



gaining your approval

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PATIENT INFORMATION LEAFLET READABILITY USER TESTING

Background

Regulis is an established consultancy organisation providing a full range of European regulatory affairs services. As such, we provide a **Patient Information Leaflet (PIL) user testing service**. Other services Regulis offer include consultancy on all aspects on pharmaceutical, biological, device and borderline substances registration and on site placement.

EU legislation requires that new Marketing Authorisations must include evidence that the PIL is clear and understandable to potential users of the medicine. Additionally, the leaflets of existing medicines must be tested to demonstrate readability by 1st July 2008. For those who wish to reference the legislation, Articles 59(3) and 61(1) of Council Directive 2001/83/EC, as amended by Directive 2004/27/EC, require that the Patient Information Leaflet 'shall reflect the results of consultations with target patient groups' and that those results 'shall also be provided to the Competent Authority.' User testing of Patient Information Leaflets meets these obligations.

Regulis conducts user testing on subjects and produces a submission-ready report for clients. Our user testing is never sub-contracted to another organisation.

User Testing

The diagnostic user testing carried out by Regulis Consulting Ltd comprises:

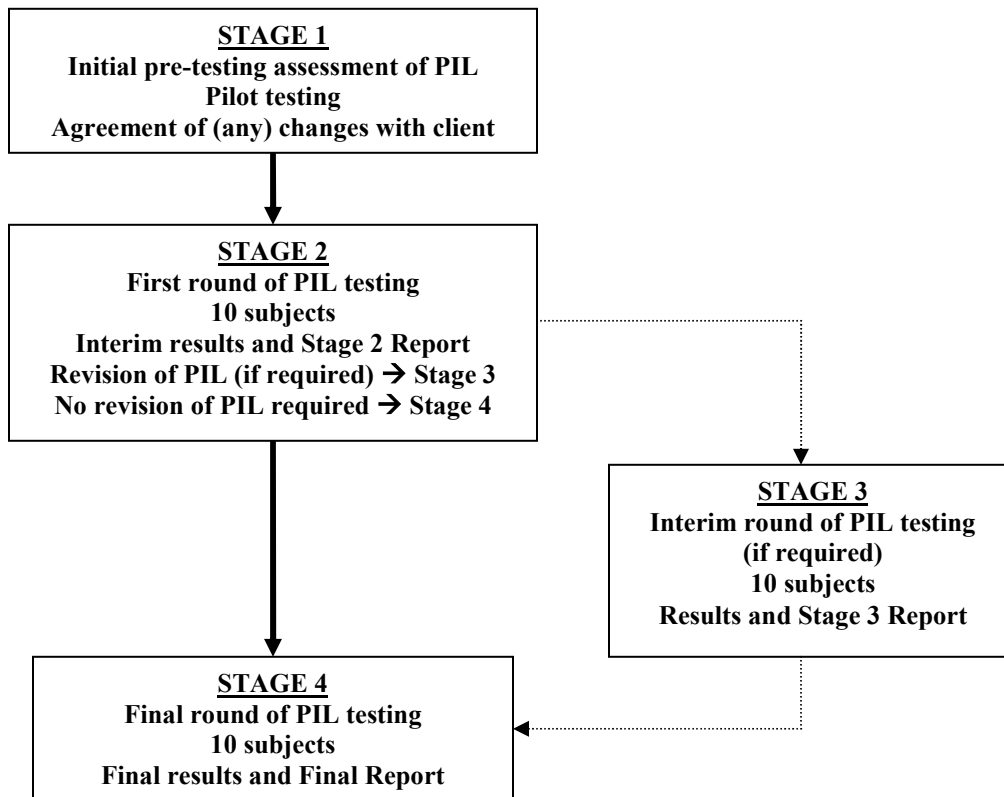
- Asking potential users questions to find information normally needed when using the medicine
- Watching and recording what they do
- Noting how users describe what they do
- Asking questions and obtaining a view about whether those undergoing testing can appropriately use the information they have read
- Recording what they report about the PIL.

As a result, our testing identifies obstacles to people's ability to understand and use the information presented. In addition, the primary objective of testing is not only to improve the quality of information *per se*, but to indicate any problem areas which need to be addressed or changes that could improve the PIL.

The Testing Process

At Regulis, we believe in offering a multi-stage approach which can be tailored to meet each client's specific needs. For each PIL we test, a consultant is allocated to manage the process and to liaise with the client throughout.

We prepare a client proposal which includes the timeline for the testing from commencement to delivery of the final submission-ready report. It also contains a clear list of responsibilities undertaken by Regulis and those for the client. We have found this removes any potential for misunderstanding and normally guarantees the testing progresses smoothly.



Stage 1

A study protocol is prepared and agreed with the client.

Working in collaboration with the client, we conduct an initial assessment of the PIL on linguistic, technical and regulatory aspects of the PIL.

Linguistic and technical evaluation cover factors that affect readability including the length of sentences, use of simple syntax, font size, line spacing and use of colour. Regulatory review involves evaluating the PIL for compliance with current leaflet and readability regulations and guidelines.

The results of this initial assessment, combined with the years of experience with PILs within Regulis, allow us, with the client, to determine any required changes to the leaflet prior to starting user testing. Thus, Stage 1 ensures that the PIL contents and format are as good as possible, thereby optimising the chance of passing user testing with two rounds (of ten subjects) of testing and being approved by the regulatory authority.

We also conduct pilot testing on a small number of subjects to identify any problems prior to full user testing. This also improves the likelihood of success in the proper test.

This stage is strongly recommended but it can be omitted if required.

Stage 2

A questionnaire is specifically designed to take into account all critical aspects of the product. The questionnaire is validated to ensure that the questions address all relevant sections of the PIL and are adequately spread. Model answers are incorporated into the questionnaire so the interviewer can accurately record whether or not each question was answered correctly.

The first round of user testing is conducted on ten subjects randomly selected from our database.

Testing is conducted by the same interviewer throughout the test in a calm and consistent environment. All answers are recorded and any additional comments noted. These are all fed back to the client in the interim and final reports. The interim report is sent to the client within 3 days of the end of the associated stage of testing. Discussions are held with the client to decide whether the PIL requires amendment before the next round of testing.

Stage 3

If Stage 3 testing is necessary, this will be carried out in a group of ten further subjects without additional cost being incurred by the client. A further report, the Interim (Stage 3) Report, will be produced for the client.

Stage 4

The Final (Stage 4) Report will incorporate the results of testing in the previous stages of testing and the results of the Final Stage (Stage 4) of testing.

Timelines

From the acceptance of the study proposal and signing of the contract, testing can normally be completed and the submission-ready report delivered to the client in 8 weeks. If an additional round of testing is required, the process normally takes an additional 3 weeks.

If the Client requests that subjects should be recruited from a specific patient group, it would be necessary to allow additional time for this.

Bridging and Portfolio Assessment

We can advise on the most effective strategy for testing a portfolio of products to bridge the results of user testing across different products. This will mean that it is not necessary to user testing every single PIL.

Subjects

At least ten subjects are required for each stage of user testing. Our database comprises members of the general public recruited by local newspaper advertising, posters and publicity campaigns. New subjects are continually being added to the database. In accordance with MHRA guidance, we do not permit subjects to participate in more than one user test every 6 months to ensure they remain representative of the general population. We capture demographic details including job and educational background to ensure the validity of our volunteer population.

Alternatively, subjects can be recruited from specific patient groups. We have agreements in place with a number of groups for rapid access to specific patients.

Costs

The cost for carrying out a study is a **fixed price** of £11,900. Should additional rounds of testing be required because of modifications to the PIL, this will be carried out at **no additional cost** to the client.

If the client chooses not to utilise the Stage 1 checking, the fixed price option cannot be offered. However, a cost for two rounds of testing is £9,900. If additional rounds of testing are required, each round of additional testing beyond the first two will be charged at £3,500.

These prices cover all aspects of the testing including protocol preparation, use of subjects, subject remuneration, report preparation and client liaison. There are no additional, hidden costs.

If the Client requests the use in the study of subjects from a specific patient organisation, additional costs will be incurred.

A detailed breakdown of costs can be provided on request.

Why use Regulis?

- We are an established regulatory consultancy company
- We have significant experience built over many years on preparing and updating PILs
- We offer a fixed price user testing service
- We have a pre-recruited subject database so there is no delay in recruiting subjects
- We make customer satisfaction as an absolute priority. Here is some of the feedback we have received on our user testing work:

“Thank you very much for the report. We submitted the MAA today on schedule.” – Regulatory Project Manager – UK.

“We were very pleased with your work and, as I advised on the phone, we would like you to user test another of our leaflets.” – Regulatory Manager, UK.

“Thanks a million. We look forward to a successful outcome with the MHRA.” – Technical Director, Ireland.