CRM
CLINICAL RESEARCH MALAYSIA
Your Global Solutions in One Nation

CLINICAL RESEARCH MALAYSIA ANTI-CORRUPTION PLAN

2023 - 2027

MESSAGE FROM MINISTER OF HEALTH & CHAIRMAN OF CRM

Yang Berhormat Dr Zaliha Mustafa

A hearty congratulations to Clinical Research Malaysia (CRM) for the success in producing its Organizational Anti-Corruption Plan (OACP) for 2023-2027.

This is one of the many efforts of the Ministry of Health to ensure that all organizations under ministry arms are committed and practice a working culture that is aligned with integrity practices. As responsible agencies, let us all strive and work together in delivering these initiatives to prevent corruption from within. It is a culture that we all need to partake in, for us to create a high-integrity work environment and build a better future for the next generation.

I wish CRM the very best success with the Organizational Anti-Corruption Plan (OACP) for 2023-2027.

> It is a culture that we all need to partake in, for us to create a high-integrity work environment and build a better future for the next generation.

MESSAGE FROM DIRECTOR GENERAL HEALTH & DEPUTY CHAIRMAN OF CRM

Tan Sri Dato' Seri Dr Noor Hisham Abdullah

I want to extend my heartfelt congratulations to Clinical Research Malaysia (CRM) on the successful launch of the Organizational Anti-Corruption Plan (OACP) for the period of 2023-2027. By successfully implementing OACP, CRM can safeguard its reputation and credibility, improve its operational efficiency, and ultimately comply with legal and regulatory requirements.

This OACP demonstrates CRM's commitment to promoting transparency, accountability, and ethical conduct, which are essential for building public trust and creating a corruption-free research industry.

We must work hand in hand to eradicate the perception of corruption, thus demonstrating our commitment to establish and strengthen Malaysia's position as the centre of high-quality research destination in this region.

I commend CRM for taking these crucial measures to ensure a work environment that prioritizes integrity and compliance.

> We must eliminate the perception of corruption to strengthen Malaysia's position as a center for high-quality research in the region.

FOREWORD BY CHAIRMAN OF AUDIT COMMITTEE, CRM BOARD OF DIRECTORS

Prof Datuk Dr A. Rahman A. Jamal

Corruption is a plague that can destroy any good initiatives to improve socio-economy justice. As the Chairman of the Audit Committee, I am proud that CRM has launched the Organizational Anti-Corruption Plan (OACP) for 2023-2027.

Our objective is to ensure CRM abides to the highest standard of preventive corruption. The organisation obtained its Anti Bribery Management System ISO 37001: 2016 in 2021, and it is my responsibility to ensure CRM withholds its reputation as a company that practices good governance and become an exemplary agency in Malaysia.

I would like to commend CRM management team including the Integrity Governance Unit for their tenacious effort in materialising this document. The commendable reputation for integrity will improve public confidence and attract more sponsored research opportunities into the country. Throughout this, the CRM Board of Directors' Audit Committee remains steadfast in supporting the initiatives aligned on integrity and good governance.

> "The commendable reputation for integrity will improve public confidence and attract more sponsored research opportunities into the country.

FOREWORD BY CHIEF EXECUTIVE OFFICER OF CRM

Dr Akhmal Yusof

Clinical Research Malaysia first took the MACC anti-corruption pledge back in 2018. Since then, CRM was accredited with ISO 9001:2015 Quality Management System (2019) and ISO 37001:2016 Anti Bribery Management System (2021) to be a global trusted research management organization.

We are steadfast with our Core Values (Transparency, Honest, Accountable and Trustworthy) which was adapted within CRM's Code of Conduct (2016). The birth of Code of Conduct has been the guidance for us in the company to conduct business with professionalism in this industry. The established procedures related to clinical research guide us to deliver with Speed, Reliability and Quality.

The conception of the Organizational Anti-Corruption Plan (OACP) 2023-2027 is another pledge by CRM to ensure order and work with integrity. I am grateful to the teamwork effort in CRM coupled with the support from the Board of Directors to promote good ethics in the company. I have never been prouder of CRM to have produced the OACP successfully with the editorial board led by the Integrity Governance Unit. The OACP marks our dedication in fighting corruption aligned with the company 3 guiding principles of Humanity, Stability, and Sustainability.

> "The conception of the OACP 2023-2027 is another pledge by CRM to ensure order and work with integrity.

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INTRODUCTION

ABOUT CRM

Established by Malaysian Ministry of Health in 2012, Clinical Research Malaysia exists to advance global health solutions for a brighter, more hopeful future for the people by providing speedy and reliable end-to-end clinical research support for quality studies. As these studies unfold, we work together with our partners to create an impetus in delivering better treatment to our end consumers, while at the same time creating high-skilled job opportunities.

CRM's three (3) guiding principles, **HUMANITY**, **STABILITY** and **SUSTAINABILITY**, guides the organisation through its actions and deliverables.

01

HUMANITY

CRM focuses on people by bringing clinical trials that address unmet needs in patient care, thus expanding the treatment options available and improving stakeholders' knowledge and expertise in medical innovation.

02

STABILITY

CRM believes in creating professional clinical trial management that can deliver clinical trial with Speed, Reliability & Quality by continuously developing people (Investigators, Study Coordinators) and their capabilities, thus creating a clear career development path in clinical trial management.

03

SUSTAINABILITY

CRM is committed in ensuring a conducive sustainable working environment as a Global Trusted Research Management Organisation. We are steadfast in maintaining Quality Management System (ISO 9001) & Antibribery Management System (ISO 37001) within the organisation, in addition to our Core Values & Code of Conduct and delivering business models that are environmentally friendly.

PURPOSE OF OACP

The purpose of the Organizational Anti-Corruption Plan (OACP) for 2023-2027 is to provide an outlook on the governance landscape of CRM, in line with its Corporate Governance, Business Integrity and Anti-Corruption agenda:

- Vision,
- Mission, and
- Strategic approaches

Serve as a strategic document for the implementation of governance processes in CRM, with emphasis on the action plan through the collective responsibility among the governance enablers in CRM by their respective roles.

Be a guiding tool for the Corporate Governance, Business Integrity and Anti-Corruption initiatives in CRM. Through this, the Organization's governance and integrity initiatives will be portrayed as a Global Trusted Research Management Organisation. The inter-related roles and functions can be seen through the established framework and structure.

OUR VISION

To establish Malaysia as a preferred destination for industry sponsored research (ISR)

OUR CORE VALUES

These values convey the philosophy behind every decision and move we make:

Trustworthiness	We adhere to the highest standards of professionalism and integrity and uphold the faith and confidence our clients have placed in us.
Honesty	We aspire to be honest with one another, our clients, and our business partners.
Accountability	We set a high-performance expectations and hold ourselves responsible for the quality of our work and the results we achieve as individuals, as a team, and as a company.
Transparency	We practice transparency and openness in all our operations, including financial processes and budget management.

OUR POLICY

We are committed to continually improve our services to meet the expectations of the clinical research industry players, regulatory agencies, and other stakeholders in our effort to build a globally trusted research organization.

CORPORATE GOVERNENCE

CRM, as a business entity, commits towards practicing good corporate governance in creating the environment of trust, transparency, and accountability necessary for achieving long-term financial stability and sustainable growth. Therefore, improving corporate governance is a journey to stay on course as Global Trusted Research Management Organisation.

Good governance is the process of making and implementing decisions. It is not about making the 'correct' decisions but using the best possible process to make those decisions. CRM Good Governance is embedded in our Core Values of Transparency, Honesty, Accountability, and Trustworthiness and our Code of Conduct.

In 2021, CRM was accredited with ISO37001:2016 Anti Bribery Management System by SIRIM QAS. CRM established its own Board of Directors Audit Committee in 2020 which established the Integrity Governance Unit directly report to the Board of Directors and the Audit Committee.

NATURE OF BUSINESS

Study Owners

Sponsors and CROs provide all study information, protocols, kits, drugs, etc. required for the clinical study to be conducted.

This party also owns all proprietary rights to the study outcome.

Principle Investigators (PIs)

PIs are doctors from public and private hospitals in Malaysia from various disciplines.

PIs report all study findings and data directly to Sponsors.

Research Service Provider

CRM matches sponsor studies to suitable PIs during Feasibility stages, and manage Ethics Committee approval if so required by Study Owners.

During study stage, CRM provides Study Coordinators to work with PIs on the study management.

CRM manages all vendor related matters that are unrelated to Clinical Research Studies.

DATA ANALYTICS

DATA ANALYSIS

MACC Risk Evaluation
CRM has been evaluated by MACC on 11 March 2020 as a **Moderate Risk** Organization for Corruption

Internal Feedback System
CRM Reporting Channel are managed by Integrity & Governing Unit. Since 2020 (when IGU was established) until 2022, zero reporting is recorded.

External Reporting
External Audits, Feedback system, etc.

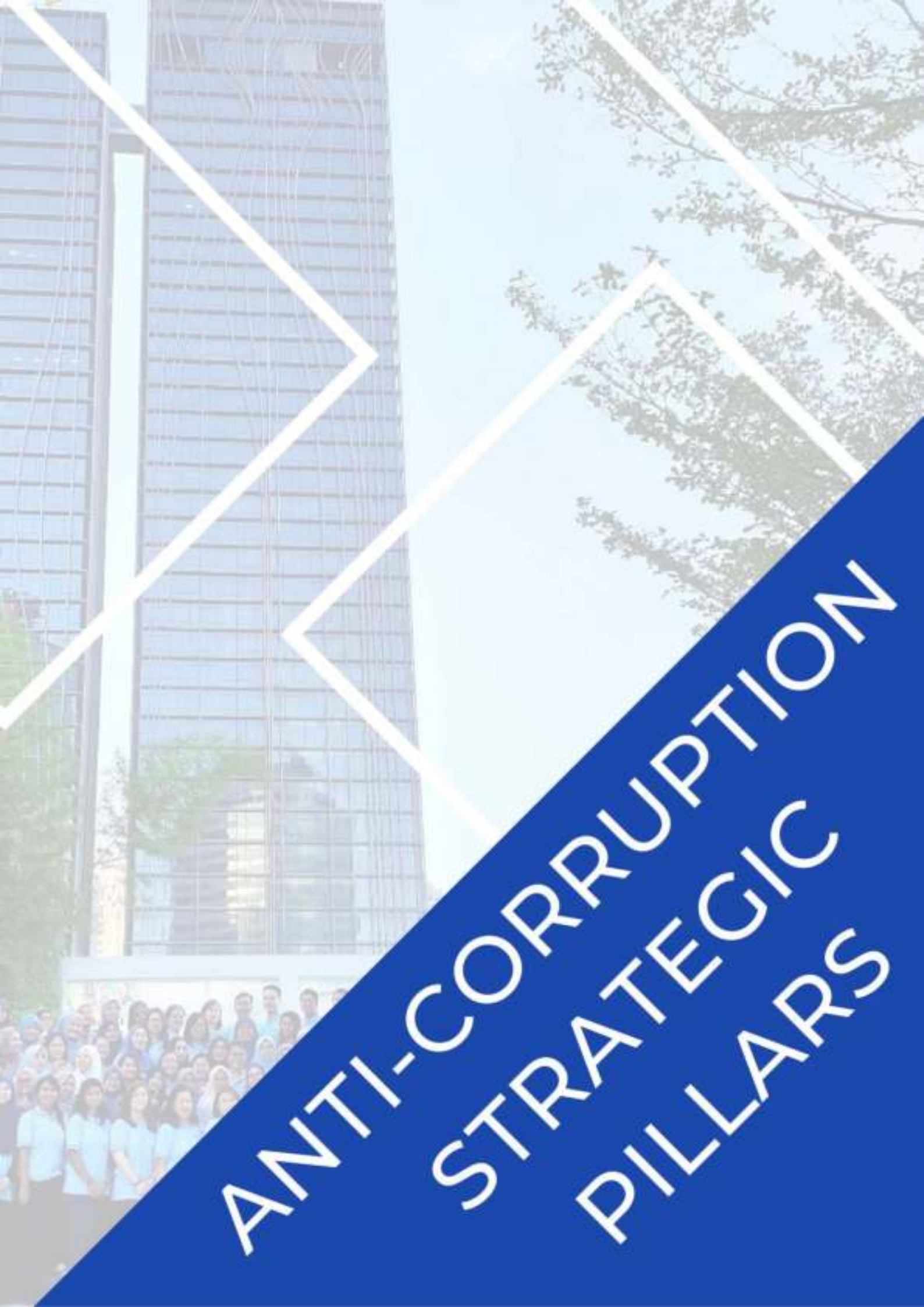
EXTERNAL AUDITS 2018 - 2022

From the data of external audit findings (2018 to 2022), there no major issues was found within the organisation. All findings were addressed following the stipulated timeline and rectified accordingly.

In 2021, CRM was successfully accredited with ISO 37001:2016 Anti Bribery Management System by SIRIM QAS without any major findings. The organisation have also successfully undergone subsequent surveillance audits by the same Certification Body.

ANTI-CORRUPTION FRAMEWORK

ANTI-CORRUPTION FRAMEWORK



ANTI-CORRUPTION STRATEGIC PILLARS

ANTI-CORRUPTION STRATEGIC PILLARS

Governance & integrity policy in procedure & guideline

ANTI-CORRUPTION STRATEGIC PILLARS

Risk Assessment & Intervention

ANTI-CORRUPTION STRATEGIC PILLARS

A) Procurement

No	Corruption Risk	Corruption Scheme	Anti-Corruption Control	Residual Risk Level
1	Bribery to secure or retain unqualified vendor	Potential improper payments to officials in facilitate process related to qualifying an unqualified vendor	• Adhere to SOP ISO 9001 & 37001. • Abide to CRM Code of Conduct (COC) and pledge. • MACC Pledge • Awareness Campaign through COC newsletter and quiz. • Whistle-blower Policy • Vendor declaration • Conflict of Interest declaration	9
2	Bribery to secure a tender or contract	Potential improper payments to secure improper or non-competitive contract/ tender awards		3
3	Bribery to accept of low quality or non-compliant goods or services	Potential improper payments to continued acceptance of low quality or non-compliant goods or services		9

ANTI-CORRUPTION STRATEGIC PILLARS

B) Clinical Operations (Project Management)

No	Corruption Risk	Corruption Scheme	Anti-Corruption Control	Residual Risk Level
1	Bribery to secure, retain, or influence project's approval	Potential improper payments/gifts to officials for expedite the project's approval	• Anti-corruption training for employees on project • Anti-bribery policy • Whistle-blower policy • Gift Declaration Policy • Follow applicable guideline (IEC/RA)	2
2	Bribery to secure, retain, or influence project's approval	Potential improper payments/gifts to officials for the project's approval		2
3	Bribery to secure, retain, or influence project's approval	Potential improper payments/incentives/gift to facilitate project management	• Anti-corruption training for employees on project • Anti-bribery policy • Whistle-blower policy • Gift Declaration Policy	4

ANTI-CORRUPTION STRATEGIC PILLARS

C) Clinical Operations (Site Operation)

No	Corruption Risk	Corruption Scheme	Anti-Corruption Control	Residual Risk Level
1	Investigator gives incentive to CRM SCs (either monetary/gift) as recognition for their hard work though knowing that SC is provided with monthly salary & recognition (via performance management system) by CRM	Investigator engaged work with CRM SCs without knowledge of the employer and payment not payable to CRM accordingly	• Gift Declaration Guideline • Anti-corruption training for staff • Ikrar Bebas Rasuah • Whistleblower Policy • Code of Conduct • Conflict of Interest Declaration	6
2	Bribery to falsify data	Bribes received to manipulate/ fabrication the study data during the trial conduct i.e.to fit into inclusion/ exclusion criteria of the protocol	• Code of Conduct • Anti-corruption training for staff • Anti-bribery Policy • Whistle-blower Policy • Follow the Good Clinical Practice	2

ANTI-CORRUPTION STRATEGIC PILLARS

C) Clinical Operations (Site Operation) - *continued*

No	Corruption Risk	Corruption Scheme	Anti-Corruption Control	Residual Risk Level
3	Falsely claiming on service(s) that was not conducted	SC fee services - False claim on the non performing job	• Code of Conduct • Whistle-blower Policy • Verification by investigator on the procedures performed (SCSBF)	6
4	Falsely claiming on service(s) that was not conducted	Claim for replacement leave without any job done	• Code of Conduct • Whistle-blower Policy • Follow CRM employee handbook • Verification from line manager (e.g: punch card)	6
5	Falsely claiming on service(s) that was not conducted	Administration claim - Claim submitted without item purchased	• Code of Conduct • Whistle-blower Policy • Obtain Line Manager's approval prior to purchase • Verification by line manager with supporting documents (e.g. receipts, delivery order etc.)	6

ANTI-CORRUPTION STRATEGIC PILLARS

C) Clinical Operations (Site Operation) - *continued*

No	Corruption Risk	Corruption Scheme	Anti-Corruption Control	Residual Risk Level
4	Any gift and monetary offered by the external parties to the employees	Introduce biasness including patient's care and treatment	• Gift Declaration Guideline • Anti-corruption training for staff • Ikrar Bebas Rasuah • Whistleblower Policy • Code of Conduct	2

D) Human Resources (Recruitment & Selection)

No	Corruption Risk	Corruption Scheme	Anti-Corruption Control	Residual Risk Level
1	Bribery to secure job in the company	• Potential improper payment to get a job (request/ask, accept, offer, promise) • Potential improper gratifications (gifts) to get a position.	• Integrated Manual, Policy of Anti-Corruption, Code of Conduct, Procedures & Processes • Documented Forms • Screening process that involves HR and hiring/line manager • Hiring decision by hiring manager and HR complete with candidate assessment forms	2

ANTI-CORRUPTION STRATEGIC PILLARS

D) Human Resources (Recruitment & Selection) - *continued*

No	Corruption Risk	Corruption Scheme	Anti-Corruption Control	Residual Risk Level
2	Bribery to avoid disciplinary action	• Potential improper practice in receiving anything in value that benefits own self in order to protect or hide certain employee's flaws/ mistakes/ misconducts or to favours particular employee in making decision or judgement. • Potential improper practice in appointing investigator and panel of inquiry	• Policy on Anti Bribery, Code of Conduct & Disciplinary Procedure • Legal panel appointment to advise and assist in the investigation and domestic inquiry	2
3	Bribery to accept of low quality or non-compliant goods or services	• Potential improper performance rating during year end performance appraisal • Potential improper gratifications (gifts) to get higher performance rating • Potential bias performance rating	• Use a standard form company wide • Begin with self-evaluation process versus KPIs agreed earlier • Review by respective line managers	2

ANTI-CORRUPTION STRATEGIC PILLARS

D) Human Resources (Recruitment & Selection) - *continued*

No	Corruption Risk	Corruption Scheme	Anti-Corruption Control	Residual Risk Level
3	*(Continued)*	*(Continued)*	• Align with respective HODs • Internal Calibration for Clinical Operations among regions • HR compilation and check for consistency, anomaly, and past records • Company-wide calibration by HODs & CEO	2
4	Bribery to accept of low quality or non-compliant goods or services	• Potential improper practice/work ethic involving hiring and favoring certain employee when comes to selection in hiring, promotion, benefits and opportunities	• Policy on Anti-Bribery, Code of Conduct, COI Declaration in Application Form • COI Declaration • Candidate Assessment Forms	2

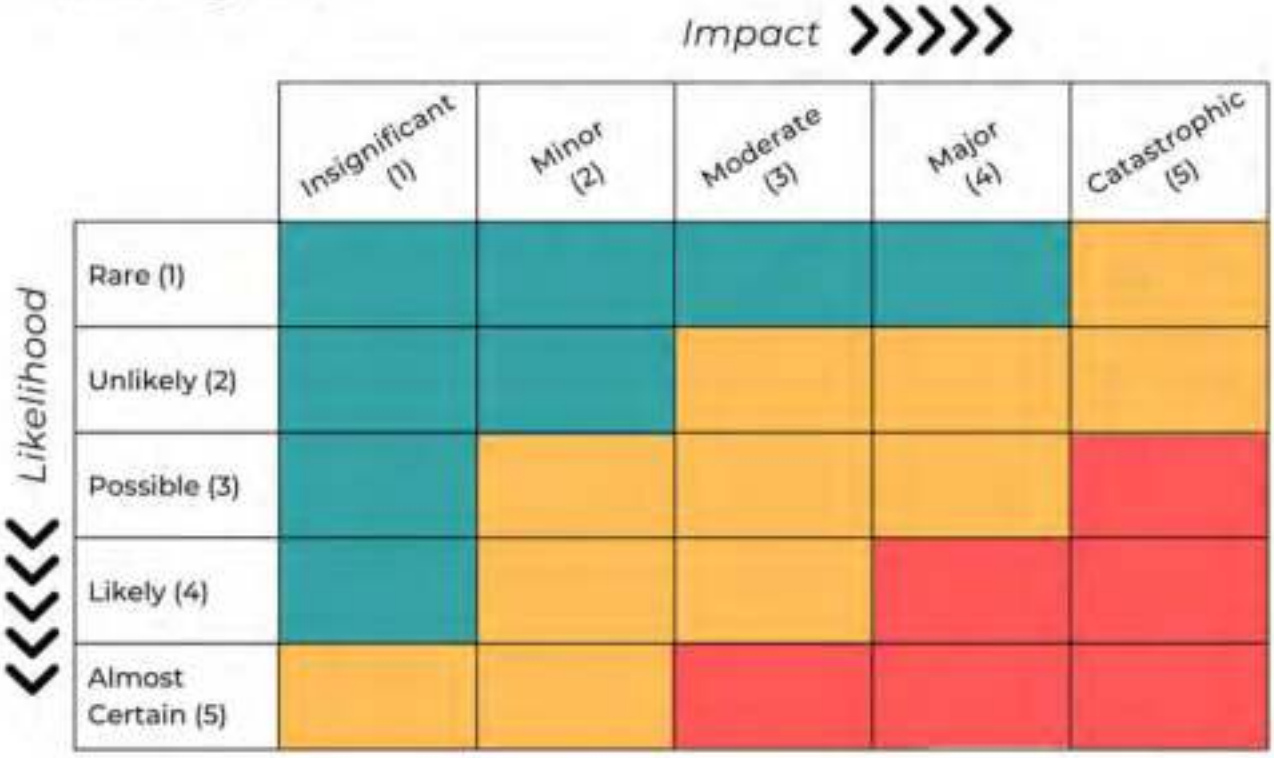
ANTI-CORRUPTION STRATEGIC PILLARS

D) Human Resources (Recruitment & Selection) - *continued*

No	Corruption Risk	Corruption Scheme	Anti-Corruption Control	Residual Risk Level
4	(*Continued*)	• Potential improper practice/work ethic by not declaring any potential conflicts of interest and/or hiding the information (employee related) • Potential improper practice/work ethic by not declaring or hiding information on vendor or 3rd party contractor (vendor or 3rd party related)	• Screening process involves hiring manager, HR PIC & HR HOD • For managerial below, interviewing process involves hiring manager, COM/SR COM and HR PIC • For managerial & above, interviewing process involves hiring manager, COM/Sr COM, HR PIC, Dept HOD, HR HOD & CEO	2

ANTI-CORRUPTION STRATEGIC PILLARS

Risk Rating Matrix



Risk Score	Risk Level	Risk Rating Focus
1 - 4		Bribery risk is considered as manageable internally , control is adequate through improvised procedures.
5 - 12		Review of policies required, specific monitoring or procedures required, management responsibility must be specified
13 - 25		Revision of policies may be required, action plan required, Management attention needed

ANTI-CORRUPTION STRATEGIC PILLARS

Assessment & Continuous Improvement

Anti-Corruption Strategies

- Strategy 1: Leadership commitment & exemplification

No.	Initiative	Responsibilities	Timeline
1.1	Educate Line Managers and Head of Departments on investigation processes, disciplinary procedures, and management of misconduct	Human Resources	Continuous
1.2	Assessment of vendor performance and anti-corruption training to vendors	Procurement	Annual
1.3	Awareness on CRM anti-bribery policy to stakeholders	All Departments	Continuous
1.4	Monitor the trend of claims for replacement leave of the individual and escalate to COMs/HOD if any potential of overclaim	Clinical Operations	Continuous

ANTI-CORRUPTION STRATEGIC PILLARS

- **Strategy 2: System enhancement to increase robustness**

No.	Initiative	Responsibilities	Timeline
2.1	Review of Standard Operation Procedures (SOP) for adequateness to actual process and relevant law, rules, and regulation.	All Departments	Annual
2.2	Developing Sponsorship criteria/ guideline	Business Development	2023
2.3	Develop Clinical Trial Advertisement Standard Operation Procedure	Business Development	2023
2.4	Develop new Standard Operating Procedure or process on verifying Study Coordinator fee	Clinical Operations	2023

ANTI-CORRUPTION STRATEGIC PILLARS

- **Strategy 3: Adequate and capable resources**

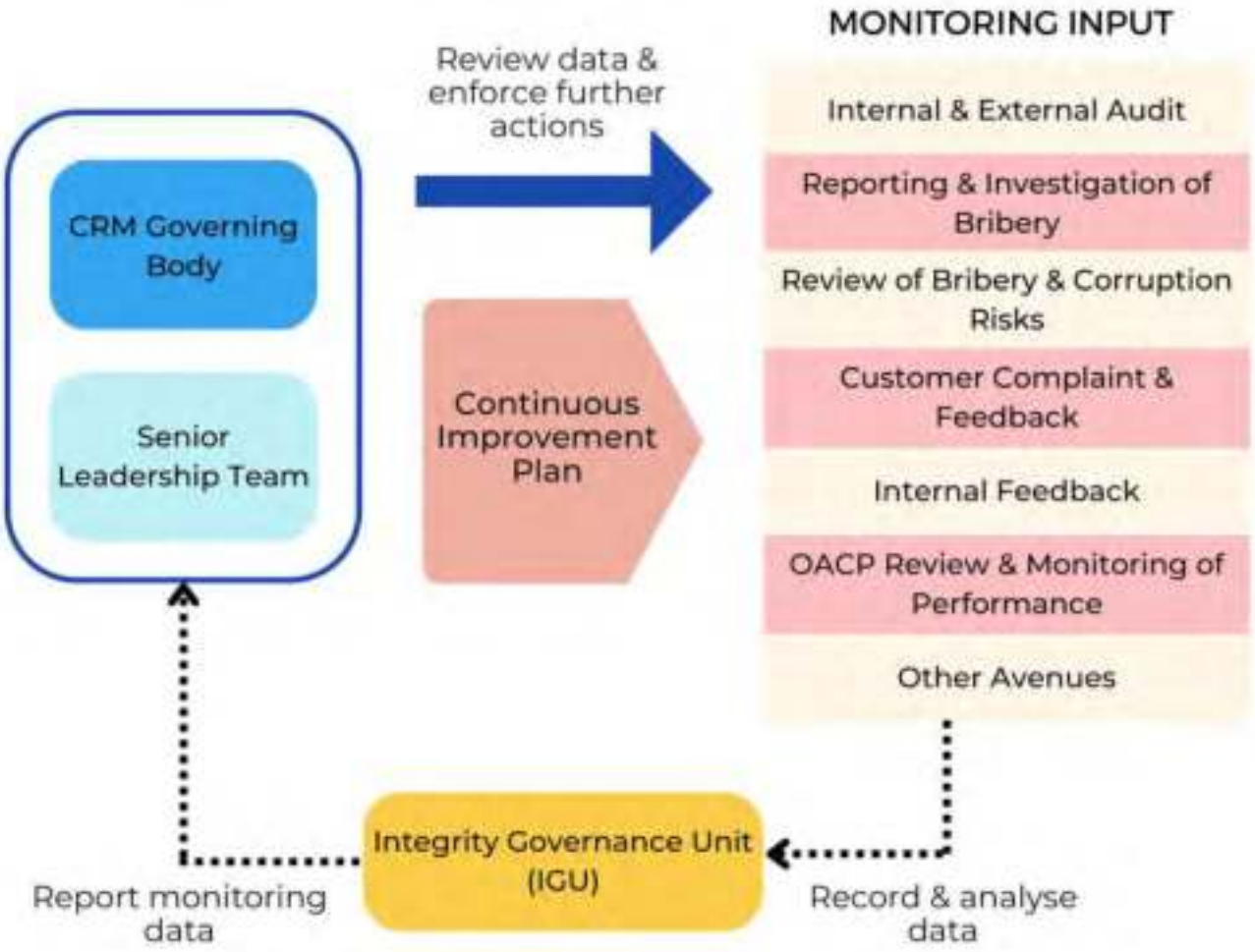
No.	Initiative	Responsibilities	Timeline
3.1	Integrity Test for recruitment of relevant position	Human Resources	2023
3.2	Background and/or Reference Check as part of employment requirement	Human Resources	Continuous
3.3	Refresher training for the project manager on the latest guideline	Clinical Operation	Continuous

ANTI-CORRUPTION STRATEGIC PILLARS

Monitoring and Evaluation

Effectiveness of strategic initiatives will be assessed through continuous monitoring and performance evaluation. Assessment data will be used to trigger needed improvements and further actions.

Monitoring & Evaluation Mechanism



ANTI-CORRUPTION STRATEGIC PILLARS

Culture Development

The key to a successful organization is to have strongly held culture based on shared core values. Both Top Management and Employees hold a vital role to support the strategies to imbibe culture of corruption free and good governance.

In CRM, we are committed to develop a robust culture of anti-corruption throughout all levels by engaging holistic actions to perpetuate highest integrity among our members.

01

Awareness and Alertness

- Onboarding program for new employees including Company Vision, Mission, Values, and Policies
- Regular sharing to all employees about relevant topics of bribery, integrity, and governance
- Encourage employees to recognize vulnerable situations and actions to be taken in those situations

02

Engagement

- Promote participation in activities conducted by the company
- Encourage exchange of ideas for continuous improvement of process and culture

03

Communication

- Open and secure channel of communications for reporting of bribery, corruption, misconduct, and grievances
- Open channel to receive feedbacks from external parties

CONCLUSION

SUMMARY

CRM is committed to good governance and integrity with the implementation of Clinical Research Malaysia Anti-Corruption Plan. The aspiration would be meaningless without participation by all the stakeholders, hence it is therefore paramount that the intent is internalized and subsequently expressed through all facets of our business. This document will strengthen CRM's commitment to be a Global Trusted Research Management Organisation with high integrity.

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