Cognoa Announces Nature Digital Medicine Publication of Pivotal Study Results Showing the Effectiveness of its Digital Diagnostic Device for Autism

Palo Alto, Calif, April 25, 2022 - Cognoa, a pediatric behavioral health company, today announced that *Nature Partner Journal (NPJ) Digital Medicine* has published data from its pivotal study of the company's AI-based diagnosis aid for autism spectrum disorder (ASD), Canvas Dx™. Canvas Dx is the first and only FDA-authorized diagnostic device designed to support providers in the diagnosis of autism in children aged 18-72 months in the primary care setting.

"With Canvas Dx, we finally have the opportunity to streamline the diagnostic journey, freeing up specialists to focus on children with complex presentations, so that families with developmental concern for their children can receive the care they need sooner," said Dr. Tom Megerian, study co-author and Medical Director of the Thompson Autism Center at Children's Health of Orange County. "This will be of critical benefit to all vested in early childhood development and autism care – pediatricians, primary care providers, specialists, payors – but most importantly, to the children and families we must be dedicated to and united in serving."

The multi-site, prospective, blinded, method-comparison cohort study included 425 children, aged 18 to 72 months, with parental or primary care provider concern for developmental delay, in 14 sites across six states. The study compared the assessments made by the device directly against the standard diagnostic approach of specialist evaluation and diagnoses. Study results demonstrate:

- Positive and negative outputs from Canvas Dx were in strong agreement with specialist diagnosis, highlighting the high accuracy of the Canvas Dx device.
- The device provided a "Positive for ASD" or "Negative for ASD" result to aid in making a diagnosis in 32% of patients. For those with a "Positive for ASD" or "Negative for ASD" result, the device results matched the panel's conclusions for 81% of patients who tested positive for ASD by the device and 98% of patients who tested negative for ASD by the device.
- The device made an accurate ASD determination in 98.4% of patients with the condition and in 78.9% of patients without the condition.
- Of the 290 children (68%) in whom output from Canvas Dx was 'indeterminate', 264 (91%) were identified as having one or more neurodevelopmental conditions.
- While the study was not powered for statistical inference on covariates, no difference in device performance was detected across participants' sex, race/ethnicity, income, or education level as determined by examining the overlap of corresponding 95% Confidence Intervals.
- No evidence of performance degradation was found when assessments were performed remotely.

"This is a significant tool in the toolbox of a primary care provider," said Rambod Rouhbakhsh, MD, MBA, principal study investigator and program director at the Forrest General Hospital

Family Medicine Residency Program. “Even when providers or parents suspect autism, the next crucial step of getting to a specialist to confirm the diagnosis is not readily available. Where I work in Mississippi, we only have one or two referral centers in the entire state. To be able to help primary care providers give families the opportunity for an accurate diagnosis, no matter where they are located, is a big deal. With the support of Canvas Dx, we can take the next step from concern to diagnosis. Earlier diagnosis is crucial. Earlier equates to less time worrying and suffering while maximizing the efficacy of interventions, enabling us to improve the outcomes for children and families.”

The peer-reviewed paper can be read in Nature Partner Journal (NPJ) Digital Medicine. A study overview, written by Andrey Ostrovsky, Dennis P. Wall, Sharief Taraman, Jonathan T. Megerian, and Carmela Salomon, is also available.

About Delay in Diagnosis of Autism Spectrum Disorder (ASD)
In the U.S., as many as 25% of children are at risk for a developmental delay, and ASD is estimated to affect 1 in 44 children. Autism can be reliably diagnosed in children as young as 18 months, yet the average of diagnosis has remained unchanged for over 20 years at over 4 years of age. Non-white children, girls, and those from rural areas or disadvantaged socio-economic backgrounds are often diagnosed even later or missed altogether. Research shows that early interventions during a critical early neurodevelopmental period, particularly before the age of 3, can improve lifelong outcomes for children with ASD. To learn more, visit www.knowautismearly.com.

Important Information

Canvas Dx Indications for Use
Canvas Dx is intended for use by healthcare providers as an aid in the diagnosis of ASD for patients ages 18 months through 72 months who are at risk for developmental delay based on concerns of a parent, caregiver, or healthcare provider. The device is not intended for use as a stand-alone diagnosis device but as an adjunct to a primary care provider's clinical judgment. The device is for prescription use only (Rx only).

Contraindications
There are no contraindications to using Canvas Dx.

Precautions, Warnings
The Device is intended for use by healthcare professionals trained and qualified to interpret the results of a behavioral assessment examination and to diagnose ASD.

The Device is intended for use in conjunction with patient history, clinical observations, and other clinical evidence the healthcare provider determines are necessary before making clinical decisions. For instance, additional standardized testing may be sought to confirm the Device output, especially when the Device result is not Positive or Negative for ASD.

Canvas Dx is intended for patients with caregivers who have functional English capability (8th grade reading level or above) and have access to a compatible smartphone with an internet connection in the home environment.

The Device may give unreliable results if used in patients with other conditions that would have excluded them from the clinical study. Among those conditions are the following:

- Suspected auditory or visual hallucinations or with prior diagnosis of childhood onset schizophrenia
- Known deafness or blindness
- Known physical impairment affecting their ability to use their hands
- Major dysmorphic features or prenatal exposure to teratogens such as fetal alcohol syndrome
- History or diagnosis of genetic conditions (such as Rett syndrome or Fragile X)
- Microcephaly
- History or prior diagnosis of epilepsy or seizures
- History of or suspected neglect
- History of brain defect injury or insult requiring interventions such as surgery or chronic medication

The Device evaluation should be completed within 60 days of the time it is prescribed because neurodevelopmental milestones change rapidly in the indicated age group.

About Cognoa

Cognoa is a pediatric behavioral health company developing digital diagnostic and therapeutic products with the goals of enabling earlier and more equitable access to care and improving the lives and outcomes of children and families living with behavioral conditions. Cognoa's products are intended to be routinely prescribed by providers and covered by insurers. For more information, visit https://www.cognoa.com/.