

CEREMETRIX™

Executive Summary

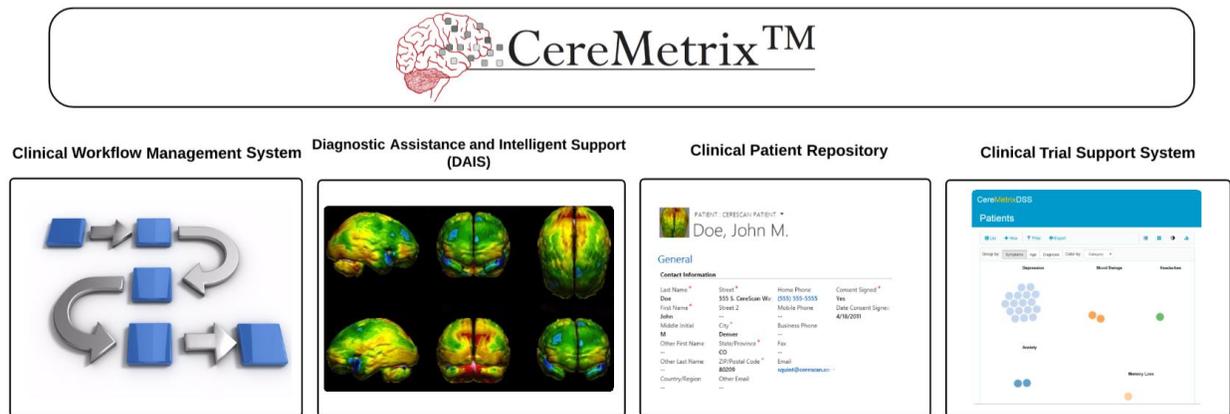
I. INTRODUCTION

CereScan, a company dedicated to providing the most accurate, comprehensive brain diagnoses available, continues to pursue disruptive changes in brain health standards of care by improving our already successful protocols and processes. CereMetrix™ is CereScan's patented database, which is a multifaceted entity that currently provides the architecture for our protocols and stores patient data for diagnosis and future analysis. As its utility expands, CereMetrix™ will eventually automate substantial components of image data analysis, assist reading and diagnosing physicians, provide intelligent information for treatment decisions, track patient outcomes, and contain searchable, accessible datasets for clinical trials and research (Figure 1). These functions, both established and in development, are expatiated in the following sections:

- Clinical Workflow Management System
- Diagnostic Assistance and Intelligent Support
- Clinical Patient Repository
- Clinical Trial Support System

This paper describes the current status of CereMetrix™ and the roadmap for future developments and applications. By implementing these strategies, CereScan will improve the quality of patient care and open opportunities for research initiatives across a broad spectrum of medical specialties.

Figure 1



Clinical Workflow Management System

The primary clinical user interface of the CereMetrix™ system is the Clinical Workflow Management System. This module is used to track patients from initial inquiry, through the imaging process, to the preparation of the final diagnostic report. To ensure each patient receives a consistent and thorough diagnostic procedure that follows ACR (American College of Radiology) guidelines, the workflow verifies required checkpoints at each step in the process. There are currently nine steps, each with information that must be acquired before advancing to the next step: Gather Data, Qualify, Schedule, Intake Process, First-Scan Prep, Concentration Scan, Baseline Scan, Physician Reading, and Patient Review.

A critical module to be added in the future is the Diagnostic Assistance and Intelligent Support system, described below. All patient intake information, scan data, and assessments will be stored in a searchable, HIPAA-compliant, de-identified database with various search criteria such as symptomology, prior diagnoses, traumas, family history, and other data. The indexing of this data allows patterns or similarities to be found between the current patient and previous ones within the database. Upon the implementation of this module, the referring physician will have access to a matching patient registry along with their diagnoses, treatment options and outcomes. This registry will aid the physician in determining the most appropriate treatment plan for the patient. Once established, CereMetrix™ will track the treatments and outcomes of the patient for future reference with new patients.

Diagnostic Assistance and Intelligent Support system

The Diagnostic Assistance and Intelligent Support (DAIS) system will improve multiple aspects of the CereScan workflow. DAIS is primarily designed to assist the physician during the diagnostic process and will provide results derived from the combination of quantitative SPECT data and the clinical information from the patient's Intake Package. The vision of DAIS is to increase the reading speed and accuracy of physicians while strengthening their confidence in their diagnoses. As a tool created to analyze current and historic patient data, all information will be stored and accessible within CereMetrix™ for future use.

Processing SPECT brain scans is the first task of DAIS. CereScan will continue to utilize third-party normative databases for comparison and processing of each new patient brain scan. Each SPECT patient dataset generates a 64 x 64 x 64 matrix of voxels with each voxel containing counts of gamma rays. These counts are direct measures of cerebral blood flow, i.e., the more counts, the more blood flow. Voxels can be grouped into regions of interest (ROIs), such as anatomical structures, function-specific areas and sub-regions in the brain. Once processed, the blood flow in each voxel within the patient data is mathematically measured against each corresponding voxel in the normative database. The result classifies each voxel as having "normal" or "abnormal" perfusion levels. To visualize differences in blood flow, a color map is generated from this voxel data and applied to the images.

Abnormal voxels do not typically occur in isolation. Usually, clusters of abnormal voxels are observed throughout the brain as a result of injury or disorder. Morphological image processing will allow these clusters to be located and measured to determine their impact on the physiological function of each ROI. CereScan's reading physicians initially interpret each brain scan without any biasing clinical information or other data about the patient. The pre-populated brain activity worksheet will allow the physician to simultaneously interpret the processed images and analyze mathematically-derived data. The

physician will be able to add comments directly to the worksheet based on experience, analysis and visual interpretation of the images. When utilized, commenting the activity worksheet will document the physician's thought process for future reference. After synthesizing the objective, quantitative results, the physician will record his or her initial impressions.

Finally, DAIS has potential applications for many other imaging fields. Medical imaging, in any modality, requires physician interpretation. Implementing clinical decision support systems into any medical imaging workflow will improve the speed, accuracy, consistency, and validity with which images are read. Thus, our DAIS system may be morphed into one that can be used for any number of modalities.

Clinical Patient Repository

The clinical patient repository module of CereMetrix™ is the backbone of the system and necessary for the other modules to work. This database is configured to be a one-to-many relationship between the patient data and the multiple visits to a CereScan facility for imaging and other diagnostic purposes. When utilized with multiple Scan Encounters, this data structure will allow tracking of quantitative changes in brain function over time. This ability will prove particularly valuable when investigating the impacts of interventions on brain function and patient quality of life. Additionally, protocols and algorithms will be established in order to provide a system to measure the progression or amelioration of certain brain disorders.

The primary purpose of the Clinical Patient Repository is to catalog pertinent clinical patient information and imaging data in order to build a comprehensive brain evaluation system; it is critical to the functionality of the Decision Support System and DAIS. The results of this searchable, HIPAA-compliant database will provide better diagnostic and research tools to the medical community. CereMetrix™ is one of a kind and will offer unique opportunities to advance the understanding of brain dysfunctions and thus improve patient outcomes. CereMetrix™ currently has over 3400 patients and is ever-growing. The larger the database of image and patient clinical data, the better the diagnostic intelligence contained in the data.

Clinical Trial Support System

The Clinical Trial Support System is a critical module that will be available for researchers via the SAAS offering. This module may be customized and implemented independently as an analytical and informatics tool for either clinical or research applications. The analytical piece will enable users to perform patient-to-patient and patient-to-normal assessments in order to monitor disease progression or to compare pre- and post-intervention perfusion levels. This module will be designed to meet the requirements of *Informatics for Integrating Biology and the Bedside* (i2b2; developed by NIH) to aid cohort identification, hypothesis generation, and retrospective data analysis.

Conclusions/Outlook for Future

CereMetrix™ is a multifaceted intelligent diagnostic system that continually gets smarter with each patient added to the database. Better diagnoses will lead to better treatments, better patient outcomes, and lower healthcare costs. Future versions will refine the brain diagnostic process while exploring its adaptation for other imaging modalities. This system is geographically independent and can be utilized anytime, anywhere in a low-cost, tele-medicine model available to all practitioners. The system's ability to extract quantitative data from brain scans and correlate that data with symptoms and outcomes will change

the way medical imaging is used. This unique approach will open the door to a revolutionary diagnostic breakthrough in healthcare.