# D7.1 Evaluation of Existing Training Modules

## EQIPD – GA 777364
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## European Quality In Preclinical Data

## WP7 - E-learning course on scientific quality

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[1] **Use one of the following codes:**
R: Document, report (excluding the periodic and final reports)
DEM: Demonstrator, pilot, prototype, plan designs
DEC: Websites, patents filing, press & media actions, videos, etc.
OTHER: Software, technical diagram, etc.

[2] **Please choose the appropriate reference and delete the rest:**
PU = Public, fully open, e.g. web;
CO = Confidential, restricted under conditions set out in Model Grant Agreement;
CI = Classified, information as referred to in Commission Decision 2001/844/EC.

| Description of Work | Version | Date |
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| | V2.0 | 28/01/2019 |

## Document History

| Version | Date | Description |
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| V1.0 | 16 April 2019 | First Draft |
| V2.0 | 30 April 2019 | Final version after comments from WP members |

## Publishable Summary

This deliverable report relates to the evaluation of existing training modules, which ultimately will form (part of) the content of the EQIPD E-learning Course[3]. Existing electronic educational materials on key principles for preclinical robustness and quality have been identified and evaluated, prior to selection for inclusion in the EQIPD E-learning Course. The scope of the training material is intended to match the training needs of EQIPD as determined by the WPs 1-9. The scope of topics for which materials were sought for the EQIPD E-learning Course was agreed upon by all participants at the start of this project, and includes: animal welfare, experimental design, validity (e.g. construct, internal, external), statistics, systematic review methodology, data handling, transparent reporting and scientific integrity, data governance and data integrity, and the set-up of industry/academia collaborations.

At the start of the project, all EQIPD consortium members were asked to identify and contribute existing training materials. An inventory of the available training materials was made, which will be updated throughout the project. All WP7 contributors were asked to use their knowledge on training materials in their respective areas of expertise to (a) record these materials in a table based on the URS for training materials, and (b) evaluate them for inclusion in the EQIPD E-learning Course.

Up to December 2018, twenty-five web-based training modules covering the required scope of topics were identified. WP7 contributors were asked to assess and evaluate content of the training modules, and seventeen materials were deemed suitable for inclusion in the EQIPD E-learning Course. The materials identified were well-matched to the User Requirements Specifications (URS) in terms of e.g. language, accessibility and required expertise. The materials identified were mostly webinars and as a result do not contain many interactive elements or options for assessment.

A mechanism for identifying, assessing and evaluating existing electronic training material has been established, using a defined process. Additionally, a mechanism for identifying and capturing gaps in available electronic training material has been developed.

## Methods

From January 2018 until December 2018, all members and collaborators of the EQIPD consortium (WP7 contributors in particular) were asked to identify web-based training modules covering the previously determined scope for the EQIPD E-learning Course (see Appendix 1 for the description of the scope). In brief, the scope covers the following 11 modules: scientific integrity, experimental design, validity, ethics and animal welfare, data handling, statistics, transparent reporting, systematic review of published literature/existing data, data governance and data integrity, set up of industry/academia collaborations, and implementing QMS in discovery research environments.

WP7 contributors recorded relevant details of the training modules identified in an MS Excel table, according to the previously specified URS for training materials (see milestone 32 report for the training material URS). Appendix 2 shows a screenshot of the table.

Based on their area of expertise, WP7 contributors were then asked to review the content of the training materials and state whether or not the materials should be included in the EQIPD E-learning Course. The table was also used to identify resource gaps, i.e. modules for which no training materials have been identified.

During the evaluation of materials (as well as during activities in other work packages) it became evident that the contributors continued to identify new training materials. In these cases, the new training materials were added (and will continue to be added) to the table and assigned reviewers as described above.

## Results

The entire table used to record and evaluate the training materials can be made available upon request.

[3] The EQIPD E-learning Course will consist of a collection of web-based training materials, for a series of defined modules that are relevant to the scope of the EQIPD project. The training materials will be placed upon a web-based e-learning platform, in the form of hyperlinks to the training material.

Twenty-five web-based training modules were identified and recorded in the table for evaluation. Each module was subsequently evaluated by two separate WP7 reviewers (one expert, one non-expert). Seventeen of these modules have been evaluated as suitable for inclusion in the EQIPD E-learning Course, three materials may potentially be suitable with some alterations (e.g. adding some background information, or shortening a video), and five were deemed unsuitable because they were out of scope. See Table 1 (below) for an overview of the evaluated and selected materials per module.

**Table 1: evaluated materials and included materials per module**

| **Module** | **# training materials evaluated** | **# training materials suitable for inclusion** |
|---|---|---|
| scientific integrity | 0 | 0 |
| experimental design | 3 | 2 |
| validity | 7 | 5 |
| ethics and animal welfare | 5 | 1 (+ 3 potential) |
| data handling | 1 | 1 |
| statistics | 5 | 4 |
| transparent reporting | 3 | 3 |
| systematic review of published literature/existing data | 1 | 1 |
| data governance and data integrity | 0 | 0 |
| set up of industry/academia collaborations | 0 | 0 |
| implementing QMS in discovery research environments | 0 | 0 |
| **Total** | 25 | 17 (+ 3 potential) |

To date, resource gaps were identified for the modules “scientific integrity”, “data governance and data integrity”, “set-up of industry/academia collaborations” and “implementing QMS in discovery research environments”. For the latter two modules, working groups have been initiated to create web-lectures, thereby filling th gap in available material. For “scientific integrity” and “data governance and data integrity” there are a number of new resources for which evaluation is pending, which may fill the gap.

After assessing the materials according to our URS, we conclude that all materials are online, open access (some require a freely available login), in English and suitable for junior researchers from both academia and industry. Some of the statistics courses were deemed more suitable for participants who are already at an intermediate level of training and require some background knowledge on statistics. The duration of the training presented in the materials was highly variable, from ~5 minutes to several hours. The materials are predominantly webinars, which does not offer many possibilities for interactive learning. The majority of the materials does not contain an assessment option. Most materials are not expected to require regular updates.

Based upon the evaluation of these materials to date, and activities in other work packages, a further 10 training materials have been suggested for further evaluations at a later date, for which the above-mentioned mechanism will be used.

## Discussion

The focus continues to be on ensuring we have sufficient training material to place upon the EQIPD web-based Learning Environment. A pilot version of the learning environment is accessible on the EQIPD website: https://quality-preclinical-data.eu/learning-environment/eqipd-e-learning-modules/

Working groups have been initiated to create web-lectures for modules for which we have not identified any materials. Other modules may also require new training materials to be made, and new working groups to be set-up accordingly, for as far as resoures allow this.

## Conclusion

It is concluded that this deliverable has been achieved, since (1) twenty-five e-learning training modules have been evaluated, and (2) there is a mechanism in place to evaluate any further e-learning training modules that are identified or developed.

**Appendix 1: Proposed scope for the EQIPD E-learning Course, to be hosted on the EQIPD web-based Learning Environment.**

| Broader topic | Learning objectives (i.e. upon completion, participants should have a basic understanding of...) | Learning outcomes (i.e. upon completion, participants will be able to...) |
|---|---|---|
| Scientific integrity | • The importance of research integrity and good data quality in research<br>• Different risk areas related to (lack of) scientific integrity, such as patient safety, intellectual property and decision making<br>• Common principles of research integrity, e.g. Scrupulousness, Reliability, Verifiability, Impartiality and Independence<br>• The current debate about the reproducibility crisis in relation to scientific integrity | • Explain why research integrity and good data quality is important in non-regulated research<br>• Explain which different risk areas are related to (lack of) scientific integrity, including examples<br>• Name a number of common principles of research integrity, give examples of best practice and describe dilemmas for each principle. |
| Experimental design | • Confirmatory *versus* exploratory research<br>• The need for well-defined, a priori, hypotheses<br>• Internal controls and external controls<br>• Study designs, e.g. parallel groups, repeated measures, cross-over, multi-center<br>• Sample size and unit of measurement considerations | • Explain the difference between exploratory and confirmatory research<br>• Formulate a well-defined hypothesis for an interventional study<br>• List different types of formal experimental designs (e.g. completely randomised, randomised block, repeated measures) and explain their advantages and disadvantages<br>• Choose the most appropriate study design for their planned study<br>• Identify the experimental unit and recognise issues of non-independence (pseudoreplication).<br>• Perform a sample size calculation for a study with a parallel group design<br>• Explain the implications of study design on the required sample size |
| Validity | • Internal validity and risks of bias in various study designs, measures to reduce bias (randomisation, blinding)<br>• External validity, predictive validity and indirectness<br>• Construct validity | • Explain what bias is and how it differs from variability and confounding<br>• Assess the risk of bias in published a study, using an appropriate tool<br>• Implement measures to reduce bias in an experimental set-up<br>• Explain what external validity is and how this is influenced by indirectness<br>• Explain what construct validity is<br>• Explain the importance of internal, external and construct validity in translational research |
| Ethics and animal welfare | • Ethics related to animal use<br>• The principles of replacement, reduction and refinement<br>• Potential effects of transport, housing, husbandry, handling, procedures and euthanasia methods on the experimental results<br>• Ethical implications of need for larger sample sizes | • Demonstrate a comprehensive understanding of the principles of replacement, reduction and refinement<br>• Identify, assess and minimise all of the welfare costs to animals throughout the animals' lifetime, including adverse effects relating to transport, housing, husbandry, handling, procedures and euthanasia methods |

| Broader topic | Learning objectives (i.e. upon completion, participants should have a basic understanding of...) | Learning outcomes (i.e. upon completion, participants will be able to...) |
|---|---|---|
| Data handling | • What constitutes an outlier and how to deal with them<br>• What missing data are and how to deal with them<br>• Methods for data documentation, e.g. electronic notebooks. | • Describe various methods for dealing with outliers and explain when these methods are appropriate<br>• Describe various methods for dealing with missing data and explain when these methods are appropriate<br>• Correctly document data and describe procedures used for data handling, e.g. how missing data were imputed or how outliers were determined |
| Statistics | • The purpose of statistics<br>• Importance of pre-specification<br>• Unit of measurement<br>• Pre- vs. post-hoc<br>• P-hacking<br>• Power<br>• P-values, multiple testing and False Discovery Rate (q-values) | • Explain and decide when it is useful / appropriate to use statistics and when not<br>• Explain the importance of pre-specification of the statistical approach of a study<br>• Explain the concepts of power calculation, p-values and corrections for multiple testing<br>• Demonstrate an understanding of the need to take expert advice and use appropriate<br>• Statistical methods,<br>• Design a detailed statistical analysis plan for their study, including (but not limited to) a power calculation, in collaboration with a statistician |
| Transparent reporting | • Open science approaches (open data, open reporting, protocol registration)<br>• Reporting guidelines<br>• Granularity of Methods and Results<br>• Publication bias and dealing with significant (negative and positive) and neutral or controversial results | • Identify several open science approaches and related platforms (e.g. preclinicaltrials.eu, open science framework, PROSPERO, data repositories etc.)<br>• Identify and use reporting guidelines relevant for their field of research (e.g. ARRIVE, CONSORT or PRISMA)<br>• Explain the concept of publication bias and how this impacts translational research |
| Systematic review of published literature / existing data (SR) | • Rationale of SR methodology<br>• Formulating a PICO SR question<br>• Building a comprehensive search strategy<br>• Selecting studies using inclusion and exclusion criteria<br>• Extracting study characteristics<br>• Assessing bias in primary studies<br>• Basics of meta-analysis<br>• Interpretation of the SR results<br>• Assessing the quality of a systematic review | • Draft a systematic review protocol<br>• Draft a comprehensive search<br>• Under expert supervision, as member of a review team, perform the basic steps of a systematic review<br>• Assess the quality of an existing systematic review, using an appropriate tool |
| Data governance | • Data governance at a discovery research level<br>• Data integrity at a discovery research level | • Identify the risks relating to data governance and data integrity<br>• Mitigate data integrity risks, having conducted data integrity risk |

| Broader topic | Learning objectives (i.e. upon completion, participants should have a basic understanding of...) | Learning outcomes (i.e. upon completion, participants will be able to...) |
|---|---|---|
| and data integrity | | assessments. |
| Set up of industry / academia collaborations | • Recommendations for content of research agreements with respect to:<br>○ Terminology & definitions<br>○ Legal requirements (litigation)<br>○ IP requirements<br>○ Scientific requirements<br>○ Quality expectations<br>○ Records Management | • Explain the strength of collaborative research<br>• Prepare a research agreement<br>• Review a research agreement<br>• Understand the risks of not having a robust research agreement |
| Implementing QMS in discovery research environments | • Components of a quality management system (QMS) in drug discovery research<br>• Conduct a gap analysis<br>• Understanding risks and limitations, and identify possible mitigations | • Conduct a gap analysis, in readiness for the introduction of a QMS in discovery research |

**Appendix 2: screenshot of the training material assessment table with information on one example material entered**

| Training course scope topics [select] | Training material title / topic | Material created / owned by | Accessibility [select online / offline and enter location] | | Login required? [select] | Type(s) of training material [select type and specify if needed] | | Training duration | Intended knowledge level [select] | Language(s) |
|---|---|---|---|---|---|---|---|---|---|---|
| Ethics and animal welfare | EAD in harmony with 3Rs and animal welfare - Micheal Sidelsky | NA3RsC Virtural Educational Community | online | https://engage.vevent.com/production?eid=6269&lc=en&cc=US&seid=14&standalone=false&target=location&location-pk=AreaPK(6269, | Yes | Recorded webinar | NA | 45 minutes | Beginner | English |

| Assessment options | Required expertise | Industry sector | Scope of material | Applicable Regulations/ Standards | Learning objectives *By the end of the module/ course, participants will achieve a basic understanding of:* | Learning outcomes ***What will the participant be able to do differently?*** *By the end of the module participants will be able to:* | Achievement of outcomes ***How will the participant be assessed?*** |
|---|---|---|---|---|---|---|---|
| none | basic knowledge on health monitoring required | Academic and Commercial Research | automized screening methods for pathogens in the an animal facility (may be going beyond our scope) | none | te become aware of the existance of automated screening methods for pathogens in the animal facility and have a basic overview of different systems and their possibilities | participant will know about the existance of automated screening methods for pathogens in the animal facility and have a basic overview of different systems and their possibilities | no assessment option present |

| Achievement of outcomes ***How will the participant be assessed?*** | Course lifespan (m/ y) | Will updates be required? | Course proposer name | Course proposer organisation | Course proposal date | WP7 Reviewer 1 | WP7 reviewer 1 comments | WP7 Reviewer 2 | WP7 reviewer 2 comments | Final inclusion? (y/n) |
|---|---|---|---|---|---|---|---|---|---|---|
| no assessment option present | unclear | yes, because technologies will be further developed? | Kim Wever | Radboudumc | 18/01/2018 | Anton Bespalov, 07.02.2019 | I would not include it because it is beyond the scope of what we need in the EQIPD learning platform | Kim Wever | agree that this is probably beyond the scope of EQIPD, plus it's a bit of a hassle to gain access to the | no |