READABILITY WITHOUT THE HEADACHE

REGULATORY AFFAIRS CHECKLIST

Before you start a readability project

10 questions. A few minutes. Fewer surprises later.

Readability testing? Bridging? PIL audit?
Before choosing a pathway, let's make sure we really know where to start.

☐ **01**

Is a full readability test really necessary?

Not every project needs to start with a new test.

RED FLAG
"Full readability testing has been added to the project timeline automatically."

☐ **02**

Is the PIL really ready for testing?

Ready from a Regulatory Affairs perspective does not always mean ready from the patient's perspective.

RED FLAG
"We can start. The PIL may still change a little."

☐ **03**

The leaflet follows the QRD template. Is that enough?

Regulatory compliance and actual readability are not the same thing.

RED FLAG
"It follows the QRD template, so we can go ahead with testing."

☐ **04**

Should readability testing be the first time problems with the leaflet are identified?

Not every problem should be discovered for the first time during testing.

RED FLAG
"Let's see what comes up in the test."

☐ **05**

Is the content alone enough?

Patients use the actual leaflet, not a Word document.

RED FLAG
"The content is final. Now it just needs to be laid out."

☐ **06**

Can the bridging strategy really be defended?

Product similarity may support the case for bridging. It is not, in itself, sufficient justification.

RED FLAG
"The products are similar, so we'll use bridging."

☐ **07**

Are we looking at one product when we should be looking at the whole portfolio?

Existing readability studies may create opportunities to bridge additional leaflets.

RED FLAG
"New product? Let's plan a full readability test."

☐ **08**

Did we start thinking about readability early enough?

This is not about testing earlier. It is about knowing early enough which readability pathway the project actually needs.

RED FLAG
"The PIL is ready. All that's left is the readability test."

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☐ **09**

The PIL has already been approved. Does that mean it cannot be changed?

Readability testing may show that the leaflet needs to be changed — in its content, its presentation, or both. Prior approval of the leaflet does not take away the purpose of testing.

RED FLAG
“We’re not changing this PIL. It has already been approved by the expert.”
“The authority has already accepted it. The text is final.”

☐ **10**

Does the chosen readability pathway address the actual need?

Readability testing, bridging, a PIL audit or PIL development — the right solution depends on the individual project.

RED FLAG
“We know what we need. We just need a contractor.”

BEFORE WE START, LET’S ASK OURSELVES THREE MORE QUESTIONS:

- **Is the PIL ready?**
- **Is a full readability test necessary?**
- **Have we chosen the right pathway?**

How many times did you answer “I don’t know”?

You don’t need a score.
One important “I don’t know” is enough to stop and ask:
Are we sure we’re starting in the right place?

WE MAKE READABILITY SIMPLE.

Not sure which pathway to start with?
Tell us what you’re dealing with.

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