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DATE RECEIVED: ***02/07/2025*** *DATE APPROVED:* ***02/07/2025***

FILE NUMBER: ***#25-023***

APPLICATION FOR STATISTICAL CONSULTING

LAST NAME**:** Amin FIRST NAME: Sarwat

DEPARTMENT (full name): BME CAMPUS MAILING ADDRESS: MJIS

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YOUR PRIMARY POSITION AT PURDUE: PhD Student

Other:

(if a student) MAJOR PROFESSOR LAST NAME: Ward FIRST NAME: Matthew

PHONE NUMBER:

MAJOR PROFESSOR CAMPUS ADDRESS (BLDG & DEPT): BME / MJIS

MAJOR PROFESSOR EMAIL: mpward@purdue.edu

HOW DID YOU FIND US: Department of Statistics website

LIST STATISTICS COURSES TAKEN AND STATISTICAL COMPUTING EXPERIENCE: STAT 514

STAGE OF RESEARCH: Analysis (all data have been collected)

IF DESIGN STAGE IS COMPLETE, WAS A STATISTICIAN CONSULTED FOR DESIGN? Yes

PREVIOUS CONSULTANT – INSTITUTION/DEPARTMENT:

ESTIMATED NUMBER OF CONSULTING HOURS NEEDED THIS SEMESTER: <5 hours

EXPECTED COMPLETION DATE OF PROJECT: 2/28/2025

IMPORTANT DEADLINE OR DUE DATES RELATED TO YOUR PROJECT:

THE RESULTS OF THIS RESEARCH WILL PROBABLY BE PUBLISHED AS:

Ph.D Dissertation,Journal Article,Technical Report

IS THIS RESEARCH SUPPORTED BY A GRANT OR CONTRACT? No

If so, give grant/contract title:

GIVE A BRIEF DESCRIPTION OF YOUR RESEARCH INCLUDING:

PURPOSE:

We have continuous electrocardiogram (ECG) data for 84 people who received COVID-19 vaccine. We have estimated heart rate variability (HRV) metrics from the ECG signal. From the different HRV metrics and physiological data (skin temperature, respiration) we want to identify which metric was the earliest

to deviate from pre-vaccination baseline. We have on an average of four days of continuous data per person as a baseline and five days of post-vaccination data from which we identify the time of onset of vaccine response per person.

vaccine induced inflammatory response and that is reflected in the heart rate, skin temperature and other physiological signals.

DESCRIPTION OF VARIABLES TO BE MEASURED:

The study is an observational study. Participants (18 and above) were recruited and were given a wearable ECG chest patch to collect physiological signals. We have computed heart rate variability (HRV) features from the ECG signals. The aim is to identify which HRV metric deviate from the baseline earliest and how long is the deviation sustained.

We have demographic information such as, age, height, weight, dosage information of the vaccine, brand information and so on.

I need consultation for two issues:

1. The heart rate and heart rate derived physiological signals are not normally distributed as they exhibit circadian rhythm. Since, I want to compute a pre-vaccine baseline to compare post-vaccine data, I assumed the distribution of physiological signals such as heart rate at any specific hour of the day is normal and therefore based my analysis on this assumption. I would like to run through my methods to identify potential caveats that I need to address.

2. I have computed a 81 by 22 array of duration of deviation, where 81 are the total number of participants and the number of physiological and HRV features is 22. I have performed a step-wise logistic regression with the 81 by 22 array as experimental factors and a binary array of 1 by 81 as a response variable that is created from self-reported systemic symptoms. I would appreciate help with interpreting the results.

RESEARCH QUESTIONS THAT YOU WANT TO ADDRESS USING STATISTICAL METHODS:

Vaccination can induce systemic symptoms like fever, malaise, chills etc. (Vaccine reactogenicity). This can be seen in continuous physiological signals from wrist/chest worn sensors. If five days of pre-vaccine data and three days of post-vaccine data is given for the same person.

1.How early can we detect a deviation of physiological data from pre-vaccine baseline?

2. How long was the deviation sustained?

STATISTICAL ISSUES:

How can we identify which feature is crucial to explain vaccine response?

Do people receiving a certain brand of vaccine have higher odds of experiencing vaccine related symptoms? Do people with a certain age or Body Mass index have higher odds of experiencing vaccine related symptoms?

ADDITIONAL INFORMATION YOU THINK WOULD BE HELPFUL:

ATTACHMENTS:

No Attachment