Problem Statement: "Pharmaquick" is a Pharma company/Hospital who has come to us with a problem statement wherein they want to predict which drug type is suitable for each patient based on the patient details provided.

They would prefer building a ML model which can do this job accurately and additionally they would love to get insights from their data and recommendations on how to utilize your model results

Problem Definition: We will create an artificial intelligence that recommends the appropriate medicine for them according to patient characteristics. While doing this, we will use the personal characteristics of former patients and the drugs they use.

Exploring the Drug Development Process

Drug development is the process of bringing a novel drug from “bench to bedside”. It can take 10 to 15 years for a drug to be designed, developed and approved for use in patients. Of course there are exceptions.

Before a drug reaches a patient, it must undergo rigorous testing to determine if it is safe, whether it is effective in treating the condition for which it was developed, and to determine the correct dosage and appropriate route of administration.

Pharmaceutical regulatory authorities are responsible for overseeing and regulating therapeutics; including prescription and over-the-counter drugs, vaccines, cell therapies, and medical devices. They play a key role throughout the drug development process and are designed to ensure the safety, efficacy, accessibility, and safety of approved drugs. Throughout the development of the drug, the responsible pharmaceutical company will carry out pharmacovigilance activities.

There are many different regulatory authorities around the world. The US regulator is the US Food and Drug Administration (FDA) and its UK equivalent is known as the Medicines and Healthcare Products Regulatory Authority (MHRA) – each country has its own regulatory authority.

The Stages of Developing a Drug

1. **Early Drug Discovery**
2. **Preclinical Research**
3. **Investigational New Drug Application**
4. **Clinical Research**
5. **Regulatory Review, Approval and Post-Marketing Safety Surveillance**

1. **Early Drug Discovery**

   There are several core "steps" that are carried out during drug discovery. Academic and industry scientists collaborate to identify potential druggable targets for a specific disease and work to discover and optimize drug compounds that can elicit an effect on a specific biological target implicated in a disease – in the hopes of treating it. Work at this stage is performed in the laboratory using in vitro and animal models.

2. **Preclinical Research**

   Preclinical testing is designed to deliver important information about a drug candidate's efficacy and safety before it is tested in human subjects. Both in vitro and in vivo models are typically used to provide evidence of a candidate's biological effect. Preclinical studies are required by regulatory authorities such as the FDA and MHRA before submitting an investigational new drug application (IND) which is required to progress to clinical development. Numerous questions are addressed at this stage:

   - What does the drug do to the body?
   - What does the body do to the drug?
   - It is potent, but is it safe?

3. **Investigational New Drug Application**

   The FDA groups INDs into three different types:

   Investigator:

This is submitted by the physician responsible for initiating and investigating. The same physician will manage the administration and/or dispensing of the investigational drug. This type of application is typically requested for the study of an unapproved drug, or an approved drug for use of the drug in an unlicensed indication, or a different patient population.

Emergency use:

An emergency use IND enables the regulator (FDA) to authorize the use of an investigational drug in an urgent situation, without the obligation to submit and IND in accordance with 21 CFR, Sec. 312.23 or Sec. 312.20. This type of application is used for patients who do not meet existing clinical study criteria, or in situations where an approved clinical protocol doesn't actually exist.

Treatment:

This type of IND application is submitted to gain access to an experimental drug that has shown promise in clinical trials for treating a serious or life-threatening condition, whilst the final clinical work is completed, and the new drug application is reviewed by the FDA.

An IND can be categorized as either "commercial" or "research". For an IND application there are key areas that must be covered; animal model pharmacology and toxicology studies, manufacturing information, clinical study protocols and investigator information.

The IND sponsor is required to wait 30 days before starting clinical trials – this delayed period gives regulators the opportunity to review the information contained within the IND application.

4. Clinical Research

Clinical trials are designed to answer specific research questions related to an investigational drug. The trials must follow a study protocol – a document that describes exactly how the clinical trial will be conducted. It details key study objectives, study design, and statistical considerations, to ensure the safety of participants and the integrity of the data collected during the study.

5. Regulatory Review, Approval and Post-Marketing Safety Surveillance

The application process for marketing authorization in the USA is known as a New Drug Application (NDA). In the European Union and other countries worldwide, this same process is referred to as a Marketing Authorisation Application (MAA).

The regulatory authority is responsible for the scientific evaluation of the NDA or MAA. The goal of the application is to provide the regulator with enough information – gathered during preclinical and clinical studies – for them to be able to determine if:

- The drug is safe and effective as a treatment for the condition it has been developed for
- The drug's therapeutic benefits outweigh the risks
- The drug's labeling is fit-for-purpose and whether all required details are included
- The methods used to manufacture the drug and measures to ensure the drug's quality are satisfactory