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Proposal Prepared for:

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Project Name:

Case Processing for Clinical Trials

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EXECUTIVE SUMMARY

Adrta Technologies Private Limited, Inc. ("ADRTA") is pleased to present this proposal to ABC Sciences, Inc (ABC) for Case Processing for Clinical Trials for its therapy currently in a Phase III study in Acute Lymphoid Leukemia. We currently provide services to biopharmaceutical companies ranging from emerging biotech companies to some of the largest global organizations and we believe that ADRTA is qualified to support your study.

ADRTA was established in Jul 2007 in London, United Kingdom (UK) with the goal to respond to the increase in regulatory and client requirements around Pharmacovigilance, Medical Information, and Regulatory services. We provide services to ensure compliance for patient safety during

- Development
- Launch Preparation
- Commercialization and throughout the life cycle of the product(s)

Our solutions and business models are cost-effective, resilient yet agile, and customized to each client's needs. Our experience and expertise, scalable operations, and consultative approach will serve you today as well as expand with you as you grow.

ADRTA Differentiators for the {{Program Name}} Program

ADRTA is excited to partner with **{{Program Name}}** to deliver high-quality services that meet and exceed your expectations for your short, medium, and long-term goals.

We believe that the following **key success factors** will help to enable the successful conduct of the **{{Program Name}}** program:

1. {{subservice selected}}
2. **Qualified and Experienced staff**: At ADRTA, you will have a team of experienced healthcare professionals and physicians with relevant expertise at your disposal to support your drug safety needs today and in the future.

3. **Niche Expertise:** ADRTA supports clients with their end-to-end safety needs. We are a PV focused life sciences organization with resources, technology, processes, and a business approach geared toward delivering the highest quality of safety services. ADRTA's customer base fosters a blend of large organizations (with mature processes) and small organizations (responsiveness and agility). ABC will benefit from the right amount of engagement, executive leadership, and responsiveness.

4. **Agility and Collaboration**: We have a proven track record of successfully delivering services for clients of varying sizes, scales, and requirements. Our long-standing decade-long relationships with many of our clients are a testament to our adaptability to changes.

At ADRTA, you will receive a sense of urgency, responsiveness, and commitment to ensure we not only meet your expectations but exceed them. We look forward to discussing our proposal with you in further detail.

We view our proposal as a working document to initiate planning and collaboration with you. As you read through the details contained within this proposal, please remember that ADRTA will always find a way to deliver the highest level of quality in a cost-effective manner to meet your expectations.

Timeline

- **Project award date: {{Project Award Date}}**
- **Project kick-off: {{Project Kick off}}**
- **Go-live: {{Go Live}}**

Budget Summary*

PROPOSED OPERATING MODEL

ADRTA's goals align with ABC's need for high quality, timely and regulatory compliant PV services within budget. The path to clinical development of CGTs/ATMPs (Cellular and Gene Therapies/Advanced Therapy Medicinal Products) can be long and arduous because of implementation of complex trial designs, manufacturing and quality assurance, translational uncertainties and commercialization, and clinical implementation and acceptance.

Considering the above challenges, we understand it may be difficult for ABC to navigate the regulatory and safety requirements. Early engagement with ADRTA as a strategic partner will alleviate some of the below challenges:

- Long-term and unknown safety concerns
- Multiple regulations
- Product complexity and novelty

The ADRTA team will engage with your team to gain a full understanding of defining the path forward, including expectations in terms of content and timelines, and workflow to ensure key milestone expectations are met. Your ADRTA team for this program will be carefully selected and will have the following:

- Ability to provide customized & tailor-made solutions for clinical case processing
- Ensuring compliance across the product life cycle by keeping well-informed regulatory updates across key regions
- Provides regular status updates and schedule review meetings/roundtable meetings with ABC at agreed-upon intervals

Based on our experience, the following are the key operational elements for the successful set-up and delivery of the project. Each of these has been detailed in subsequent sections:

1. Pharmacovigilance Services – Clinical case processing
2. Resourcing and key staff
3. Implementation plan and timelines
4. Training management
5. Governance and Communication Structure
6. Quality Management System
7. Information Technology Infrastructure
8. Business Continuity Planning and Disaster Recovery

PHARMACOVIGILANCE SERVICES

CLINICAL CASE PROCESSING

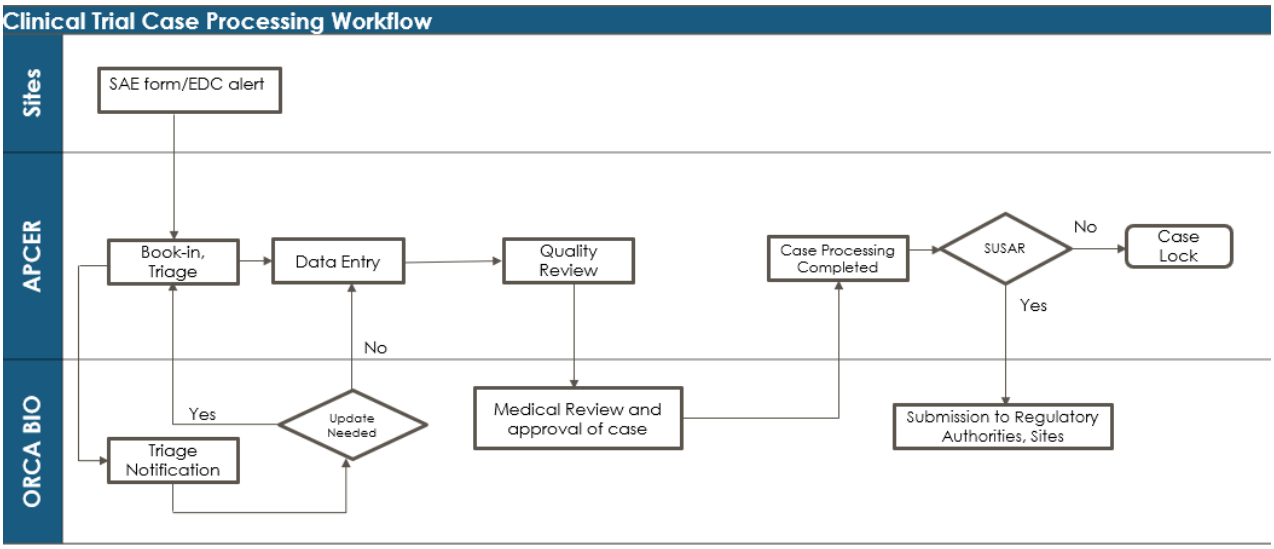
ADRTA will perform Individual Case Study Report (ICSR) processing on behalf of ABC in the ARGUS safety database hosted and maintained by ABC bio. Our processes are well established to handle the intricacies of case processing activities and nuances for cases received from clinical trial sources. Our team is flexible to be trained and work as per the client-specific processes and workflows.

ADRTA's case processing activities would include:

- Case intake, duplicate search, data entry, coding, narrative creation, quality control review (for completeness and accuracy). Medical review will be done by ABC Bio.
- Source documents are attached to the case in the safety database for easy retrieval.
- ADRTA provides case processing activities, including 7-day and/or 15-day report preparation.
- Follow-up with the clinical site and/or reporters will be managed by ABC and ADRTA team will liaise with ABC until queries are appropriately closed and databased.
- Our trained staff members will receive and triage inbound serious adverse event (SAE) cases, initiating the process of detailed case entry.
- An AE will be triaged based on whether it is serious, causally related, and reportable.
- Every case will be data entered and will undergo a quality review.
- ADRTA will work closely with ABC's team to streamline the case processing functions.
- The complete clinical case processing activity will be performed as per ABC Bio's procedural documents (SOP).

As a standard practice, the Turn Around Time (TAT) for each case, depending upon seriousness and reportability, will be pre-agreed with ABC at the time of our implementation and transition.

Figure 2: Clinical case processing workflow



RESOURCING AND KEY STAFF

The ADRTA team that will be responsible for managing the services in scope will be based out in the US as well as India. We will leverage the already trained, qualified, and experienced resources to deliver these services for you. Please refer to Figure 3 below for the team structure for this scope of work that we propose for ABC.

Figure 3: Proposed Team Structure for ABC

Our structured approach with a Delivery Head (DH) based out of the India office will ensure a high quality of deliverables along with timely management of issues or concerns before or as they arise.

Dr. Deepak Kumar Singh, as the Delivery Head, will be responsible for the overall delivery and ensuring compliance with the processes and Service Level Agreements (SLAs) and be the point of contact for routine operational discussions.

ADRTA will also deploy a Project Manager in the India office, who will be instrumental in the project set-up and implementation activities.

We understand the need to provide a solution that brings ABC not only a quality-driven team that is skillful and domain expert but also brings in cost efficiencies and high compliance standards.

Leadership Profiles

ADRTA is pleased to put forward a highly experienced and qualified team of professionals with medical and PV qualifications for ABC. They will be knowledgeable about your program and possess the expertise to support you through this transformative phase in your journey. This operational leadership team is passionate about what they do and unified in their belief that compliance is our highest priority. Their profiles are shared below.

TEAM MEMBER	EXPERTISE
Co-Founder, Managing Director and Global Technical Head, UK	Dr. Kacker is a pharmacologist with a PhD in pharmacology from All India Institute of Medical Sciences, India. He transitioned his focus from academia to private industry 23 years ago and has managed the regulatory and PV functions

TEAM MEMBER	EXPERTISE
	at large pharma organizations in previous roles. He will provide executive leadership to the ABC project.
Vice President, Pharmacovigilance, IN	Dr. Thakkar is a Physician by qualification and holds a Master's in business administration (MBA) degree. He has over 19 years of experience in Clinical Research and PV. He will act as the functional head of the ABC project.
General Manager, Pharmacovigilance, IN	Dr. Deepak Kr. Singh is a Physician by qualification. He has over 19 years of combined experience working as a clinician for 5 years initially, and then as a Pharmacovigilance professional for 14.5 years now. He will act as delivery head for the ABC project.

IMPLEMENTATION PLAN AND TIMELINES

We understand that engagement of this nature requires robust planning and prioritization with clearly defined milestones and the involvement of responsible stakeholders right at the outset. Immediately following the kickoff meeting (KOM), we will prepare a Microsoft Project plan to include detailed milestones and timelines.

Based on our understanding of the scope requirements, we have provided a high-level implementation plan and timelines as a starting point for our engagement. Below are a few key project milestones:

- Initiation: Governance structure and core implementation formation take place along with the execution of key agreements like master service agreement (MSA) and statement of work (SOW)
- Planning: This includes project kick-off meeting, creation of the technical agreement, project-specific documents, and service level agreement (SLA) finalization
- Implementation: This phase includes Argus database setup for ABC and team training

This is an estimate only and is subject to change once the final project scope has been determined and agreed upon. We would like to acknowledge that the implementation plan can be customized to ABC's specific requirements.

Figure 4: Detailed Implementation Plan and Timelines

TRAINING MANAGEMENT

Training at ADRTA is structured in accordance with applicable global regulations, directives, guidelines, standard operating procedures (SOPs), working practices, and applicable client's SOPs/conventions.

At a broader level, all positions and jobs functions have a defined role attached to them. A role-based Position Curriculum (PC) is prepared for all key functions/processes for performing day to day activities.

Training, both in product knowledge and understanding of processes, is ongoing, usually on a semi-annual basis. Each individual working on the project will undergo various stages of training as described below, before handling any regulated tasks:

Table 2: Training Management

Type of Training	Description
Orientation, Induction Training	• Role/process-specific PC assigned at the time of joining ADRTA • Includes ADRTA's background, core values, procedures, and policies according to their team member's roles

PV Training	• All new hires undergo PV training to ensure an adequate understanding of basic principles and global regulations.
	• Current team members receive it when a procedure from existing PCs is revised or when a new procedure is added to the existing PCs
	• Three types of ongoing training are:
	  ○ Overview of product portfolio
	  ○ ADRTA Specific Controlled Documents
	  ○ Regulatory Updates
	  ○ MedDRA Update Trainings

Refresher and Gap Analysis Training	• Designed for current team members to reacquaint them with the processes required to maintain and improve their performance on the job annually
Skills Enhancement and Capabilities Training	• A skill-based training approach, which includes knowledge-sharing sessions, seminars, conferences, and workshops. • Multiple best-in-class online learning platforms to employees for continuous growth

Learning Management System

ADRTA's learning management system (LMS) has been validated on GAMP Principles and implemented at ADRTA as per requirements of Annex 11 and 21 CFR Part 11. Below is the list of documents of an individual employee at ADRTA that are managed through LMS.

- Curriculum Vitae (CV)
- Job Responsibility
- Position Curriculum
- Training Summary Records
- On the Job Training Records (as applicable)

GOVERNANCE AND COMMUNICATION STRUCTURE

For the in-scope services, we will plan collaboratively with ABC to understand all needs upfront so that the workflow and delivery go without any disruptions. We will run a collaborative governance platform that is active

throughout a project's life cycle, ensuring that the slightest exception is flagged, considered for long-term impact, and resolved swiftly at an operational level. We will modify the governance structure to ensure that it covers the following:

- Implementation
- Ongoing operations
- Stakeholder communication
- Escalation/problem-resolution process

Governance and Communication Structure

Below are key processes and monitoring steps that would be taken at each of the key stages through the life of a project to anticipate, manage, and deal with any matters that affect the success of the project.

Figure 5: Governance structure

Project Meetings:

1. Service Delivery: During the implementation period, ADRTA will hold weekly service delivery meetings with ABC and then monthly to review open issues, pending questions, clarifications, metrics, volumes, resource utilization, new requests, updates on deviations, CAPAs, etc. The meeting discussions are reported by way of minutes and action items which help to ensure the project's success.

2. Operational Governance: Meetings held monthly with the joint operational management teams, as well as Quarterly business reviews (QBRs), addresses the project performance and status, resources, achievements, challenges, and risk mitigation and process improvements help our clients to view our relationship over time and to plan for key events or milestones effectively.

3. Executive Steering Committee (ESC) meetings are held quarterly and would cover a few key areas including:

    - A snapshot of our engagement journey
    - Operational performance reviews
    - Challenges/priorities and feedback for the success of our engagement

We will have a Steering Group/committee which will consist of senior management from ADRTA and ABC to enable the execution of this project and to resolve issues of policy, cross-department interaction, and other significant matters relating to the project. The Steering Group will meet at the start of the project and then quarterly after going live. The extended role of this group then goes into annual discussions, negotiations, scope extensions, etc.

Escalation Pathway

There are internal processes set up within ADRTA to inform the senior management of any findings, exceptions, missed timelines or similar service/quality-related matters automatically. We take our commitment to quality seriously, and we proactively communicate with our clients should there be any potential issues that may affect a project.

We will structure and set up an escalation pathway with the ABC team anticipating the areas where we would need to communicate with each other to resolve any issues. The matrix also has provisions for notifications to senior management and stakeholders for events where appropriate.

Figure 6: ADRTA Escalation Process for ABC

QUALITY MANAGEMENT SYSTEM

We believe that a strong quality management system (QMS) lays the foundation for safety services and at ADRTA, our QMS provides cross-functional support to all our projects and will be applicable for ABC as well. ADRTA has a well-defined and established robust quality management system for the oversight of the project, routine operational activities, responsibilities, and service delivery. Our quality policy is based on four fundamental principles:

- Compliance with laws and regulations: Monitoring includes these aspects and is reported objectively to our clients
- External/Internal Stakeholder Communication Quality: Excellence in everything we do
- Accurate, timely identification of delivery outputs and reporting
- Quality control (QC) and Quality assurance (QA) processes to identify important areas and an empowered team to take corrective action wherever necessary

Our Quality System comprises the basic four components of a compliant quality monitoring program:

- Procedures
- Training
- Audit
- Corrective and preventive actions

Our team has repeatedly accomplished stringent compliance goals; our organizational quality accuracy and regulatory compliance have consistently remained at 99.6% and 99.9%, respectively.

The QA team at ADRTA is well-trained and experienced with domain experience of 500+ Good pharmacovigilance practice (GVP), and Good Clinical Practice (GCP) audits within the QA team.

In the last five years, ADRTA has provided support and participated in over 55 inspections by various health authorities including the United States Food and Drug Administration (USFDA).

INFORMATION TECHNOLOGY (IT) INFRASTRUCTURE

We understand our clients trust us with confidential and sensitive information such as patient data, adverse event information, and other sensitive data that must be kept secure, and to fulfill our obligation in this regard, we have all the necessary security measures in place which include as follows. As mentioned previously, we also have ISO certifications for information security (ISO 27001: 2013) as well as data privacy (ISO 27701: 2019).

Physical Security

We have the security controls implemented at ADRTA office locations in India (Delhi and Ahmedabad), the US, and the UK for our servers and network rooms, such as:

- CCTV surveillance
- Fire Protection
- Biometric (fingerprint) access control (India)
- Controlled temperature and humidity control
- Provision of uninterrupted Power Supply
- Physical log to record access to the server room or network room
- Maintenance Log for recording maintenance activities
- List of authorized personnel who can access the network room

Logical Security

We have logical security controls in place to secure IT systems and information at all ADRTA locations and through virtual means also. Below are the controls in place for logical security.

- Operating System Logon Accounts, Security and Maintenance
- Password Storage and transmission
- Unique User Identification
- Software Security Updates
- Internet Firewall
- Restricted use of Public Domain Software
- Regular Back-up

BUSINESS CONTINUITY PLANNING AND DISASTER RECOVERY

ADRTA has a defined business continuity plan (BCP) and governance structure to oversee PV activities. Disaster recovery plans (DR) are in place for all business-critical systems. In order to ensure the robustness of our BCP, there are several measures that have been embedded within the way we work and set up and operationalize our projects:

- **Multi-Location**: ADRTA has four offices in geographically distant locations and covering major time zones globally: New Delhi, India; Ahmedabad, India; London, UK; and Jersey City, NJ. Each location has the capability to serve as the backup site of other locations in times of critical business need.
- **Emergency Response Plan** and Business continuity plan are in place to tackle natural disasters like earthquakes and pandemic situations.
- **Redundancy:** Safeguards such as periodic offline backup, server/ instance replication, redundant network connectivity, etc., have been implemented to ensure the continuity of IT services in case of disaster. Scenario-based testing is done for all continuity plans on a periodic basis to validate their effectiveness.

ADRTA has redundancy via its delivery center locations to ensure the continuity of PV services. Sufficient backup ensures client responsiveness. **To date, we have never experienced a loss of service.** Our resource management methodology considers resource planning with the availability of backup/buffer resources, appropriate succession planning, and cross-training of PV resources.

BUDGET AND ASSUMPTIONS

Please refer to the attachments for more details regarding budget.

- Attachment-1_ ABC _Budget for PV Services_ V 1.0_22May2023

Implementation: Next Steps

We are delighted with the prospect of working with you and would like to host you for an inspection of our facilities and to review our processes. We are confident we will provide you with the highest level of service that is timely and compliant and ensures your complete satisfaction. We hope you choose to place your trust in us to partner with you for your very important and critical functions.

On behalf of the entire ADRTA Team, thank you for this opportunity to work with you.

VP and US Head of Business Development
Adrta Technologies Private Limited, Inc.
adrta@yopmail.com
+(91) 568989432

Accepted Proposal: Subject to the agreement of detailed terms and conditions with respect to the services proposed. Both parties have agreed to negotiate reasonable contractual terms of the contract in good faith.

For and on behalf of,

ABC Sciences, Inc.

_____

By

_____ _____

Name Date

_____

Position