancer patients will benefit from the combination of ConcertAI's industry-leading RWE capabilities, and Syneos Health's deep expertise running clinical trials and launching therapies, to more effectively improve patient outcomes."

To learn more about this collaboration and the value of external control arms in oncology studies, view an on-demand webinar, "[Using Real World Data in Single-Arm Clinical Trials: When It's Done, Why It's Done, How It's Done](#)."

#### **About Syneos Health**

Syneos Health (Nasdaq:SYNH) is the only fully integrated biopharmaceutical solutions organization. Our Company, including a Contract Research Organization (CRO) and Contract Commercial Organization (CCO), is purpose-built to accelerate customer performance to address modern market realities. We bring together approximately 24,000 clinical and commercial minds with the ability to support customers in more than 110 countries.

Syneos Health leverages the Company's Dynamic Assembly network – a broad and growing group of best-of-breed data and technology collaborators – to be data dynamic and ahead of the curve. By curating an open ecosystem of the best, most agile data and technology partners, Syneos Health is able to deliver fit-for-purpose solutions designed to strategically address the nuances of unique customer engagements. To learn more about how we are shortening the distance from lab to life®, visit [syneoshealth.com](https://syneoshealth.com).

#### **About ConcertAI**

ConcertAI is the leader in real-world evidence (RWE) and patient outcomes solutions for the biopharmaceutical and healthcare industries. ConcertAI has definitive real-world data (RWD) in oncology and urology; the leading enterprise RWE technology SaaS and AI solutions; and the world's top outcomes research and data science talent. Our singular mission is partnering with leading biopharma and healthcare providers to revolutionize clinical research and patient therapeutic journey to realize the best possible outcomes. ConcertAI is a portfolio company of SymphonyAI, an operating group of leading companies that transform business with advanced AI and data solutions. eurekaHealth is a trademark of ConcertAI. For more information, visit us at [www.concertai.com](https://www.concertai.com).

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Source: Syneos Health, Inc.