



**Luto.**

**Risk Managment Planning.**



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# Case Study.

Are Risk Management Plan (RMP) summaries fit for purpose?

## Introduction to User Testing

User Testing examines how well users can find and understand key information in patient information materials.

- In individual interviews, real people (not expert patients) are asked to find and explain the key points - and then give their general opinions on the good and bad points of the information.
- Then the results are analysed, and high-level expertise in information writing and design is applied to improve the document.
- The revised document then undergoes a further round of testing.

In the European Union (EU), the mandatory patient leaflets supplied inside every pack must be User Tested on members of the public before the European Medicines Agency (EMA) grants marketing authorisation.

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## What is an RMP summary?

Increasing numbers of regulatory documents are being made available as public or lay summaries.

In the EU, one such document is the Risk Management Plan (RMP), which describes the identified potential risks of a medicine and how these risks will be managed. It is similar to the US 'REMS' (Risk Evaluation and Mitigation Strategy).

- The EMA publish a public summary of the RMP for all new medicines. This document is intended for the lay reader, amongst others.
- According to the EMA, this new document 'increases transparency and public access to relevant information on medicines'.



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## Luto's strong academic links

Luto was founded by researchers at the University of Leeds in the UK. Co-founder, Professor Theo Raynor remains an academic advisor, and the University and Luto undertake joint research such as described here.

## What did the study involve?

A 'typical' RMP summary from the EMA website was selected shortly after they were first published in Spring 2014. The aim was to determine how readable and understandable the summary was. Two rounds of testing were undertaken with members of the public.

## What did we find?

- The first round of testing found many aspects of the summary did not perform well.
- Best practice in information writing and design was then applied and a second round of testing undertaken.
- The second round of interviews showed improvements, but with problems remaining.

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## Preliminary conclusions

- Current summaries do not meet the needs of lay people. However, the application of User Testing can help to improve people's ability to find and understand the information.
- Lay people need a clear explanation at the start of the summary - what it is about and who should read it.
- The current structure and headings do not work well - it needs a more lay friendly structure.
- Lay readers may not want or need all of the current content in the summaries. The more complex information could be placed in an appendix - where readers can attend to this information if they wish to.



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## About Luto.

**We specialise in creating user friendly communications through good information design. We can work with you to produce both print and digital communications, from health information leaflets, Instructions for Use (IFUs) and educational materials to animations, apps and websites.**

Luto has a proven track record of working with a range of healthcare organisations, including the top ten international pharmaceutical companies. We also work with medical device companies, regulators, government departments, universities and charities.

Our process is backed by over a decade of evidence based academic rigour – we understand how users interact, read and engage with healthcare products and information. Our methods are proven to enhance readability and usability in a variety of communications aimed at patients, carers, clinicians and academics.

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## Services.

### Write & Design

Luto are experts in writing and designing clear health communications. Our evidence based approach and unique 'Audience Design' service means that users will find your communications easier to use.

#### Our services include:

- Instructions for Use (IFU)
- Package leaflets (PIL)
- Patient Package Inserts (PPIs)
- Medication guides
- Risk communication materials
- Educational tools
- Marketing materials
- Animations, apps and websites.



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## Delivering Quality and Value

Luto strives to understand your needs and deliver a service that reflects the best elements of price, quality, speed and expertise.

We are proud to be an ISO 9001 accredited company and believe that our formula of experience and quality provides the best value in the marketplace.

## Study

Let us help you understand how users interact with your communications or device. We offer a range of study methods and tools. Our academic links mean we can design any study to meet your needs.

### Our services include:

- Readability User Testing
- Usability Testing
- Heuristic evaluation
- Expert usability reviews
- Eye tracking
- Focus groups
- Workshops.

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## Reviews

Development of packaging and instructions for use.

**"Delighted with the service, the diligence, the knowledge and expertise made available to us."**

Managing Director, Forte Medical

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Reviewing the content of a Risk Management Plan Lay Summary

**"I consider your work very professional and the input is of great value,"**

Senior Regulatory Professional

