The Fearless Statistician: Psychological Safety in Drug Development

PSI Conference 2025

Notes

Session info

1. **Introduction to psychological safety and its relevance to statisticians working in the pharmaceutical Industry** - Dirk Klingbiel

2. **Organizational Approaches to Psychological Safety: Building Inclusive and High-Performing Statistical Teams** - Clélia Cahuzac

3. **Quantifying the costs of a lack of psychological safety** - A case series - Anna Wiksten

4. **Panel discussion**:

   Justine Rochon, Dirk Klingbiel, Clélia Cahuzac and Anna Wiksten
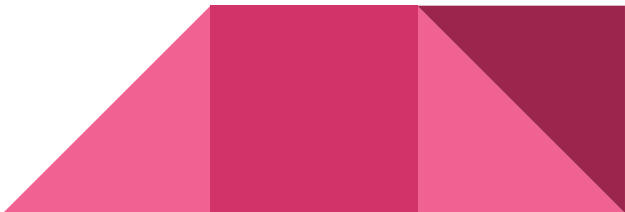
Contributors

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Thank you

- Antonella Mazzei
- Joana Marques-barros
- Lukas Widmer
- Manuela Zimmermann
- Nicola Hewson
- Olympia Papachristofi

A special thank you to **Jevgeni Nietosniitty,**

Organisational psychologist

Aims for today's session

- ➢ Grounding in what Psychological safety is & isn't

- ➢ Why it's important to us as Statisticians in the Pharma industry

- ➢ Building Inclusive and High-Performing Statistical Teams

- ➢ Quantifying the costs of not having Psychological safety

- ➢ Give you the opportunity to think about your own teams and work

- ➢ Build actions and steps you can take with you

Toyota's Andon Cord

Any worker on the production line can pull to **stop the entire line** if they notice a problem

Sign of **ownership**, not failure

Fosters **trust** and **continuous improvement**

Shifts **power to the individual**, signaling that **quality and safety trump speed or hierarchy**

Visibility builds **collective responsibility**.

The Andon cord is built-in **system where people are safe to speak, proud to act, and trained to learn**.

That's a **competitive advantage** many rivals are still trying to catch up with.

DISCLAIMER

The views and opinions expressed in this session are those of the author/speakers and do not necessarily represent the official policy of the companies the speakers are employed at.

Psychological Safety

and its relevance to statisticians
working in the pharmaceutical Industry
Speaker: Dirk Klingbiel

What is Psychological Safety?

"A shared belief that the team is safe for interpersonal risk-taking."

Amy Edmondson

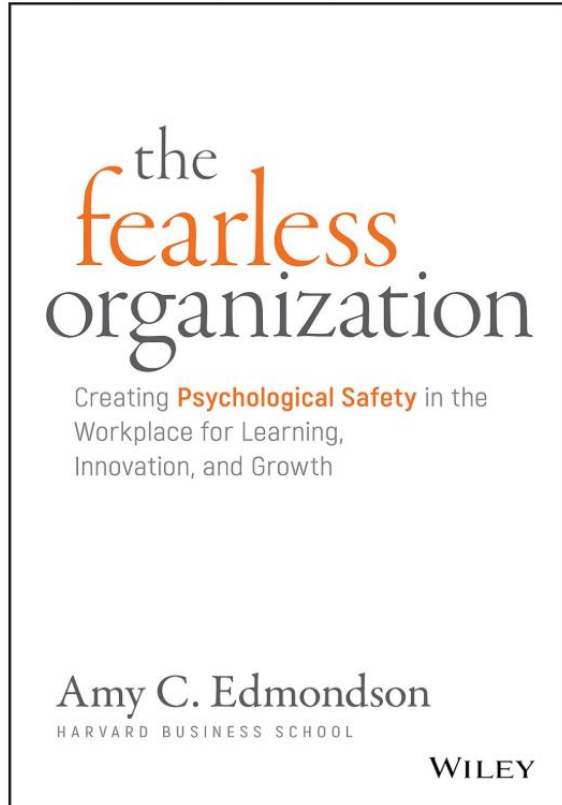# What does a team with psychological safety look like?

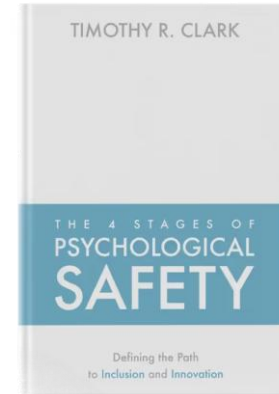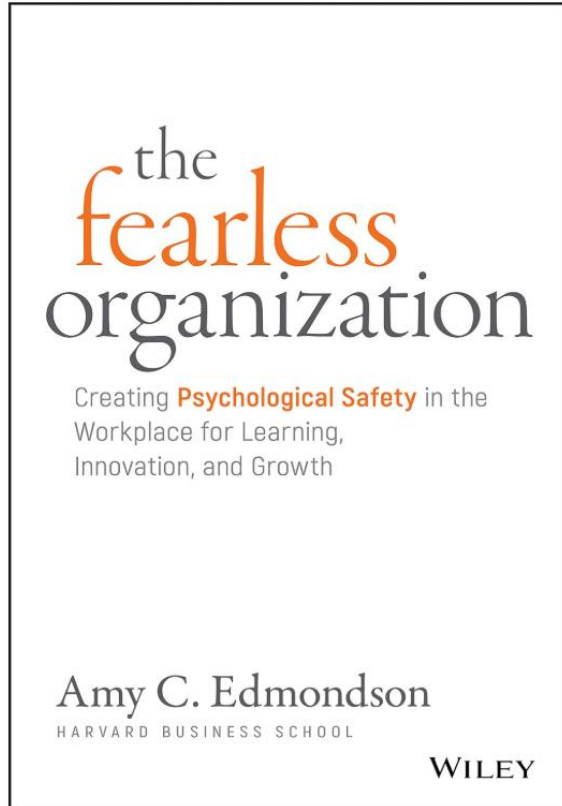pflege-today.de

What does a team with psychological safety look like?

- Speak up without fear
- Acknowledge mistakes freely
- Ask questions safely
- Share ideas openly
- Avoid embarrassment or punishment

pflege-today.de

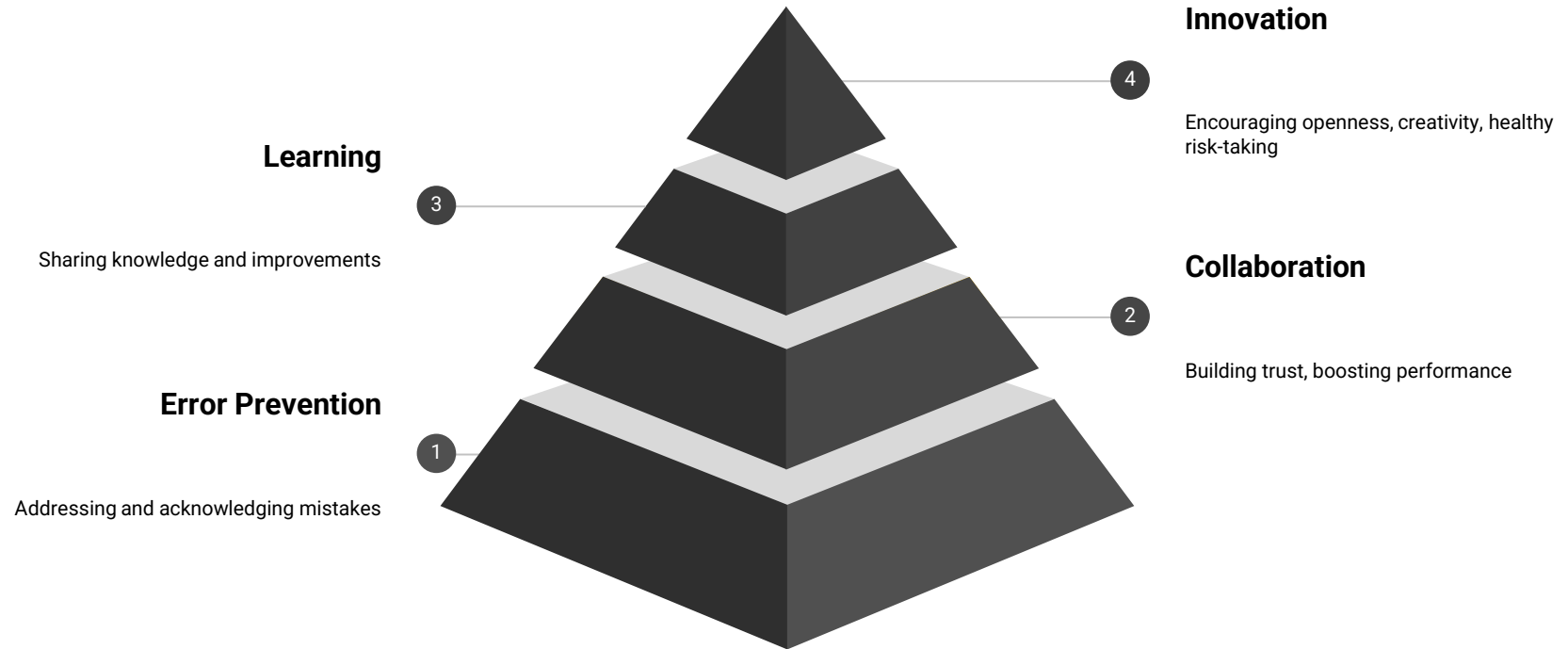# Where did this come from?

the
fearless
organization

Creating **Psychological Safety** in the
Workplace for Learning,
Innovation, and Growth

Amy C. Edmondson
HARVARD BUSINESS SCHOOL

WILEY

Where did this come from?

→Talk 2

Why Does Psychological Safety Matter?

Innovation

4

Encouraging openness, creativity, healthy risk-taking

Learning

3

Sharing knowledge and improvements

Collaboration

2

Building trust, boosting performance

Error Prevention

1

Addressing and acknowledging mistakes

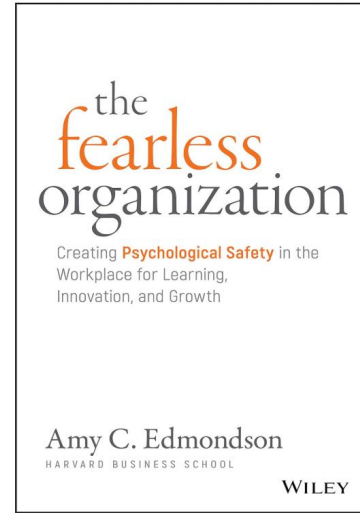# Dispelling Misconceptions:
It's Not Just Being "Nice"
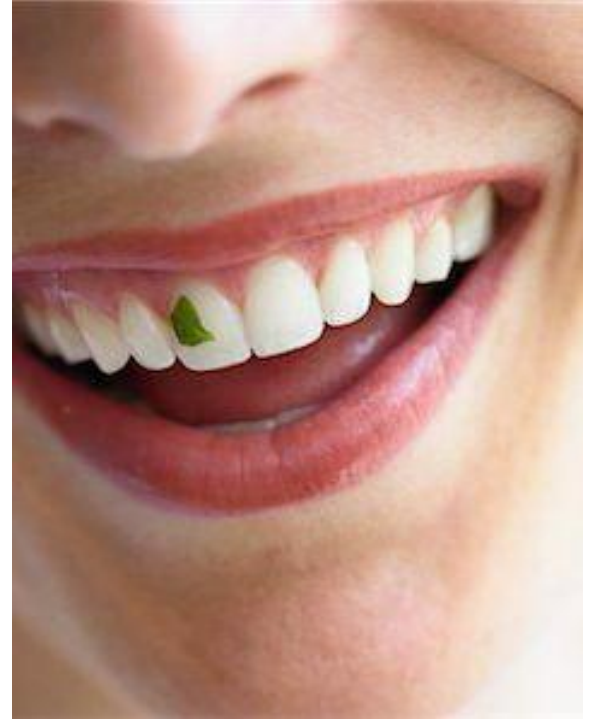
Dispelling Misconceptions:
It's Not Just Being "Nice"

- Not avoiding conflict
- Not just harmony
- Not glossing mistakes
- Requires candor
- Embraces critical thinking

Key Findings From Amy Edmondson's Work

- Share and learn from mistakes
- Embrace critique for progress
- Solve complex problems
- Freely take risks

the
fearless
organization

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HARVARD BUSINESS SCHOOL

WILEY

What might this mean for statisticians?

- Promote rigorous data analysis
- Try innovative solutions
- Remove the fear of critique

Velvetech.com

Three Pillars of Psychological Safety

1. Open communication
2. Learning culture
3. Support for risk

How Leaders Foster Psychological Safety

How Leaders Foster Psychological Safety

- Model openness and humility
- Encourage feedback and questions
- Normalize respectful debate
- Speaking up > Correct answer
- Highlight team member's strengths

https://hernewstandard.com

Common Challenges in Building Psychological Safety

Challenges	Solutions:
Fear of judgment	Encourage respectful feedback
Reluctance to express dissent	Normalize debate and uncertainty
Misconception: Psychological Safety = no accountability	Foster Psychological Safety alongside accountability

Psychological Safety for Statistical Teams

Importance of Psychological Safety in Analyses

master.math.u-paris.fr

Psychological Safety for Statistical Teams

Importance of Psychological Safety in Analyses

- Encourage data uncertainty discussions
- Address assumptions and limitations
- Identify analysis gaps openly
- → Improve decision-making quality
- → Foster informed, robust outcomes

master.math.u-paris.fr

Psychological Safety for Statistical Teams

Embracing Methodological Diversity

Psychological Safety for Statistical Teams

Embracing Methodological Diversity

- Welcome alternative methods

- Support varied interpretations

- Enable inclusive dialogue

- Enhance analytical rigor

- Foster innovative solutions

Psychological Safety for Statistical Teams

Building a Trustful Environment

Psychological Safety for Statistical Teams

Building a Trustful Environment

- Normalize honest feedback
- Allow safe critique space
- Minimize negative consequences
- Treat mistakes as learning
- Celebrate growth from errors

https://theamericangenius.com/trust-coworkers-competitive-work-environment/

Final Thoughts: A Call to Action

- Prioritize psychological safety in teams
- Model openness and trust-building behaviors
- Encourage constructive debate and critique
- Create space for tough conversations
- Champion statistical excellence as a team

Organizational approaches to Psychological Safety:
Building inclusive and high-performing statistical teams

The Fearless Statistician: Psychological Safety in Drug Development

Clélia Cahuzac
PSI conference 2025

DISCLAIMER

Psychological Safety Long-Term Learner Journey

Understand

Diagnose

Caring

Review

What does psychological safety mean?

What is the psychological safety level in your team?

How can we nurture it?

How do we monitor progress?

The 4 stages of Psychological Safety™ by Timothy Clark
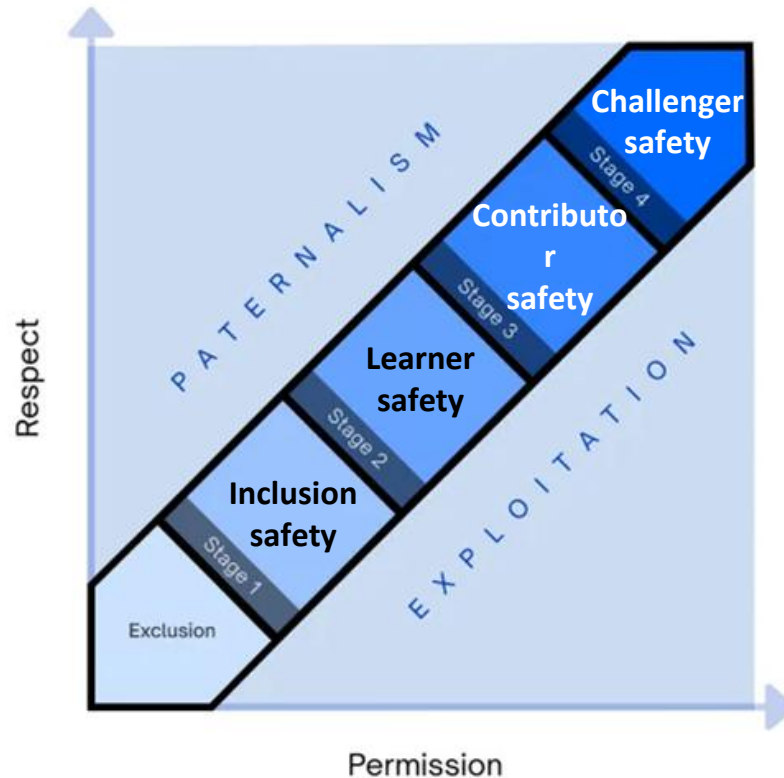
Inclusion Safety: Can I be my authentic self?

- Do all members feel welcome, accepted, valued and respected **as they are** and regardless of their identity, background, function, seniority, etc?

- Are all members **included** in conversations, key meetings or informal networks?
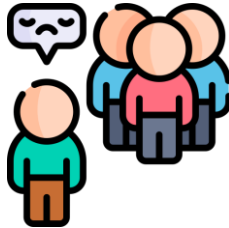
Learner Safety: Can I learn through asking questions?

- Are members able to **ask questions** and/or **admit they don't know** something without any fear to be labeled as incompetent?

- Are mistakes treated as part of the process and seen as an **opportunity to learn**?
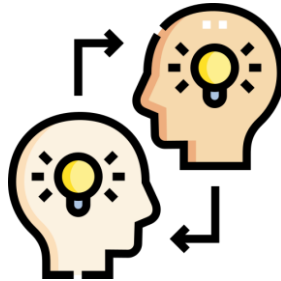
Contributor Safety: Can I contribute with my own ideas?

- Do members **feel empowered** to work in autonomy (with guidance of leaders), to think outside the box and share original ideas?

- Are contributions recognized through **feedback** and **acknowledgment** from peers and supervisors?

"It doesn't make sense to hire smart people and then tell them what to do. We hire smart people so they can tell us what to do."

Steve Jobs

Challenger Safety: Can I question others' ideas or suggest significant changes?

Do members feel safe enough to **challenge** the status-quo, **make suggestions** for improvement or **raise concerns** (even with their hierarchy), without the fear of losing their job or damaging their reputation?

What is the level of psychological safety in your team?

■ Ensure everyone has a **shared understanding** of the key underlying concepts

■ **Reflect** on your habits, **ask** the hard questions

■ **Be open** to the eventuality of a low psychological level in you team and ready to receive honest answers

> → *Are people so afraid of making a mistake that they avoid doing anything new or different? When they need help, do they feel comfortable to ask?*
> → *Do they lack the time or space to learn new things?*
> → *Do superiority and hierarchy dictate who participates, who contributes, and who doesn't?*
> → *Do people are provided with autonomy, guidance, and encouragement in exchange for efforts?*
> → *Are ideas and opinions ignored when they go against the company norms?*

What is happening in a company with a high level of psychological safety?

Company

Train leaders and individuals and promote Psychological Safety

Uphold transparent and fair decision-making processes

Support and provide resources for learning and development

Leader

Lead by example

Encourage dissenting opinions

Value speaking up over having the correct answer

Help members of their team to see their strengths

Individual

Ask for help/opinion

Practice active listening

Are not afraid to share draft work

Voluntarily share past mistakes and what they have learned from them

Which actions can you take tomorrow?

- Make yourself available. Small actions matter!

- Help identify the right person to ask across experience / expertise levels

- Request, give and be open to receive quality feedback (timely, constructive, development-oriented)

Building Psychological Safety takes time and requires the support of **everyone** in the team.

You don't have to start big. Identify **small steps** and continue from there, testing for changes as you go.

Psychological safety is a **journey** rather than a destination.

Ressources

- Clark, T. R. (2020). *The 4 Stages of Psychological Safety: Defining the Path to Inclusion and Innovation*. San Francisco, CA: Berrett-Koehler Publishers
  - [Resources](#) available online on the author's website

- American Psychological Association. (2024, March 4). *What is psychological safety at work? Here's how to start creating it*. [Online article](#).

Quantifying the costs of a lack of psychological safety - A case series

Presenter: Anna Wiksten

High psychological safety and high performance are complementary not competitive

How psychological safety relates to performance standards?
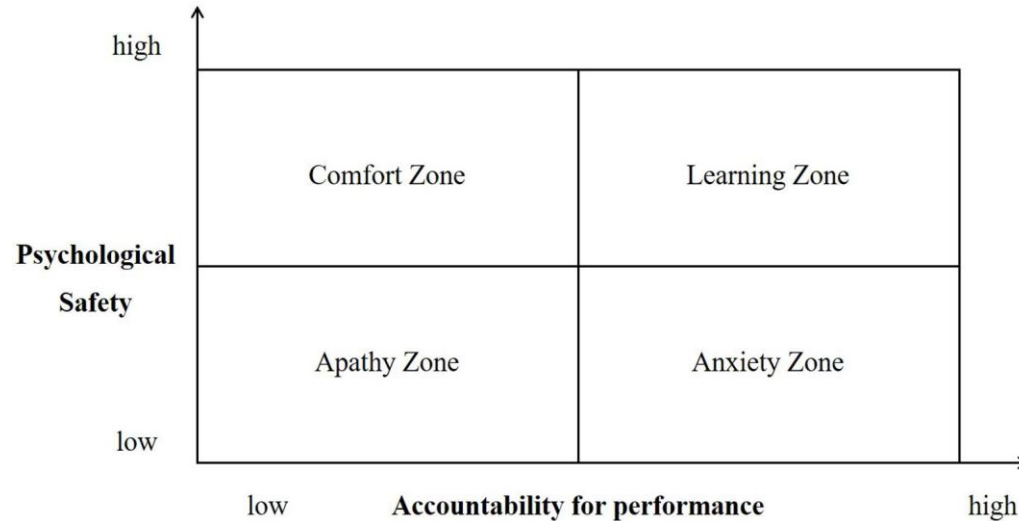
"The Fearless Organization", Edmondson, 2019

Psychological safety is #1 predictor of team effectiveness

Benefits of high psychological safety:
Accenture, 2021: Employee Belonging | Net Better Off People Strategy | Accenture

27% Reduction in turnover	**40%** Less burnout
76% More engagement	**57%** Workers more likely to collaborate
50% More productivity	**74%** Less stress

Toyota – the andon cord

- Ask for help in the heat of the moment-learner safety
- Suggest an idea for improvement when it can endow maximum benefit – contributor safety
- "Stop the line" to prevent an issue getting worse– challenger safety

What is the impact of an "andon cord" for us in drug development?

Let's simulate!

"A simulation is an imitative presentation of process or a system that could exist in real word."

Let's simulate

- The parameters and assumption
- Scenario 1 – Sending emails – learner safety
  - psychological safety in our daily interactions
- Scenario 2 – Proposing an alternative method – contributor safety
  - psychological safety in embracing innovation
- Scenario 3 – Reporting a mistake in blockbuster submission – challenger safety
  - Psychological safety in crisis situation

Let's simulate – parameter and assumptios

- Cost of an hour of working time 100 USD

- Daily sales of a blockbuster drug > 2.7mUSD
  - Definition of blockbuster is annual sales exceeding 1 bn USD

- Disclaimer: The numbers are made up, but should reflect the scales we deal with in drug development

Scenario 1 - sending emails

Have you ever been in a situation that you had a simple

question,

proposal, or

correction

you wanted to sent via email, but you hesitated to send it?

Why did you hesitate?

- Were you afraid that people would think you are incompetent?
- Did you need to correct or give feedback someone who is higher in the hierarchcy and you were afraid the person would not like it?

Scenario 1 - sending emails

- If we spend 3 hours drafting the simple email, what is the cost?

- Cost of drafting the email: 300USD - Not a big deal?

- What if this happens 5 times per year to 200 employees?
  - 300usd*5*200=300kUSD

- What if this happens 10 times per year to 500 employees?

- ....

- At organizational level the culture in daily communications make a difference!

Scenario 2 – proposing an alternative method

- **Situation:**
  - CRO statistician is working on implementing statistical analyses. The analysis plans are specified by the sponsor statistician.
  - While doing the work the CRO statistician comes accross an idea to do the analyses in a better and faster way.
  - Because there is a high psychological safety between the sponsor team and the CRO statistician she proposes the idea to the sponsor statistician and it is implemented in all future analyses.

How much will the sponsor save by not missing the better approach?

Scenario 2 – proposing an alternative method

- Let's assume the idea saves 100 hours of sponsors statistician works in this project
    - The saving is 100USD*1000=10 kUSD
- Let's assume it can be used in 10 future projects
    - The saving 10*10 kUSD=100kUSD

Scenario 3 - Reporting a mistake in blockbuster submission

- **Situation:**
  - Trial statistician(TS) works in high priority submission of a potential blockbuster.
  - Just few days before finalization of the CSR he notices an issue affecting the primary endpoint.
  - The mistake is critical and it should be corrected. Correcting the mistake takes 5 days of extra work and will delay the approval by 5 days.
  - If the mistake is not corrected, it will be found in regulatory review and it will delay the approval by 90 days.

        What are the potential actions of trial statistician?

Scenario 3 – Potential actions of trial statistician

- Potential actions of TS:
  1. **High psychological safety** : TS immediatly informs the project statistician(PS).
  2. **Moderate psychological safety** :TS is afraid of telling about the issue and waits 2 days to think how to inform. After 2 days he/she informs the PS.
  3. **Low psychological safety**: TS panics about the situation and decides not to infrom the PS.

Scenario 3 - Potential actions of project statistician

- Project statististician after being informed:
  1. **High psychological safety** : PS immeadiatly makes an action plan to evaluate the impact and corrective actions
  2. **Moderate psychological safety** : PS is afraid of the upper leadership and and waits 2 days before taking action.
  3. **Low psychological safety:** PS panics and tells to TS not to tell anyone and doesn't inform the upper management.

Scenario 3: psychological safety and financial impact

Level of psychological safety		Impact			
Between TS and PS	Between PS and management	Delay in submission (Days)	Delay in approval (Days)	Lost in sales due to delayed approval (million USD)	Negative External reputation
High	High	5	5	13.7	No

13.7 million USD is the minimum loss in sales

Scenario 3: psychological safety and financial impact

Level of psychological safety		Impact			
Between TS and PS	Between PS and management	Delay in submission (Days)	Delay in approval (Days)	Lost in sales due to delayed approval (million USD)	Negative External reputation
High	High	5	5	13.7	No
High	Moderate	7	7	19.18	No
Moderate	High	7	7	19.18	No

Scenario 3: psychological safety and financial impact

Level of psychological safety		Impact			
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High	High	5	5	13.7	No
High	Moderate	7	7	19.18	No
Moderate	High	7	7	19.18	No
Moderate	Moderate	9	9	24.66	No

Scenario 3: psychological safety and financial impact

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Between TS and PS	Between PS and management	Delay in submission (Days)	Delay in approval (Days)	Lost in sales due to delayed approval (million USD)	Negative External reputation
High	High	5	5	13.7	No
High	Moderate	7	7	19.18	No
Moderate	High	7	7	19.18	No
Moderate	Moderate	9	9	24.66	No
High	Low	0	90	246.6	Yes
Moderate	Low	0	90	246.6	Yes
Low	Not applicaple	0	90	246.6	Yes

The comparison of interest...

246.6 million USD-13.7 million USD=
232.9 million USD

The value of having a working "andon cord" is

232.9 million USD

Scenario 3 : psychological safety between TS and management

Level of psychological safety		Impact			
Between TS and PS	Between PS and management	Delay in submission (Days)	Delay in approval (Days)	Lost in sales due to delayed approval (million USD)	Negative External reputation
High	Low	0	90	246.6	Yes
Moderate	Low	0	90	246.6	Yes

- If there is a high psychological safety between TS and management and TS can inform about the mistake to higher up

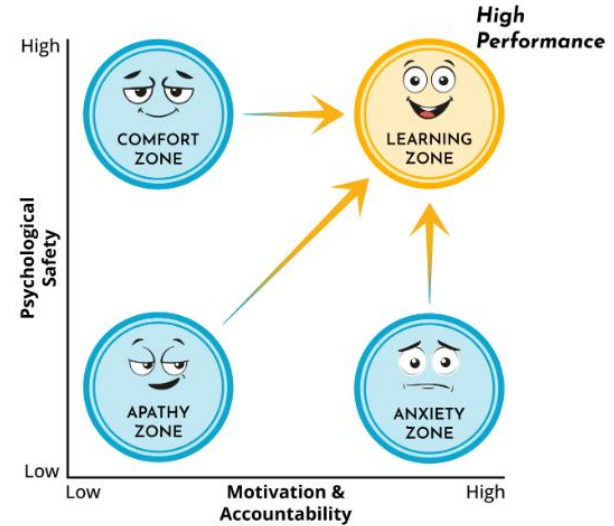# Scenario 3 : What are the factors affecting the decisions of TS and PS?

- Origin of mistake
    - Mistake in own line function vs other line function
    - Own mistake vs colleagues mistake
- Previous experiences of reporting mistakes
    - In other organisations
    - In current position
- Availability of relevant stakeholders
    - Can you get an access to the supervisor?

Value of a good night sleep?

- So far we have only spoken about the impact on financial side...
- But... what is the value of our mental and physical well-being?
- Hiding mistakes takes lot of energy and causes anxiety
- The later we find out the mistakes the more energy it takes to correct them
- Good night sleep is also a predictor of work performance

Summary

Source: Psychological Safety - Ripple Rock

- Data base locks, submissions, planning new studies and programs, ... can be stressfull.

- Being in the learning/performance zone is both more efficient and better for our well-being

High psychological safety and high performance are complementary not competitive

Panel discussion:

Panel Discussion

Dirk Klingbiel

Associate Director Biostatistics @Bristol Myers Squibb

Clélia Cahuzac

Senior Statistical Scientist @ Roche

Anna Wiksten

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Justine Rochon

SVP Global Biostatistics & Data Sciences @Boehringer Ingelheim

What is one actionable insight or key takeaway that resonated with you?

How you can apply it within your own teams or projects?