From: Alliance for Digital Pathology

Subject: Alliance Updates and Opportunities

Date: Monday, May 11, 2020 5:44:58 PM

Good evening Alliance members,

The Alliance is working closely with the FDA and other agencies to progress collective goals. Don't forget to check out our most recent virtual update meeting on our new <u>YouTube channel</u> or our latest project updates on <u>the Alliance website</u>.

Other updates and learning opportunities:

**FDA Grand Rounds** is hosting an event on <u>Artificial Intelligence for Regulatory Science</u> Research

Thursday, May 14, 2020, 12:00 p.m. - 1:00 p.m. EST. Register here for webcast (CE Credit Available)

Presented by:
Weida Tong, PhD
Division Director, NCTR
National Center for Toxicological Research (NCTR), FDA

## About the Presentation:

Artificial Intelligence (AI) is a broad concept of training machines to think and behave like humans. It consists of a wide range of statistical and machine learning approaches to learn from the existing data/information to predict future outcomes. It has impacted a board range of scientific disciplines that are important to public health, ranging from clinical diagnosis and prognosis, drug and food safety, disease prevention, precision medicine and nutrition. The rise of AI has also offered both opportunities and challenges to regulatory agencies with questions such as (1) how to assess and evaluate AI-based products and (2) how to develop and implement AI-based application to improve the agencies functions. In this presentation, the current thinking and on-going efforts at NCTR in the area of AI will be discussed with examples from drug and food safety, natural language processing of regulatory documents, and biomarker discovery and development. The guiding principle and best practice of applying AI in regulatory science research will also be discussed with respect to the context of use and fit-for-purpose application.

What you'll learn from this FDA Animal Scientist:
Explain the basic principles and methodologies of AI
Describe different AI methods
Describe ways in which AI methods can be applied for drug and food safety, biomarker development and text mining

## The FDA's Enforcement Policy for Remote Digital Pathology Devices

FDA issued this "Enforcement Policy for Remote Digital Pathology Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency" guidance to provide policy and to expand availability of pathology devices during the pandemic. Devices covered by the

guidance include remote reviewing and reporting of scanned digital images of pathology slides.

"This policy is intended to remain in effect only for the duration of the public health emergency related to COVID-19 declared by HHS, including any renewals made by the HHS Secretary in accordance with section 319(a)(2) of the Public Health Service Act (42 U.S.C. 247d(a)(2))."

The Alliance approached the problem through CMS/CLIA, to allow temporary remote signout during the COVID-19 pandemic. See our Q&A on the resulting allowance with Dr. Richard Huang here.

There are many ways to get involved with Alliance projects, all while remaining socially distant! **Email us to get started.** 

We hope that you continue to stay safe and we look forward to continuing to work alongside you to transform the field of Digital Pathology.

Sincerely,

The Alliance for Digital Pathology digitalpathologyalliance.org

Join the Alliance

