Workshop 3

Experiences with National Differences in Information Package Constitution

Chair: Heike Mehrer / Rapporteur: Nicky Dodsworth

Premier people. Premier process. Premier performance.

Heike's Thesis (1)

Subject information and informed consent for subjects participating in clinical trials: How a good document can look like

Wissenschaftliche Prüfungsarbeit

zur Erlangung des Titels
„*Master of Drug Regulatory Affairs*"
der Mathematisch-Naturwissenschaftlichen Fakultät
der Rheinischen Friedrich-Wilhelm-Universität Bonn

Vorgelegt von
Heike Mehrer
aus Freiburg

Bonn 2010

Heike's Thesis (2)

Seeking consent: remembering the patient's perspective

Figure 1: Seeking consent: remembering the patient's perspective
(Source: Reference [41], p. 32, appendix E)

[41]
Good practice in consent implementation guide: consent to examination or treatment, November 2001

Workshop 6 – Discussion Topics (1)

1. EU Regulations applicable to Informed Consent:

- ICH Topic E6 - Guideline for good clinical practice (Note for Guidance on good clinical practice – CPMP/ICH/135/95)
- Directive 2001/20/EC, April 2001
- Directive 2005/28/EC, April 2005
- Detailed guidance ENTR/CT2, Rev 1, Feb 2006
- Declaration of Helsinki, 1996
- Country-specific legislation

Workshop 6 – Discussion Topics (2)

2. ICH GCP E6 – Essential Elements (section 4.8.10) – 20

3. Examples of templates available – Austria, Germany, Netherlands, Switzerland and UK

4. Review of templates:

a. Were they missing any aspects of ICH GCP?

b. Were there any additional requirements mentioned in the templates?

c. Where were these additional items defined in regulations?

County-specific findings (1)

Austria:

a. No requirements missing – ICH GCP 4.8.10
b. 3 additional requirements added
c. 1 – template specific
   2 – ICH GCP 4.8.5; ICH GCP 4.3.3 + ENTR/CT2

Netherlands:

a. Approx nos subjects missing (ICH GCP 4.8.10 t)
b. 3 additional requirements added
c. 1- Declaration of Helsinki 2008
   2- ICH GCP 4.8.5; ICH GCP 4.3.3 + ENTR/CT2

County-specific findings (2)

Germany:

a. No requirements missing – ICH GCP 4.8.10
b. 6 additional requirements added
c. 1 – template specific
   2 – ICH GCP 4.8.5; ICH GCP 4.3.3
   3- ENTR/CT2

Switzerland:

a. Subject rights missing (ICH GCP 4.8.10 q)
b. 4 additional requirements added
c. 2- template specific
   1- ICH GCP 4.3.3
   1- ENTR/CT2

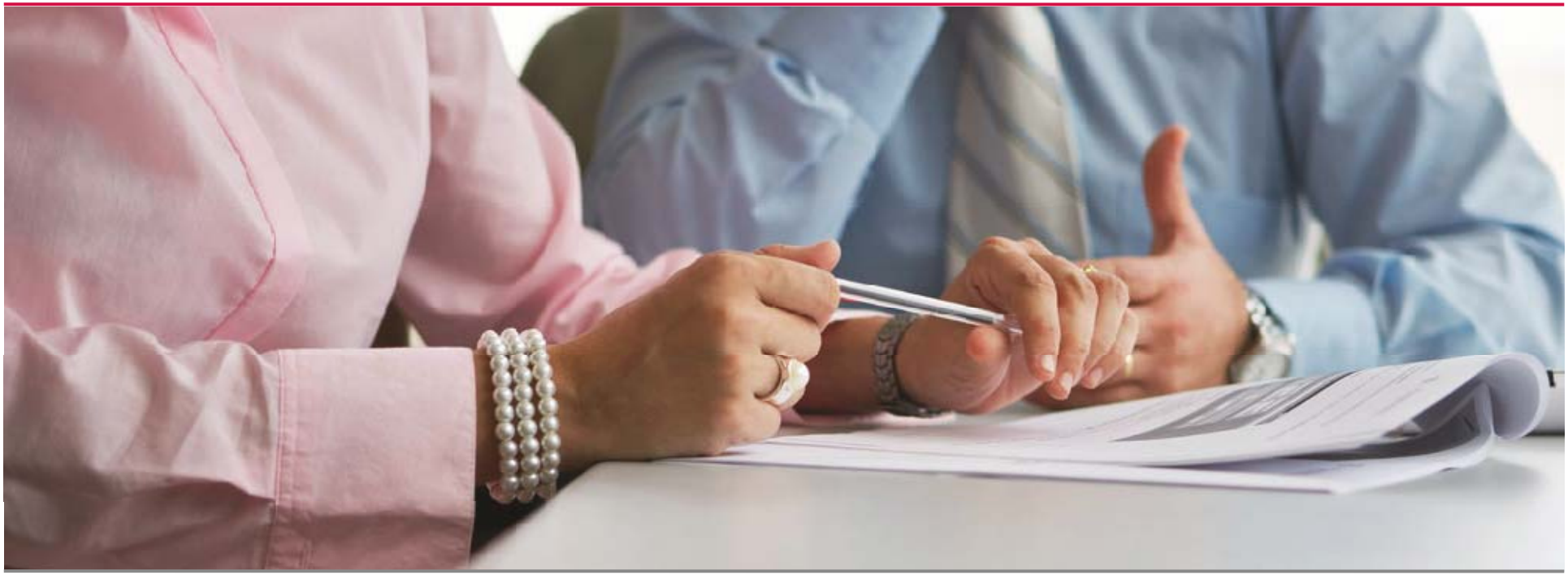
County-specific findings (3)

UK:

a. Circumstances for termination missing (ICH GCP 4.8.10 r)
b. 10 additional requirements added
c. 3- template specific
    1- Declaration of Helsinki 2008
    1- ICH GCP 4.3.3
    1- ICH GCP 4.8.5
    4- ENTR/CT2

Template Styles & Sizes

- Size of ICF templates – range from 7-17 pages long
- Consent forms – range 1-8 pages long
- Many sections – usually at least 13
- Subjection information and consent forms separate for 3 countries and combined for 2
- Written as an 'invitation' - 'we' = sponsor; 'you' = subject
- Reading level 3 (as defined by NL understandable for all persons older than 12years)
- Lay language; short sentences; use of headings, size 12 font



Workshop Groups

3 Groups

Premier people. Premier process. Premier performance.

Handouts

Groups were provided with 2 handouts:

1. Guideline for ICH GCP, section 4.8.10 ; Directive 2001/20/EC, Article 3 ; ENTR/CT2 Detailed Guidance on the application format and documentation to be submitted in an application for an Ethics Committee opinion on the clinical trial on medicinal products for human use
2. PICF (Participant Information & Consent Form) – an example template

Workshop

Groups were asked to focus on particular sections of the PICF provided as to suggest how these can be reduced/refined:

Group 1: Introduction + Purpose of Research sections

What does participation in research involve – to what extent would tables/diagrams help?

Group 2: What are the risks section

Are there alternatives to participation – how detailed does this section need to be?

Group 3: What will happen to information about me + what happens if I am injured as a result of participation?

Consent section – what information needs to be repeated here? Can we just use a simple statement?

Conclusions: Key Points for Improvement (1)

- Making sure Doctors are trained on delivering patient consent
- Doctors to provide in detail ALL treatment options – 1 option is a Clinical Trial
- Summary – start (who, what and why)
- Purpose of trial important – why take part?
- Number of times to attend
- Risks need to be defined early in the document
- End points need to be communicated better
- Q&A format
- Short sentences/no commands – invitation
- Important to talk about placebo/comparator
- Insurance section may be separate

Conclusions: Key Points for Improvement (2)

- Handling of samples if patient drops out of study – clarity for future use
- Patient access to medical records at any time
- Withdrawal from study will not affect health insurance
- Differences – North/South EU – Template vs. Checklist
- 2 part documents liked
- Future -> Patient Groups to check Information Sheets

Closing thought (internet research):

ONLY 5% of information read by participant