Report on optimal methodologies for the education of regulatory assessors MS 5.1

WP5 – Delivery of training materials

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1.0	10.06.2024	Comments by EU NTC Core Team	Sheila Kennedy Esther Martinez Marianne Van Heers Yanislav Pacherazov
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1. Introduction

The aim of the IncreaseNET Joint Action (JA) is to increase the necessary regulatory expertise and competences in the European Medicines Regulatory Network (EMRN) and to develop additional capacities to face challenges represented by upcoming scientific developments.

Work Package 5 (WP5) of IncreaseNET involves the delivery of training materials based on EMRN learning needs. Delivery of effective training materials is a complex, multi-stage process involving learning needs identification, development of curricula / competency frameworks / learning objectives, instructional design planning, learning resource development and evaluation (1).

To date, there is no consensus on either optimal learning approaches or learning modalities for the education and training of regulatory professionals (2). This report will summarise current available literature on learning modalities for regulatory professionals and discuss other closely interrelated factors pertaining to real world experiences and opinions, the process of learning evaluation and the potential role of learning design professionals. It is hoped that this report will provide concise, relevant, and useful information for the development of regulatory training going forward.

2. Methodology

A WP5 Task 5.2 Subgroup was created to plan, develop and peer review this report. A Kick Off Meeting was held in which the group undertook a brainstorming session to determine an approach for data gathering and the structure of the report (Table 1).

Table 1:	
What information is already out there?	Review, and summarise pertinent findings, of a recent systematic scoping review pertaining to the education of regulatory professionals (2).
	Review and interpret learner evaluation data from previous regulatory training courses on the European Network Training Centre (EU NTC) Learning Management System (LMS).
	Present theories underpinning good pedagogical training design and evaluation.
What information can we generate?	Short survey for circulation to WP5 participants. Aim to ascertain perceived efficacy of different learning modalities in the setting of regulatory training.
	Question regarding learning modalities inserted into BWP Learning Needs Analysis survey.
	Focus group discussions: Aim to ascertain real life experiences and opinions on training approaches for regulatory assessors. WP5 participants selected based on survey responses and can be considered a type of “Expert Group” for regulatory education.

3. Learning Modalities

3.1. Literature Review

A systematic scoping review of literature pertaining to the education of regulatory professionals was undertaken by the author in 2022 as part of their MSc Health Professions Education (HPE) dissertation* (2). This review is the first of its kind to attempt to collate and compare approaches to regulatory education and is therefore considered highly relevant for discussion in this report.

It is worth noting that this review incorporated the following terminologies under the combined term "Regulatory Professional": Regulatory science; regulatory affairs; regulatory assessment; regulatory research. This was done to broaden the amount of literature available for review to a general cohort of regulatory professionals that likely share key learning traits.

This review utilised the following databases: *PubMed, Embase, CINAHL, ERIC (EBSCO)* and *Scopus*. In addition, article reference lists were scanned to identify additional studies ('snowballing') (3). Lastly, a grey literature search was performed. This utilised two resources: 1) Relevant professional regulatory and pharmaceutical organisations and 2) The Grey Matters Checklist.

Eighteen articles addressing learning modalities for regulatory professionals were identified. Articles reviewed do not contain any level of comparative assessment of efficacy. In addition, many articles do not provide in-depth discussions of their associated learning modalities, instead outlining in brief their use in the setting of regulatory professionals. Nevertheless, it is helpful to see the breadth of learning modalities that have been used in training regulatory professionals.

Table 2 outlines different modalities that each article addresses. These have been divided into two categories: Online Learning and Experiential Learning. Whilst several modalities categorised in Experiential Learning can be undertaken online, the key characteristic of these modalities is felt to be the experiential element and is therefore prioritised in this table. This list can be considered a "cache of ideas" for future approaches to training development in this setting.

*Article available upon request from the author – email naomi.beard@hpra.ie.

Table 2:		
Medium	**Modality**	**Articles (n = 18)**
Online Learning	Lectures (live/pre-recorded)	Greenberg-Worisek et al. 2019 (4), Holbein et al. 2014 (5), Anatol et al. 2013 (6), Olson S & Clalborne A B 2012 (7)
	Digital Resources (e.g: PDFs)	Holbein et al. 2014 (5)
	Forums	Brownley et al. 2021 (8), Kerpel-Fronius et al. 2015 (9)
	Interactive online modules / courses	Steinert et al. 2013 (10), Cruz Rivera et al. 2021 (11), Dance A. 2013 (12)
	Seminars	Anatol et al. 2013 (6)
	Videos	Greenberg-Worisek et al. 2019 (4)
	Webinars	Cruz Rivera et al. 2021 (11)
	Workshops	Spindler et al. 2016 (13), IMI Socio-Economic Impact Report 2021 (14), Holbein et al. 2014 (5)
Experiential Learning	Entrustable Professional Activities	Bridges W. 2019 (15)
	Fellowships	Cruz Rivera et al. 2021 (11), Semete-Makokotlela et al. 2021 (16), Olson S & Clalborne A B 2012 (7), Dance A 2013 (12), Calvert et al. 2021 (17)
	Case Studies	Sakuma 2013 (18), Kerpel-Fronius et al. 2015 (9)
	Internships/Rotations in academia, industry, and regulatory agencies	Kerpel-Fronius et al. 2015 (9), Cruz Rivera et al. 2021 (11)
	Mentors	Semetke-Makokotlela et al. 2021 (16), Olson S & Clalborne A B 2012 (7), Adamo et al. 2015 (19), Kerpel-Fronius et al. 2015 (9)
	One-to-one training	Holbein et al. 2014 (5)
	Participation in review board sessions (e.g: Mayo Clinic), involvement in guideline development	Greenberg-Worisek et al. 2019 (4), Semetke-Makokotlela et al. 2021 (16)
	Projects	Springer et al. 2016 (20)

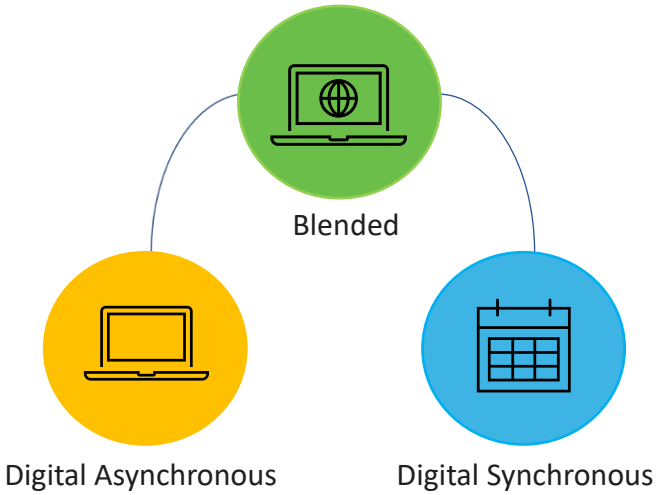
Several aspects of learning highlighted in this review are considered relevant for discussion in this report. A summary of each of these aspects is provided below.

Blended learning

When developing training, one must consider the optimal mode of delivery. Traditionally, blended learning has been considered a combination of online and face-to-face learning (21). However, in this era of ever-expanding digitalisation, and the European-wide setting of regulation, the efficacy and feasibility of face-to-face learning is called into question. A number of authors advocate for elimination of in-person sessions, to broaden accessibility, and use of an asynchronous (self-paced) learning approach to support maximum enrolment opportunities (10) (20). However, the value of synchronous learning (live sessions) should not be forgotten as it is an effective way to impart complex information (2).

A different definition of blended learning is proposed: "*An instructional approach that includes a mixture of formats and delivery approaches, both synchronous (live) and asynchronous (self-paced) sessions, in conjunction with tailored tutorial support*." This emphasises utilisation of a variety of approaches, regardless of whether these are online or face-to-face (Figure 1).

Figure 1



Experiential learning

Experiential learning is defined as “learning by doing” (22) and is highlighted as a critical and central component of education and training in regulatory science (19).

Several authors advocate use of case studies to augment didactic education methods, and that these should occur at all stages of the career cycle (19) (18).

Entrustable Professional Activities (EPAs) are units of professional practice that capture essential competencies in which trainees must become proficient before undertaking them independently (23). EPAs have been trialled in the regulatory setting to define easily measured units of work based on different regulatory competencies (15). EPAs are widely used in general medical education and may be a useful tool in regulatory education.

Lastly, it has been proposed that learning occurs via involvement in international guideline development as iterative cycles involved in developing guidelines are a way to cultivate expertise whilst engaging with the thought process of how to develop standards that one is required to apply (16).

Social learning

Social Learning is defined as a collaborative way of learning through peer interactions. It deals with how learners share experiences, reflections, content and ask questions as they engage with learning content or participants in a program (24). One medium of social learning that has been utilised in the training of regulatory professionals is the use of a forum (9) (8).

Forums provide a platform for learners to create information, collaborate and interact simultaneously or asynchronously in an online learning environment (25). An effective example of this is the Regulatory Guidance for Academic Research of Drugs and Devices (ReGARDD) forum. This provides a platform for regulatory professionals to meet and build interpersonal connections, share best

practices, discuss complex regulatory issues, and learn from one another and from external speakers. Members have reported an increase in regulatory knowledge after forum participation (8).

Conclusion

There is no consensus on a defined training pathway or learning approach for the education of regulatory assessors, nor is there a consensus as to what the optimal learning modalities are. The cited review (2) acknowledges the paucity of high-quality literature in this area and recommends further research focussing on: Needs assessment of regulatory learning needs; in-depth comparison and evaluation of the efficacy of different learning modalities in the regulatory setting; and broad stakeholder engagement to inform training and professional development in regulatory education.

Despite a lack of high-quality literature, the above points serve to emphasise modalities of training that have been utilised or that are considered potentially efficacious by experts in the field. IncreaseNET can use these findings as a basis to develop its approach to regulatory training. In addition, it is worth noting that IncreaseNET is uniquely placed to add to the pool of data highlighted as lacking in the concluding recommendations of the cited review.

3.2. Survey

A short survey was conducted with WP5 participants to ascertain perceived efficacy of a range of different learning modalities in the regulatory setting (see Appendix 1 for full T5.2 survey). Questions 1 and 2 were used to ascertain whether participants have experience in developing training materials, and if yes then which types of modalities they have used. These answers were utilised to form balanced focus groups (see Section 3.3). Question 3 asked participants to rank each learning modality using two different criteria: knowledge acquisition (KA) and skills application (SA). Participants were advised to base their answers on their own experiences with the modality, as per a 0-3 rating scale (Figure 2). This same question was embedded in a learning needs analysis survey to Biological Working Party (BWP) members.

Figure 2

Q.3: Please rate each of the following learning modalities with regards to training efficacy. This rating is subjective and should be based off you own experience educating individuals with a scientific background OR your personal experience undertaking learning via the modality.

For modalities that you have no experience with (either developing or using) please select not applicable (N/A).

Training efficacy is divided into knowledge acquisition and practical application of skills, as per the following rating scale (0-3):

0: No improvement
1: Small amount of improvement
2: Moderate improvement
3: Significant improvement

Learning Modality:	Knowledge Acquisition	Practical Application of Skills
Case Studies - use of a case (e.g: assessment report) to illustrate principles and approaches		
Webinars - live online learning event in which learners can gain information on a topic and have the opportunity to ask questions in real time		
Recorded Lectures - a pre-recorded lecture on a topic, generally around 30 minutes in duration		
Interactive Modules - a dynamic learning experience using a combination of multimedia elements, interactivity and feedback mechanisms		
Forums - an online communication channel for knowledge-sharing and information exchange		
Podcasts - a digital medium consisting of audio episodes that relate to a specific theme/topic		
Microlearning Videos - a short video (approx. 2-5 minutes) that usually only has a single learning objective. Breaks material down into short, easily digestible components		
Scenario-Based - a learner is given the opportunity to develop a skill by practicing in a true-to-life simulated environment that "replicates job conditions"		
Workshops - an interactive learning session with peer-to-peer and learn by doing elements		

The results from the WP5 participant and BWP surveys were combined and are presented below.

In total, there were 40 responses for knowledge acquisition and 39 responses for skills application (due to a technical issue with one set of responses). The survey was circulated to 63 individuals (23 WP5 participants and 40 BWP members), giving a completion rate of 63.5% and 62% respectively. 17/23 (74%) WP5 participants and 23/40 (57.5%) BWP members responded. These completion rates are considered acceptable as a response rate of 60% should be the goal for most research (26).

Figures 3 and 4 show a percentage breakdown of rankings per modality divided by criterion. Note: Modalities are ranked from highest to lowest for the criteria: significant improvement (top to bottom). Figure 5 shows average score per modality for both criteria.

Figure 3: Efficacy of Knowledge Acquisition: Learning Modalities (n=40)

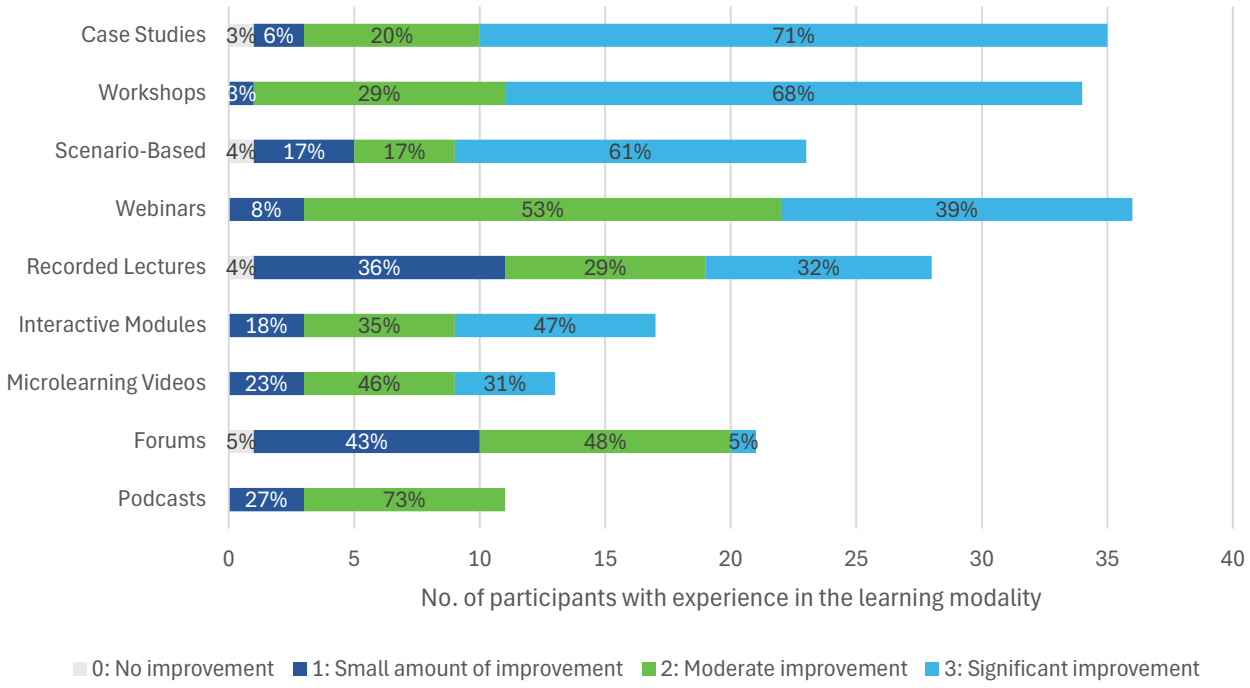


Figure 4: Efficacy of Skills Application: Learning Modalities (n=39)

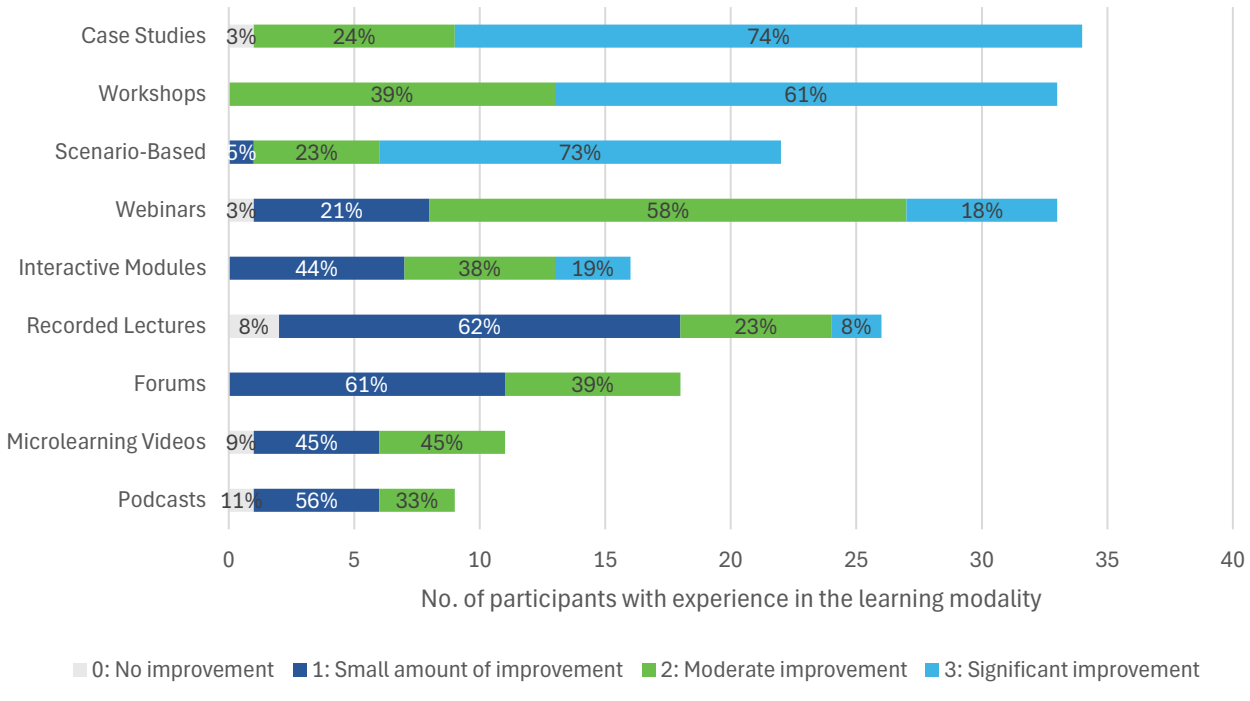
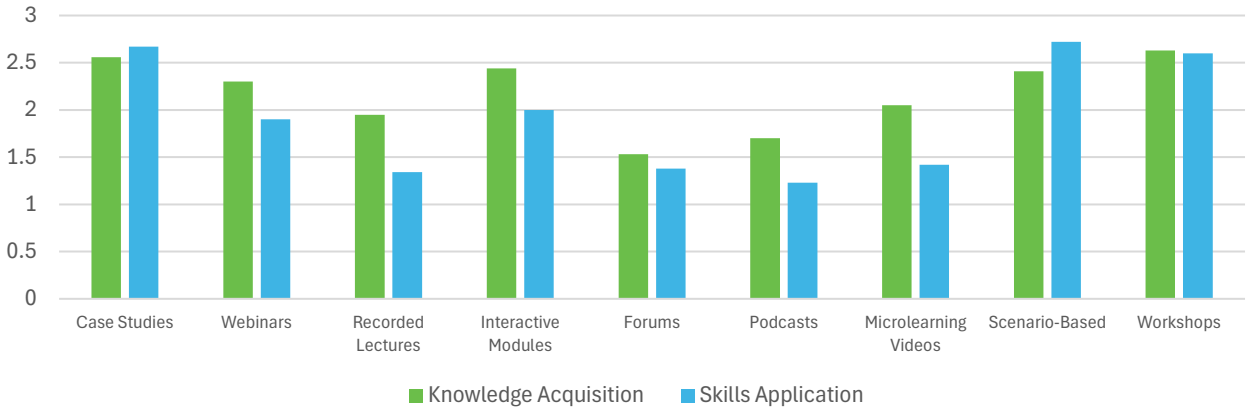


Figure 5: Efficacy of Learning Modalities: Average Score



Participants were also given an open text box to highlight any additional learning modalities not covered in the survey. Four additional modalities were mentioned: Round table discussion, problem-based learning, simulation training, PDF documents/links to guidelines.

Not all respondents have experience with every learning modality listed above. The percentage of overall respondents with experience is as follows (combined average of KA and SA): Case studies, webinars, and workshops ≥85%; Recorded lectures 68.5%; Scenario-based 56.75%; Forums 49.25%; Interactive modules 41.75%; Microlearning videos 30.25%; Podcasts 25.25%.

Figures 3 and 4 show that a high percentage of respondents feel that case studies, scenario-based learning and workshops significantly improve both regulatory knowledge and skill (KA: 71%, 61% & 68%; SA: 74%, 73% & 61% respectively). Webinars are also considered efficacious with 92% and 76% of respondents selecting moderate or significant improvement in KA and SA respectively.

Figure 5 demonstrates highest average scores for case studies (KA 2.56, SA 2.67), workshops (KA 2.63, SA 2.6) and scenario-based (KA 2.41, SA 2.72) modalities. Forums and podcasts scored lowest for KA (1.53 & 1.7), whilst recorded lectures and podcasts scored lowest for SA (1.34 & 1.23).

3.3. Focus Groups

Two focus groups were conducted by the author. The methodology and results are outlined below.

Methodology

Purpose: To ascertain real world opinions and experiences pertaining to the education of regulatory assessors.

Participant Selection: A short survey was circulated to WP5 participants to identify individuals for inclusion. These participants were considered to have both experience and interest in training and education of regulatory assessors. Representatives from the EU NTC core team were also present.

Discussion Points: Three points for discussion were presented:

1. Optimal online **modalities** for imparting training to assessors

2. Pros and cons of different **learning formats**
3. Imparting information on **"grey areas"** of assessment (tacit knowledge).

Each point was discussed for approximately 20 minutes, with time for questions or additional comments given at the end of the session. Focus Groups 1 & 2 contained 10 & 6 participants respectively.

Results

Written minutes were reviewed, and a thematic content analysis was carried out to identify common and distinctive themes. A six-phase guide developed by Maguire and Delahunt was used as a guideline to perform this analysis (27) (see Appendix 2 for a detailed overview of this process). Results were divided by different themes and subthemes and are presented in Table 3.

Three different themes were identified: Learning Experience Design; Modalities; and Evaluation. Each of these themes contains a range of subthemes, and a significant amount of input and discussion were dedicated to subthemes within Learning Experience Design. The need for learner centred training with strong instructional and universal design principles was echoed in both groups. Focus Group 2 placed particular emphasis on optimising training from an English language perspective, to ensure maximum accessibility for non-native English speakers (i.e. the majority of the EMRN).

Focus Group 1 highlighted the benefits of videos as a training aid, in particular to present complex concepts in a user-friendly way and to improve learner engagement. Both groups flagged the importance of experiential learning, in the form of case studies and practical examples, and strongly advocated for incorporation of experiential learning modalities into any future training developed for assessors.

Lastly, there was a general consensus from both groups that it is difficult to make specific recommendations on optimal learning modalities. It was concluded that rigorous learner evaluation, and incorporation of this information into an iterative approach to training development, could be recommended for future training development.

Table 3: Focus Group Results

Learning Experience Design*	
Learner Centred Approach	"Learner Journey": Need to create a cohesive learning experience from beginning to end. Modality choice should be based on what is best for the stage the learner is at (e.g: basic vs complex concepts).
Instructional Design**	Professional(s) in learning design: Required to guide the process and maximise learning effectiveness. Learning formats: Group consensus on a blended learning approach (mixture of asynchronous, synchronous, and social learning): • Asynchronous: To develop basic knowledge in own time • Synchronous: ○ "On demand" learning sessions (number & frequency determined at start of learning development process) ○ Informal sessions: Opportunities to have question and answer (Q&A) session with a subject matter expert (SME), less preparation required from SME, simply providing a platform for learners to raise questions ○ Live sessions considered more useful later in the learner journey (e.g: when working on case studies). • Social Learning: ○ Imperative to create opportunities for learners to discuss queries and cases ○ Forum could provide a platform for this (mix of self-paced and live question opportunities) ○ Mimic internal facilitation of teamwork in national competent authorities (NCAs) on a larger scale (e.g: regarding discussion of a difficult case) ***"Maybe a universal modality recommendation cannot be given, and only good practices and recommendations can be defined for learning development. Maybe the real goal is to increase the awareness of these kinds of decisions"*** **–** Tivadar Szabo.
Universal Design Principles***	Learners are often non-native English speakers whose use of the language is generally in the written form. Several measures were recommended to optimise learning development in this learner cohort: • Simple language structures, avoid jargon and colloquial language • High quality sound and clear, neutral pronunciation (suggested use of artificial intelligence [AI]). Use of transcript and subtitles • PDF glossary of terms. Recommend pre-recorded lectures explaining any new terminology to the learner (prior to starting training course) • PDF summary of key learning points & guide to layout of learning material.
Modalities	
Videos	Demonstration of practical information (e.g: handling of technologies) Subdivide a longer video into smaller learning "bites" (microlearning) Useful to present complex concepts in a simple way (e.g: mixture of graphics and narration)
Case Studies	Imperative for transforming knowledge into practical skill. Useful as an anchor for identification of competencies. Review cases where queries or issues have arisen – numerous real-world learning points.
Live Sessions	Opportunities for discussion with SMEs are very important for understanding complex concepts (e.g: Q&A sessions, panel discussions, facilitated forum discussions).
E-Learning Modules	Embed different learning modalities in a module, include quizzes, videos, didactic lectures etc.
Podcasts	Short audio recordings discussing specific complex learning points.
Evaluation	
Learner Evaluation	Self-assessment Provision of regular learner feedback Assignments have been trialled in the past with success (e.g: assessing part of a dossier which is then reviewed by an SME)
Course Evaluation	Need to determine best approach to evaluating effectiveness of the developed learning.

*Learning Experience Design (LXD) is a user-centric approach that involves designing learning experiences that help learners to accomplish the learning objectives as easily as possible. LXD is a combination of instructional design and user experience design (32).
**Instructional Design (ID) is the analysis of learning needs and systematic development of instruction (34).
***Universal Design Principles (UDL) involve the design of an environment so that it can be accessed, understood, and used to the greatest extent possible by all people (35).

3.4. EU NTC Learner Evaluation Data

The EU NTC Learning Management System (LMS) provides a centralised digital platform cataloguing training courses applicable to the EMRN (28). An online course feedback form is attached to most learning courses on the EU NTC LMS (see Appendix 1 for full form).

Due to time and resource constraints, a sample of 12 courses were selected from the EU NTC LMS. These courses were selected based on the following criteria: Online courses only (limited to online courses as this will be the main focus of IncreaseNET training development); use of EU NTC general evaluation form for quick and easy comparison between course data; alignment of course topics with proposed topics for training development under IncreaseNET (i.e: advanced therapy medicinal products [ATMPs], biological active substances, general induction, drug/device combination products, statistics, simulation & modelling). A number of courses were then selected at random from the range of courses that fulfilled the above criteria. Table 4 gives further detail on each of these course codes.

Table 4: EU NTC Course Details				
Course Code	**Title**	**Format**	**Length**	**Response No.**
354032	Landscape of data sources – Real World Data sources chapter 1	Pre-recorded narrated lectures (x3), quizzes	Total: 88 minutes (Lecture 1: 46 mins, others not visible)	1
205001	Basics of Survival Analysis	Pre-recorded narrated lectures x4 (pre-recorded videos as part of a blended learning program)	~30 minute each	29
249001	EU Regulatory Awareness Session: impact of Brexit vol 1	Recorded webinar	1 hour 25 minutes	7
208001	Basic Training on Classification of Advanced Therapy Medicinal Products (ATMP)	Recorded webinar	1 hours 5 minutes	66
237001	Basic principles of the Mutual Recognition Procedure & the Decentralised Procedure	Pre-recorded narrated lecture	45 minutes	231
268044	Clinical development of biosimilars with emphasis on monoclonal antibodies	Pre-recorded narrated lecture	1 hour 8 minutes	32
267007	Basic Knowledge of EU Medicines Regulation	Pre-recorded narrated lecture (x3)	29, 69 & 27 minutes	238
305008	Guideline on adjustment for baseline covariates in clinical trials	eLearning module	N/A	7
315013	Introduction to ATMPs, ATMP procedures and Committee activities	Pre-recorded narrated lecture (x3)	37, 47 & 6 minutes	5
324008	Scientific advice for advanced therapy medicinal products (ATMPs): what and when to ask	Recorded webinar	1 hours 2 minutes	4
328002	EU Network awareness session on In Vitro Diagnostics Regulation (IVDR) implementation	Recorded webinar	1 hour 54 minutes	6
352072	Genetically modified cells: quality, non-clinical and clinical requirements	Pre-recorded lecture	31 minutes	1

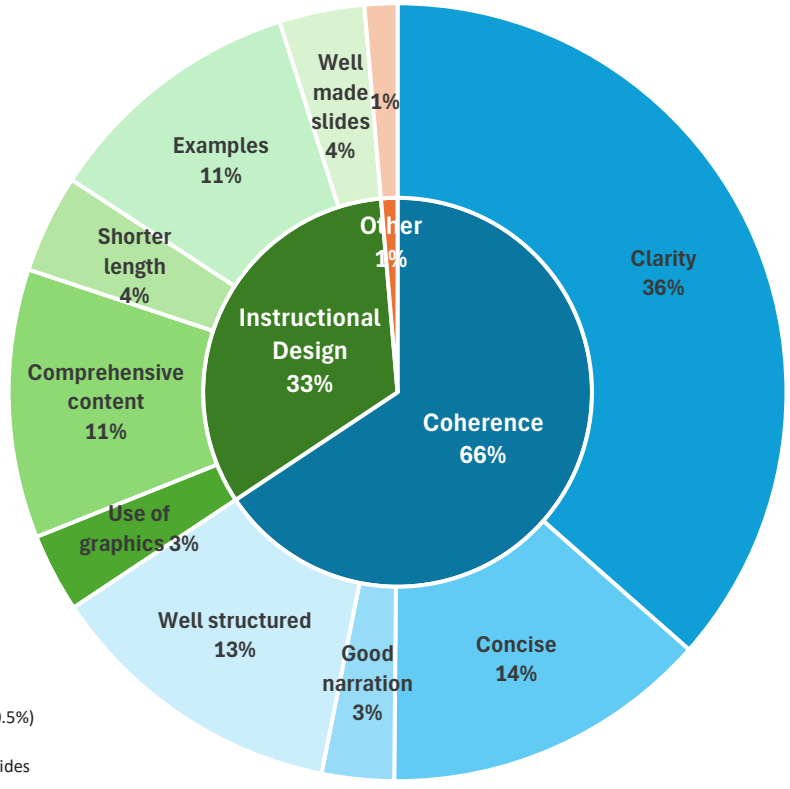
It is important to note that there are several limitations to the extracted information:

- Small data set with limited scope of delivery formats (i.e. majority are narrated lectures and recorded webinars*). Therefore, this data does not represent the full range of modules on the EU NTC and should not be interpreted as such.
- These 12 courses were published on the LMS during the period 2018 – 2023, with most recent courses published only at the end of 2023. This may have an impact on the number of completed evaluations (in particular for more recently published courses).
- Users can follow the course but may not ultimately complete the evaluation form, which means that the number of responses may not be indicative of full uptake of the courses.

Qualitative Analysis

All open text responses were read thoroughly, and categories were developed based on these responses. All text was then re-read, the number of times a statement pertaining to each category occurred noted and added to an Excel spreadsheet for tracking and analysis. Results are presented in figures 6 and 7.

Figure 6: EU NTC Learner Survey Data: Positive Factors (n=367)



Other:

- Up to date information (0.5%)
- Interactivity (0.5%)
- Narrator elaborated on slides (0.3%)

*Note: Webinars also have a separate EU NTC webinar assessment form for attendees of the live session. These forms have not been reviewed in this report.

Figure 7: EU NTC Learner Survey Data: Factors needing improvement (n=223)

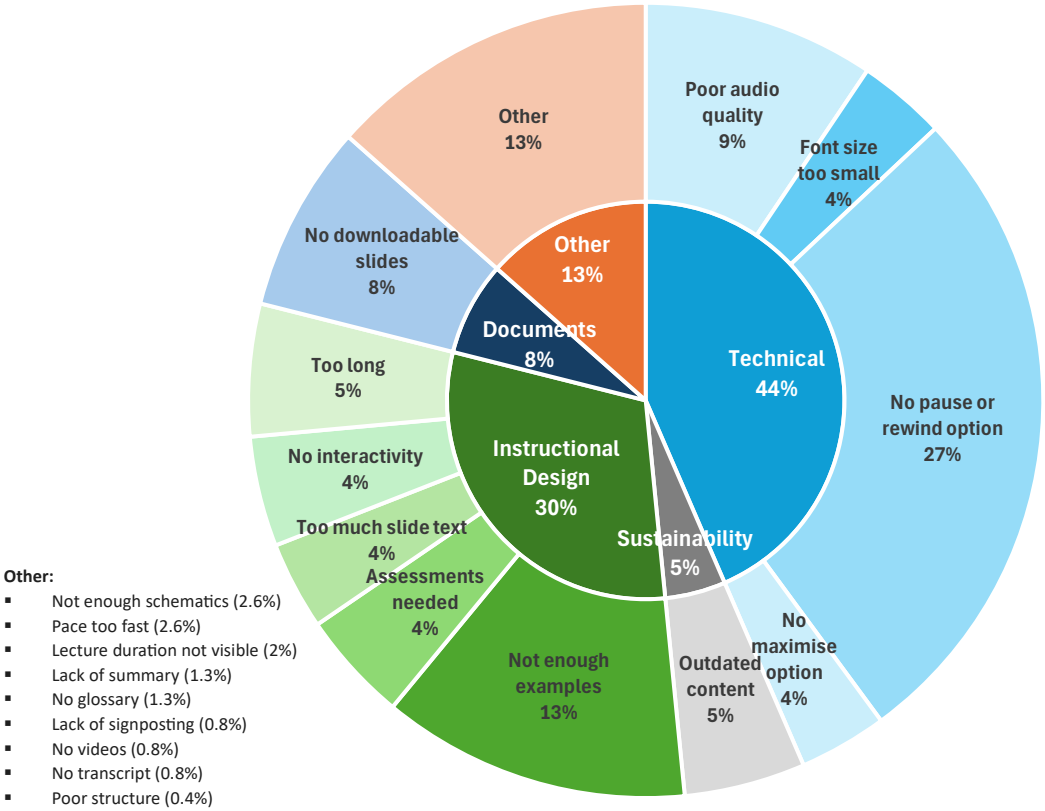


Figure 6 highlights the importance of a coherent learning experience with a strong pedagogical basis. Several demonstrative quotes from the evaluation data were noted and are as follows:

*"The slides **did not have too much text** and the content was very well presented in a **simple format** that is easy to follow."*

*"The speaker was **clear and concise**. The processes were presented in **plain language** that was easy to understand."*

*"Everything is **in one place** and **connected together**. It gives an overview of our job and connected procedures."*

Due to a general lack of elaboration from users on their comments pertaining to coherence (in particular "clarity"), it is not possible to definitively state which aspects contributed to this clarity. However, the majority of other comments praise different areas of the instructional design approach, and so it is possible (and logical) that there is a correlation between clarity and good instructional design.

Figure 7 highlights two main factors in developed trainings that require improvement: Instructional Design and Technical. Interestingly, technical comments make up almost half of the responses, in particular flagging the need for a pause/rewind option (27%) to allow users to re-listen to complex

points and take notes (courses 237001, 268044, 267007). Comments regarding audio quality appeared frequently (9%) and included microphone interference, low volume, background noise and poor-quality sound (courses 205001, 237001, 267007).

The need for use of practical real-world examples was cited on numerous occasions (13%) to aid in the transition of knowledge from theory to practice (courses 208001, 268044 and 267007). This is supported by data from Figure 6 where use of examples makes up 11% of positive factors from training courses (courses 208001, 205001, 249001, 237001, 268044, 267007). It is evident that there are conflicting opinions regarding sufficient amounts of examples (i.e: overlap of comments for courses 208001, 268044 and 267007). This is likely due to variation of user opinion on appropriate number of examples per training course.

Lecture length was cited as both a positive factor (4%) and a factor needing improvement (5%). When reviewed in more detail, courses 208001 (length: 1 hour 5 minutes), 237001 (length: 45 minutes) and 267007 (length 29, 29 & 27 minutes) have positive comments pertaining to lecture length. Course 267007 also has comments for improvement pertaining to lecture length. This is likely in reference to the 69-minute-long lecture. This data is conflicting (in that a length of approx. 1 hour and 5-10 minutes is cited as both a positive and needing improvement). However, it is clear that a length of ≤45 minutes is received positively.

The lack of downloadable slides appeared regularly (8%) and it is worth noting that a number of factors in the "other" section (detailed in the lower left hand list of Figure 7) also pertain to the provision of supporting documents, such as summaries, glossaries and transcripts (courses 237001 & 267007).

Lastly, information presented in Figure 7 serves to reiterate the importance of good instructional design. Several demonstrative quotes from the data were noted and are as follows:

*"Some slides were very **text heavy**, causing me to read while listening, and maybe **not being very focussed**."*

*"What was said was also included in the slide text. I think an improvement would be to have **pictures and schematic overviews** and the narrator adds to this and provides the content. "*

*"Make it more **interactive** with pit stop **questions for the viewer** to respond to before moving on to a new subject."*

*"Maybe insert an **interactive element** every now and then. This makes it easier to retain information and **less of a barrage of knowledge**."*

It is important to note that a significant percentage of comments outlined in Figures 6 & 7 originated from courses 237001 and 267007 (77% & 84% respectively), which limits the generalisability of this

data both to the full sample of courses reviewed in this report, and also to EU NTC courses as a whole. Nevertheless, the information outlined above provides an interesting basis for discussion and consideration with regards to the development of any future training courses.

Quantitative Analysis

Courses were rated on a scale of 1-6 via four questions evaluating the following: Covered all relevant aspects of the topic; Clear and understandable presentation of topics; Information useful for job; Appropriate length* (see Appendix 3 for full details of these questions). These results are presented in figures 8 and 9. EU NTC course codes are used in these figures.

Note: For clarity of graphic presentation, values using the 1-6 rating scale have been converted into percentages (%) in figures 8, 9 and 10.

*Note: Course 354032 does not have a defined total length of time and hence a question pertaining to length of course was not included in this course specific evaluation form.

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Figure 8: EU NTC Learner Survey Data: Average Score and % Response Rate (n=627)

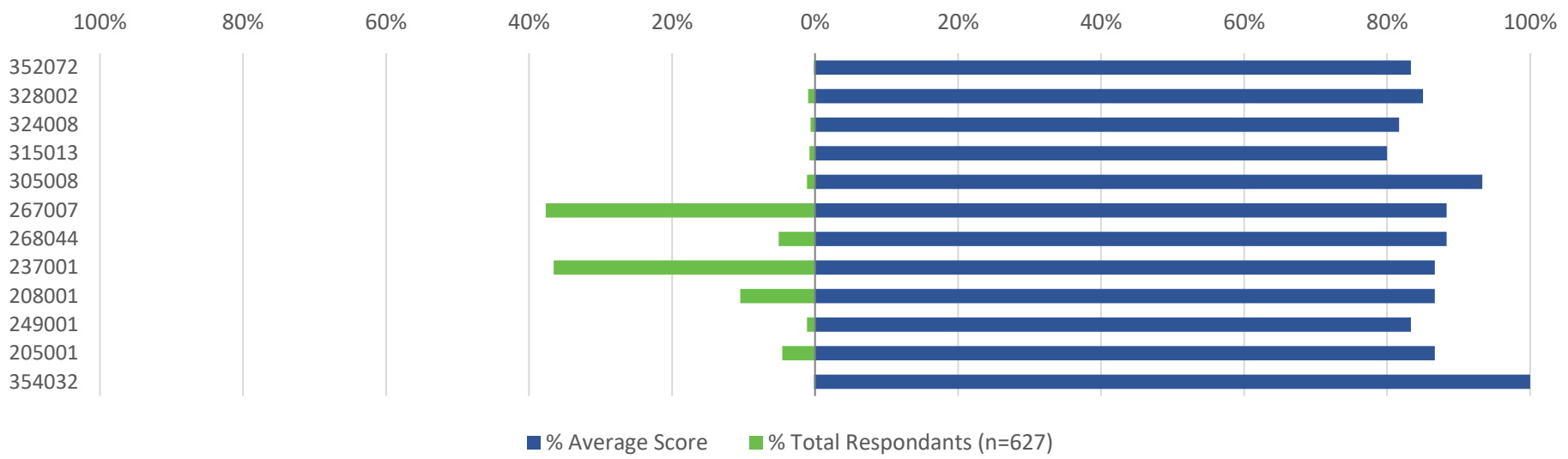


Figure 9: EU NTC Learner Survey Data: Average Score per Question (n=627)

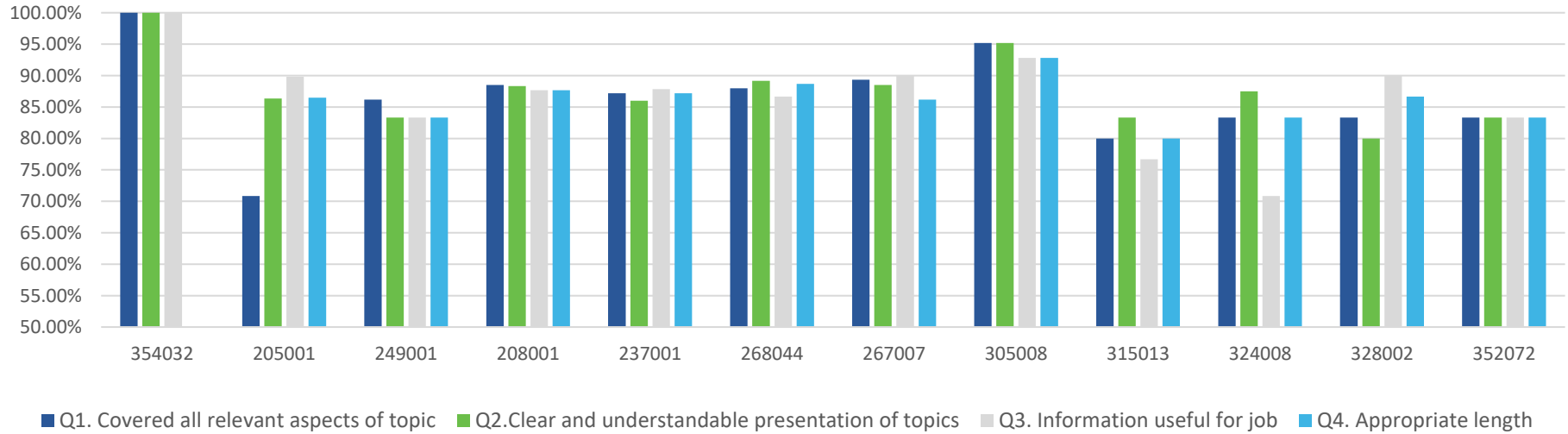
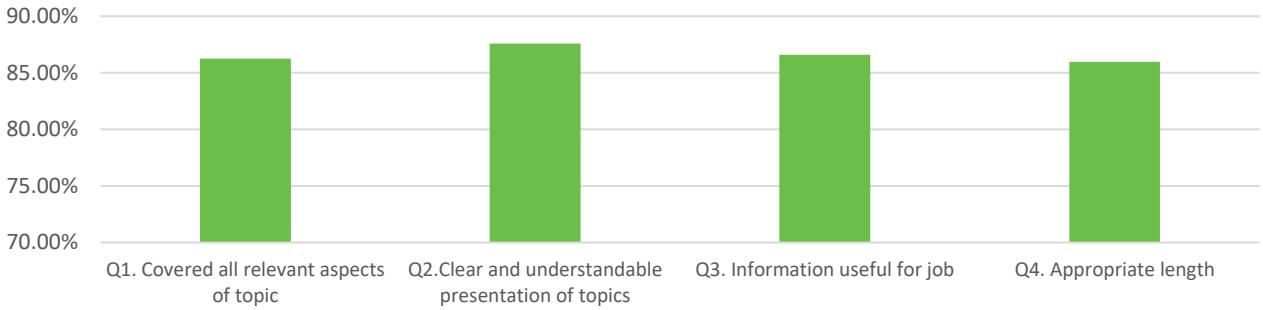


Figure 10: Average % Total Score per Question



The majority of responses (94.4%) are clustered in five courses (267007 [37.7%], 237001 [36.6%], 208001 [10.4%], 268044 [5.1%], 205001 [4.6%]). All of these course formats are recorded lectures. Course 305008 (eLearning module) responses make up 1.1% of the total.

The average overall score for each course ranges from 4.8 – 6 (80% - 100%). Courses 354032 and 305008 scored highest (6 [100%] and 5.6 [93%] respectively), however the number of respondents was low (1 and 7). Courses 267007 and 237001 had the highest number of respondents (238 and 231 respectively) and scored an average of 88% and 87%.

It is clear from Figure 10 that all aspects scored highly (85.97% – 87.58%). However, when viewing these results in the setting of the qualitative data above, certain areas are not captured in the numerical rating questions (e.g: technical).

In addition, questions are broad, and so it is difficult to definitively determine specific actionable aspects that are effective or require improvement (e.g: clarity of learning outcomes). A likert-like scale is used which does not give learners clear distinctions between answer choices and can produce unclear guidance for action (29). Lastly, learner surveys are based on subjective inputs of learners, who may not always be accurate in assessing their own learning.

It is important to note that the information presented above pertains to a small sample of EU NTC evaluation data and has a number of limitations (as outlined at the start of Section 3.4). In addition, 74.3% of quantitative responses come from courses 267007 & 237001, which limits the generalisability of this data, both to the full sample of courses reviewed in this report, and to EU NTC courses as a whole. Therefore, whilst the above quantitative data is positive, it is important to interpret this with caution. In general, learner surveys should not be used in isolation and instead augmented with outcome measures that address learner understanding, remembering and application (29).

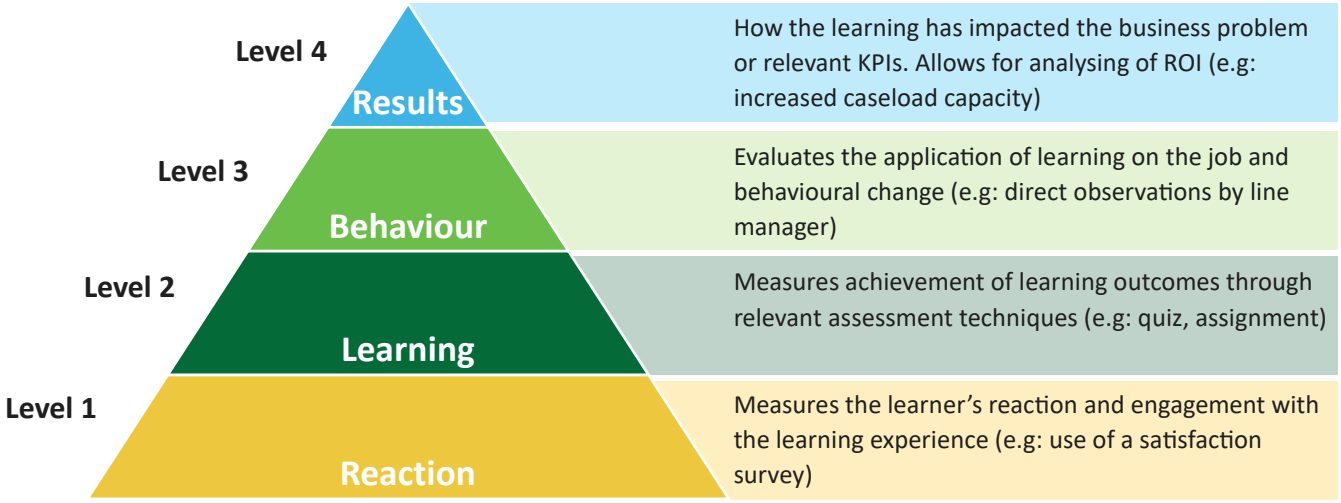
4. Learning Evaluation

It is clear from the information presented in this report that there is no definitive data on the most efficacious learning modalities for use in the training of regulatory professionals, with the majority of learner evaluation data coming from learner satisfaction surveys. To date, regulatory education is a relatively unexplored area from a research perspective.

Without valid feedback it is impossible to know how successful a learning design has been (29). IncreaseNET is well positioned to generate focussed, usable data pertaining to the efficacy of different learning modalities and instructional design approaches in the training of regulatory professionals. Therefore, it is imperative that robust evaluation processes are embedded into all training developed by IncreaseNET, with the potential to expand these evaluation approaches to the wider EMRN training network to promote optimal learning design and sustainability in the future.

This section will present a brief overview of factors involved in effective and comprehensive learning evaluation, with the intent that this information can be used a basis for evaluation process(es) developed for use in IncreaseNET WP5.

Figure 11: Kirkpatrick's Model of Evaluation



Donald Kirkpatrick's Model of Evaluation is a well-known and widely used framework for planning and conducting learning evaluation (Figure 11).

This four-level model shows that learning should not be the sole focus when developing training, but also creating on-the-job behaviour and organisational results.

This model highlights the low priority that should be given to learner surveys (29). Learners aren't experts in gap and need analysis or learning theory and behaviour change (30). In addition, learning that leads to actionable shifts in culture or behaviour often requires an element of discomfort, dissonance, conflicting ideas, or elements of unlearning (30). Therefore, learner satisfaction data should be interpreted with caution. This is not to say that there is no value in this information, rather that it should be interpreted in conjunction with data from other levels of the evaluation model.

Effective learning involves successful transfer of knowledge (Level 2) with subsequent changes in behaviour via the competent application of new knowledge (Level 3). Level 4 measures how the training's learning outcomes were met and supported by stakeholders (31). When designing an evaluation process, it is important to do this prior to developing the training. It is essential to plan

from level 4 down to ensure focus on results that you want the training to achieve ("flip the model") (30).

To date, almost all learning evaluation data in the EMRN has focussed on Level 1 only. A comprehensive evaluation process, guided by business aims, targeting all levels of the Kirkpatrick Evaluation Model, and developed in conjunction with training courses is recommended. Only when robust evaluation data is generated, can definitive conclusions on optimal learning modalities be made.

5. Discussion and Recommendations

The range of information presented in this report shows a set of common trends pertaining to the education of regulatory professionals.

Firstly, it is not possible to identify optimal learning modalities for regulatory training at present. This is a relatively unexplored area of research, with a paucity of high-quality comparative literature (2). However, both literature and "real-world" opinions and experiences (i.e. focus group and survey data) cite experiential learning as a critical and central component of regulatory education. In particular, case studies are recommended as a practical and relevant learning tool in this setting.

Secondly, the importance of good instructional and universal design is frequently highlighted throughout the report. Focus group discussions emphasised the need for a learner-centric approach, with a strong pedagogical basis, that is as accessible as possible to learners. In addition, there was a general consensus on the need to provide a wider variety of learning formats (e.g. interactivity, videos etc) and that a universal modality recommendation cannot be given, rather modalities should be dependent on the information to be imparted. These are complex decisions that would benefit from input from a learning professional.

EU NTC evaluation data demonstrates both a range of positive factors and areas for improvement with regards to instructional and universal design. 33% of users cited instructional design as a positive factor in the reviewed courses (e.g. comprehensiveness of content [11%] and use of examples [11%]), whilst 30% of users identified areas of instructional design that could be improved (e.g. lack of examples [13%]). From a universal design perspective, users cited a range of technical factors that can be improved upon, including audio quality (9%) and availability of a pause/rewind option (27%). Whilst this data set has a number of limitations (as outlined in the body of this report), the importance of instructional and universal design is still evident from these results.

Lastly, well-designed, focussed evaluation processes are imperative to identifying optimal approaches to the education of regulatory professionals. These processes should be timely, comprehensive and evidence based.

A comprehensive comparative review of all EU NTC learner evaluation data would provide additional usable and informative data for both IncreaseNET and the wider EMRN. IncreaseNET will undertake further collaborative discussions with the EU NTC core team to assess the feasibility of performing such a review.

Therefore, this report makes the following three recommendations for incorporation into the WP5 training development process:

1. Apply a logical basis to the choice of learning modalities used (e.g: experiential methods), whilst incorporating innovative and engaging approaches where feasible and appropriate.

2. Incorporate strong instructional and universal design bases into training development. This should be overseen by a professional in learning design.

3. Develop a comprehensive, evidence-based evaluation process for all developed trainings that is “results-focussed”.

It is hoped that utilising these recommendations as the basis for WP5 training development will result in an improved quality of learning that is transferable to the practical setting, along with generation of valuable data that can be used to iteratively improve future training courses. These learnings will be incorporated into the IncreaseNET sustainability report.

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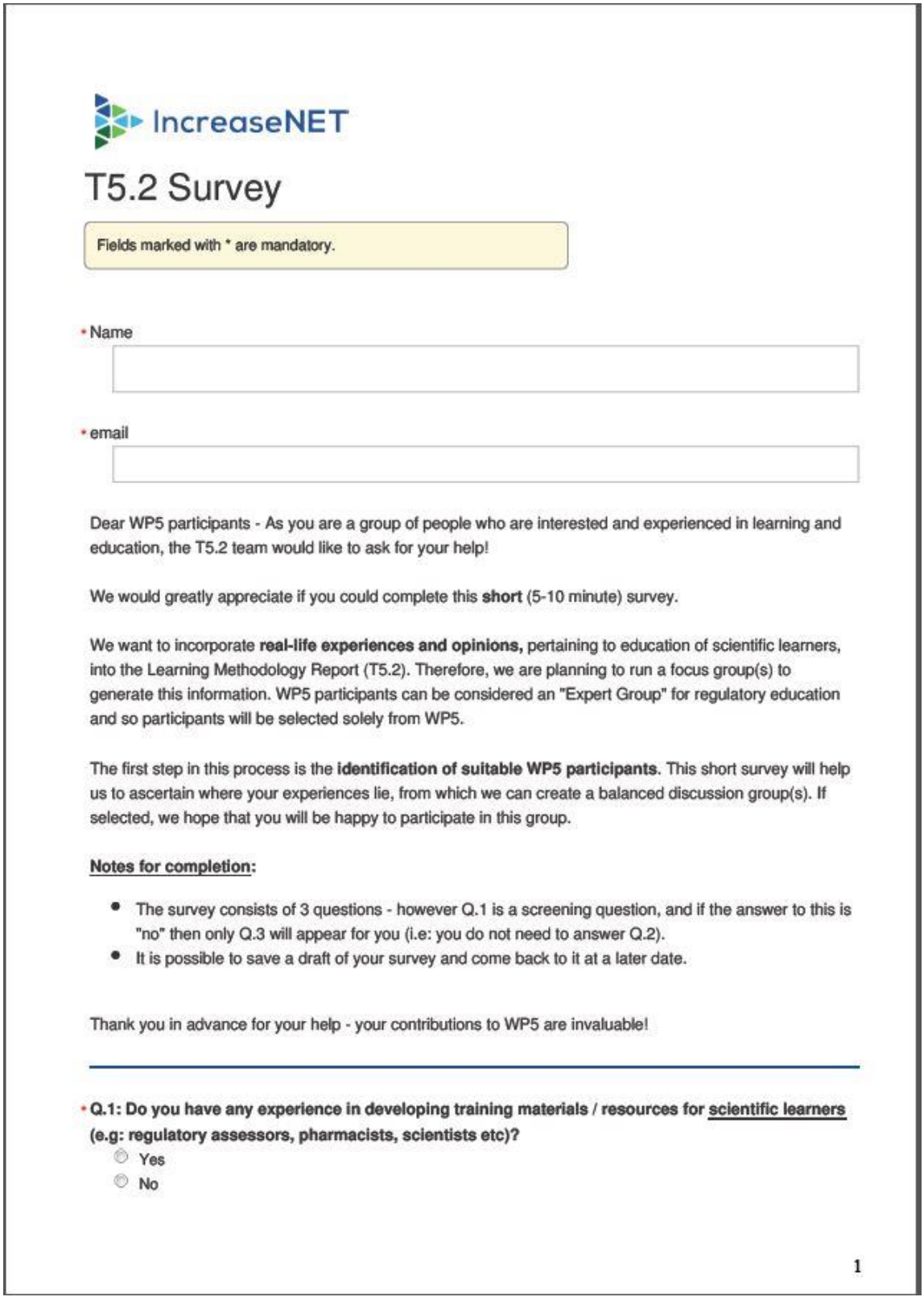
Appendix 1



IncreaseNET

T5.2 Survey

Fields marked with * are mandatory.

* Name

* email

Dear WP5 participants - As you are a group of people who are interested and experienced in learning and education, the T5.2 team would like to ask for your help!

We would greatly appreciate if you could complete this **short** (5-10 minute) survey.

We want to incorporate **real-life experiences and opinions,** pertaining to education of scientific learners, into the Learning Methodology Report (T5.2). Therefore, we are planning to run a focus group(s) to generate this information. WP5 participants can be considered an "Expert Group" for regulatory education and so participants will be selected solely from WP5.

The first step in this process is the **identification of suitable WP5 participants.** This short survey will help us to ascertain where your experiences lie, from which we can create a balanced discussion group(s). If selected, we hope that you will be happy to participate in this group.

Notes for completion:

- The survey consists of 3 questions - however Q.1 is a screening question, and if the answer to this is "no" then only Q.3 will appear for you (i.e: you do not need to answer Q.2).
- It is possible to save a draft of your survey and come back to it at a later date.

Thank you in advance for your help - your contributions to WP5 are invaluable!

* **Q.1: Do you have any experience in developing training materials / resources for scientific learners (e.g: regulatory assessors, pharmacists, scientists etc)?**
  - Yes
  - No

1

Q.2: Please select which types of learning modalities you have developed training in and your level of experience.

Learning Modality:	No Experience	Some Experience	Extensive Experience
* **Case Studies** - use of a case (e.g: assessment report) to illustrate principles and approaches			
* **Webinars** - live online learning event in which learners can gain information on a topic and have the opportunity to ask questions in real time			
* **Recorded Lectures** - a pre-recorded lecture on a topic, generally around 30 minutes in duration			
* **Interactive Modules** - a dynamic learning experience using a combination of multimedia elements, interactivity and feedback mechanisms			
* **Forums** - an online communication channel for knowledge-sharing and information exchange			
* **Podcasts** - a digital medium consisting of audio episodes that relate to a specific theme/topic			
* **Microlearning Videos** - a short video (approx. 2-5 minutes) that usually only has a single learning objective. Breaks material down into short, easily digestible components			
* **Scenario-Based** - a learner is given the opportunity to develop a skill by practicing in a true-to-life simulated environment that "replicates job conditions"			
* **Workshops** - an interactive learning session with peer-to-peer and learn by doing elements			
* **Other** - please provide details in the below comment box			

Please detail here the "other" learning modalities that you have indicated you have experience in. This will help to ensure we are capturing all modalities.

Q.3: Please rate each of the following learning modalities with regards to training efficacy. This rating is subjective and should be based off you own experience educating individuals with a scientific background OR your personal experience undertaking learning via the modality.

For modalities that you have no experience with (either developing or using) please select not applicable (N/A).

Training efficacy is divided into knowledge acquisition and practical application of skills, as per the following rating scale (0-3):

2

0: No improvement
1: Small amount of improvement
2: Moderate improvement
3: Significant improvement

Learning Modality:	Knowledge Acquisition	Practical Application of Skills
Case Studies - use of a case (e.g: assessment report) to illustrate principles and approaches	○ 0 ○ 1 ○ 2 ○ 3 ○ N/A	○ 0 ○ 1 ○ 2 ○ 3 ○ N/A
Webinars - live online learning event in which learners can gain information on a topic and have the opportunity to ask questions in real time	○ 0 ○ 1 ○ 2 ○ 3 ○ N/A	○ 0 ○ 1 ○ 2 ○ 3 ○ N/A
Recorded Lectures - a pre-recorded lecture on a topic, generally around 30 minutes in duration	○ 0 ○ 1 ○ 2 ○ 3 ○ N/A	○ 0 ○ 1 ○ 2 ○ 3 ○ N/A
Interactive Modules - a dynamic learning experience using a combination of multimedia elements, interactivity and feedback mechanisms	○ 0 ○ 1 ○ 2 ○ 3 ○ N/A	○ 0 ○ 1 ○ 2 ○ 3 ○ N/A
Forums - an online communication channel for knowledge-sharing and information exchange	○ 0 ○ 1 ○ 2 ○ 3 ○ N/A	○ 0 ○ 1 ○ 2 ○ 3 ○ N/A
Podcasts - a digital medium consisting of audio episodes that relate to a specific theme/topic	○ 0 ○ 1 ○ 2 ○ 3 ○ N/A	○ 0 ○ 1 ○ 2 ○ 3 ○ N/A
Microlearning Videos - a short video (approx. 2-5 minutes) that usually only has a single learning objective. Breaks material down into short, easily digestible components	○ 0 ○ 1 ○ 2 ○ 3 ○ N/A	○ 0 ○ 1 ○ 2 ○ 3 ○ N/A

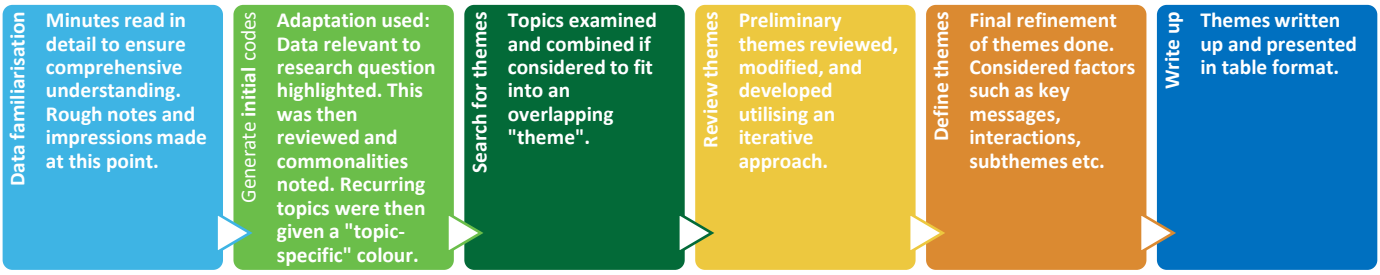
3

Scenario-Based - a learner is given the opportunity to develop a skill by practicing in a true-to-life simulated environment that "replicates job conditions"	○ 0 ○ 1 ○ 2 ○ 3 ○ N/A	○ 0 ○ 1 ○ 2 ○ 3 ○ N/A
Workshops - an interactive learning session with peer-to-peer and learn by doing elements	○ 0 ○ 1 ○ 2 ○ 3 ○ N/A	○ 0 ○ 1 ○ 2 ○ 3 ○ N/A

4

Appendix 2

Thematic analysis as per Maguire and Delahunt six-phase guide (27)



Appendix 3

HMA Heads of Medicines Agencies

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Standard Feedback Form

EU NTC Course feedback form

The below questions are included in the standard feedback form in the EU NTC LMS.

Additional questions can be added to this standard form. Please contact the EU NTC support team (networktraining@ema.europa.eu) to inform them of the additional questions you would like to add to the feedback form for your course, or with any further questions about the feedback in the LMS.

Please reply to following questions related to the content and format of the session	
Training content	**The course covered all relevant aspects on this topic.** ☐ **1 - Strongly disagree** ☐ **2 - Disagree** ☐ **3 - Somewhat disagree** ☐ **4 - Somewhat agree** ☐ **5 - Agree** ☐ **6 - Strongly agree** ☐ **7 – N/A** Comment: **The topics were presented in a clear and understandable way.** ☐ **1 - Strongly disagree** ☐ **2 - Disagree** ☐ **3 - Somewhat disagree** ☐ **4 - Somewhat agree**

See websites for contact details

Heads of Medicines Agencies www.hma.eu
European Medicines Agency www.ema.europa.eu

The European Medicines Agency is an agency of the European Union

	☐ **5 - Agree** ☐ **6 - Strongly agree** ☐ **7 – N/A** Comment: **The information in this course was useful for my job.** ☐ **1 - Strongly disagree** ☐ **2 - Disagree** ☐ **3 - Somewhat disagree** ☐ **4 - Somewhat agree** ☐ **5 - Agree** ☐ **6 - Strongly agree** ☐ **7 – N/A** Comment:
Training Format	**The length of the training course was appropriate.** ☐ **1 - Strongly disagree** ☐ **2 - Disagree** ☐ **3 - Somewhat disagree** ☐ **4 - Somewhat agree** ☐ **5 - Agree** ☐ **6 - Strongly agree** ☐ **7 – N/A** Comment:
Please let us know your feedback on the following questions:	
1. What did you most like about the webinar?	
2. What are your suggestions for improvements?	
3. Do you have any other comments or feedback?	

Thank you for your feedback.

Abbreviations

AI	Artificial Intelligence
ATMP	Advanced Therapy Medicinal Products
BC	Beneficiary
BEMA	Benchmarking of the European Medicines Agencies
BWP	Biological Working Party
CHMP	Committee for Medicinal Product for Human Use
CMDh	Co-ordination Group for Mutual Recognition and Decentralized Procedures (human)
CMS	Concerned Member States
CT	Clinical Trial
DCP	Decentralised Procedure
EC	European Commission
EDQM	European Directorate for the Quality of Medicines and Health Care
EMA	European Medicines Agency
EMRN	European medicines regulatory network
EU	European Union
EU NTC	EU Network Training Centre
HMA	Heads of Medicines Agencies
HPE	Health Professions Education
ICH	International Conference on Harmonisation
IncreaseNET	Supporting the increased capacity and competence building of the EU medicines regulatory network
KPI	Key Performance Indicator
LMS	Learning Management System
MA	Marketing Authorisation
MD	Medical Device
MRP	Mutual Recognition Procedure
MS	Member State
PRAC	Pharmacovigilance and Risk Assessment Committee
ROI	Return on Investment
SME	Subject Matter Expert
WP	Work Package