

# JANSSEN AUTISM KNOWLEDGE ENGINE (JAKE®) SYSTEM IN AUTISM SPECTRUM DISORDER

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## ABSTRACT

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 workbench that contains selected biosensors to assess physiological characteristics and behavior related to core symptoms of ASD. The input from My JAKE and JAKE Sense will be processed separately via the My JAKE Data Pipeline and JAKE Sense Data Pipeline systems, where raw data are archived, and feature extraction occurs. Data collected through the JAKE Sense Workbench, a platform that will link together and synchronize all components of the Periodic Biosensor collection as well as the Continuous Biosensor while presenting the JAKE Task Battery, is transmitted directly to the JAKE Sense Data Pipeline, and further mapped to SDTM. My JAKE reads and writes to individual HealthVault (HV) accounts and uses HV as the primary source of health data and subject authentication. My JAKE will have access to the full HV account, but any data transferred to the clinical database will be scrubbed of personally identifiable information. My JAKE data is translated in a multiple csv file structure described in the Analytics Data Elements (ADE), which is utilized as specification document for SDTM mapping.

## INTRODUCTION

Autism spectrum disorder (ASD) is a developmental disability that can cause significant social, communication and behavioral challenges. 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.

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 United States of America [USA]), the significant unmet medical need, and long-term associated morbidity, there are multiple facets of the disorder that could benefit from novel treatments.

Physiological and psychological instruments designed to detect change over time in core and associated symptoms of ASD are lacking. As ASD is a neurodevelopmental disorder with its roots in brain structure and function, it is reasonable that physiological and psychological measurements that assess this structure and function would be useful. In addition, monitoring of ASD symptoms in naturalistic settings will likely both improve care of people with ASD and yield insights into the condition. Such tools are needed to address significant unmet medical needs for improved diagnosis and expanded treatment options in ASD, and to develop novel therapies that target core and associated symptoms.

## THE JAKE SYSTEM

The JAKE system is an exploratory integrated system of tools and technologies designed to optimize clinical trials for ASD. Previous studies supported the usability of the JAKE System for monitoring clinical outcomes in ASD. It consists of three components:

- My JAKE: a web and mobile application for use by caregivers and clinicians to log symptoms, record treatments, track progress, and gather comprehensive medical information.
- JAKE Sense: research biosensors and tasks designed to detect and monitor changes in experimental, proof-of-concept ASD biomarkers.
- JAKE Stream: a system designed to collect, time-synchronize, and process data from both My JAKE [My JAKE Data Pipeline] and JAKE Sense [JAKE Sense Data Pipeline]).

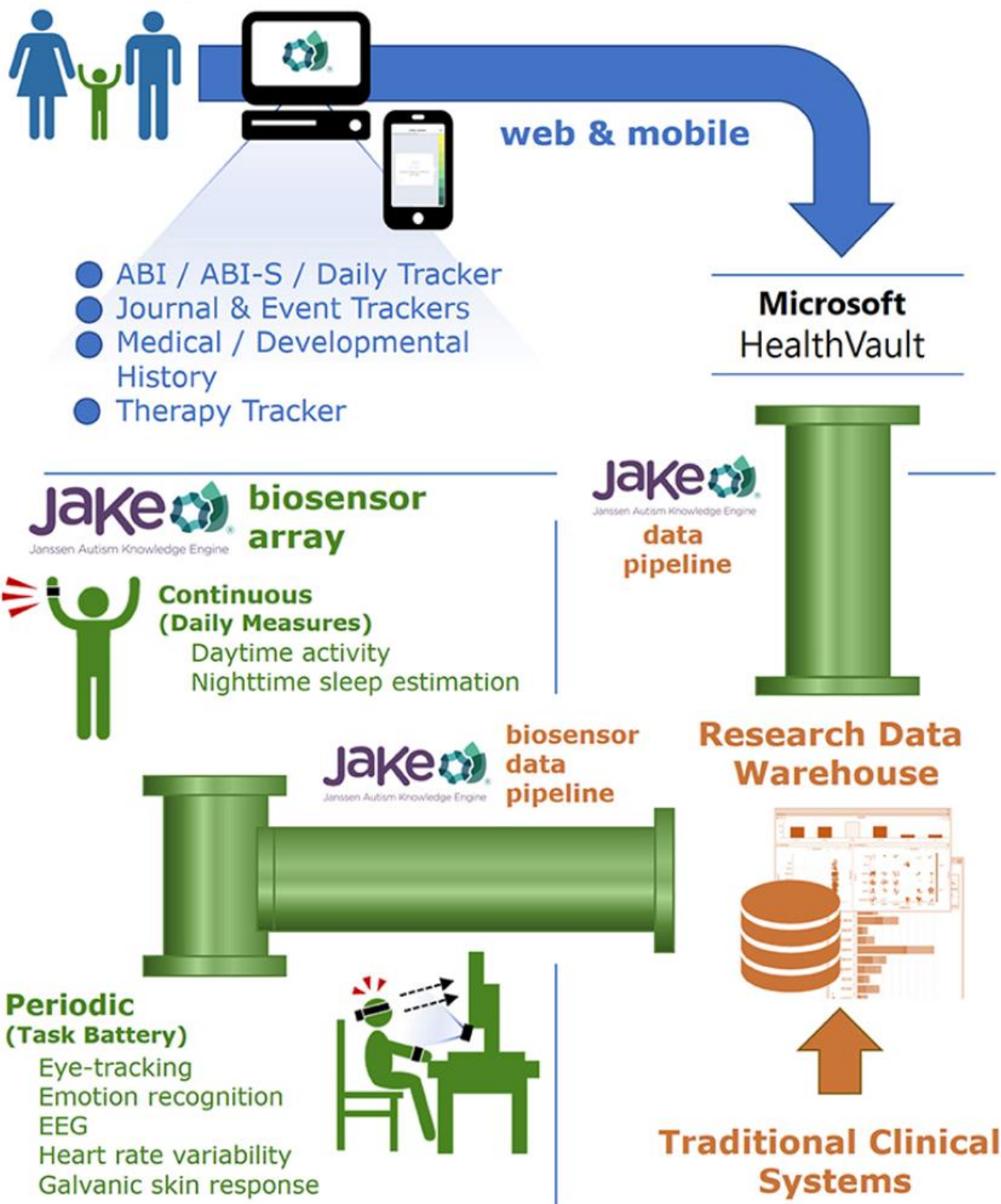
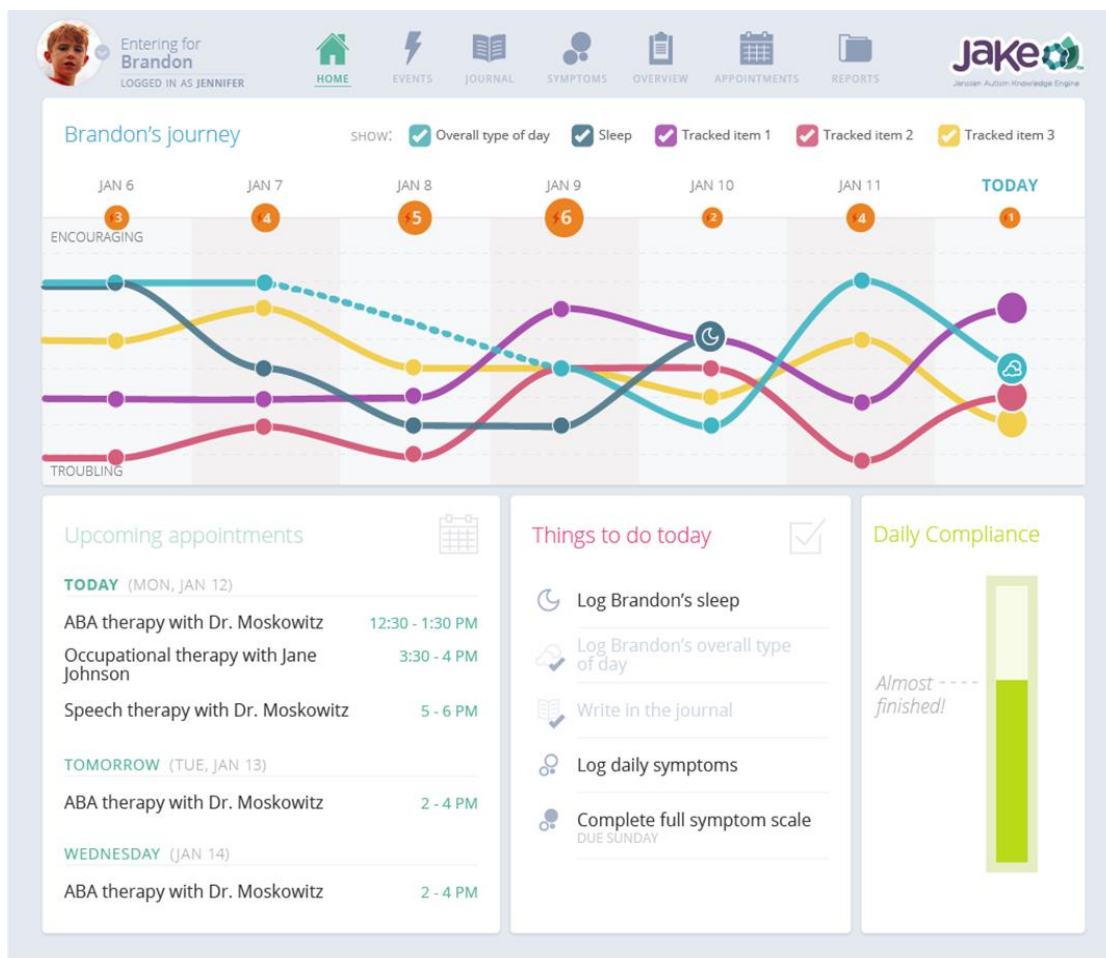


Figure 1. The following schematic shows the overall structure of the JAKE System and its data flows.

## My JAKE

My JAKE is a web and mobile application (iOS+/Android+) consisting of various modules to help caregivers and healthcare providers who support individuals with ASD to log symptoms, demarcate events of interest, record treatments and medical information, and track overall study progress. People with ASD often have problems with social, emotional, and communication skills. They might repeat certain behaviors and might not want change in their daily activities. Many people with ASD also have different ways of learning, paying attention, or reacting to things. Signs of ASD begin during early childhood and typically last throughout a person's life.

Currently there are no measures which have been specifically designed to measure change in behavior in ASD. This impacts the development of new treatments for autism, since effectiveness cannot be established and compared across interventions. Many of the existing ASD scales have been developed to diagnose and classify, rather than detect change over time. My JAKE is designed to capture sufficiently variable presentations across all the key domains, while providing a high level of utility – effectively making it simple for caregivers and other observers to record critical information on improvement or worsening of symptoms and behaviors.



**Figure 2. Web-and-mobile phenotyping portal to organize and access data easily across providers**

My JAKE is composed of the following components:

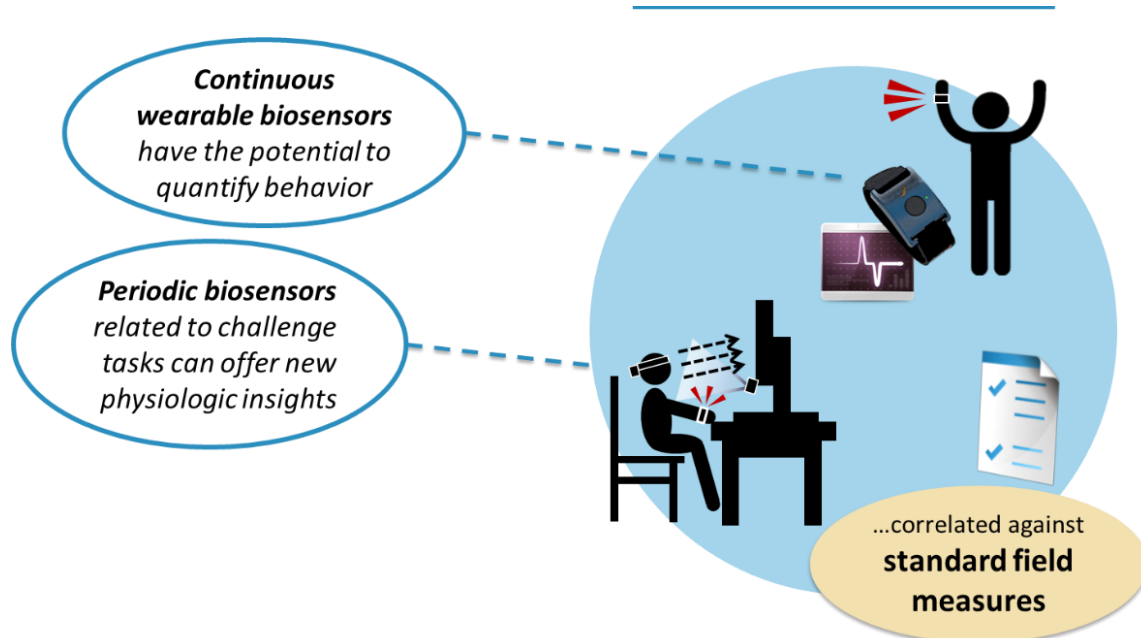
- ABI: A rating scale consisting of approximately 65 questions related to the core and associated symptoms of ASD.
- ABI-S: A shorter version of the ABI.
- Daily Tracker: In the morning, the caregiver will be asked to report on their dependent's quality of sleep the night before. Additionally, caregivers will be required to select 3 behaviors related to

ASD to track on a daily basis. After 6 PM each day, the caregiver is required to report on these behaviors and on their dependent's overall type of day. All reports use an 8-point scale, ranging from 'troubling' to 'encouraging'.

- **Mood Report:** A report that allows caregivers to report on the subject's mood, in terms of emotional valence and energy levels.
- **Journal and Event Trackers:** A tracking system that allows caregivers to quickly log key 'events' and text-based descriptions as they happen – such as a bad night's sleep or a positive improvement. This can be in the form of free-text journal entries or common ASD events from a picklist.
- **Therapy Tracker:** A calendar-like 'therapy tracker' that allows caregivers to keep track of their dependent's care-related appointments, organized in weekly or monthly views. In addition, it can keep track of treatments, and other therapies. It can also be used to set up and schedule study visits.
- **Medical/Developmental History:** A detailed medical and developmental history form designed to construct a picture of the subject's ASD including treatments and other information, and personalize the caregiver's view of this information.

### JAKE Sense

The literature has shown that differences between typically-developing (TD) children and autistic children can be detected by various physiologic and cognitive biomarkers. It is expected that biosensors will provide more direct characteristics of the ASD population than indirect assessment via questionnaires filled in by caregivers. It is also expected that changes in features extracted from the biosensors will be detected prior to changes observed in scales. 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: a set of continuous, wearable biosensors that gather information on a daily basis, and a set of periodic biosensors designed to gather feedback during a battery of experimental tasks administered via computer in a lab setting.



**Figure 3. 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.**

### Continuous biosensors

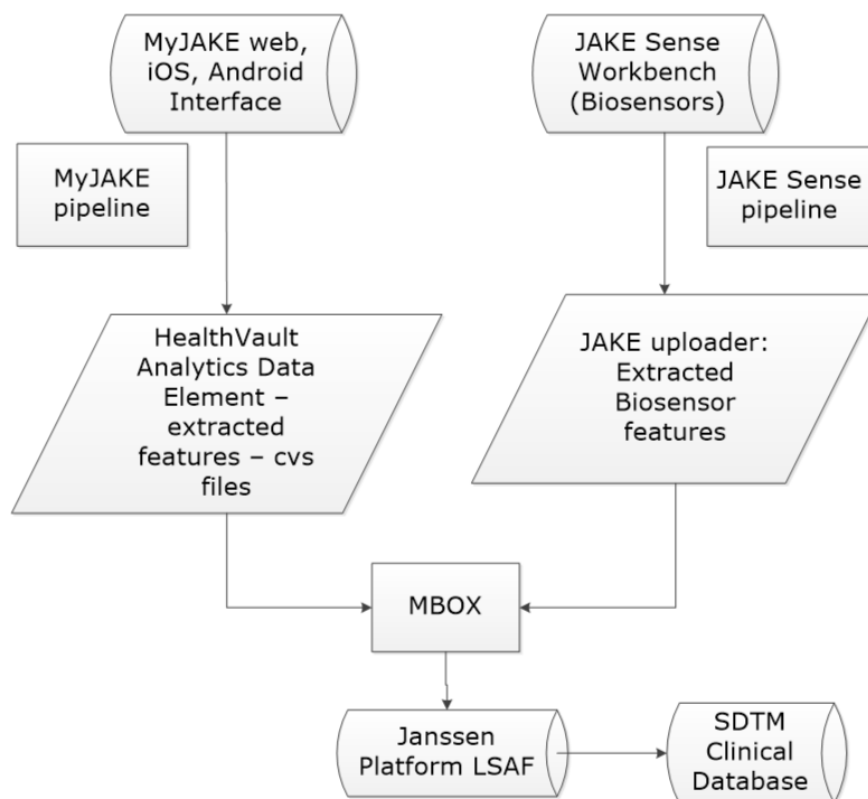
An actigraph measures activity while worn on a subject's wrist like a watch. Based on data recorded during the day, time periods of child involvement in sedentary, light, moderate, and moderate-to-vigorous activities are expected to correlate with disease severity, where an ASD population is expected to spend more time in sedentary activity, with less time in light, moderate and moderate-to-vigorous activity than TD children of the same age.

### Periodic biosensors

Periodic Biosensors will be assessed only during the time that the subject is exposed to specific visual and auditory tasks or stimuli via a computer interface (the JAKE Task Battery). The Periodic Biosensor array consists of an EEG, an eye-tracker, facial affect recognition via webcam, and a device for ECG recordings.

### **JAKE stream**

JAKE Stream was designed to collect and process data from both My JAKE and JAKE Sense. The input from both systems will be processed separately via the My JAKE Data Pipeline and JAKE Sense Data Pipeline systems, respectively. Inputs from the JAKE Portal and JAKE Sense all feed through the JAKE Data Pipeline, where raw data are archived, and feature extraction occurs. Finally, cleaned data and analyses are stored in the Janssen Research Data Warehouse (Janssen RDW) and combined with clinical trial databases.



**Figure 4. The input from My JAKE and JAKE Sense will be processed separately via the My JAKE Data Pipeline and JAKE Sense Data Pipeline systems, respectively.**

### **MY JAKE DATA PIPELINE**

My JAKE Data Pipeline (JDP) refers to all feature extraction methods, processes, and procedures, as well as the study data archive for maintaining traceability of all My JAKE datasets. My JAKE daily reads and

writes to individual HealthVault (HV) accounts and uses HV as the primary source of health data and subject authentication. My JAKE will have access to the full HV account, but any data transferred to the clinical database will be scrubbed of personally identifiable information. My JAKE data, transcribed to HV, is translated in a multiple csv file structure described in the Analytics Data Elements (ADE). The ADE document is utilized to map the relationships between the data elements in My JAKE (Web and Mobile) applications to Microsoft Healthvault and the My Jake Data Pipeline extracts. it contains the attributes, definitions, data mapping, and user roles for the My JAKE system. These data are linked with clinical trial data, to allow integration of multiple experimental features and novel variables into analyses.

### **JAKE SENSE DATA PIPELINE**

JAKE Sense Data Pipeline (JSDP) refers to all feature extraction methods, processes, and procedures, as well as the study data archive for maintaining traceability of all JAKE Sense datasets. It is designed to process and extract biometric features from data packages provided by JAKE Sense. After packages are archived to ensure traceability of derived analyses, a collection of MATLAB utilities scanned the packages to produce a series of extracted features as flat.CSV-formatted files transmitted via the secure file transfer protocol application MBOX sent to the Janssen data management department.

### **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.

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