***Case Study: Development Plan for phase 1 clinical trial – Pharma\****

***Product – Your product named CovSHOT is a mRNA vaccine against a new variant of the virus in Covid-19 disease. The variant is named P.1-Gamma will enter a phase 1 clinical trial. Your company is named VaudBioTech with headquarters in Switzerland. This company is the discoverer of the vaccine in question. The planned phase 1 clinical trial will be conducted in Germany.***

References are given but students are also expected to do their own literature search.

With reference to the European Public Assessment Report (EPAR) below:

[Comirnaty | European Medicines Agency (europa.eu)](https://www.ema.europa.eu/en/medicines/human/EPAR/comirnaty)

[Comirnaty, INN-COVID-19 mRNA Vaccine (nucleoside-modified) (europa.eu)](https://www.ema.europa.eu/en/documents/product-information/comirnaty-epar-product-information_en.pdf)

And the guidance

<https://ec.europa.eu/health/documents/eudralex/vol-10_en>

With the above information you are expected to write a report for the Board of Directors of your company containing the following regulatory plan:

**Part A: Preclinical Plan**

Write a clear preclinical plan on the work that needs to be done and included in the application for the above mentioned Investigational Medicinal Product. On other words, describe in short the preclinical studies to cover the clinical trial, namely the animal studies, the duration of treatment, pharmacology and toxicology studies in the appropraire animal model.

Guidance:

<https://database.ich.org/sites/default/files/M3_R2__Guideline.pdf>

<https://database.ich.org/sites/default/files/S9_Guideline.pdf>

* <https://journal.emwa.org/preclinical-studies/an-introduction-to-little-known-aspects-of-nonclinical-regulatory-writing/>

**Part B: Clinical Plan**

Draft a Clinical Trial Protocol to be included in the application for the above-mentioned Investigational Medicinal Product.

*Define the main points of the clinical trial protocol, can you consider a Master Protocol:* [*http://www.nature.com/news/master-protocol-aims-to-revamp-cancer-trials-1.13176*](http://www.nature.com/news/master-protocol-aims-to-revamp-cancer-trials-1.13176) *and* [*http://www.nejm.org/doi/full/10.1056/NEJMra1510062#t=article*](http://www.nejm.org/doi/full/10.1056/NEJMra1510062#t=article)

*Consider PRIME and Breakthrough Designations*

Guidance and reference:

<https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf>

**Part C: Chemistry, Manufacturing and Controls, CMC**

Write a clear CMC plan on the work that needs to be done and included in the application for the above mentioned Investigational Medicinal Product. (Emphasize the level of detail required.)

Guidance and reference:

[**https://ec.europa.eu/health/documents/eudralex/vol-10\_en**](https://ec.europa.eu/health/documents/eudralex/vol-10_en)

<https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-10/18540104en_en.pdf>

**Part D: Pre-IND Meeting / Scientific Advice**

*Include a summary of the project background, the questions with the opinion of the company, number of attendees, and the time for the meeting (ideally)*

<https://www.pei.de/EN/information/license-applicants/advice/scientific-advice/scientific-advice-node.html>

<https://www.ema.europa.eu/en/human-regulatory/research-development/scientific-advice-protocol-assistance>

**Part E: Inspection Readiness**

Please write a summary of the work that a company needs to have ready before the inspection to ensure compliance to GxP. Extract some details from the Week 3 presentation. Important is the know the points the inspector normally go through during an inspection.

Guidance:

<https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-10/2008_11/vpl10_an5_10-2008_en.pdf>

* This is a case study for this course. Names are “invented” and are just for the course purposes.