WORKING WITH IMARC:

YOUR PARTNERS IN COMPLIANCE

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FROM THE DESK OF SANDRA MADDOCK

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From our conversations with clients, we know how difficult it can be to hand over a portion of your study to anyone, even a well-established CRO. Can you trust them? Will they do a good job? Will they understand the importance of this study to our company? Will they "burn" us like the last CRO we hired? Will they be worth the investment or just cause us even more work than we had before?

This is understandable. What we have found at IMARC is that our clients are much more at ease once they get to know our team and our process. They view us as an extension of their team, and have confidence in knowing that we'll get the job done.

This guide offers an overview of our team and our process, highlighted through a series of short case studies. The foundation of our company lies in having a strong team whose practice is based in the regulations and whose people-skills, critical thinking and problem-solving abilities are stellar.

Now that we have grown to a sizeable team, we consider it our greatest privilege to help sponsors run well-controlled clinical trials by offering them a second set of eyes. We welcome the opportunity to introduce you to our team and are eager to get to know yours. Please feel free to contact us with any questions. We look forward to being your partners in compliance!

Sincerely,

Sandra Maddock

Sandra Maddock, CEO, IMARC Research

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GETTING TO KNOW US:

WORKING WITH IMARC

OUR TEAM

Our contract research organization has almost 20 years of experience ensuring patient protection and regulatory compliance through clinical monitoring, auditing, project management and other services.

With expertise ranging from cardiology and neurology to orthopedics and wound care, our team has significant depth. We consider it our privilege to help sponsors run well-controlled, compliant clinical studies so that the data they submit for worldwide regulatory approvals is beyond reproach.

Our team will act as a true partner, fully integrating with your teams and processes while providing objective, independent oversight and consulting.

HERE'S A LOOK AT SOME OF THE ROLES WITHIN OUR ORGANIZATION AND HOW THEY WORK WITH YOURS.

LEADERS

IMARC's leadership team has a diverse background and is always looking for new ideas to problem-solve and improve processes. They will not be shy about making suggestions or offering up alternatives if they believe it will help the study.

MONITORS

Enforce compliance requirements and ensure patient safety. These are your team of people out in the field who do much more than ensure that "X=X" and "Y=Y." They will critically think through what they are seeing out in the field and will escalate significant issues promptly.

AUDITORS

Offer a process-level look at compliance, identifying trends and reporting to you what site or study-wide risks may need attention. If conducted early in the study process, their audits can help prevent situations that could later result in a negative outcome.

PROJECT MANAGERS

Manage the day-to-day activities of a study with attention paid to proper resourcing, budget, and timelines. Will provide regular dashboards to keep you informed of the study status and will provide leadership to the entire study team as it relates to proper planning, training, and addressing difficult situations.

OUR VALUES AND MISSION

We believe clinical trial success is based on careful planning, thorough training and consistent application of a rigorous process rooted in regulations. Our team sets the highest standards for study conduct. We are committed to providing competent, confident oversight to ensure every study adheres to these standards to achieve the ultimate goal of protected patients and data that has integrity.

OUR PROCESS:

ENSURING COMPLIANCE THROUGHOUT THE CLINICAL TRIAL LIFECYCLE

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During a trial, clinical professionals encounter a number of hurdles that can put human subjects at risk, result in costly delays and even compromise the integrity of their data.

Having independent oversight from a compliance-minded contract research organization can keep your trial on track and ensure you achieve regulatory approval.

Our team can support yours at any point in the process or manage your entire project, serving as a single point of contact for the study teams.

The following snapshots offer a glimpse at how we have worked with teams during various stages of their clinical research studies, from the initial planning and risk assessment to data closeout.

VISIT OUR PROCESS >

MONITORING:

A PARTNER FOR COMPLIANCE FROM DAY 1

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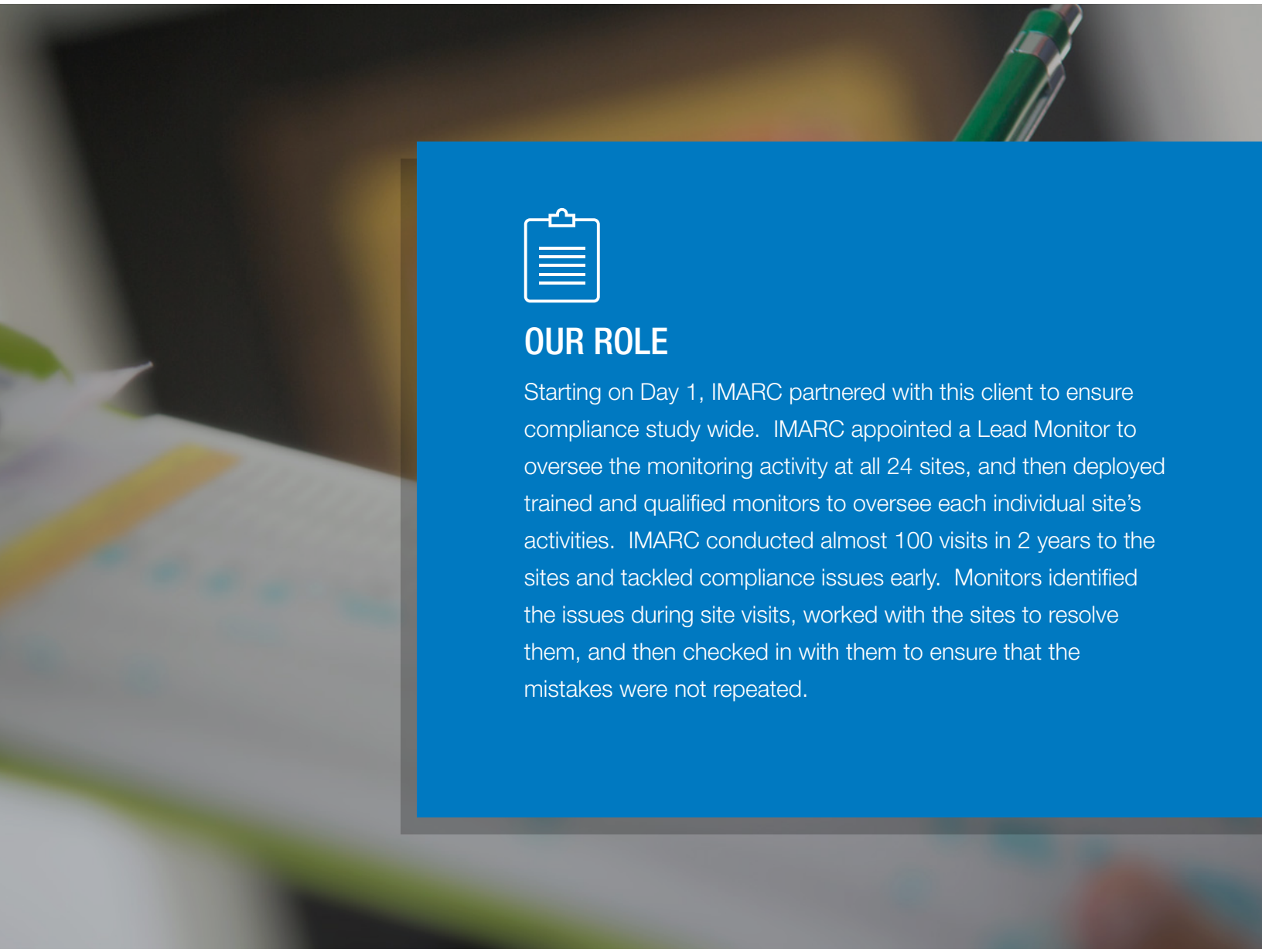
SUMMARY

A client was conducting a clinical study of a significant risk device at 24 sites and was in need of monitoring support.

KEY CHALLENGES

The high-risk nature of the study, the complexity of the patient population, the quick enrollment rate, and the significant imaging requirements that differed from standard of care combined to raise a number of potential compliance concerns.



OUR ROLE

Starting on Day 1, IMARC partnered with this client to ensure compliance study wide. IMARC appointed a Lead Monitor to oversee the monitoring activity at all 24 sites, and then deployed trained and qualified monitors to oversee each individual site's activities. IMARC conducted almost 100 visits in 2 years to the sites and tackled compliance issues early. Monitors identified the issues during site visits, worked with the sites to resolve them, and then checked in with them to ensure that the mistakes were not repeated.

RESULTS

The FDA audited three sites mid-trial with little notice. IMARC monitors prepared the sites for the FDA inspection and assisted them onsite during the inspections. Although there had been some compliance issues identified through monitoring efforts at each of the sites, the issues were addressed with the guidance of the monitors and did not recur. All three sites passed their FDA inspections with no findings.

AUDITING:

PERIPHERAL DRUG-COATED STENT RECEIVES WORLDWIDE APPROVALS WITH NO SIGNIFICANT INSPECTIONAL FINDINGS

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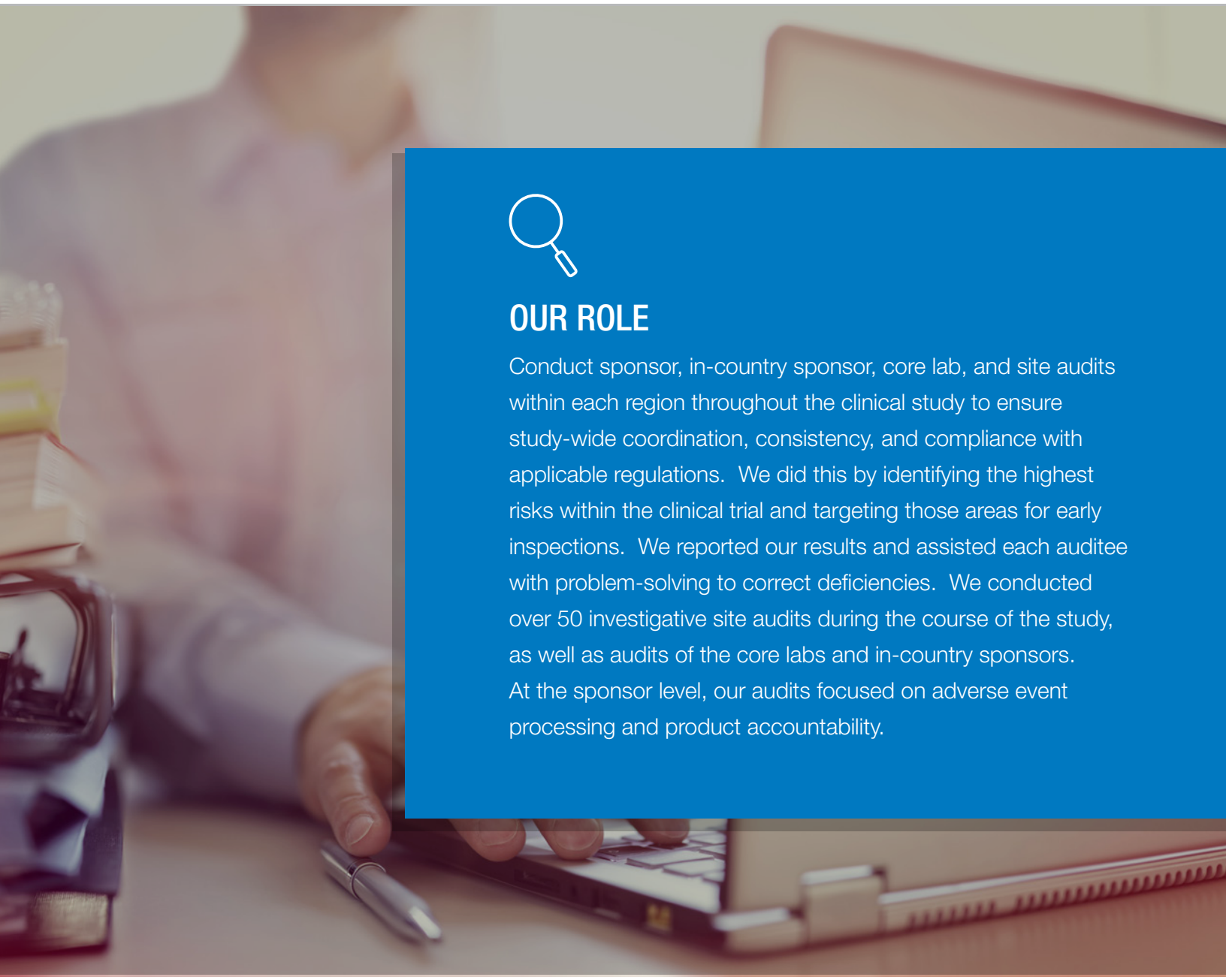
SUMMARY

IMARC was hired by a company to conduct multiple types of audits throughout the course of a study being conducted simultaneously in the US, Europe, and Japan.

KEY CHALLENGES

The involvement of multiple regions meant multiple sets of regulations were in play. The study had a complex design and different versions of the protocol were utilized in each region to accommodate for varying standards of care. Language barriers, differing cultures, and multiple time zones added to the complexity.



OUR ROLE

Conduct sponsor, in-country sponsor, core lab, and site audits within each region throughout the clinical study to ensure study-wide coordination, consistency, and compliance with applicable regulations. We did this by identifying the highest risks within the clinical trial and targeting those areas for early inspections. We reported our results and assisted each auditee with problem-solving to correct deficiencies. We conducted over 50 investigative site audits during the course of the study, as well as audits of the core labs and in-country sponsors. At the sponsor level, our audits focused on adverse event processing and product accountability.

RESULTS

The client underwent regulatory inspections at the sponsor and site levels across multiple regions with no significant findings noted worldwide. The device received approval in all targeted markets.

PROJECT MANAGEMENT:

AN OUS START-UP COMPANY IN NEED OF RESCUE

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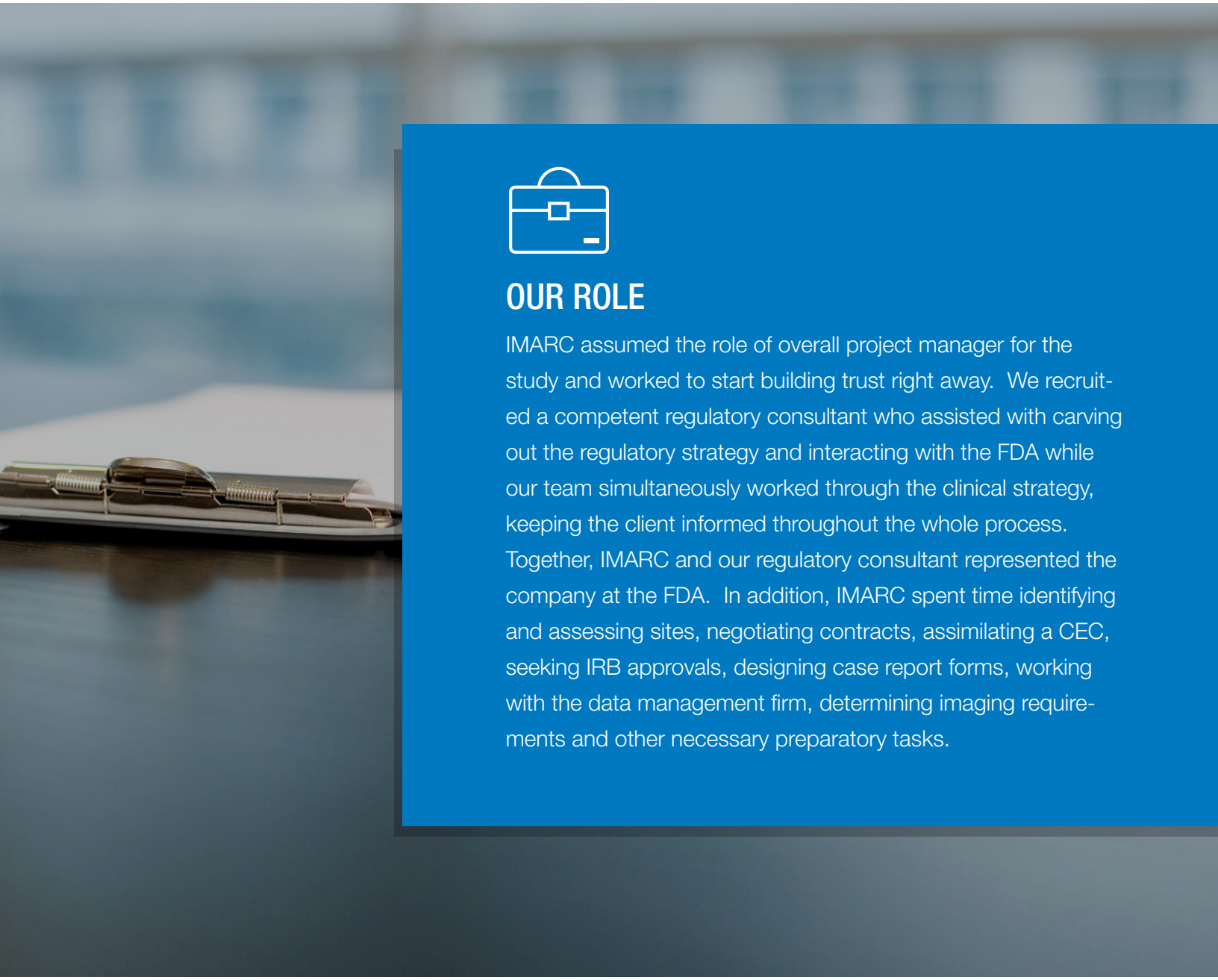
SUMMARY

An Israeli-based start-up company had contracted with another CRO to assist them with navigating the regulatory and clinical trial requirements in an effort to obtain FDA approval for their significant risk device. The CRO had gone through significant turnover of key personnel which impacted the progress with the FDA application and subsequent clinical trial. Despite charging the company a significant fee, the CRO was no closer to gaining FDA approval to run the clinical trial than they had been when they started the project a year earlier. The company then sought assistance from IMARC.

KEY CHALLENGES

IMARC did not have the historical knowledge that had been acquired by the first CRO with regards to previous FDA interactions, and from what they could piece together; it appeared that the CRO had not been properly advising the company. Because of that, IMARC was essentially starting "from scratch" to carve out the regulatory and clinical strategies for a company whose shareholders were growing inpatient and whose trust in CROs was eroding.



OUR ROLE

IMARC assumed the role of overall project manager for the study and worked to start building trust right away. We recruited a competent regulatory consultant who assisted with carving out the regulatory strategy and interacting with the FDA while our team simultaneously worked through the clinical strategy, keeping the client informed throughout the whole process. Together, IMARC and our regulatory consultant represented the company at the FDA. In addition, IMARC spent time identifying and assessing sites, negotiating contracts, assimilating a CEC, seeking IRB approvals, designing case report forms, working with the data management firm, determining imaging requirements and other necessary preparatory tasks.

RESULTS

Within a year of first meeting this company, IMARC had obtained full FDA and IRB approvals to conduct the study.

SAFETY MANAGEMENT:

OPERATING DATA SAFETY MONITORING BOARDS AND CLINICAL EVENTS COMMITTEES

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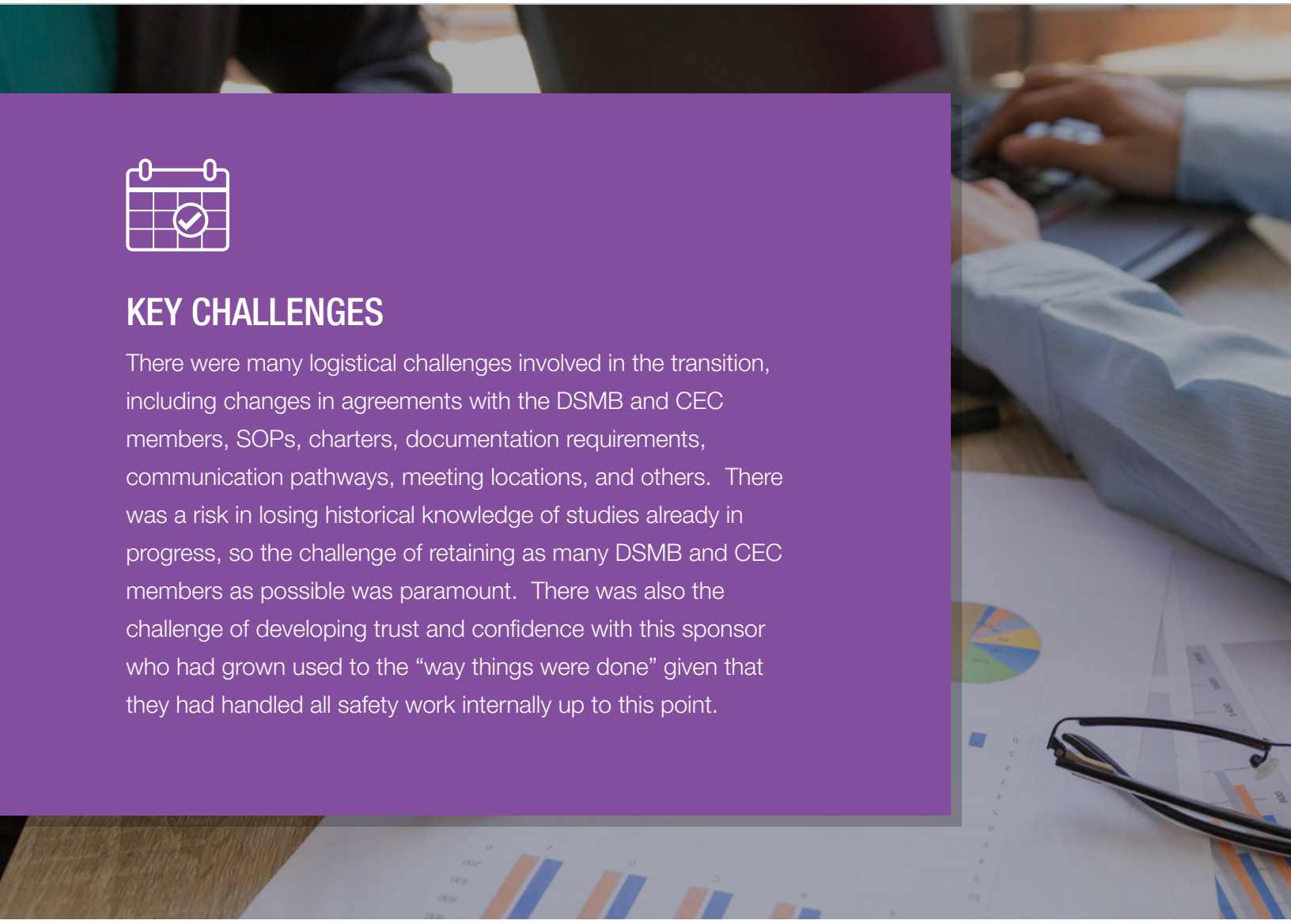
SUMMARY

A client conducting studies in several therapeutic areas had historically relied on its internal team for data safety monitoring and clinical event adjudication but made a strategic decision to transition these important tasks to an independent third party to add another layer of oversight. They hired IMARC's DSMB and CEC to fulfill this role.



KEY CHALLENGES

There were many logistical challenges involved in the transition, including changes in agreements with the DSMB and CEC members, SOPs, charters, documentation requirements, communication pathways, meeting locations, and others. There was a risk in losing historical knowledge of studies already in progress, so the challenge of retaining as many DSMB and CEC members as possible was paramount. There was also the challenge of developing trust and confidence with this sponsor who had grown used to the "way things were done" given that they had handled all safety work internally up to this point.

OUR ROLE

TO ENSURE A SMOOTH TRANSITION, IMARC TOOK THE FOLLOWING APPROACH:

- Appointed a DSMB/CEC administrator specifically assigned to this project
- Attended DSMB/CEC meetings prior to the transition to observe typical practice
- Reviewed the client's SOPs to determine where synergies may exist and where modifications could be made to IMARC's SOPs to improve the transition
- Providing regular updates to all DSMB/CEC members and client regarding timeline, action needed on their part, and expected changes
- Provided face-to-face and remote trainings on new procedures to all DSMB/CEC members
- Recruited additional DSMB/CEC members as necessary
- Revised existing charters to note changes in administration of the DSMB/CEC
- Sent multiple staff to the first several DSMB/CEC meetings to ensure a smooth transition
- Sought feedback from both the client and board members to ensure satisfaction

RESULTS

IMARC now handles the DSMB and CEC activity for over 20 significant risk device and biologic studies for this client, with the typical study averaging anywhere from 2-4 meetings per year. IMARC has successfully recruited and retained experts in all therapeutic areas and acts as the main line of communication between the boards and the client. The client is confident in its efforts toward ensuring patient protection knowing these boards are reviewing their data with true objectivity.

TRAINING:

PARTNERING WITH A CLIENT TO ENSURE ADEQUATE GOOD CLINICAL PRACTICE TRAINING FOR SPONSOR AND SITE PERSONNEL

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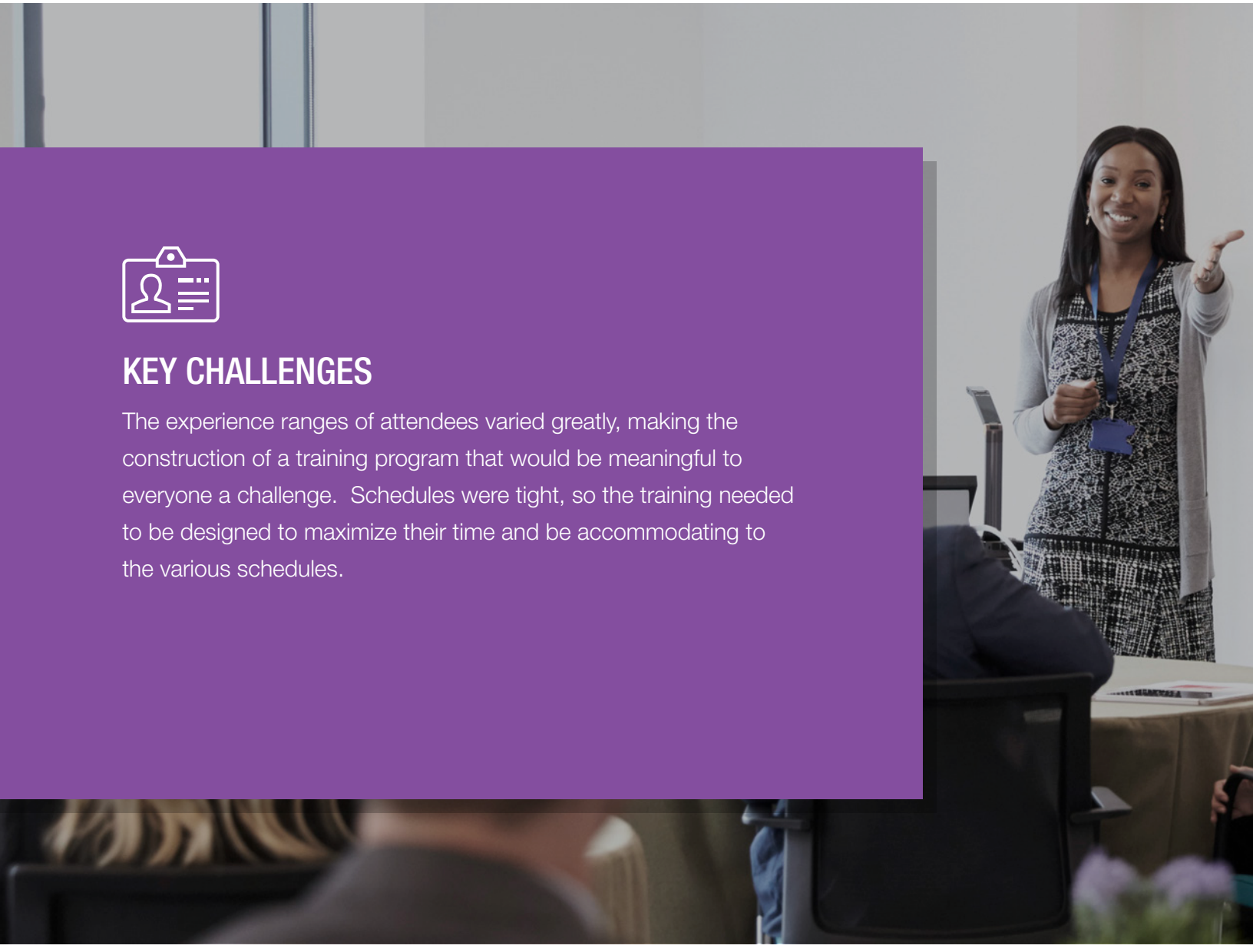
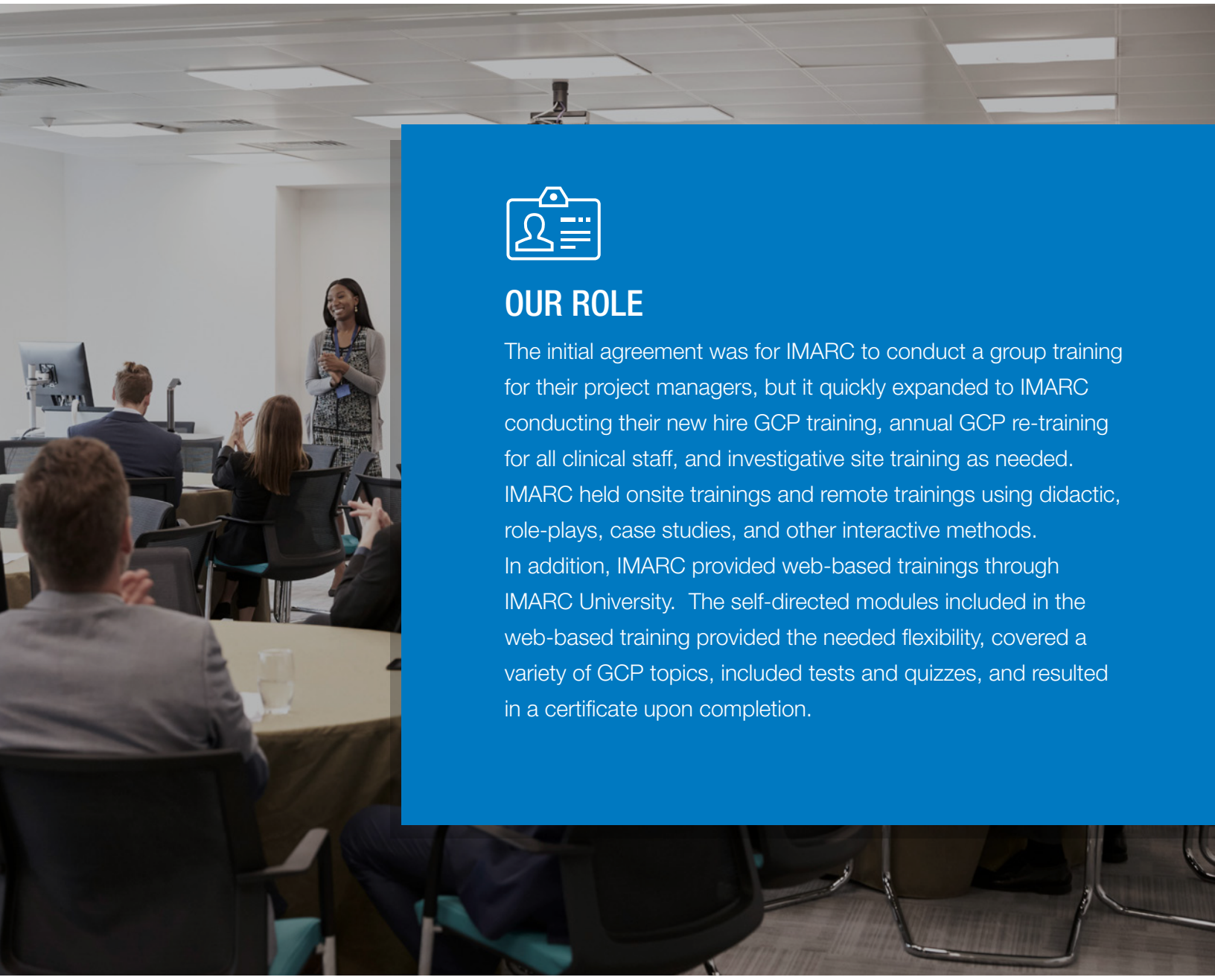
SUMMARY

A medical device client had project managers with varying levels of experience running clinical trials. To bridge any gaps in understanding of Good Clinical Practice (GCP), the client hired IMARC to conduct some internal clinical team training.



KEY CHALLENGES

The experience ranges of attendees varied greatly, making the construction of a training program that would be meaningful to everyone a challenge. Schedules were tight, so the training needed to be designed to maximize their time and be accommodating to the various schedules.



OUR ROLE

The initial agreement was for IMARC to conduct a group training for their project managers, but it quickly expanded to IMARC conducting their new hire GCP training, annual GCP re-training for all clinical staff, and investigative site training as needed. IMARC held onsite trainings and remote trainings using didactic, role-plays, case studies, and other interactive methods.
In addition, IMARC provided web-based trainings through IMARC University. The self-directed modules included in the web-based training provided the needed flexibility, covered a variety of GCP topics, included tests and quizzes, and resulted in a certificate upon completion.

RESULTS

With a firm commitment to ensure that they have a clinical team with a strong foundation in GCP and that they arm their clinical sites with the same knowledge, this client is far better prepared to run compliant, well-controlled studies having gone through IMARC's GCP training regimen. IMARC is now their go-to partner for training of new staff and sites in need of additional training support.

CONSULTING:

ADVISING A CLIENT ON THEIR RESPONSE TO A FORM FDA 483

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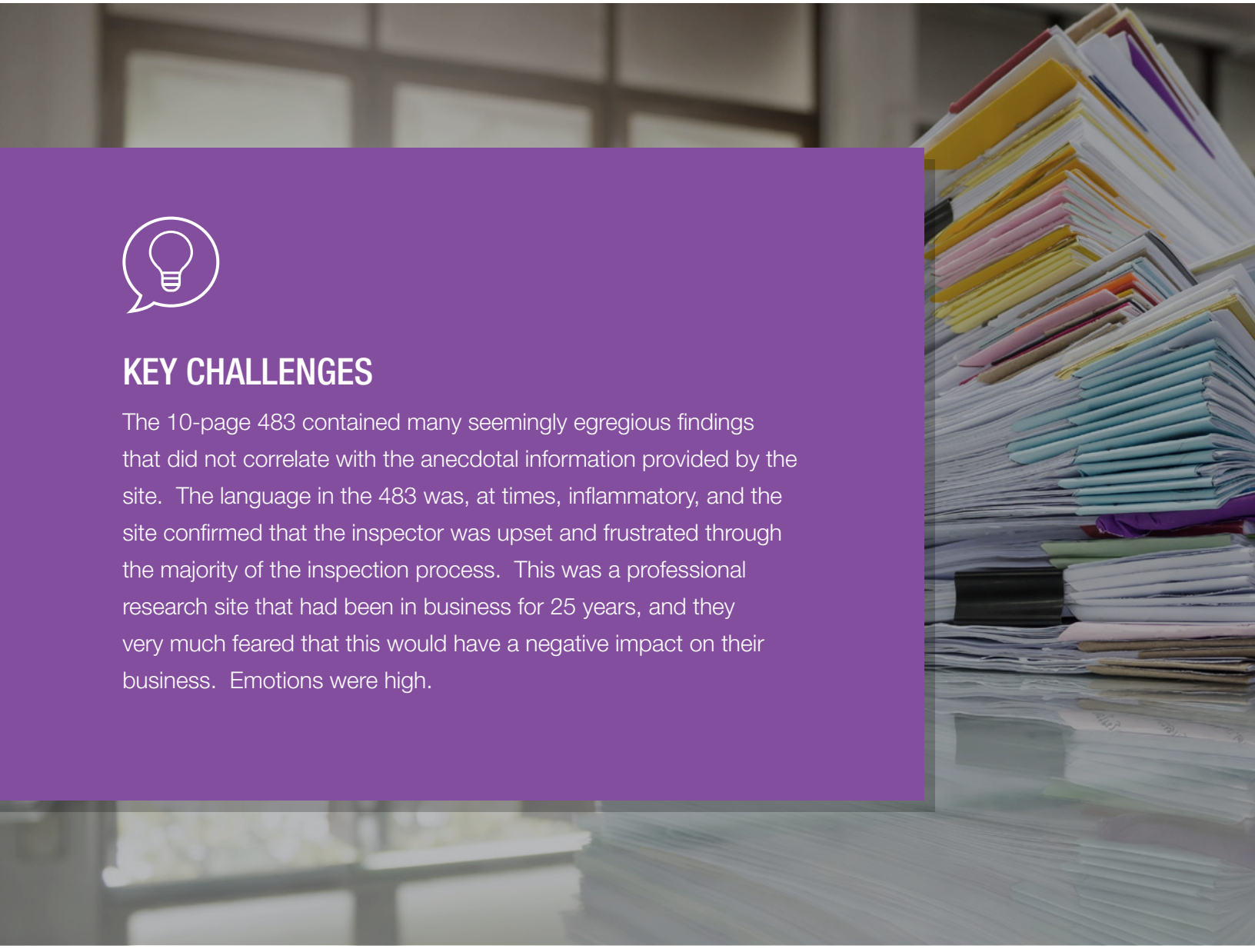
SUMMARY

A client previously unknown to IMARC contacted us for assistance in responding to a Form FDA 483 (483) after a month-long FDA inspection.



KEY CHALLENGES

The 10-page 483 contained many seemingly egregious findings that did not correlate with the anecdotal information provided by the site. The language in the 483 was, at times, inflammatory, and the site confirmed that the inspector was upset and frustrated through the majority of the inspection process. This was a professional research site that had been in business for 25 years, and they very much feared that this would have a negative impact on their business. Emotions were high.

OUR ROLE

First, time was spent with the site gaining a thorough understanding of the inspection process and the findings. Very early in the process, it became clear that the 483 contained inaccurate observations, and reassurance was provided to the principal investigator and management personnel from the site to reduce the overwhelming feeling of failure they felt. IMARC investigated each observation to determine its validity. One by one, IMARC helped craft a response, using source data, medical records, and other evidence, that indicated the reasons why each observation was or was not a deviation as described. IMARC was able to effectively negate the majority of the findings. Evidence to corroborate IMARC's assessment was attached to the final response which totaled almost 50 pages.

RESULTS

Six months after the site submitted their response letter, the FDA issued them a untitled letter indicating that the site's response was adequate. Because of the erroneous nature of this particular 483, IMARC has written about this experience, interviewed with an online journal, and assisted with wording for a potential House bill to be introduced to Congress that would reduce the likelihood of this type of erroneous reporting by the FDA.

TIPS FOR A SUCCESSFUL COMPLIANCE PARTNERSHIP

A sponsor's job is much easier when they have a strong partnership with a compliance-minded CRO. Sites are engaged in the study and hit their milestones for start-up, enrollment and completion. Study data is entered, monitored, cleaned and locked on time. When all is running smoothly, the sponsor may not give much thought to the relationship with their CRO, but they know they cannot afford to lose them.

When a sponsor's relationship with the CRO is strained, however, nearly every area of the study could suffer. Red flags pop up everywhere. Enrollment is slow. Sites enroll ineligible subjects and deviate from the protocol, jeopardizing the integrity of the data. The study goes over budget and misses critical deadlines. Work may have to be redone, and the sponsor may need to find another CRO midway through the study.

HIRING THE RIGHT CRO IS ESSENTIAL TO SUCCESS. BUT IT'S ONLY HALF OF THE EQUATION. TO MAKE THE MOST OF YOUR PARTNERSHIP, WE RECOMMEND THE FOLLOWING BEST PRACTICES:

- **Hire a CRO whose practice is firmly based in the regulations.** IMARC has a strong regulatory basis for making decisions in the clinical research setting.
- **Hire a CRO with therapeutic expertise.** IMARC focuses on medical device trials and has extensive experience in a variety of therapeutic areas.
- **Proven track record.** IMARC has a proven track record with the FDA and can provide you with the needed services to ensure compliance through the life of your trial.
- **Provide budget management.** Providing an accurate estimate is essential and managing the budget to ensure no overages is one of IMARC's strengths.
- **Understand that your team's participation is crucial.** We are the experts when it comes to managing compliance, but your team members are the experts when it comes to your device. Both are needed to successfully run a well-controlled clinical trial.
- **Trust us.** Your success is our success. You can count on us to provide competent, confident oversight to ensure every study adheres to the highest standards.

READY TO TAKE THE NEXT STEP TO ENSURE COMPLIANCE?

CONTACT US FOR A FREE CONSULTATION. ›