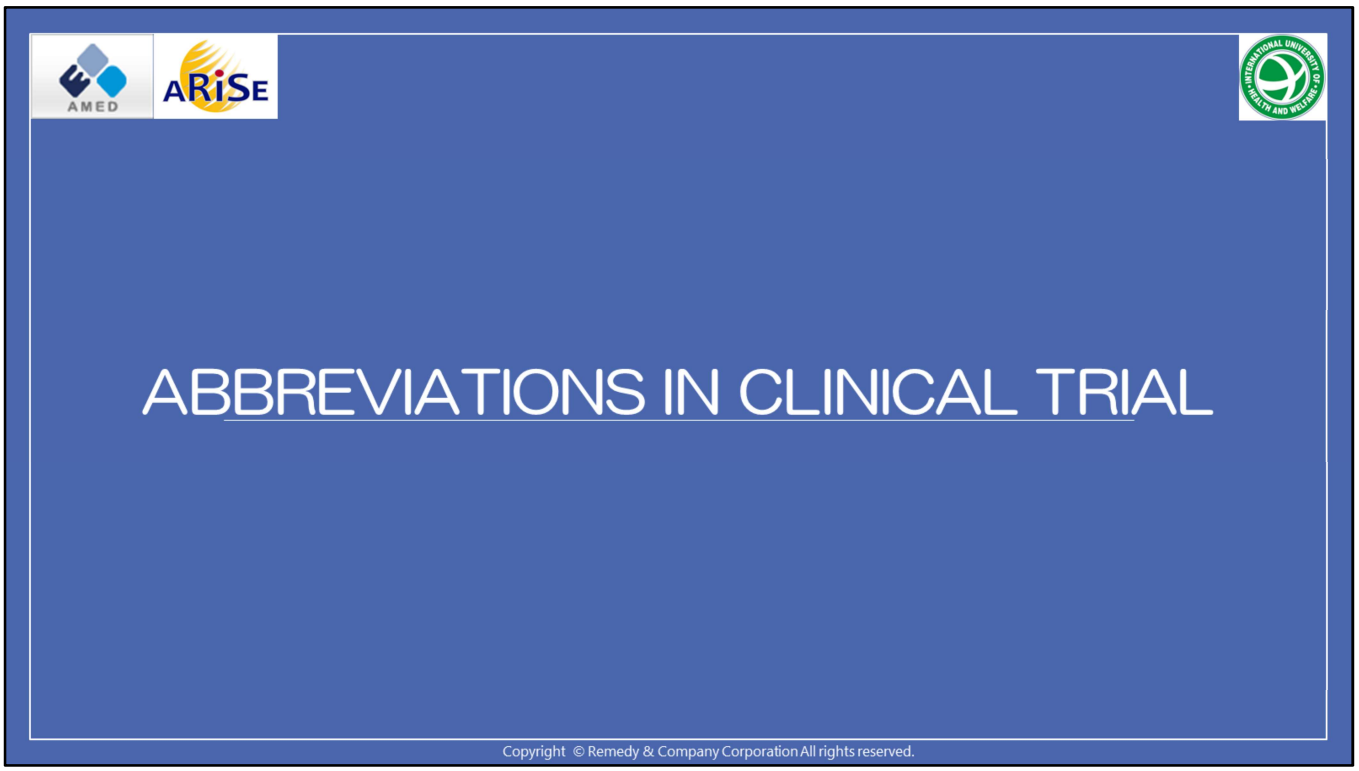
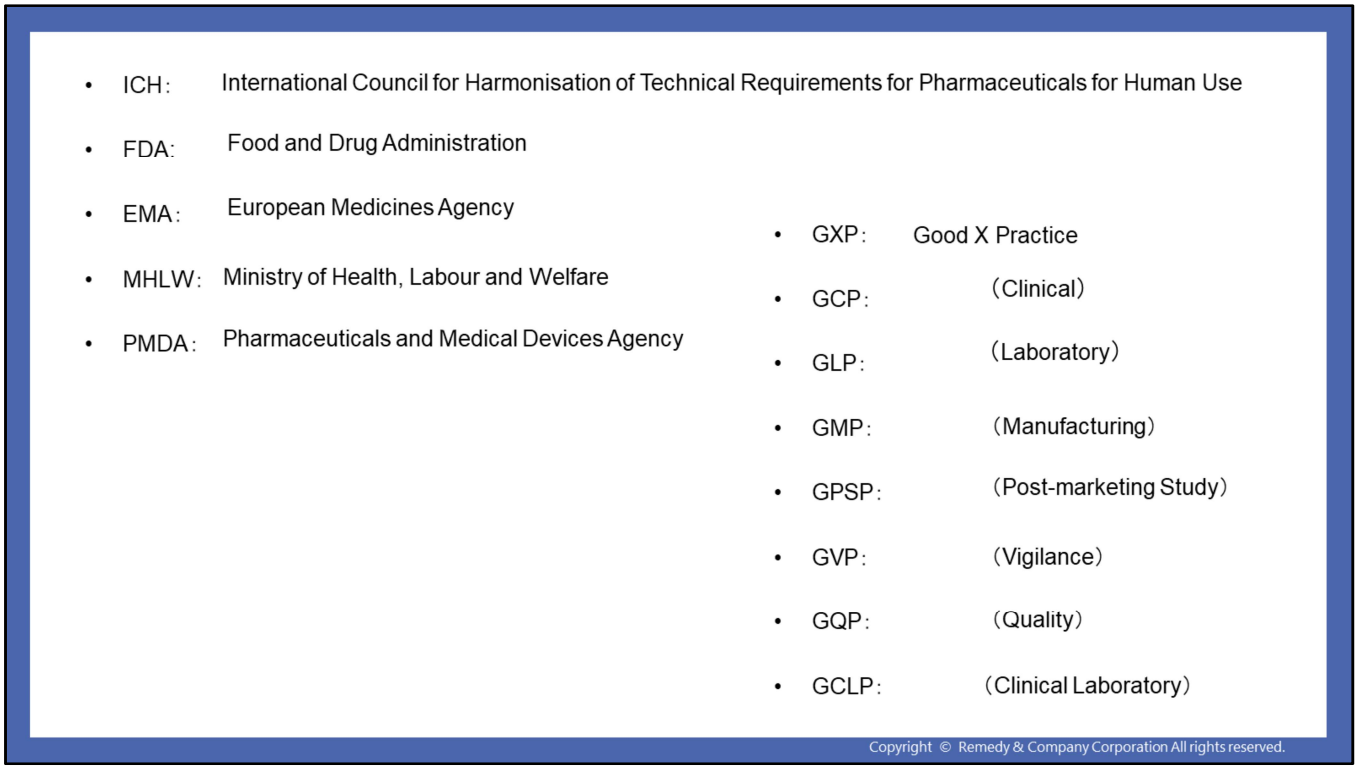


Understanding Key Terms in Clinical Development.



Good day everyone! Today, we will be discussing some important terminologies widely used in the research and medical fields. It's essential that we get familiar with them to better understand the process and the roles they play in the sector.

Our first term is **ICH**. This stands for International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. It's a global project that brings together the regulatory authorities and the pharmaceutical industry to discuss scientific and technical aspects of pharmaceutical product registration.

FDA stands for the Food and Drug Administration, which is the American federal agency responsible for protecting and promoting public health through the regulation and supervision of food safety, dietary supplements, pharmaceutical drugs, and other areas.

Next on the list is the **EMA**, which stands for the European Medicines Agency. This European Union agency is responsible for the evaluation and supervision of medicines, ensuring their safety, quality and efficacy.

Then we have **MHLW**, which stands for 'Ministry of Health, Labour and Welfare'. This ministry oversees the health, labour, and welfare policies in Japan.

Next, **PMDA** is the acronym for 'Pharmaceuticals and Medical Devices Agency'. This is the independent administrative agency responsible for the comprehensive management of pharmaceuticals and medical devices in Japan.

GCP, stands for Good Clinical Practice. It refers to the guidelines regulating the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of various clinical trials that involve human subjects.

Next, we have **GLP** - Good Laboratory Practice. These are non-clinical safety testing guidelines that are applied to laboratories to ensure the quality and integrity of the test

data.

GMP or Good Manufacturing Practice ensures that products are consistently produced and controlled according to quality standards. It minimizes the risks involved in any pharmaceutical production.

GPSP, which stands for Good Post-marketing Study Practice, is all about the standard for implementing surveys and tests after manufacturing and sales.

GVP or Good Vigilance Practice stands for quality guidelines for managing safety after manufacturing and sales for pharmaceuticals, quasi-drugs, and cosmetic products as well as medical devices.

GQP or Good Quality Practice ensures that appropriate quality controls are present across all stages from the production and sale of pharmaceuticals, quasi-drugs, cosmetics, and medical devices.

GCLP or Good Clinical Laboratory Practice is the standard for clinical laboratories dealing with clinical trial specimens.

The next is **CRO**, or Contract Research Organization. These are companies that provide research services to the pharmaceutical, biotechnology, and medical device industries. They play a crucial role in helping these industries develop their products efficiently and, most importantly, safely for public use."

Clinical Research Associate, commonly known as **CRA**. A CRA is primarily responsible for monitoring clinical trials, ensuring the integrity of the data collected and the protection of the rights and welfare of the human subjects.

We have the Clinical Project Leader, abbreviated as **CPL** or **PL**. A Clinical Project Leader is primarily responsible for the overall coordination and management of a clinical trial, from its design and planning, through execution, data collection and analysis, to result interpretation and presentation.

Furthermore, we also have the role of Project Manager or **PM**. The PM, similar to the CPL, manages the whole project, but their focus is more on time management, resources and ensuring that the project objectives are met.

The next term is **HP**, short for Hospital. It refers to the comprehensive medical institutions where most clinical trials and researches are frequently conducted.

GP is short for General Practitioner, a medical professional who treats acute and chronic illnesses, provides preventive care and health education for all ages and both sexes.

Next is **SMO**, short for Site Management Organization. SMOs are organizations that provide support services to the medical researchers conducting clinical trials. Their services range from maintaining and managing research sites to ensuring compliance with protocols.

Now we have **PI** or Principal Investigator. These are research experts, typically doctors in

the field of the specific treatment or medicine being studied, who are responsible for leading and overseeing the clinical trial.

The **SI**, or Sub-Investigator, assists the Principal Investigator in conducting the clinical trial. They work under the supervision of the PI and are responsible for various tasks such as patient recruitment or data collection.

CRC, which stands for Clinical Research Coordinator, is another important role in medical research. They ensure that the clinical trials run smoothly by handling logistics, communicating with participants, and ensuring data integrity.

Now, moving onto the **ARO**. This stands for Academia Research Organization. These are institutions that primarily focus on academic clinical research, often associated with universities or medical faculties.

Next up is the **CSO**, which stands for Contract Sales Organization. These are entities employed by pharmaceutical companies for their sales and marketing activities.

We have the **IRB**, which stands for the Institutional Review Board. This is an administrative body established to protect the rights and welfare of human research subjects. It is essential in ensuring the ethical standards of the research.

The **IM**, Investigator's Meeting, which refers to a meeting of all the investigators involved in a clinical trial to discuss the protocol, responsibilities, and other key topics related to the trial.

FPI or First Patient In refers to the date when the first patient enrolled in the study as a participant. It marks the beginning of the patient enrollment process.

Secondly, we move on to **FPFV** or First Patient First Visit. This is the date when the first patient makes their initial visit to the clinic after enrollment, signaling the start of the data collection process.

Next, we have **LPI** or Last Patient in. This term refers to the date when the last patient was enrolled in the study. This signifies the closure of the recruitment phase, moving the study onto the next stage.

Subsequently, we shift our focus to **LPLV** or Last Patient Last Visit. This term indicates when the last patient participant involved in the study made their final visit to the clinic. This event typically marks the end of active data collection and initiates the data analysis process.

We touch on **LPO** or Last Patient Out. It is the date when the last patient completes the final activities of the study, it is essentially marking the end of the patient’s involvement in the study.

Taken together, these terms or milestones provide us a rough timeline of a clinical study,

from patient enrollment to the end of their participation, underlying the flow of a clinical trial. This understanding is crucial to track and manage the progress, and ensuring the efficiency and effectiveness of a clinical trial.

PRT, which stands for the Protocol. The Protocol is the blueprint of the clinical study and comprises the trial's purpose, methodology, statistical information, and organization. It is a crucial document that ensures the uniformity of the experiment across all study sites, providing reliable and comparative data.

Next, we have **CRF**, also known as the Case Report Form. This document collects pertinent and crucial data for each trial participant. As such, it serves as the primary data collection tool for organizing and managing patient data during a study.

Now moving on to the Informed Consent Form or, in short, **ICF**. This document is critical in protecting the patients' rights. It outlines the study's purpose, procedures, risks, benefits, alternatives, and confidentiality to participants, allowing them to make informed decisions regarding their involvement in the trial.

Let's talk about **EDC** or Electronic Data Capture. EDC Systems are software that stores patient data collected in clinical trials. Electronic data capture allows the collected information to be easily accessible for analysis and reporting, enhancing the accuracy and speed of the data management process.

The fifth document is the Investigator's Brochure, or **IB** for short. This report provides clinical and non-clinical data about the investigational product, giving investigators a comprehensive understanding of the investigational product, thus ensuring the safety and efficacy of the participants in the trial.

We have **SOPs**, known as Standard Operating Procedures. SOPs detail the regularly recurring work processes that are to be conducted in the same manner to ensure consistency in the work process.

SAP, which stands for Statistical Analysis Plan. It is a vital document that lays out the detailed methodology for analyzing collected data during a clinical trial. Sound planning

equates to reliable results, hence a comprehensive SAP is fundamental to the overall success of any trial.

Next, we have **CSR** or Clinical Study Report. This is a comprehensive, detailed summary of a clinical trial, pulled from the investigators' studies and written in a structured, standardized format. As its name implies, this document serves as the report card for the trial, tracking everything from the trial's inception to its conclusion.

Moving forward, let's talk about **RBM** or Risk-Based Monitoring. This is an adaptive approach to assessing and mitigating potential risks throughout the entire process of a clinical trial. Rather than relying on traditional, more rigid monitoring methods, RBM allow for more flexibility while maintaining the credibility and integrity of the trial.

SDV stands for Source Data Verification. It refers to the process of verifying the accuracy of data by cross-checking with original documents or records. This crucial process ensures all entries are consistent with the original data.

We have **CTN**, which stands for Clinical Trial Notification. This is a notification plan for clinical trials.

In the quality domain, we have **QA** and **QC**.
QA refers to Quality Assurance — a process-centered approach to ensure that a company or organization is providing the best possible products or services.
QC, Quality Control, stands for activities that focus on identifying defects in the actual products produced.

There are a few key events or terms worth noting. The **AE**, or Adverse Event, refers to any undesired events in a trial subject during a clinical trial.

The **SAE**, Serious Adverse Event, refers to an Adverse Event which results in death, requires hospitalization, causes disability or incapacity, or is life-threatening.

The **IM**, investigator's meeting, which refers to a meeting of all the investigators involved in a clinical trial to discuss the protocol, responsibilities, and other key topics related to the trial.

We have **CTD**, which stands for Common Technical Document. This is an internationally harmonized document required for the approval of pharmaceutical products in Japan, the United States, and the European Union.

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