Good day everyone! Today, we will be discussing about sponsors expect ARO-CRA ideal image.

Introduction

Please note the following points when reading this text.

- focuses on site monitoring.
- The ideal CRO/CRO-CRA that a sponsor expects will differ depending on each sponsor's background and individual mindset.
  - ✓Foreign Sponsor / Domestic Sponsor
  - ✓Sponsor's organizational structure
  - ✓Outsourcing experience to CRO
  - ✓Episodes of individual experiences ····· etc.

This story is an ideal image.
Please treat it as just one opinion and keep it as a reference.

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The perception of an ideal Clinical Research Organization or CRO-CRA often varies greatly from one sponsor to another, based on several factors. These factors can range from whether the sponsor is foreign or domestic, to the structure of the sponsor's organization, and whether they have past experiences with outsourcing to a CRO.

The factors that can be significantly influential when it comes to sponsors' expectations include:

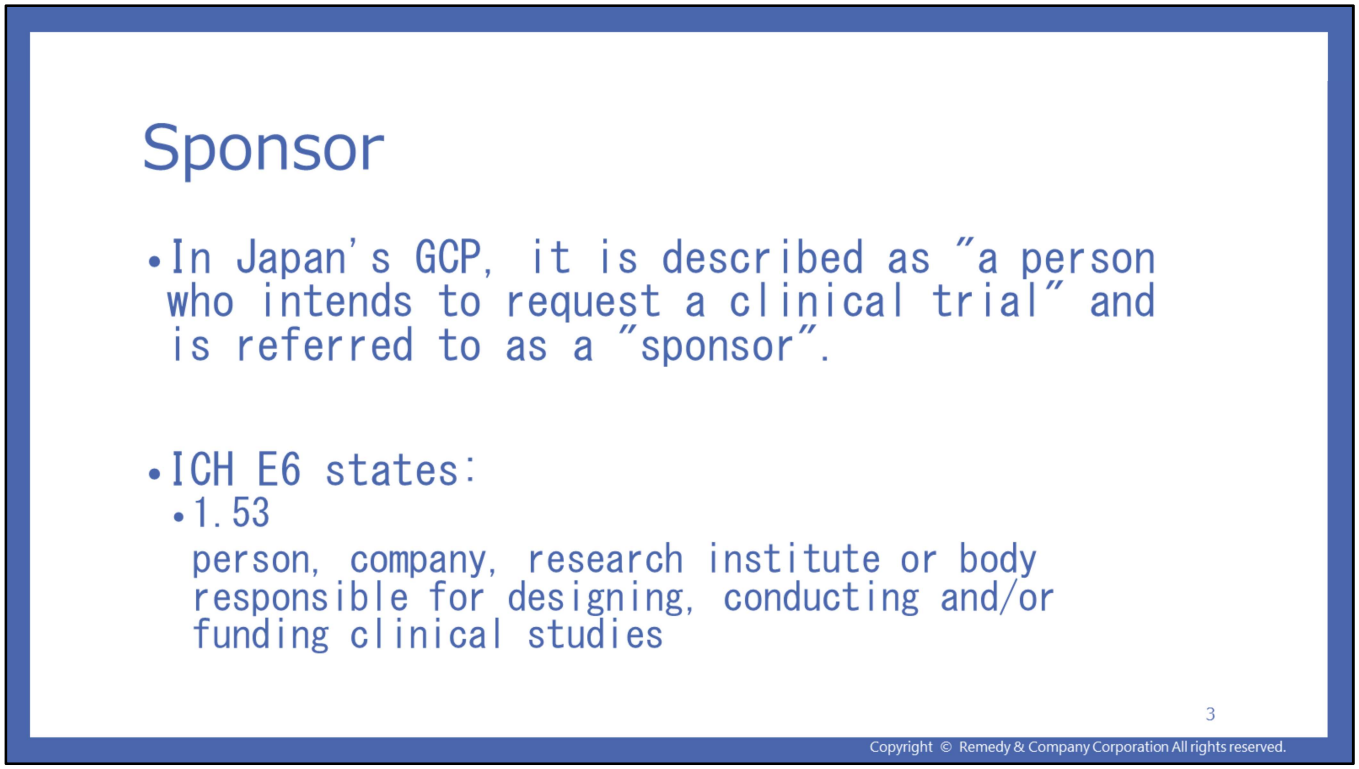
1.Whether the sponsor is foreign or domestic. The nationality of the sponsor can considerably shape their understanding and expectations of the CRO-CRA.

2.The sponsor's organizational structure. This factor can immensely impact how sponsors view their ideal Clinical Research Organization.

3.The sponsor's past experience with outsourcing to a CRO, as past experiences can significantly shape current expectations and future decisions.

4.Individual experiences or episodes can also play a crucial role. The personal experiences of the sponsor can give a unique perspective on their specific preferences, biases, and expectations.

Please Note
Let's keep in mind that today's presentation is based on our own subjective viewpoint on what an ideal CRO-CRA should look like for a sponsor. We am sharing our thoughts and opinions, which may or may not align with the views of different individuals in this room or outside it. Please treat this perspective as just one of the many possible viewpoints out there and use it as a reference you might find helpful in the grand scheme of things.

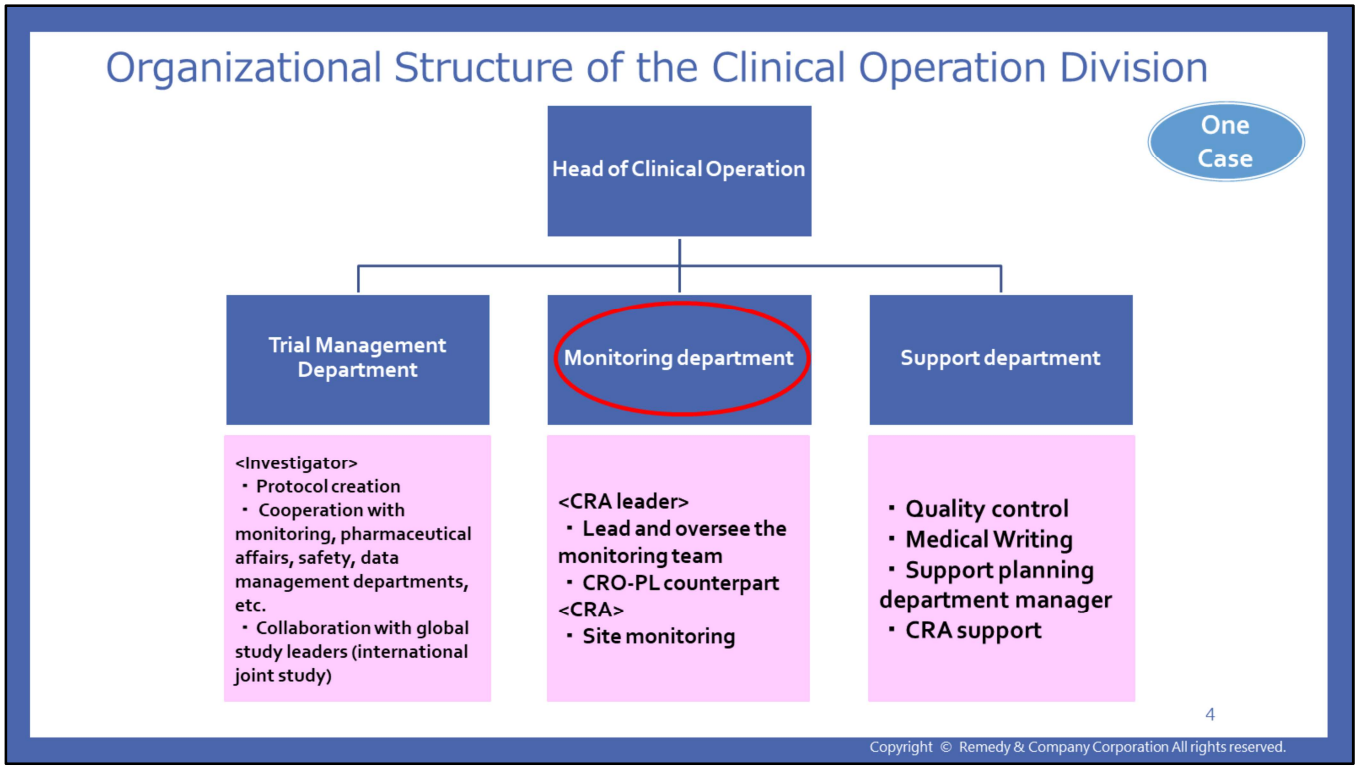


The ideal image of CRO/CRO-CRA expected by an individual who used to be on the sponsor side.

According to Japan's GCP guidelines, a sponsor is defined as "a person who intends to request a clinical trial." Notably, it doesn't state any explicit roles or responsibilities, rather focusing on the intention to initiate a clinical trial.

In contrast, ICH E6 provides a more comprehensive definition. According to ICH E6, a sponsor is understood as a "person, company, research institute or body responsible for designing, conducting and/or funding clinical studies." By this definition, the sponsor holds significantly more accountability in the process of conducting a clinical trial, and plays a broader role than merely initiating the trial.

It can be seen from these definitions, that while Japan's GCP suggests a more 'initiator' centric role of a sponsor, ICH E6 paints a picture of a much more involved entity, potentially responsible for the design, conduct and funding of the study. This highlights the variability in the way different regulatory or guidance documents interpret the role of a sponsor.



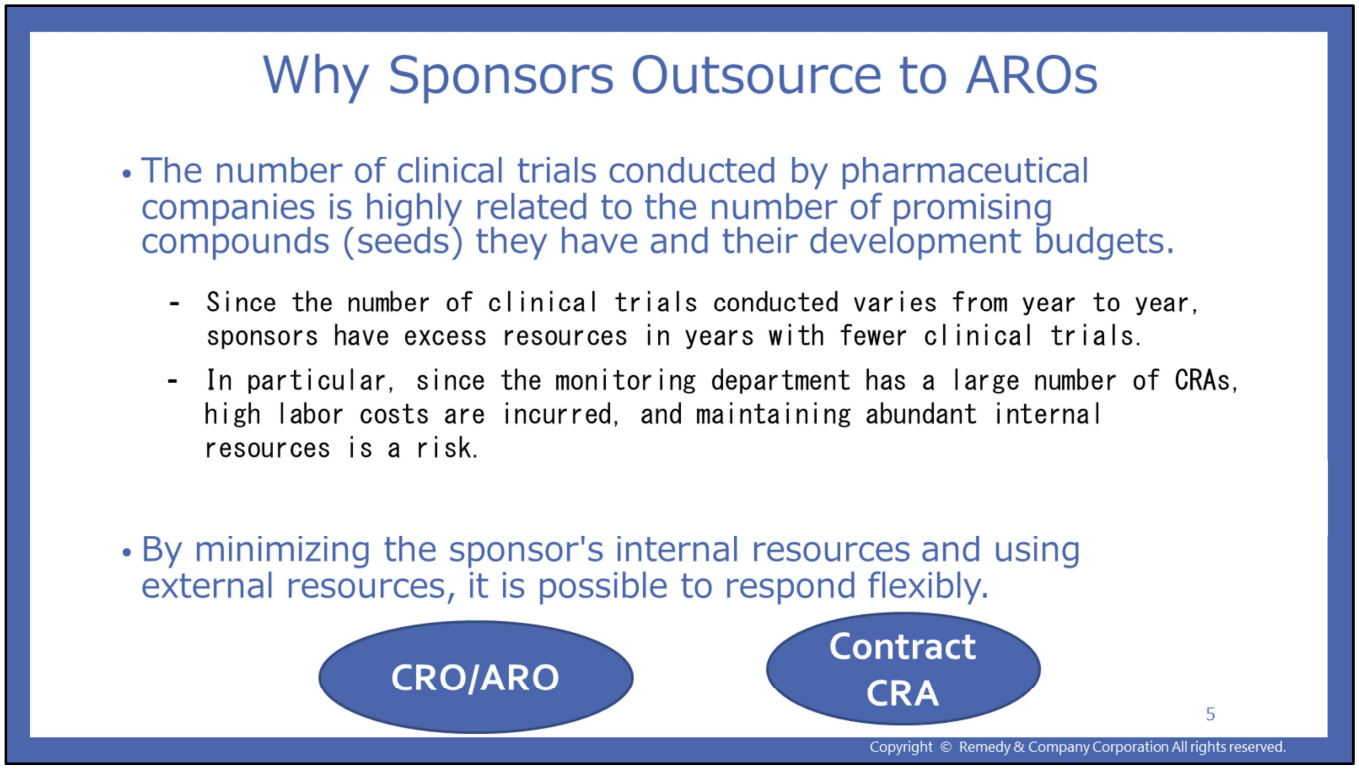
We would now like to elucidate ordinary organizational structure of a Clinical Operation Division in foreign pharmaceutical companies.

The division is primarily bifurcated into the Trial Management Department and the Support Department, with both of them operating under the adept supervision of the Head of Clinical Operation.

The Trial Management Department is primarily concerned with investigation, protocol creation, and fostering cooperative relationships with other essential departments such as pharmaceutical affairs, safety, and data management, amongst others. They also collaborate closely with global study leaders, specifically in the context of international joint studies.

Coming to the Head of Clinical Operations, besides overarching supervision, they bear the important responsibility of leading the Monitoring Department. CRA leader takes up the mantle of guiding and overseeing the monitoring team, acting as the CRO-PL counterpart and handling site monitoring.

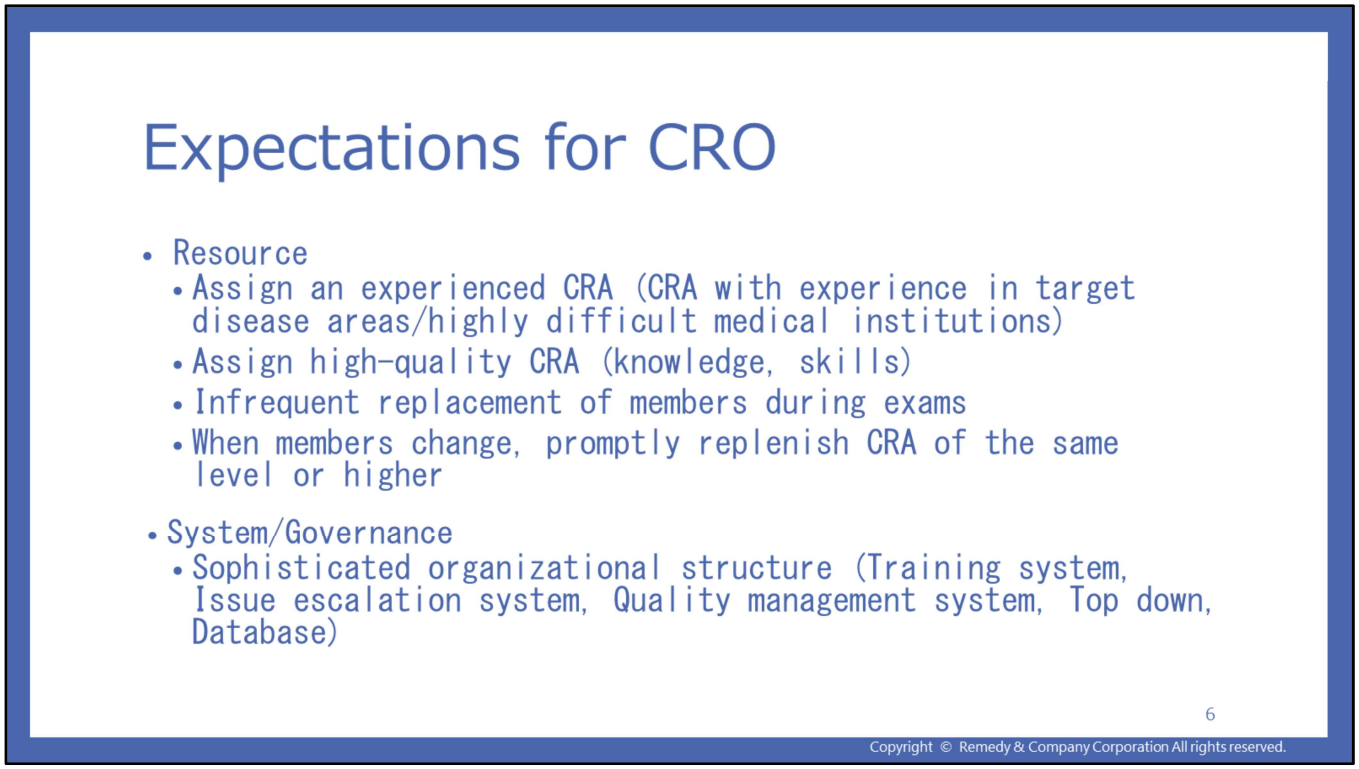
Lastly, we have the Support Department. Their pivotal roles include quality control, medical writing, and support planning. They also assist the department manager and extend their support to the activities of the CRA.



A good starting point is looking at how the number of clinical trials spearheaded by pharmaceutical companies, and stands in direct relation to the quantity of promising compounds or what we call ‘seeds’ that they have in the developmental pipeline. This situation inherently creates a close link between the number of trials and the budget allocated for developmental processes.

Now, due to the capricious nature of these developments, the number of trials conducted can fluctuate significantly from year to year. This unpredictability can leave sponsors dealing with excessive, unnecessary resources during years with less clinical trials. The monitoring department, which usually includes a high number of Clinical Research Associates, or CRAs, incurs substantial labor costs, and retaining a surplus of internal resources can become a risk for sponsors.

This is where AROs come into the equation. By streamlining their internal resources and strategically leveraging external resources available through AROs, sponsors can maintain a level of flexibility in dealing with the dynamic landscape of pharmaceutical developments. Outsourcing to AROs thus helps maximize efficiency, ensuring that resources are disbursed effectively and according to the immediate needs of the sector’s research environment.

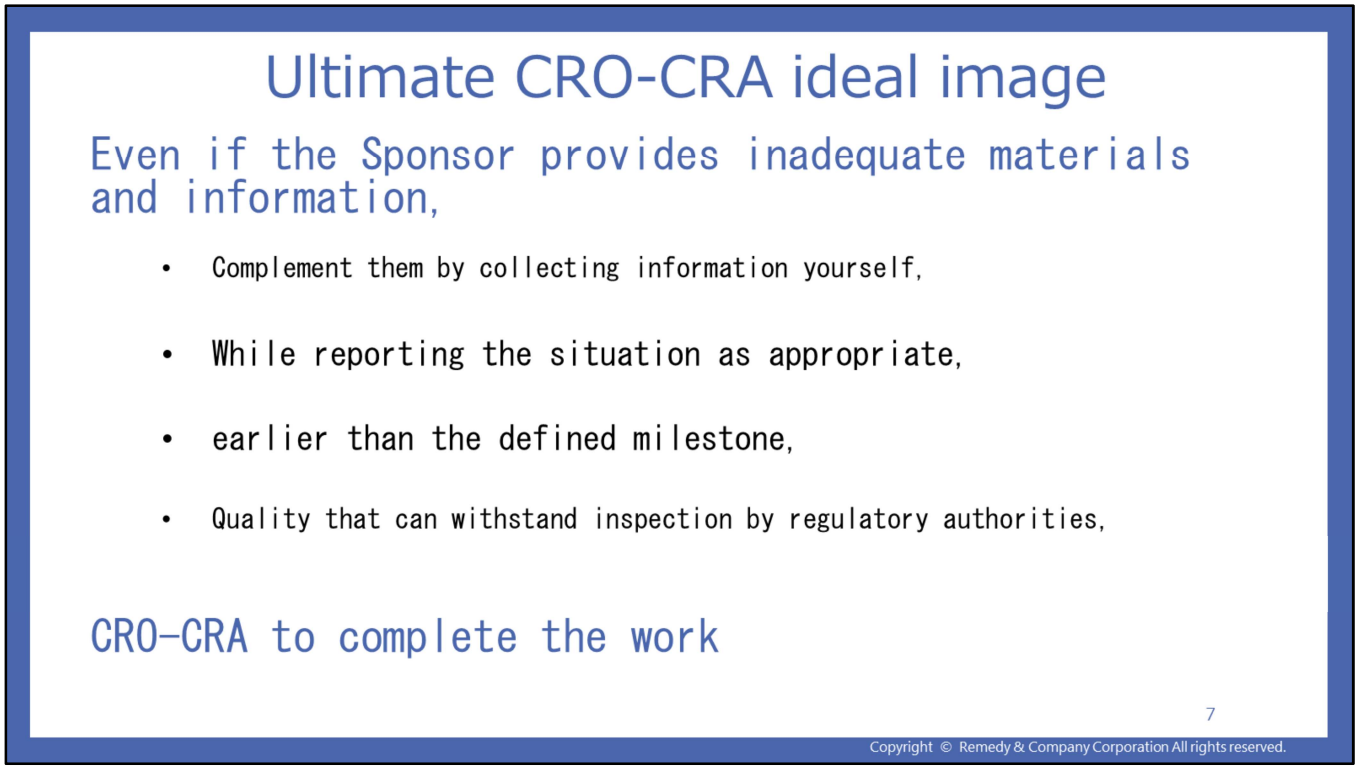


Resource Expectations
In regards to resources, we have two fundamental expectations. Firstly, we expect the CRO to assign an experienced Clinical Research Associate (CRA), specifically, one with significant experience in our target disease areas and performance in challenging medical institutions. Secondly, we also require high-quality CRAs. This refers to CRAs who possess in-depth knowledge and well-honed skills.

Consistency in Team Composition
An additional resource expectation is consistency. There should be infrequent replacement of team members during the entirety of our collaborative project. We believe that maintaining the same team will ensure more productive operational dynamics and more consistent results.

Replenishment with Quality
In the circumstances where team changes are necessary, there should be a quick replacement process. However, the quality should not be sacrificed over expediency. Newly assigned CRAs should equal, if not exceed, the expertise level of the preceding individual.

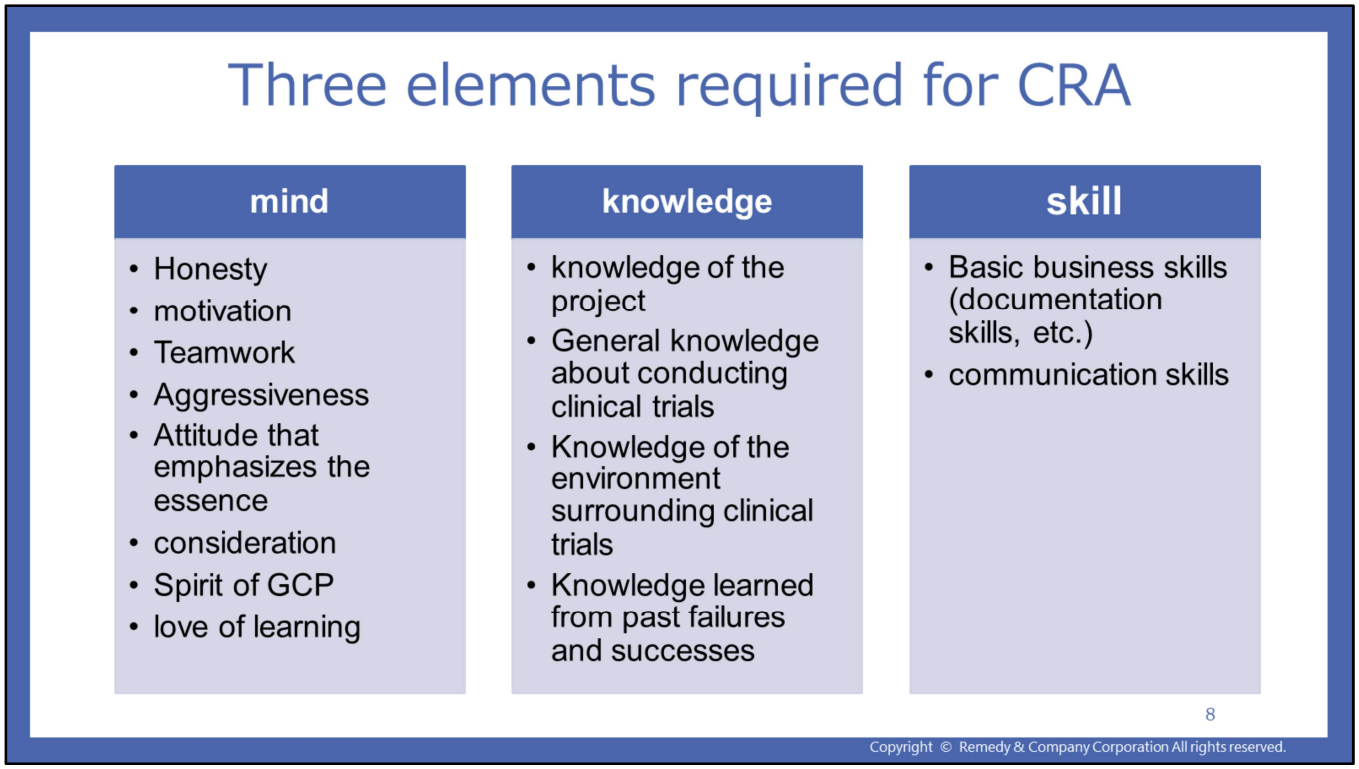
System and Governance
Now, moving onto our expectations for system and governance. We desire a sophisticated organizational structure from our CRO. This structure should be multi-faceted, including a strong training system, a responsible issue escalation system, an intricate quality management system, and a top-down approach. Furthermore, a structured database for easy access and management of data is crucial.



Ultimate CRO-CRA ideal image

Even if the Sponsor provides inadequate materials and information, CRO-CRA are expected to complete the work.

After complement by collecting information yourself, reporting the situation as appropriate, earlier than the defined milestone, the quality can withstand inspection by regulatory authorities.



The crucial elements required for an effective Clinical Research Associate, usually referred to as CRA.

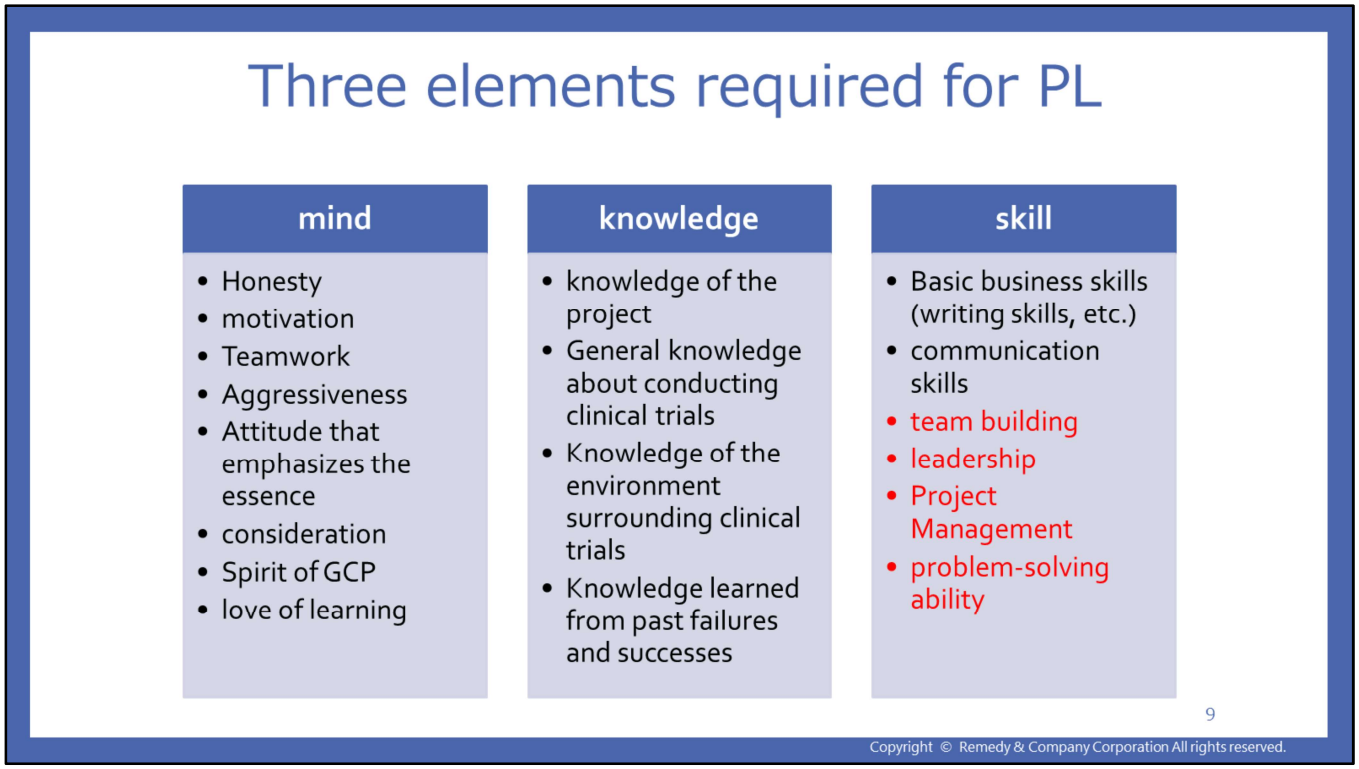
If you want to excel as a CRA, there are three major areas that you need to focus on: mindset, knowledge, and skills.

Starting off with the **mindset** - one of the most important aspects of CRA. It includes vital traits such as honesty, motivation, and aggressiveness. These traits are not just about personal growth, but they are about delivering the essence of the profession. Being a CRA, one needs to have love for learning and the attitude that underlines the importance of teamwork and consideration.

You need to possess the spirit of Good Clinical Practice (GCP), which essentially means adhering to the ethical standards in clinical trials.

Moving on to **knowledge** - knowing the ins and outs of your project is imperative. This entails having thorough understanding of conducting clinical trials. It also includes being aware of the environment encompassing clinical trials and possessing wisdom learned from past failures and successes. A generalized understanding would not suffice, it is the details that matter.

Finally, **skills** - a key element that underlies the performance of every CRA. This extends beyond just practical abilities, including indispensable communication and basic business skills such as documentation. As a CRA, you need to amalgamate your knowledge and mindset, then put these into practice through your skills.



The key elements required for project leadership.

We have categorized these essential elements into three main groups: mind, knowledge, and skill.

Starting with **mind**, this pertains to the attitude, motivation, and spirit that you bring to your project leadership. Honesty is imperative since your team looks to you for direction and trusts your judgment. Teamwork, on the other hand, manifests in the way you value the contributions of each member and foster an environment of cooperation. Aggressiveness is about proactively addressing challenges and pursuing project goals. An attitude that emphasizes essence refers to valuing the true substance and purpose of your work over superficial appearances. Lastly, your love of learning fuels continuous improvement from both past successes and failures.

Next, we have **knowledge**. Knowledge here doesn't only mean being aware about general business information but it extends to having in-depth understanding about your specific project and its surrounding environment. This entails recognition of the complexity of conducting clinical trials and compliance with the Good Clinical Practice (GCP) guidelines that apply in the clinical research industry.

Now, on to the third element: **skill**. These are practical abilities you apply directly to your work. Basic business skills, writing skills, communication, team building, leadership, project management and problem-solving abilities are just a few examples.

Each project might require unique skills, but these are the fundamental ones that are universally applicable to most, if not all, project managements.

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