
Request for Information (RFI) on Public and Private Sector Uses of Biometric Technologies: Responses

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We are grateful for the opportunity to comment on the Office of Science and Technology Policy (OSTP) Request for Information on past deployments, proposals, pilots, or trials, and current use of biometric technologies for the purposes of identity verification, identification of individuals, and inference of attributes including individual mental and emotional states.

We are employees of Cognoa, a privately held, 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 health conditions, starting with autism. Cognoa was founded in 2013.

Cognoa believes there is enormous potential for innovations based on artificial intelligence (AI) to help facilitate transformative benefits to healthcare outcomes, streamline diagnostic and treatment pathways, and reduce healthcare inequities. Cognoa also recognizes potential harm related to both the goal and design of AI-enabled systems. We believe AI is not a “silver bullet” for goals of improving healthcare outcomes, and a critical aspect to socially responsible AI systems is the data used to train them.

With our comments, we focus on the use case of Cognoa’s AI-enabled diagnosis aid, Canvas Dx. 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). There are no contraindications to using the device.

Current diagnostic processes are highly variable, subjective, and rely primarily on referral to a limited number of specialists with ASD diagnostic expertise. We believe a data-driven approach, one that is designed to support rather than replace providers’ clinical judgement, can help address the inherent limitations of current ASD diagnostic approaches by facilitating expedited diagnosis, improving access to timely intervention, and reducing confounding bias.

We strive to be an example of socially-responsible AI implementation, and we hope to serve as a key contributor to the evolving structure and best practices of AI-enabled innovations. We invite the OSTP to contact us for any questions, further information or discussion based on our submission below.

Best regards, and thanks again for the opportunity,

Halim Abbas & Sharief Taraman, MD, DABPN, DABPM, FAAP

Important Information

Indications for Use
Canvas Dx is intended for use by healthcare providers as an aid in the diagnosis of autism spectrum disorder (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 diagnostic device but as an adjunct to the diagnostic process. 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.
Authors

Halim Abbas
Halim Abbas is the Chief Artificial Intelligence Officer at Cognoa. Halim a high tech innovator who spearheaded world-class AI projects at game changing techs like eBay and Teradata. His technical interests span digital diagnostics and therapeutics, predictive modeling, computer vision, information retrieval, natural language processing, and big data. Halim has a proven track record of leading cross-functional teams to research and develop first-in-class products and services using novel AI techniques. His experience spans multiple industries such as healthcare, BioPharma, eCommerce, web and mobile services. He holds an B.Eng degree in Computer Systems from Carleton University and an M.Sc. degree in Machine Learning from Columbia University. Halim is a strong believer in the necessity for a socially responsible framework around the application of AI in healthcare, and leading the technology teams at Cognoa to be a paragon in the healthcare industry and a proactive participant in an effort to elevate AI research and development nationwide to a higher diversity, equity, inclusion standard.

Sharief Taraman, MD, DABPN, DABPM, FAAP
Sharief Taraman, MD is the Chief Medical Officer at Cognoa. Dr. Taraman also serves as Division Chief of Pediatric Neurology for Children’s Health of Orange County, Associate Clinical Professor at the University of California-Irvine School of Medicine, Affiliate Professor at Chapman University Dale E. and Sarah Ann Fowler School of Engineering, President of the American Academy of Pediatrics-Orange County Chapter (AAP-OC), and on the Board of Directors for AAP-OC, AAP-California, and the International Society for Pediatric Innovation. He is dual board-certified in Neurology with special qualifications in Child Neurology from the American Board of Psychiatry and Neurology and Clinical Informatics from the American Board of Preventive Medicine. He completed his medical education at Wayne State University School of Medicine in 2006 and went on to complete residency training in pediatrics and pediatric neurology at the Children’s Hospital of Michigan. Dr. Taraman is enthusiastic about using artificial intelligence to diagnose and treat neurodevelopmental and neurobehavioral disorders early to help children reach their fullest potential.
**Topic 1: Descriptions of use of biometric information for recognition and inference**

The prevalence of autism spectrum disorder (ASD) has risen steadily since 2000 and is now estimated to affect 1 in 44 children in the United States. Early initiation of ASD-specific intervention has been shown to improve long-term outcomes in several research studies (Estes A., et al., 2015; MacDonald R, et al., 2014; Peters-Scheffer N, et al., 2011; Strain PS, Bovey EH., 2011). Receiving an ASD diagnosis is a key first step in that process. However, families of children who are at risk of developmental delay typically experience an average delay of three years between a parent reporting a concern to a physician and the formal ASD diagnosis (Maenner MJ, et al., 2020; Hyman SL, et al., 2020; Baio J, et al., 2018; Zuckerman KE, et al., 2015). Additional factors, including race/ethnicity, socioeconomic background, and geographic location, may exacerbate this issue. These delays in diagnosis may prevent children from receiving ASD-specific intervention during a key neurodevelopmental window when there is greater potential to improve long-term outcomes.

Cognoa has developed a Software as a Medical Device (SaMD), Canvas Dx, a diagnosis aid intended to help healthcare providers diagnose or rule out autism spectrum disorder (ASD) in the primary care setting, which may streamline the diagnostic process and allow for more efficient specialty referrals. The goal of Canvas Dx is to help physicians and families arrive at diagnostic answers efficiently and thereby enable children to receive appropriate treatment as early as possible. ASD-specific early intervention within the first 4 years of life, particularly before the age of 3, can positively impact the development of a child with ASD and yield significant improvements in behavioral, social, emotional, and cognitive functioning (Estes A., et al., 2015; MacDonald R, et al., 2014).

Canvas Dx harnesses clinically validated AI technology to aid physicians in diagnosing ASD in children between the ages of 18 and 72 months who are at risk of 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 healthcare provider’s clinical judgment. The device is for prescription use only. There are no contraindications to using the device.

Canvas Dx is a data-driven diagnosis aid that integrates three distinct inputs for accurate and timely ASD evaluation in the primary care setting:

- A parent/caregiver questionnaire that asks about the child’s behavior and development collected via a parent/caregiver facing app.
- A questionnaire completed by a video analyst who reviews two videos of a child’s natural behavior in their home environment, recorded by a parent/caregiver. Video analysts are trained professionals with at least a master’s degree and more than five years of experience diagnosing and/or treating children with ASD.
- A healthcare provider (HCP) questionnaire completed by a physician who meets with the child and a parent/caregiver, collected via a healthcare provider portal. Cognoa has contracted with a pediatric care provider to offer the option to have a qualified HCP complete the HCP questionnaire via a video visit with the caregiver and child, with the goal of allowing for a streamlined experience. Alternatively, the prescribing physician can complete the questionnaire.
The main component of the Canvas Dx software system is the underlying, clinically validated machine learning algorithm that drives device output. The algorithm evaluates the three device inputs based on key developmental behaviors that are most indicative of autism and provides one of three outputs for use in conjunction with the child’s clinical presentation: positive, negative, or indeterminate. An indeterminate output is given when Canvas Dx inputs are insufficiently granular for the algorithm to render a highly predictive output. For example, a patient may exhibit an insufficient number and/or severity of features to be confidently placed within the algorithmic classifier as being either ASD negative or ASD positive. Canvas Dx's indeterminate output is a standard method of risk control in machine learning algorithms, also referred to as an 'abstention' or 'no result' output.

- The algorithm was developed and trained using patient records belonging to thousands of children of both genders with diverse conditions, presentations, and comorbidities who were diagnosed based on the clinical reference standard (Abbas H, et al., 2018; Abbas H, et al., 2020). In conjunction with algorithm training and validation, specialists with expertise in diagnosing ASD were consulted during development of the Canvas Dx clinician questionnaire to understand which questions would most benefit from clinician input as a complement to caregiver input (Abbas H, et al., 2020).

Back-end services and infrastructure, including security encryption, are in compliance with privacy laws and HIPAA. Canvas Dx is available by prescription only and is distributed via Orsini Specialty Pharmacy.

Canvas Dx received FDA Breakthrough Device Designation in October 2018, and FDA De Novo marketing authorization in June 2021. Cognoa has since begun to make Canvas Dx available for prescription use. To our knowledge, Canvas Dx is the only diagnosis aid for ASD that has been granted FDA marketing authorization to date.

**Topic 2: Procedures for and results of data-driven and scientific validation of biometric technologies**

Cognoa conducted multiple feasibility and validation studies over the course of several years (Abbas et al., 2018; Abbas et al., 2020; Du Y et al., 2019). Through data-driven experimentation, these early stage feasibility studies informed the algorithm’s evolution with regards to biometric feature selection, modality selection, age range determination, optimal siloing, need for algorithm abstaining, and prioritization and tradeoffs between net positive/negative values, sensitivity, specificity, and coverage.

In support of Cognoa’s De Novo classification request to the FDA, the accuracy of Canvas Dx was assessed in a multisite, prospective, double blinded, active comparator cohort study conducted between August 2019 and June 2020 (currently in peer-review; see abstract here). The Canvas Dx pivotal study measured the accuracy of output from Canvas Dx in comparison to the standard diagnostic approach of the child’s evaluation and diagnosis by an experienced specialist using DSM-5...
criteria, whose finding was confirmed by independent review. Participation required a commitment to an in-person visit with a specialist.

The study included 425 children, aged 18 to 72 months, whose caregivers or pediatricians had expressed concern about their development but who were never formally evaluated or diagnosed with autism. The children in the study were broadly representative of the U.S. population in terms of race, ethnicity, and socioeconomic background.

The primary endpoints included measurements of positive predictive value (PPV) and negative predictive value (NPV) among subjects with a determinate result, and the indeterminate rate. The secondary endpoints were sensitivity and specificity.

Pivotal study results demonstrate the potential for Canvas Dx’s accurate, efficient, and consistent performance:

- The output from Canvas Dx was compared against specialist diagnosis and shown to have a PPV of 81% (95% CI: 70%–89%) and an NPV of 98% (95% CI: 91%–100%) in those patients with a determinate device result (32%).
- Among patients with a determinate result, Canvas Dx was shown to have a sensitivity of 98% (95% CI: 92%–100%) and specificity of 79% (95% CI: 68%–88%).
- Canvas Dx performed consistently regardless of subjects’ gender, race/ethnicity, income levels, parental education levels, demonstrating its potential to help address racial, ethnic, gender, and socioeconomic disparities in ASD diagnosis.
- Canvas Dx did not exhibit degradation of performance across sexes. Accuracy in females was important to establish because of the existing biases in diagnosis for females with ASD. When Canvas Dx provided a result, it correctly identified 92.3% of girls with ASD.
- In the Canvas Dx pivotal study, the average age of children diagnosed with ASD was 2.8 years, which is approximately 1.5 years earlier than the average age of diagnosis in the U.S.

Canvas Dx delivers an indeterminate output as a risk control measure when inputs are insufficiently granular to make a determinate recommendation with confidence. This allows the algorithm to render a highly predictive diagnostic output, minimizes the likelihood of false negatives, and is a common method of risk control in machine learning.

Of the 68.2% of subjects with an indeterminate result, 91.0% were identified by specialists as having one or more neurodevelopmental disorders:

- 71% (206/290) were ASD negative, with at least one other non-ASD developmental or behavioral condition.
- 20% (58/290) were ASD positive.

**Topic 5: Exhibited and potential benefits of a particular biometric technology**

Many children with ASD are not being diagnosed during the critical early neurodevelopmental period. While a reliable ASD diagnosis can be obtained for a child as young as 18 months, multiple factors have driven the average age of diagnosis to 4 years, 3 months, and this has remained unchanged for over 20 years (Hyman SL, et al., 2020; Zwaigenbaum L, et al., 2016). Children who are non-white, female, or
from rural areas or disadvantaged socioeconomic backgrounds are often diagnosed even later or missed altogether (Velott DL, et al., 2016).

To date, there is no medical test or procedure to diagnose ASD, and behavioral assessments that inform the diagnostic application of the DSM-5 criteria for ASD are the only available means of diagnosis (Hyman SL, et al., 2020). The median 3-year delay between initial concern and ASD diagnosis often encompasses the critical early neurodevelopmental period (Estes A., et al., 2015; MacDonald R, et al., 2014; Peters-Scheffer N, et al., 2011).

- Currently, primary care physicians are the first to screen children for developmental delays and refer those with suspected delays to specialists, including developmental pediatricians, child psychologists, child and adolescent psychiatrists, neuropsychologists, and pediatric neurologists. (Monteiro SA, et al., 2019; Hyman SL, et al., 2020).
- A shortage of specialists and time-intensive evaluations are both factors resulting in long wait times (as long as one year) for diagnostic appointments, causing substantial delays in diagnosis (Gordon-Lipkin E, et al., 2016).
  - In the United States, the number of developmental-behavioral pediatricians by state ranges from 0 to 4.4 per 100,000 children (Monteiro SA, et al., 2019).
  - Approximately 47% of hospitals report staffing vacancies in child and adolescent psychiatry and developmental pediatrics; 34% report vacancies in neurology departments (Gordon-Lipkin E, et al., 2016).
- In a 2018 study, nearly 1 in 10 respondents needed to travel more than 60 miles for diagnosis; 1/3 reported problems finding a specialist (Martinez M, Thomas KC, Williams CS, et al., 2018)
- In-person evaluations can take up to 3 hours to complete, which can be difficult for children with ASD and parents/caregivers, and multiple visits may be required (Gordon-Lipkin E, et al., 2016).

Until now, there has not been a tool designed for use in the primary care setting to aid in the diagnosis of ASD. While pediatricians can use diagnostic tools such as ADOS®-2* and ADI-R®*, these tools were designed and validated for specialists, require extensive training, and are time-consuming (Gordon-Lipkin E, et al., 2016; Rutter M, et al., 2003). Primary care providers (PCPs) report a lack of training, knowledge, and confidence in assessing ASD, as well as the time necessary to administer the assessments and to counsel caregivers following a positive diagnosis (Beggiato A, Peyre H, Maruani A, et al., 2017; Fenikilé TS, Ellerbeck K, Filippi MK, Daley CM, 2015; Golnik A, Ireland M, Borowsky IW, 2009). As a result, while PCPs are often the first point of contact with families with concerns about a child’s development, current tools are not practical for use in this setting.

To help facilitate access to early intervention services, the American Academy of Pediatrics’ recently updated clinical report for ASD encourages general pediatricians comfortable with the application of the DSM-5 criteria to make a clinical diagnosis of ASD for children not requiring specialist referrals (Hyman SL, et al., 2020). However, there is a critical need to provide PCPs with the training and tools that provide a higher level of diagnostic support consistent with the DSM-5 criteria than are currently available, thus enabling them to render a diagnosis without referral to a specialist.
As demonstrated by the pivotal study results, Canvas Dx has the potential to help primary care providers effectively diagnose or rule out ASD when used in conjunction with their clinical assessment so that intervention can be initiated earlier than the current average age of diagnosis. The use of Canvas Dx to help PCPs diagnose or rule out an ASD diagnosis in the primary care setting may allow for more efficient specialist referrals and streamline the diagnostic process.

Potential to Reduce Confounding Bias

Boys are more commonly diagnosed with ASD than girls, with a male-to-female prevalence ratio of 4.3:1 as of 2016. (Maenner MJ, Shaw KA, Baio J, et al., 2016). ASD diagnostic tools were initially developed with primarily male subjects, resulting in a sex-related bias in both ASD characterization and diagnosis (Beggiato A, Peyre H, Maruani A, et al., 2017). Studies have shown that racial and socioeconomic disparities in referrals for or access to ASD diagnostic and interventional services contribute to an ASD prevalence gap seen in non-white children (Durkin MS, Maenner MJ, Baio J, et al., 2017; Baio J, Wiggins L, Christensen DL, et al., 2014; Mandell DS, Wiggins LD, Carpenter LA, et al., 2009). In the current diagnostic pathway, girls, African American children, and Latinx children are misdiagnosed more often, diagnosed less often, and diagnosed later, on average (Mandell DS, Wiggins LD, Carpenter LA, et al., 2009; Constantino JN, Abbacchi AM, Saulnier C, et al., 2020; Ros-Demarize R, Bradley C, Kanne SM, et al., 2020; Becerra TA, von Ehrenstein OS, Heck JE, et al., 2014;).

Canvas Dx may help relieve some of the inequities that exist with the current paradigm for diagnosing and treating ASD.

- In the Canvas Dx Pivotal Study, there is no evidence of device performance inconsistency across sex, race/ethnicity, income, or education level.
- By reflecting the demographics of the general population in the U.S., the Canvas Dx Pivotal Study demonstrated how Canvas Dx has the potential to perform consistently across a diverse population.
- The consistency in the performance of the Canvas Dx Pivotal Study when HCP assessments were performed remotely suggests that this device has the potential to facilitate equitable access to ASD diagnoses regardless of location.
- Use of Canvas Dx has the potential to reduce geographic barriers to care and open the door to expanded diagnostic opportunities in rural and underserved communities.
- Canvas Dx provides consistent results across a diverse population and may be used remotely, which may lead to earlier ASD-specific intervention, which in turn could lead to better long-term developmental outcomes.

Use of Canvas Dx requires a smartphone and a prescription and a primary care provider, which may present access challenges in some populations.

Potential Comparative Effectiveness

Until now, there have not been widely-available ASD diagnostic tools designed specifically for use in the primary care setting—Canvas Dx is the first ASD diagnosis aid with FDA marketing authorization.

- There is no widely accepted biomarker or medical test (eg, laboratory or genetic test) to diagnose ASD.
- Current standard of care assessments made by specialists are time-intensive, subject to interpretive bias, and require extensive training, limiting their use in the primary care setting.
PCPs who completed the Canvas Dx questionnaire reported the time it took was approximately 10 minutes.

- Current specialist tools have not been validated for use in a remote setting. The consistency in the performance of the Canvas Dx Pivotal Study when HCP assessments were performed remotely suggests that this device has the potential to facilitate access to ASD diagnoses regardless of location.

**Potential Economic Value**

Use of Canvas Dx in the primary care setting may allow children with ASD to be diagnosed over 1.5 years earlier than the current average age of diagnosis. The use of Canvas Dx to help pediatricians in diagnosing or ruling out an ASD diagnosis in the primary care setting may allow for more efficient specialty referrals, potentially streamlining the diagnostic process. Direct medical cost savings per early patient diagnosis are estimated to be $817,114 - $1,347,740 (in 2021 dollars) over 50 years (Sharpe DL., 2011; [CPI inflation calculator](https://www.cpi-inflation.com/)). Use of Canvas Dx may result in cost-savings related to the shortened path to an ASD diagnosis for children with concern for developmental delay.

Diagnosis of ASD in the primary care setting may help shorten the diagnostic journey and facilitate earlier ASD-specific interventions. For families for whom there may be concern of ASD, and for those who receive a “negative for ASD” output, Canvas Dx may minimize use of specialists to rule out ASD. In addition, Canvas Dx has the potential to reduce geographic barriers to care, potentially enabling expanded diagnostic opportunities in rural and underserved communities.

**Potential Benefits for Children and Families**

The impacts of ASD include decreased parenting efficacy, increased stress, and increase in mental and physical health problems (Karst JS, Van Hecke AV, 2012). ASD imposes significant financial strain and time pressures, and results in high rates of divorce and lower overall family well-being. Over 50% of families with a child diagnosed with ASD report parental need to reduce work time or resign from work to provide needed care (Kogan MD, Strickland BB, Blumberg S, et al., 2008; Parish SL, Cloud JM., 2006).

Use of Canvas Dx in the primary care setting may allow children with ASD to be diagnosed over 1.5 years earlier than the current average age of diagnosis. Diagnosis of ASD in the primary care setting may help shorten the diagnostic journey and facilitate earlier ASD-specific interventions which can in turn improve lifelong outcomes for children.

- Earlier age of diagnosis and intervention—before the age of 4— is among the contributing factors that may help up to 25% of children with ASD progress beyond the original ASD diagnosis (Helt M, et al. 2008).
- Improvements in the domains of cognitive function, behavior, educational achievement, child maltreatment, health/accidents/injuries, and crime have been documented.

In addition, ruling out ASD in the primary care setting may spare those children and families from further diagnostic processes or interventions that are not necessary.

**Topic 6: Governance programs, practices or procedures applicable to the context, scope, and data use of a specific use case**
Cognoa’s practices regarding data collection, useage, safeguards for the approved use of data, and post-deployment are in compliance with HIPAA and applicable privacy laws and include the following:

**Data Collection**
- Measures taken to ensure users are aware of what data is being collected and what it is used for, and that users consent to such collection and use
- Measures taken to ensure data is representative of the target population across all relevant demographic dimensions including gender, age, race, ethnicity, geography, level of education, socio-economic status
- Measures taken to ensure a sufficiently sized, sufficiently representative segment of data is held aside for validation and not used to train or tune the algorithms
- Best practices applied to securing access to data in a matter well controlled and logged and audited, with data access and sharing policies automatically applied
- Best practices applied to sharing data with 3rd parties and getting data from 3rd parties through data partnerships

**Data Use**
- Safeguards around the storage and access of data such that appropriate data access policies are enforced and automated data governance is applied in the right contexts. For example, data must be deidentified/anonymized for access purposes related to aggregate analysis and model training/validation.
- Safeguards around the use of data to create algorithms that power products and services consistent with our mission
- Safeguards and best practices to ensure data is only used as consented to during data collection
- Log trails to ensure all data use is documented and auditable
- Endeavoring to ensure any future product or service is validated and performance-gauged on data that is representative of the intended target population

**Post Deployment**
- Ongoing monitoring of device performance and data integrity through audits and summary metrics