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# Clinical Trial Results Summary for Laypersons – a user testing study

## ABSTRACT

**Background:** The objective was to apply ‘user testing’ to maximise readability and acceptability (for all education levels) of a Clinical Trial Results Laypersons Summary – a new European requirement for trials of new medicines.

**Methods:** ‘User testing’ using mixed methods (questionnaire and semi-structured interview) was used to assess document performance — can people find and understand key points? Findings were used to improve document content and design, which was then tested again. Participants were members of the UK public with a range of levels of health literacy and a higher education group. **As the summaries will be made available on a website, participants accessed the summary on screen.** In Round 1 we tested 12 points of information. In Round 2 a revised summary addressing the findings of Round 1 was tested. A third final version was then prepared.

**Results:** In Round 1, 2 of the 12 points of information did not reach the target and semi-structured interviews raised further issues related to both format and content (participants being distracted by some technical explanations and the inability to find or understand the two main purposes of the study. . These findings informed revisions for the version tested in Round 2, where 2 different points did not reach the target. One of these points focused on inclusion criteria relating to duration of seasonal allergies, the other related to how the researchers found out about participants’ symptoms. The identified problems in both rounds were addressed and reflected in the final version. Despite improvements, participants did not consistently

understand the summaries were intended for the general public, or that results of single trials should only be interpreted in the context of additional trials. All readers, including those with higher education, found the clear and straight forward language acceptable.

**Conclusions:** Applying 'user testing' resulted in a largely health literate summary suitable for people across a range of backgrounds.

**Key words:**

- Clinical trial
- Lay summary
- User testing
- Readability
- Health literacy

## INTRODUCTION

In Europe, clinical trial sponsors will soon be required by the new EU Clinical Trials Regulation (1) to publish a public summary of clinical trial results within one year of the trial ending. The purpose of the public summary is to provide information on the background of the trial, the processes, study population, trial medicines used and any side effects, as well as the overall results (2). It is **intended** to be read by the general public. **This regulation only applies in Europe, however in some countries such summaries are available for people who have taken part in a trial.**

The Regulation provided little detail on how the summaries should be written and presented – only the ‘elements’ that must be included in the summaries - which have been interpreted as headings (see Table 1).

Subsequently, in 2016, a consultation from the European Commission detailed recommendations from the “Expert Group on Clinical Trials” for the implementation of the regulation. (3) This draft guidance noted that ‘where feasible, sponsors should consider testing the readability of an initial version of the study results summary with a small number of people who represent the target population’. However, it appears that no such testing has been applied to the text, the guidance itself recommends for inclusion in the summaries.

### **(Table 1 Here)**

As a result, we decided to test the readability of a proposed summary consistent with the EU guidance (but with lay friendly headings replacing the original ‘elements’). We used the process for assessing the readability of documents called ‘user testing’.

This method, developed in the 1990s in Australia is a type of “performance-based

testing” (4). It simultaneously tests the usability of both **content** and **structure** of a document with potential users. It is routinely used across Europe to test the readability of the mandatory leaflets for patients included in every medicine pack (5). Such user testing has also been used to test a wide range of lay health information, including clinical trial informed consent forms (ICFs) (6). In particular, it has also been used to test other regulatory lay summaries:

- the European Public Assessment Report (EPAR) summary (8)
- the Risk Management Plan (RMP) summary (9)

The objective of this study was to apply ‘user testing’ to maximise the readability and acceptability of a ‘Clinical Trial Results Laypersons Summary’, to determine whether **it meets** lay people’s needs, including those with a range of health literacy levels.

The findings were intended to inform the above public consultation on the summaries **(3)**.

## **METHODS**

We tested a sample laypersons’ summary based on the results of a previously completed clinical trial: ‘A Multi-Center, Double-blind, Randomized, Parallel-Group Study Investigating the Effect of Montelukast in Patients With Seasonal Allergic Rhinitis - Spring 2001 Study’ (10). The summary was prepared before the draft guidance was released, but after the ‘elements’ were available in the Regulation. However, for headings, we replaced this wording with lay friendly headings (see Table 1 and additional explanatory text in Materials Tested below). **The summary was tested on a computer screen.**

User testing tests the usability of both content and structure in a written material using mixed methods:

- quantitative questioning: can the reader find key pieces of information and express the information in their own words?
- qualitative questioning – this augments the quantitative data, giving insights into the positive and negative aspects of the information from the participant's perspective.

Use testing is a diagnostic process which can identify problems with information content and design using small samples. In line with the iterative nature of user testing, the principles of good information writing and design were applied, in a formative, iterative way, to identify and rectify readability problems within information (5), along with recommendations from the subsequently released draft guidance for consultation. **User testing differs significantly from the use of 'readability formulae' such as SMOG and Flesch. These are based on word and sentence length only – a very small part of the totality of influences on readability.**

## Participants

Participants were members of the general public - the target group for the summary - recruited from the database of Luto Research, the company which undertook the user-testing interviews. The database draws on people in the Leeds area of the North of England, and comprises people who have volunteered to take part in the testing of health information materials. **The main exclusion criteria were people who have taken part in a user test in the previous 6 months and those with a health professional or pharmaceutical background.**

Each round of user testing interviews was **intended** to include at least ten participants, across different genders, age groups and educational backgrounds (up to Bachelor's degree level) and computer confidence. **Computer confidence was**

**self-reported by participants in answer to a question about how confident they were when using computers (very confident, quite confident, or not confident).**

To ensure we had a range of levels of health literacy in this 'core' group, we assessed this using a validated UK version of the "Newest Vital Sign" which measures text and numerical literacy. **This measure was chosen because of its acceptability and ease of application compared to other methods** (11) (NVS – see Appendix A). We aimed to recruit participants across a range of health literacy levels as follows:

- between 2 or 3 participants 'low' - a score of 0 or 1
- between 2 or 3 participants 'intermediate' - a score of 2 or 3
- the remainder with a score of 4 or above on the UK NVS ('adequate')

A total of 13 participants were recruited to the core group in Round 1 of testing so as to meet the quota of participants with "low" health literacy. In Round 2, the quota was met with the first ten participants, so additional participants were not recruited.

We also wanted feedback from participants who had undergone higher education. This means that as well as the 'core' group, we included an additional 'higher education' (HE) group of four participants in each round of testing. The criteria for this was having a masters, doctorate or equivalent (**all of whom had adequate health literacy**).

A new cohort of participants was used in the second round of testing, to prevent a learning effect. Summary demographics for age, gender, education level, use of literature, health literacy level and computer confidence were matched as far as possible across Round 1 and Round 2 of testing.

## Materials tested

### Round 1

In the sample summary tested, the headings (or 'elements') included in the EU Regulation were replaced with lay friendly headings instead of the terminology proposed (see Table 1). This was because non lay-friendly technical wording such as '*Indication if follow up trials are foreseen*' in headings has been shown to be detrimental to readability, particularly for people with low to average reading skills (8,9).

Also, it was agreed that the summary would be anonymized and all identifying information would be removed e.g. product names replaced with "Medicine A" etc. The summary tested in Round 1 is shown in Figure 1.

In accordance with good practice (12,13), **and taking account of the information being presented on screen**, we formatted the original summary to include:

- sub-headings
- blue banded main headings in larger text
- bullet points
- bolding
- white space.

### Round 2

Following the first round of testing, a number of improvements to the summary were agreed, based on:

- Results from the quantitative testing in Round 1 i.e. where problems in finding or understanding points of information were identified



- Comments from participants given during the qualitative feedback section in Round 1
- Recommendations from the subsequently published consultation document from the Commission
- Good practice in information writing and design.

The resulting revised summary tested in Round 2 is shown in Figure 2.

### Procedure

Participants were interviewed individually and the summary was presented on a computer screen – how the summaries will be available on the EMA website. Each participant was given time to read the document at their own pace.

The 12 key points of information for testing were agreed by all team members and a questionnaire devised to evaluate these points (see Appendix B). The questionnaire and leaflet were pilot tested with two people from a “convenience sample”, following which 2 questions were removed (as the interview was over-long), and 2 questions were re-worded for clarity.

The questionnaire was split into two main parts:

- quantitative section – with questions designed to determine whether information could be found and understood.
- qualitative section – to elicit feedback on participants’ views of the document; what they may have found easy or difficult. In addition, we asked a number of targeted questions about the summary’s intended audience, usefulness to the public and why it was written (see also Appendix B).

For the quantitative questions, the success criteria in current European guidance for patient leaflets **(13)** were used as a guide:

- 90% of participants tested should be able to find the information in the summary
- 90% of participants who found the information should also be able to understand it.

'Indicative answers' were developed to ensure consistent scoring for each question. The interviewer noted whether the participant had any difficulty finding each piece of information (defined as taking more than two minutes to find the information or needing more than two "permitted prompts", such as repeating the question).

The responses to the qualitative questions were recorded and transcribed verbatim. We looked for recurring patterns of comments and chose quotes which illustrated these points.

The study was reviewed and approved by the University of Leeds, School of Healthcare Research Ethics Committee (HREC15-054). Each participant was paid £30 for travel and other expenses.

## RESULTS

31 participants were interviewed in 2 rounds:

- Round 1: 13 'core' participants plus 4 higher education (HE) participants
- Round 2: 10 'core' plus 4 HE participants

Participant demographics are described in Table 2.

**(Table 2 Here)**

## Round 1

### Quantitative findings

In the core group, 11 of the 12 items of information from the summary passed the user testing criteria in Round 1. That is, at least 90% of participants were able to find each item of information and of these, at least 90% understood it correctly. Again, in the HE group, 11 of the 12 items of information passed the user testing criteria in Round 1. Note that the items that did not meet the criteria differed between the core group and the HE group (Core group: Q11; HE group: Q1) – both are discussed below along with other questions that participants found more difficult to answer.

#### **(a) Questions that did not meet the test criteria**

**Q11** *“For this question, I’d like you to think about the patients who had Medicine A and Medicine B. After the study, how did they feel overall about their seasonal allergies?”*

- Core group:
  - 3 found with difficulty (Health Literacy: 2 intermediate; 1 adequate);
  - 3 unable to find (HL: 2 intermediate; 1 adequate);
  - 2 not understood (HL: 1 low; 1 intermediate).
- HE group:
  - 1 found with difficulty (HL: adequate)

Participants appeared distracted by technical descriptions of the study measures e.g. *“Patient’s Global Evaluation of Seasonal Allergy Symptoms”*. Also, readers generally focus on information presented first on a bullet point. Hence the order of information on the bullets were swapped - with the lay description first and technical term after in inverted commas.

**Q1** *“What were the two main purposes of the study?”*

- Core group:
  - o 1 unable to find (HL: 1 low);
  - o 1 not understood (HL: 1 low).
- HE group:
  - o 1 unable to find (HL: adequate)

Following Round 1, the structure and format of information under “Why was this study done?” was therefore refined, as the overall purposes of the study may have been lost in this relatively long section of information. In addition, a bolded introduction to each purpose was added at the start of each bullet point (“To look at daytime nose symptoms” and “To look at safety”) - to clarify that these were the main points. Also, extraneous information that was not directly related to the purpose of the study was moved to elsewhere in the document. This was intended to help to focus the reader’s attention on the two purposes of the study rather than other related information. See Table 3.

**(Table 3 here)**

**(b) Questions that were more difficult to answer**

**Q7** “How did the change in daytime nose symptoms compare in the three groups after two *weeks*?”

- Core group:
  - o 2 found with difficulty (HL: 1 intermediate; 1 adequate),
  - o 1 unable to find (HL: 1 intermediate).
- HE group:
  - o no negative scores

Following Round 1, several changes were made as a result to the presentation of information under “What were *the results of the study?*”. The original sub-headings were “Primary finding” and “Other findings”. It was considered “Primary finding” would not be understood by many lay people not familiar with research. The sub-headings were therefore refined to focus on the symptoms, i.e. “Daytime nose symptoms” and “Other symptoms”.

**Q12** “*How did researchers find out about patients’ symptoms while they were in the study?*”

- Core group:
  - o 2 found with difficulty (HL: 1 intermediate, 1 adequate)
  - o 1 unable to find (HL: 1 intermediate)
- HE group:
  - o no negative scores

Following Round 1, the sub-heading for this information was simplified and re-ordered to focus on “symptoms”. Additionally, the information under this sub-heading was split into two more distinct sections of information and bold text was added at the start of each paragraph to draw the reader to the information, this included “Diary” and “Patients’ scores”.

The full set of quantitative findings are presented in Table 4.

**(Table 4 here)**

## Qualitative findings

As part of Round 1, participants were asked to provide feedback in terms of their impressions of the leaflet. In general, the language was well received. As expected, those with lower health literacy generally showed more difficulty with the words.

*“I found it straight forward. I could understand everything through that, apart from some of the words I couldn’t pronounce them.”* (Core group; Low HL)

People liked the use of colour and bold text for the main section headings. One said *“(the blue headings) projected the areas that you need easier”*. Others also commented on the wording of the headings: *“It has sensible sub-titles in between the blue banners, so ‘Why was the study done?’, ‘How was the study done?’”*.

As participants in this study viewed the information on screen, the blue banding all across the page helped them to see clearly that they were in a new section as they scrolled down: *“It was quite easy (to find information). Because you can scroll down and with the blue heading as well [...], that’s very helpful.”*

Findings from the targeted questions asked at the end of the qualitative questions have been combined and presented at the end of this section.

## Revising the summary after Round 1

Following the first round of testing, the changes described above were made. In addition a number of further improvements were agreed based on:

- Guidance in the consultation document
- Good practice in information writing and design.

**General format changes**

- To reduce overall line length, margins were widened on left and right - a shorter line length is more readable, particularly for people with low health literacy.
- Guidance says not to use long and complex sentences – so for long sentences we either split them into two smaller sentences, or used a hyphen within the sentence, to separate the information into manageable chunks. For example:

Tested wording (Round 1)	Tested wording (Round 2)
To see how well a drug called Medicine A could improve symptoms of seasonal allergies (seasonal allergic rhinitis) compared to a “sugar pill” that didn’t contain any drug (placebo).	To see how well a drug called “Medicine A” could improve symptoms of seasonal allergies (seasonal allergic rhinitis). This was compared to a “sugar pill” that didn’t contain any drug (placebo).

- Guidance says to “remove unnecessary words” - we identified such words and phrases and removed them, for example:

Tested wording (Round 1)	Tested wording (Round 2)
1 out of every 10 people (10%) of the world’s population	1 out of every 10 people (10%) in the world

- We found that information about the doses was included twice. This information was therefore removed under “How was this study done?”
- The opening section was amended to give more prominence to the lay title - by increasing the font size and using a bold font. Also, the prominence of the

numbers and references that identify the trial was reduced - in line with draft guidance to “avoid overwhelming the reader with too much information”.

- New sub-headings were added under “What side effects did patients have? - in line with the guidance recommendation on the use of sub-headings to organize information.
- One participant would have liked to have seen section numbers in the summary – and this has been found helpful in the user testing of other lay summaries.

*“The pages are numbered but the sections are not. “Who took part in the study”, that could have been number three or something.”* (Core group; Intermediate HL)

However, as the comment was from only one participant this was not implemented and an additional question added to the questionnaire for Round 2.

### **Chart in ‘What were the results of the study’ (see Figure 1)**

During Round 1, several core group participants described the chart as “confusing” or “too simple” and that it “means nothing”. However, some did say they found the chart clear and helpful. There were two main themes in the comments:

- Numbers, figures, axis labels:

*“There’s no numbers so it’s hard to know whether a smaller bar, initially looking at it, is a good or a bad thing”* (HE group; Adequate HL)

- Bars below axis:

*“I only understood it when I read text underneath. It looked a bit random with the black line at the top.”* (HE group; Adequate HL)



One of the participants in the pilot test had also commented that the chart looked “upside-down”.

Hence, the main change implemented following Round 1 was the direction of the bars was reversed - so an improvement in symptoms was shown as a bar above the horizontal axis line, rather than below. The updated chart is shown in Figure 2.

Alternative versions of the chart were also created (see Appendix C) and feedback obtained in Round 2.

## Round 2: revised version

### Quantitative findings

In the core group, 10 of the 12 items of information from the summary passed the user testing criteria in Round 2. Performance on the two questions that had not met the criteria in the first round (Q1 and Q11) was improved, but there was difficulty instead with two different questions (Q 8 and Q12). Suggestions to improve the summary further were discussed. All 12 items passed the user testing criteria in the HE group in Round 2.

#### **(a) Questions where performance was improved in Round 2**

**Q11** *“For this question, I’d like you to think about the patients who had Medicine A and Medicine B. After the study, how did they feel overall about their seasonal allergies?”*

- This question met the test criteria in Round 2 across both core and HE groups.

**Q1** *“What were the two main purposes of the study?”*

- All participants in Round 2 were able to find and understand this information following amendments implemented between rounds..

**(b) Questions that did not meet the test criteria (Round 2) and improvements**

**Q8** *“To take part in the study, how long must people have had seasonal allergies for?”*

- Core group:
  - o 2 found with difficulty (HL: 2 intermediate)
  - o 2 unable to find (HL: 1 low, 1 intermediate)
- HE group:
  - o no negative scores

Examination of the data showed that participants seemed unable to identify this information in the text, possibly because it is “hidden” at the end of a bullet point (as described above). Hence “seasonal allergies” were re-positioned at the start of the bullet in the final version.

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<b>Tested wording</b>	<b>Final wording</b>
<ul style="list-style-type: none"><li>• Have a doctor say that they’ve had seasonal allergies for 2 years or more</li></ul>	<ul style="list-style-type: none"><li>• Have had seasonal allergies for 2 years or more (confirmed by a doctor)</li></ul>

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**Q12** *“How did the researchers find out about patients’ symptoms while they were in the study?”*

- Core group:
  - o 2 found with difficulty (HL: 1 low, 1 intermediate)
  - o 3 unable to find (HL: 1 low, 2 intermediate)
- HE group:
  - o 2 found with difficulty (HL: 2 adequate).

The sub-heading for this section was amended after Round 1 to make it simpler and to focus on “symptoms” (see middle wording below). A suggested further amendment to the heading is shown below on the right.

Round 1 heading	Round 2 heading	Suggested final heading
How did researchers measure symptoms?	How were symptoms measured?	How were symptoms measured by researchers?

The final version of the summary is provided in Figure 3.

**Qualitative findings - targeted questions**

After the general qualitative questions, the following targeted questions were asked:

- **Who do you think this summary has been written for?**

Across both rounds, most were not aware that this document was intended for the general public. Only 12 / 31 (39%) mentioned patients / general public / lay people.

**Others** referred to **included** doctors, the drug company or researchers. That the document is for lay people is not explicitly stated in the document (in line with the current guidance) so it is unsurprising that participants gave varied answers.

- **How useful do you think the information in the summary would be to members of the public?**

There was a general consensus that the information would be useful if you were thinking of taking the study medicines or if you had seasonal allergies. However, responses about usefulness to the wider public varied.

*“This won’t actually affect part of the public. It’s only going to affect the people who applied to help out on the study”* (Core group; low HL)

*“I can’t imagine a member of the public wanting to know this unless they were particularly interested in the process of drug creation or the studies behind it”* (HE group; Adequate HL)

- **Why do you think this summary has been written?**

Those that referred to the purpose of the summary gave a variety of responses.

**for example:**

*“I have no idea actually. [...] Do these studies come out into the public arena? I don’t know. I would have thought it would have just stayed in the medical profession.”* (Core group; Intermediate HL)

*“To research it and so it can be given out to the public [...] you need volunteers don’t you to help with the research”* (Core group; Intermediate HL)

- **This summary tells you about the results from one study - other studies may show different results. How clearly was this described in the document?**

We used the wording suggested in the guidance: “This summary only shows the results from this one study. Other studies may find different results.”. However, across both rounds, 20 / 31 (65%) participants either did not recall this information or did not think that this was highlighted enough in the document.

As described above, another version of the summary with section numbers on each of the main section headings was shown to participants and the following question asked during Round 2 only.

- **Tell me whether you prefer the headings with or without numbers and why?**

In the core group, 8 / 10 participants (80%) preferred the numbered headings. In the HE group, all 4 participants (100%) did not think the numbers were needed.

Those that preferred the version with numbers gave reasons such as:

*“because it makes it stand out to me”* (Core group; Adequate HL)

*“because you know they’re separate paragraphs”* (Core group; Adequate HL)

Following testing, it was agreed that numbered headings should be incorporated into the summary to aid readers. This is shown in the final version of the summary in Figure 3.

- **What is your view on the reading level of the document - did it seem appropriate to you?**

This was asked to the HE group only. All eight of the HE participants found the language to be acceptable and remarked positively on the words used:

*“It was appropriate for the majority of the population. It was fine for me”*

*“It seems about right. You’ve got the right balance, the right terminology”.*

- **Looking at the chart showing you the results, what were your views on the chart? What do you think it is telling you?**

Feedback from Round 1 was used to inform the development of alternative chart formats, one of which was included in the version tested in Round 2. Three other versions were shown to the participant at the end of testing. The four alternative chart formats are shown in Appendix C, along with the feedback for these alternatives: Most participants (9 / 14; 64%) across both groups in Round 2

preferred the chart included in the main body of the summary and were generally able to describe what the chart is showing to a good degree of understanding.

## DISCUSSION

### Main findings

The development of the final version of this clinical trial *layperson's summary* was informed by the draft guidance on writing such summaries and then testing using the method of 'user testing' with the target audience. The user testing process showed that it is possible to create a largely health literate **summary for most people across a range of backgrounds**. However, it has also highlighted areas within the summary that could be improved to increase the readability.

Notably, the majority of participants were unaware that the summary was intended for the general public – they suggested a wide range of other audiences. The summary therefore needs an introductory section that makes it clear to the reader who it has been written for and why it has been written (not present in the current draft guidance). Such an introduction has been found useful for readers in testing of EPAR and RMP summaries (8,9) and should be included in all clinical trial summaries.

Readers must understand that the results are only from one study and that other studies may have different results. The single sentence from the draft guidance was included in the tested summary, but the majority in both rounds did not recall this information or thought it was not clear or highlighted enough in the document. More prominence is needed to emphasize that 'Other studies may show different results' by the use of an additional sub-heading and adding more detail to emphasize its importance.

In more general terms, the user feedback and the consideration of good practice showed that improvements were needed to both the content of the information (the words used), and the design of the original summary. This is because people had problems finding as well as understanding information. These findings which can guide the preparation of such summaries in the future are summarized in the Recommendations in Table 5.

### People with higher education

All readers, including those with higher education qualifications, appreciated the clear and straight forward language used in the tested summary. That the participants with higher education qualifications were positive about the revised summary is important. This is because, anecdotally, some argue that writing in straightforward plain language will not be acceptable to those with higher educational backgrounds - given that they may be used to reading more technical or complicated information.

### Charts and graphs

A number of participants had difficulty with the chart, one thinking that it was 'upside-down'. Members of the public not familiar with charts or graphs may be confused by numbers or the presentation of a graph if it is too technical. Any chart or graph should be supported by a simple description of what it is showing, and numbers or scales included only if they are simple to understand. Discussing or testing any chart or graph with lay readers will provide valuable feedback on whether the graph is effective.

**(Table 5 here)**

There is a general learning that when presenting the main aims or purpose of a study, the summary wording should be concise and not contain too much additional information as this may distract from the overall purpose.

## Limitations

**User testing uses small sample sizes, but this is commensurate with a diagnostic approach.** It is recommended by the European Medicines Agency, and extensive experience across Europe has shown that it can be useful in identifying problems with information using only small numbers.

One limitation is that these findings arise from the testing of one example summary, and further testing of other summaries would be beneficial, particularly as experience develops. However, much of what we have found has general applicability across all types of trials. A further limitation is that the headings (or 'elements' as they are described in the Regulation) are described as not being able to be changed. An example of the wording is 'Investigational medicinal products used'. Our findings depend on lay-friendly wording of these headings being used – a way around this needs to be found.

**The testing was undertaken with participants reading the information on a screen – as the summaries will be made available on the EMA website. Most of the findings could be applied to paper-based versions of such summaries, as they relate to the text – however any layout and design aspects would need to be tested on paper.**

## Relationship with wider literature

The summaries of clinical trials being considered here are a new concept, being addressed to the general public. Such summaries designed for people who have



**taken part** in a clinical trial have been available for some time. However, these are not routinely produced and there have been calls in the United States for them to be widely available (14). It is noteworthy that some participants in this study questioned the usefulness of such summaries to members of the general public.

This user testing follows on from such testing on other lay summaries required in the EU. Testing of a lay summary of a European Public Assessment Report (EPAR) was undertaken in 2013 and it found that people had difficulties finding and understanding key messages (8). Subsequently, testing of a summary of the Risk Management Plan found similar problems, notably non-lay friendly lay headings, complex tables, and a lack understanding of who the summary was written for (9). The European Medicines Agency have subsequently positively responded to these findings for both documents.

There has been a wider discourse on the concept of 'transparency' and how it is being applied in the context of medicines regulation in the EU. Way et al suggested that 'by focusing transparency policies on the full disclosure of regulatory information, EMA has inadvertently ignored the complexities of communicating to patients'. They go on to describe the danger of 'decontextualized and complicated medicines information' and that it 'will decrease rather than increase their confidence in taking their medicines'. (15) This emphasizes the need for all lay summaries to be clearly contextualized and described in non-complicated language. This study, through the methodology of 'user testing' has identified ways in which such health literate summaries can be produced.

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