

# LabCIRS

**L**aboratory **C**ritical **I**ncident **R**eporting **S**ystem

**A tool for transparent error culture in preclinical research**

QUEST Seminar on Responsible Research

January 31<sup>th</sup> 2023

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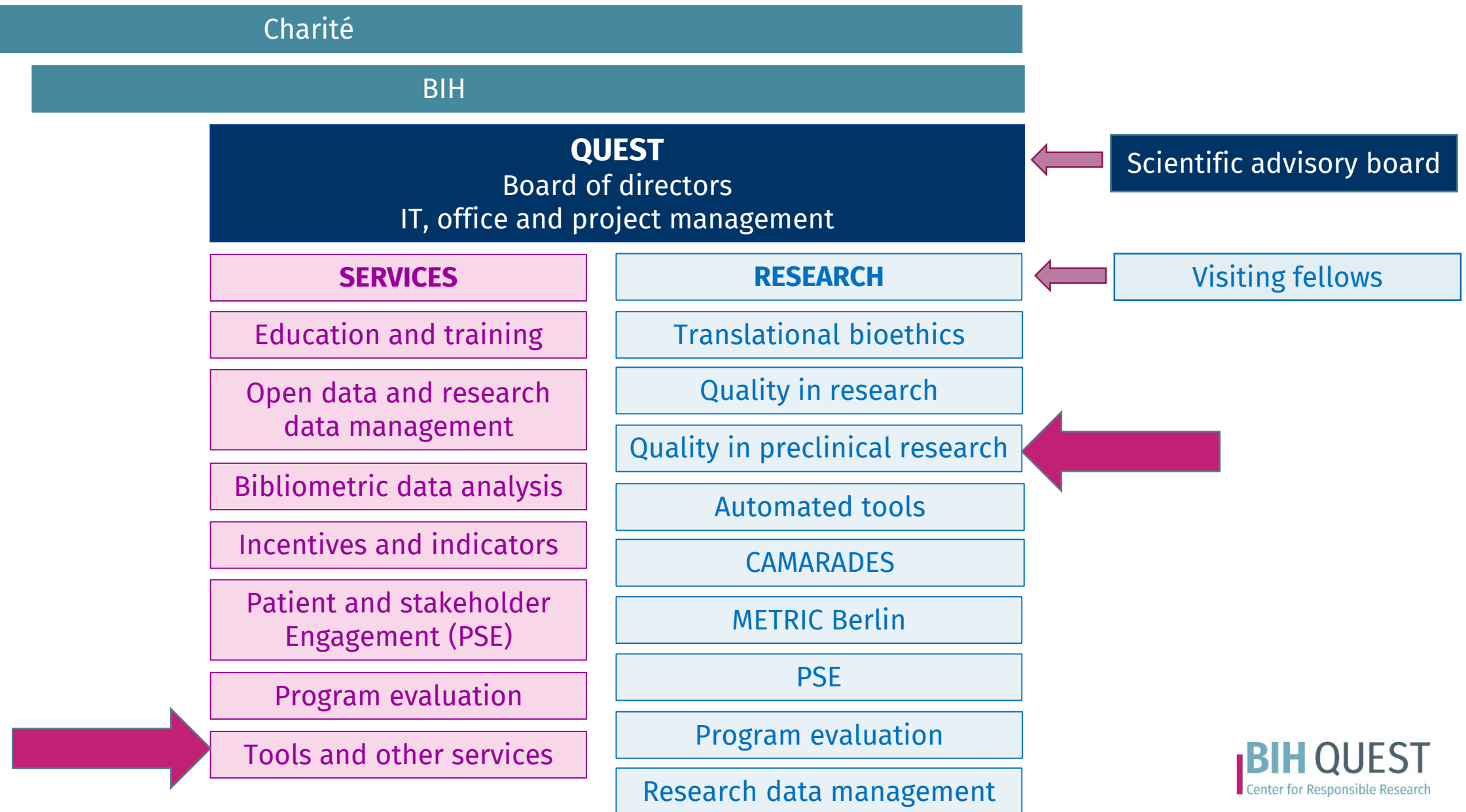
**BIH QUEST**  
Center for Responsible Research



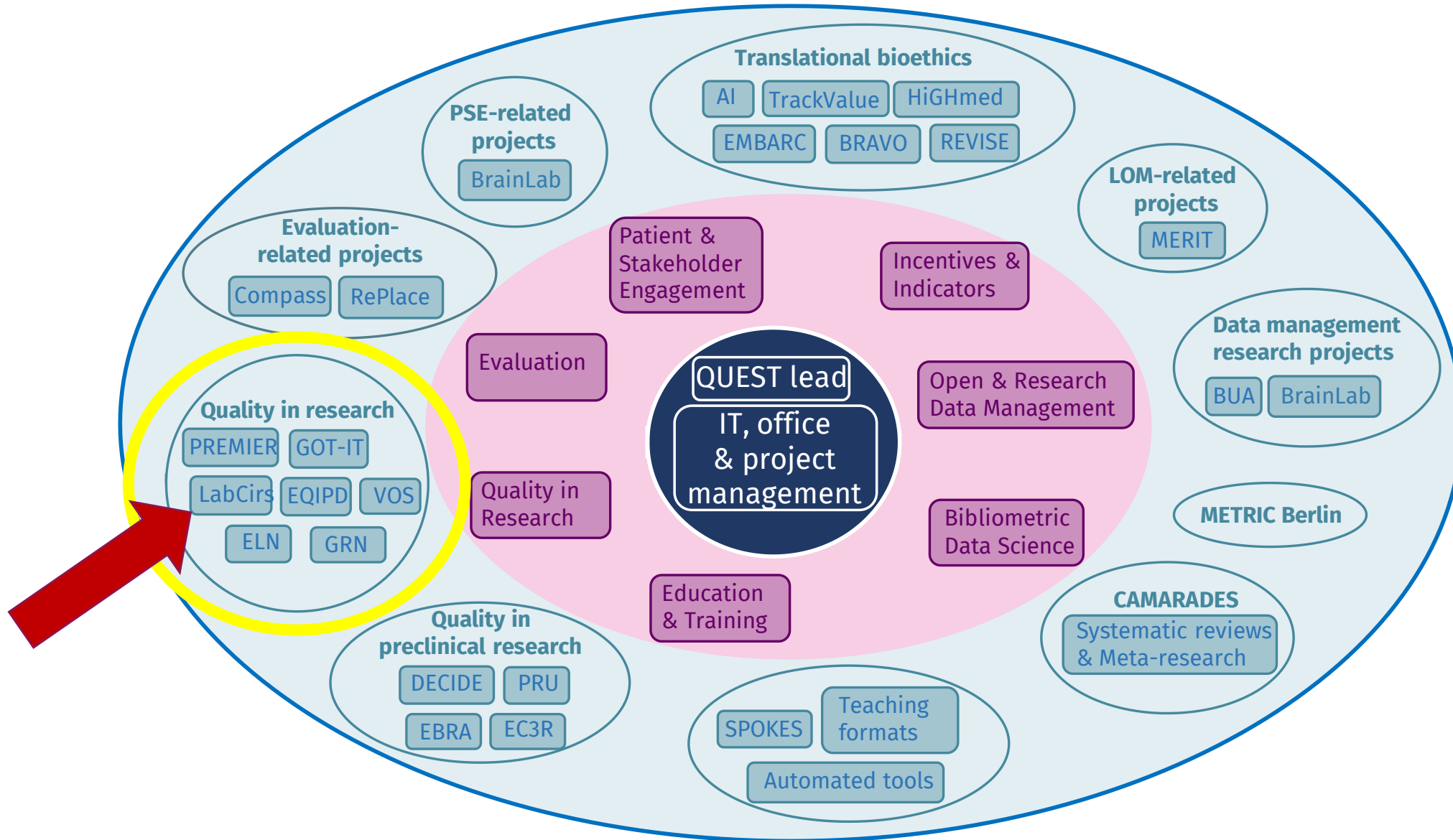
STIFTUNG CHARITÉ

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# QUEST structure and work within the BIH and Charité



# QUEST internal structure



# Dealing with errors in research

- Critical incident reporting in clinical medicine has long been an internationally recognized tool for improving patient safety, required by law in many countries.
- In biomedical research, such a concept has been completely missing, even though a number of critical incidents and errors can occur in the complex environment of a research laboratory.

# Dealing with errors in research

**Which errors are not uncommon in the laboratory? What can they influence in research?**

Errors in research have the potential to affect:

- the integrity of data
- the experimental results
- animal welfare
- the safety of personnel or
- affect the integrity of expensive reagents or equipment

**-> These errors and critical incidents, are often reported only sporadically or not at all.**

# Why is it so difficult to talk openly about errors in research?

- Reporting critical incidents are covered up for fear of negative consequences (researcher have short contracts).
- There has been no lived error culture in research, such as exists in the clinical field, where it is required by law.
- A lot of people do not see the need to openly discuss errors from the research environment.

**Making mistakes does not have to be negative if we are willing to learn from them and come to the right conclusions.**

**-> It is essential to create a positive error culture!**

# Dealing with errors in research

- The topic first came into awareness during the implementation of ISO 9001 (Quality Management System) in the Department of Experimental Neurology.
- Requirement of the QM system:
  - > to manage the handling of errors within the organization.

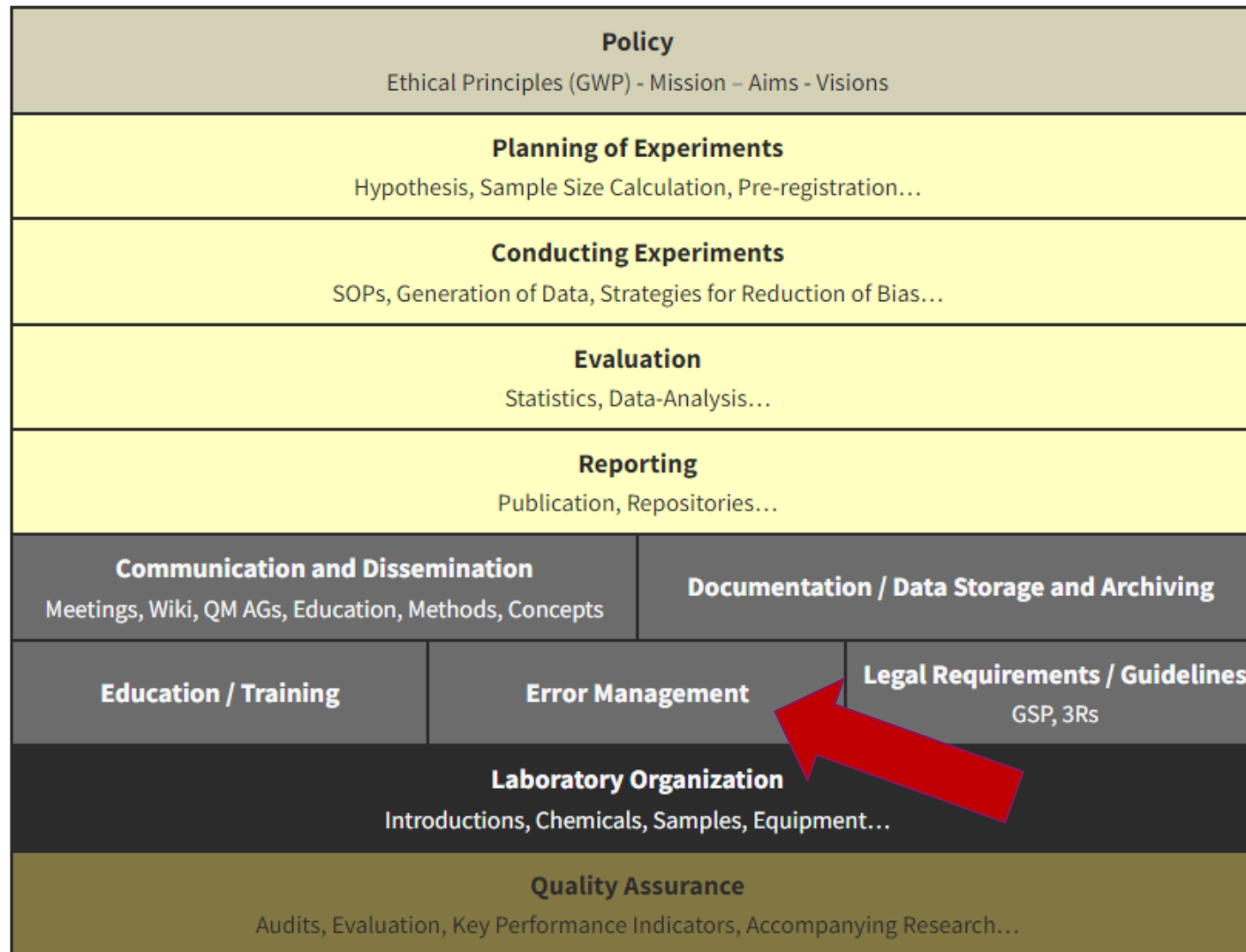
# Dealing with errors in research

- **First step: error collection list**
  - > was not very successful because employees were afraid that anonymity would not be maintained.
- **Further development: an electronic solution**
  - > programming / development of the LabCIRS software
- Dealing with errors is also a requirement in PREMIER (QM system which is specially tailored to basic research).





# PREMIER



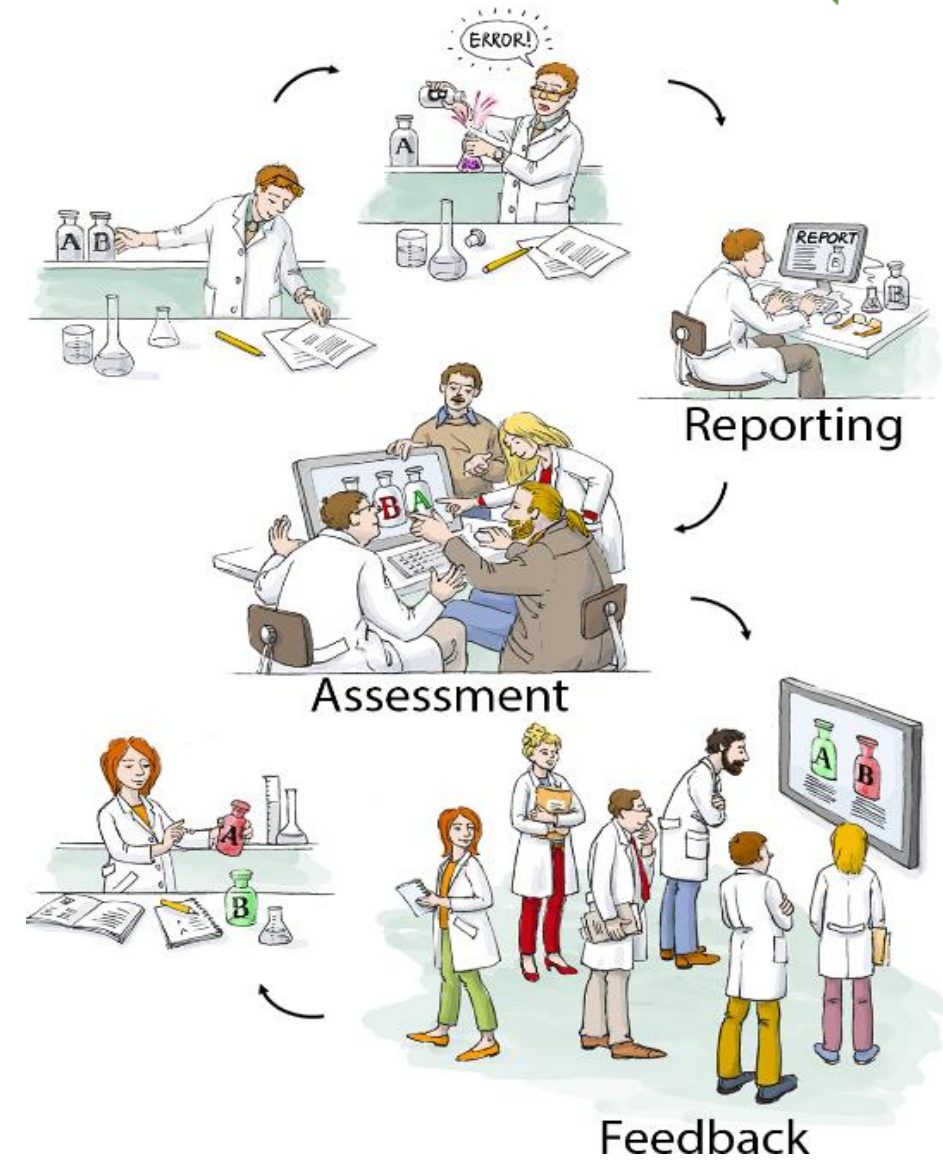
CC BY 4.0

<https://premier-qms.org/>

# LabCIRS (Laboratory Critical Incident Reporting System)



- LabCIRS is an anonymous error reporting system developed by the Department of Experimental Neurology.
- This structured error management is intended to make it easier to learn how to deal with errors and to create a positive error culture.
- Aim is to prevent re-occurrence and identification of risk areas.
- If we want to learn from errors and critical incidents, these errors must be reported, analyzed and improved.



Publication:

<https://journals.plos.org/plosbiology/article?id=10.1371/journal.pbio.2000705>

# Access to LabCIRS

**LabCIRS is an open-source software and can be used by every laboratory.**

## Charité internal labs:

- Service QUEST Center:

[labcirs-admin@charite.de](mailto:labcirs-admin@charite.de)

## External:

- Demo Version:

<http://labcirs-demo.charite.de>

- PREMIER Homepage:

[PREMIER toolbox - Premier \(premier-qms.org\)](http://premier-qms.org)

- Github:

[GitHub - major-s/labcirs: LabCIRS - a lightweight anonymous Laboratory Critical Incidence Reporting System](https://github.com/major-s/labcirs)

# LabCIRS

- With the help of LabCIRS, a large number of errors have been recorded since its introduction, their recurrence could be avoided, the laboratory could be made safer, and the error culture could be improved.
- Crucial to the success of this process is the willingness to report, discuss, and openly communicate errors and countermeasures.
- The success of the LabCIRS depends largely on maintaining anonymity or confidentiality. This concerns both the identity of the person reporting and the identity of the persons involved in the specific CIRS case.

# Requirements of LabCIRS

## Requirements:

- critical incidents must be analyzed regularly
  - > **It is crucial that one person keeps the tool running continuously.**
- conclusion and consequences of the analyses must be communicated with involved persons
  - > **Trust and acceptance need to be created.**
- reports and measures need to be visible in LabCIRS for all employees
  - > **Transparency needs to be created.**
- reported errors must receive positive feedback and be appreciated
  - > **It is essential that leadership supports a positive error culture.**
  - > **Feedback of the implemented measures prevents the reoccurrence of the same error.**



## SOP Steriles Arbeiten Zellkultur

### English Version

Revision	Stand	Autor
03	08.10.2021	DFRE

#### Inhaltsverzeichnis [Verbergen]

- 1 Änderungen gegenüber der vorherigen Version
- 2 Ziel
- 3 Hintergrund
- 4 Geltungsbereich
- 5 Prozessbeschreibung, Handlungsabläufe
  - 5.1 Material
  - 5.2 Durchführung der Arbeiten
  - 5.3 Abfall und Reinigung
- 6 Bewertung/Kontrolle
- 7 Mitgeltende Unterlagen

### Änderungen gegenüber der vorherigen Version [ Bearbeiten | Quelltext bearbeiten ]

- |      |                                   |
|------|-----------------------------------|
| 5.3. | Abfall und Reinigung aktualisiert |
|------|-----------------------------------|

### Ziel [ Bearbeiten | Quelltext bearbeiten ]

Eine Grundvoraussetzung für erfolgreiches Arbeiten in der Zellkultur ist es, Kontaminationen der Kulturen mit Bakterien, Hefen, Mykoplasmen oder Fremdzellen zu vermeiden.

### Hintergrund [ Bearbeiten | Quelltext bearbeiten ]

Maßnahmen zur Vermeidung der o.g. Kontaminationen werden unter dem Begriff „steriles Arbeiten“ zusammengefasst. Die Anforderungen an steriles Arbeiten sind für jedes Forschungslabor etwas anders und unterscheiden sich außerdem von denen im klinischen Bereich.

### Geltungsbereich [ Bearbeiten | Quelltext bearbeiten ]

Fachbereich Zellkultur

### Prozessbeschreibung, Handlungsabläufe [ Bearbeiten | Quelltext bearbeiten ]

Die im Folgenden aufgeführten Handlungsanweisungen stellen keine Reihenfolge dar, sind aber beim sterilen Arbeiten in der Zellkultur grundsätzlich einzuhalten.

Zusätzliche Schutzmassnahmen (Kittel, Handschuhe, Abflammen der Flaschenöffnungen,

Abwischen mit Descosept u. a.) sind aber jederzeit nach eigenem Ermessen möglich.

### Material [ Bearbeiten | Quelltext bearbeiten ]

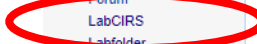
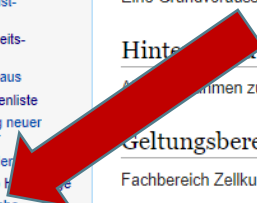
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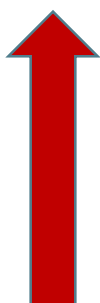
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## Critical incidents for ExpNeuro

Show  entries

Search:

Incident	Description	Measures and consequences	Photo	Date
Neuron prep: Tissue could not be completely dissociated.	Overall workup was obvious. (for further details see Labfolder Project Prep Ctx Mouse 2022). This was observed in all 5 approaches. The number of cells recovered was significantly lower than the long-term average. Cause of error: Based on the protocol aliquots, it could be understood that the newly prepared trypsin/EDTA solution was 1 x solution, but was used like 10 x solution. Therefore, no regular digestion of the intercellular compounds.	Some of the aliquots are thrown away and the rest are provisionally labeled with appropriate note. Aliquoting of 10 x trypsin. Proposal: in future, four-eye principle for aliquoting and labeling of aliquots.		September 2022
The filter slides in the Tecan-Reader were blocking the fluorescence light so that no reliable measurements were possible, it showed only negative results.	Since the button for the wavelength filters is next to the plate out/plate in button, it might happen that its pressed accidentally, and then the filters were pushed inside again to strong, they are very sensitive and only need a light touch to be in their correct position.	If the button for the filter slides on the Tecan machine is pressed accidentally, please contact someone responsible for the device, e.g. Dorette Freyer, or when filter slides are pushed back in the machine, please do so very carefully and validate their correct position with a short measurement afterwards. Thank you!		May 2022
96-well plate was jammed inside of the Tristar-platereader.	The lid was still on the 96-well plate and additionally the second black frame -> that was too high.	The 96-well plate could be removed successfully and the device is functional again. In the future: please measure without the black frame or remove the lid. If possible: I recommend to measure without the lid.		June 2022
The milligram scale in laboratory 2 was not cleaned after use.	On the scale there is a not small amount of white substance. It could be the same that was entered in the scale book, but not necessarily. I.e. it is not clear whether it is not a hazardous substance! It is probably not the first time it has occurred (refers to all scales), however, the frequency is not known. Cause of error: Carelessness?	The last registered person was addressed and was very sure to have left the scale clean after use. Incident was also addressed in the lab meeting and the person who caused it was asked to remove it. The main problem is that the substance on the scale is not known for sure and it could be a hazardous substance.		May 2022

Date of incident:

Mistake / problem / critical incident:

Cause of failure:

Immediate action / suggestion:

Immediate action or suggestion regarding prevention / troubleshooting

Preventability:

In your opinion, was the incident avoidable or not?

Photo:  Keine ausgewählt

Publication:  I agree that this report will be made public to people outside the quality management team after copyedit.  
 I DO NOT agree that this report will be made public to people outside the quality management team even after copyedit.

Anonymous report will be send. There is no possibility to change the report.



## Change Critical incident

[HISTORY](#)[VIEW ON SITE](#) >

## Reported incident

Date of incident: Sept. 6, 2022 Date of report: Sept. 6, 2022

Publication: I agree that this report will be made public to people outside the quality management team after copyedit.

Mistake / problem / critical incident: Neuronenpräp: Gewebe konnte nicht vollständig dissoziiert werden, insgesamt war die Aufarbeitung auffällig. (weitere Details s. Labfolder Projekt Präp Ctx Maus 2022). Das wurde bei allen 5 Ansätzen festgestellt.  
Die Anzahl der gewonnen Zellen war deutlich niedriger als im langjährigen Durchschnitt.

Cause of failure: Anhand des Protokolls Aliquotierungen konnte nachvollzogen werden, dass die neu angesetzte Trypsin/EDTA Lösung 1 x Lösung war, aber wie 10 x Lösung verwendet wurde. Daher kein regulärer Aufschluß der interzellulären Verbindungen.

Immediate action / suggestion: Ein Teil der Aliquots wird verworfen, der Rest vorläufig mit entsprechenden Hinweis versehen.  
Aliquotierung von 10 x Trypsin.  
Vorschlag: zukünftig Vieraugenprinzip beim Aliquotieren und Kennzeichnen der Aliquots  
Immediate action or suggestion regarding prevention / troubleshooting

Preventability: appraisal not possible  
In your opinion, was the incident avoidable or not?

Photo:

Photo:

## Review (Hide)

Review date: 2022-09-06 Today  Status: in process 

Immediate action or suggestion regarding prevention / troubleshooting

Preventability: appraisal not possible

In your opinion, was the incident avoidable or not?

Photo:

Photo:

Review (Hide)

Review date:

2022-09-06

Today | 

Status:

in process



Risk classification:

low



Frequency:

singular case (for the first time)



Hazard:

low



For employees or science

Responsibility:

alle, die die Neuronenpräp durchführen

Action:

Besprechung im Labmeeting

Category:

- organisation/communication
- technique/methods
- knowledge/training
- concentration/attention (mistake/slip)
- infrastructure
- other



Category:

- organisation/communication
- technique/methods
- knowledge/training
- concentration/attention (mistake/slip)
- infrastructure
- other

German

English

PUBLISHABLE INCIDENTS

INCIDENT	DESCRIPTION	MEASURES AND CONSEQUENCES	PUBLISH	TRANSLATION INFO
<p>Neuron prep: Tissue could not be completely dissociated.</p> <div style="border: 1px solid #ccc; padding: 5px; min-height: 20px;">Neuron prep: Tissue could not be completely dissociated.</div>	<p>Overall workup was obvious. (for further details see Labfolder Project Prep Ctx Mouse 2022). This was observed in all 5 approaches. The number of cells recovered was significantly lower than the long-term average. Cause of error:</p>	<p>Some of the aliquots are thrown away and the rest are provisionally labeled with appropriate note. Aliquoting of 10 x trypsin. Proposal: in future, four-eye principle for aliquoting and labeling of aliquots.</p>	<input checked="" type="checkbox"/>	<p>Translation complete!</p>

Save and continue editing

SAVE

# LabCIRS at Charité level

- Ombudsman and GSP office would like LabCIRS to be raised to the Charité level, like the clinical CIRS system, so that all researchers have the opportunity to report errors and critical incidents from research in order to learn from them.
- LabCIRS is only used by a few labs yet.
- Our goal is to increase the number of LabCIRS users to network with them in order to exchange information and experiences.

# LabCIRS at FEM

- One LabCIRS user has been the FEM (the animal facility of the Charité) for several years.
- Mrs. Grote is the quality manager of FEM and has introduced LabCIRS in her department some years ago. She will now report on her experiences.