# I. INTRODUCTION

## 1. Background information

A normal human can release body odor that can be bothersome to certain people. Although it is a normal condition exhibited by the human body, excessive and malodorous body odor could be bothering the surrounding people. Moreover, extreme body odor might affect the physiological condition of body odor sufferers due to the social stigma given by society (Sorokowska, Sorokowski, & Szmajke, 2012). The presence of an unpleasant smell is caused by the mixing of perspiration (or sweat) and bacteria on the skin, especially in the axillary area. The body odor is primarily the result of the apocrine sweat glands, which secrete the majority of chemical compounds that the skin flora metabolizes into odorant substances (Lundström & Olsson, 2010). The causes of body odor are characterized by several factors that are either stable over time (genetic factors) or vary with environmental or internal conditions (Pandey & Kim, 2011). Because of this, deodorant is invented and used to prevent the growth and activity of the degrading apocrine gland secretion bacteria found in the axillary area.

According to Darlenski and Fluhr (2011), deodorant is a cosmetic product that is applied to reduce body odor by its absorbing, masking (fragrances), and antibacterial properties. In a broader sense deodorant also acts as an antiperspirant by decreasing the amount of substrate for malodor generation by the skin microbiota. These days, many dermatology companies have come up with various ingredients used for deodorants that are marketed among consumers; and currently, one of the most well-known dermatology clinic in Indonesia are formulating a deodorant using natural ingredients, namely compound H and S. Furthermore, the deodorant sample would be called “Product E”.

To test a newly formulated dermatology product, a clinical trial must be conducted as the main requirement before releasing it to the consumers. The clinical trial would be done to

measure the antibacterial activity that is essential to do to identify the effectiveness of the antibacterial agent in the product. According to The National Institutes of Health (NIH) ("Learn About Clinical Studies - ClinicalTrials.gov", 2021), a clinical trial is a research study using human volunteers that are intended to add to medical knowledge to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. By this definition, many requirements need to be fulfilled before conducting the actual clinical trial by the research team. That being said, the protocol or the research plan should be constructed beforehand to answer the specific research questions, as well as explain the safeguard of the health of participants. The protocol should contain information such as:

a. The reason for conducting the study
b. Who may participate in the study (the eligibility criteria)
c. The number of participants needed
d. The schedule of tests, procedures, or drugs and their dosages
e. The length of study
f. What information will be gathered about the participants

("Learn About Clinical Studies - ClinicalTrials.gov", 2021)

Other than professional research requirements, another process needs to be done to have the participant's permission to be involved in the clinical trial. The selected candidates for the clinical trial should be given informed consent, which is intended to protect participants ethically and should provide enough information for a person to understand the risks of, potential benefits of, and alternatives to the study. The participants need to understand the risks, potential benefits, and alternatives of the study before signing the informed consent document; nonetheless, they may withdraw from a study at any time even when the study is still ongoing ("Learn About Clinical Studies - ClinicalTrials.gov", 2021).

Until now, the clinical trial has become a standard procedure in terms of cosmetic product testing before being marketed, even though some complicated requirements need

to be fulfilled and the willing suitable participants need to be gathered. In this research, the study of the dermatology product -in this case, deodorant- would be done using *in vitro* method. Some antimicrobial testing methods can be adapted based on the research needs. Some basic methods like disc diffusion and broth dilution can be used to identify the antimicrobial activity of an extract or pure compound; other extended testing methods such as time-kill assay and flow cytofluorometric methods can provide broader information on the nature of the compound's inhibitory effect (bactericidal or bacteriostatic) (time-dependent or concentration-dependent) and the cell damage inflicted to the test microorganism (Balouiri, Sadiki, & Ibnsouda, 2016). That being the case, *in vitro* testing may offer a shorter period of trials by adapting the various technique to the experimental activity, which further would also potentially extend the study scope in terms of the study of the microbiome and the microorganisms' response to the active component (Balouiri, Sadiki, & Ibnsouda, 2016).

In response to the project activity, this research project is funded by Skinproof, a private Clinical Research Organization (CRO) specializing in dermatology testing. In collaboration with one of the well-known dermatology companies in Indonesia, a clinical study of a new natural deodorant product will be conducted with the help of i3L students from Biomedicine, Biotechnology, and Pharmacy study programs as the member of the research team. The research conducted by i3L students consists of clinical trials and *in vitro* tests. The clinical trial will involve 22 male subjects from the age of 18 to 40 years old as the participants, while *in vitro* testing would be adapting some of the antimicrobial testing methods to see the effectiveness and the efficacy of the adopted methods of the deodorant towards the skin microbiota.

The successes of the in vitro testing method would be further submitted to the National Agency of Drug and Food Control (BPOM) as another affordable yet effective method for dermatology product testing. Since the clinical trial has not been conducted yet, this research would focus on comparing the result of other clinical trial studies with the adapted

*in vitro* testing in this research project to determine the effectiveness of a new deodorant product against the microbiome in the axillary.

## 2. Objectives

The objective of this research project is to test the antimicrobial activity of Product E deodorant by the adopted *in vitro* testing methods against the Indonesian males' axillary microbiome.

## 3. Hypothesis

a. N0: The *in vitro* methods can effectively indicate the antibacterial activity of the natural deodorant

b. N1: The *in vitro* methods cannot effectively indicate the antibacterial activity of the natural deodorant