

Practical Risk management

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MB&C course 2026

Agenda

1. Basics of Risk Management
2. Practical applications in the laboratory
3. Risks outside laboratories, that may concern you !
4. Conclusions

Participants introduction

- Could you provide us your name, position and affiliation ?
- What do you expect from this workshop ?
- When we speak about risk, is there something specific that comes to your mind ?

- Speakers' introduction

Agenda

- 1. Basics of Risk Management**
2. Practical applications in the laboratory
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1. Basics of risk management

- Activities in a molecular and flow cytometry laboratories, like in all diagnostic laboratories, can expose *patients*, *workers* or *other stakeholders* to a variety of hazards
- Hazards can lead directly or indirectly to varying degrees of *harm*
- *Risk* is a concept with two components :
 1. The *probability* of occurrence of harm
 2. The *severity* of that harm

1. Basics of risk management

- Examples of hazards:
 - Erroneous patient result in qPCR due to sample contamination
 - Destruction of expensive NGS equipment due to inadequate maintenance
 - Cancer risk for technologists due to formaldehyde exposure
 - Laboratory explosion due to inadequate handling of chemical reagents
 - Cyberattack with ransom ware
 - ...

1. Basics of risk management

- In the latest version of ISO 15189: 2022, there is a significant emphasis on patient risk

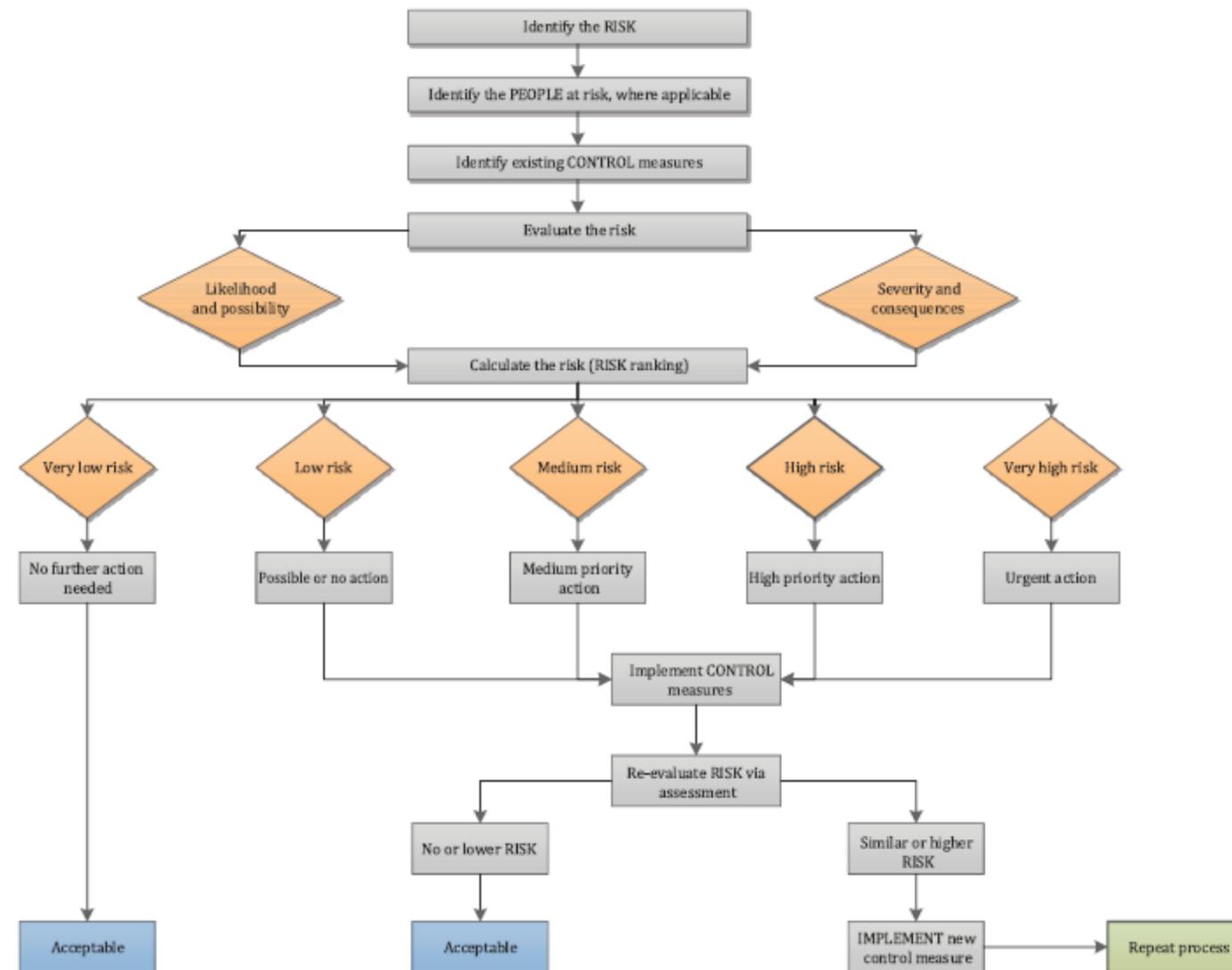


Figure A.1 — Risk assessment flow chart

1. Basics of risk management

Goals of risk management



1. Basics of risk management

Regulatory framework and reference document

ISO 15189

8.5 Actions to address risks and opportunities for improvement

Practical guidelines (BC, AP)

ISO 31000

General guidelines on risk management

ISO 22367



Specific guidelines on risk management within medical laboratories

“**Bridge**” between ISO 15189 and ISO 31000

Main focus on patient safety

1. Basics of risk management

ISO 22367 – general principles

- ISO 15189 describes WHAT to do
- ISO 22367 describes HOW to do this in a lab environment

Primary focus on PATIENT SAFETY

Prevent mistakes that could potentially harm the patient

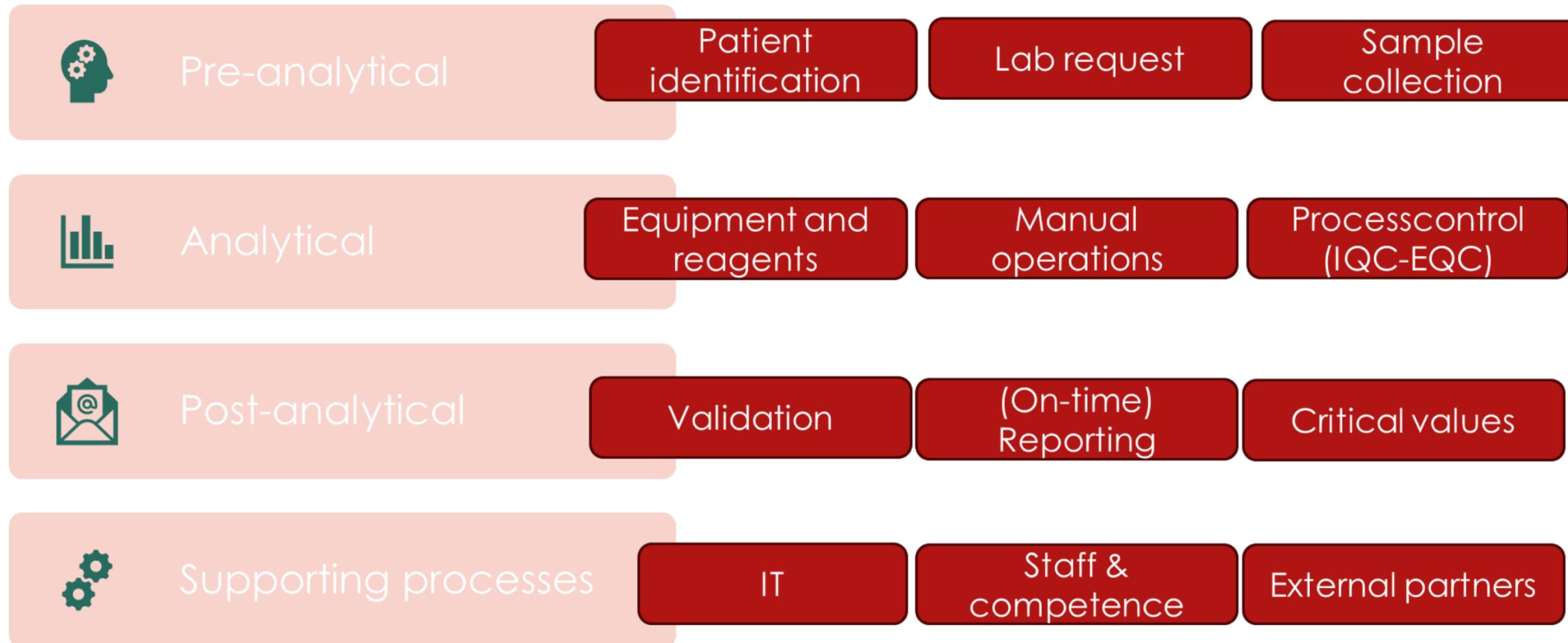
No focus on business risks, but on clinical risks

Risk management is **not a one-off exercise**, but rather a continuous process

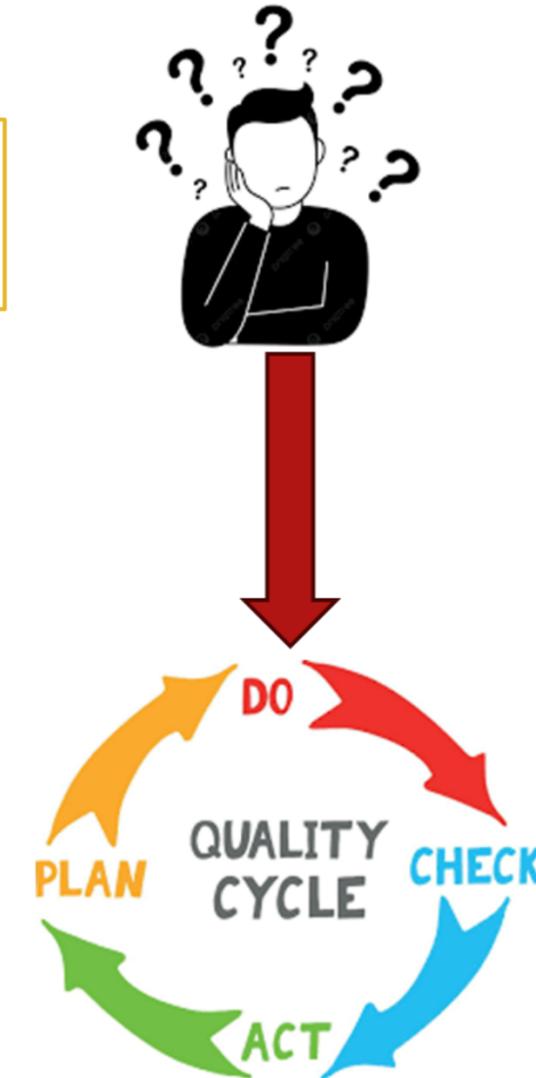
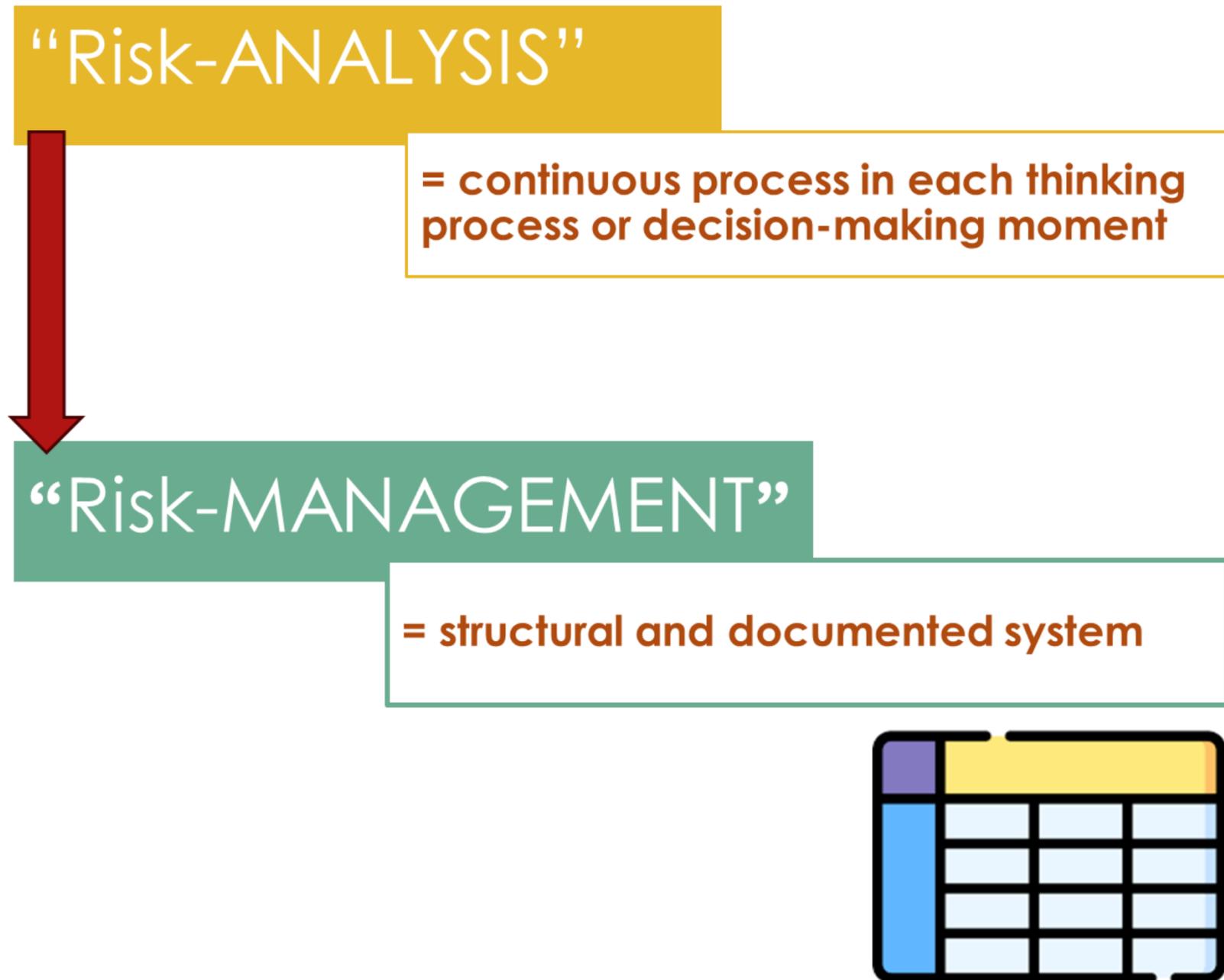
Risk = combination of **HAZARD + HARM to the patient**

1. Basics of risk management

ISO 22367 – areas within the laboratory



1. Basics of risk management



1. Basics of risk management

Incidents & complaints **Mandatory!**

New processes/equipment

Crucial alterations

IT-adjustments

Consultation sessions

Internal audits

...

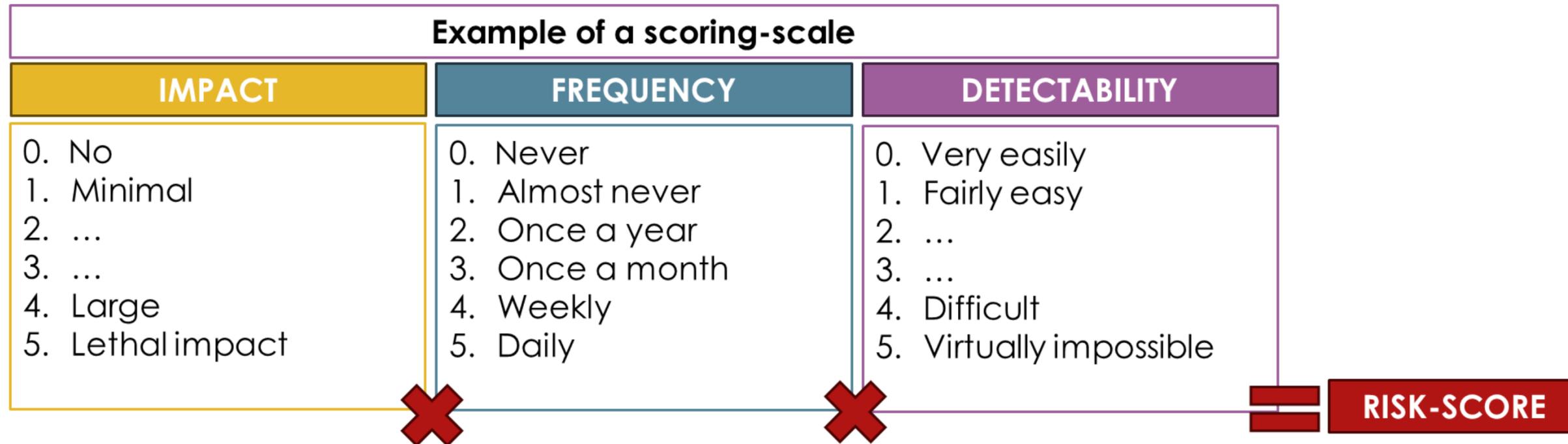
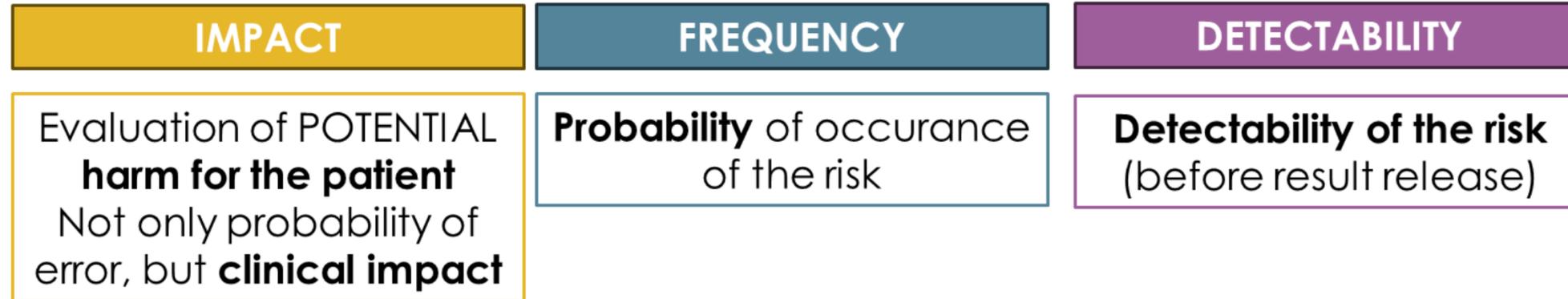


Formal record

- What can go wrong?
- What's the cause?
- What's the possible clinical implication?
- Which patients could be affected?

1. Basics of risk management

ISO 22367 requires explicitly 3 cornerstones

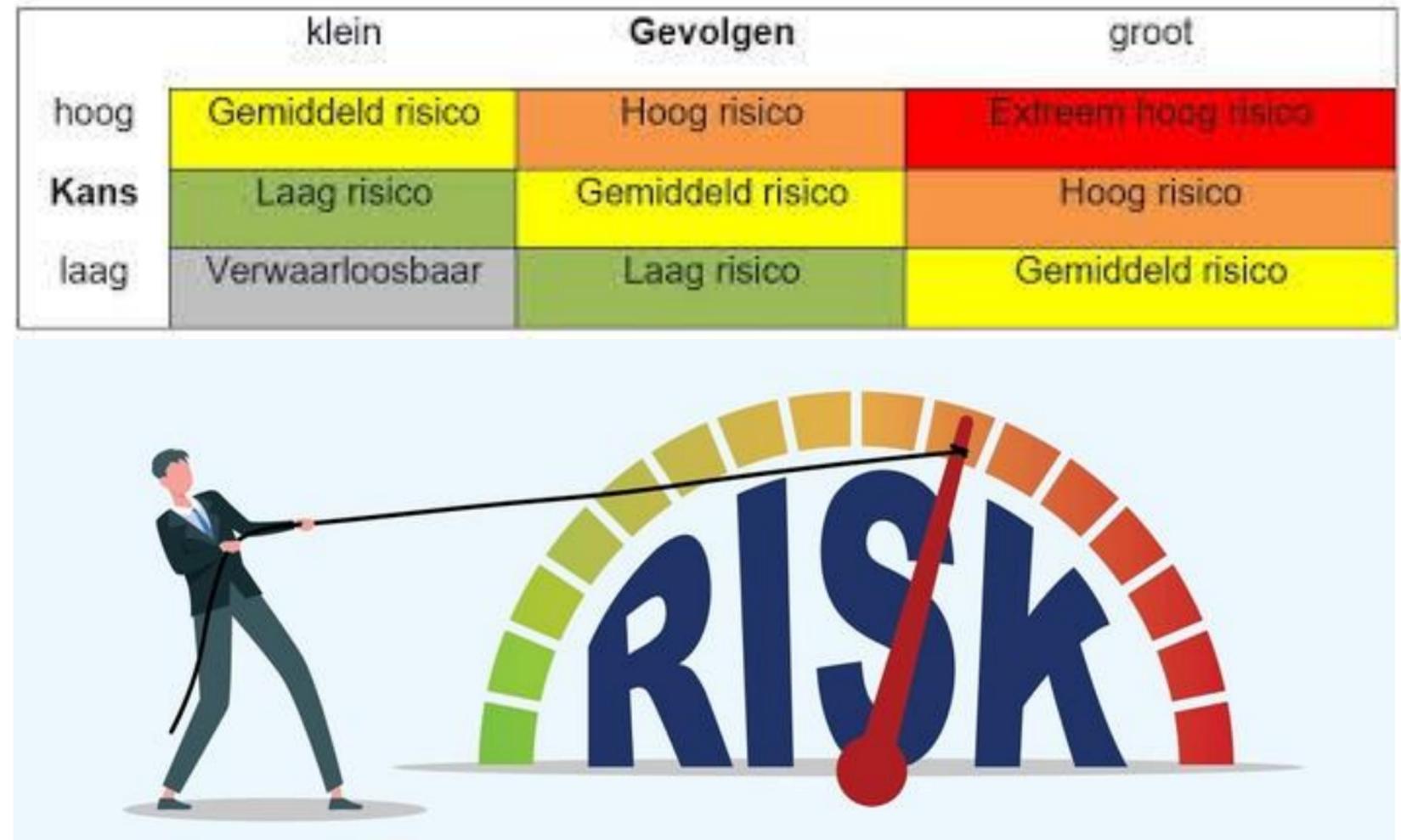


1. Basics of risk management

ISO 22367 requires explicitly 3 cornerstones

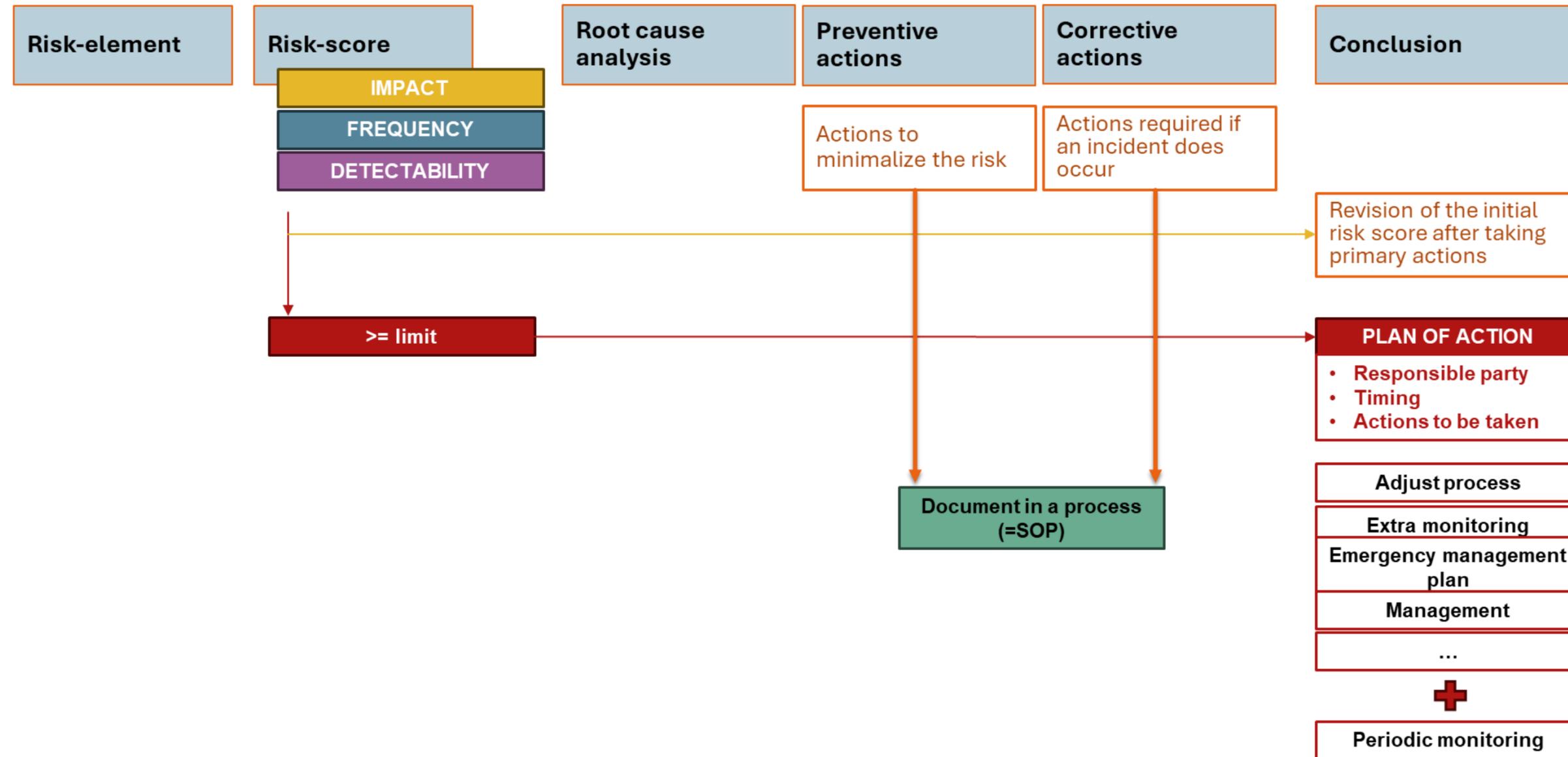
- Low risk
- Medium risk
- High risk

→ Actions required from a certain score
(not fixed, to be determined)



1. Basics of risk management

Basic scheme risk-management



1. Basics of risk management

Periodic monitoring

- Follow-up on high risks and associated action plans
- Follow-up monitoring and KPI's
- Reanalysis in case of changes
- Management review
- ...

→ re-evaluation of existing risks
(=reduce/maintain/increase where relevant)

1. Basics of risk management

Employee engagement

- **QA-staff**
 - Structural approach and comprehensive follow-up
- **Management**
 - Strategy: priorities & resources
 - Yearly review
- **Laboratory staff**
 - Implement & document in daily processes and decision-making moments
 - Raising employee awareness of risks
- **Lab technicians**
 - Consciously dealing with existing risks in daily processes



1. Basics of risk management

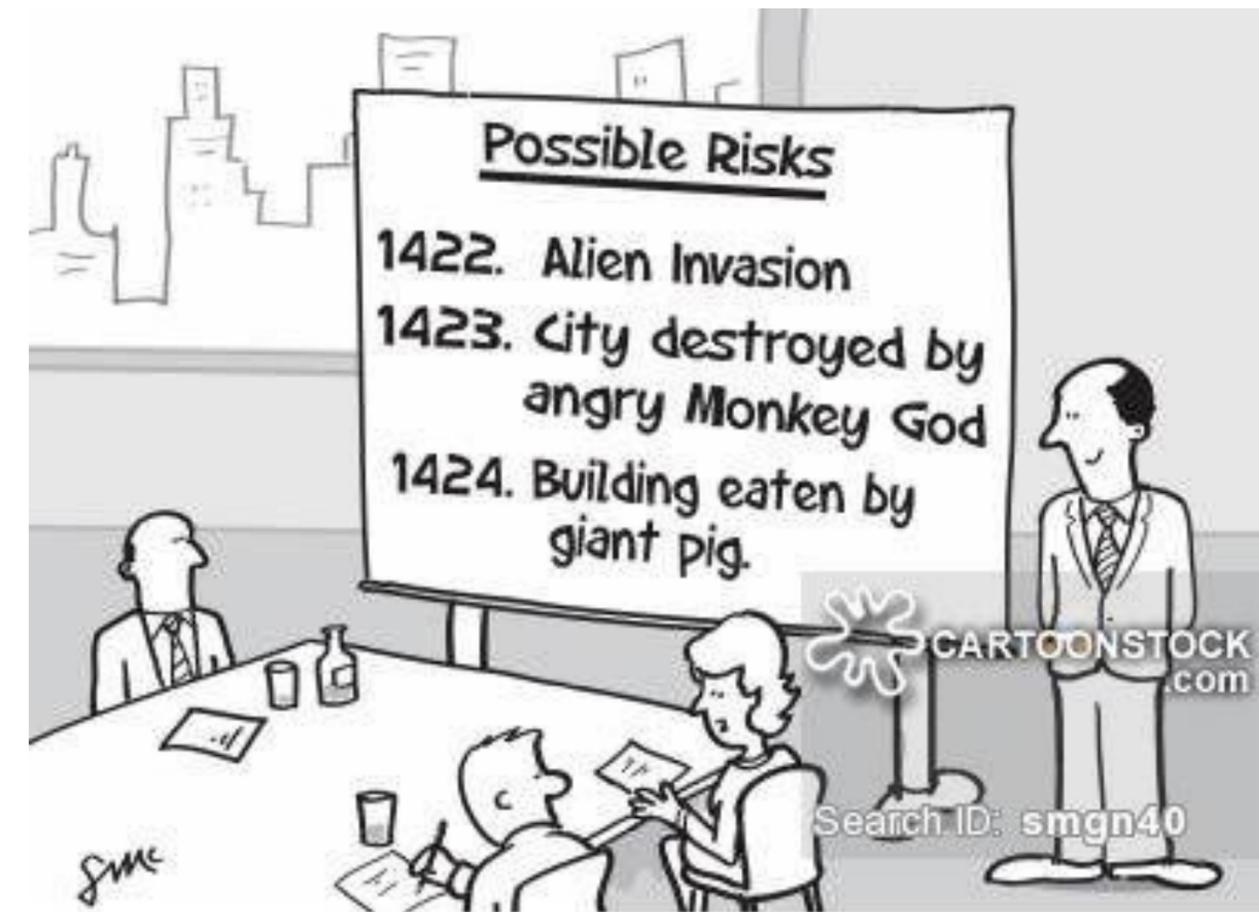
Pitfalls (1/2)

- Converting theoretical exercises into formal procedures
→ lack of documentation
- Workplace involvement
→ risk analysis often only carried out by managers
- Assessment of risk-scores
→ always “subjective” / difficult to measure
- Highly unlikely scenarios receive low scores in practice (frequency) but are actually very serious (failure LIS, power failure,...)

1. Basics of risk management

Pitfalls (2/2)

- Primary risk assessment (without measures) vs final risk assessment (after measures have been taken)
- Periodic monitoring
 - → extra resources
- Some risks are difficult to mitigate/control (human error)
 - → classified as “real but acceptable”



“Well he certainly does a very thorough risk analysis.”

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2. Practical applications in the laboratory

General principles of risk management at IPG

- Follows the FMEA principles
- One specific document “Technical risk analysis” (Reference IPG-FE- 708) is created for every diagnostic application
- This document is an add-on to every verification or validation file
- Technical risk analysis follows a ***workflow-based approach***

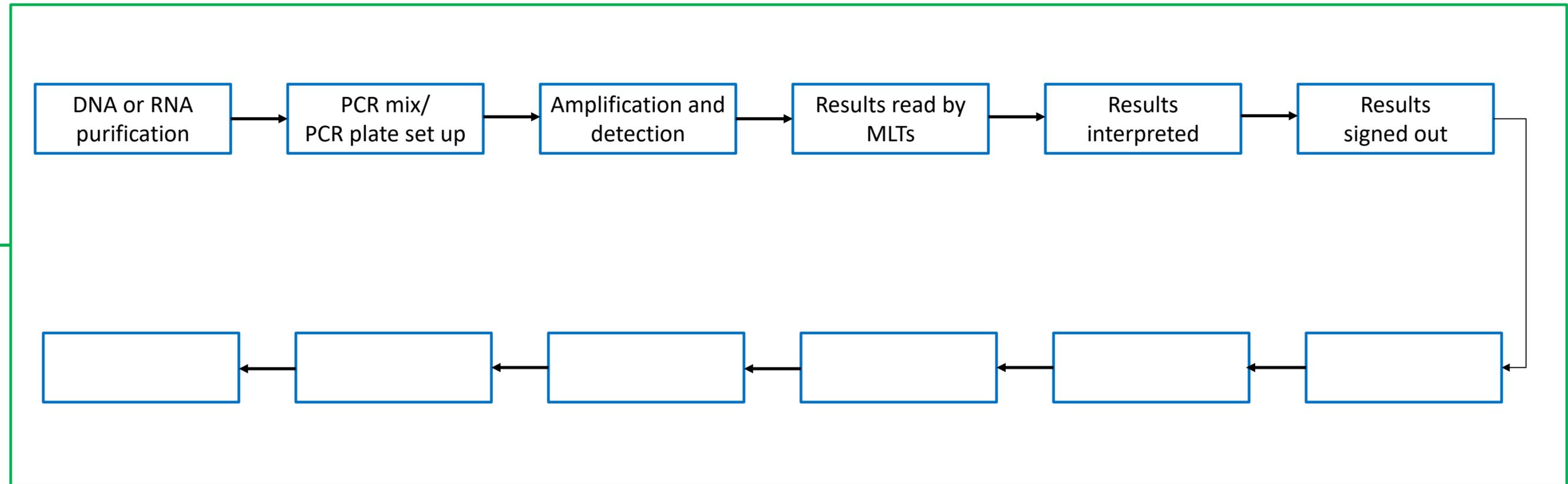
2. Practical applications in the laboratory

Example 1 : qPCR

- Multiple steps that can be manual
- Amplification means contamination risks
- Multiple applications run on same instruments
- Short TATs
- Increased competition between labs

2. Practical applications in the laboratory

qPCR: workflow



2. Practical applications in the laboratory

q PCR

Steps	Risks	Measures in place to reduce Risks
DNA or RNA purification	Sample tube inversion	MLT Training (IPG-FE-548) Verification of concordance between tubes and working list Sample barcoding and scanning at every step
	Quality of purification	Internal controls (ICs) guarantying purification quality and potential absence of amplification

2. Practical applications in the laboratory

q PCR

Steps	Risks	Measures in place to reduce Risks
PCR mix and PCR plate set up	Pipettes	Preventive calibration Maintenance Traceability of both actions
	Mix preparation	MLT Training (IPG-FE-548) Dedicated procedures

2. Practical applications in the laboratory

q PCR

Steps	Risks	Measures in place to reduce Risks
Amplification and detection	QS5 PCR machine	Dedicated procedure IPG-MO-435 Preventive maintenance according to IPG-P-005 Traceability 3 QS5 systems in total Evaluation of intersystem robustness
	Reagent stability	Dedicated procedure IPG-AN-031 Fridges and freezers under monitoring 24/7
	Contamination	Use of multiple separate rooms
	Failed amplification	Sufficient NA or sample to repeat amplification

2. Practical applications in the laboratory

q PCR

Steps	Risks	Measures in place to reduce Risks
Results read by MLTs	Failed controls	Possibility to repeat run
	Error in reading	Formal training by scientific expert Operating Mode (IPG-MO-) for every qPCR
Results interpreted	Error in interpretation	Formal training by scientific expert
Results signed out	Mistake by MD	Validation with raw data Formal training Multiple pre-existing steps

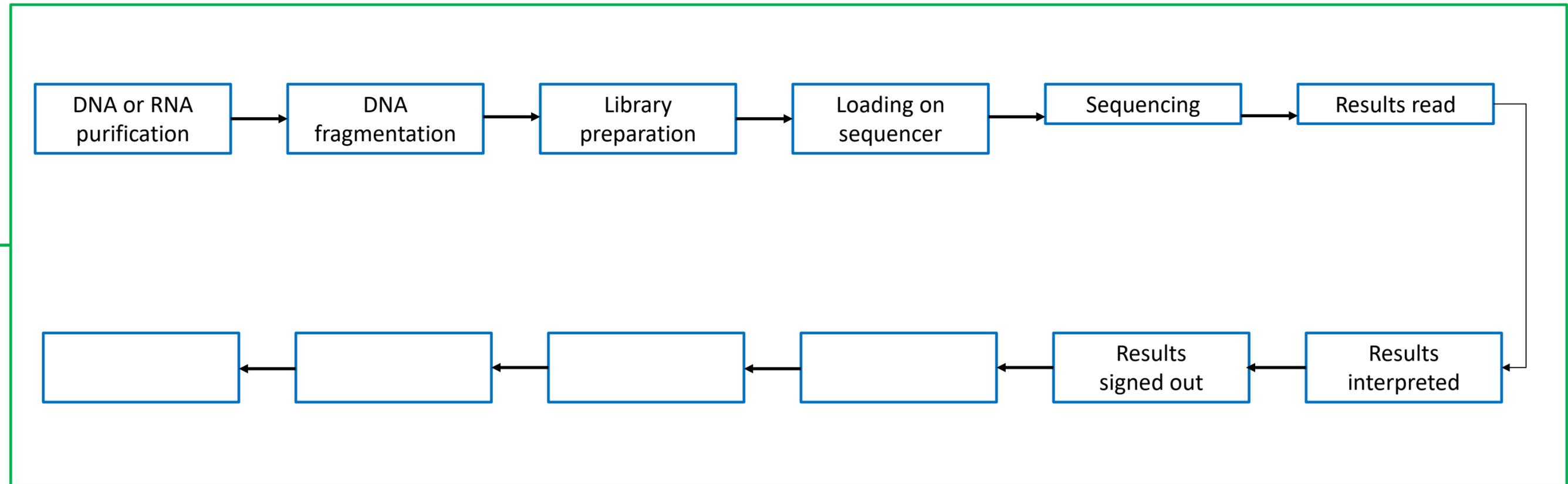
2. Practical applications in the laboratory

Example 2 : NGS for solid tumors

- More complex workflow than qPCR
- Longer TATs
- Patients with serious diseases that may targeted therapy
- Strategic (reimbursement with the NGS convention in onco-hematology)
- Costly reagents
- Higher reimbursements

2. Practical applications in the laboratory

NGS for solid tumors: workflow



2. Practical applications in the laboratory

NGS for solid tumors

Steps	Risks	Measures in place to reduce Risks
DNA or RNA purification	Sample tube inversion	MLT Training Verification of concordance between tubes and working list Sample barcoding and scanning at every step
	Quality of purification	NA quantification Concentration threshold and NA qualitative analysis before launching workflow

2. Practical applications in the laboratory

NGS for solid tumors

Steps	Risks	Measures in place to reduce Risks
DNA fragmentation	Errors in sample dilution	MLT Training Worksheet with pre-filled calculation

2. Practical applications in the laboratory

NGS for solid tumors

Steps	Risks	Measures in place to reduce Risks
Library preparation	Barcode inversion	MLT Training Dedicated instructions
	Errors in pool dilutions	MLT Training Dedicated instructions Library quantification
	Failed library	Sufficient sample material to repeat analysis
	Down thermocycler	Use of multiple systems

2. Practical applications in the laboratory

NGS for solid tumors

Steps	Risks	Measures in place to reduce Risks
Loading on sequencer	Chip selection Library dilution	MLT Training Worksheet with pre-filled calculation

2. Practical applications in the laboratory

NGS for solid tumors

Steps	Risks	Measures in place to reduce Risks
Sequencing	Use of sequencer	MLT training
	Down sequencer	Maintenance contract UPS (Uninterruptible Power Supply) electric alimentation
	Sequencer failure	Reloading chip if possible Restarting analysis from DNA

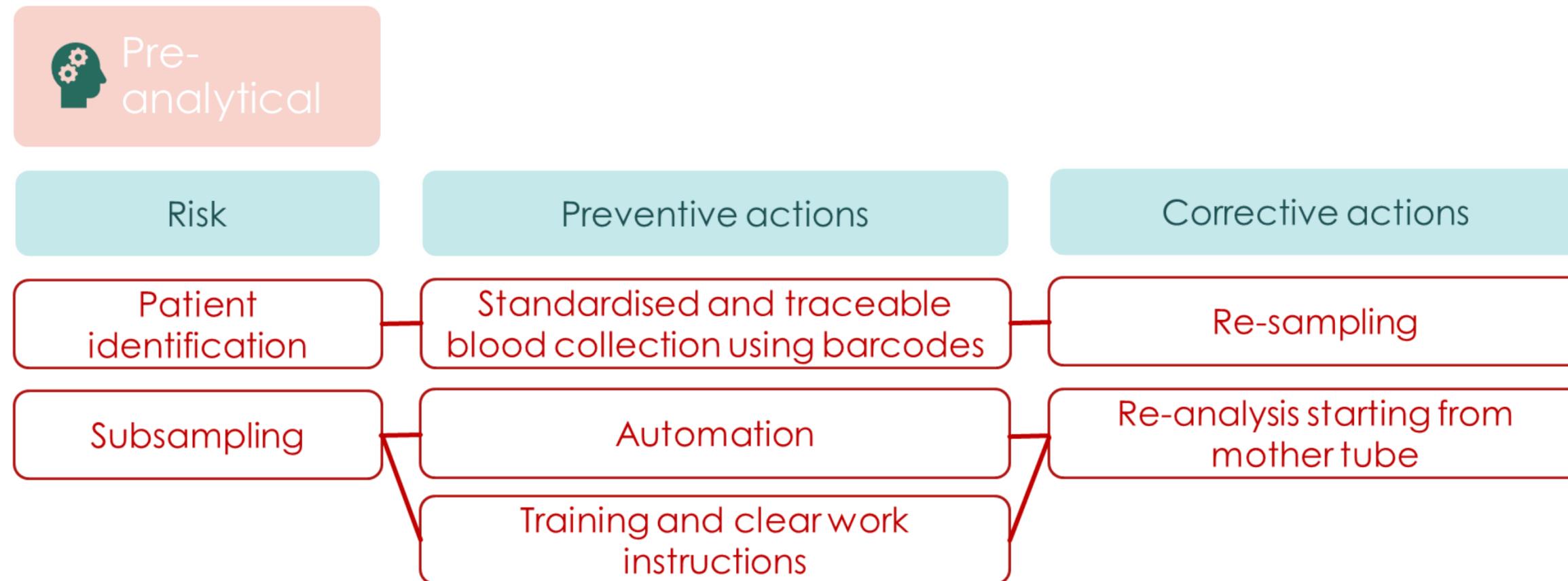
2. Practical applications in the laboratory

NGS for solid tumors

Steps	Risks	Measures in place to reduce Risks
Results read	Erroneous use of interface	Scientific expert training
Results interpretation	Inter-operator variability	Scientific expert training Team review of cases interpretation

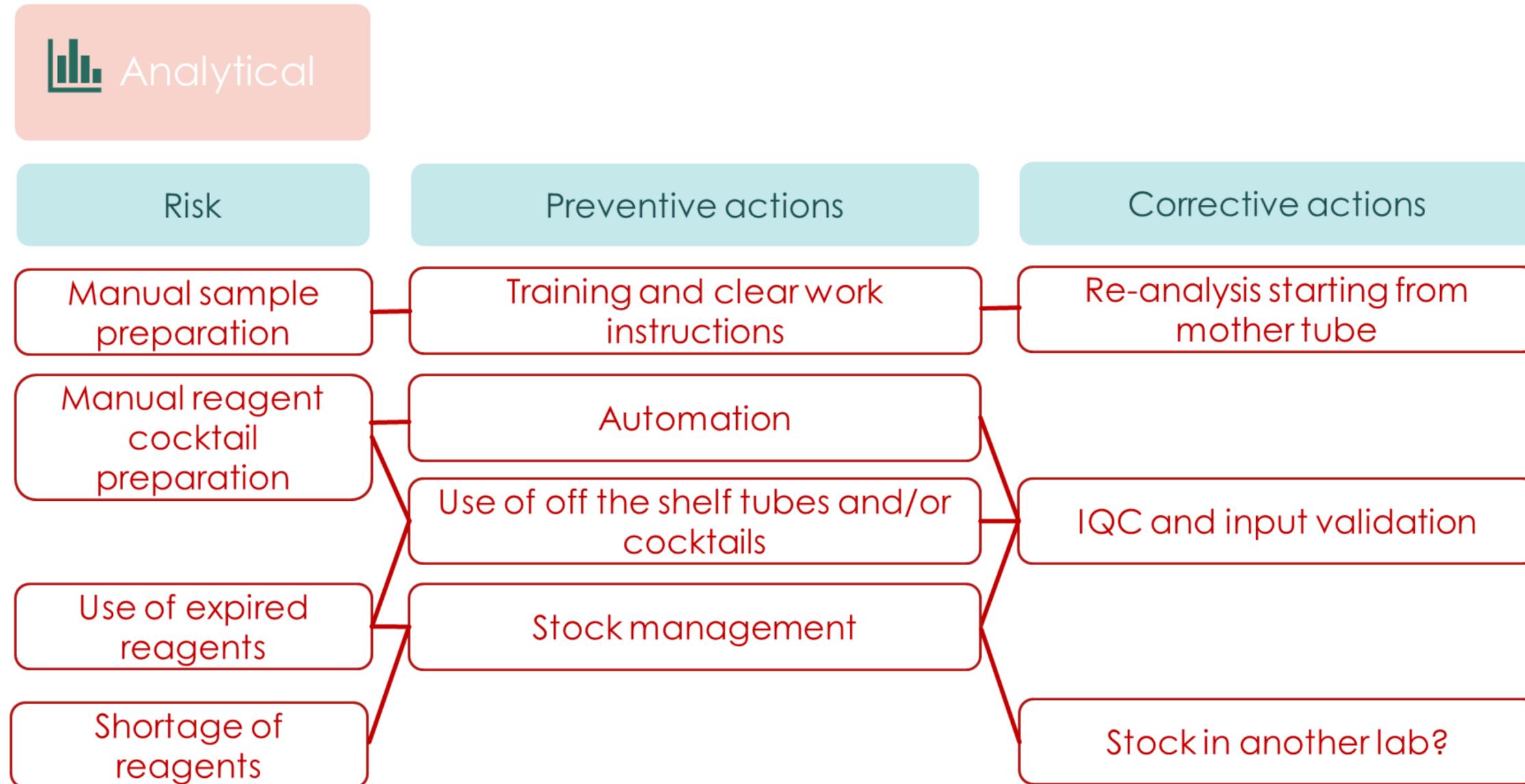
2. Practical applications in the laboratory

Example 3: flow cytometry



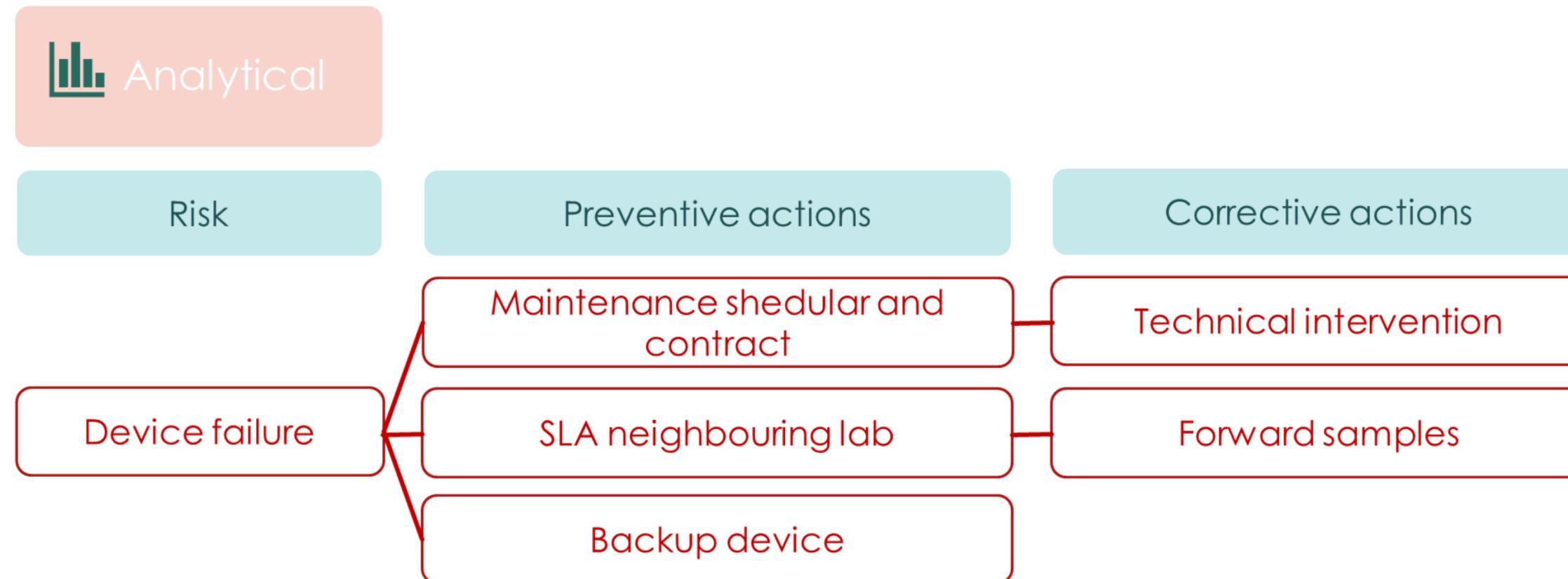
2. Practical applications in the laboratory

Flow cytometry



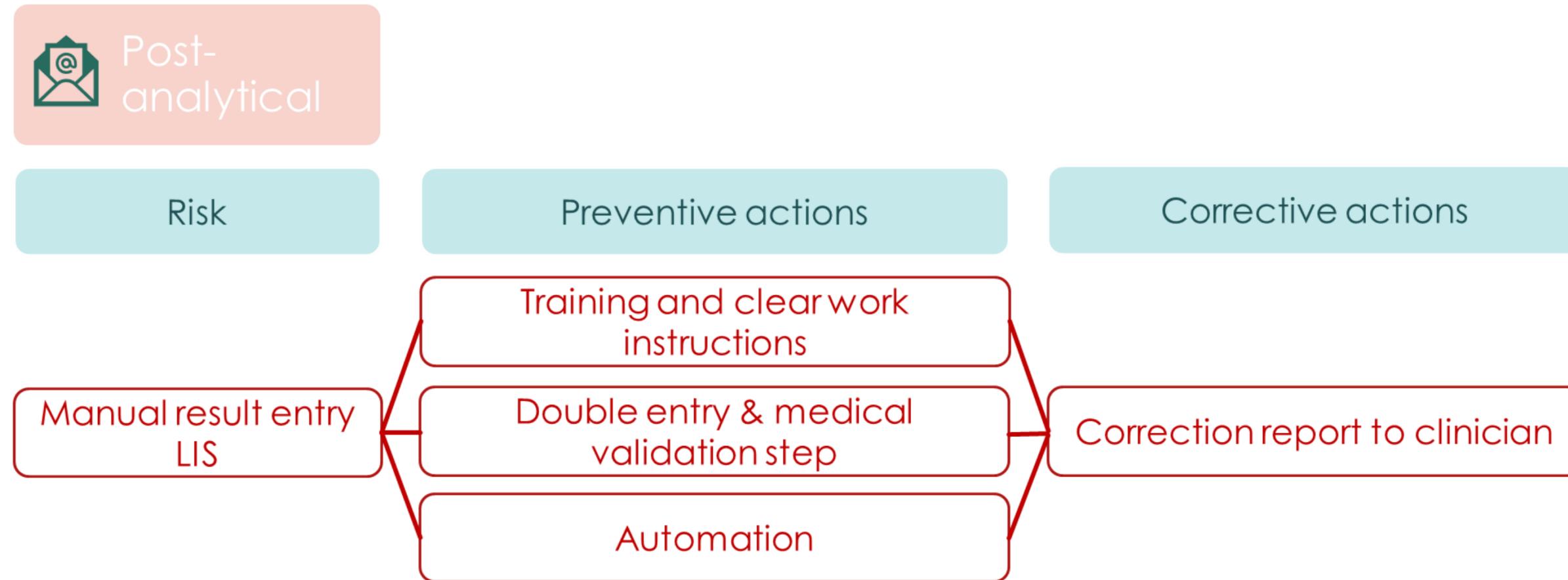
2. Practical applications in the laboratory

Flow cytometry



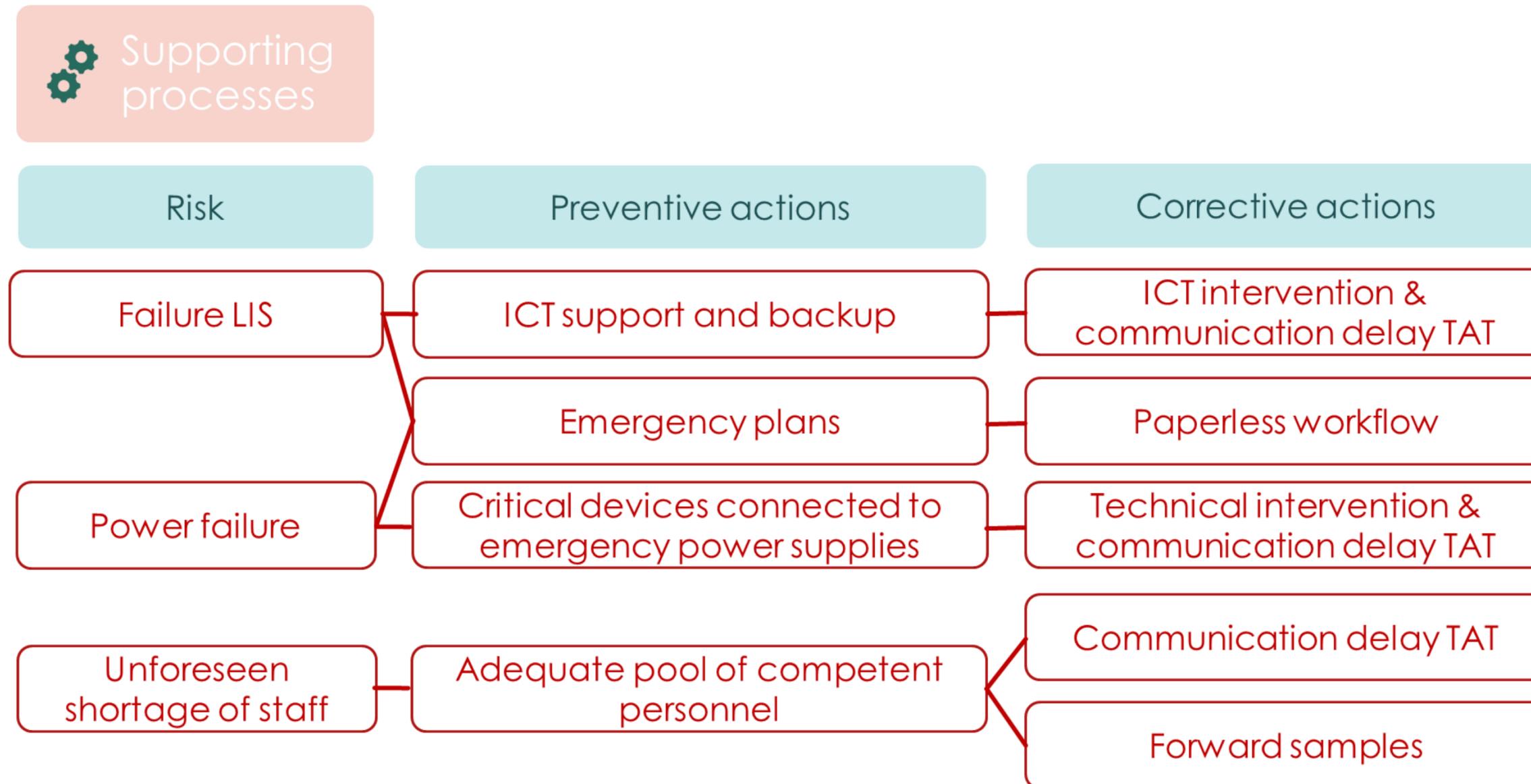
2. Practical applications in the laboratory

Flow cytometry



2. Practical applications in the laboratory

Flow cytometry



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3. Risks outside laboratories that may concern you !

- We are exposed to risks other than to generate an erroneous results
- It may be your responsibility to speak up and discuss it with your manager or Laboratory director – **never underestimate your potential responsibility !**
- Some examples:
 - Physical safety risks (explosion, ...)
 - Cybersecurity risks (ransom ware attacks, ...)
 - Healthcare risk (exposure to carcinogens, ...)
 - Psychosocial risk ((sexual) harassment, ...)
 - ...

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4. Conclusions

- Risk management is an essential task in clinical laboratories
- ISO 15189:2022 puts a significant emphasis on patient risk
- Risk is a concept composed of frequency and severity of harm

- ISO 22367 provides a detail framework for risk management
- Laboratory risk can be mitigated by using a workflow-based approach
- Risks other than patient risk may occur in your work environment and may involve your responsibility

Thanks for your attention and active participation !

