# Electronic Lab Notebooks @MDC

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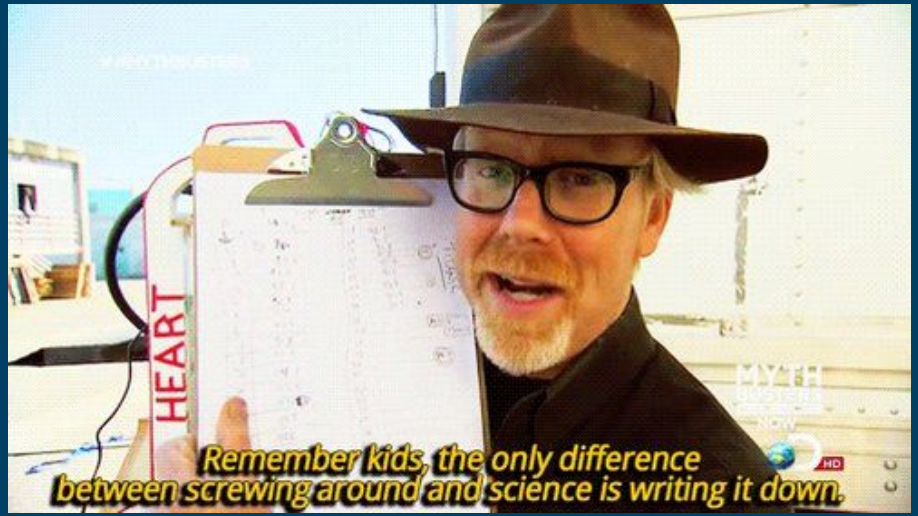
# Research Data Management at the MDC

Supporting researchers through all phases of the **research data life cycle**

- Planning
- Data collection, Management and Analysis
- Preservation and Sharing

*Everyday management of research data during the lifetime of a research project to preserve and share it beyond the project completion.*

# Data documentation




https://www.tested.com/making/557288-origin-only-difference-between-screwing-around-and-science-writing-it-down/

# Anonymous survey

- What are the current practices?
- What are people using?
- What are their needs and requirements?
- What challenges do they face and what is deterring them from using an ELN?

## Researchers

- Functionalities differ between Mac and Windows users.
- Not academically oriented (chemical structures, formulas, protocols)
- Data integration from multiple devices is not supported

## RDM

- Limited metadata capturing
- Content locking-only through PDF (not open format)
- No stable URLs or persistent identifiers for entries
- No API connections to other resources- data loss
- Data reusability by other solutions is limited

## Technical

- Microsoft is sunsetting OneNote 2016
- Overseas cloud storage requires data processing agreements and certifications in place
- OneNote 2016 still has a number of features that OneNote for Windows 10 lacks (creating outlook tasks, tags, applying templates)
- Retaining old versions of a software presents security risks

## Legal

- Signing and witnessing is not straightforward
- Time/date stamps can be easily modified
- Ensuring **compliance** is relatively difficult

# Compliance

**EU**

**Good Manufacturing Practice (GMP)** introduced by EudraLex Volume 4 —GMP Guidelines, Annex 11.

EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Public Health and Risk Assessment
**Pharmaceuticals**

Brussels,
SANCO/C8/AM/sl/ares(2010)1064599

**EudraLex**
**The Rules Governing Medicinal Products in the European Union**

**Volume 4**
**Good Manufacturing Practice**
**Medicinal Products for Human and Veterinary Use**

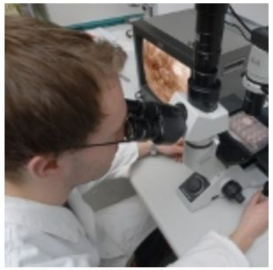
**Annex 11: Computerised Systems**

**Legal basis for publishing the detailed guidelines:** Article 47 of Directive 2001/83/EC on the Community code relating to medicinal products for human use and Article 51 of Directive 2001/82/EC on the Community code relating to veterinary medicinal products. This document provides guidance for the interpretation of the principles and guidelines of good manufacturing practice (GMP) for medicinal products as laid down in Directive 2003/94/EC for medicinal products for human use and Directive 91/412/EEC for veterinary use.

**EU**

**Good Laboratory Practice (GLP)** introduced by Organization for Economic Co-operation and Development(OECD).

## GLP Federal Bureau



**What is GLP?**

"Good Laboratory Practice (GLP) is a quality system concerned with the organisational process and the conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported."

This is the definition of "Good Laboratory Practice" in the "OECD Principles of Good Laboratory Practice" which were then transposed into EC Directives and, after that, into German law as Annex 1 of the German Chemicals Act. The entire sixth section of the Chemicals Act is devoted to Good Laboratory Practice. In paragraphs 19a to 19d the scope and type of monitoring of GLP are laid down by law.

# Compliance

**USA**

**Title 21 CFR Part 11 of the Code of Federal Regulations** introduced by US Food and Drug Administration (FDA).

Title 21: Food and Drugs

**PART 11—ELECTRONIC RECORDS; ELECTRONIC SIGNATURES**

**Contents**



**System requirements**

- Data is true and accurate with built in checks
- Data is secure against damage, accidental loss, manipulation
- Everything including older versions remain available for inspection, including deleted files
- Human readable exports for inspection
- Secure audit trail that records all user actions with timestamps
- All changes are visible
- Digital signatures and witnessing

# Background Assessment

- Which solutions are most commonly used in life sciences? How are they comparable?
- What are the processes of integration of ELNs in different organisations?

**Guides & websites:**

- **Research Notebooks Blog** - Working Group https://researchnotebooks.wordpress.com/outputs/
- **ZBmed** https://www.zbmed.de/en/about/press/latest-news/article/electronic-labnotebooks-guide-now-also-available-in-english/
- **IT and Research Data Management in the Gurdon Institute** https://www.gurdon.cam.ac.uk/institute-life/computing/elnguidance & https://gurdoncomputing.blog/
- **Open Working from 4TU.ResearchData** & TU Delft Library *Open Science Framework: https://doi.org/10.17605/OSF.IO/JR9U2*
- **Harvard Matrix** https://shrtco.de/G55Dy

# Background Assessment

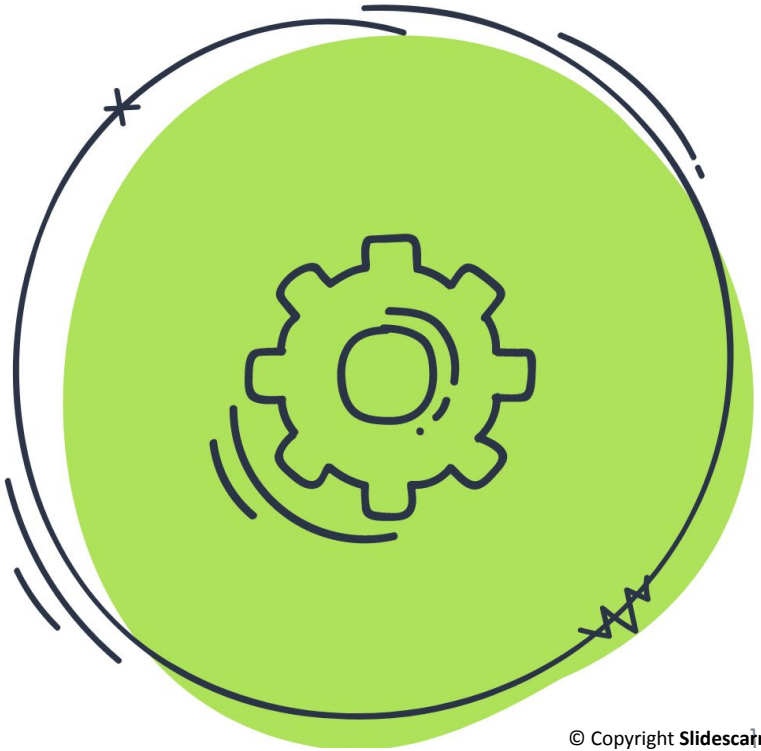
**Workshops and interviews:**

- Researchers suggestions
- Current practices
- Enlisting support of researchers to promote the use of ELNs

# Requirements assessment

- Identifying technical and security requirements from stakeholders ( IT, ISO, DPO):
  - On-premise installation
  - SSO integration
  - Test installation
  - Open source components

- Compliance



# Solutions selection

In-depth analysis of 6 solutions

- Benchling
- LabArchives
- LabFolder (used by MDC researchers)
- OneNote (used by MDC researchers)
- Rspace
- SciNote

| | ELN solutions | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Features/ELN solution** | **Benchling** | **LabArchives** | **Labfolder** | **OneNote** | **RSpace** | **SciNote** | | |
| Features and Design | | | | | | | Scale | |
| Intuitive Interface Design | 2 | 2 | 2 | 1 | 2 | 2 | 0 | no |
| Able to search for documents within the platform | 2 | 2 | 2 | 1 | 2 | 2 | 1 | partial-see com |
| Able to search beyond file formats | 2 | 2 | 2 | 2 | 2 | 2 | 2 | yes fully |
| Able to search beyond typographical errors | 2 | 2 | 2 | 2 | 2 | 2 | | |
| Transparency of file structure | 2 | 2 | 2 | 2 | 2 | 2 | | |
| Can manipulate text documents | 2 | 2 | 2 | 2 | 2 | 2 | | |
| Can manipulate spread sheets | 2 | 2 | 2 | 2 | 2 | 2 | | |
| Can manipulate images | 2 | 2 | 2 | 2 | 2 | 1 | | |
| Can manipulate datasets | 2 | 2 | 2 | 2 | 2 | 0 | | |
| Can manipulate other elements | 1 | 2 | 0 | 2 | 2 | 0 | | |
| Support for multiple open windows | 2 | 2 | 2 | 2 | 2 | 2 | | |
| Ability to link out | 2 | 2 | 2 | 2 | 2 | 2 | | |
| Training | 2 | 2 | 2 | 0 | 2 | 2 | | |
| Documentation | 2 | 2 | 2 | 2 | 2 | 2 | | |
| Links to open repositories | 0 | 1 | 2 | 0 | 2 | 0 | | |
| Links to DropBox/ OneDrive/GoogleDrive | 1 | 1 | 1 | 1 | 2 | 0 | | |
| Recovery Options | 1 | 2 | 2 | 2 | 2 | 2 | | |
| Single Sign-on (institutional ID) | 2 | 2 | 2 | 2 | 2 | 2 | | |
| Windows Compatible | 2 | 2 | 2 | 2 | 2 | 2 | | |
| Macintosh Compatible | 2 | 2 | 2 | 0 | 2 | 2 | | |
| Linux Compatible | 2 | 2 | 2 | 0 | 2 | 2 | | |
| Android Compatible | 2 | 2 | 2 | 2 | 2 | 2 | | |
| iOS Compatible | 2 | 2 | 2 | 0 | 2 | 2 | | |
| Web interface | 2 | 2 | 2 | 2 | 2 | 2 | | |
| Open Science/Open Data Efforts | 0 | 1 | 2 | 0 | 2 | 1 | | |
| Academically Oriented | 2 | 2 | 2 | 0 | 2 | 2 | | |
| Can be expanded to LIMs/Integrated with another LIMs | 2 | | 0 | 0 | 2 | 2 | | |

https://shrtco.de/hXqXa

# Introduction of Rspace

## 01 Onsite installation

Data security controlled by us, connected to local storage

## 02 User Friendly

Search, Easy to use, academically oriented, 24h chat support services, training videos

## 03 Compliant

GLP (Good Laboratory Practice) Compliance & FDA 21 CFR Part 11

## 04 Workflows

Standardized workflows and templates, saves time, quality assurance

## 05 Open Export

Export in **open formats**, you can export your data and use the free version

## 06 Inventory Module

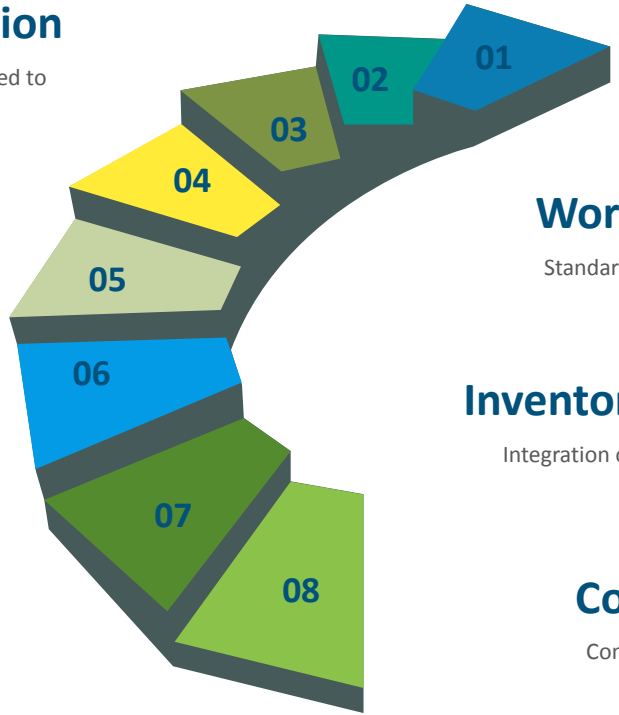
Integration of sample management and tracking system

## 07 Integration

Integration through API, can connect to instruments

## 08 Compatible

Compatible with different systems; Windows, Mac, Linux, Android, IOS



# How to choose an ELN?

## Identify your needs

What are the main criteria when it comes to:

- Features and design
- Content creation tools
- Hosting
- Security
- Storage

## Compare products

- What is commonly used in your field?
- Narrow down the products based on the must have criteria
- Use comparison Matrices
- Try out free versions!

## Consults Stakeholders!

Check if the product you chose fulfills RDM, Data protection and Information security requirements

# How to get in touch

**Website:**

https://www.mdc-berlin.de/research-data-management#t-rdm

**Email**:

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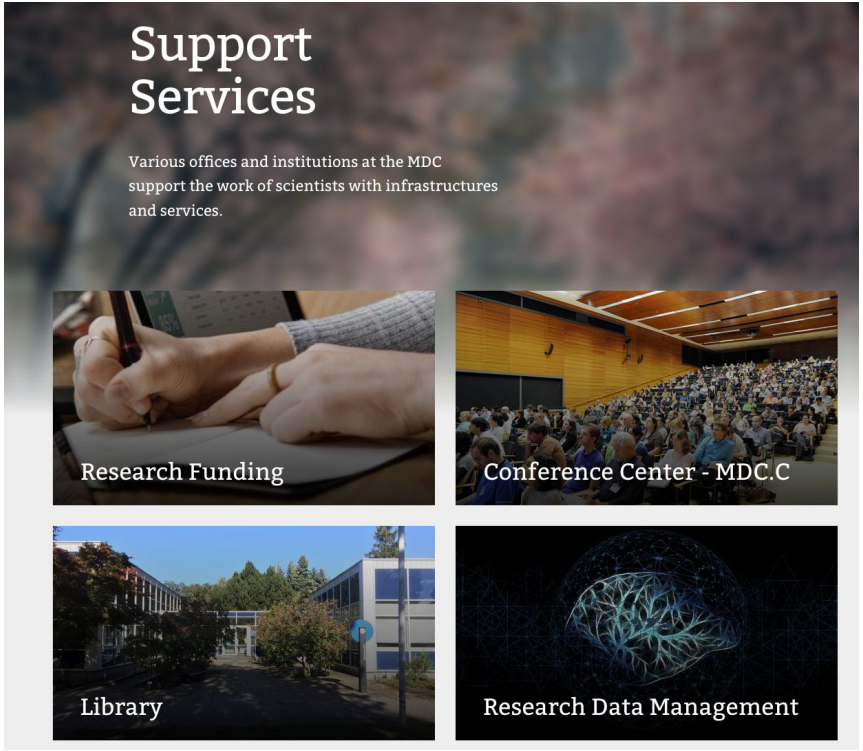
- Özlem Özkan: oezlem.oezkan@mdc-berlin.de



# Resources

- **GLP Federal Bureau** https://www.bfr.bund.de/en/glp_federal_bureau-1488.html
- **Handbook: Good laboratory practice** https://www.who.int/tdr/publications/training-guideline-publications/good-laboratory-practice-handbook-ver1/en/
- **EudraLex** https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-4/annex11_01-2011_en.pdf
- **OECD-GLP** http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/mc/chem(98)17&doclanguage=en
- **Cambridge University Guide** https://www.data.cam.ac.uk/data-management-guide/electronic-research-notebooks/electronic-research-notebook-products
- **LabFolder white papers on Compliance** https://www.labfolder.com/white-papers/
- **Electronic Code of Federal Regulations-CFR** https://www.ecfr.gov/cgi-bin/text-idx?SID=140a04c31974ef0891cfb2555bc3a865&mc=true&node=pt21.1.11&rgn=div5
- **Cost-benefit analysis for FAIR research data** https://op.europa.eu/en/publication-detail/-/publication/d3766478-1a09-11e9-8d04-01aa75ed71a1/language-en
- **Harvard Matrix** https://shrtco.de/G55Dy
- **University of Glasgow Adapted Matrix** https://docs.google.com/spreadsheets/d/1egUW3ZewyIaJ_IhEe8uJrd-69ycVbqQjiqbJxbs_jVY/edit#gid=1172088166
- **Research Notebooks Blog** https://researchnotebooks.wordpress.com/outputs/
- **Electronic Code of Federal Regulations** https://www.ecfr.gov/cgi-bin/text-idx?SID=140a04c31974ef0891cfb2555bc3a865&mc=true&node=pt21.1.11&rgn=div5