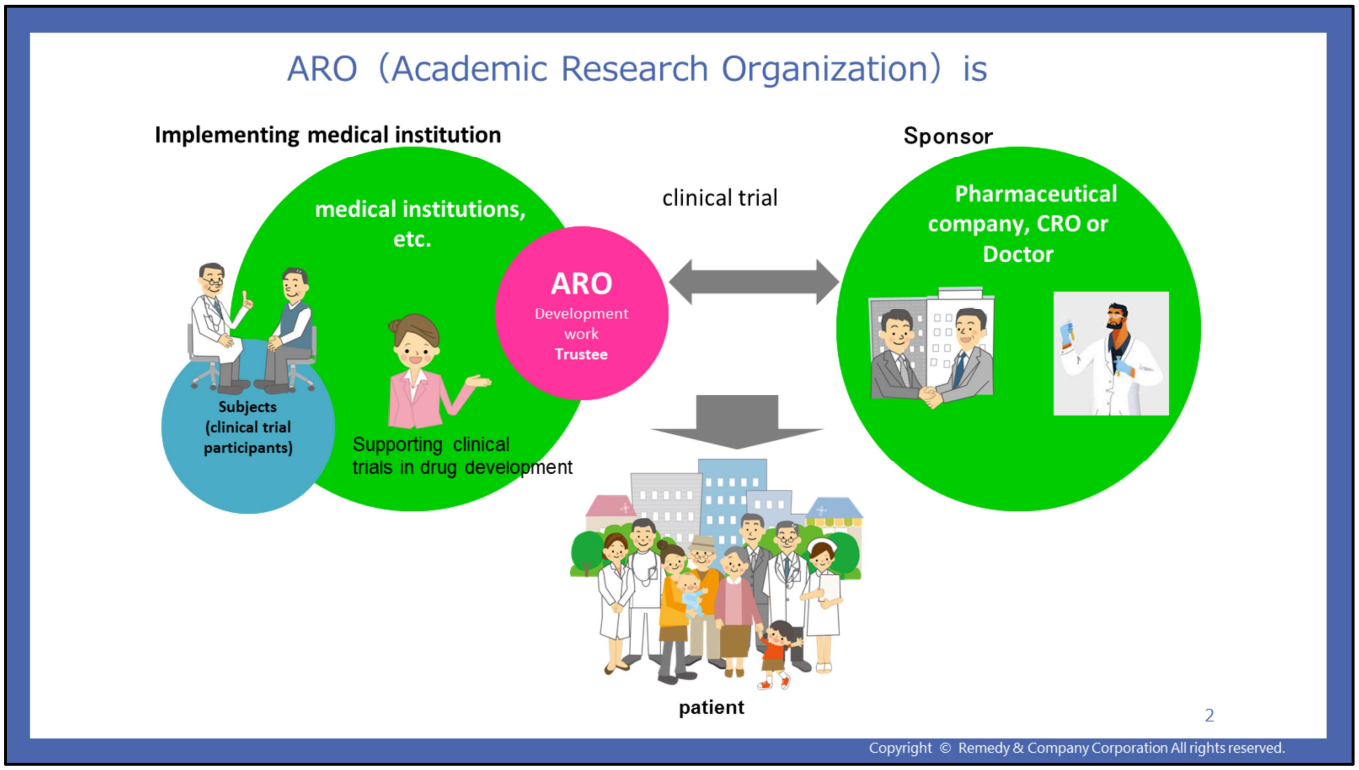
Good day everyone! Today, we will be discussing about the relationship between medical institutions and CRA



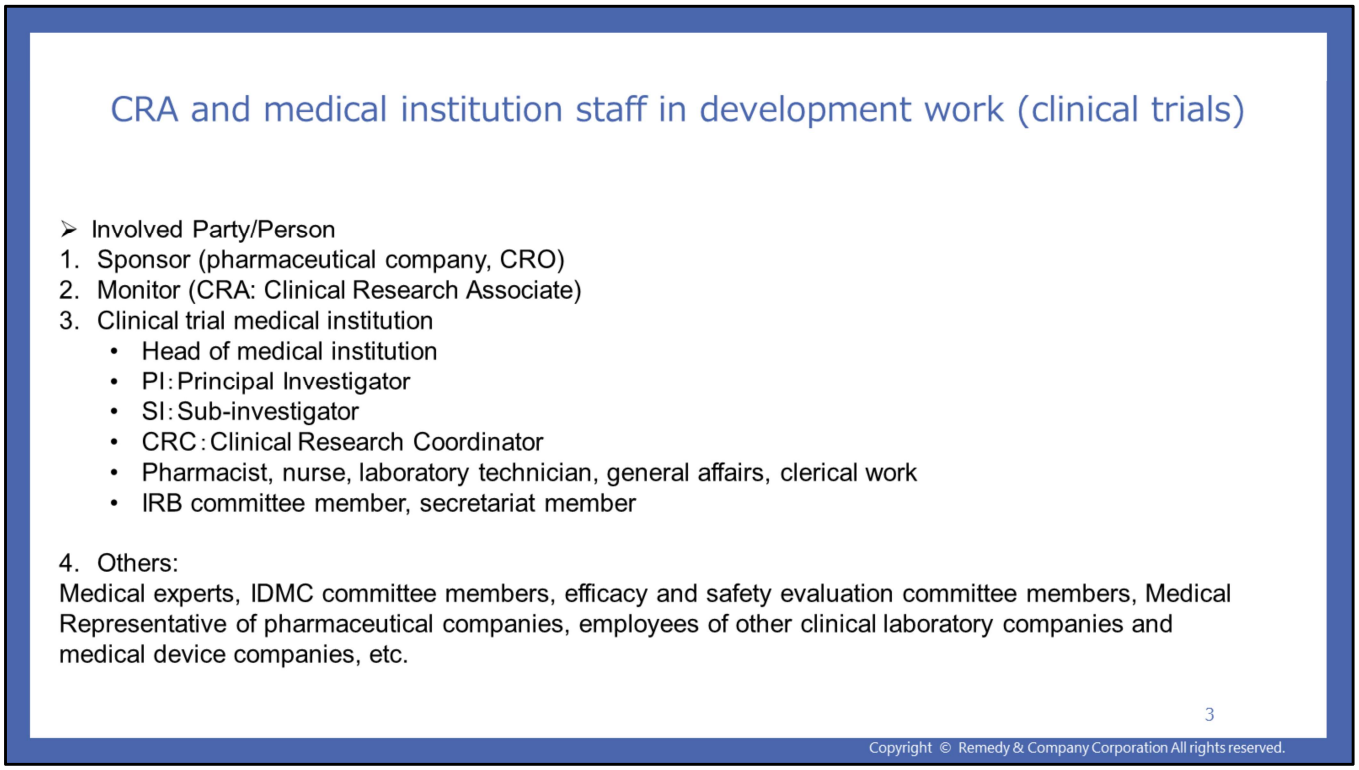
ARO stands for academic research organization inside an institution, usually in an university or a hospital, which manages clinical trial inside their institution.
Sponsor can be a pharmaceutical company, a CRO contracted by a pharma comp or a doctor/researcher.

Academic Research Organizations or AROs. Predominantly, AROs play an instrumental role in advancing clinical trials which pave the way for breakthroughs in the medical world. They serve as a bridge connecting medical institutions and the sponsors that incline towards the development of something revolutionary and beneficial to mankind.

These sponsors could be pharmaceutical companies, General Research Organizations, or even an individual medical practitioner. The role of a sponsor crafts the substance of the research to be embarked upon, casting a direct influence on the conduct of the clinical trial concerned.

AROs are predominantly associated with medical institutions and other similar establishments where they function to implement the course of the clinical trial. The participants of these trials, known as subjects, are managed solely by the ARO linked with the specific medical institute.

In sum, AROs stand as a pillar in the field of drug development, offering invaluable support to clinical trials, thereby shaping the future of medicine. They help to implement the clinical trials, ensuring the smooth progression of drug development. The interaction and collaboration between medical institutions, sponsors, and AROs, results in a multi-faceted approach to our endeavors in creating more efficient and effective healthcare solutions.



At the onset, let us introduce the key stakeholders involved in these trials. They are fundamentally classified into four parties, first and foremost, the sponsor, which is typically a pharmaceutical company or a Clinical Research Organization (CRO).

Next in line, is the monitor, precisely the Clinical Research Associate, or CRA. A CRA primarily oversees the clinical trials, ensures protocol adherence, monitors the progress, maintains communication between all parties involved, and ensures the authenticity and integrity of data collected.

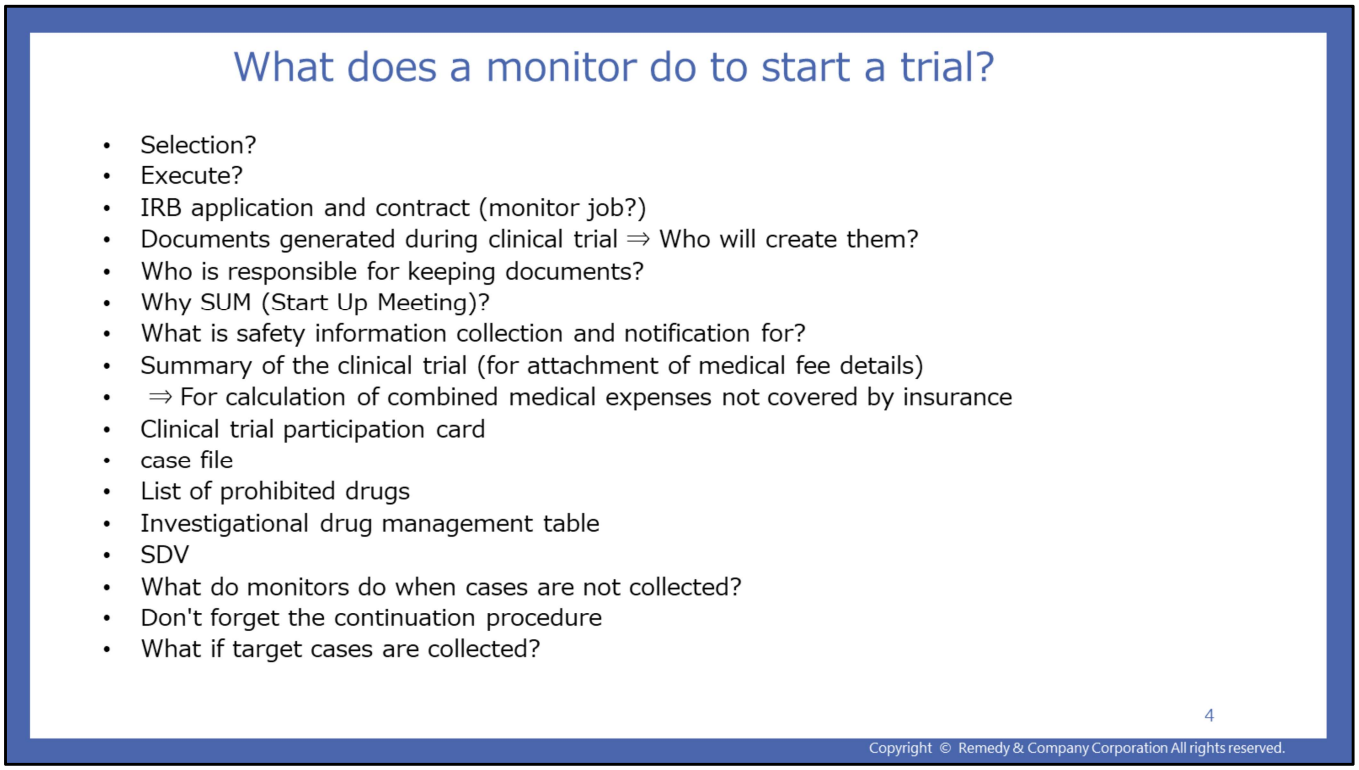
The third entity is the clinical trial medical institution, where the trial is put into practice. This includes a range of personnel, such as the head of the institution and principal investigator or PI, who designs and manages the entire clinical trial.

The PI is assisted by sub-investigators, or SIs, who support in conducting the trials and collating the data. Also, Clinical Research Coordinators, or CRCs, manage the conduct of clinical trials within each institution.

Additionally, we also have pharmacists, nurses, laboratory technicians, and other staff who offer their expertise in conducting the trials.

The Institutional Review Board (IRB) committee members and secretariat members safeguard the rights, safety, and wellbeing of human subjects involved in a clinical trial.

Lastly, the fourth list of stakeholders includes medical experts, members of the Independent Data Monitoring Committee, or the IDMC, employees of clinical laboratory companies, medical device companies, and so on.



In starting a trial, a monitor plays several key roles, with the initial step being the **selection** and **execution** of the appropriate trial. Not only does the monitor oversee the entire process, but they also are responsible for handling and submitting the essential **IRB application and contract**.

The documents generated during a clinical trial are often produced by the chipset that is involved in the project i.e., the investigators, sponsors, regulatory personnel. It is crucial to understand the importance and necessity of these documents as they maintain the integrity of the trial and provide a permanent record of the events, findings, and actions.

Keeping track of these documents falls under the responsibility of the monitor along with the research team. It's a collective task that requires thoroughness, accuracy, and attention to detail.

Ensuring a smooth start to the trial, we conduct a **Start-up Meeting or SUM**. This allows everybody involved in the trial to understand their roles, responsibilities, and the various aspects of the trial.

For the welfare of the trial subjects, **safety information collection and notification** is implemented. This effectively identifies, collects and evaluates information about adverse events, thereby improving the protection of the subjects and the reputation of the trial itself.

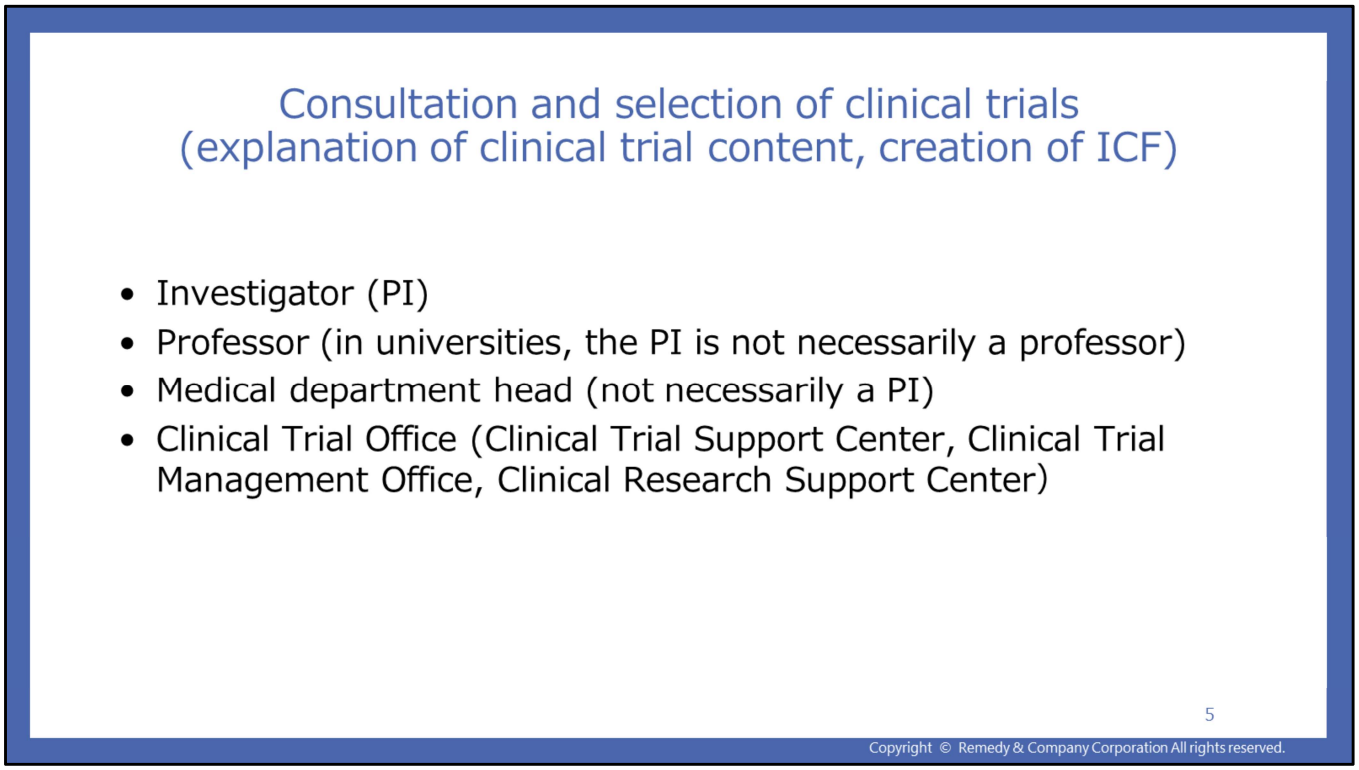
The **summary of the clinical trial** is provided for attaching medical fee details. This helps in calculating composite medical expenses not covered by insurance, thereby eliminating financial ambiguities.

Additional items include a **clinical trial Participation Card**, a list identifying the **drugs prohibited** during the trial, an **investigational drug management table**, and a **case file**.

The **subject data verification or SDV** helps ensure that data entered into the case report forms are consistent with the patient clinical notes.

If cases are not collected, the monitors need to evaluate why, create new strategies to target collection, and potentially re-evaluate the selection protocols.

Furthermore, the **continuation procedure** of the trial should not be overlooked. It outlines the steps taken if the patient continues in the trial **after completion** and the rules and regulations that apply.



The consultation and selection of clinical trials. We will discuss the steps involved, the key roles played by different individuals, and the organizations that provide support throughout the entire process.

Understanding Clinical Trials
Clinical trials are vital to medical research. These studies help us understand how different treatments work. The results of these trials can lead to new drugs, medical procedures, or even preventative measures for various diseases.

Consultation and Selection Process
The consultation and selection process is integral to a successful clinical trial. It helps set the parameters, decide on the type of trial, and determine its scope, including the population, and intervention.

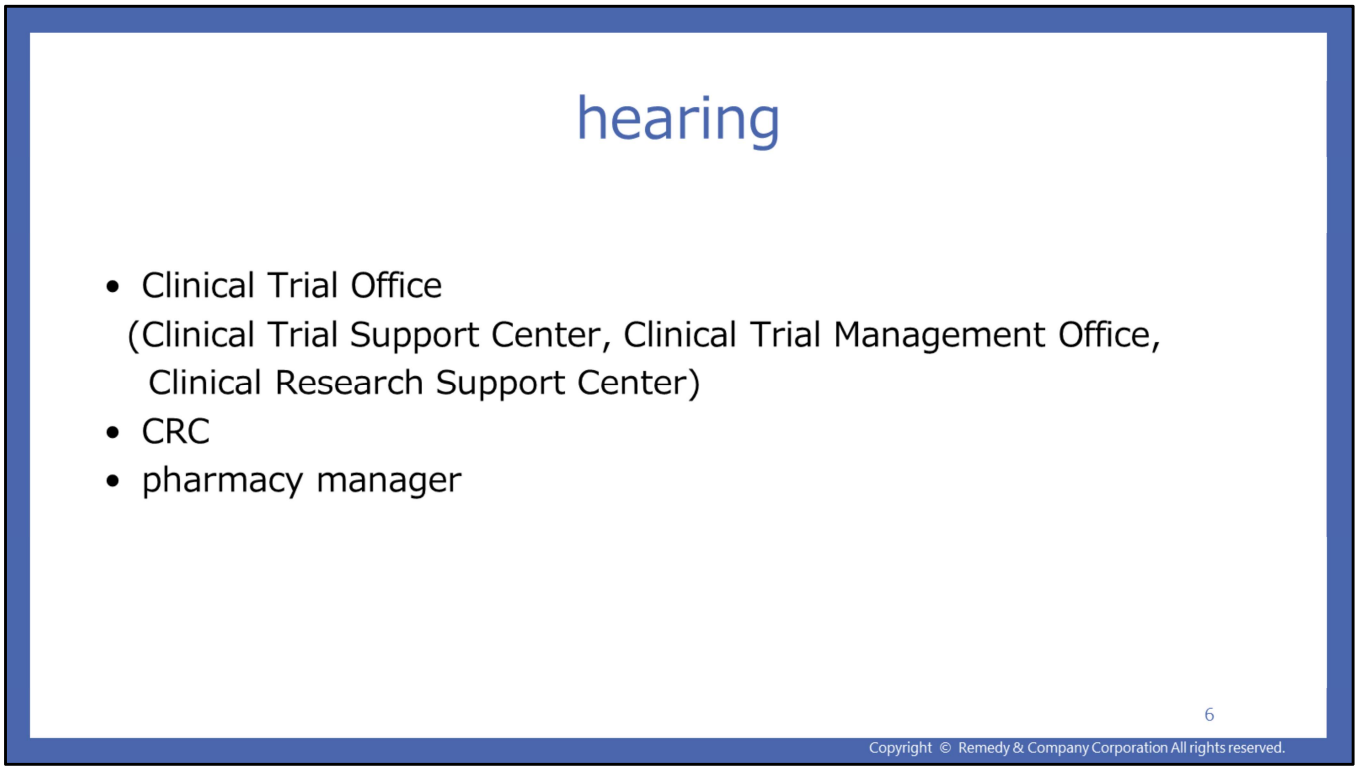
Creating an Informed Consent Form (ICF)
Each participant in a clinical trial must understand what they are getting into. This is accomplished by the creation of an Informed Consent Form (ICF), a document that explains the study's objectives, potential risks and benefits, and the participant's rights.

The Role of Principal Investigator (PI)
The Principal Investigator (PI) holds the great responsibility of overseeing the entire clinical trial. They supervise the trial, ensure compliance with all regulations, and ensure the safety and ethical treatment of all participants.

The Role of Professors and Medical Department Heads
Not all PIs have to be professors, nor all professors are PIs. Medical department heads may play diverse roles in a clinical trial, ranging from managing parts of the trials, supervising the administrative work, or even participating as investigators themselves.

Clinical Trial Offices
Clinical Trial Offices such as the Clinical Trial Support Centre, the Clinical Trial

Management Office, and the Clinical Research Support Center, provide valuable assistance throughout these trials. They coordinate between different teams, ensure compliance with regulations, manage resources and help in handling documentation.



Hearing for collect information related Trial

- Clinical Trial Office (Clinical Trial Support Center, Clinical Trial Management Office, Clinical Research Support Center)
- CRC
- Pharmacy manager

Institutional Review Board (IRB) application

- PI
- Professor, Head of Department (Signature or seal is required on the IRB deliberation request form)
- Clinical Trial Office (Clinical Trial Support Center, Clinical Trial Management Office, Clinical Research Support Center)
- CRC(Hearing at the time of submission of sub investigator / collaborators list)
- Medical Affairs Division (Hospital Affairs)

After IRB review then Contract

- Clinical Trial Office (Clinical Trial Support Center, Clinical Trial Management Office, Clinical Research Support Center)
- Medical Affairs Division (hospital administration (often in charge of contracts))

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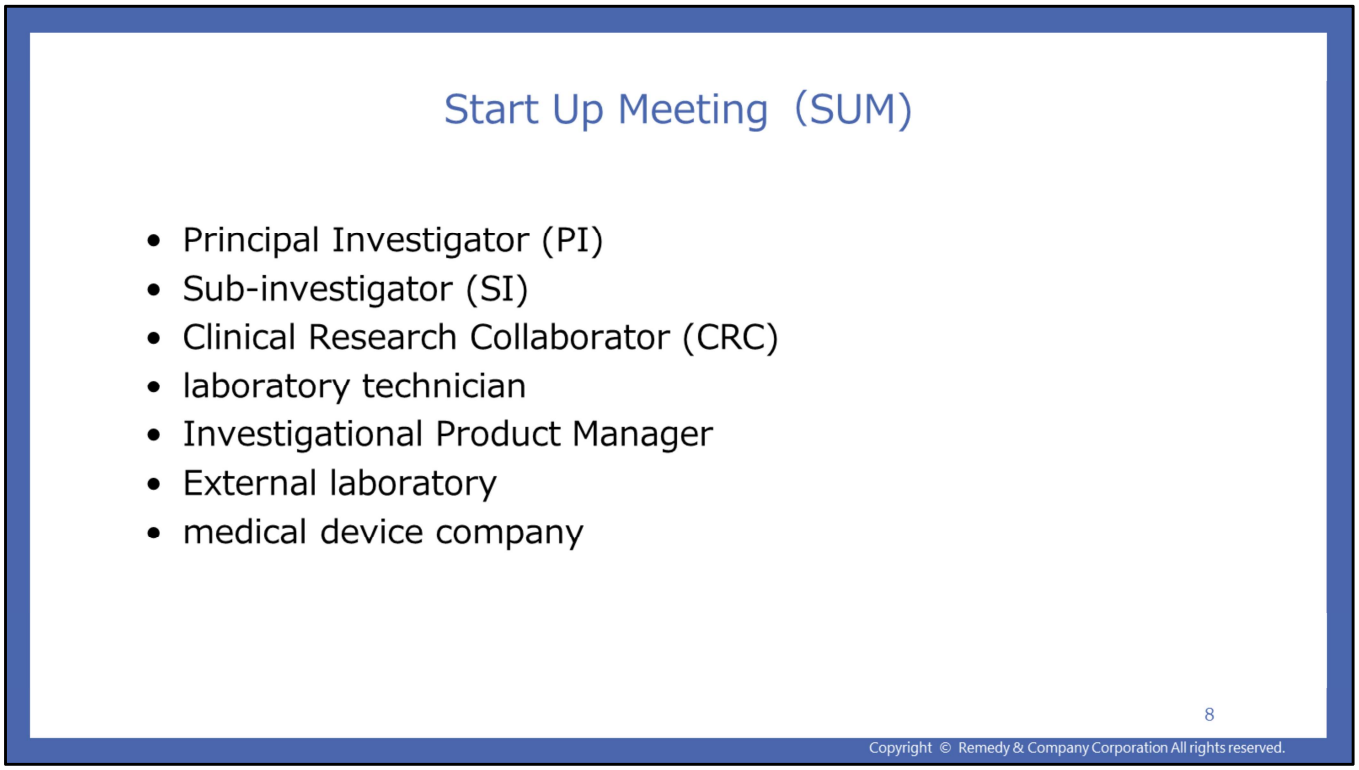
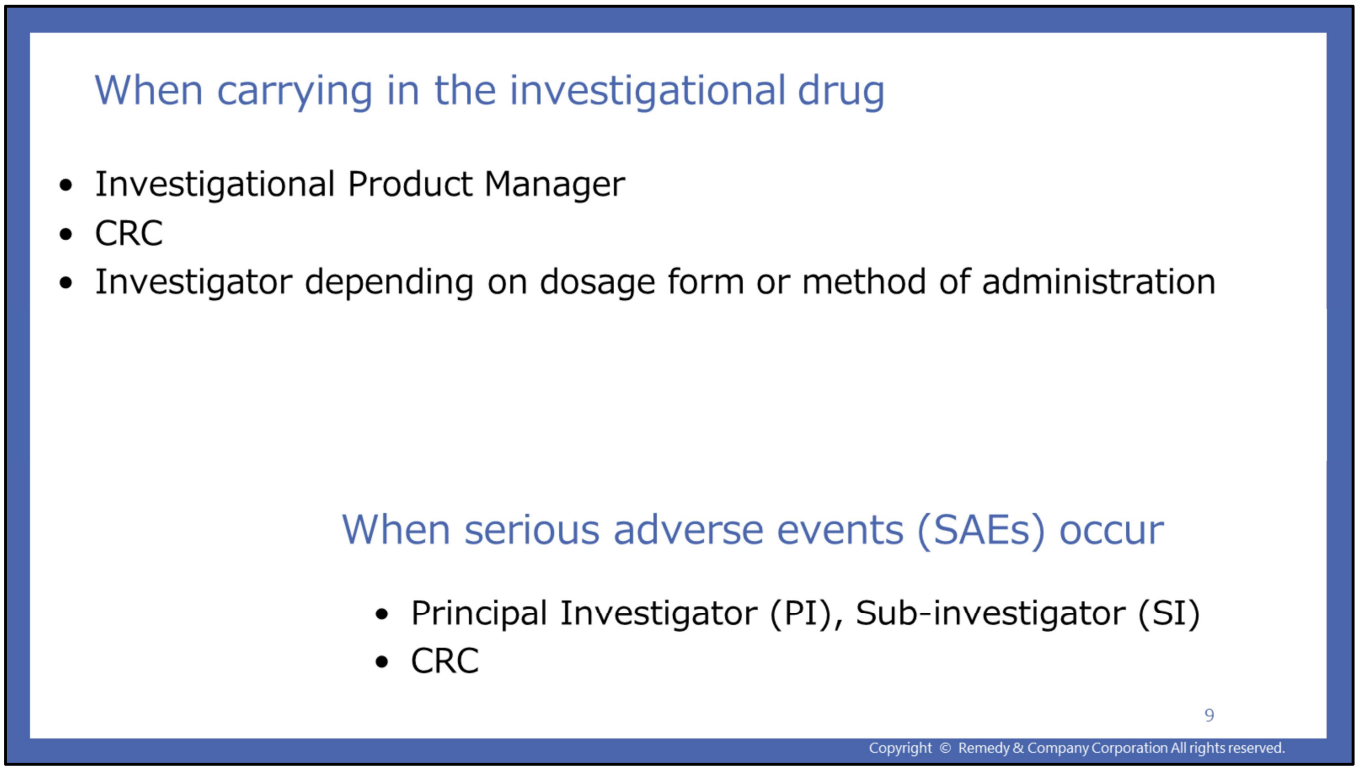
Regarding Institutional Review Board (IRB) application, we may need to collaborate or communicate with,

- PI
- Professor, Head of Department (Signature or seal is required on the IRB deliberation request form)
- Clinical Trial Office (Clinical Trial Support Center, Clinical Trial Management Office, Clinical Research Support Center)
- CRC (Hearing at the time of submission of sub investigator / collaborators list)
- Medical Affairs Division (Hospital Affairs)



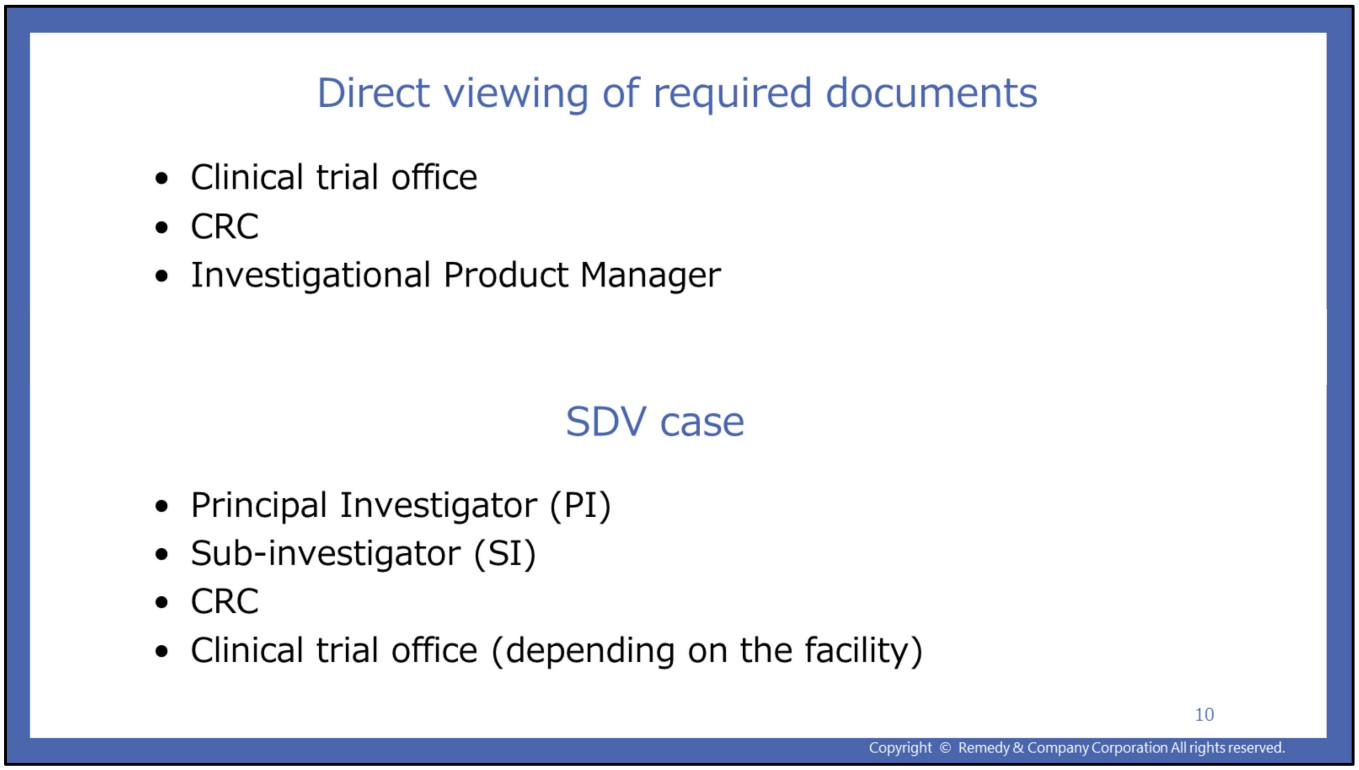
For Start Up Meeting (SUM), we may need to collaborate or communicate with;

- Principal Investigator (PI)
- Sub-investigator (SI)
- Clinical Research Collaborator (CRC)
- Laboratory technician
- Investigational Product Manager
- External laboratory
- Medical device company



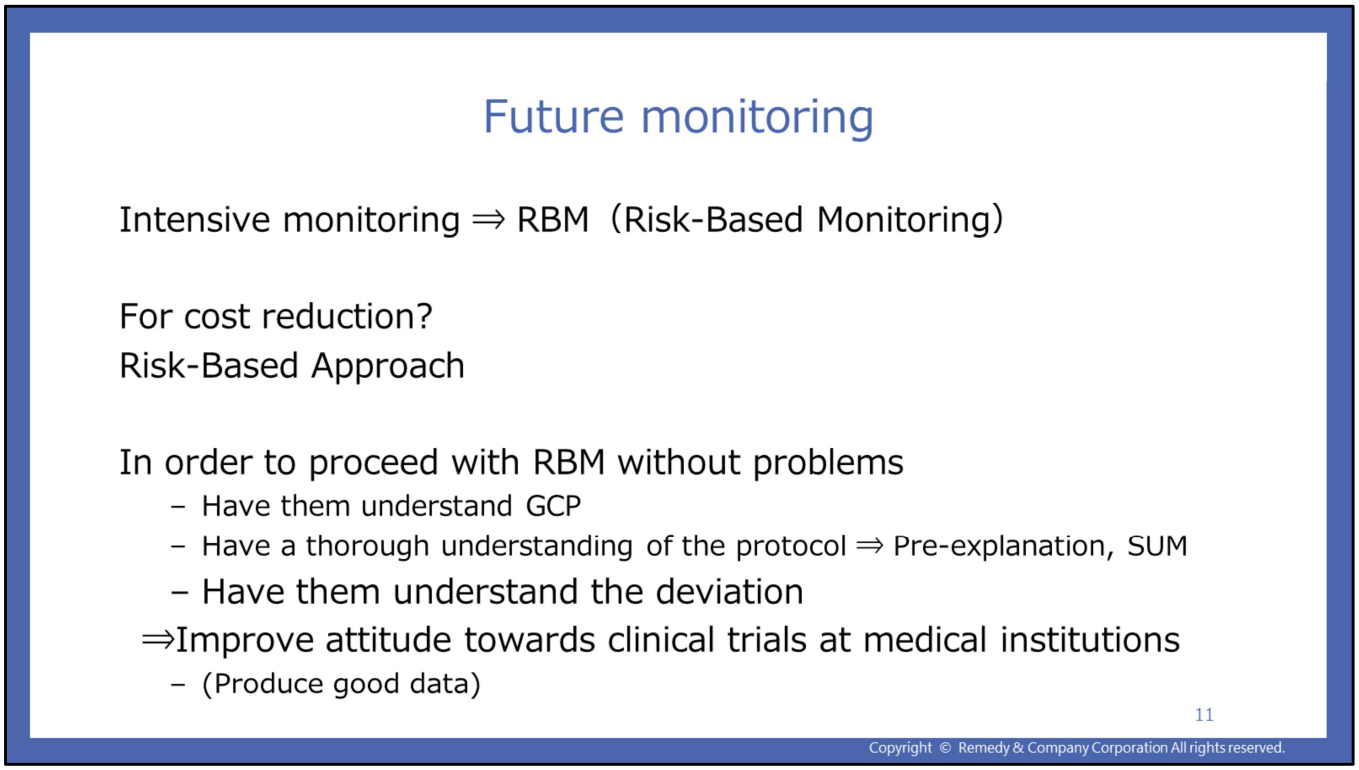
When carrying in the investigational drug, we may need to collaborate or communicate with;

- Investigational Product Manager
- CRC
- Investigator depending on dosage form or method of administration



For direct viewing of required documents, we may need to collaborate or communicate with;

- Clinical trial office
- CRC
- Investigational Product Manager



Implementing Risk-Based Monitoring or RBM in our future operations to conduct more efficient and cost-effective clinical trials.

Risk-based monitoring (RBM) is an innovative solution in clinical environments that offers intensive monitoring and could potentially reduce costs. However, to execute this without obstacles, it is crucial that we first ensure that everyone involved fully understands Good Clinical Practice or GCP.

GCP is an international ethical and scientific standard for designing, conducting, recording, and reporting trials. A firm grasp of GCP guidelines will ascertain that the rights, safety, and wellbeing of trial subjects are protected, and that the clinical trial data we gather are credible and accurate.

Secondly, it is equally important to have a thorough understanding of the protocol. Pre-explanation is critical to avoid any confusion or errors during operation. Using a Study Understanding Meeting or SUM can be beneficial in accomplishing this task.

During the SUM, every aspect of the study protocol would be discussed and clarified, ensuring a unified understanding and approach among team members.

Our next key consideration is to understand the deviation. Deviations from the study protocol may occur during clinical trials. It’s vital for our team to comprehend potential deviations and how to address them appropriately without compromising the quality or integrity of the data collected.

Lastly, improving the formulation and culture of clinical trials at medical institutions is paramount for producing high-quality data. Having a positive attitude towards clinical trials is essential among all stakeholders (researchers, clinicians, staff, etc.) and contributes to better primary data quality, reduces errors and omissions, and increases the efficiency in delivering timely, accurate findings.

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