



A.R.C.O. Programme – Analysis, Risk and Organisational Control

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Laura Giuliani

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København 7 October 2025

Public Declaration of transparency/interests*

The view and opinions expressed are those of the individual presenter and should not be attributed to AIFA

Interests in pharmaceutical industry	NO	Current	From 0 to 3 previous years	Over 3 previous years
<i>DIRECT INTERESTS:</i>				
1.1 Employment with a company: pharmaceutical company in an executive role	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> mandatory
1.2 Employment with a company: in a lead role in the development of a medicinal product	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> mandatory
1.3 Employment with a company: other activities	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> optional
2. Consultancy for a company	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> optional
3. Strategic advisory role for a company	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> optional
4. Financial interests	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> optional
5. Ownership of a patent	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> optional
<i>INDIRECT INTERESTS:</i>				
6. Principal investigator	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> optional
7. Investigator	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> optional
8. Grant or other funding	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> optional
9. Family members interests	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> optional
10. Serious reasons of convenience	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> optional

***Maria Letizia Affronti**, in accordance with the Regulation for the prevention and handling of conflicts of interest of the Italian Medicines Agency, approved by AIFA Board of Directors (Resolution no. 9 - 12 February 2025).

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Why the A.R.C.O. Programme



- A response to the BEMA 2022 Assessment: SOP 365 on Risk Management
- A drive for improvement
- A pilot project for a systemic change

Agenda

1. Context analysis
2. A.R.C.O. Programme's Objectives
3. Risk based approach
 - a) Risk data form > risk identification questionnaire
 - b) Risk ranking
 - c) Impact scale > risk assessment questionnaire
 - d) Data processing
 - e) The risk cycle
 - f) A.R.C.O. App: RTP and CAPA Management

AIFA Quality Assurance System

268 Documents divided into:

- Standard Operating Procedures (SOPs): 220
- Quality System Documents (QSD): 35
- Operating Instructions (Op.Is.): 10
- Manuals: 3

Biennial audits of the European pharmacovigilance system:

Ex-post Audit :

- Coverage: 40% of the operating documents
- Focus on technical processes (EMA, European Commission)
- Examples: GMP compliance, international mutual recognition

ISO 9001 and ISO 31000

ISO 9001

- quality of services
- quality audits
- Introduction of 'Risk Management' as 'Risk-based Thinking'

ISO 31000

- All dimensions of Risk Management
- Universal framework for RM
- Introduction of the following concepts: context, risk assessment, communication, monitoring, continuous improvement of the RM system

- Promotion of process management
- PDCA cycle (Plan-Do-Check-Act)
- Leadership and Governance
- Documented Management
- Stakeholder Orientation

Needs Identification

Comprehensive and timely overview of process compliance

Mapping of standard processes and identification of KPIs

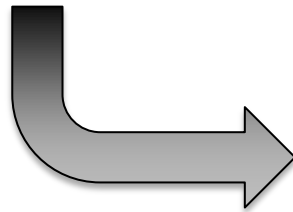
Definition of early warning thresholds

Definition of impact measures (outcomes) linked to the Agency's strategic objectives

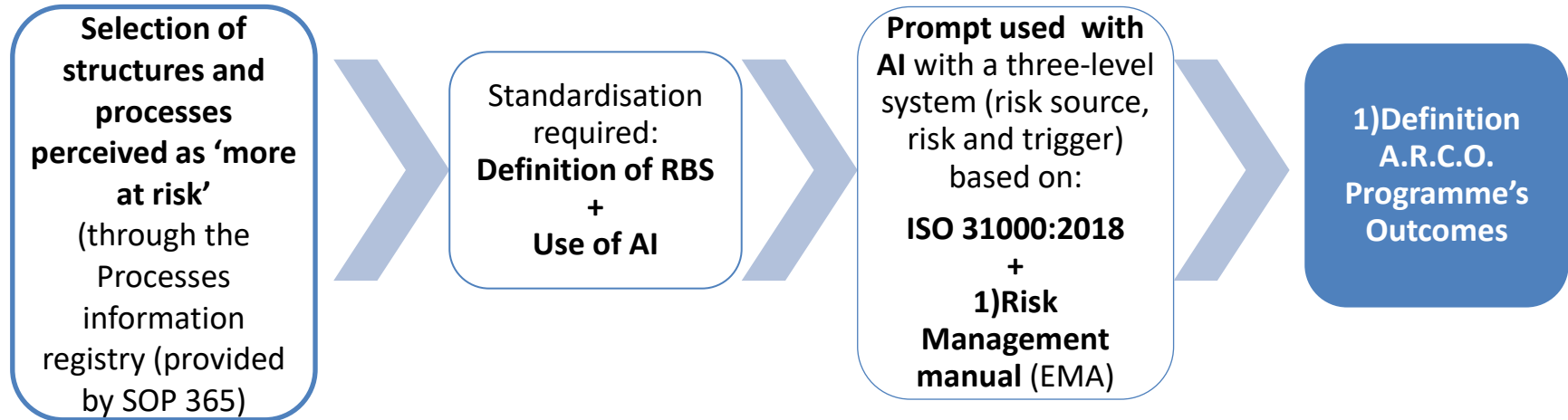
Performing trend analysis and constantly updating information.

WE ASKED ALL OUR EMPLOYEES FOR HONEST FEEDBACK
AND THEY HAVE TRUTHFULLY TOLD US THAT EVERYTHING
IN THE COMPANY IS 100% PERFECT

SOP 365 'Risk management':



The starting point of A.R.C.O. Programme



A.R.C.O.'s Outcomes

Classification of processes based on risk level (excluding corruption and cyber risk)

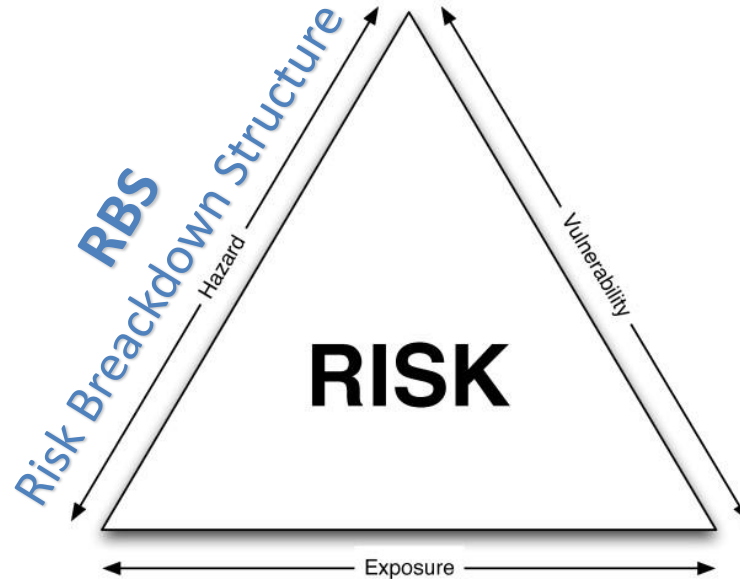
Review & Update of quality documents **while mapping AIFA's processes** according to the BPMN2.0 standard and **identification of KPIs**

Creation of an **App** based on Microsoft Power **Platform for risk cycle** and **audit management**

Design and adoption of a **Governance, Risk And Compliance (GRC) framework** with KPIs and a management dashboard (Balanced Scorecard)

Establishment of an **internal community for risk management.**

Risk triangle

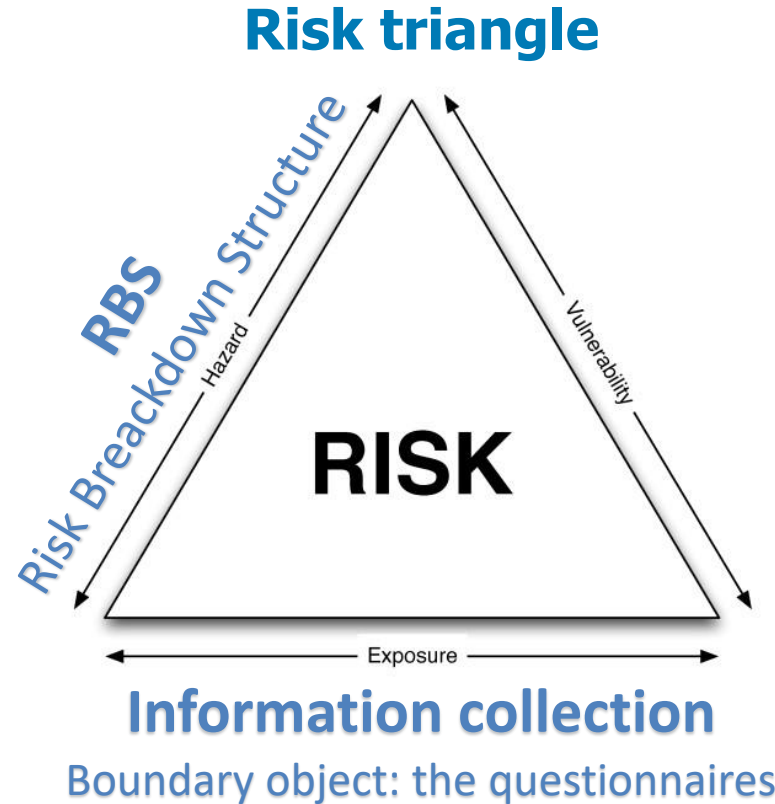


Risk Data Form

Risk Source (<i>Hazard</i>)	Personnel – Human Resources
Risk	Personnel – Human Resources allocation
Risk statement	Since the number of resources allocated to this task is limited or shared with other tasks/processes, periods of dedicated resource shortages may occur, resulting in slowdowns in activity and delays in process execution.
Risk description	<p>Shortage of dedicated resources may be due to two main factors: limited number of resources and resource-sharing with other tasks/processes. This shortage leads to an activity slowdown, which may entail:</p> <ul style="list-style-type: none"> • Delays in completion times • Reduced service quality • Stress and overload for staff
Trigger	<ul style="list-style-type: none"> • TR01 - How many people are assigned to implement this process? • TR02 - What percentage of the people working on this process are assigned to other processes? • TR61 –As of 31 December of the previous year, what is the average percentage of holiday leave per person for the people involved in this process that will need to be used within the current year? • TR07 - What is the average age of the staff assigned to the process? • TR62 - Number of staff assigned to the task who have children under the age of 15

Risk Data Form

Risk Source (Hazard)	Processes
Risk	Absence/obsolescence of operating procedures
Risk statement	Since there are no standard operating procedures (or they are obsolete) for this particular task, situations of excessive discretion may arise.
Risk description	<p>In the absence of defined or updated operating procedures for a particular task, situations of excessive discretion in the execution of activities arise. This lack of SOPs can lead to various problems, including inconsistency in results, difficulty in maintaining quality standards, and an increased risk of errors. It is also more difficult to ensure accountability and transparency, as decisions can be made subjectively, without a shared frame of reference. Excessive discretion can also lead to inefficiencies and slowdowns, as people may have to “invent” solutions or processes on the spot, rather than following predefined guidelines. Furthermore, the absence of operating procedures makes it more complex to train new staff and transfer know-how within the organisation.</p>
Trigger	<ul style="list-style-type: none">• TR45 - Are SOPs defined for the process under review?• TR46 - In addition to any SOPs present in AIFA, are there other procedures or reference standards from other bodies/organisations (e.g. ISO, UNI, EMA, etc.) for the process under review?• TR47 - Have the SOPs been updated in the last three years?



AIFA Organisational Risk Identification Questionnaire

The questionnaire aims to gather useful information for identifying potential risks to which an AIFA process (or individual task) be exposed. These risks are identified by checking for the presence or absence of vulnerabilities that may have been encountered in other similar situations. If your answer falls between two options, select the option with the higher number.

Hi <user>. When you submit this form, the owner will see your name and email address.

* compulsory

Indicate the process for which you are filing the questionnaire

Enter your answer

2. TR01 - How many people are assigned to implement this process

- ☐ 1 Person
- ☐ 2-3 People
- ☐ 4-5 People
- ☐ 5-6 People
- ☐ More than 6 People

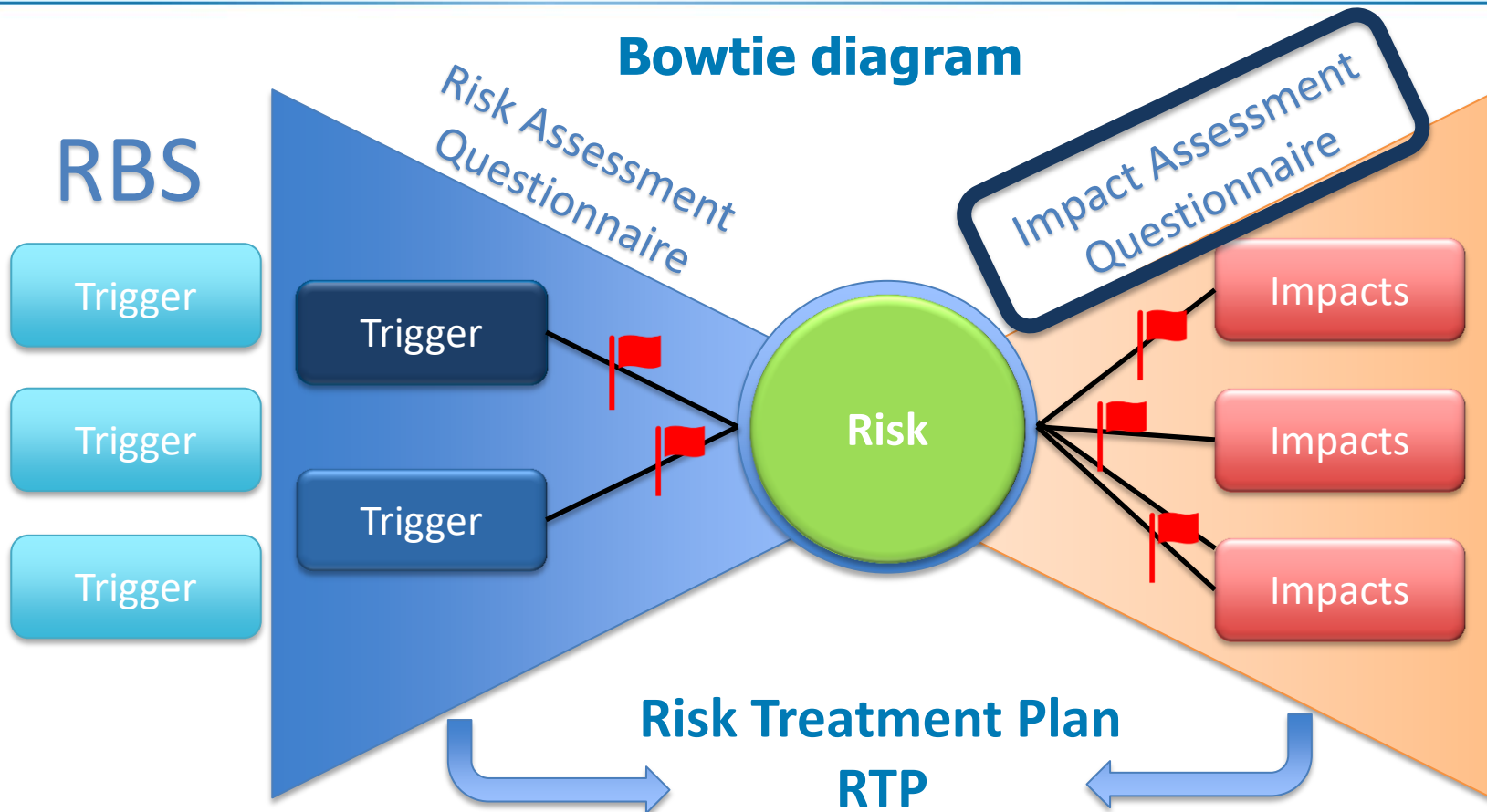


Risk Ranking

Information collection is essential to assess the **Risk exposure** and rank the risk

Risk		Risk Description	Risk Ranking	Total score
1.1	Personnel allocation	Since the number of resources allocated to this task is limited or shared with other tasks/processes, periods of dedicated resource shortages may occur, resulting in slowdowns in activity and delays in process execution.	■	■
4.2	Ongoing regulatory processes	Since there are regulatory processes in place that could impact SOPs, there may be changes to processes.	■	■
5.2	Tool availability	Since specific equipment/tools are required to perform the task, there may be shortages during task execution.	■	■
3.2	Interfaces with other processes	Since the process/task involves interaction with other processes, there may be interruptions in the value chain or inconsistencies in the information in the various processes.	■	■

Bowtie diagram



ISO 31000: Setting objectives



Strategic



Operational



Financial



Legal & regulatory



Public Health













Reputational

AIFA should be able to operate continuously every day of the week, ensuring both efficiency and reliability of its daily activities.

The Agency should be able to adapt and respond effectively to unforeseen events or emergencies, demonstrating strong operational resilience. Therefore, any event that compromises its operational continuity or ability to recover quickly from disruptions constitutes an operational risk.

Qualitative and quantitative impact scale

 <p>Irrelevant</p> <p>The events do not affect business continuity. Daily operations proceed without interruption or delay, and the resilience of the system is not tested.</p>	 <p>Minor</p> <p>The events cause minor operational disruptions, with possible slowdowns but no significant negative effects on productivity or expected results. Resilience is sufficient to manage the event without the need for extraordinary measures.</p>	 <p>Moderate</p> <p>Events significantly affect business continuity, causing delays or partial interruptions. The organisation must implement more complex recovery measures to restore normality.</p>	 <p>Major</p> <p>The events severely compromise business continuity, with extended interruptions affecting the achievement of daily objectives. Recovery measures require considerable time and significant resources.</p>	 <p>Catastrophic</p> <p>Events completely disrupt business continuity, with devastating effects on productivity and overall effectiveness. Restoring normal operations requires extraordinary measures and a prolonged period of time, putting a strain on the organisation's resilience.</p>
 <p>Irrelevant</p> <p>Interruption 0 delay in activities: 0 hours; Availability of operational resources: 100%; Recovery time (in case of incident): immediate (less than 1 hour).</p>	 <p>Minor</p> <p>Interruption or delay of activities: < 4 hours; Availability of operational resources: >= 95%; Recovery time 1 – 4 hours.</p>	 <p>Moderate</p> <p>Interruption or delay of activities: 4–12 hours; Availability of operational resources: 80–94%; Recovery time: 4–12 hours.</p>	 <p>Major</p> <p>Interruption or delay of activities: 12–24 hours; Availability of operational resources: 50–79%; Recovery time: 12–24 hours.</p>	 <p>Catastrophic</p> <p>Interruption or delay of activities: > 24 hours; Availability of operational resources: < 50%; Recovery time 24 hours.</p>

Organisational risks analysis

Risk analysis

L'analisi del rischio ha l'obiettivo di valutare sia la probabilità di accadimento sia l'impatto potenziale dei rischi che potrebbero compromettere il raggiungimento degli obiettivi dell'AIFA. Attraverso una valutazione qualitativa e quantitativa, l'Agenzia identifica e classifica ogni rischio in base alla sua gravità, descrivendo in modo dettagliato la possibile entità dell'impatto su obiettivi specifici (reputazionale, strategico, operativo, economico, legale e regolatorio, salute pubblica). Tale analisi fornisce una base per definire le priorità d'intervento e per adottare azioni correttive e preventive adeguate.

5. Identifica il rischio a cui il processo risulta esposto *

L'esposizione al rischio è stata valutata dal gruppo di lavoro sul rischio organizzativo di AIFA e comunicata all'ufficio. Devi compilare un questionario che identifichi i rischi, ma puoi anche aggiungerne altri.

1.1 Allokazione del personale

6. Indica la probabilità **stimata** di occorrenza del rischio. *

La probabilità rappresenta la stima della frequenza o della possibilità che un determinato evento rischioso si verifichi. In un contesto di gestione viene valutata per determinare quanto è probabile che un rischio specifico influenzi gli obiettivi organizzativi. La probabilità viene misurata su una scala da "Bassa" a "Molto Alta" e può essere espressa in termini qualitativi o quantitativi. Questa valutazione è essenziale per stabilire le priorità di intervento e concentrare le risorse su quei rischi che, con maggiore probabilità, potrebbero influenzare negativamente l'organizzazione.

- ☐ 1 - **Molto Bassa**: Probabilità di accadimento **inferiore al 5%**. L'evento è estremamente raro e poco probabile.
- ☐ 2 - **Bassa**: Probabilità di accadimento compresa **tra il 5% e il 20%**. L'evento è poco probabile, ma possibile in circostanze eccezionali.
- ☐ 3 - **Media**: Probabilità di accadimento compresa **tra il 20% e il 50%**. L'evento è relativamente probabile e può verificarsi in determinate circostanze.
- ☐ 4 - **Alta**: Probabilità di accadimento compresa **tra il 50% e l'80%**. L'evento è molto probabile e potrebbe verificarsi in più occasioni.
- ☐ 5 - **Molto Alta**: Probabilità di accadimento **superiore all'80%**.

Risk Assessment questionnaire

Organisational risks analysis

* Obbligatoria

Impact on Specific Objectives

Per ciascun obiettivo, seleziona il livello qualitativo e il relativo descrittore quantitativo e specifica la motivazione della scelta.

8. Quale impatto avrebbe questo rischio sulla **reputazione** dell'AIFA? (Obiettivo Reputazionale) *

L'AIFA ha l'obiettivo di mantenere un alto livello di fiducia da parte degli stakeholder, in particolare nei momenti decisionali, grazie alla percezione positiva della propria immagine. Una reputazione solida non solo rafforza la cooperazione con partner istituzionali e internazionali, ma aumenta anche l'efficacia delle politiche e delle iniziative promosse dall'Agenzia. Pertanto, qualsiasi evento che abbia un impatto sul grado di fiducia percepito e sull'immagine costituisce un rischio reputazionale.

- ☐ 1 - **Irrilevante**: nessun impatto rilevante sulla reputazione; copertura negativa su media a livello locale.
- ☐ 2 - **Minore**: basso impatto sulla reputazione; copertura negativa su media regionali.
- ☐ 3 - **Moderata**: impatto significativo sulla reputazione; copertura negativa su media internazionali con insoddisfazione dei principali stakeholder.
- ☐ 4 - **Maggiore**: impatto elevato sulla reputazione; copertura negativa a livello internazionale con molti stakeholder insoddisfatti.
- ☐ 5 - **Catastrofica**: impatto molto elevato sulla reputazione globale; copertura negativa continua a livello globale con quasi tutti gli stakeholder insoddisfatti.

9. Motivazione della valutazione di impatto scelta per l'obiettivo reputazionale. *

Inserisci la risposta

Risk triangle

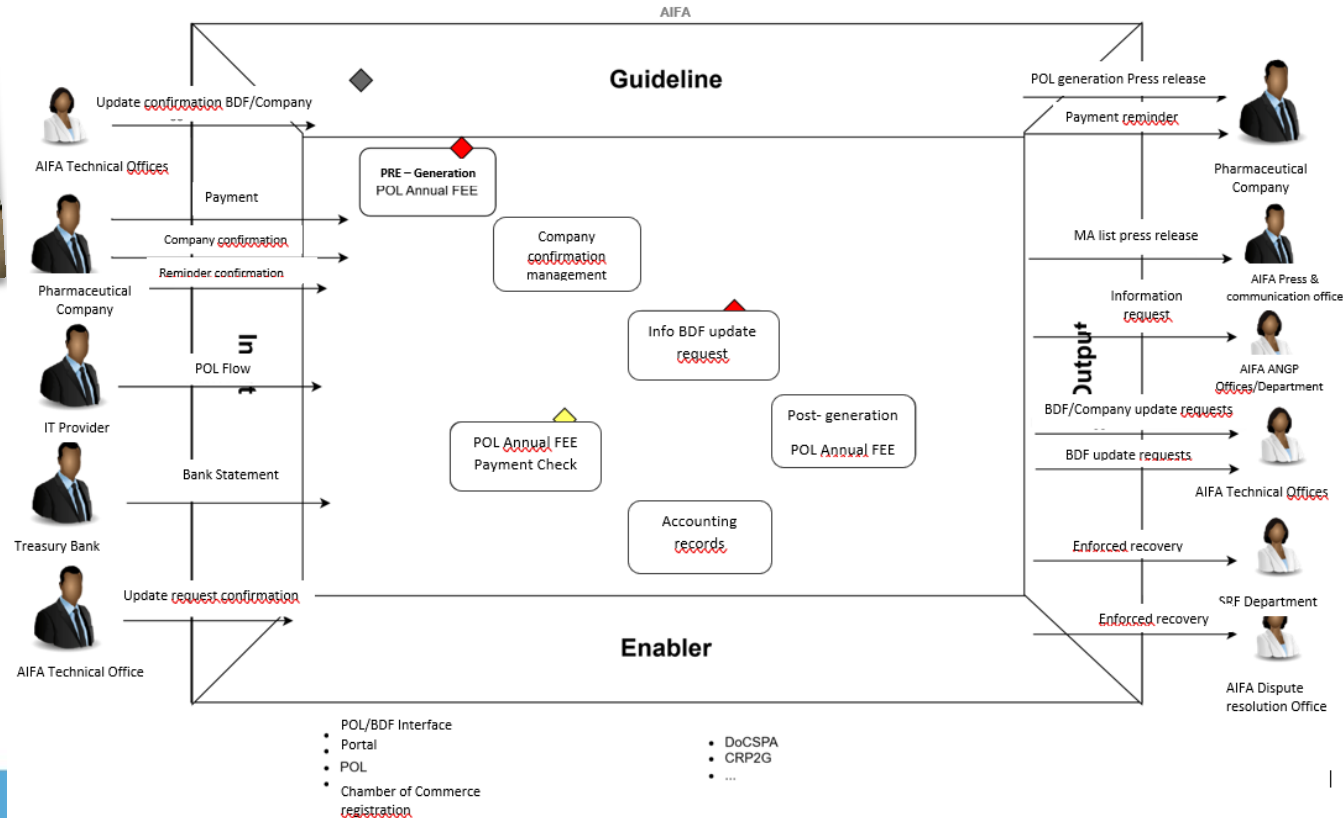


DATA PROCESSING: IGOE



“Risk talk”

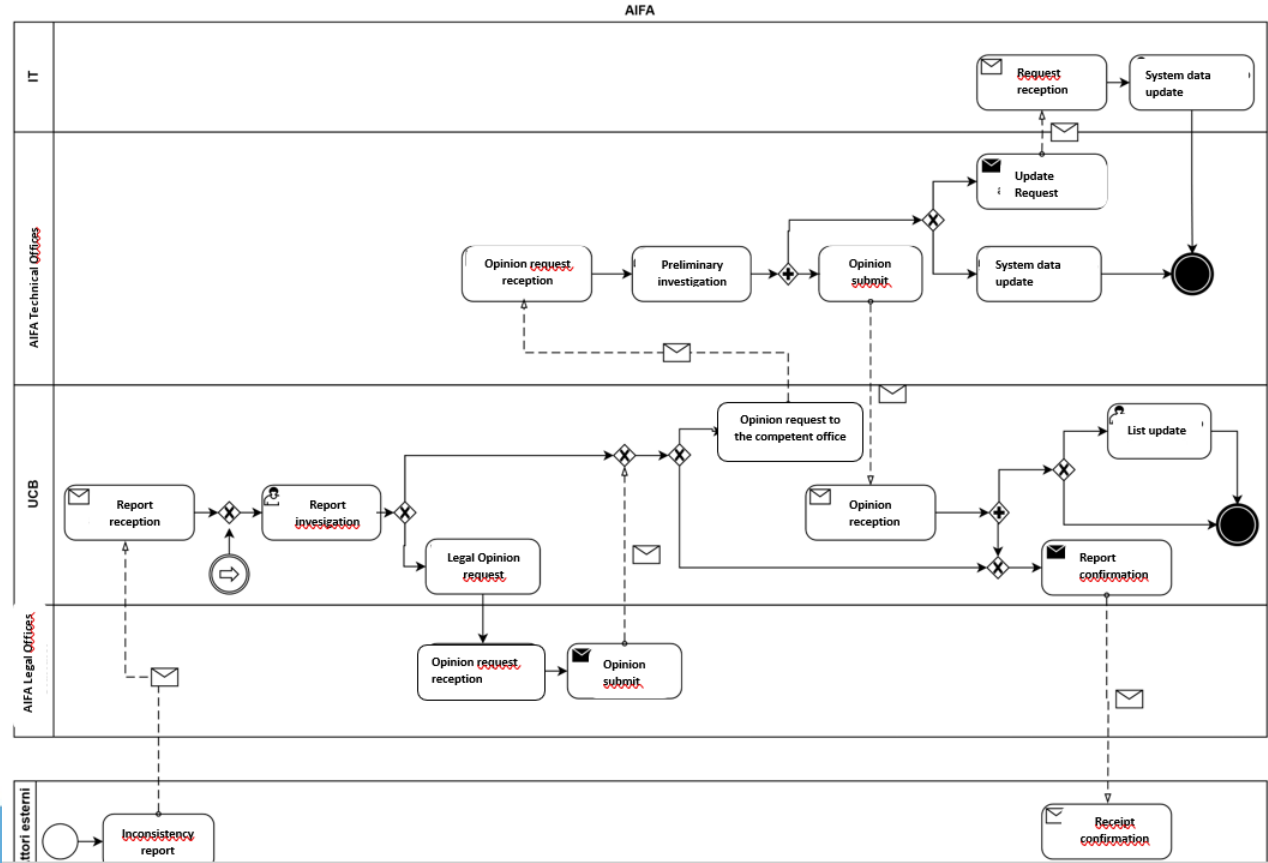
- Article 17, paragraph 10, letter d) of Decree Law No. 98 of 6 July 2011, converted into Law No. 111 of 15 July 2011;
- Article 4, paragraphs 5 and 6 of Decree No. 53 of the Minister of Health of 29 March 2012
- Board of Directors Resolution No. 21 of 30 May 2012;
- Decree of the Minister of Health of 6 December 2016 (Articles 2, 3 and 6, paragraph 2); - Article 3 of the Decree of the Minister of Health of 13 September 2023.

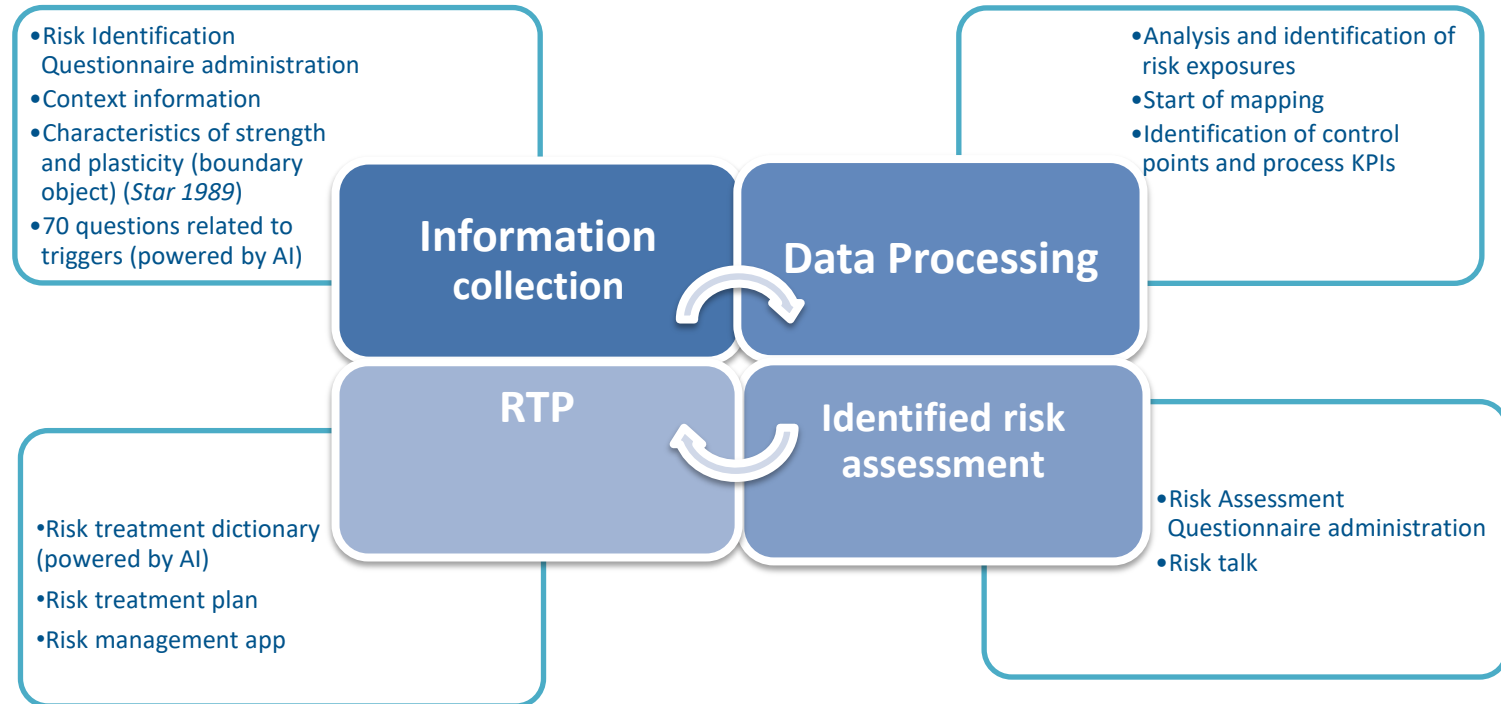


DATA PROCESSING: BPMN2.0



“Risk talk”







PROGETTO A.R.C.O. Piattaforma Gestione Rischio



MENÙ PRINCIPALE

Elenco Rischi

Nuovo Rischio

Elenco RTP

Risk Map

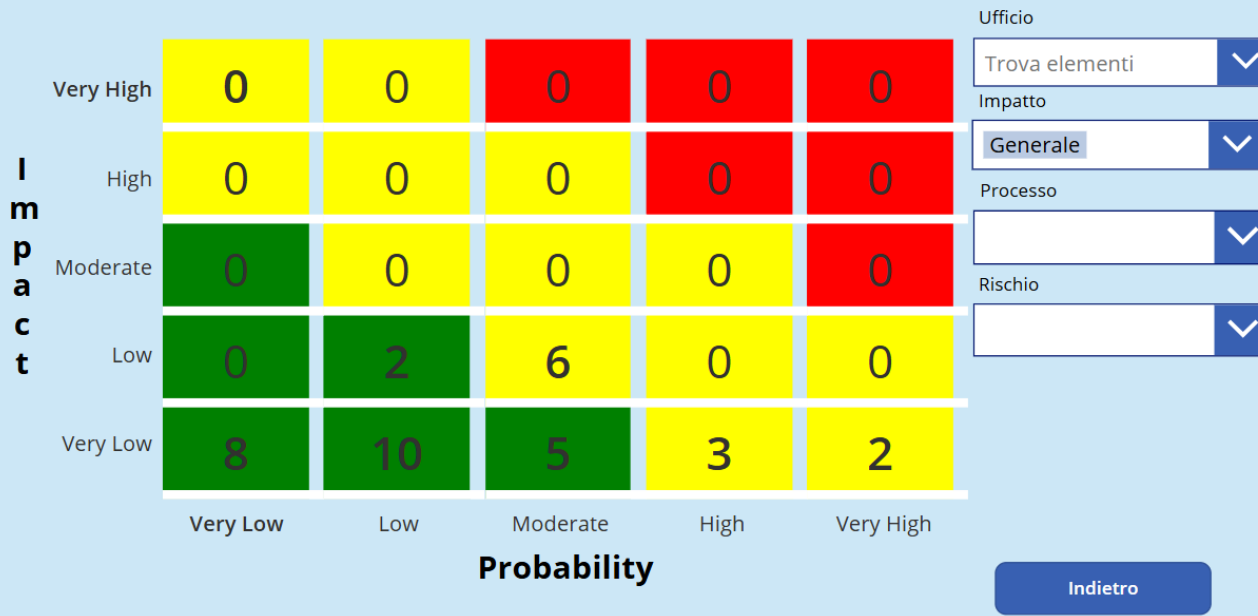
Nuovo Piano Audit

Elenco Piani

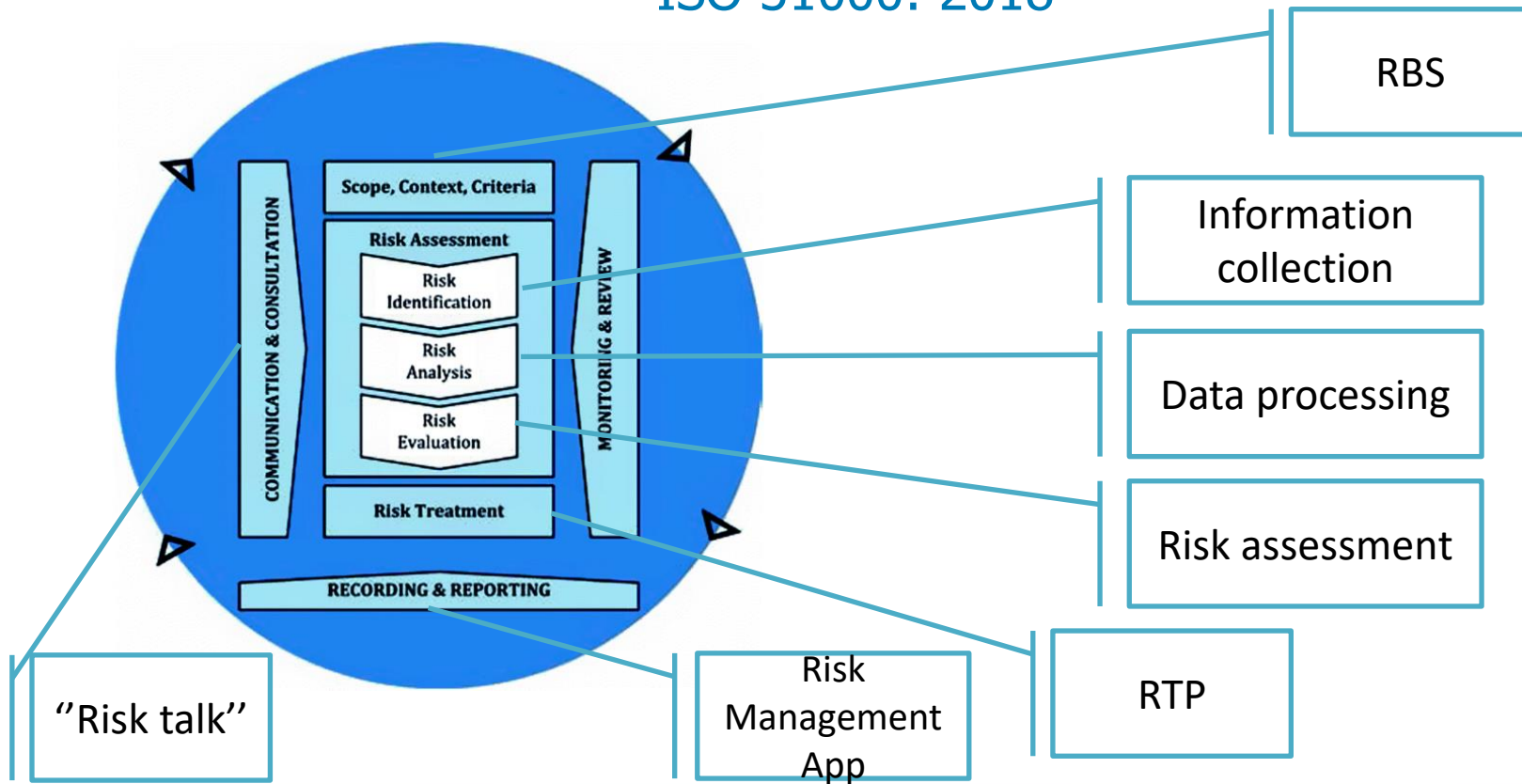
Elenco CAPA

PROGETTO A.R.C.O. Risk Map

Risk Score: 853



ISO 31000: 2018



Definition of RBS &
A.R.C.O. programme's outcomes



Risk Identification Questionnaire &
Risk Ranking



Risk Assessment Questionnaire &
Impact scale



Risk Talk & Data Processing



Risk Treatment Plan &
Risk Management App



Questions



Suggestions

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