

## Improving the readability of the participant information sheet for a Phase 1 trial by User Testing

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Research for  
Clear Communication



## Summary

- ~ The participant information sheet for a Phase 1 trial did not perform well in readability testing (User Testing)
- ~ Could trial participants have given informed consent?
- ~ Revision of the PIS (re-wording and re-design) improved it significantly
- ~ User Testing can identify strengths and weaknesses of participant information sheets



## Participant consent

- ~ IRB / REC approval
- ~ Participant Information Sheet + opportunity to ask questions (Helsinki Declaration)
- ~ Role of the PIS:
  - . Pre-consent description & explanation
  - . Post-consent reminder & explanation
- ~ Phase 1 trials PIS complex, lengthy, technical information



## Concern over consent

- ~ Important information not stated
- ~ Patient understanding not checked (*Jenkins et al 1999*)
- ~ 40% did not know they could withdraw (*Lynoe et al 1991*)
- ~ 33% did not know the trial was primarily for research (*Lavori et al 2007*)
- ~ TGN1412 information & consent questioned in reports (*Expert Scientific Group 2006; Royal Statistical Society 2007*)



## Are PIS too difficult?


- ~ Written at the %college graduate level%  
(*Paasche-Orlow et al 2003*)
- ~ Most forms require a level of literacy that is too high (*Burman et al 2003*)
- ~ Many US IRBs require a readability formula test (eg SMOG; Flesch-Kincaid) giving a reading age




## Readability formulae

- ~ Easy to use
- ~ Available on many word processors
- ~ Mostly based on word length and sentence length
- But crucially...**
- ~ Can $\neq$  indicate meaning
- ~ "Intravenously given is drug the" = "The drug is given intravenously"
- ~ Can $\neq$  indicate performance




 **Results: original PIS**

- ~ 1 round of 10 participants
- ~ Many items not found (12 / 210)
- ~ Many items not understood (21 / 210)
- ~ Six items found and understood <8/10
  - . Emergency telephone number
  - . Presence of placebo
  - . Action required if have insurance
  - . Informing the GP
  - . Pre-drug fasting
  - . Number of clinic visits
- ~ **Would have "failed" a readability test**


 **PIS Revision**

- ~ **Re-wording**
  - . Short sentences
  - . Lay language
  - . Remove repetition
  - . Clear structure & headings
  - . Table of contents
  - . ~~Headlines~~ section
- ~ **Re-design**
  - . A4 booklet
  - . Page numbers
  - . Use of ~~bullets~~ for lists

 **Revised TGN1412 PIS**


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 **Results: Revised PIS**


- ~ 2 rounds of 10 participants
- ~ Few items not found (2 / 420)
- ~ Few items not understood (2 / 420)
- ~ No item found and understood by less than 19/20
- ~ **Would have "Passed" a readability test**
- ~ Asked which PIS version they preferred:  
**17/20 (85%)** chose the revised version




### Results

	Original	Revised
<b>Total items not found</b>	12 / 210	2 / 420
<b>Total items not understood</b>	21 / 210	4 / 420

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- ### The original TGN1412 PIS
- “ ...did not perform well
  - “ Participants could not find important information
  - “ ...and could not understand important information
  - “ Could the PIS have informed consent?

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- ### The revised TGN1412 PIS
- “ Performed much better in User Testing
  - “ Almost all items of information found and understood by all participants
  - “ Need for RCT confirmation?

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- ### Summary
- “ The TGN1412 PIS did not perform well in readability testing
  - “ Could trial participants have given informed consent?
  - “ Revision (re-wording and re-design) improved it significantly
  - “ Wording and layout both matter
  - “ **User Testing** can identify strengths and weaknesses of participant information sheets
  - “ **User Testing** could reassure trial sponsors that participants **can** give consent