EQIPD- a Quality Management System with Industry Standards for Preclinical Research

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The project leading to this application has received funding from the Innovative Medicines Initiative 2 Joint Undertaking under grant agreement No 777364. This Joint Undertaking receives support from the European Union's Horizon 2020 research and innovation programme and EFPIA.

Outline

- Part 1: Why do I need a quality system?
  - What is quality
  - What is a system
  - Benefits of a quality system
  - Can a quality system bring harm
- Part 2: What is the EQIPD quality system about?
  - Key principles
  - Core requirements
  - Framework
  - Users
- Part 3: How do I implement the EQIPD quality system?
- Current and Future Developments

EQIPD Quality System: Why, What and How

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Why do *we* need more quality in research?

- **Meta-research** reveals the extent and illustrates the impact of questionable research practices
- **Ethical concerns** about wasted and misused resources call for action in certain areas of science (such as animal research)
- **Reduced productivity** in drug R&D is linked to lacking robustness of preclinical data
- Questionable practices become part of a **research integrity** agenda

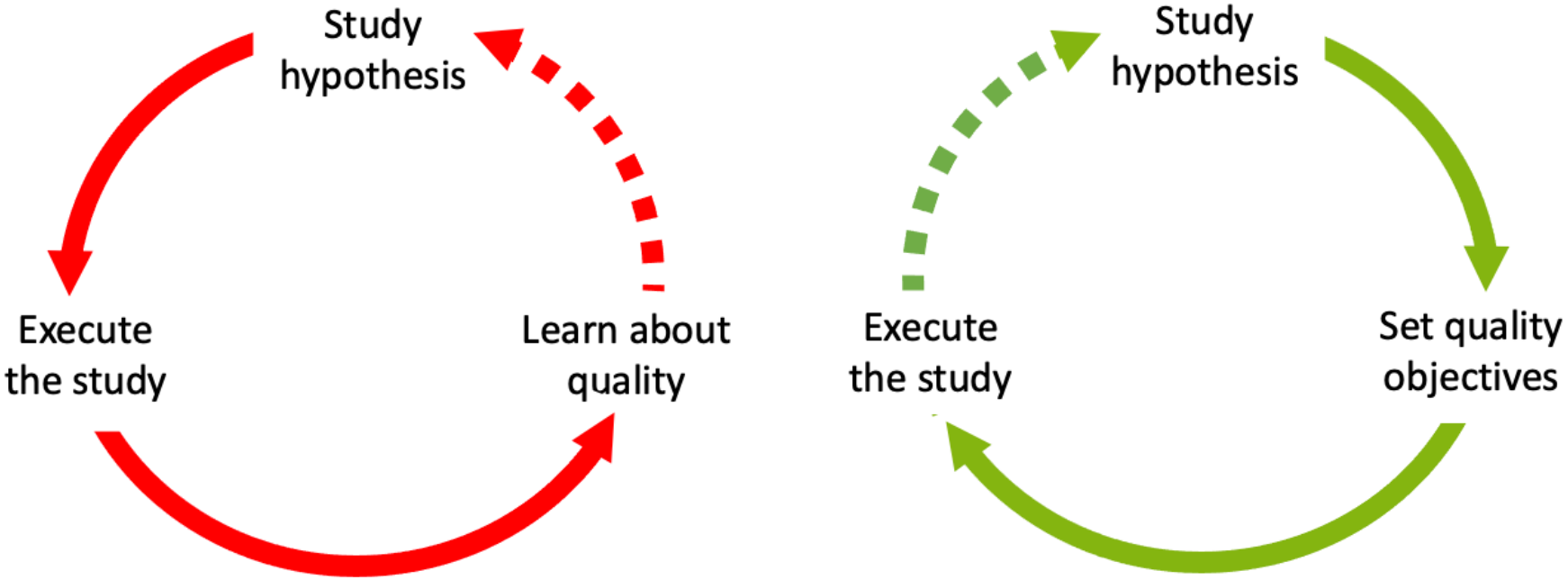
[1] https://www.nature.com/articles/d41586-019-01307-2

European Quality in Preclinical Data

- First IMI consortium completely dedicated to **improving preclinical data quality (2017-2021)**
- Joint undertaking by **Big Pharma**, **CROs**, **Academia** and **Scientific Associations**
- **110+** member organizations, advisors, stakeholders around the globe
- Scientific leaders, researchers and quality professionals with **unique expertise in various aspects of Good Research Practice**

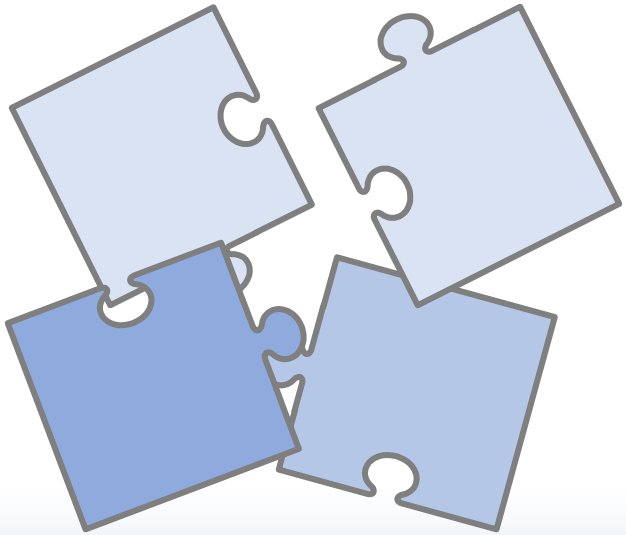
EQIPD definition of quality

- Quality defined as research data being fit for intended use
- Fitness is defined by the scientists based on the needs of their organizations, funders, collaborators, and publishers



A quality system

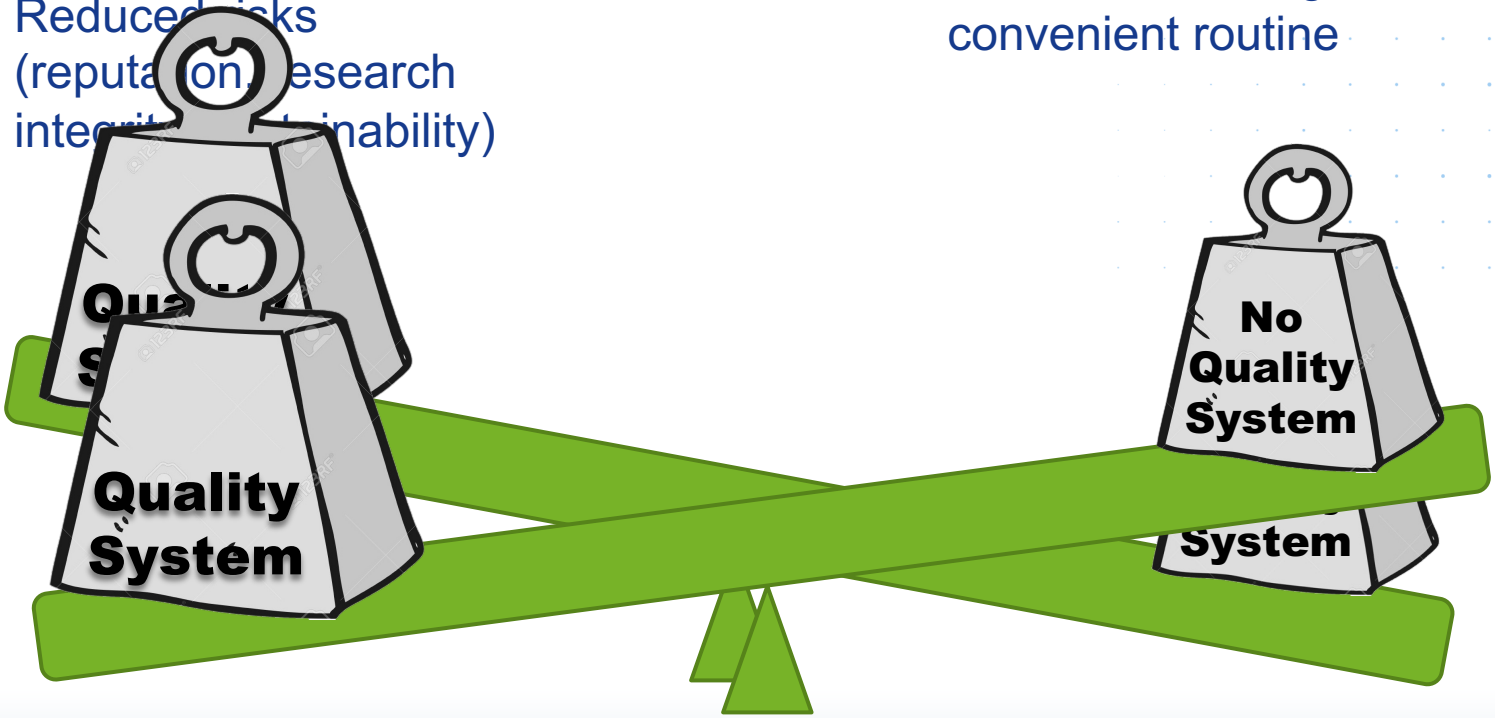
- A tool to coordinate and direct an organization's activities to meet quality objectives and to improve its efficiency on a continuous basis
- A „mirror" that we use to evaluate how we perform and what needs to be changed or improved



EQIPD quality system: Harm-benefit analysis

- Better publications
- Better results
- Ethical and responsible use of resources
- Reduced risks (reputation, research integrity, sustainability)

- More publications
- More positive results
- More unexpected findings
- No need to change the convenient routine



EQIPD Quality System: Why, What and How

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EQIPD Quality System: Core Requirements

Good Research Practice will be maintained

Continuous improvement

6 core requirements

Quality System

Good Research Practice is established

Data integrity and rigor in study design, conduct, analysis & reporting

9 core requirements

Purpose-fit

Good Research Practice is enabled

Defined quality objectives, research integrity, compliance with applicable law

3 core requirements

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Can we get there?

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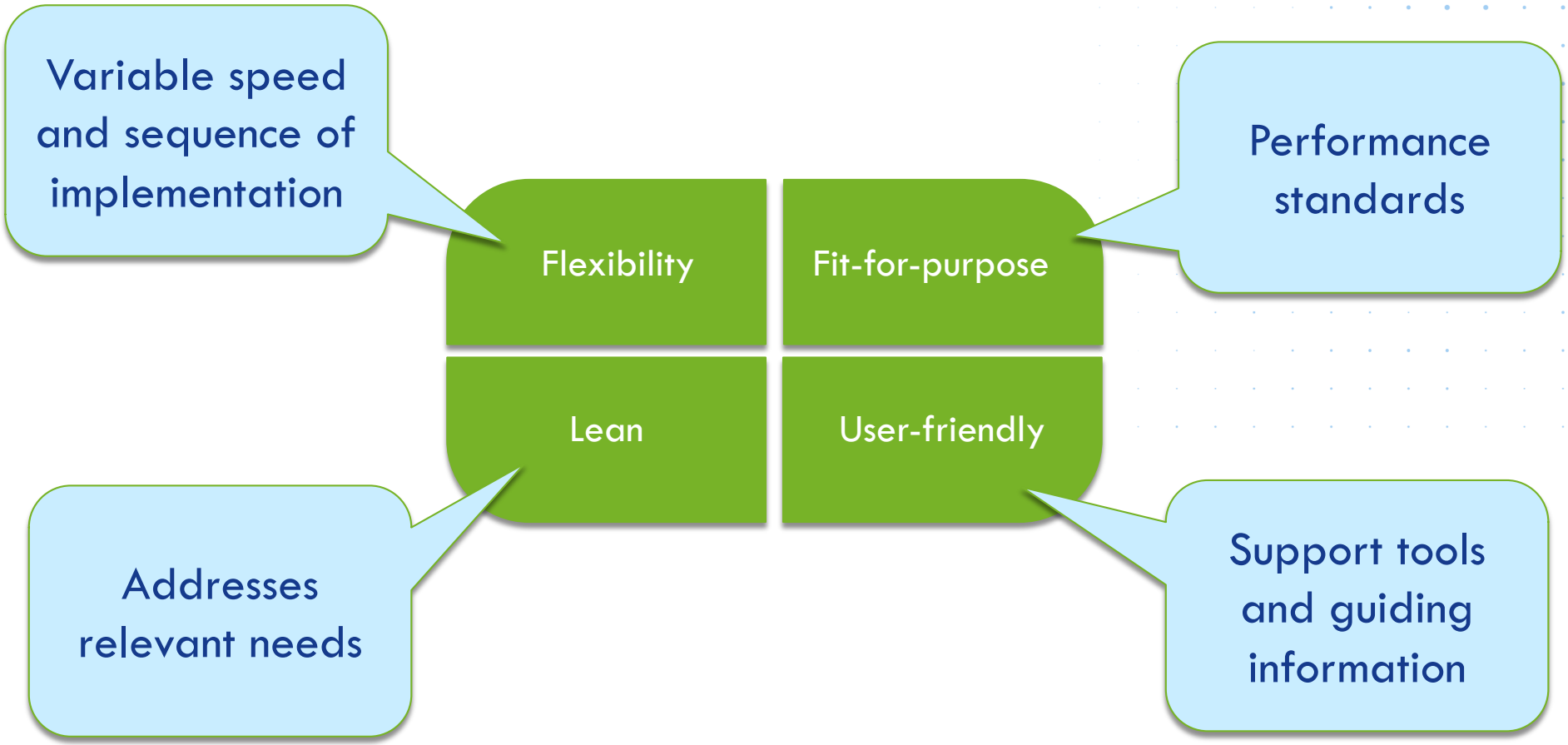
Yes, we can and there is more than one route!

EQIPD Quality System: Key Principles



EQIPD Quality System: Why, What and How

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Implementing the Quality System

Get familiar with the key terms defined by EQIPD

Take a closer look at EQIPD's expectations

Are most core requirements met?

YES

Scenario 1

- Complete self-assessment
- Consult with the EQIPD team
- Address remaining core requirements

NO

Scenario 2

- Follow suggested implementation path
- Use EQIPD tools for support
- Seek advice from the EQIPD team

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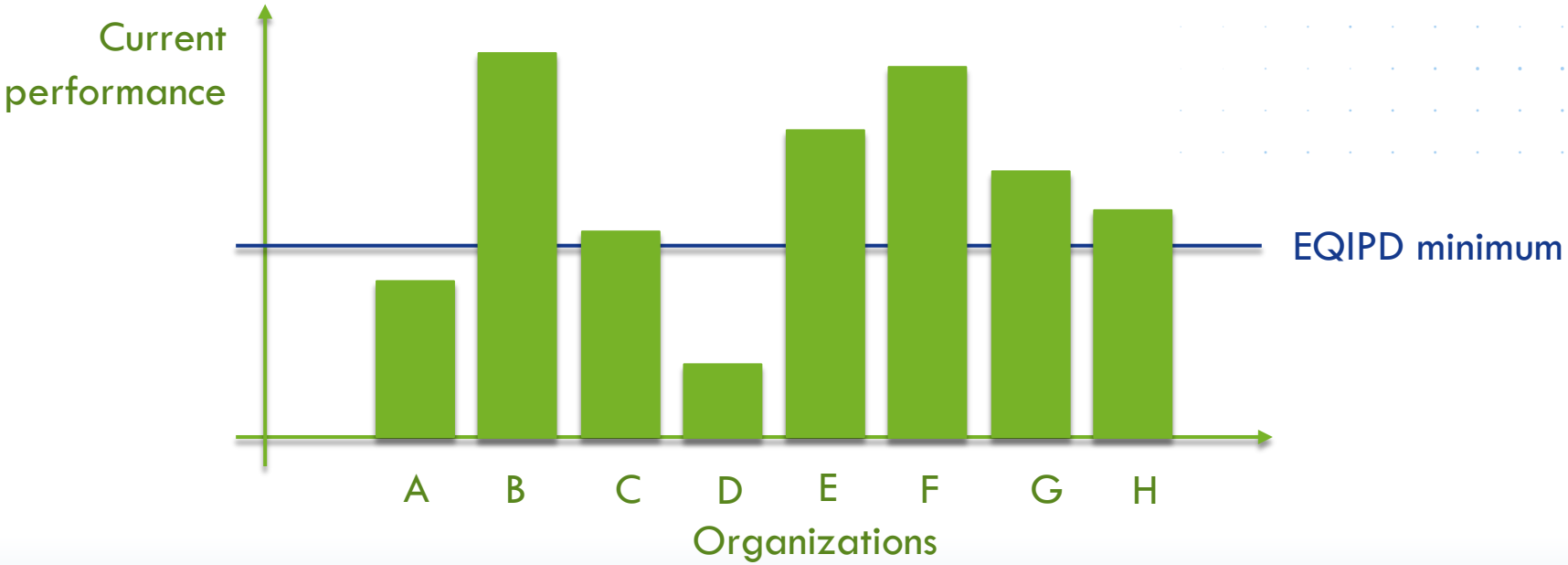
Implementation of core requirements

- Initial setup
- Process owner
- Communication plan
- Documentation plan

Everyone made alike or everyone to meet a minimum standard?

- Cultural differences
- Different starting levels
- Many organizations exceeding EQIPD expectations without further effort



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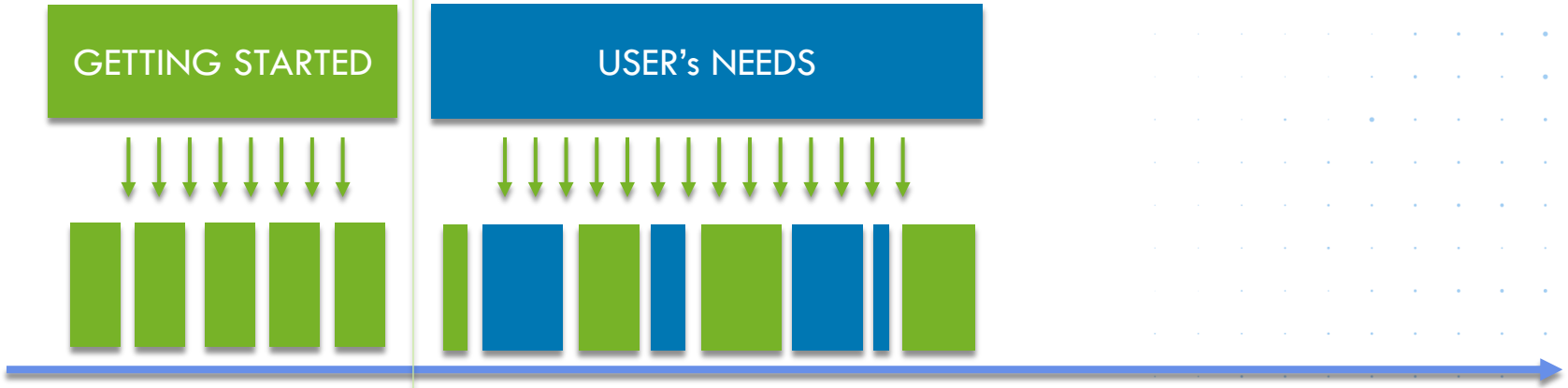
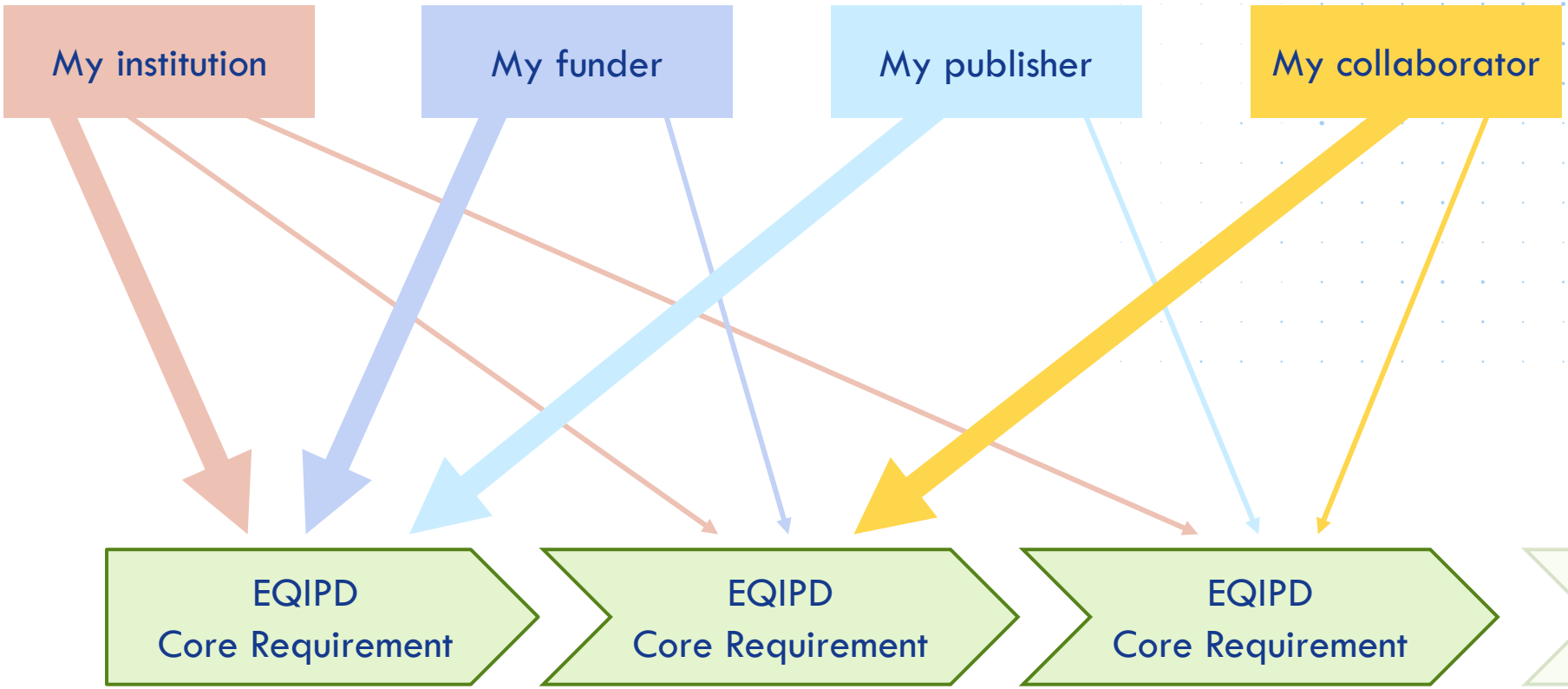
Implementation of core requirements



- Initial setup
- Process owner
- Communication plan
- Documentation plan

- Core requirements linked to or derived from the user-specific needs

Implementation of core requirements: Driven by user's needs



A need:
My funder has set certain research rigor expectations

A challenge:
I have to apply randomization and may have not done it (properly) before

A solution:
Develop and implement a Randomization Protocol

- EQIPD provides:
  - Recommendations
  - Templates / examples
  - Literature and links to tools

We (my team and I):
- Develop a protocol
- Communicate to all affected colleagues
- Provide training (if necessary)

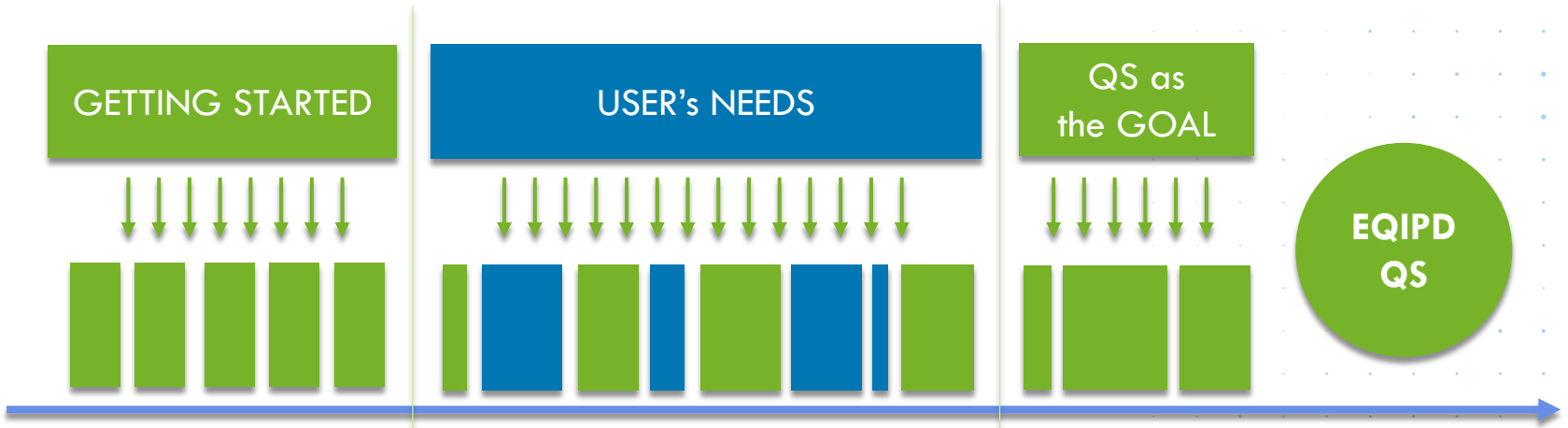
We (my team and I):
- Apply the protocol
- Monitor performance
- Manage errors
- Revise the Protocol (if needed)

EQIPD

efpia imi

- You decide on how the solution looks like, when and how it is implemented
- You work on what you need and, as a by-product, develop what the system ~~needs~~ is

Implementation of core requirements



- Initial setup
- Process owner
- Communication plan
- Documentation plan

- Core requirements linked to or derived from the user-specific needs

- Remaining core requirements

Amount of required documentation

- EQIPD Quality System is built on trust, not on excessive documentation
- Resources for sustaining the EQIPD Quality System must be available
  - ❖ Research unit decides whether any documentation is needed
  - ❖ EQIPD guidance: Lack of resources is not an acceptable argument for not following the best research practices

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Assessment keyword: Transparency

- Critical incidents and errors during study conduct must be analyzed and appropriately managed
- What information is more useful:
  - A document describing how incidents and errors should be managed
    or
  - Actual examples of incidents and errors?

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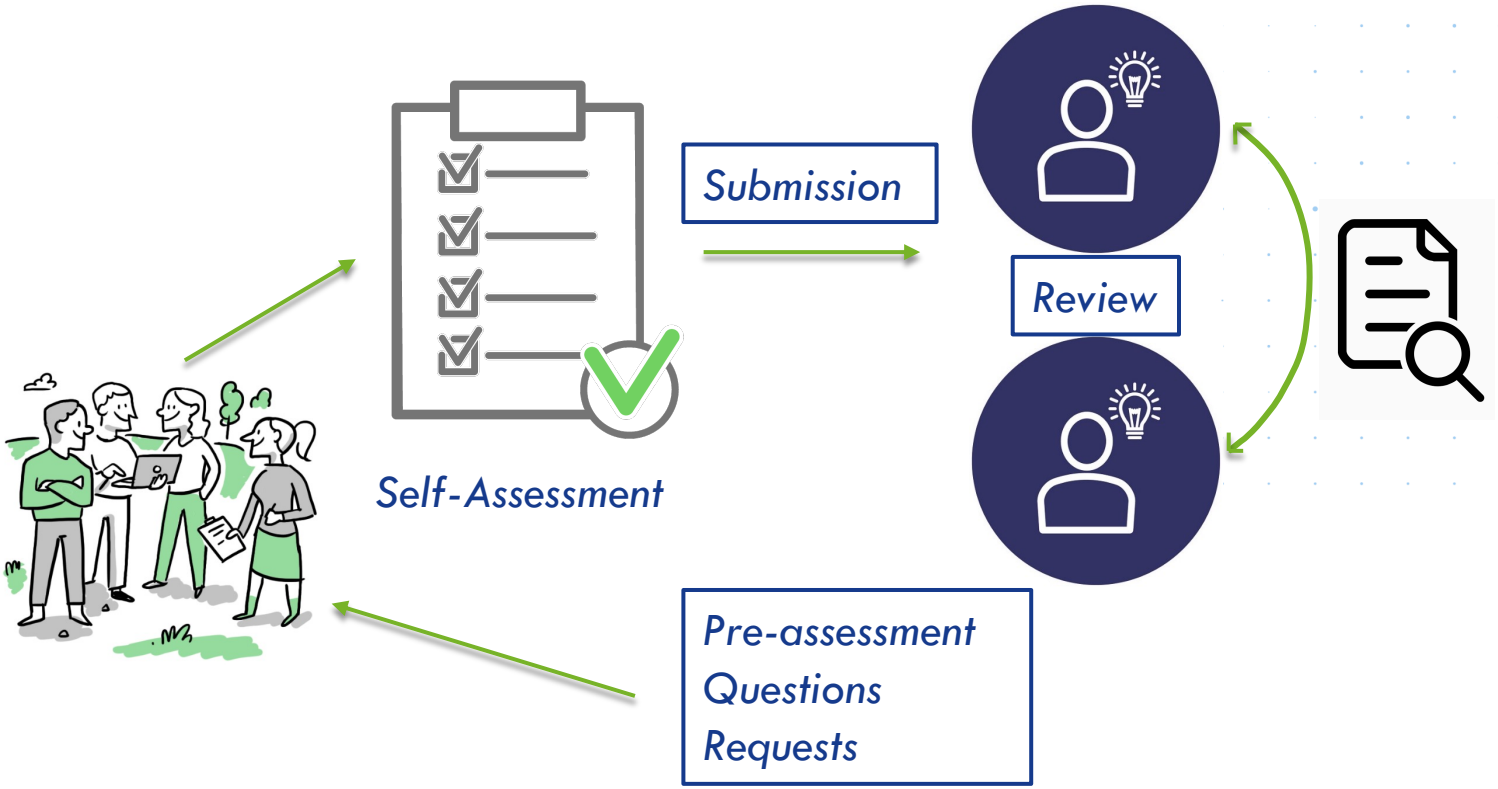
Guideance is good, assurance is better!

- *Did we implement the EQIPD QS in our research environment as intended?*
- *Our self-assessment looks good but an independent verfication would give us and our collaborators more confidence*
- *How do we ensure that we meet future challenges and that my quality keeps improving?*

Expert assessment

Assessment in EQIPD - Step 1



Assessment in EQIPD - Step 2

Assessment interview

- *Results from review of self-assessment and documents*
- *Questions & answers relating to solutions to core requirements*
- *Spot Checks*

Assessment report

EQIPD certificate

EQIPD Quality System: Why, What and How

Sneak Peak

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Dashboard

5 IMPORT NEED | 1 SHOW WIZARD | RISK ASSESSMENT | SELF ASSESSMENT | HELP on u the Planni

CHALLENGE (2)	IMPORTANCE / PRIORITY	GUIDANCE TO DEVELOP SOLUTIONS (3)	SOLUTION (4)	COMMENTS	RI Ar re
EQIPD Core Requirements * Challenge: Process owner must be identified for the Quality System		1.5.2.3 Process Owner	Rene B		
EQIPD Core Requirements * Challenge: Communication process must be in place		1.2 Scope	Communication Plan		
EQIPD Core Requirements * Challenge: The research unit must have defined quality objectives		1.1 Mission	Mission Statement		
EQIPD Core Requirements * Challenge: Generation, handling and changes to data records must be documented		2.3.1 Generation, recording, handling and archiving of raw data	Documentation Plan		
EQIPD Core Requirements * Challenge: Data storage must be secured at least for as long as required by legal, contractual or other obligations or business needs		3.1.3 Data security	Documentation Plan		
EQIPD Core Requirements * Challenge: Reported research outcomes must be traceable to experimental data		3.1.2.1 Traceability of data and any person having impact on data	Documentation Plan		
EQIPD Core Requirements * Challenge: All activities must comply with relevant legislation and policies	3,00 - Must have	1.4.2 Adherence to legal and regulatory consideration	Short answer or link to file.		
EQIPD Core Requirements * Challenge: The research unit must have a procedure to act upon concerns of potential misconduct	3,00 - Must have	4.2.3 Responsible conduct of research	Short answer or link to file.		
EQIPD Core Requirements * Challenge: All personnel involved in research must have adequate training and competence to perform assigned tasks	3,00 - Must have	3.2.1 General guidance and training	Short answer or link to file.		
EQIPD Core Requirements * Challenge: Adequate handling and storage of samples and materials must be ensured	3,00 - Must have	3.3.3 Management of research materials and reagents			
EQIPD Core Requirements * Challenge: Research equipment and tools must be suitable for intended use and ensure data integrity	3,00 - Must have	3.3.2 Enabling computerized and non-computerized systems			
EQIPD Core Requirements * Challenge: Reported data must disclose all repetitions of a study, an experiment, or a test regardless of the outcome	3,00 - Must have	2.4 Reporting			
EQIPD Core Requirements * Challenge: Protocols for experimental methods must be available	3,00 - Must have	3.5.2 Protocols for methods and assays			
EQIPD Core Requirements * Challenge: Critical incidents and errors during study conduct must be analyzed and appropriately managed	3,00 - Must have	4.2.2 Error and incident management			

Dashboard | Risk Assessment | +

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EXAMPLE OF TOOLBOX ITEM – LINKED TO DASHBOARD

EQIPD

Page | Discussion | Read | Edit | View history | Search

Home
Recent changes
Random page
Help

Tools
What links here
Related changes
Special pages
Printable version
Permanent link
Page information

3.1.2.1 Traceability of data and any person having impact on data

A. Background & Definitions [edit]

This item refers to one of the Core Requirements (Core Requirement 8 - "Reported research outcomes must be traceable to experimental data") and is, therefore, considered as essential.

Traceability: The ability to find the source of data (primary and secondary) and any person having relevant impact on data sets that are presented in a report or other presentation.

Experimental Record: An entry in an (electronic) laboratory notebook for an experiment recording all data and pertinent details of an experiment such that a peer could repeat the experiment.

The user must ensure the traceability and integrity of the data so that the reported results can be reconstructed.

Traceability is directly related to the FAIR principles that are endorsed by both academic and industry research communities as well as by the growing number of funders.

B. Guidance & Expectations [edit]

- Each experimental record should contain or cross-reference/link to:
  - Names of all individuals involved in generating the content of the experimental record.
  - Specific research plan, objective, or hypothesis to be addressed by the experiment.
  - All protocols, standard operating procedures, test methods, statistical tools (and/or software used for data analysis) used.
  - Description of all materials and equipment used, including the source and lot number of all starting materials and test compounds.
  - Date each activity was performed.
  - Location of records and materials: Clearly identified location(s) of data files and their content.
  - Other supporting information needed for independent analysis of raw data obtained in experiment and interpretation of results.
  - All raw, processed, and final/reported data generated in the experiment.
  - A proper cross-reference should be added if any raw data is kept separate from the experimental record and cannot be attached to the experimental record, or any raw data is obtained by other researchers performing supporting experiments.
- Expectation: A qualified reviewer should be able to:
  - link figures, graphs, conclusions, and other summary data to the raw data that was processed/analyzed.
  - link the summary data to the corresponding experiment described in a lab notebook entry.
  - link the lab notebook entry to the raw data (e.g., where generated by an automated instrument).
- All related experimental records and supporting research must be linked/cross-referenced in the main experiment (via the respective unique identifiers).
- The raw data obtained in an experiment may be stored in a separate archival system but should be referenced in the experimental record (see 3.1.2 Procedures for how and when to record data).
- If a new analysis of data from previous experimental records needs to be performed to generate a new result or conclusion, a new experimental record should be created, which should clearly cross-reference the earlier experimental records (by their unique identifiers) and conc
- The EQIPD template "Documentation Plan" located in folder 3.1 in the Dossier (and below in Section C) provides a central space to describe this Core Requirement. The document is also used in the Toolbox items 3.1.3 Data security and 2.3.1 Generation, recording, handling a data.

Extra care has to be taken:

- The author(s), all individuals who participated and/or contributed to the experiment, including, where applicable, recorder(s) must be clearly identified, so that the data can be traced, by name and date to each individual's contribution. The above ensures that the record is attribut
- Clear guidelines and conventions on file-naming for all data files and experimental record should be established for consistency and traceability (see Traceability of data and any person having impact on data).

For technical non-public reports (e.g. R&D reports used in regulatory submissions), it is easy and fairly common to provide direct references to a lab notebook containing the relevant information.

For scientific publications, it is not common to include such references and the following options may be considered to establish traceability between published data and internal records:

- develop a "for internal use" system (e.g. a plain Excel file accessible to all members of the research unit) where reports about completed studies (and associated manuscripts and publications) are matched with the corresponding unique study IDs
- including unique study IDs or references to the laboratory notebooks in the publications themselves (e.g. in the supplementary materials)
- include unique study IDs in the preregistered protocols

PLEASE DO NOT FORGET

- To ensure traceability, each experimental record should have a unique identifier in accordance with the applicable procedure(s), e.g., SOPs.
- Responsibility for creating experimental records and documentation of the resulting data rests with the researcher who generates the data. If multiple researchers collaborate in data generation, then it should be identified as such.

C. Resources [edit]

EQIPD Documentation Plan template - 3.1 Documentation Plan.docx

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Current and Future Developments

- Developed a tool for funders and grant applicants to snapshot important quality aspects – EQPID tool https://public-funding-tool.paasp.net/
- Involve more stakeholders (institutions, funders, journals)
- Training program for assessors

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Scientist.com Expands Award-Winning Compliance Platform to Include International Research Consortium's Preclinical Study Standards

COMPLi® solution will support guidelines set forth by Enhancing Quality In Preclinical Data (EQIPD) to improve data integrity standards and accelerate novel drug development

December 01, 2020 07:02 PM Eastern Standard Time

Enhancing Quality in Preclinical Data

Strategic level

EQIPD Guarantors – GoEQIPD e.V.

Operational level

PAASP GmbH for the PAASP Network

- North America
- Europe
- Other regions

Community level

Stakeholder group
Researchers / institutions / societies / publishers / funders / research tool & software manufacturers

Scientific Community

For more information, please visit …

General information on EQIPD : www.eqipd.org

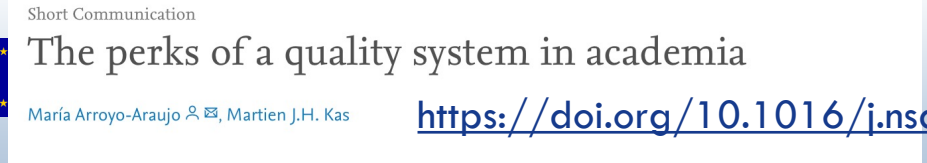
Twitter: @GoEQIPD and LinkedIn: https://www.linkedin.com/company/goeqipd/

EQIPD Quality System toolbox: www.eqipd-toolbox.paasp.net

EQIPD project materials at www.osf.io/vduze/

Email: info@quality-preclinical-data.eu

https://elifesciences.org/articles/63294



https://doi.org/10.1016/j.nsa.2022.100001

https://doi.org/10.1038/s41592-022-01615-y