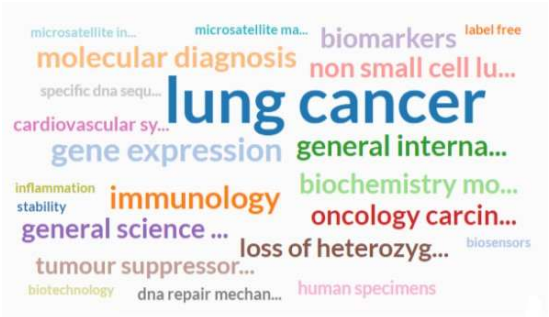
Risk Management in R&D projects

Karolina H. Czarnecka-Chrebelska, Prof. UM

In Life | Instytut Rozrodu Zwierząt i Badań Żywności Polskiej Akademii Nauk

Karolina H. Czarnecka-Chrebelska
BIO

- I am a scientist, researching in the field of molecular biology, human genetics, oncology and epigenetics (thyroid and lung carcinogenesis, COPD and autoimmune diseases).
- I have focused on identifying epigenetic or molecular genetic markers, particularly gene methylation, non-coding RNA and cfDNA markers, in tissue and circulating blood.
- I am experienced in developing new grant proposals, joint grants with companies and creating new cooperation platforms with businesses.



I have over twelve years of experience as an external advisor, evaluating grant and scholarship applications for major Polish national funding agencies and UE projects (mainly for EIT Health). I am helping start-ups shape their message to the investors and specify their market purpose.

Risk Management in R&D projects

The Objectives of the seminar:

Developing the following skills:

1. Identification of objectives of risk analysis in R&D project management. Provide the overview of the types of risks in scientific and development projects.

2. Tools and methods for identifying potential risks that may affect a project, both internal (e.g. technical) and external (e.g. regulatory). Use of SWOT technique. Assessment of the likelihood of a risk and its potential impact on the project vs project milestones.

3. Strategies for mitigating, avoiding, accepting, and transferring risks; developing risk response plans (particularly for the project documentation); tools for tracking risks, monitoring their change over time; and analyzing the effectiveness of preventive and corrective actions.

Research project management competences

- Knowledge of the preparation of:
  - a scientific project plan,
  - techniques used at individual stages of project creation,
  - project management,
  - controlling the course of the project i.e. using web tools and applications.

B+R projects Management using on-line tools

- **Ability to perform risk assessment in B+R projects**
- **Ability to select information necessary to operate programs / decide on the project course in case of presence of the major risk**

Topic of this seminar

- **controlling the course of the project regarding the newly identified risk** (i.e. impact of Covid in 2020, impact of Russian agression on Ucraine in 2022).

Risk management - definitions

- Risk management is the systematic process of identifying, assessing, and mitigating threats or uncertainties that can affect your organization. It involves analyzing risks' likelihood and impact, developing strategies to minimize harm, and monitoring measures' effectiveness.
- Risk analysis and risk management is a process that allows individual risk events and overall risk to be understood and managed proactively, optimising success by minimising threats and maximising opportunities and outcomes.
- Risk: The possibility that the occurrence of an event will adversely affect the achievement of the organization's objectives.

According to Strategy Execution, strategic risk has three main causes:

- Pressures due to growth: This is often caused by an accelerated rate of expansion that makes staffing or industry knowledge gaps more harmful to your business.
- Pressures due to culture: While entrepreneurial risk-taking can come with rewards, executive resistance and internal competition can cause problems.
- Pressures due to information management: Since information is key to effective leadership, gaps in performance measures can result in decentralized decision-making.

4 reasons why risk management is important

RMA RISING MANAGERS' ACADEMY

According to Harvard Business School

1. Protects Organization's Reputation
In many cases, effective risk management proactively protects your organizatio from incidents that can affect its reputation.

2. Minimizes Losses
Most businesses create risk management teams to avoid major financial losses. Yet, various risks can still impact their bottom lines.

3. Encourages Innovation and Growth
Risk management isn't just about avoiding negative outcomes. It can also be the catalyst that drives your organization's innovation and growth.

4. Enhances Decision-Making
Risk management also provides a structured framework for decision-making. This can be beneficial if your business is inclined toward risks that are difficult to manage.

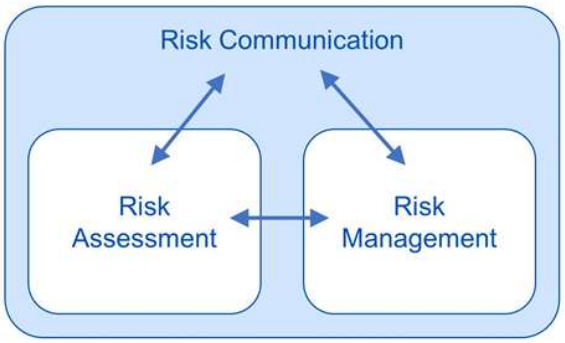
The risk owner

RMA RISING MANAGERS' ACADEMY

The individual who is ultimately accountable for ensuring the risk is managed appropriately.

There may be multiple personnel who have direct responsibility for, or oversight of, activities to manage each identified risk, and who collaborate with the accountable risk owner in his/her risk management efforts.
Usually Project manager/Principal Investigator/

Examples - the risk related with:
the recruitment of the patients
– nurse/personnel from CRO /doctors/ patients
the purchases/equipment/reactive
– Investigators/ technicians /University administration



https://ocro20200317.sites.stanford.edu/

- **Inherent risk:** The risk to an entity in the absence of any mitigation plans and actions by leadership.
- **Impact:** The extent to which a risk event might affect the enterprise. Impact assessment criteria may include financial, reputational, regulatory, health, safety, security, environmental, employee, customer, and operational impacts.

https://ocro20200317.sites.stanford.edu/

Risk assessment

The likelihood of something happening and the severity of its consequences.

When it happens…

- Would it hurt?
- Would it cost?
- Would it block the project?

Risk management

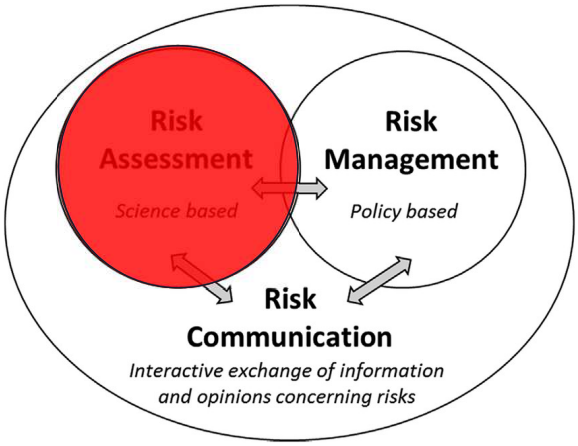
- Risk management involves identifying and addressing potential **threats** that could hinder the achievement of objectives.
- It is an essential aspect of good management, requiring managers to be aware of potential barriers to success and leadership to **recognize unexpected events that could disrupt operations**.
- Effective risk management should be integrated into daily business operations and decision-making processes.
- It should prioritize **management of risk rather than avoiding it.**
- It should assist in prioritizing tasks in a fast-paced environment.

The risk management plan:

•analyzes the potential risks that exist in your organization or project

•identifies how you will respond to those risks if they arise

•assigns a responsible person to monitor each risk and take action, if needed.



In the internet there are many free charts/templates/risk analysis score cards.

But before using them let's start with analysis of different risk identification methods

What are the methods to identify risks?

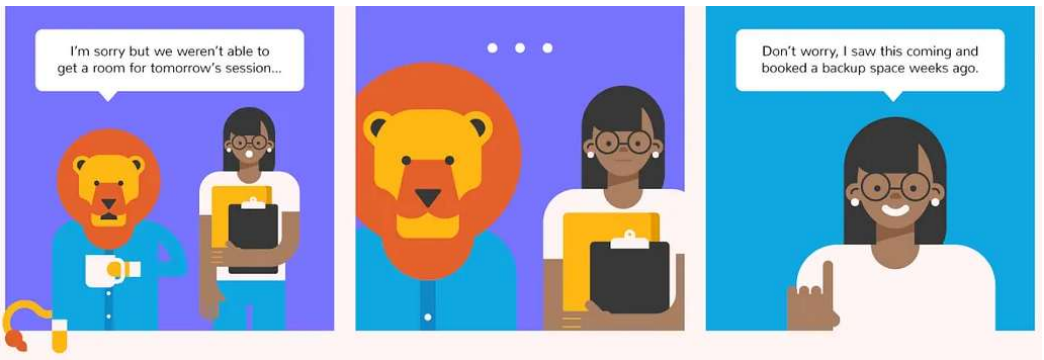
- **History analysis**
- **Brainstorming**
- **SWOT analysis**
- **Checklists and templates -** Risk Breakedown Structure
- **Industry research**

Once identified the risks
in the planned / ongoing endavour
we can start stratify them…

https://medium.com/the-digital-project-manager/what-is-how-to-create-a-risk-management-plan-2ded4dd60e54

History analysis

Helpful questions:
What's happened in your team/Dept/Clinic in the past that you can learn from?
What went right or wrong in your projects?
When in the project are we getting ahead of schedule? Has this happen ever?
Are there ongoing project risks that you should account for?



Internal history: Talk to your project team, project stakeholders, suppliers, and customers for their perspectives.
Extremely valuable input of the information -> hidden fails

External history (or why other projects fail): Look at incidents or problems that happened to competitors / similar projects.

https://medium.com/the-digital-project-manager/what-is-how-to-create-a-risk-management-plan-2ded4dd60e54

Networking can significantly help deal with risks in projects

- By building relationships that facilitate the identification of potential risks,

Networking provides access to a broader range of experts and individuals with experience in your field, enabling you to better understand potential risks and threats.

- by sharing knowledge and resources and providing support in crisis situations.

Quick access to resources: Personal contacts can make it easier to get the necessary resources or support quickly when problems arise, such as a lack of staff or a shortage of funds.

- Networking enables a deeper understanding of the project environment and facilitates a prompt response to emerging issues.

History analysis

Excersize 1

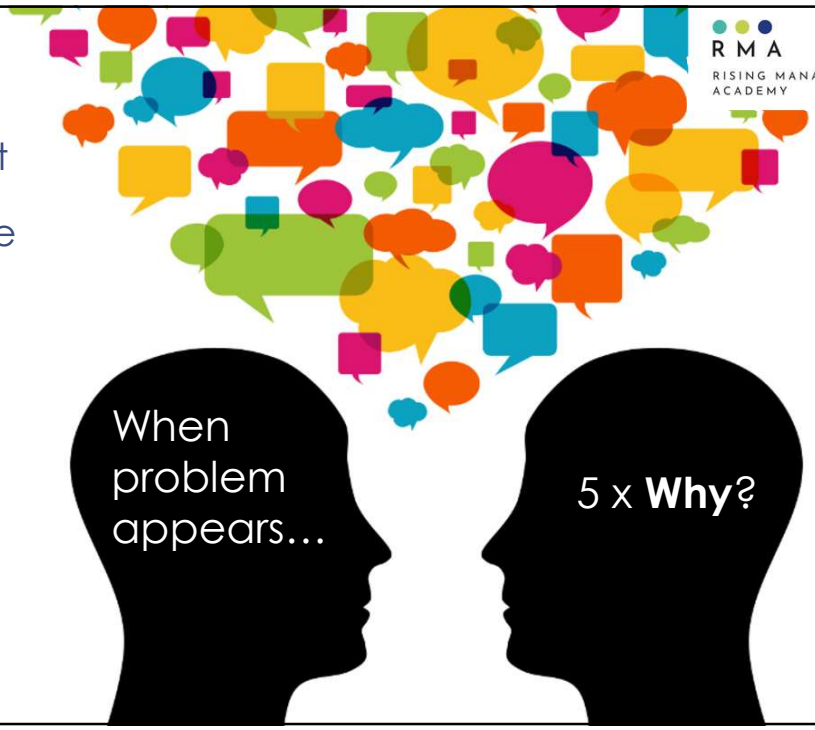
RMA
RISING MANAGERS' ACADEMY

- Lets talk about our experiences ☺
- Recall a situation when a projects did not finished in the planned time, or there were big delays that were dangerous for the project outcome.
- Let's divide into 4 groups
- Discuss the common problems leading to project delays

Internal history: Think about the situation You have had experienced?
Extremely valuable input of the information -> hidden fails

External history (or why other projects fail): Look at incidents or problems that happened to similar projects.

Analysis of the past projects and identification of the problems that occcured



Investigation into the problem by **deduction**

Q1: Why do you throw paper towels on the floor?

R: Because the floor is slippery and threatens safety.

Q2: Why is the floor slippery and threatens safety?

R: Oil is on it.

Investigation into the problem by **deduction**

RMA
RISING MANAGERS' ACADEMY

Q3: Why is oil on it?

R: The machine is leaking.

Q4: Why is the machine leaking?

R: There is a hole in the gasket.

Q5: Why is this happening?

R: Because the gasket is old.

Using individual experience in groups.

Creation of the list of small changes / amendments / corrections that can help the project to go smoothly.

Preparation of the list of putative risks with the

Case: contamination of yogurt batches - presence of yeast

Situation description: A dairy processing plant discovered that one batch of natural yogurt (5,000 units) was microbiologically contaminated due to the presence of yeast. The product has been withdrawn from the market, and the plant must identify the cause of the contamination and implement measures to prevent similar incidents in the future.

Factors Contributing to Yeast Contamination:

- **Inadequate Pasteurization:** If milk isn't properly pasteurized, it can retain wild yeasts that can contaminate the yogurt.
- **Manufacturing Environment:** Contamination can occur during processing, with yeasts originating from the dairy plant environment, equipment, ingredients, or even the air.
- **Temperature Abuse:** Elevated temperatures, especially during storage, can promote yeast growth.
- **Storage Conditions:** Improper storage of yogurt (e.g., at the wrong temperature or in unclean containers) can lead to spoilage.
- **Certain Yeast Strains:** Some yeast strains, like *Kluyveromyces marxianus* and *Debaryomyces hansenii*, are known for spoilage in yogurt.

Investigation into the problem by **deduction**

RMA RISING MANAGERS' ACADEMY

Contamination of yogurt batches - presence of yeast

Question	
1. Why was the batch of yogurt withdrawn from the market?	Because microbial growth was detected in several samples from the same bath during quality control.
2. Why was there microbial growth?	Because the packages were not tight enough.
3. Why was the packaging leaky?	Because there was insufficient sealing of the lid film.
4. Why was the sealing of the film inadequate?	Because the temperature of the sealing machine was too low for part of the shift.
5. Why was the temperature too low?	Because the temperature sensor was defective and was not detected by the operator.

✅ **Root cause:** Failure of the temperature sensor of the welding machine, which was not detected due to lack of regular calibration and monitoring.

Investigation into the problem by **deduction**

Excersize 2

RMA RISING MANAGERS' ACADEMY

- Lets discuss and ask many questions – the more the better
- And try to find the answer -> Why exactly something fail
- Firstly, we will work collaboratively on the **Scenario 1 (food production): Contamination of a batch of yogurt**
- Then You will work in 4 or 5 groups using the prepared scenarios 2 or 3 ☺
- **We will come back to those scenarios afterwards while discussing the Ishikawa diagram**

Based on a properly performed risk assessment, we can produce a risk mitigation plan

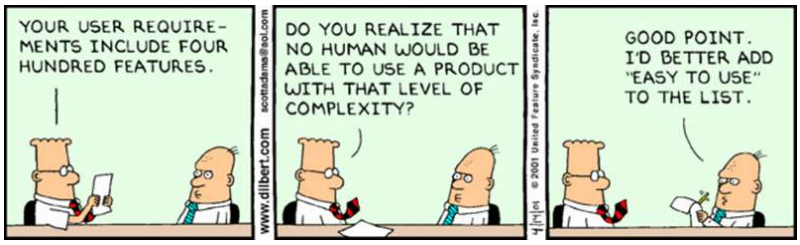
Brain storming

Helpful questions:

Imagine the best version/the best features of the projects r

What will happened if we obtain all the grant we are applying for?

RMA RISING MANAGERS' ACADEMY



This approach gives the opportunity to Focus on the positive elements not only on the failures.

What happen if You will move to another city?
What will happen if the main diagnostic method will be unavailable?

https://medium.com/the-digital-project-manager/what-is-how-to-create-a-risk-management-plan-2ded4dd60e54

Brain storming

What may happen if :

- You will move to another city?
- the main diagnostic method will be unavailable?
- The patients will not be interested in the new therapy?
- The Bioethical committee will reject Your experiment plan?

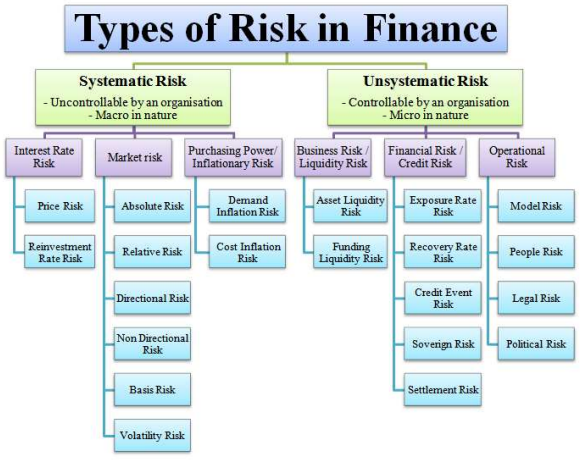
This approach gives the opportunity to focus on innovative ways to overcome problems that highly probable to happen (or failures).

REMEMBER:

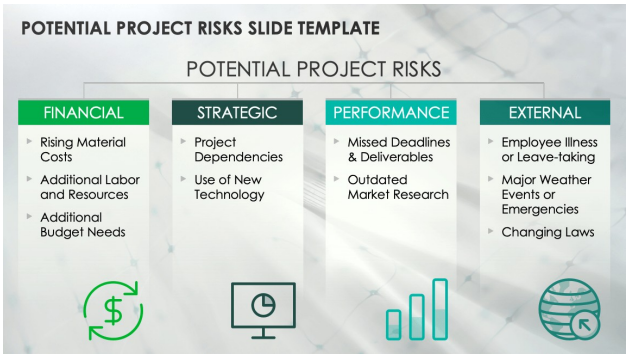
* it is important to determine one goal/problem to be solved;
* enable people to create crazy ideas;
* many points of view can be taken into account;

https://medium.com/the-digital-project-manager/what-is-how-to-create-a-risk-management-plan-2ded4dd60e54

Risk categories – dependant on the market



https://kalyan-city.blogspot.com/2012/01/types-of-risk-systematic-and.html



https://www.smartsheet.com/content/project-risk-types

Common Categories of Project Risks

1.Financial Risks: These risks directly impact the project's budget and can include unexpected costs, budget overruns, or changes in funding. For example, a sudden increase in material costs could significantly affect a construction project's financial health.

2.Schedule Risks: Delays and timeline issues fall under this category. These risks can stem from resource shortages, dependencies on external factors, or underestimated task durations. A software development project, for instance, might face schedule risks due to unexpected technical challenges or integration issues.

3.Technical Risks: These involve risks related to the technology or technical aspects of the project. In IT projects, technical risks might include compatibility issues, software bugs, or hardware failures.

4.Operational Risks: These risks are associated with the day-to-day operations of the project. They can include issues with processes, systems, or people. For example, in a manufacturing project, operational risks might involve equipment breakdowns or supply chain disruptions.

https://www.6sigma.us/six-sigma-in-focus/project-risk-management/

RMA RISING MANAGERS' ACADEMY

External Risks: Factors outside the project's control fall into this category. These can include:

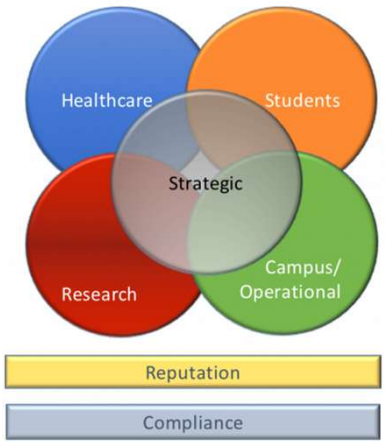
- regulatory changes,
- market fluctuations,
- natural disasters i.e. global pandemic

Stanford | Office of the Chief Risk Officer

RMA RISING MANAGERS' ACADEMY

According to Stanford Chief Risk Officer risks are categorized as follows:

- **Strategic** – an event that affects the high-level goals and vision of the University
- **Healthcare** – an event that could impact the delivery of healthcare activities
- **Students** – an event that could negatively impact current or potential students
- **Research** – an event that could encumber the University's research mission
- **Operational/Campus** - an event that affects ongoing management processes
- **Financial** - an event that affects the financial well-being of the institution



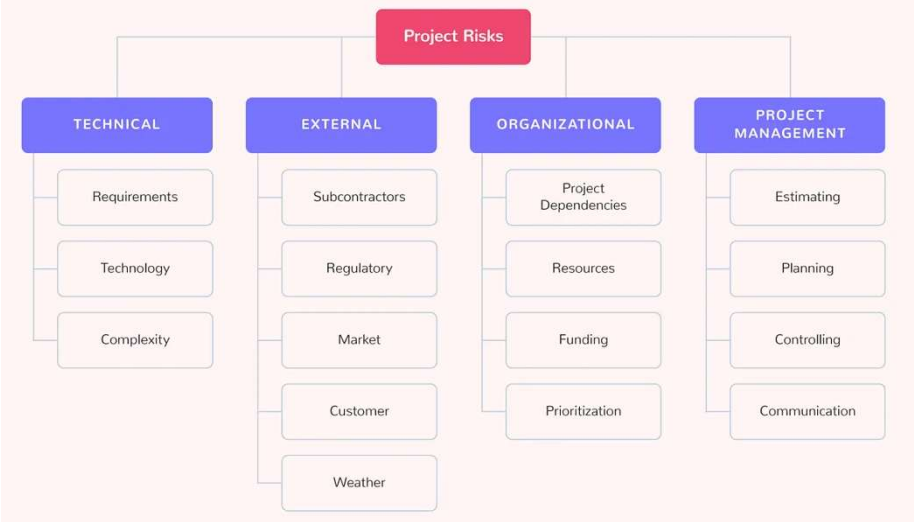
compliance or reputational aspect

- **Compliance** - an event that affects the institution's adherence to applicable laws and regulations or University policies and guidelines
- **Reputational** - an event that affects the image, standing or character of the organization

https://ocro20200317.sites.stanford.edu/

Risk assessment in grant planning - using **Risk Breakedown Structure**

RMA RISING MANAGERS' ACADEMY

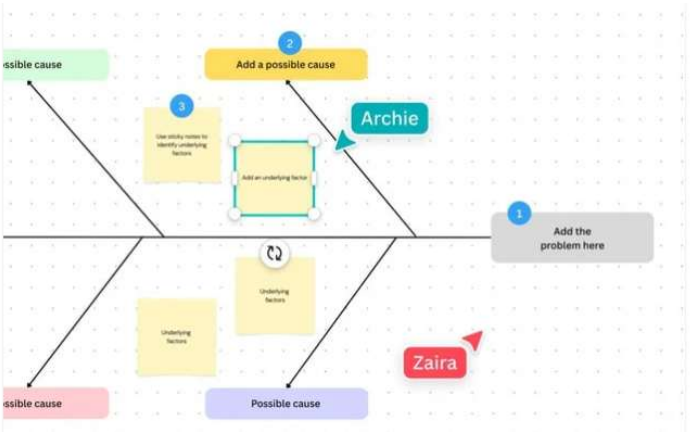


https://medium.com/the-digital-project-manager/what-is-how-to-create-a-risk-management-plan-2ded4dd60e54

RMA RISING MANAGERS' ACADEMY

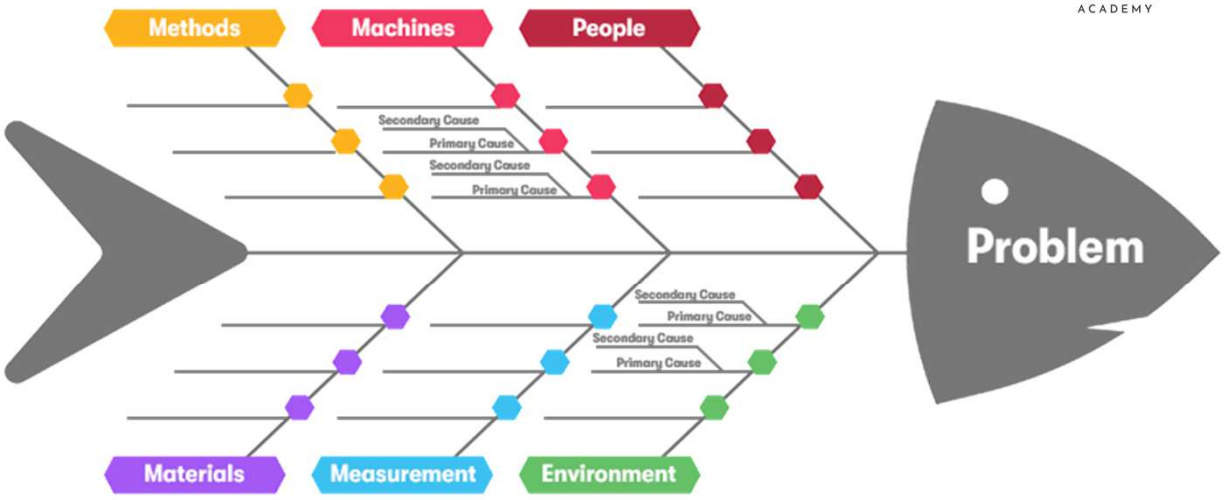
- In the **root-cause analysis** approach, proponents believe that to solve a problem, you need **to address the underlying issues first**.
- **Ishikawa diagrams** are great for visualizing that very process, with a structure that encourages looking at a problem from multiple angles.

Example of Ishikawa diagram made using CANVA software



https://www.canva.com/graphs/fishbone-diagrams/

Ishikawa diagrams – root analysis



Ishikawa diagrams (also called fishbone diagrams, cause-and-effect diagrams) are causal diagrams created by Kaoru Ishikawa that show the potential causes of a specific event.

How to conduct the risk analysis using an Ishikawa diagram?

1. **Define the problem (effect / observed situation)**

Clearly define the problem you want to solve. Write it on the "main axis" of the diagram - to the right of the fishbone, e.g. "Leakage of a chemical during transportation."

2. **Select the main categories of causes**. Identify the main areas that can affect the problem.

The most common categories are:

- **People** - competence, training, errors
- **Methods** - procedures, instructions
- **Machines** - tools, equipment
- **Materials** - raw materials, packaging
- **Environment** - external conditions
- **Management** - policies, supervision

You can customize the categories according to the specifics of your industry.

How to conduct the risk analysis using an Ishikawa diagram?

RMA RISING MANAGERS' ACADEMY

3. Identify specific causes in each category
Within each main "bone" of the diagram, list specific factors that may be contributing to the problem.
Ask questions like:
- Why is this happening?
- What is happening?
- What are the possible sources of the error?

4. Gather a team and brainstorm
Involve people with knowledge of the problem. Together, complete the diagram, adding possible causes.
Try to be as specific as possible and rely on facts.

How to conduct the risk analysis using an Ishikawa diagram?

RMA RISING MANAGERS' ACADEMY

5. Analyze and prioritize causes
Once you have collected all the causes, evaluate their impact on the problem. Identify the most important ones that are most likely to cause the problem - focus your attention there.

6. Identify corrective actions
Based on the most important causes, plan actions that will eliminate or minimize the problem. Actions may include training, changes in procedures, replacement of equipment, etc.

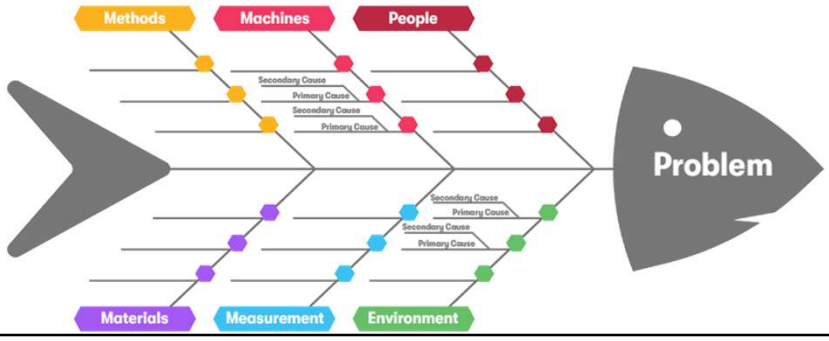
7. Document and monitor effects
Record the results of the analysis and the actions taken. Determine how to monitor the effectiveness of the actions and when the next evaluation will take place.

Excersize 3

RMA RISING MANAGERS' ACADEMY

Lets try to categorize the defined risks/risks factors

- Lets Focus on the main 6 categories of risk and try to **assign the risk to a category**
- Let's divide into 4 or 5 groups and work using the prepared scenarios 1,2,3 and **Ishikawa diagram**



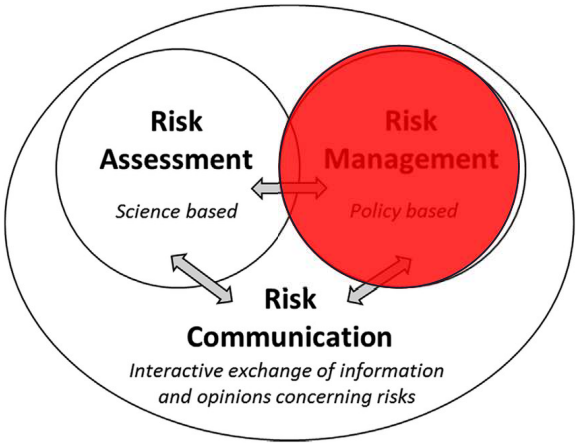
RMA RISING MANAGERS' ACADEMY

The risk management plan:

•analyzes the potential risks that exist in your organization or project

•identifies how you will respond to those risks if they arise

•assigns a responsible person to monitor each risk and take action, if needed.



A project risk management plan seeks to answer::

- Why is risk management important for the project's success?
- **What will the team do to identify, log, assess, and monitor risks throughout the project?**
- **What categories of risk will we manage?**
- What methodology will be used for risk identification and to evaluate risk severity?
- How much risk is too much risk?

How are risks scored?

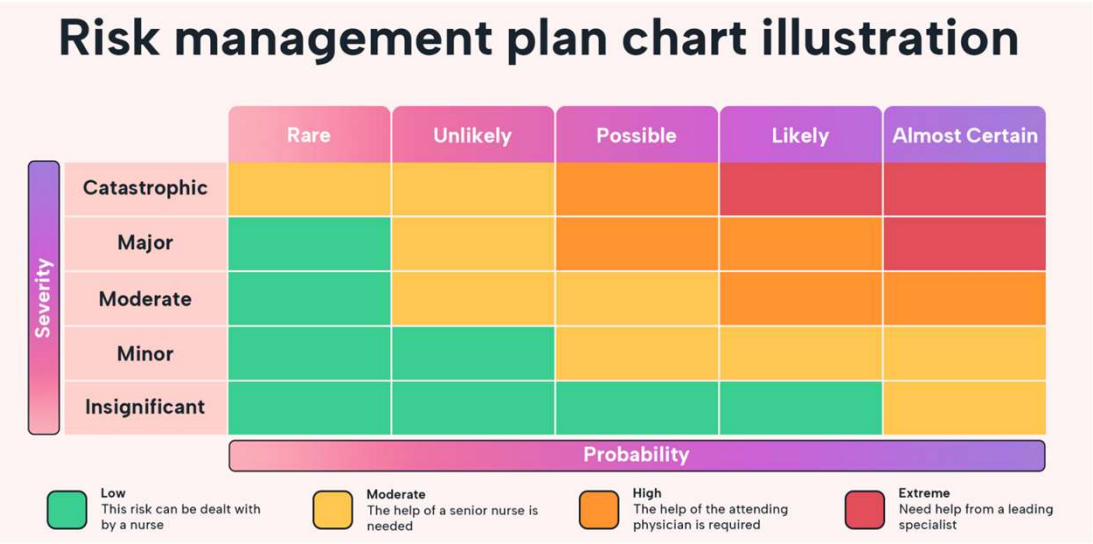
Likelihood (could it happen)

x **Impact** (would it hurt)

https://medium.com/the-digital-project-manager/what-is-how-to-create-a-risk-management-plan-

Example of risk chart for the hospital

RMA RISING MANAGERS' ACADEMY



https://www.usemotion.com/blog/risk-management-plan

Level 1	Level 2	Level 3
All Project Risks	Business Risk	• Competitors • Suppliers • Cash flow
	Technical Risk	• Hardware • Software • Network
	Organizational Risk	• Executive Support • User Support • Team Support
	Project Management Risk	• Estimates • Communication • Resources

RMA RISING MANAGERS' ACADEMY

- Which of the following risks can You identify in the projects/endavours You're working currently?
- Try to identify one in each group in the level 2

https://www.slideteam.net/blog/top-7-supplier-risk-assessment-templates-with-samples-and-examples

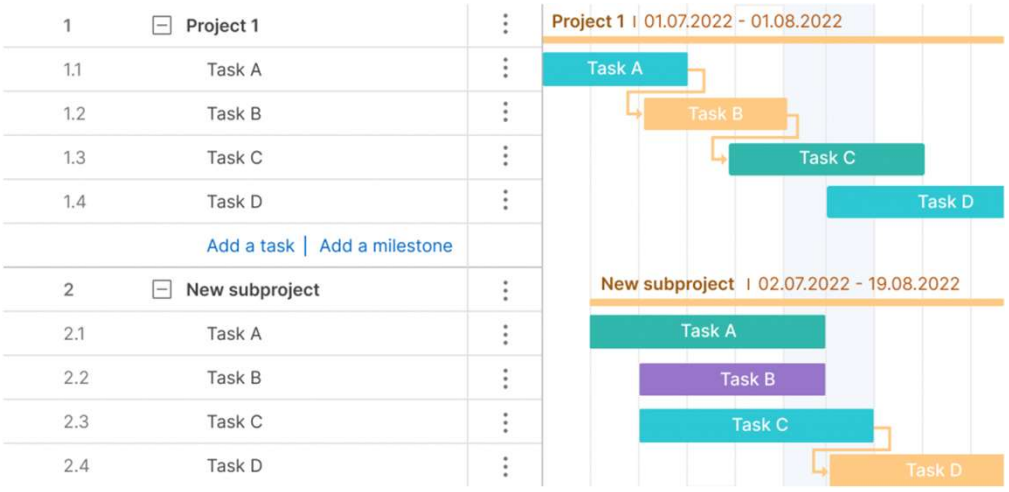
Risk mitigation plan

RMA
RISING MANAGERS' ACADEMY

A simple matrix into which identified risks and planned actions can be entered - this can be done both before the project and during the project - when a risk/event arises.

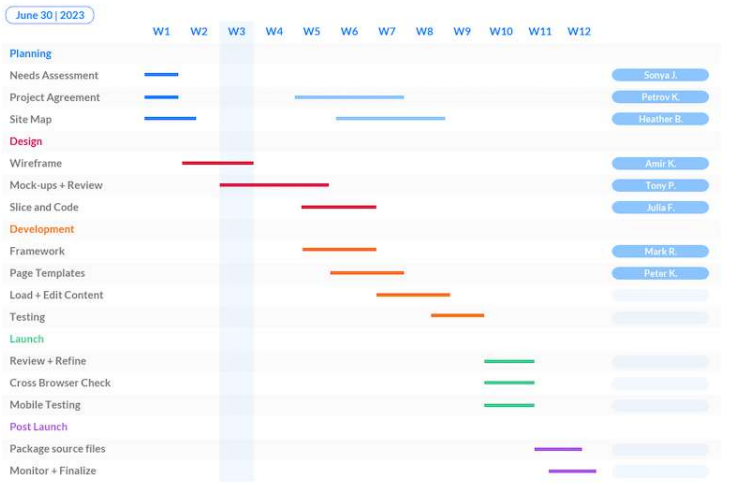
Identified risk	Description of the situation	Risk category	Response to the risk	Risk owner
Description of the identified risks	What happened, when, what is happening in the aftermath of the situation	technical/ operational/ administrative/ managment	What actions were taken immediately after the incident, what actions are planned	Who has identified, who was informed, and who is monitoring the risk.

Work Breakdown Structure → Ghannt charts



https://blog.ganttpro.com/en/work-breakdown-structure-example-wbs/

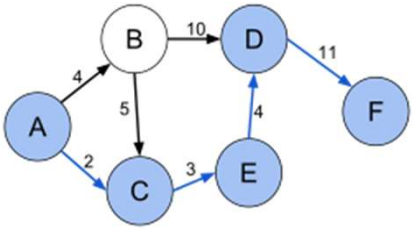
Gantt Chart



https://venngage.com/blog/gantt-chart-example/

The lenght of each task

- We need to analyse the **minimal** and **max** lenght of each task.
- To complete the action defined in the node the number (given over the arrow) of days/weeks is needed
- First of all we will define **the shortest path**
- i.e. she shortest way to complete the project from A to F?

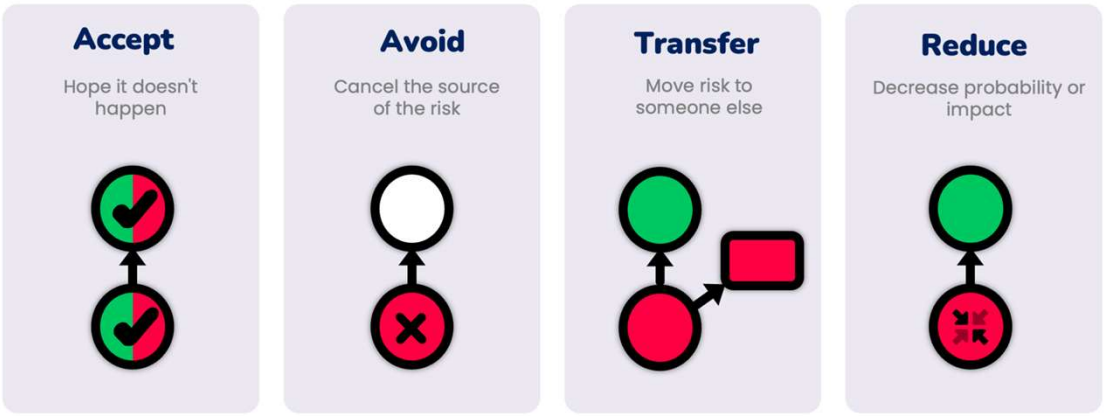


- And now the **maximal lenght of each task**

© Karolina H. Czarnecka-Chrebelska

Risk mitigation strategies

Four basic ways how to treat the risk



https://aptien.com/en/kb/articles/what-are-risk-treatment-strategies

Risk mitigation plan

We can use the performed before:

- **History analysis**
- **Brainstorming**
- **SWOT analysis**

	Description		Proximity	Risk Response Categories	Risk Response	Risk Status	Risk Owner
Cause	Event	Effect					
Delay in project causes increased Load on current server/database	Servers fill up sooner than laned	Potential data loss	During Project	Reduce	Enhanced reporting on server status and database capacity	Active	IT Director

Examples of risk analysis and mitigations plan

- **Project risks for the organization of a new course of study or summer school**
- **Risk 1 - illness of lecturer or student;**

1. Probability of occurrence of the risk - low;
2. Impact of the risk on the proper course of the Project if it occurs- low
3. The way to prevent the occurrence of the risk and minimize the consequences - In each module there are min. 2 teachers from UMED and 1 foreign teacher to conduct classes. If someone cannot attend the event, they will be replaced by another teacher or the class will be taught by 2 instead of 3 teachers (the decision will be made by the coordinator depending on the specifics of the class). In addition to the list of students qualified to participate in the summer school, a reserve list will be drawn up; an ill student resigning from participation will be replaced by a person from the reserve list.

Examples of risk analysis and mitigations plan

- **Project risks for the organization of a new course of study or summer school**
- **Risk 2 - The problem with recruiting participants for the project;**

1. Probability of occurrence of the risk - low;
2. Impact of the risk on the proper course of the Project if it occurs- low
3. The way to prevent the occurrence of the risk and minimize the consequences - The recruitment campaign will be carried out using all possible channels of reception: fb, websites, owned direct contacts at foreign universities, informational emails, promotional activities directly abroad during visits of PB employees.

Examples of risk analysis and mitigations plan

- **Recognition by students of the summer school topics as outdated, far from current state of technical knowledge;**

1. Probability of occurrence of the risk - low;
2. Impact of the risk on the proper course of the Project if it occurs- low
3. The way to prevent the occurrence of the risk and minimize the consequences - It was planned to prepare new materials to include all technical innovations, innovative solutions implemented in 2025. Classes will be conducted using the latest versions of industry computer programs, in modern laboratories. .

Examples of risk analysis and mitigations plan
Project risks for the new planned project

- **Communication problems between the project manager - team coordinators;**

1. Probability of occurrence of the risk - low;
2. Impact of the risk on the proper course of the Project if it occurs- medium
3. The way to prevent the occurrence of the risk and minimize the consequences –

How to prevent the occurrence of risks and minimize the impact - project meetings were scheduled from the beginning of the project; to improve the communication process between the project team.

Examples of risk analysis and mitigations plan
Project risks for the new planned project

- **A threat to the schedule (tasks may take longer than expected);**

1. Probability of occurrence of the risk - low;
2. Impact of the risk on the proper course of the Project if it occurs- medium
3. The way to prevent the occurrence of the risk and minimize the consequences –

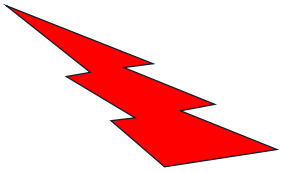
The schedule at the planning stage includes more time for tasks resulting from unexpected problems, so that time can be disposed of more flexibly. A Gantt chart has been drawn up, which will make it easier for the project manager to adapt dynamically to time-related risks that arise, even in the event of minor delays. .

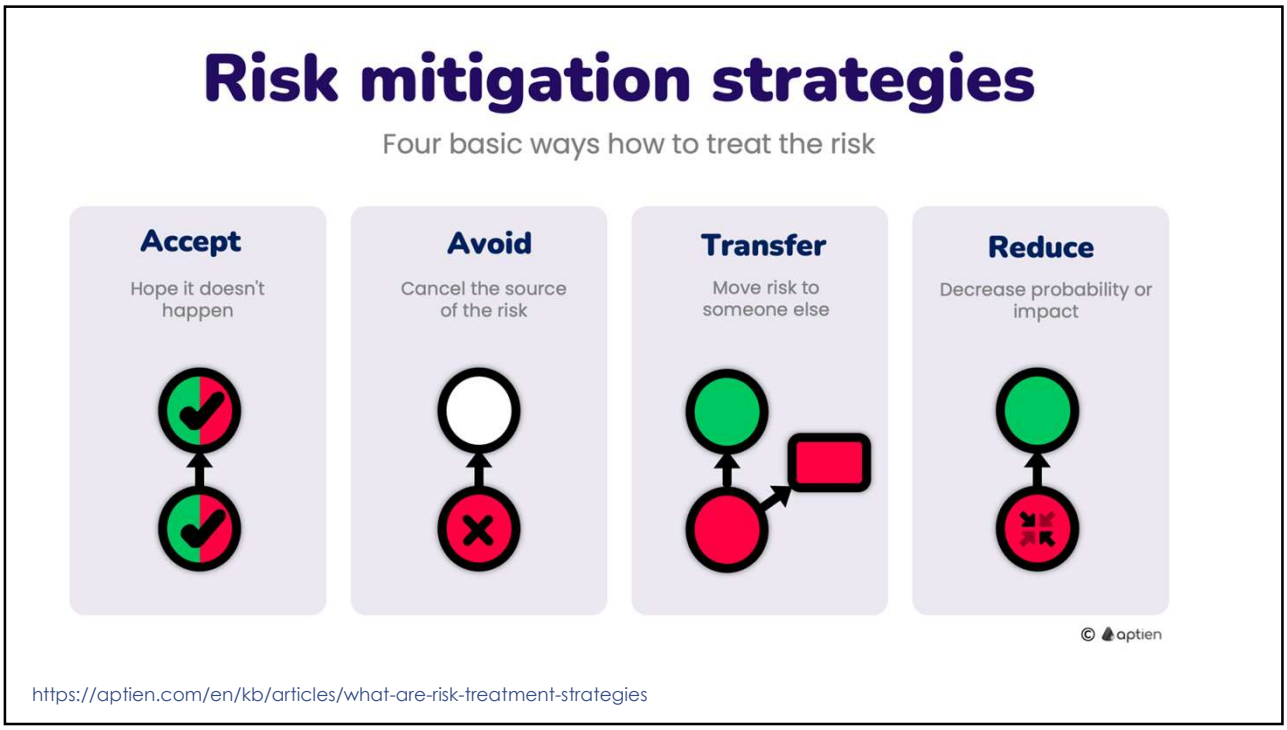
Examples of risk analysis and mitigations plan
Project risks for the new planned project

- **Lack of availability of reagents/cell lines**

1. Probability of occurrence of the risk - ?;
2. Impact of the risk on the proper course of the Project if it occurs- ?
3. The way to prevent the occurrence of the risk and minimize the consequences –

- Xxxxx
- Xxxxxx
- xxxxxx.





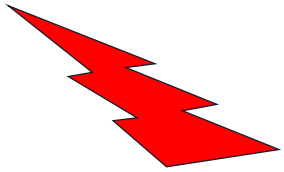
https://aptien.com/en/kb/articles/what-are-risk-treatment-strategies

Examples of risk analysis and mitigations plan
Project risks for the new planned project

- **problem with obtaining research approvals / regulatory change**

1. Probability of occurrence of the risk - ?;
2. Impact of the risk on the proper course of the Project if it occurs- ?
3. The way to prevent the occurrence of the risk and minimize the consequences –

- Xxxxx
- Xxxxxx
- xxxxxx.



SWOT analysis

RMA RISING MANAGERS' ACADEMY

- SWOT stands for strengths, weaknesses, opportunities, and threats. Helpful questions you might ask yourself are:
- What are your solution's / method's / business' / strengths?
- What are its weaknesses?
- What opportunities aren't you taking advantage of right now?
- How can you beat your competitors to those opportunities?
- What threats exist in your industry/research field?

RMA RISING MANAGERS' ACADEMY

SWOT analysis - template

https://project-management.com/swot-analysis/

In a SWOT analysis

RMA
RISING MANAGERS' ACADEMY

Strenghs

refer to internal initiatives that are performing well. In particular, the analysis of this factor may consist of a comparison with other initiatives or the activities of competitors.

- What are we good at?
- What makes our company different?
- What aspects of our business do our target audiences value?

Weaknesses

refer to less successful internal initiatives. Identifying internal weaknesses helps to find a starting point for improving related projects.

- Which initiatives are performing poorly and why?
- What can we improve?
- What resources can improve our performance?

It is recommended to analyze the project strengths before weaknesses to establish a baseline of successes and failures

https://asana.com/pl/resources/swot-analysis

RMA
RISING MANAGERS' ACADEMY

Opportunities

are the **result of your current strengths and weaknesses**, as well as any external initiatives that will help you achieve a stronger competitive position. They may be weaknesses you want to improve, or areas that were not addressed in the first two phases of the analysis.

- What resources can we use to work on the weaknesses?
- Can our services fill market gaps?
- What are our goals for the year?

Threats

refer to areas that can cause problems. Unlike Weaknesses, these are external and usually beyond your control, such as a global pandemic or changes in the competitive environment.

- What changes in the industry are of concern?
- What market trends are on the horizon?
- In which areas are competitors performing better?

https://asana.com/pl/resources/swot-analysis

© Karolina H. Czarnecka-Chrebelska

University / Academia:

Purpose and Focus

- Scientific projects in universities are often driven by the pursuit of advancing scientific understanding, contributing to the academic community, and training future scientists.

Team Composition and Expertise

- The team composition tends to be more academically focused, consisting primarily of faculty members, postdoctoral researchers, graduate students, and occasionally undergraduate students.

Stable employment?

Biotech Company / SMEs:

RMA RISING MANAGERS' ACADEMY

- The primary focus of a biotech company is to develop and commercialize products or technologies for the market.
- Scientific projects in biotech companies are often driven by the goal of achieving specific business objectives, such as developing a new drug, diagnostic tool, or biotechnological process.
- Scientific projects in biotech companies often involve multidisciplinary teams consisting of scientists, researchers, engineers, business professionals, and project managers.
- These teams may have diverse expertise and skill sets required to address scientific, technical, regulatory, and commercialization aspects.

Dynamic changes of the team?

University / Academia:

Funding

- Universities typically secure funding through grants from government agencies, foundations, and philanthropic organizations.
- However, the funding available to universities is often more limited, leading to a greater need for securing grants and competing for resources.

Timeframe and Pressure

- Scientific University projects may have more flexible timelines, allowing researchers to explore complex questions and focus on long-term goals.
- While project milestones and deadlines may be associated with grant funding, the emphasis is often on scientific rigor and the quality of research outcomes.

Biotech Company / SMEs:

RMA RISING MANAGERS' ACADEMY

- Scientific projects in biotech companies usually require funding from various sources, such as private investments, venture capital, partnerships, and potential revenue streams.
- Companies typically have greater financial resources than universities (grant, loans,) which allows for increased investment in research and development.
- Scientific projects in biotech companies are typically subject to more stringent timelines and commercial pressures.
- There is often a need to deliver results within specified timeframes to meet business objectives, secure investments, and gain a competitive advantage in the market.

1. How the situation of not gaining the grant or termination of the project due to not fulfilling the milestones will affect those institutions?
2. Think about the financial risk and performance risk.

Excersize 3

SWOT analysis

Imagine we're applying for the R+D grant, and by this analysis, we would like to underline opportunity for Academia

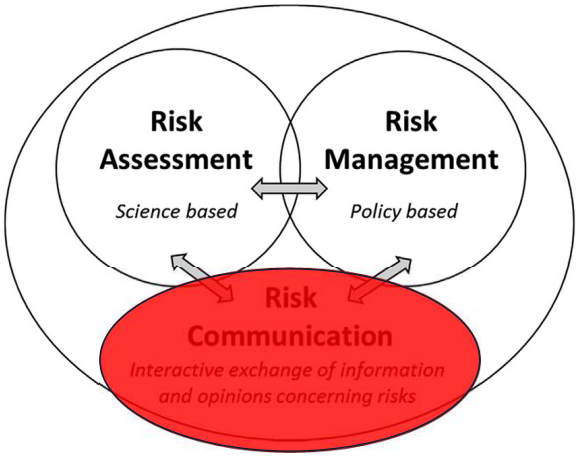
- Applying for grants **in the same calls as SMEs or Start-ups**.
- Main issue goal definition and data required by the financing institution are based on the assessment of the output indicator (product indicator)
- Let's analyze different risks but also the strengths, depending on the organization

The risk management plan:

•analyzes the potential risks that exist in your organization or project

•identifies how you will respond to those risks if they arise

•assigns a responsible person to monitor each risk and take action, if needed.



Case study

- **Envision the potential of our project, where we will be testing new nutraceutical formulations on a group of patients with Crohn's disease, IBS, SIBO and a group of overweight volunteers without inflammatory disease, offering them hope for improved health.**
- This new superfood will be developed in the initial stage of the project by top Polish scientists working at the Institute of Animal Reproduction and Food Research of the Polish Academy of Sciences in cooperation with pharmacists and biotechnologists from Medical University of Lodz. They have experience in developing food additives and nutraceutical formulations. However, those scientists haven't cooperated yet in the projects.
- After the superfood formulation development, the nutraceutical formula will be tested on the mouse IBS model to prove its immunomodulatory potential

Case study

- **Envision the potential of our project, where we will be testing new nutraceutical formulations on a group of patients with Crohn's disease, IBS, SIBO and a group of overweight volunteers without inflammatory disease, offering them hope for improved health.**
- Patients with Crohn's Disease, IBS will be recruited by the Clinicians from the Clinics associated with MUL
- Patients with SIBO and healthy volunteers will be recruited by the dietitians associated with MUL, but through their private practice
- Project Participants will undergo a 4-month nutritional intervention and be supervised by a dietitian during this period.
- During the project we will collect biological samples and test participants when they enter the project and every month thereafter.

How we can start?

If this risk analysis would be carried out along with the project plan, we can decide to select on of the following approaches (or use elements from all of them):

- Writing down all the planned actions and divide them into smaller pieces –tasks. This will enable us to prepare step by step plan and to identify the bifurcations in the project line.
- Analysing the needed resources
- Analysing the people responsible for given activities/actions
- Using pre-defined templates

Analysis of resources is important element of risk analysis

NEEDED

- People (full-time, part-time, advisors)
- Reagents and kits
- Software and computers
- Analysis (i.e. outsourced services like bioinformatic analysis, oligo synthesis, immune-deficient mice in the animal facility detention and care)
- no of patients
- No of site-visits

AVALAIBLE

- ..
- ..
- ..
- ..
- ..

Let's begin by defining the tasks in relation to the people.

RMA RISING MANAGERS' ACADEMY

The work commitment of the project team

- Analyse :
  - How many people needed in total
  - How many people should commit fulltime
  - What different specialties we need in the project -> what professional skills have to be represented
  - We need doctors, nurses, dieticians, lab analysts, biotechnologists, and epidemiologists? -> who can be employed on the contract? Pay per capita?

Let's begin by defining the tasks in relation to the people.

RMA RISING MANAGERS' ACADEMY

- **Researchers** in PAS/MUL will be developing the nutraceutical formulations
- **Researchers** in PAS/MUL will be performing analysis on the IBS mouse model.
- **Clinititians/doctors** will recruit patients in the Clinical hospitals .
- **dieticians** will recruit volunteers and SIBO patients at the dietetic center.
- **dieticians** will be supervising the 4-month nutritional intervention
- **Nurses** will collect blood samples
- **Lab analysts** will perform basic blood and urine analysis
- **Molecular biologist and biotechnologists** will perform scientific analysis from the blood, stool, and urine
- **Doctors** to perform clinical assessment of the disease (After the study)
- **PI** will manage the process
- …patients

Let's begin by defining the tasks in relation to the people.

RMA RISING MANAGERS' ACADEMY

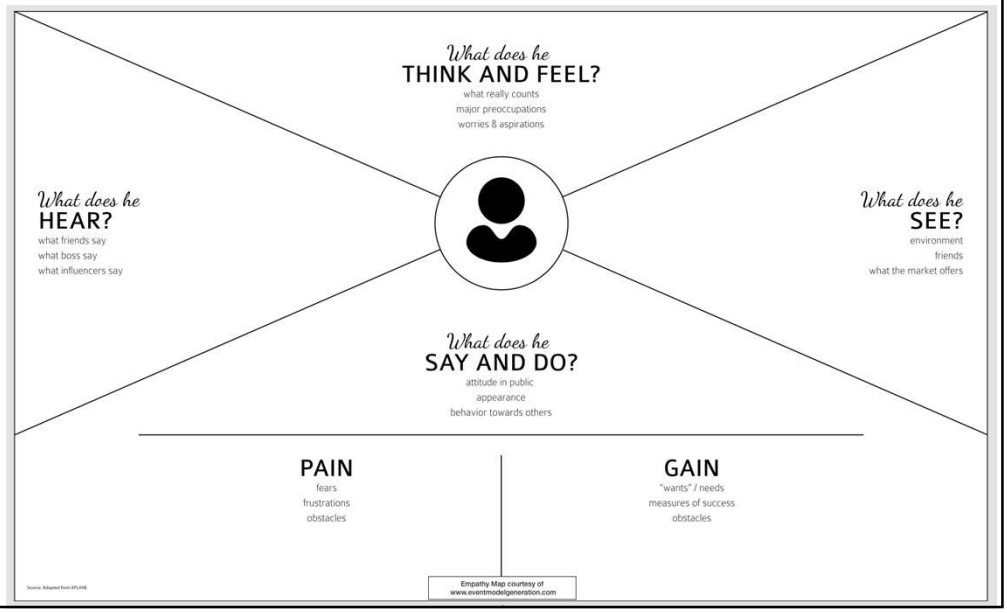
- **Researchers** in PAS/MUL will be developing the nutraceutical formulations
- **Researchers** in PAS/MUL will be performing analysis on the IBS mouse model.
- **Clinititians/doctors** will recruit patients in the Clinical hospitals .
- **dieticians** will recruit volunteers and SIBO patients at the dietetic center.
- **dieticians** will be supervising the 4-month nutritional intervention
- **Nurses** will collect blood samples
- **Lab analysts** will perform basic blood and urine analysis
- **Molecular biologist and biotechnologists** will perform scientific analysis from the blood, stool, and urine
- **Doctors** to perform clinical assessment of the disease (After the study)
- **PI** will manage the process
- …patients

Let's begin by defining the tasks in relation to the people.

RMA RISING MANAGERS' ACADEMY

- **Researchers** in PAS will be developing the nutraceutical formulations.
- **doctors** will recruit patients in the hospital.
- **dieticians** will recruit volunteers at the dietetic center.
- **dieticians** will be supervising the 4-month nutritional intervention
- **Nurses** will collect blood samples
- **Lab analysts** will perform basic blood and urine analysis
- **Molecular biologist and biotechnologists** will perform scientific analysis from the blood, stool, and urine
- **Doctors** to perform clinical assessment of the disease (After the study)
- **PI** will manage the process
- **Researchers** in PAS will write the paper

Risk related to people drop-out from the projects
– clinical projects / medical experiments / end-users during aplication testing



Inne przykłady gotowych matryc

https://www.projectmanager.com/blog/free-risk-management-templates

Risk Tracking Template

Date of last review:

ProjectManager

ID	Description of Risk	Impact	Risk Reponse	Risk Level	Risk owner	Notes
1	Supplier delay	Pushes launch	Confirm delivery dates by Phase 2	High	Clarissa	SAMPLE
2	Factory availability	Cost overruns	Stakeholder trip to China	High	Dave, Rajesh & Nina	SAMPLE
3	Steering committee unavailable	Delay launch marketing	Define marketing plans in March	Low	Tyrell	SAMPLE
4						
5						
6						
7						

Issue Tracking Template

ProjectManager

ID	Description	Potential Impact	Priority	Date Opened	Date Closed	Issue Owner	Department	Status	Notes
1	Website loading slowly on ie10	5% of visitors may expereince lag	Critical	5-Apr		Dale	IT	Open	For whenever Dale has free time
2	Website crashing at credit card collection screen	Massive loss of revenue	Low	9-Apr		Julie	IT	Open	Need to send report to C-suite on this
4	Serving old format images	poor SEO results	Medium	25-Mar		Sarah	SEO	Open	See Google's reccomendartions
5	Login icons broken on Homepage	Some users unable to login w/ icons	High	3-Apr	9-Apr	Julie	IT	Closed	Completed 4/6/20
6									
7									
8									
9									
10									

The use of individual experience in groups.

When we work with a group of people (even very cool ☺) they may be:

not always satisfied with the work or its results

not fully informed

feeling unheard

Their knowledge and experience in identifying problems may be underestimated.

Useful methods: 5 x Why; Brainstorming; Kai Zen

How the position in the team change perception of what might be a risk

- For an undergraduate student, the risk may be related to the narrow area in which he/she is working
- For the lab manager with many years of experience working in the same institution will Focus on risk related with his area of expertise, but in the same tim will have many clues hot to manage risk
- Post-doc with experience from other institution will bring new persepective
- Also our perception of the risk is rerlated with our leadership skills!
- But when safety manager will come – we will see a dozen of „new" risks ☺

Risks associated with not following clean work or health and safety rules in the laboratory →

Safety Management

Scientists* vs. health and safety and risk management

(*especially those doing experimental work))

"Since the beginning of my security career, I have seen many places, companies and institutes that were at different levels of security culture and had different attitudes towards research laboratories and their 'occupants' - scientists."

Petr Prochazka

https://www.linkedin.com/pulse/biggest-killers-research-derived-from-mistakes-safety-petr-prochazka/

The most common types of accidents in medical laboratories

- **Chemical spills and exposures**: These accidents involve the release of hazardous chemicals, which can lead to potential health hazards, fires or environmental contamination.
- **Sharp instrument cuts and punctures**: Needlesticks and cuts with other sharp instruments are common causes of injury, often leading to infection or bleeding.
- **Fires and explosions**: Flammable chemicals and gases pose a significant risk of fire and explosion, especially when proper handling and storage protocols are not followed.
- **Biological hazards**: Exposure to pathogens or biohazardous materials can result in serious health risks, including infections and chronic diseases.
- **Injuries from poor ergonomics** : Poor ergonomics and repetitive motion can lead to musculoskeletal disorders, affecting workers' well-being and productivity.
- **Electrical hazards**: Faulty wiring, exposed electrical parts and improper grounding can lead to electric shock or fire.

- Scientists are unique people who should be “handled” differently than most safety people in companies such as Oil & Gas or the mining industry.
- The main positive characteristic of a scientist is that he always and under all circumstances wants to achieve results and will do everything in his power to achieve the goal. This drive is the safety specialist's greatest ally.
- The scientist simply will not let you sleep.

Petr Prochazka

https://www.linkedin.com/pulse/biggest-killers-research-derived-from-mistakes-safety-petr-prochazka

Not all options are accepted in the case of Safety management

https://aptien.com/en/kb/articles/what-are-risk-treatment-strategies

Safety Management

It is a process aimed at ensuring safe operations in organizations and for individuals. This involves identifying hazards, assessing risks, and implementing preventive measures to minimize potential dangers.

Elements of Security Management:

- Hazard identification:

Detecting potential hazards that could lead to accidents, injuries or damage. Informing of the observed incidences.

- Risk assessment:

Analyzing the likelihood of a hazard and the potential consequences of its occurrence.

- Implementing preventive measures:

to eliminate or minimize risks, such as training, procedures, and technical solutions.

- Monitoring and control:

Regular evaluation of the effectiveness of implemented measures and identification of new risks.

- Safety culture:

Creating an environment in which safety is a priority and all employees are aware of their duty to safety.

Learning from typical lab accidents to prevent them in the future

Links

- https://www.slideteam.net/blog/top-10-research-plan-templates-with-samples-and-examples
- https://conceptshacked.com/types-of-research/
- https://www.usemotion.com/blog/project-management-software-for-creatives
- https://www.projectmanager.com/blog/free-risk-management-templates