



CONTENT

PROBING QUESTIONS

- Which content types will be used in decentralized and centralized trial elements?
- Which purposes do they serve (scientific/regulatory review, user instructions, training, information exchange, consent, monitoring, reporting, accountability records, etc.)?
- Is the content needed in technical or non-technical language?
- Which formatting/graphical elements may support the understanding and interpretation of the content?

TYPES OF CONTENT

- Patient-facing content
- Content intended for investigators/site personnel
- Content intended for regulators and ethics boards
- Content intended for service providers of the content

AUDIENCE

PROBING QUESTIONS

- Who is/are your audience(s)?
- What are their literacy skills?
- What is their level of knowledge about the disease/condition?
- Which language style and tone of voice is effective and accepted by your audience(s)?
- Which natural language(s) is/are best suited for your audience(s)?

TYPES OF AUDIENCES

- Trial participants
- Caregivers
- Investigators
- Site personnel
- Service providers

PLATFORM

PROBING QUESTIONS

- Which lines of communication/technology platforms are involved in the trial procedures? (Centralized and Decentralized elements)
- Which lines/technology platforms are most effective for each element based on your risk-assessment, content types and audiences?
- Is there a risk of excluding or burdening trial populations or site personnel that lack access to, or skills with, mobile/digital tools?
- Which lines/technology platforms require local language and training to ensure effective transfer of information/execution?

TYPES OF PLATFORMS/LINES OF COMMUNICATION

- eDiaries
- ePROs
- Wearables/mobile devices
- Phone calls
- Video consultations/online appointments
- On-site patient visits