Medidata and Oxford University Innovation's Clinical Outcomes Team Announce Addition of Gold Standard Questionnaires to eCOA Library

Medidata and its customers gain access to pre-configured, pre-approved questionnaires in multiple languages to support clinical study start-up, quality, and efficiency

LONDON, UNITED KINGDOM - 12 November 2020 - Medidata, a Dassault Systèmes company and the global leader in creating end-to-end solutions to support the entire clinical trial process, today announced a collaboration with Oxford University Innovation's Clinical Outcomes Team (OUI) to begin proactively adding OUI's stable of clinical outcome assessments (COAs) into Medidata's electronic COA (eCOA) Global Library. This significant collaboration will help accelerate clinical study start-up, support quality improvements, and drive study management efficiency.

This agreement will give both Medidata and its customers access to questionnaires that are pre-configured, pre-approved, translated in multiple languages, and stored for future use. Author approved versions of these electronic patient reported outcome (ePRO) measures will be stored in Medidata's eCOA library, ensuring easy use within future projects for both Medidata and OUI's customers.

Minimizing the time required to properly deploy COA instruments (or questionnaires or surveys) within an eCOA study system is a key benefit for any clinical trial sponsor. This process has traditionally taken months, or even years, to ensure instrument developers (and sponsors) are confident in the precise reproduction of their work. This collaboration allows for the OUI portfolio of COAs regularly used by trial sponsors to be ready for trial deployment, following rigorous review and testing, straight out of the Medidata eCOA library. OUI's questionnaires, including the Parkinson's Disease Questionnaire (PDQ), the Endometriosis Health Profile (EHP), the Amyotrophic Lateral Sclerosis Questionnaire (ALSAQ), and the Oxford Participation and Activities Questionnaire (OxPAQ), are viewed as industry gold-standard instruments and are widely used. These have proven to effectively measure how a patient is feeling or functioning with a certain disease or condition.

"This collaboration marks an important relationship with a prestigious partner and is another step forward to building our eCOA global library," said Anthony Costello, senior vice president of mHealth at Medidata. "This joint project helps standardize these questionnaires and collate them on a unified digital platform, removing the need to build and reproduce the same questionnaire multiple times for different studies, customers, and regions."

Medidata's [Rave eCOA](#) is an easy-to-use, full-service offering that includes best-in-class technology, flexible deployment options, pre-validated global instrument library, professional services, and dedicated customer support. Medidata's eCOA library - the first in the industry - now contains more than 200 forms and is being actively used to positively impact timelines and quality of ongoing studies. Medidata has seen hours of work reduced by more than 50 percent in some cases when using questionnaires from the eCOA library.

"We manage some of the most widely regarded and relied upon condition-specific COAs used by the pharmaceutical sector, which means we have a significant responsibility to ensure any electronic reproductions of our COAs are true to the validated original," said David Churchman, Business Manager of Clinical Outcomes at Oxford University Innovation. "Collaborating with a trusted partner like Medidata

to reliably deploy our well-known instruments is essential so that more companies can access and use our high quality questionnaires, and all stakeholders can have confidence in the end product."

Medidata is a wholly owned subsidiary of Dassault Systèmes, which with its 3DEXPERIENCE platform is positioned to lead the digital transformation of life sciences in the age of personalized medicine with the first end-to-end scientific and business platform, from research to commercialization.

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About Clinical Outcomes
Clinical Outcomes, part of Oxford University Innovation (a UK-based company) and solely owned by the University of Oxford, specialises in the management and support of high-quality Clinical Outcome Assessments. The Clinical Outcomes team has been active in supporting COA users for over 14 years and supports COA developers from academia, healthcare providers and commercial organisations to ensure their instruments are properly managed and supported. Our international clients, which includes over 750 new users every year, spans the healthcare spectrum including academic research, publicly and independently funded healthcare providers, medical device companies and the pharmaceutical sector. For more information, visit innovation.ox.ac.uk/clinical-outcomes or email healthoutcomes@innovation.ox.ac.uk.

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