

Low Literacy Review of ICD Templates

Patients as Partners Europe conference
London UK | 19 May

NIHR | National Institute for
Health and Care Research

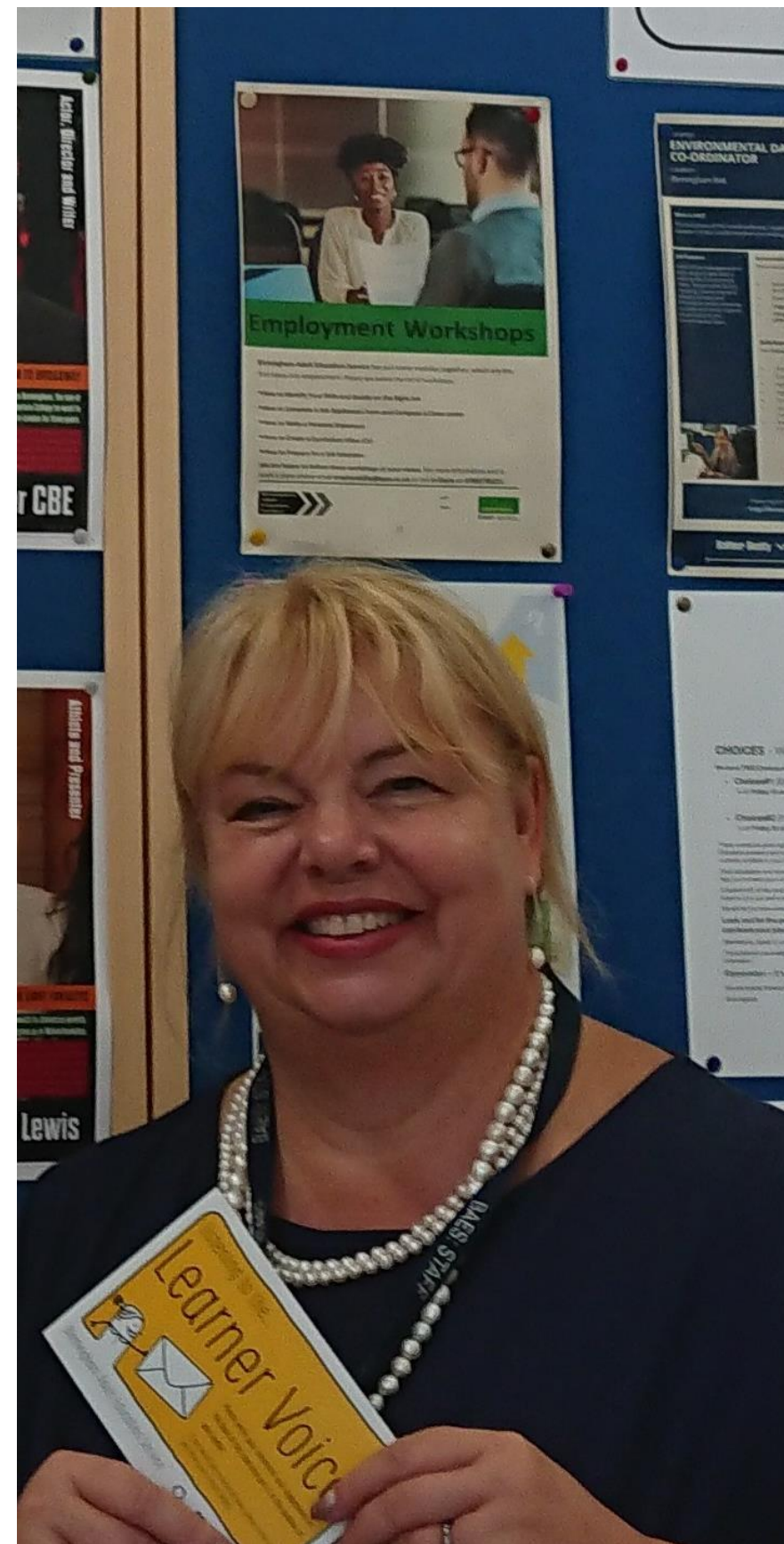
Birmingham
Adult
Education
Service



Meet our presenters



Emily Pickering
PECD Service Lead
NIHR



Lucy Ellenor
Programme
Manager for English
Birmingham Adult
Education Service



Sally Dews
Director Global
Patient Partnerships
Pfizer

Which of these terms do you think require simplification or explanation?

Accidental disclosure

Acknowledge

Adverse event

Affiliated companies

Alternative (in the context of options for participation)

Assessments

Authorities

Benefits

Chronic

Clinical Practice

Cloud based system

Collaborating

Current treatment status

Eligibility

Guaranteed

Indirect/Indirectly

Inflammation

Intrusive

Leave the study site (in the context of data processing)

Non-interventional

Non-physical risks

Observational/Observe

Penalised

Person taking consent

PRO

Protocol

Questionnaire window

Rectal bleeding

Reimburse/Reimbursement services

Screening/Screening visit

Serious Adverse Event

Site/Sites

Sponsor

Stool

Study

Study doctor

Study materials


Unique code

Web-based tools

Why review ICDs?

Informed Consent Document

Original ICD



Pfizer, Inc. / [Redacted]

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**INFORMED CONSENT
AND
AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH
INFORMATION**

Sponsor / Study Title: [Redacted]


Protocol Number: [Redacted]

**Principal Investigator:
(Study Doctor)** «PiFullName»

Telephone: «IcfPhoneNumber»

Address: «PiLocations»

Revised ICD



Informed Consent Document

Study Sponsor / Study title: Title:	Sponser, Inc. / "A multicenter, prospective, non-Interventional study of real-world effectiveness of ColitiClear® in patients with Ulcerative Colitis (GutCalm)"
Protocol Number:	ABC123
Principal Investigator (Study Doctor)	Dr Smith
Telephone	+44 0121 1234 5678
Address	Birmingham, UK

This informed consent document will help you learn about this research study. Please read it carefully or have someone read it with you. Talk about it with your family or friends. If there is anything you do not understand, please talk to the study doctor or team. Have your questions answered to your satisfaction before signing the consent form.

Flesch Reading Ease: 49.6
Flesch Kincaid Grade: 9.6

Flesch Reading Ease: 63.8
Flesch Kincaid Grade: 6.9

Before and After: ICD metrics comparison

Metric	Change			Interpretation
Flesch Reading Ease	49.6	→ 63.8	+14.2	Reading Ease improved
Flesch-Kincaid Grade	9.6	→ 6.9	- 2.7	Grade reading level decreased (meets goal ≤8)
SMOG	12.5	→ 9.9	- 2.6	Fewer polysyllabic words on average
Gunning Fog	11.1	→ 8.7	- 2.4	Reduced sentence complexity
Adverbs	128	→ 63	- 51%	Fewer fillers; more direct wording
Pages	20	→ 14	- 6	More white space

Meaningful change (examples before → after quote)

Before: No explanation	After: plain-language definition
<p>“ Non-interventional...” (no explanation)</p>	<p>“ Non-interventional <i>or observational study</i>, <u>which means</u> <i>it collects information only. It does not change your medicines.</i>”</p>

Key Learnings from the Low Literacy Review

- **Plain language and a welcoming tone build trust:** Plain language was essential for understanding. Thankyou statements made participants feel valued,
- **Visual aids and structured formatting improve comprehension:** Tables, bullet points, icons, and trust symbols helped readers navigate content more effectively. The PIF Tick, once explained, was seen as a strong signal of trustworthiness.
- **Technical and medical terminology creates barriers:** Terms such as “non-interventional”, “PRO”, and assessment tool names caused confusion. Inconsistent terminology compounded the problem.
- **Document length and cognitive load overwhelm readers:** Dense, lengthy sections felt intimidating. One session could not complete the full review due to comprehension challenges among learners with lower literacy.
- **Risk and safety information needs greater prominence:** Readers wanted risks presented earlier, with explicit actions to take if problems arise. The rationale for adverse event reporting and pregnancy reporting was not understood.
- **Privacy and data protection language causes fear:** Phrases like “absolute confidentiality cannot be guaranteed” alarmed participants. Familiar frameworks and real-world examples provide needed reassurance.
- **Readers need explicit reassurance and support:** Participants wanted to know who would help them understand the document, what the study demands on their time, and more about the company conducting the research.

Actions



Use plain, specific language

Replace technical terms with everyday words.
Where technical terms are unavoidable, provide **clear definition boxes before the relevant text**, not after.



Restructure documents for readability

- Use shorter sections, more white space, and a glossary.
- **Clear signposting**, information in small chunks.
- Use familiar comparison “1 year” instead of “52 weeks.”



Incorporate visual elements throughout

- Add culturally accessible icons, images, tables, and trust symbols alongside text.
- Include **simple diagrams** where possible.



Prioritise risk and safety information

- Move risk sections earlier in documents.
- Expand **detail on side effects** and why adverse events are reported.
- Provide **clear guidance** on what to do if problems arise.



Simplify privacy and data protection

- Ground explanations in familiar frameworks.



Build trust through transparency and gratitude

- **Appropriately share study sponsor details.**
- And give thanks to participants.



Ensure inclusive accessibility

- Offer paper-based alternatives alongside digital tools.
- Consider **audio** and **video** adaptations.
- Use consistent **terminology** for supported reading and discussion.

Now: Which of these terms do you think require simplification or explanation?

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