PLENARY SESSION 2
ADAPTING THE INFORMED CONSENT PROCESS TO PATIENTS' NEEDS

The EFGCP Initiative on Patient Information Sheet (PIS) Improvement

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How it “began”?

EFGCP Annual Conference 2012
- Informed Consent – How Less Could Be More:

Effecting a paradigm shift so we do inform participants -

- “There is widespread concern that the information we give research participants isn’t fit for purpose
- Information sheets are now too long, incomprehensible and don’ t match the risk of the study”

Remember: We were asking during workshops to think how we might develop informed consent that matches the risk of the study and gives a fair, understandable description of the research study

Brussels January 2012 – take - home - message

Consensus with conference motto – “less is more”

- Forms to be shorter
- Content more readable

However still to be considered

- Do we tell the right things helping potential participants to reach their decision?
  - Decision-aid-model approach (Jerry Menikoff)

The way forward

Developing an EFGCP template for the PIS based on the discussions during our Annual Conference

- Who is the receiver?
- One core document plus supplementary material in separated templates
- Plus some sort of guidance/instructions on writing the PIS
- What else is needed?

Should not be too difficult, isn´t it? Let´s see!

Overall goal

Comprehensive framework covering (all) aspects in regard to informed consent

- Comprehensive vs unmanageable
- Comprehensive AND supportive
  - Supportive - e.g. easy to use, easy to navigate within the framework, easy accessible

Purpose of today´s presentation

To pick up the conclusion of the Annual Conference

- EFGCP-Model of a PIS
- Call for contributors

BUT most important

- Fixing the EFGCP strategy for this project, e.g.
  - What do we want to deliver?
  - How do we want to deliver, e.g. at once/consecutively?
  - How to validate the project results?
  - Timelines involved?

How to start best?

Good news - no need to start from scratch!

- Various initiatives exist and their results/documents are available (for review)
- Considering this it´s even more important to define the EFGCP-project and its perspective – no adoption-approach!?
- EFGCP-initiative vs country specific initiatives – how could we make best use of synergetic potentials?
- Is an upfront communication required and if so, to whom?
  Who are the local project owner?
  Upfront communication = increase of acceptance?

Just an idea?

Project communication tool - development of a website?

- Accessible by all EFGCP-members (access controlled)
- After project completion, website to be made publicly accessible through link on EFGCP homepage
- Repository of draft pieces (open for review and comments by EFGCP members)

Just an idea? [continued]

Project process (EFGCP consensus driven approach!)

- Development of draft pieces (guidance documents, process flow-maps, core template, supplementary templates etc.)
- Posted on website for review and comments
- Finalisation of pieces during (face-to-face) meetings (task force and ethics working party)
- Final pieces to be presented during a workshop on EFGCP Annual Conferences and/or Regional Conferences – "validation"
- "EFGCP validated" pieces posted on project website with link to EFGCP homepage – publicly available!

Just an idea? [continued]

Step-by-step approach (Pieces 1 – 8 to be completed prior to Annual Conference 2013)

(underlying premiss – patient oriented - *ADAPTING THE INFORMED CONSENT PROCESS TO PATIENTS' NEEDS)*

- Piece 01 – Writing instructions (some general guidelines for writing and how to improve readability)
- Piece 02 – Summary document on goals of the informed consent process – EFGCP perspective (outcome of Annual Conference 2012)
- Piece 03 – Consent process diagram to visualize the entire process and to be used for training purposes
- Piece 04 – Investigator responsibilities in regard to informed consent (short and to the point, no repetition of requirements listed elsewhere, focussed on how to apply those in practice – pocket guide?)
- Piece 05 - Consent by Legally Authorised Representatives
- Piece 06 – Assent
- Piece 07 – Annotated Core ICF (template)
- Piece 08 and further – Supplements, such as consent for research in emergencies, in genetic research, etc.)
- Comments piece 07 + 08: first developed in English, supplements as text modules to allow easy insertion in core ICF when needed)

Next steps

<u>Our project strategy</u> – any comments, any new ideas are welcome!

- *What do we want to deliver?*
- *How do we want to deliver, e.g. at once/consecutively?*
- *How to validate the project results?*
- *Timelines involved?*
- *EFGCP-initiative vs country specific initiatives – how could we make best use of synergetic potentials?*
  - *Who are the local project owner?*
- *Is an upfront communication required and if so, to whom? Increase of acceptance?*

Did I forget something substantial?

Next steps

Who wants to help?

Any additional idea how to best set up a proper working environment?

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- For any additional information, please call +49 151 11 323 722

How to start?

An further idea how we could structure the project differently?

Any further comments not addressed so far?

Thank you very much

For your attention &

your active contribution!