



Integrated Compliance Management @Bayer (ICM)



December 2018



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ICM enables to move from “Compliance 1.0” to “Compliance 2.0”



Compliance Management in the past “Compliance 1.0”

- // **Issue** driven
- // **Enforcement** focused
- // **Repetitive** audit findings
- // Compliance as an **extra activity** on top of day-to-day business, not handled on an integrated basis



Integrated Compliance Management “Compliance 2.0”

- // **Preventive, systematic approach** based on Corporate Compliance Policy / Global Compliance Charta
- // Enable business with Compliance / Integrate Regulations and Functional Processes **in business actions – the Business Partnership Concept**
- // Implement **systematic continuous learning** using audit findings and business dialogue as components to the Bayer Compliance Management System
- // **Communicate** on ICM Elements (Regulations, Functional Processes, Monitoring, Training) to all employees concerned (incl. Dos and Don'ts regarding day to day business activities)



ICM aims at implementing a sustainable and effective Compliance Management System



Goal

Develop and incorporate preventive measures into daily business activities to address the most significant compliance risks.

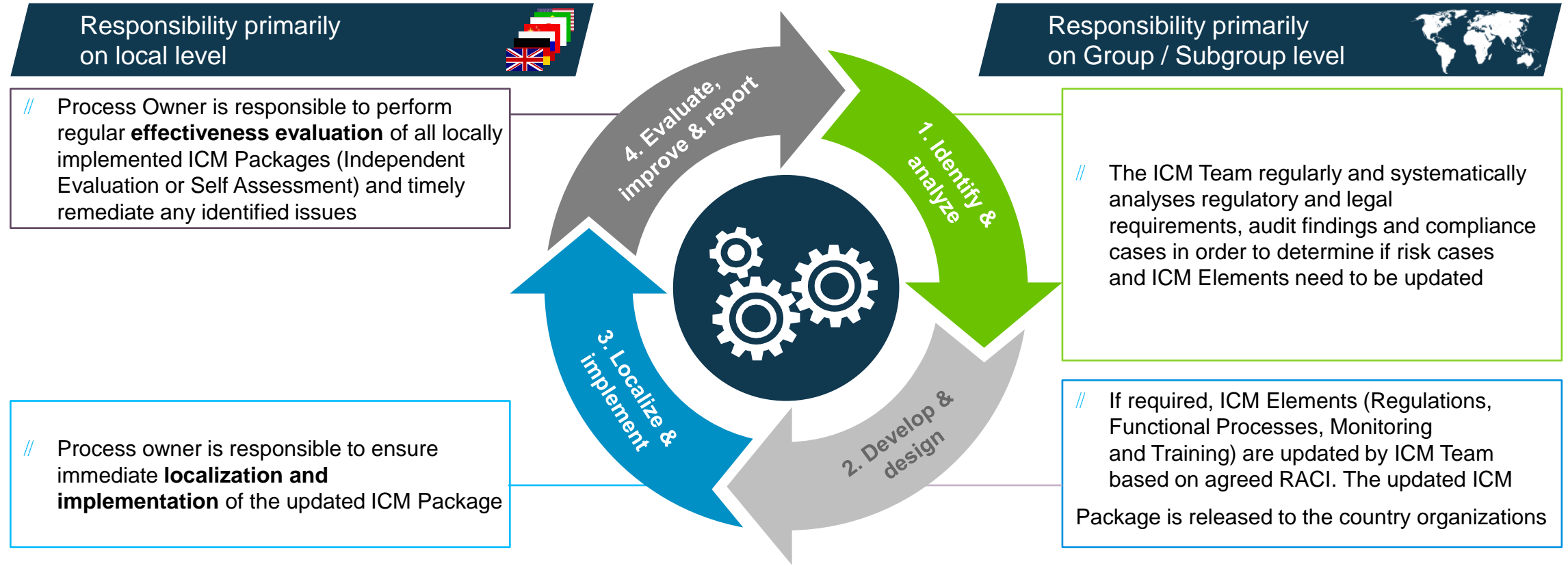


Requirements

- // Proactively identify and address the most significant compliance risks
- // Use ICM Methodology to:
 - // Establish clear standards and rules
 - // Implement procedures to help employees adhere to Bayer policies
 - // Ensure implemented measures are effectively mitigating the identified risks
 - // Provide specific compliance training to employees based on their job responsibilities



LifeCycle Management (LCM) consists of 4 key phases combining global and local activities

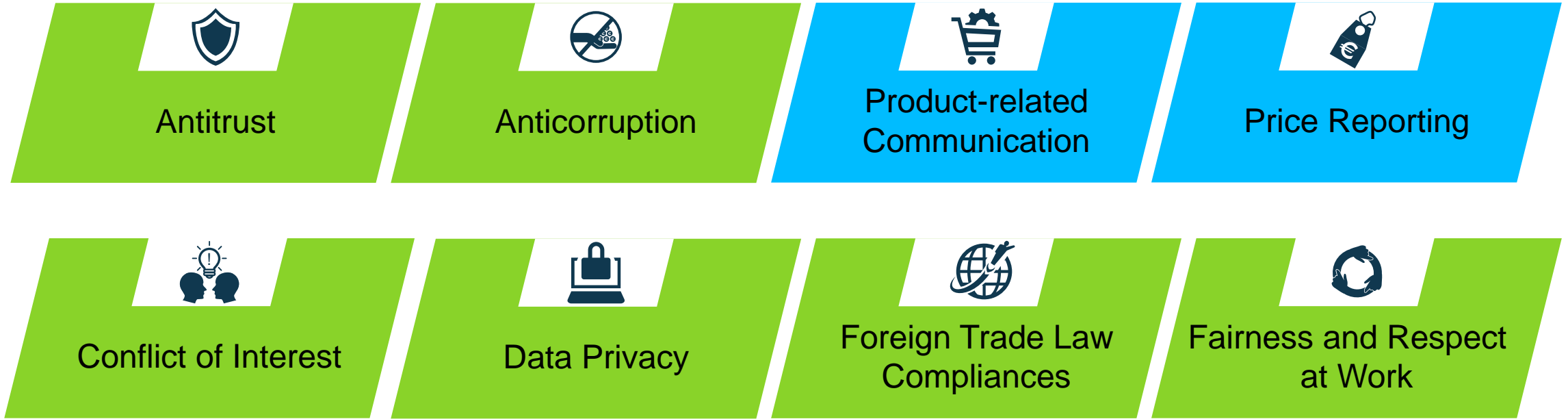


// ICM LCM ensures that ICM Packages are updated as needed according to a systematic process – thereby ensuring effective ICM on sustainable basis.

// The systematic approach also ensures consistent alignment between global and local activities.



ICM Risk Areas

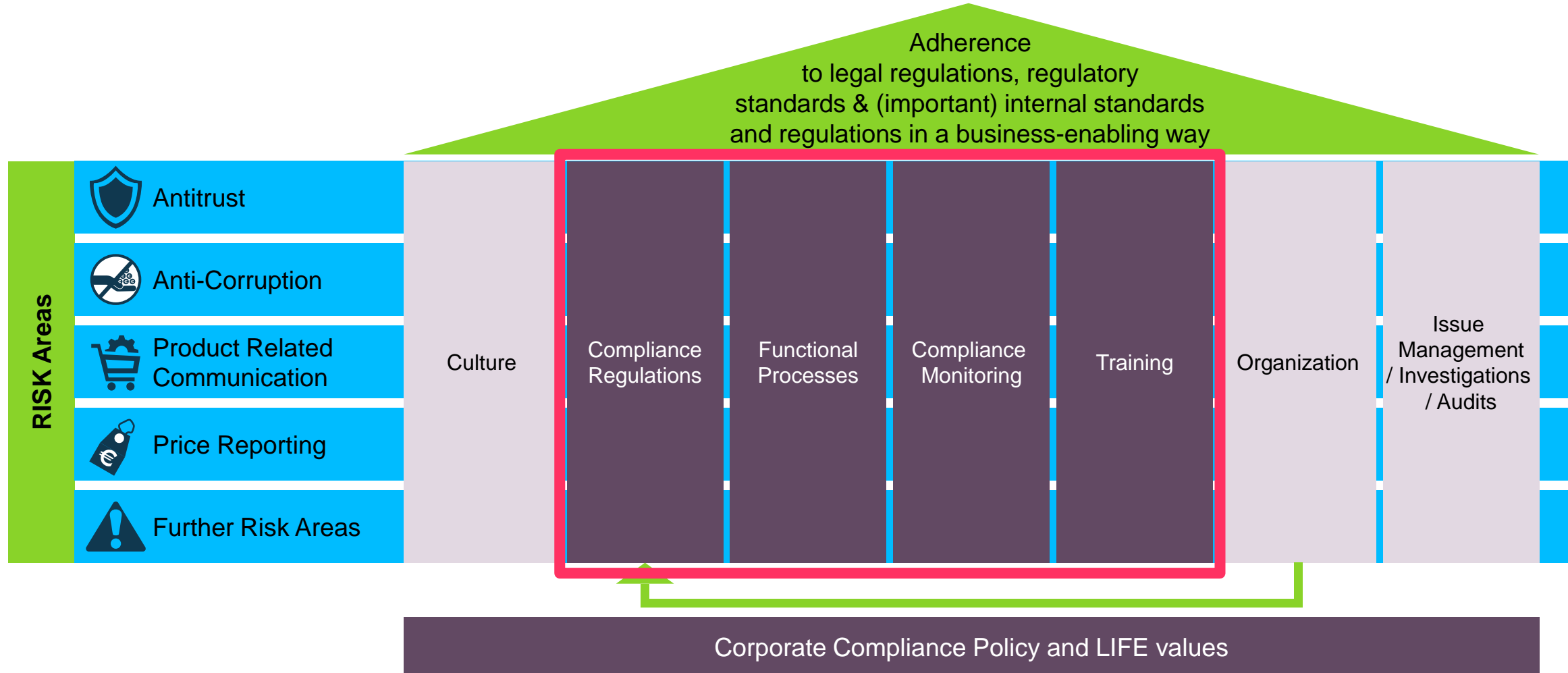


 Division specific ICM risk areas

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The ICM four-pillar approach applies for all Risk Areas





Based on the pillars of the “House of Compliance”, four ICM elements will be established for all Risk Areas



Compliance Regulations

Clear standards and rules to help employees carry out their job responsibilities in compliance with applicable laws and regulations



Functional Processes

Procedures and methods at global and local levels that help employees adhere to Bayer policies in their daily business activities and prevent compliance violations



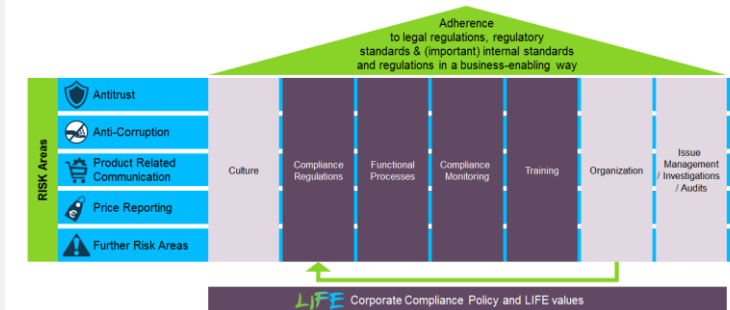
Compliance Monitoring

Assessments performed on a regular basis to ensure the implemented measures are effectively mitigating the identified compliance risks

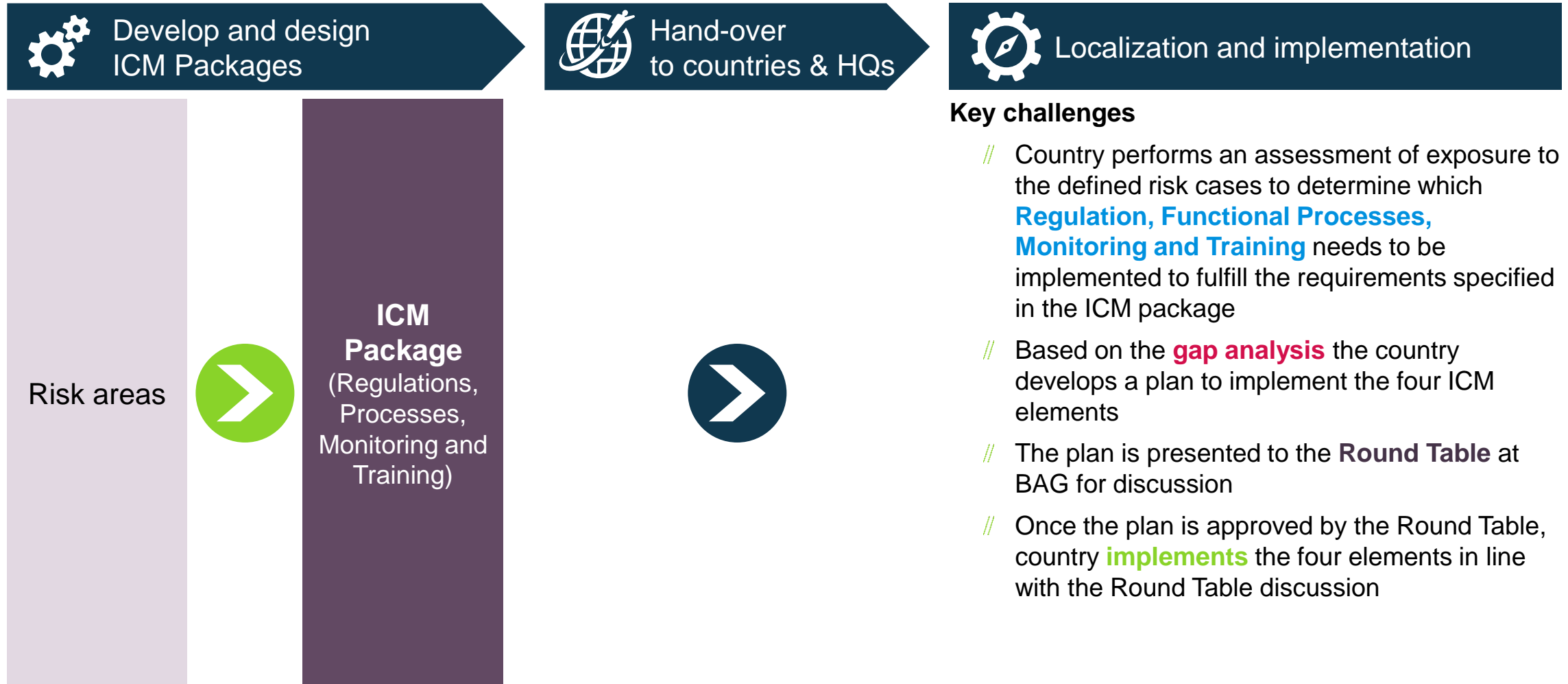


Training

Targeted training based on job responsibilities so that employees receive guidance about the specific compliance topics and risks most relevant to their positions



Localization and Implementation of ICM Elements

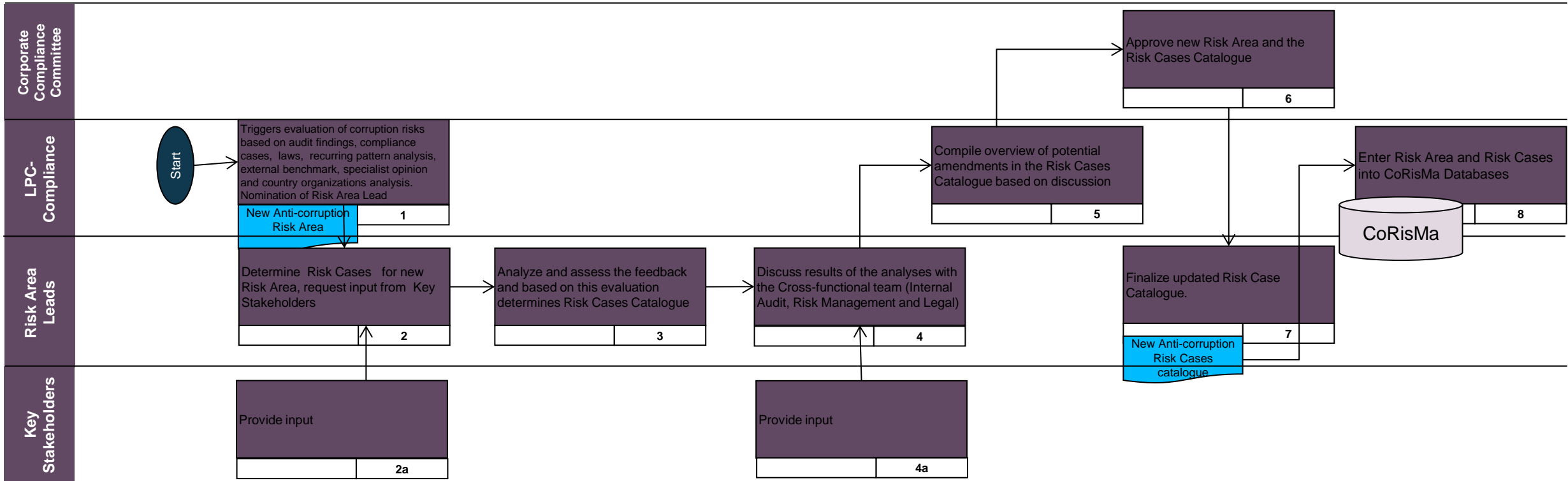




BACK-UP

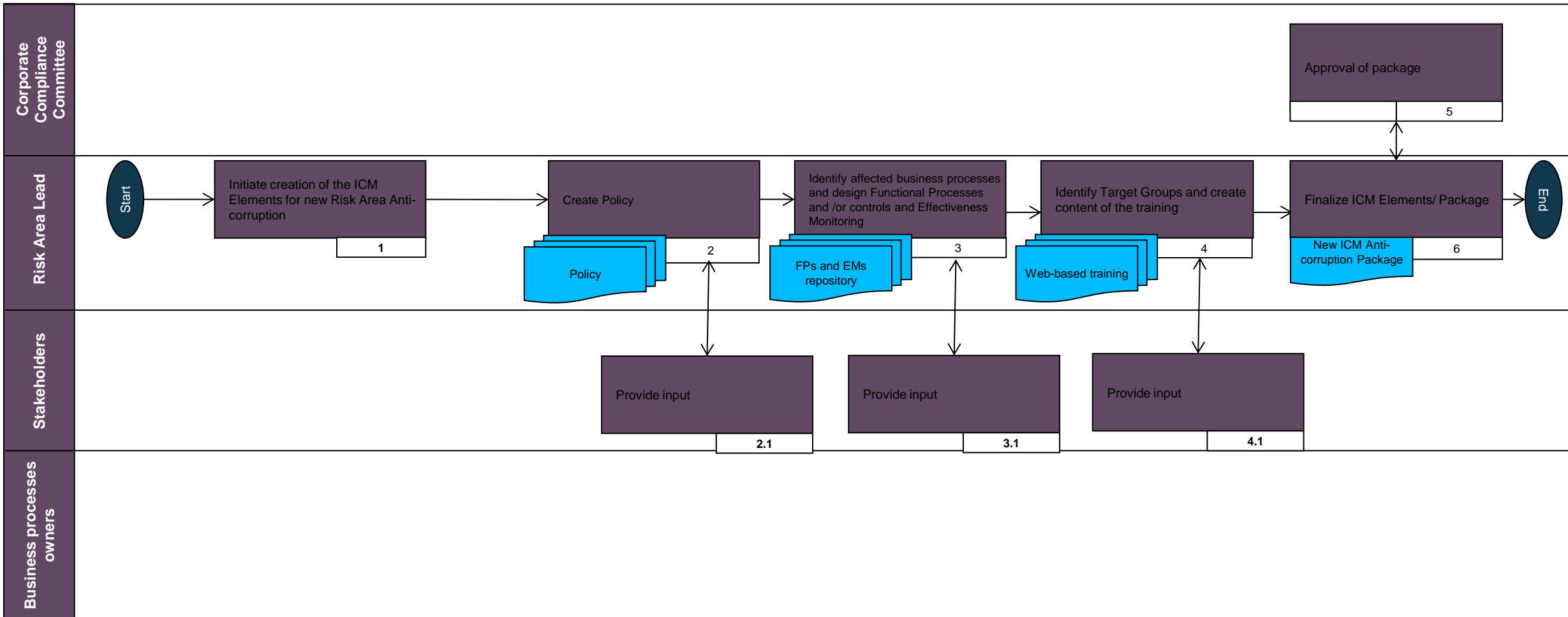
1. Identify & Analyze – Flowchart

Identification of Risk Area and Creation of Risk Cases for (example) Anti-corruption (AC)



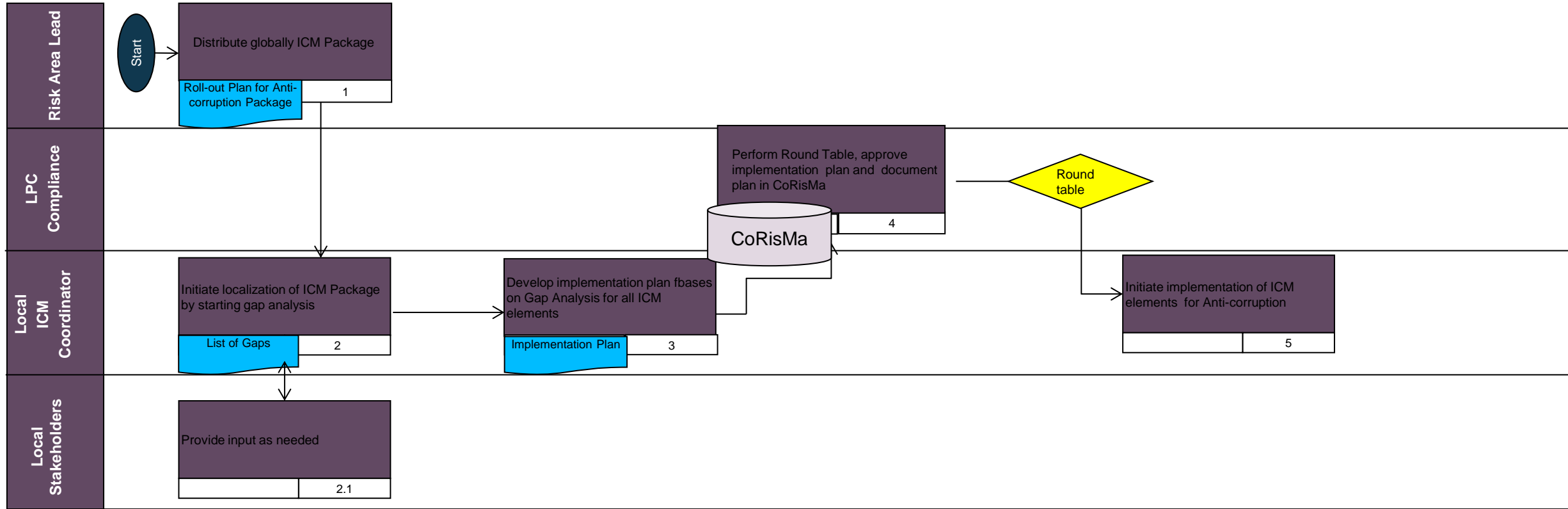
2. Develop & Design – Flowchart

Create ICM Package content across all ICM Elements (Policy, Functional Processes, Effectiveness Monitoring and Training) for AC



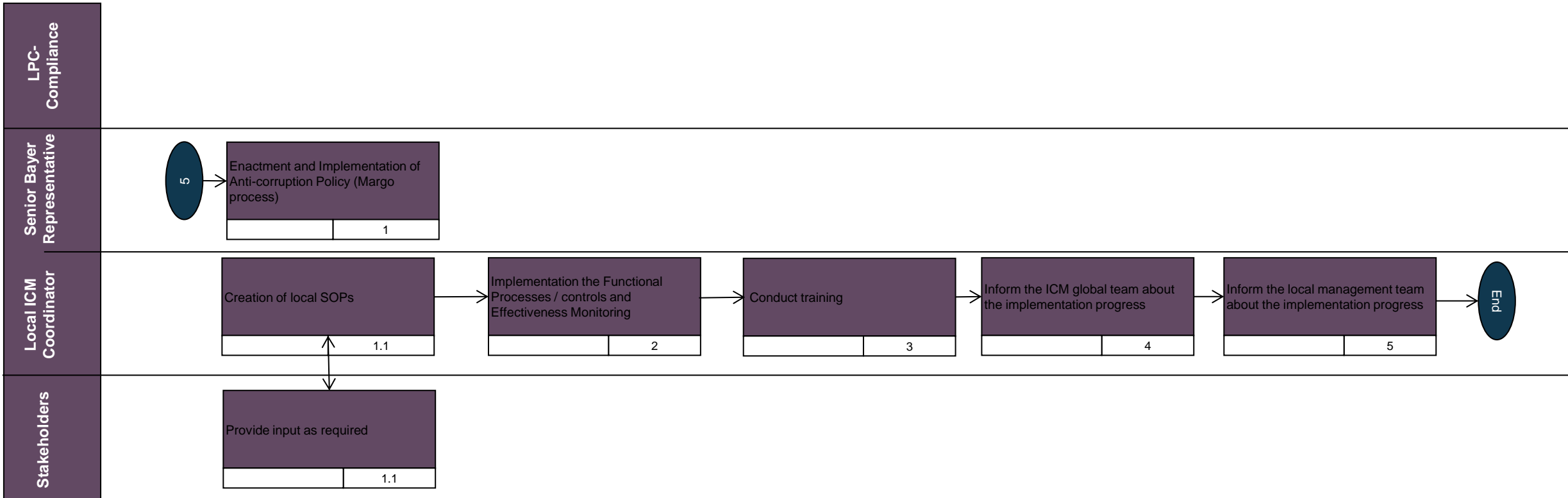
3. Localize & Implement – Flowchart

Countries localize and implement new ICM Anti-corruption Package



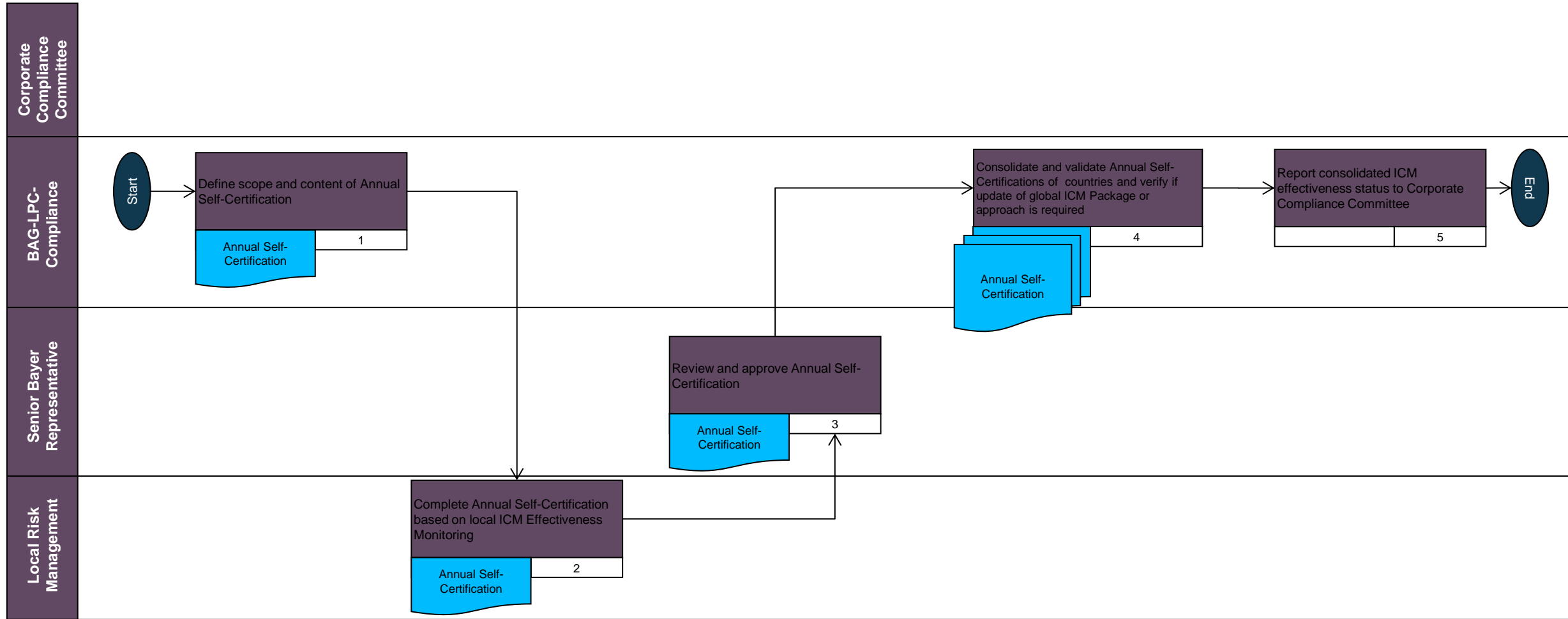
3. Localize & Implement – Flowchart

Countries localize and implement the ICM Package



4. Evaluate, Improve & Report – Flowchart

Report on ICM Effectiveness





Risk Area: Anti-corruption

ICM Risk Case Catalogue


ID	Risk Case	Risk Case Description
AC01	Offering gifts, travel, meals and/or hospitality to wrongfully influence third parties	Exertion of wrongful influence on government officials or business partners* – which can be either done by a Bayer employee or by an assigned third party – through an inappropriate provision of gifts (incl. cash), travels, meals or other hospitality.
AC02	Wrongful influence in tender business	Exertion of wrongful influence on the deciders in public or private tenders (bidding processes) which can be either done by a Bayer employee or by an assigned third party. This risk case also applies where a supplier does not participate directly in the tender but cooperates with its customers to exert undue influence on the deciders in a tender or bid process
AC03	Using donations, sponsorships, social development contributions to wrongfully influence third parties	Exertion of wrongful influence on government officials or business partner* through inappropriate political and charitable donations, sponsorships or social development contributions which can be either done by a Bayer employee or by an assigned third party.
AC04	Using exchange of services (contracting) to wrongfully influence third parties	Conclusion of service agreements which can be either done by a Bayer employee or by an assigned third party with government officials or business partners* in order to conceal the fact that the payments are used for the exertion of wrongful influence on these government officials or business partners.
AC05	Generation of disposable funds	Employee or third party working for Bayer fraudulently generates funds to enable the exertion of wrongful influence on government officials or business partners*. Examples include: <ul style="list-style-type: none"> Employee requests reimbursement of costs or expenses based on falsified documents. Employee misappropriates Bayer property and sells it.
AC06	Providing samples to wrongfully influence third parties	Exertion of wrongful influence on government officials or business partner* through inappropriate provision of samples. This includes, for example: <ul style="list-style-type: none"> provision of samples as concealed inducement to prescribe or purchase Bayer products provision of samples, especially medical samples, with violation of rules set out in applicable laws and/or codes, and making samples available for sale by business partner in case this would be not admissible, e.g. commonly in the case of HCPs (e.g. by not labeling them as free medical samples).
AC 07	Using invitation of HCPs to events to wrongfully influence third parties	PH/CH/AH employee or an assigned third party invites HCPs to (national or international) events/meetings without observing global and/or local code/law requirements or the requirements of the Bayer policies. Examples include: <ul style="list-style-type: none"> Invitations to scientific events are not made based on factual criteria (such as the medical expertise of the invited HCP) but rather as a means to unduly influence prescribing patterns. Paying or facilitating leisure activities in connection with invitation to scientific events “Extension days” used for private purposes, accompanying persons, entertainment programs
AC 08	Using advisory boards and investigator meetings involving HCPs to wrongfully influence third parties	PH/CH/AH employee or an assigned third party sets up advisory boards without meeting any or all of the following: establishing clear business/scientific needs; performing adequate compliance check of (i) the location/venue where the ad board takes place, (ii) the remuneration, (iii) travel/accommodation of the participating HCPs; obtaining documentation of the results of the ad board demonstrating that the bona fide services have actually been utilized, within PH/CH/AH; maintaining follow-up documentation. This creates a risk of exertion of wrongful influence on government officials or business partner* through inappropriate invitations to advisory boards and investigator meetings involving HCPs
AC 09	Using study support involving HCPs to wrongfully influence third parties	PH/CH/AH employee or an assigned third party selects investigators for (PH/CH/AH -sponsored) clinical trials not only based on medical need/objective criteria, but rather to influence prescription behavior of HCPs (e.g. sales team misuses prescription data of single HCPs). PH/CH/AH employee or an assigned third party supports an investigator initiated study or initiates a non-interventional study (post marketing) with the intent to create a stream of income to the HCPs participating. Mostly, such faked studies have a formal protocol and generate some documentation. However, from the outset, there is no “real” interest in the data that the study superficially helps to generate. PH/CH/AH employee or an assigned third party contracts HCPs for a study as well as for consultancy, which might lead to double payments for the same task.

*The term also includes Healthcare Professionals (HCPs) and Healthcare Organizations (HCOs).
For case involving bribery of Bayer employees (“passive bribery”), please refer to the risk area “Conflict of Interest”.



Risk Area: Anti-Corruption


Global Group Policy



Procedure
Anti-Corruption

Group Regulation No. 2041 (Edition: 1)

Scope: Group
Effective: January 1, 2012



Anti-Corruption Group Regulation No. 2041
Effective: January 1, 2012

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Riusk Area: Anti-Corruption

Functional Processes / Controls and Effectiveness Monitoring Repository



Overview of the Anti-Corruption Minimum Requirements and Controls

- FP01 – Events / Meetings
- FP02 – Travel and Hospitality
- FP03 – Gifts
- FP04 – Donations, Healthcare-specific Contributions and Sponsorships
- FP05 – Tender Management
- FP06 – Compliance Third Party Due Diligence
- FP07 – Contract Management
- FP08 – Procurement
- FP09 – Limited access rights to prescription data (PH / CH/ AH)
- FP10 – Sample Management
- FP11 – Study Support (PH / CH / AH)



FP01 – Events / Meetings

Mandatory Minimum Requirement

Introduce a process for organizing and documenting Events / Meetings. Implement the following process steps and controls:

AC_FP_01_01 Approval of Events / Meetings

Approval by LPC and/or Code Compliance Officer of Events / Meetings prior to Event / Meeting taking place, including International Events, Advisory Boards and Investigator Meetings according to the local regulations (SOPs, Policies, etc.).

- LPC / Code Compliance determines for which Events / Meetings LPC / Code Compliance approval applies according to the local risks
- LPC / Code Compliance decides whether the Event / Meeting meets legal requirements in global and local policies, laws and regulations.
- In case of international events for HCPs, host country rules also needs to be followed.

For exchange of services related to Events / Meetings, e.g. speaker arrangements or advisory board consultations, please refer to FP07.

Related Risk Cases	Link to further Examples and Guidance	Reference to Regulations
Offering gifts, travel, meals and/or hospitality to wrongfully influence third parties (AC01); Using exchange of services (contracting) to wrongfully influence third parties (AC04); Generation of disposable funds (AC05); Using invitation of HCPs to events to wrongfully influence third parties (AC07); Using advisory boards and investigator meetings involving HCPs to wrongfully influence third parties (AC08)	<ul style="list-style-type: none"> - Event Checklist v.2: Link - RD-OI-0268 - Manage Scientific Event – Link - RD-OI-0270 - Manage invitation of healthcare professional to scientific event – Link 	<ul style="list-style-type: none"> • Policy No. 2041 Anti-Corruption • Policy No. 1001 Event Management • Policy No. 2067 Procurement • Policy No. 2004 Verification of Payment Transactions

Proposed Documentation	Potential Effectiveness Monitoring (EM01)
SOP or similar binding document	Sample based check whether: <ul style="list-style-type: none"> - approvals were obtained for the events subject to LPC and/or Code Compliance approval - post-report (if applicable) of events/meetings and evidence documents are complete

Level of Applicability	Responsible Function	Process and Sub-Process affected
HQ/Region/Country	Business Services	Global Event Management Operations



Risk Area: Anti-corruption

List of ICM Functional Processes / Controls and Effectiveness Monitoring

Risk Area	Risk Case	FP title	Mandatory controls to be included in local SOP (or similar document)	Potential Effectiveness Monitoring (Control Assessment)
Anticorruption	AC01; AC04; AC05; AC07; AC08	FP01 – Events / Meetings	AC_FP_01_01 Approval of Events / Meetings Approval by LPC and/or Code Compliance Officer of Events / Meetings prior to Event / Meeting taking place, including International Events, Advisory Boards and Investigator Meetings according to the local regulations (SOPs, Policies, etc.).	Sample based check whether: - approvals were obtained for the events subject to LPC and/or Code Compliance approval - post-report (if applicable) of events/meetings and evidence documents are complete
Anticorruption	AC0; AC04; AC05; AC07	FP02 – Travel and Hospitality	AC_FP_02_01 Approval of Travel / Hospitality Expenses Approval by supervisor of expense reports in line with applicable policies and regulations.	Annual sample based examination of expenses (e.g. Concur report) in order to determine if the approved T&E claims are in line with local policies
Anticorruption	AC01; AC02; AC04; AC05	FP03 – Gifts	AC_FP_03_01 Approval of Gifts Approval by appropriate function of gifts in scope of approval according to the local gift policy.	Sample based examination of gift expenses (e.g. a report from Concur, a report from SAP or AMS tool) in order to determine whether gifts in scope of approval were approved according to the local gift policy and whether gift records are maintained by Division/Function.
Anticorruption	AC03; AC05	FP04 – Donations, Healthcare-specific Contributions *and Sponsorships	AC_FP_04_01 Approval of Donations Approval of donations in line with Corporate Policy No. 1978 Donations.	Sample based check of donation and healthcare-specific contribution expenditures (e.g. a report from SAP) in order to check whether the transactions are processed in line with policies / local laws and guidelines.
Anticorruption			AC_FP_04_02 Approval of Sponsorships Approval by an appropriate function of sponsorships based on local regulations (SOPs, Policies etc.).	Sample based check of sponsorship expenditures (e.g. a report from SAP) in order to check whether the transactions are processed in line with policies / local laws and guidelines.
Anticorruption			AC_FP_04_03 Approval of Healthcare-specific Contributions Approval by an appropriate function of healthcare-specific contributions according to local laws, guidelines and "Interpretation Guide for Bayer Donation Directive".	refer to EM for AC_FP_04_01 (EM for donations and HC specific contributions combined)
Anticorruption	AC02	FP05 –Tender Management	AC_FP_05_01 Corruption Risk Assessment of Direct / Indirect Tender Assessment of corruption risks is performed by LPC for a given tender or given tender business model (in the case of repetitive tenders following the same pattern) before tender participation.	Sample based review of tenders in order to verify that a risk assessment is performed and documented and the tender is in line with the risk assessment
Anticorruption	AC04; AC05	FP06 – Compliance Third Party Due Diligence	AC_FP_06_01 TPDD Appropriate function conducts third party due diligence using the COMPASS tool in line with Procedure No. 2083	Sample based check of third parties, a list from the partner registry is obtained (e.g. new suppliers, consultants / sales agents / logistic service providers / event managers / contract research organizations / lobbyists / / registration, licensing or permit agents / public accountants) in order to determine whether COMPASS procedure has been applied
Anticorruption	AC02; AC04; AC05; AC08; AC09	FP07 – Contract Management	AC_FP_07_01 Approval of Contracts Review and approval of contracts by appropriate function. - In case of PH/CH HCP contracts, Fair Market Value (FMV) is reviewed by the Local Code Compliance or appropriate function. The selection process of HCP is reviewed by appropriate function, e.g. Medical	Sample based check of contracts whether approval by appropriate function was obtained. Sample based check of HCP contracts whether Fair Market Value (FMV) is reviewed by the Local Code Compliance or appropriate function and HCP selection process is reviewed by appropriate function
Anticorruption	AC01; AC04; AC05; AC07; AC08	FP08 – Procurement	AC_FP_08_01 Involvement of Procurement Function Involvement of Procurement function in defined procurement activities in line with Corporate Policy 2067 and local policies	Sample based check of invoices without a purchase order whether those spents are in line with the "Approved Ways to Buy and Pay" guidance (Maverick spent or Non PO reports)
Anticorruption	AC04; AC05; AC07; AC08; AC09	FP09 – Limited access rights to prescription data (PH / CH / AH only)	AC_FP_09_01 Approval for Collection of Prescription Data Approval by LPC before collecting prescription data of individual HCPs	Confirmation by Division that prescription data of individual HCPs was not collected without the approval by LPC. For approved collection activities, sample based check whether LPC approval date is not later than the actual collection date
Anticorruption			AC_FP_09_02 Approval for Access to Prescription Data Approval by LPC for granting access to prescription data of individual HCPs	Review by LPC of appropriateness of access rights to prescription data
Anticorruption	AC05; AC06	FP10 – Sample Management	AC_FP_10_01 Review of Sample Records Annual random review of sample records by appropriate function outside of Sales / Marketing (e.g. Finance Business Partner, Controlling etc.) to ensure: - Samples were distributed according to local policies, laws and regulations. - Acknowledgement of sample receipt if required by local laws and codes was obtained. - Sample records are kept by Divisions in line with the sample management process	Confirmation by appropriate function whether annual random review of sample records was performed.
Anticorruption	AC04; AC09	FP11 – Study Support (PH /CH /AH only)	AC_FP_11_01 Approval of Study Support Activities Approval by Medical Department or appropriate function for study support activities (clinical trials, non-interventional studies (NIS) and investigator initiated research (IIR)) according to applicable global SOPs.	Sample based check of study support activities whether approval by Medical Department or appropriate function were obtained.