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Software for Evaluating Drug Induced Hepatotoxicity

Description of Technology: This invention pertains to a software tool for assisting differential medical diagnosis of drug-induced liver injury (hepatotoxicity) using clinical trial data. The software is capable of identifying a small subset of patients at risk for hepatotoxicity out of a pool of thousands of clinical trial participants. This software tool is the only one of its kind developed using SAS/IntrNet®.

Potential Commercial Applications:

- Hepatotoxicity detection
- Drug interactions

Competitive Advantages:

- Personalized predictions
 - SAS/IntrNet® compatible
- Development Stage: Prototype
Inventor: Ted J. Guo (FDA)

Publications:

1. Guo T, et al. A Tool to Help You Decide [detect potentially serious liver injury]. Silver Spring, Maryland: Presentation at the Annual Conference of the American Association for the Study of Liver Diseases, 2008.

2. Guo T, et al. How a SAS/IntrNet tool was created at the FDA for the detection of potential drug-induced liver injury using data with CDISC standard. San Diego, California: Proceedings of the Western Users of SAS Software Annual Conference, 2009.

3. Watkins PB, et al. Evaluation of drug-induced serious hepatotoxicity (eDISH): application of this data organization approach to phase III clinical trials of rivaroxaban after total hip or knee replacement surgery. *Drug Saf.* 2011 Mar 1;34(3):243–52. [PMID 21332248]

Intellectual Property: HHS Reference No. E–103–2012/0—Software Tool. Patent protection is not being pursued for this technology.

Licensing Contact: Michael Shmilovich; 301–435–5019; shmilovm@mail.nih.gov.

Hexanucleotide Repeat in the C9orf72 Gene for the Diagnosis and Treatment of Amyotrophic Lateral Sclerosis and Frontotemporal Dementia

Description of Technology: This invention relates to the discovery of a pathogenic GGCCCC hexanucleotide repeat expansion in the first intron of the C9orf72 gene on chromosome 9p21 in patients exhibiting amyotrophic lateral sclerosis (ALS) and/or frontotemporal dementia (FTD). The

inventors have previously identified a strong association signal in this genomic region and used this information to identify the underlying pathogenic mutation. The pathogenic repeat expansion accounts for up to 50% of familial ALS and familial FTD cases and up to 10% of sporadic ALS and sporadic FTD cases in European ancestry populations. The inventors represent that this finding will be the basis of diagnostic screening for ALS and/or FTD patients, as well as an important target in the development of therapeutics for ALS and/or FTD.

Potential Commercial Applications: Diagnosis and treatment of ALS and/or FTD.

Competitive Advantages: Improved diagnosis and treatment of ALS and/or FTD.

Development Stage: In vitro data available

Inventors: Stuart Pickering-Brown (The University of Manchester), Bryan Traynor (NIA), Andrew Singleton (NIA), Huw Morris (Cardiff University), Peter Heutink (Vu University Medical Center Amsterdam), John Hardy (University College London), Pentti Tienari (University of Helsinki)

Intellectual Property: HHS Reference No. E–275–2011/0—

- US Provisional Application No. 61/529,531 filed 31 August 2011
- PCT Application No. PCT/GB2012/052140 filed 31 August 2012

Licensing Contact: Jaime M. Greene; 301–435–5559; greenajaime@mail.nih.gov

Dated: December 19, 2013.

Richard U. Rodriguez,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2013–30745 Filed 12–24–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center For Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material,

and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict; Biological Chemistry and Macromolecular Biophysics.

Date: January 6, 2014.

Time: 1:00 p.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: John L. Bowers, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4170, MSC 7806, Bethesda, MD 20892, (301) 435–1725, bowersj@csr.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Myalgic Encephalomyelitis/Chronic Fatigue Syndrome.

Date: January 16, 2014.

Time: 2:30 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Lynn E. Luethke, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5166, MSC 7844, Bethesda, MD 20892, (301) 806–3323, luethkel@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Program Project: Research Resources Reverse Site Visit.

Date: January 21–23, 2014.

Time: 7:00 p.m. to 12:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Crowne Plaza Washington, DC—Rockville Hotel, 3 Research Ct., Rockville, MD 20850.

Contact Person: Lee Rosen, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5116, MSC 7854, Bethesda, MD 20892, (301) 435–1171, rosenl@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: December 19, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–30747 Filed 12–24–13; 8:45 am]

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