

An integrated system of tools and technologies designed to optimize collection of behavior and biosensor data in clinical ASD trials.

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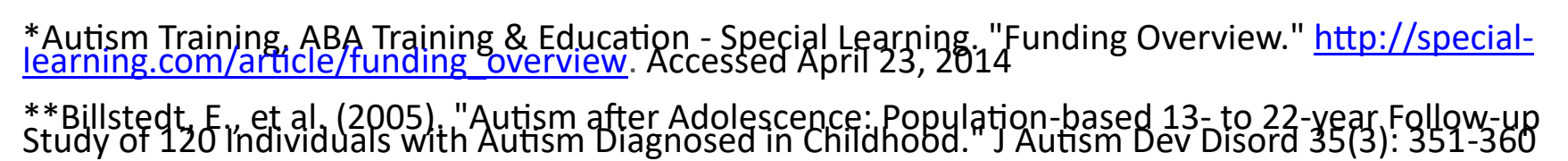
Autism spectrum disorder (ASD) is a developmental disability that can cause significant social, communication and behavioral challenges. Given the high incidence of ASD, the significant unmet medical need, and long term associated morbidity, there are multiple facets of the disorder that could benefit from novel treatments. The JAKE system is an exploratory integrated system of tools and technologies designed to optimize collection of behavior and biosensor data for research purposes in clinical ASD trials. It consists of various components including My JAKE and JAKE Sense. My JAKE is an interface to an autism personal healthcare record with tools and technologies tailored to individuals with ASD, and their caregivers/parents and healthcare providers. JAKE Sense is an experimental workbook that contains selected biosensors to assess physiological characteristics and behavior related to core symptoms of ASD. Currently, the JAKE system is exploratory, but it may potentially lead to detecting changes in response to treatment and be utilized as endpoint for interventions in ASD.

Autism spectrum disorder (ASD) is a developmental disability that can cause significant social, communication and behavioral challenges. There are currently no medications approved for the treatment of core symptoms of ASD. Given the high incidence of ASD (1 in 59 births in the USA), the significant unmet medical need, and long-term associated morbidity, there are multiple facets of the disorder that could benefit from novel treatments.



The total costs per year for children with ASD in the United States were estimated to be between \$11.5 billion – \$60.9 billion (2011 US dollars). This significant economic burden represents a variety of direct and in-direct costs, from medical care to special education to lost parental productivity.

Atypical antipsychotics **target only associated symptoms** of aggression and irritability



Previous studies supported the usability of the JAKE System for monitoring clinical outcomes in ASD.

MENTIS-HV-001 : Tested some biosensors in Janssen employees

MENTIS-AUT001 : Tested some biosensors and simple software in ASD children

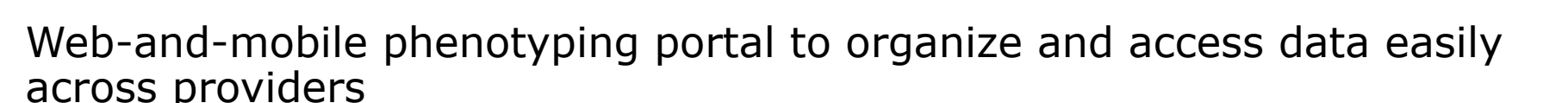
MENTIS-HV-002 : Compared our selected biosensors to gold-standards in HVs in a lab setting

MENTIS-ASD-001: Testing the full JAKE System in ASD and (not-typically developing (NT) children and adults ~30 subjects to date

MENTIS-ASD-002: Tested the final system in 150 ASD subjects and 30 NTs, with attempt to detect changes due to coincident behavioral

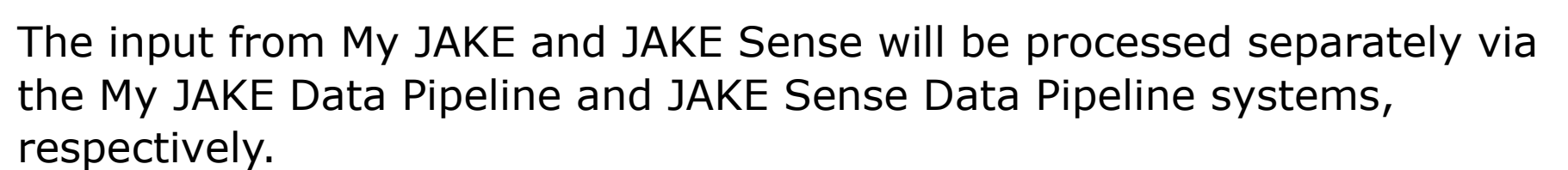
interventions. Study identified the combination of biosensors and task/stimuli is most likely to be able to detect changes in response to treatment.

42165279AUT2001 is the **first exploratory study including drug treatment** to assess the utility of the JAKE System as an endpoint for interventions in ASD



JAKE Sense includes selected biosensors to assess physiological characteristics and behavior related to the core symptoms of ASD. It is divided into two primary components:

- continuous, wearable biosensors that gather information on a daily basis
- periodic biosensors designed to gather feedback during a battery of experimental tasks administered via computer in a lab setting.



Data transfer mapping specifications

My JAKE— Analytics Data element

Extracted features—cvs files

Data transfer mapping specifications

SDTM clinical database

CONCLUSION

Currently, the JAKE system is exploratory, but it may potentially lead to detecting changes in response to treatment and be utilized as endpoint for interventions in ASD.

References

Center for Disease Control and Prevention. Autism Spectrum Disorders; Data and Statistics. <http://www.cdc.gov/ncbddd/autism/data.html>. Accessed August 21, 2019

Ness et al. (2017); JAKE® Multimodal Data Capture System: Insights from an Observational Study of Autism Spectrum Disorder: *Front. Neurosci.*