**EXECUTIVE SUMMARY**

**THE PROBLEMS:** In Canada, the USA and Australia 20% of the population suffer from a mental illness, 9% to 14% of adults take an antidepressant medication (ADM) and suicide is a leading cause of death. While good psychiatric training and clinical experience are crucial determinants of outcome, current “best practice” management is driven entirely by clinical interview and observation. However, in the absence of validated biomarkers, diagnosis is often inaccurate and delayed[1] and treatment choice is often suboptimal. Studies have shown that, on average, 5 years of symptoms and 4 psychiatric assessments are required before ta diagnosis of bipolar disorder is correctly made [1, 2]. Currently decisions about effective treatment are informed by the results of clinical trials conducted in large numbers of study participants. Although the average clinical response might be good many individuals do not respond well, likely due to individual biological differences. A large clinical trial to test current patterns of treatment choice (Sequenced Treatment Alternatives to Relieve Depression or STAR\*D trial) [3] revealed that only 37% reached full remission with the first medication employed. Consequently most experts regard the current “best practice” method of antidepressant selection as “serial trial and error”. Suicide risk assessment is similarly inaccurate. In their scientific review of all suicide risk assessment methods over the last 50 years of research Franklin et al concluded that risk prediction was “only slightly better than chance”[4]. These startling inefficiencies of current psychiatric practice lead to much potentially avoidable suffering, lost productivity, increased healthcare costs and greater risk of death by suicide.

**OUR SOLUTION:** Every psychiatric illness is the consequence of altered brain functioning. As the brain is essentially an electrical organ, measures of brain electrical activity, made using the electroencephalograph (EEG), might contain information of great relevance to the diagnosis and treatment of mental illness. Over the past 2 decades the scientists who founded Digital Medical Experts Inc (DME) have developed artificial intelligence algorithms (AIAs) capable of analyzing an individual’s EEG to render highly accurate diagnoses, precise estimates of response probability across a variety of different forms of psychiatric treatment and a highly accurate and non-verbal method of suicide risk assessment.

**HOW OUR SYSTEM WORKS:** Our suite of AIAs have been trained to make clinical decisions using clinical, electrophysiological and epidemiological data collected from over 2000 patients and healthy volunteers (see Appendix 1). These data include EEG and information on i) diagnosis, ii) personality, iii) social support, iv) symptom severity, v) physical and mental disability, vi) cognitive functioning and vii) suicide risk, viii) response to different forms of treatment. Our AIAs use complex computational methods uncover patterns within the dataset that can be used to accurately determine the diagnosis, treatment response profile and suicide risk. Once the relevant pattern has been identified it can be calculated in seconds using a few minutes of EEG collected either in a hospital laboratory or, using portable EEG equipment, in an office setting.

**DIAGNOSIS:** DME AIAs have identified specific electrical interactions that are associated with particular psychiatric illnesses. In our first study in 207 persons our AIA’s could differentiate healthy volunteers (HV) from persons with Bipolar Disorder-depressed phase (BD-D), Major Depressive Disorder (MDD) and Schizophrenia (SCZ)[5] with 85% accuracy. More recently in 648 persons emplying more complex EEG connectivity analyses, we were able to differentiate MDD, atypical MDD, psychotic MDD, BD-D, Bipolar disorder -manic episode, SCZ and HV with over 90% accuracy [6].

**TREATMENT RESPONSE:** In our earliest study we built an AIA that employed resting EEG in 22 subjects to predict response to sertraline with 88% accuracy [7]. These findings were replicated by an independent group in 34 subjects[8]. Subsequently, using the data from 224 persons and more advanced analytic methods, our AIA’s predicted response to sertraline [9] and to bupropion [not yet published] with accuracy ranging from 89 to 94%. We have tested these methods for other forms of treatment as well as ADM. Our AIAs generated treatment response profiles with accuracy of 79-90% in the prediction of response to the antipsychotic clozapine[10, 11], cognitive behaviour psychotherapy[12], and repetitive transcranial magnetic stimulation [13]. We were able to predict response to placebo medication in a multi-centre randomized ADM study [9]. Prediction of placebo response would be of interest to pharmaceutical companies doing clinical trials of new psychotropic medications.

**CONFIRMATION BY OTHER GRUPS:** The utility of AIAs in the prediction of response to antidepressant treatment has been independently confirmed by independent researcher groups [8, 14]. A recent meta-analysis of 15 studies using AI to predict antidepressant treatment response reported sensitivity of 83 % and a specificity of 86 % [15].

**ASSESSING SUICIDE RISK:** In our first study we employed AIA’s to analyze questionnaire data collected from 800 military veterans. Our AIAs found that 10 non-suicide related items could identified those with suicidal thinking with 75% accuracy [16]. In our first EEG study, conducted in 68 depressed persons, we were able to use the EEG alone to identify suicidal ideation with 70% accuracy (unpublished). Most recently, using EEG connectivity measures across 81 brain regions calculated in 60 depressed persons (matched for sex, race, ethnicity, marital status, the number of people living in the household, employment status, education, monthly household income, history of sexual or physical abuse) we were able to identify suicide risk with 89% accuracy (unpublished). It is important to note that 80% of those who die by suicide will deny suicidal ideation when asked [17].

**COST SAVING:** We estimate that our technology will generate savings of over $4000 in medical costs and $8000 in income replacement costs for each person treated for MDD or bipolar disorder. (see Appendix 2).

**PROVIDING EXPERT ADVICE REMOTELY:** In the USA, Canada and Australia there are 277,000 primary care physicians but only 58,500 psychiatrists. In the USA most of the 21 million mental health visits annually occur in the primary care setting. Portable EEG headsets and cloud-based data transfer protocols we have already operational would allow our technology to be used in any primary care office setting with internet access, including those in remote and under-serviced locations. In our test cases we have been able to provide a digital report within 1 hour of receiving the EEG data. We have created a consumer version of our technology intended for use by Universities, the Military and Industry to screen for mental illness and suicide risk.

**PATENT PORTFOLIO**

DME has been allowed patents in Canada ([Canadian patent website](http://brevets-patents.ic.gc.ca/opic-cipo/cpd/eng/patent/2715825/summary.html)), the USA<https://patents.google.com/patent/WO2009103156A1/en>, Australia (see [Aust patent website](http://pericles.ipaustralia.gov.au/ols/auspat/applicationDetails.do?applicationNo=2009217184))

**AWARDS and RECOGNITION**

2014, September 14: Canadian Psychiatric Association Annual Meeting, Toronto, Ontario, Canada:

**Representing Digital Medical Experts, Dr Hasey receives the 1st Place R.O. Jones Award for Best Paper.**  Title: *Building a Virtual Psychiatrist: Using Digital Technology to Assist With Diagnosis and Treatment Planning.* <https://www.newswire.ca/news-releases/psychiatrists-recognize-outstanding-contributions-to-mental-health-at-their-annual-conference-515619411.html>

2017, 25-28 October, 35th Brazilian Congress of Psychiatry, Sao Paulo, Brazil:

**Representing Digital Medical Experts,** Dr Hasey delivers a **keynote address** entitled: “Developing Artificial Intelligence Tools for Diagnosis and Treatment of Mood Disorders and Schizophrenia” <http://www.cbpabp.org.br/english/?p=3221>

2017, November 29-30, John H. Chapman Space Centre, Saint-Hubert, Quebec, Canada:

**Representing Digital Medical Experts,** Dr Hasey presents on “**Transforming Healthcare through Artificial Intelligence”** at the Canadian Space Agency meeting entitled “**Planning Canada's next chapter in human space exploration: health and biomedical roles”,** (see <http://www.asc-csa.gc.ca/eng/events/2017/planning-canada-next-chapter-human-space-exploration-health-and-biomedical-roles.asp> for program see <http://www.asc-csa.gc.ca/pdf/eng/events/2017/planning-forum-program.pdf>**)**

2018, October 10, Paris, France:

Digital Medical Experts is one of the first North American Companies to win the **Universal Biotech Innovation Prize** (Digitech category) offered by France’s Universal Biotech group

<http://www.universal-biotech.com/wp-content/uploads/2018/10/2018-10-Communique-de-presse-EN-compressed.pdf>

2018, November 29–30, Embassy of Canada to the United States, Washington, D.C.:

Digital Medical Experts addresses the North Atlantic Treaty Organization (NATO) **North Atlantic Treaty Organization Human Factors and Medicine (HFM)** section title . Leveraging Technology in Military Mental Health Big Data & Machine Learning, Meeting #4 see <https://www.cstsonline.org/assets/media/documents/NATO_Program_Nov29_30_2018.pdf>

2019 March 23

Digital Medical Experts receives the top score in the information technology category at the Sci Innovation China-CANADA competition at Toronto City Hall and is among the 20 (out of 200) Canadian companies invited to present their technology in Shenzhen China. <https://www.lawtimesnews.com/news/general/gowlings-advises-2019-sci-innovation-competition-winner/266865>

2020 October

Digital Medical Experts is accepted as a company to be mentored by the Creative Destruction Laboratory <https://www.creativedestructionlab.com>

2022 October 10

DME Scientists M Ravan and G Hasey are interviewed by IEEE Spectrum. Published article entitled “[AI Can Offer Insight Into Who Responds to Antidepressants](https://spectrum.ieee.org/at-last-insight-into-who-responds-to-anti-depressants) <https://spectrum.ieee.org/at-last-insight-into-who-responds-to-anti-depressants>

2022 Nov 21

Digital Medical Experts advances to tier 2 in theSci Innovation China-CANADA entrepreneurial competition

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**Appendix 1 (Training database)**

|  |  |  |  |
| --- | --- | --- | --- |
| **PRIMARY VARIABLES** | **STUDY TYPE** |  | **NUMBER OF SUBJECTS** |
| Standardized diagnosis plus 20-48 lead EEG with eyes open and eyes closed | Machine learning analysis of EEG data to make diagnosis  (Diagnosis and EEG data) | **DIAGNOSIS DATA** |  |
| Major depressive Disorder (MDD) | 169 |
| MDD atypical | 27 |
| MDD psychotic | 35 |
| Bipolar disorder-depressed phase | 84 |
| Bipolar disorder- manic Phase | 49 |
| Schizophrenia | 163 |
| Healthy Volunteers | 308 |
| Standardized diagnosis plus treatment response data including mood rating scales plus 20 lead EEG with eyes open and eyes closed | Machine learning analysis of EEG to predict Treatment response  (Diagnosis, treatment response, suicide and EEG data) | **TREATMENT TYPE** |  |
| SSRI antidepressants | 22 |
| Repetitive Transcranial Magnetic Stimulation | 82 |
| Clozapine | 37 |
| Cognitive Behaviour Therapy | 22 |
| Electroconvulsive therapy | 11 |
| Standardized diagnosis plus treatment response data including mood rating scales plus 20 lead EEG with eyes open and eyes closed | Diagnosis, treatment response suicide and EEG data | Sertraline bupropion or placebo | 238 |
| Test battery including, MINI, HVLT, RBANS, long form of the PAI, WHODAS and Beck Depression rating scale pre and post ECT | Machine learning analysis of pre-treatment cognition and personality to predict side effects and response to ECT  (Diagnosis, treatment response and suicide data) | Electroconvulsive therapy | 120 |
| SF-36, PHQ, PCL-Vs., History re Deployment, trauma, alcohol/drug abuse, supports, psych symptoms | Detect Suicidal ideation  Using questionnaire data  (Diagnosis and suicide data) | Various therapies | 821 |
| **TOTAL NUMBER OF INDIVIDUAL SUBJECTS IN ABOVE DATABASE** |  |  | **2188** |

**Appendix 2 (Insurance savings)Graphical user interface, application, table

Description automatically generated**