**TUESDAY MORNING WORKSHOP (8:30 am – 11:30 am)**

**D. Machine Learning/Artificial Intelligence**

**Organizer/Chair: Kyoungah See, Eli Lilly**

1. Intro talk about AI for Drug Development

 **Speaker:  Phil Bowser, RStudio**

Posit/RStudio will be presenting an overview of AI for Drug Development. This short talk will provide an update on tools in the AI space and investments by Posit/RStudio. This is a great opportunity to learn about new tools for drug development such as Hugging Face, ChatGPT, PyTorch, TensorFlow and others. Talk will highlight interoperability and the capability of these different languages to work together harmoniously. This workshop will focus on the interoperability of the top 2 programming languages in the data science space, R and Python, and how they can be combined to achieve great results for your clinical workflow.

2. Let's Deploy an AI Model

 **Speaker:  Phil Bowser, RStudio**

In this talk, Posit/RStudio will walk through the MLOps concept of Model Monitoring by deploying a model as a RESTful API using Plumber. Users will get a chance to see live what it is like to deploy an AI model. Talk will discuss the landscape for AI (Hugging Face, ChatGPT, PyTorch, TensorFlow and others) and Tidymodels. We will highlight a collection of packages for modeling and machine learning using tidyverse principles. In this session we'll introduce Tidymodels and functions from rsample, recipes, parsnip, and yardstick. You'll learn how to split data, fit a model, predict, and compare outcomes with a workflow that easily allows you to change and compare model types. We’ll use a Quarto document to regularly assess model performance by:

Sending the deployed model new observations via httr
Evaluating how the model performed with these new predictions using model metrics from yardstick
Versioning the model metrics using the pins package
Summarize and visualize the results using flexdashboard
Schedule the R Markdown dashboard to regularly evaluate the model and notify us of the results

We will also review the vetiver package to provide fluent tooling to version, share, deploy, and monitor a trained model.

3. Machine Learning for Precision Medicine

**Speaker: Xin Huang, AbbVie**

In this talk, we discuss how machine learning methods can be applied for predictive biomarker discovery and development, and how it is related to the causal inference framework and to apply on treatment responder subgroup identification problems.

**4. Identify and Characterize Super-Responder Profile: Application of ML**

**Speaker: Kyoungah See, Eli Lilly**

 What is the Patient Profile That Could Benefit from Ixekizumab the Most?

Identify and characterize ”Super Responder” patient profile based on individual response trajectories and assess any prediction factors for IXE long-term efficacy. A two-Step Strategy with GMM (clustering) and CART (identify predictors) will be discussed.

**TUESDAY AFTERNOON WORKSHOP (1:30 pm – 4:30 pm)**

**D. Machine Learning/Artificial Intelligence**

**Organizer/Chair: Kyoungah See, Eli Lilly**

1. Statistical versus Machine Learning and Natural Language Processing Approaches in the Assessment of Drug Induced Liver Injury

 **Speaker: Melvin S. Munsaka, AbbVie**

Drug Induced Liver Injury (DILI) is a leading cause of acute liver failure. Severe DILI is a life-threatening illness and mild-to-moderate DILI can reduce availability of effective therapies. It is thus not surprising that DILI is a leading cause of drug withdrawal from the marketplace and the most common cause of Food and Drug Administration (FDA) regulatory action, including label changes and boxed warnings. Both the FDA and the Council for International Organizations of Medical Sciences (CIOMs) have issued guidelines governing the assessment of DILI. The pre-marketing safety assessment of DILI has traditionally leveraged clinical trial data, specifically, clinical laboratory data along with reported adverse events. With the current ongoing transformation of drug safety and pharmacovigilance, new data sources and analysis approaches have emerged, that can be used in enhancing the assessment of DILI both pre- and post-marketing. In this discussion, we will compare traditional statistical approaches versus machine learning (ML) methods including deep learning and natural language processing (NLP) in identifying and assessing DILI. Selected tools and software resources that can be leveraged for the analysis of DILI using ML methods will also be highlighted.

2. Generative Models for Diabetic Retinopathy Image

 **Speaker: Linsong Zhang, Purdue University**

In this talk, an analysis of diabetic retinopathy data will be presented. A two-stage approach will be discussed. In the first stage, a novel generative model will be used to simulate the vessel structure for diabetic retinopathy. In the second stage, another different generative model will be proposed to generate the details and other information based on a different stage of diabetes. Extensive simulations will be used and a new measure of the performance will be discussed in this talk as well.

3. Challenges of estimating individual treatment effects using machine learning

 **Speaker: Ilya Lipkovich, Eli Lilly**

In this talk we review recent advances in estimating individual treatment effects, or conditional average treatment effect (CATE), from randomized clinical trials and observational data using statistical/machine learning based strategies. We discuss common measures for evaluating performance of estimated CATE and illustrate some challenges using simulated data.