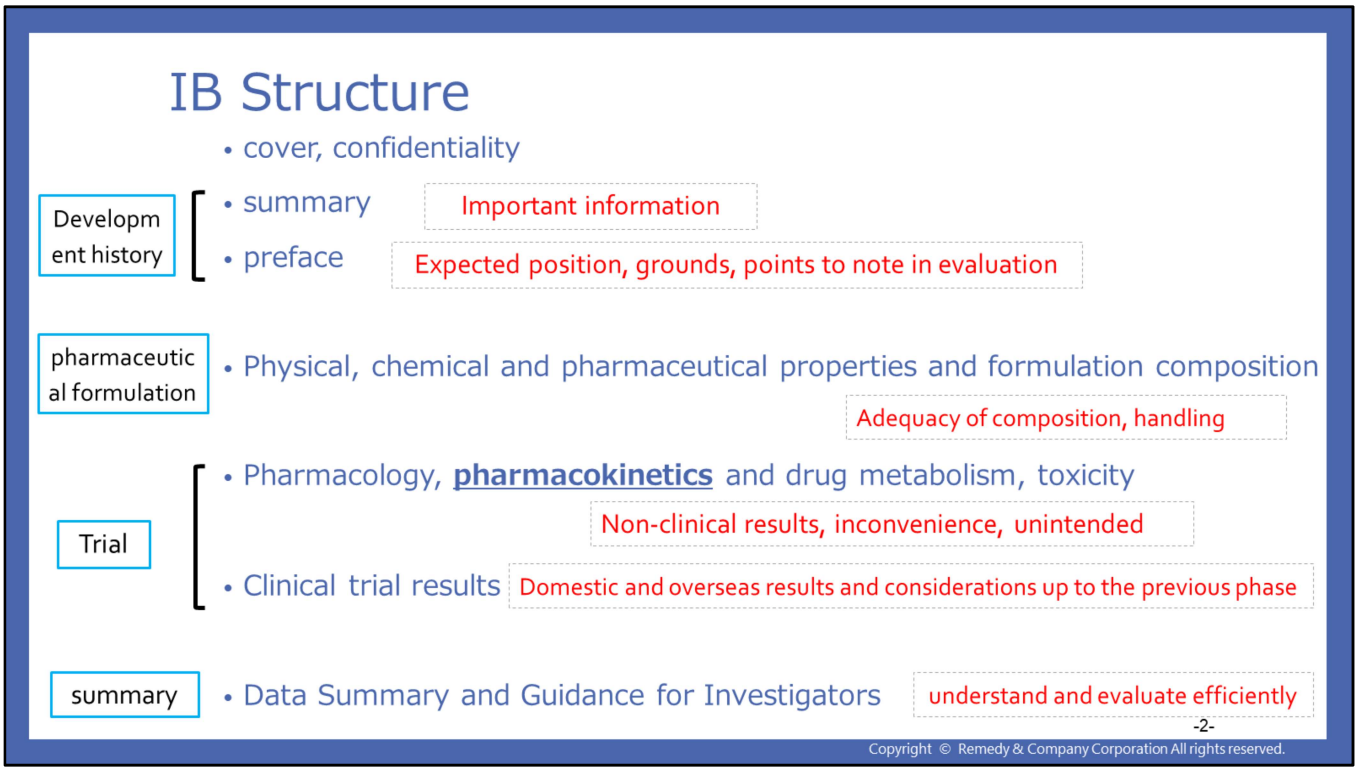
Good day everyone! Today, we will explain about pharmacokinetics of drugs, particularly for Investigator's Brochure, IB for short.



The Investigational Brochure is divided into the following 4 big sections: Development History, Pharmaceutical Formulation, Trial, and Summary. We will explain about what kind of information that you can learn from each section.

Development History

Beginning with an overview of the pharmaceutical's development history, briefly discusses the critical points in the drug's research journey, significant discoveries, stages it cleared, and perhaps any hurdles overcome in the process.

In Development History's summary, we can get an Important Information. You can find many important and relevant information related to the drug. In preface, you can acquire information about expected results, background, and critical points of drug evaluation.

Pharmaceutical Formulation

Talking about the pharmaceutical formulation of the drug, this section discusses the method involved in the formulation, mentions the ingredients used, and spells out its structure, chemical properties, and how it functions to alleviate, cure, prevent or reduce the symptoms of a certain illness. In this section, you can get important information about how to handle the drug. The discussion embraces how the drug should be properly stored and handled, including temperature ranges, light sensitivity, and potential reactivity with other substances.

Trial

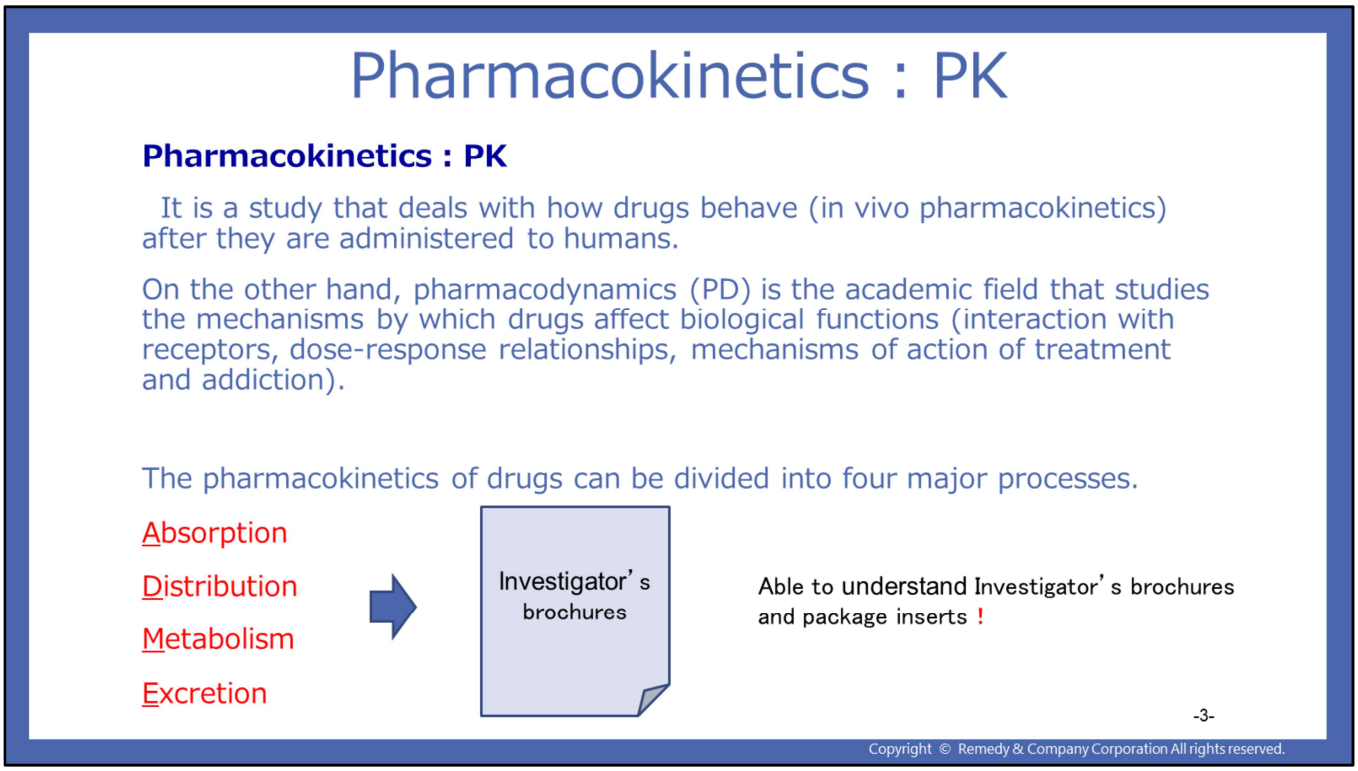
The section is about trial itself.

The first part will discuss about Pharmacology, pharmacokinetics and drug metabolism, toxicity. You can get information about non-clinical results, inconvenience, unintended events.

The second part is about Clinical trial results, speaking about the clinical trials that the drug has gone through, and about the types of trials done, the duration, how many stages were there, and what each of them insisted of, mentioning the sample size of the population involved in these trials and their demographics. In Clinical trial results, you can find the results obtained from those trials. The discussion includes the outcome in terms of efficacy, safety, possible side effects, and the overall patient's response from domestic/overseas results and

considerations up to the previous phase, mentioning the statistical significance of the results too.

Summary
This section summarizes the Clinical Trial Data, highlighting the most important findings, the drug's potential impact, and what future developments are anticipated.



We are here to talk to you about Pharmacokinetics, also known as PK, which is a field of study focusing on understanding the behavior of drugs when they are administered to human bodies.

Pharmacokinetics can be distinguished from a closely related field known as pharmacodynamics. While pharmacokinetics (PK) focuses on how drugs move within the body, pharmacodynamics (PD) studies the mechanisms by which drugs affect biological functions. These include interactions with receptors, dose-response relationships, and the mechanisms of action for treatment and addiction.

The study of pharmacokinetics is incredibly important within the pharmaceutical industry. By mastering this knowledge, we can gain valuable insights into how to develop safer and more effective drugs for a range of health conditions and diseases.

The process of pharmacokinetics can be broken down into four major stages: absorption, distribution, metabolism, and excretion.

When a drug is administered, it first needs to be absorbed into the bloodstream. This absorption can occur through various mechanisms and involves the movement of the drug from the site of administration to the systemic circulation.

Once the drug is in the bloodstream, it is distributed to the tissues and organs where it will have its impact. The drug disperses throughout these areas depending on properties such as blood flow and the affinity of the drug for different tissues.

The metabolism phase involves the drug being converted into a more easily excretable form. This process largely takes place in the liver.

Finally, in the excretion phase, the metabolized drug is removed from the body through routes such as urine, feces, exhaled air, bile, or breast milk.

Through all these stages, the pharmacokinetics of a drug has a profound impact on its dosing, potential for interactions, the duration of its action, toxicity, and therapeutic effects.

So in conclusion, the study of pharmacokinetics offers invaluable insights in the ongoing

endeavor to produce drugs that are safe and effective in treating human disease and improving the quality of life.

Basic Concept: Efficacy and Absorption

・When a drug is administered, its efficacy (E) is expressed as "E=A, C, S".

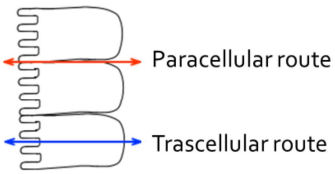
A is the pharmacological activity of the drug itself.

C is the drug concentration at the site of action.

S is the susceptibility of the living body.

passage of drugs

When a drug is absorbed or distributed to each tissue, either "transcellular route" or "paracellular route"



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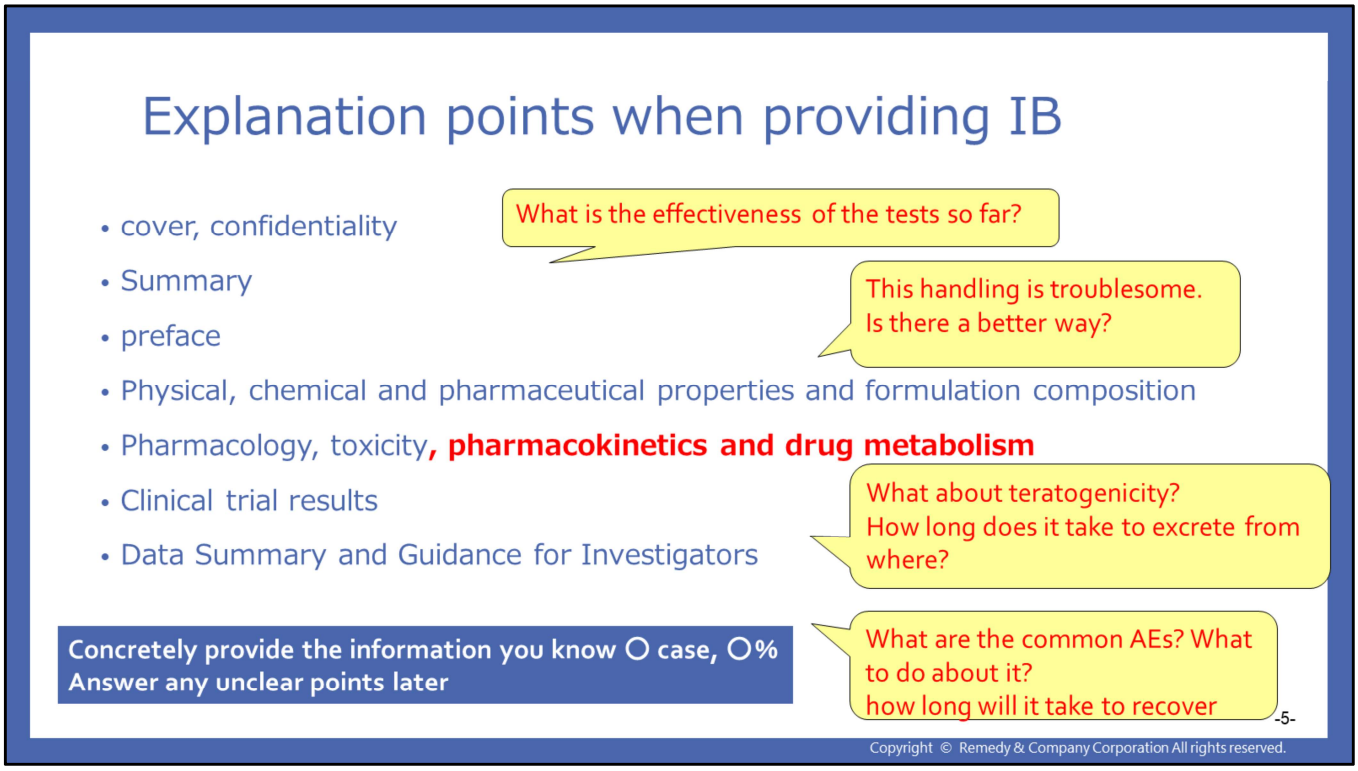

We want to present on the important information contained in the Investigator's Brochure.

Cover, confidentiality
To begin with, we assure you that all information shared is confidential.

Summary
In summary, with regard to the effectiveness of the tests that have been conducted so far, the detailed results are included in this section.

Physical, chemical, and pharmaceutical properties and formulation composition
Next, we want to draw your attention to the details provided on the physical, chemical, and pharmaceutical properties of the drug. We have also included information about its formulation composition. Handling of investigational drugs may appear complex due to the rigorous safety protocols in place. However, we need to explore the strategies to simplify this process.

Pharmacology, toxicity, pharmacokinetics and drug metabolism
Our presentation would be incomplete without a mention of the drug's pharmacology, toxicity, pharmacokinetics and drug metabolism. This information would provide us with full understanding of the drug. "What about teratogenicity?", you might ask. The clinical trial results point out the potential risks and benefits of the drug and discuss any concerns regarding teratogenicity. You will find answers to questions such as, how long it takes for the drug to excrete from the body. This is crucial for investigators to correctly schedule drug doses and monitor any side effects.

Data Summary and Guidance for Investigators
In our data summary, we can find the common adverse events; and how to handle them are also included. The specific practical guidance is provided on managing these events.

And lastly, there is a section that discusses the estimated numbers in cases of adverse events.

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