

P5 - Informed consent forms (ICFs): deploying AI and lean principles to make them simpler and more concise

Azuka Iwobi - Staburo GmbH

Tatiana R. Martins - Staburo GmbH

Ulrike Fischer - Staburo GmbH

Kathi Künnemann - Staburo GmbH

Seyma Öztürk - Staburo GmbH

Roelof Maarten Van Dijk - Staburo GmbH

Habib Esmaeili - Staburo GmbH

INTRODUCTION

Informed consent is a fundamental right for trial participants. Federal regulations emphasize that documents should be brief and presented in lay language. Currently, many ICFs score low in metrics assessing ease of readability, clarity and appropriate length. In an age where infographics and media are increasingly popular, bloated and wordy documents impede understanding, and an overhaul of current practices is essential.

Using specific strategies, we present a useful approach to making informed consent fit for purpose.

METHODS

Specific strategies to reduce verbiage and simplify writing with lean principles in mind will be discussed, with examples. The skilful use of infographics and icons to increase engagement, and the value of leveraging artificial intelligence (AI) to create impactful and leaner documents will also be highlighted.

RESULTS

We show how tried approaches such as writing short and direct sentences in active voice will improve readability and length of ICFs. Through skilful deployment of prompts, we show how AI can be used to create brief and impactful text, while incorporating mandatory elements.

Drawing on lean principles, we additionally show how focusing on the key message can help reduce redundancies and eliminate excessive verbiage. Lastly, we show the effectiveness of infographics and pictures in portraying otherwise complex ideas.

CONCLUSIONS

Simplified ICFs will go a long way in enhancing reader experience and engagement. Trial participants will be better able to understand the ‘whys’, ‘whats’ and ‘ifs’ of a study and be in a better position to give consent (or not) in such a transparent setting.