

Using design to maximise patient safety

Presentation by Brian Johnson – Head of Product Information - Fulcrum Pharma (Europe) formerly Unicus Regulatory Services, a leading International PIL user testing company.

The presentation covers the experience gained through the many user tests conducted by Fulcrum Pharma and how the use of design when preparing a Patient Information Leaflet (PIL) and any packaging particularly for OTC medicines can help maximise patient safety.

We will look at examples of how the content, design and layout of a PIL and packaging can help patients find important safety information, and how being able to navigate a leaflet more easily improves both finding and understanding key safety details.

Additionally information will be shared on how the use of global templates can help improve standards of PILs across different countries, whilst respecting different language and cultural needs.

Regulation in most regions is increasingly focused on effective communication of medicine information to patients. This is especially advanced in Europe where consultation with and user testing by target patient groups is required to demonstrate that patients can find and understand key messages for the safe use of the medicine.

Whether you require one test or the testing of your entire portfolio, Fulcrum Pharma provides comprehensive solutions to meet your needs. If your portfolio contains several similar patient information leaflets (PILs), we can conduct a detailed assessment of these to create a strategy to ensure that user testing is carried out in the most cost effective way.

Fulcrum Pharma provides a highly experienced team of Regulatory Professionals, Interviewers and Data Analysts to support the testing and reporting of your PILs, we are focused on a quality service that is continuously reviewed to keep up to date with regulatory agency guidance and client needs. Our clients range from large multinationals to small start-up companies.

All interviewers are fully trained in the specific field of user testing patient information. As a member of the Market Research Society (MRS) Fulcrum Pharma ensure that all interviewers are accredited members of the society.

User testing experience includes:

- PIL - readability user testing
- Bridging techniques including - statements, reports and studies.
- Rewrite or align PIL to QRD format.
- Conversion of SmPC to PIL.
- Leaflet, pack advice and design guidance.
- Multi-lingual translation services.
- Prompt responses to any questions from competent authorities.

Practical experience of user testing in a wide range of products and procedures:

- POM, OTC and Generics PILs, Devices and Packaging.
- Centralised, Decentralised, Mutual Recognition, and National submissions.

We also test in other languages, if for example, you require your PIL to be tested in your local language, using mother tongue subjects and interviewers.

Further information is on our websites: www.fulcrumpharma.com or www.unicus.co.uk