Informed consent of trial participants

Session 2: ICH E6(R3) main changes - Informed consent

ACT EU workshop on ICH E6 (R3)

19-20 February 2025, EMA, Amsterdam

disclosure

Engaged in the design and conduct of more than 77 clinical trials since 1994

Took part in clinical trials, 4 as healthy volunteer, and 3 as patient

- Member of the ACT EU Multistakeholder Platform Advisory Group
- Member of the DCT implementation working group
- Founder of EuroCAB, European network of Community Advisory Boards (partnership EURORDIS / EUPATI-Spain)

disclaimer

- Any views expressed in this presentation are mine and should not be understood or quoted as being made on behalf of or reflecting the position of ICH, the ICH E6 Expert Working Group, European Medicines Agency, or one of its committees/working parties or other organisation. They should also not be understood as an official interpretation of the ICH E6 guideline, but are intended to stimulate thoughts and discussion on the topics.

Consent in ICH E6

- Consent is a 3-step process. Are we loosing quality?

2.8.1: other formats are valid

2.8.1: paper or electronic format (ignoring other formats)

• Informing, explaining

A 4-pages document should be possible

Calendar of visits and exams++

For adults and for children: cf Medicines for Children Research Network & Scottish Children Research Network (5th ENPREMA workshop June 2013)

Meetings with up to 20 potential trial participants+++: time saving and high quality

• Obtaining

What do you prefer? A face-to-face consultation, or remotely (e-consent)? Own preference +++

cf DCT project recommendations EMA/HMA Eudralex V10

Video-conference ok: Q&A possible

Online form with tick boxes: level 0 of communication

• Documenting

Participant and investigator should both sign:

Participants: I understand that….

Investigator: I informed about…

For long-lasting trials: info to remind of the trial (newsletter, closed IT tools…)

Role of the GenerationR Alliance Young People's Advisory Groups

Similar to Community Advisory Boards, 11-18, 8 to 10 meetings/year

Training and communication

1

- Learn about research
- Consultees e.g. NHS Guidance on information sheets
  https://www.ouh.nhs.uk/researchers/planning/documents/participant-information-sheet.pdf
- Ambassadors for young people in research

Review of CTs documents, protocols

2

- Comment on language, terminology, design and content of research documentation i.e. protocols, reporting forms, information sheets, methods, schedules and questionnaires
- Comment on age appropriateness of information sheets, consent forms and assent forms
- Comment on materials, apps, diaries, produced for children in clinical trials.

https://generationr.org.uk/scotcrn-ypag/

Modernisation of clinical trials

- More complex designs:
  - Limits of written information for the consent
  - AI dialogue or cartoons generators +++
- Treatment strategy trials (so called “public health trials”)
  - Low-intervention trials (products all authorised)
    - Which class to start with? What after failure? When to start? Which optimum dose?
    - Less information on products at start, more information during the trial (as usually long duration) / dynamic consent
- New forms of clinical trials: cluster trials, human challenge studies (vaccines)
  - Annex 2? ACT EU? Or where can we discuss them?

Ban of waivers

Problem : the legal value of the consent is not clear. Is there one? Part of CTR, but not part of contractual law.

If no legal value, then what is it for? What do we sign exactly?

Participants often think they are renouncing to something when signing a consent, but they don't clearly see what.

for clarification

Consent is becoming commonplace

They're everywhere in care

- For clinical trials
- For off-label use
- For compassionate use
- For complex procedures / medicines
- For patient registries
- For data sharing
- For blood/tissue banking
- For gene testing
- …

Also to consider

- Consent withdrawal: treatment or trial?
  - Agree on the importance to secure data already collected, and to make all necessary efforts to continue collecting data, without putting pressure on trial participant
  - But in practice, how? Via GP or own clinician (when different from investigator)?
- Amendment: proportionality of medical and ethical relevance on the need to re-consent or not
  - The re-consent information should be limited to the purpose of the amendment or to the new information (unexpected adverse event)
  - 1 page

To be reminded

- Each time a patient is taking a new medicine: a n-of-1 experiment
  - No guarantee of a positive effect
  - Efficacy / effectiveness and safety data collection should be the norm
- A physical consent / inclusion visit = a solemn occasion to remind you that you are a partner in a collective clinical research project
  - E-consent: risk of losing the solemn aspect of the procedure
  - E-consent with e-start: the recipe for failure?

Missing

- *Top 1 question received from trial participants!*

- 2.8.11: Declaration of Helsinki § 34.
  - *In advance of a clinical trial, sponsors, researchers and host country governments should make provisions for post-trial access for all participants who still need an intervention identified as beneficial in the trial.* ***This information must also be disclosed to participants during the informed consent process***
- 2.9.3: *Information on trial results and treatment received when this information is available from sponsor after unblinding*
  - After unblinding: of all participants? Or the one asking to know?
  - Does this include own trial data?

Data sharing 2.8.11 (m)

The process by which data will be handled

- Own experience: academic trial, information reviewed by community advisory board
- Consent form: sponsor and investigator(s) clearly defined
    - But then the text only referred to “trial organisers”, terms “sponsor” or “investigator” never used
- Data available to organisers, the manufacturer and its partners “only”: partners not defined
- And national health authorities or other international agencies: how many in total?
- Legal advice: lawyer considered I had consented to share my data with everyone

Some conclusions on consent

- E6 revision on consent is rich, some refinement needed
- Many links with ongoing initiatives (IMI Facilitate for CT results to participants, IMI PEARL for platform trials…)
- Interesting proposals were not considered (information meetings, quizzes to check if information understood…)
- LLM tools can help improving materials for the 3 steps written information not the only possible format

Thank you for your attention.

- François Houÿez

Director of Treatment Information and Access

francois.houyez@eurordis.org