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CASE STUDY

Guiding a Cardiac CDSS to Market Success with Elexes

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INTRODUCTION

- The Clinical Decision Support System (CDSS) are becoming important tools in this rapidly changing healthcare ecosystem, enabling medical professionals to make prompt and well-informed medical decisions.

- Bringing such innovative medical devices to the market involves navigating an intricate regulatory framework, especially in regions like the United States, Canada, Australia, and the European Union.

- This case study explores how Elexes, a leading medical device regulatory and quality consulting firm, helped a promising health technology startup overcome regulatory uncertainties and successfully chart its path toward market approval.

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BACKGROUND

- A medical technology startup developed an innovative Clinical Decision Support System (CDSS) designed to analyze ECG (Electrocardiogram) data and predict potential cardiac events such as arrhythmias, myocardial infarction, and sudden cardiac arrests.

- The system made use of different AI algorithms which facilitate timely interventions so as to improve the outcome of patients.

- As the startup was new to the medical device industry, they faced certain regulatory challenges for launching the product in the market.

- The company was unclear about the regulatory pathways, product classification and the clinical evidence required to support the claims of their device.

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PROBLEM STATEMENT

The startup approached Elexes with the following challenges:

- **Regulatory Pathway Ambiguity:** Uncertainty about the correct regulatory routes for entering the U.S. and EU markets.
- **Product Positioning Dilemma:** Difficulty in defining the intended use and optimal positioning of their CDSS within the clinical workflow.
- **Clinical Validation Concerns:** Unclear on the design and execution of the clinical studies.

These uncertainties posed significant barriers to the timely and successful commercialization of their innovative CDSS.

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METHODOLOGY

Elexes implemented an exhaustive methodology to address Client's challenges

01. **INITIAL REGULATORY GAP ANALYSIS**

02. **REGULATORY ROADMAP DEVELOPMENT**

03. **CLINICAL DUE DILIGENCE**

04. **CLINICAL STUDY DESIGN**

05. **COMPREHENSIVE DOCUMENTATION AND SUBMISSION SUPPORT**

METHODOLOGY

Some of the methods employed are described below:

1. Initial Regulatory and Quality Gap Analysis:

- Elexes had meetings with the CTO, clinical head, and Founders of the company to understand the target customer population, intended use, indications for use, and product's technological characteristics.
- Elexes provided inputs on the various aspects of the product from a regulatory perspective and assessed the gaps in the current documentation, product positioning, and indications for use to get the product to the market.

2. Regulatory and Quality Roadmap Development:

- Based on the gap analysis, Elexes developed a regulatory and quality roadmap which identified the important milestones to be achieved for a successful product launch in the target markets.
- This included deliverables on both the regulatory side for a 510(k) clearance and CE Marking and the quality side for an ISO 13485 and 21 CFR Part 820 compliance.

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METHODOLOGY

3. Clinical Due Diligence:

- Given that the product was a CDSS with clinical application in critical areas, it was required to be demonstrated that the product will work as intended at all times and will provide reliable, reproducible and accurate information with good sensitivity and specificity.
- For this purpose, a clinical due diligence was conducted.

4. Clinical Study Design:

- Elexes helped determine the kind of clinical testing (retrospective, prospective, etc.) which will be best fit as per the product's indications for use.
- A need for a reference or control device was also assessed and a rationale for using a gold standard to compare with was provided.
- Elexes helped prepare protocol while interacting with the Client's cross functional team and stayed next to the client throughout the conduct of the clinical study.

5. Comprehensive Documentation and Submission Support:

- After addressing all the identified gaps in the gap assessment phase, creating software Design History File (DHF), and achieving various other milestones (e.g., clinical studies), Elexes prepared the entire submission and presented information to the regulatory bodies just the way they like it.

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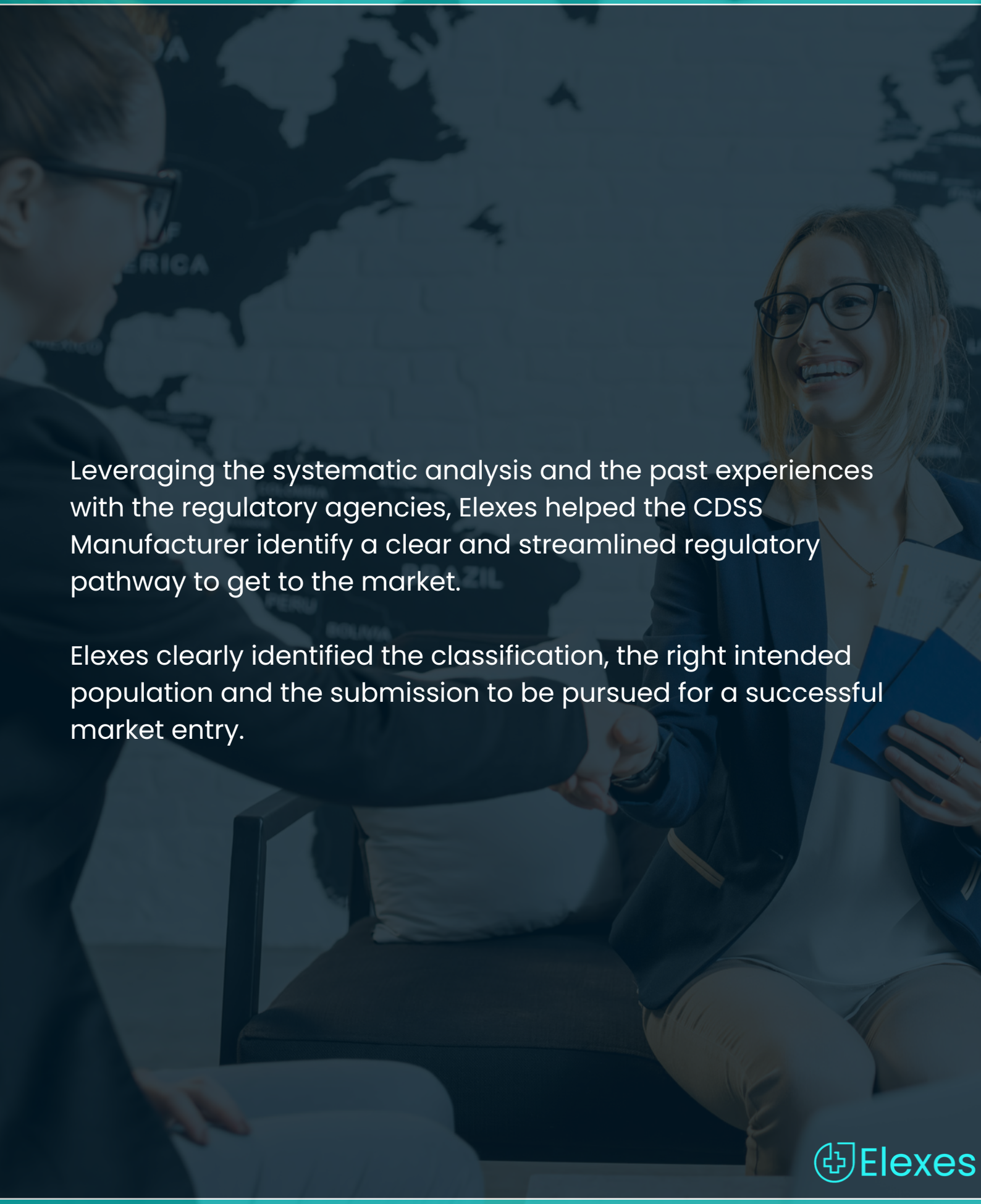
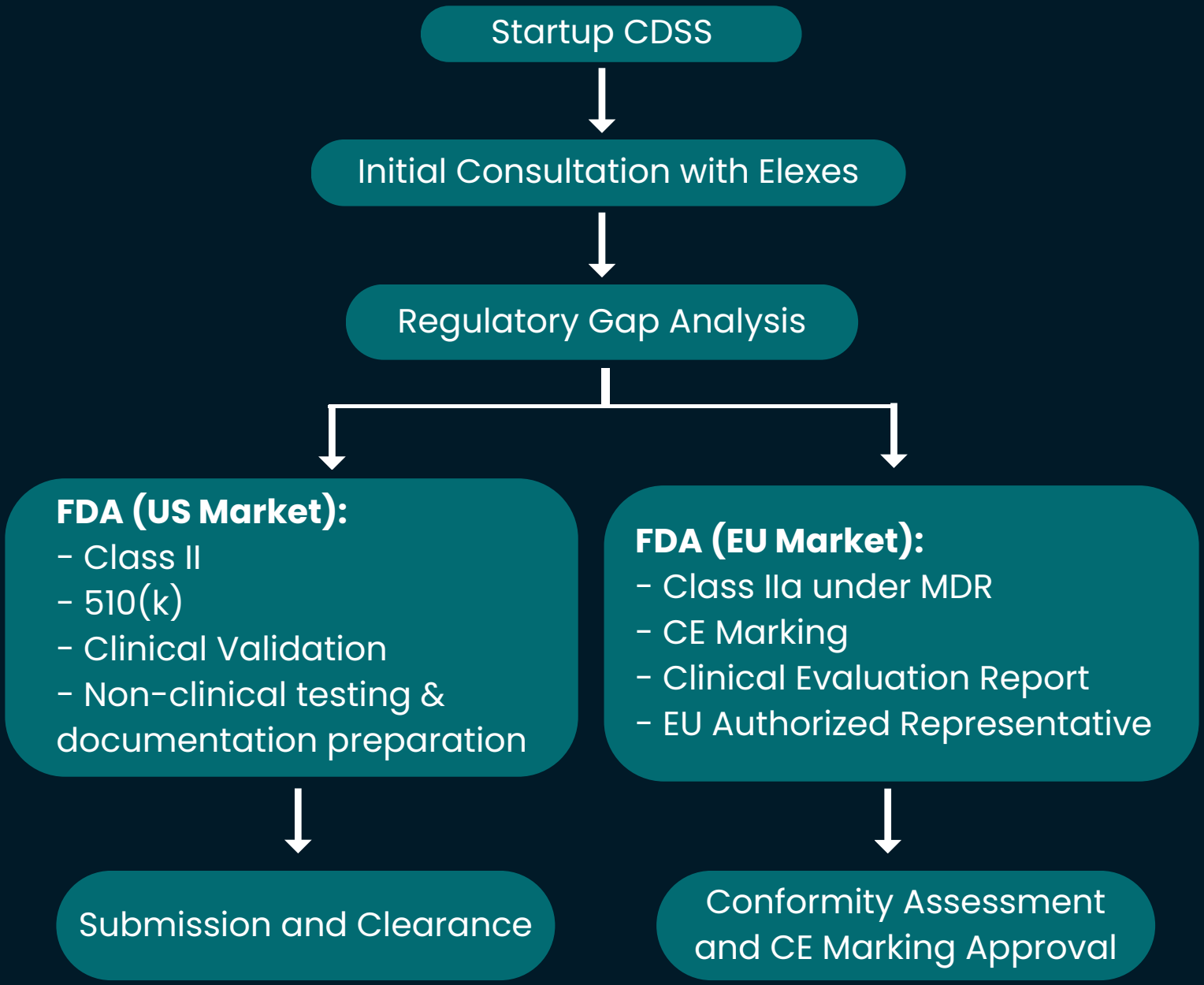
SOLUTION & DISCUSSION



Leveraging the systematic analysis and the past experiences with the regulatory agencies, Elexes helped the CDSS Manufacturer identify a clear and streamlined regulatory pathway to get to the market.

Elexes clearly identified the classification, the right intended population and the submission to be pursued for a successful market entry.

REGULATORY ROADMAP FOR US AND EU MARKETS



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SOLUTION & DISCUSSION

Given the predictive nature of the CDSS for cardiovascular conditions, rigorous clinical validation was mandatory.

Elexes's clinical due diligence from a regulatory perspective made it clear how to implement the device into patient workflows in such a way that meets with both regulatory standards and clinical requirements.

Following are the clinical study design considerations that Elexes helped the Client with:

- Patient Population: Patients presenting ECG data suggestive of cardiac risk.
- Purpose of the Clinical Study: To validate sensitivity, accuracy and specificity.
- Study Group: Prospective observational study group.
- Primary Outcome: Accuracy and sensitivity in predicting cardiac events.
- Secondary Outcome: Reduction in time-to-treatment and clinical decision-making.
- Inclusion Criteria: Adults with existing cardiovascular risks and accessible ECG data.
- Exclusion Criteria: Patients already experiencing cardiac events, pregnant patients, patients with pacemaker, and so forth.

CLINICAL STUDY DESIGN FOR CDSS

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QUALITY MANAGEMENT SYSTEM (QMS) STRUCTURE

Elexes established an efficient quality system for the CDSS company which was right for its size and the kinds of processes being carried out at the company.

QUALITY MANUAL
Describes documentation hierarchy and defines scope and exclusion to the QMS

FORMS & TEMPLATES
Important for implementation

STANDARD OPERATING PROCEDURES (SOPS)
Several SOPs like the Management review, Document Control, Design Control, etc are applicable

RECORDS
Serves as an evidence or proof for the utilization of SOPs

With a well structured QMS and regulatory and quality strategy all the challenges were effectively addressed.

CONCLUSION

- Initiating regulatory and quality strategy endeavors at an early stage was a great initiative and investment by the CDSS company.
- First, the regulatory gap assessment conducted by Elexes helped the client clearly identify the missing pieces in their regulatory and quality compliance puzzle.
- This proactive step empowered the client with foresight, much like plotting a detailed roadmap before starting out on a long and unfamiliar journey—knowing the destination early prevented unexpected detours later.
- Although the finer nuances were continuously refined by Elexes, having clarity about the big picture early on made the journey smoother and less daunting.
- The regulatory roadmap facilitated precise allocation of resources and established a realistic and achievable timeline.
- The client's stakeholders and investors were transparently informed about both the best-case and worst-case scenarios, which enabled them to confidently commit to each subsequent step.

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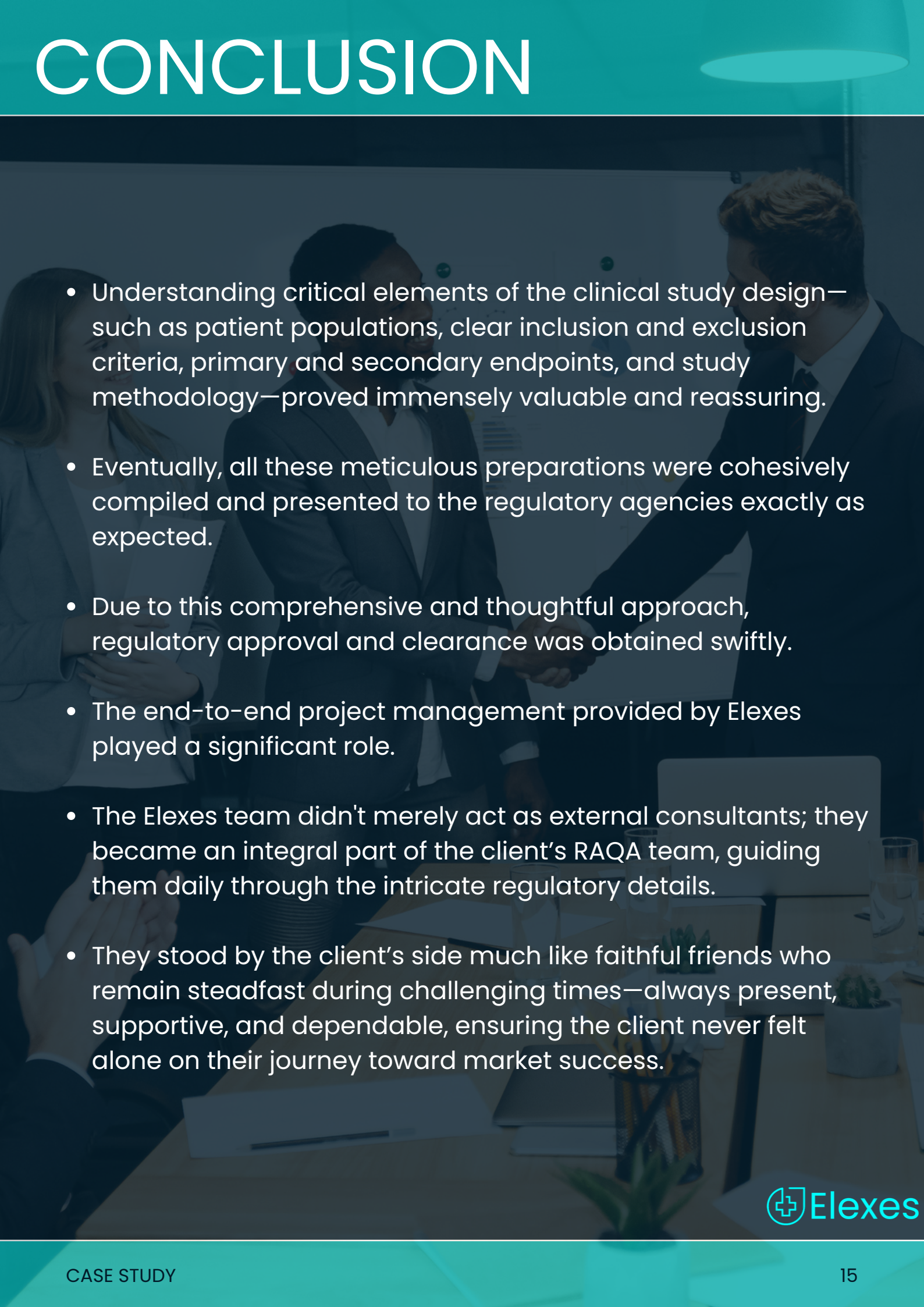
CONCLUSION



- Understanding critical elements of the clinical study design—such as patient populations, clear inclusion and exclusion criteria, primary and secondary endpoints, and study methodology—proved immensely valuable and reassuring.
- Eventually, all these meticulous preparations were cohesively compiled and presented to the regulatory agencies exactly as expected.
- Due to this comprehensive and thoughtful approach, regulatory approval and clearance was obtained swiftly.
- The end-to-end project management provided by Elexes played a significant role.
- The Elexes team didn't merely act as external consultants; they became an integral part of the client's RAQA team, guiding them daily through the intricate regulatory details.
- They stood by the client's side much like faithful friends who remain steadfast during challenging times—always present, supportive, and dependable, ensuring the client never felt alone on their journey toward market success.

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