ViewPoint

documentation of clinical trials

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The Be-Up Study is a randomized-controlled, multi-centre trial (RCT) that examines whether the birthing environment has an influence on the course of birth itself. At the time of admission for birth, the study participants who consent to participate are randomly assigned to either one of the normal birthing rooms or the alternatively designed birthing room (see www.be-up-studie.de). The Be-Up Study is the largest research project in obstetric departments in Germany that aims at promoting natural birth and examining the impact of the intervention in this respect.

For many midwives and physicians in obstetric departments in Germany this clinical trial is a first time experience; except for university hospitals, they do not normally participate in clinical trials.

Statutory quality assurance in obstetric clinics demands standard documentation of certain routine data (e.g. mode of birth, interventions, or complications). In a clinical trial, the guidelines of ICH-GCP[1] (good clinical practice) are observed which aim at the correctness, completeness and validity of data collected. Up to date, yet quite often case case report forms (CRFs) are used for data collection. However, *it is of great advantage if routine data can automatically be transferred to the CRF*. Here IT solutions play an important role.

For the Be-Up trial, GE Healthcare has provided an error-free and convenient solution for those hospitals using ViewPoint for their standard documentation: a digital form of the CRF. The advantage for the user lies in the straightforward design, which displays procedures in the correct logical order (history taking, care in the birthing room, birth outcomes-1 and birth outcomes-2). The midwives and physicians document routine data which in turn are filled in the individual CRF – mirroring the routine documentation – and automatically displayed on the screen.

This means that approximately 30 of 48 items that are required for the Be-Up Study need not be documented a second time. Other data which is not routinely documented can be entered by the midwives and physicians in the digital CRF on ViewPoint with free-text entry. Concluding the documentation process, the four pages can be printed out, signed and filed in the CRF folder.

The advantages of using the digital form of ViewPoint are manifold: The data fields are completely and accurately named, therefore all entries will be made easily and concisely. The automatic transfer of the routine data ensures the legibility of the entries. Moreover, *double documentation is avoided and saves a lot of time*, which makes the participation in a clinical trial much easier for the midwives and physicians.

This is particularly advantageous because in many hospitals staff shortages result in a heavier workload for those on duty. In addition, *data quality is ensured* and thus queries regarding data validity can be avoided.

In particular, in the case of multiple choice data entries, for which other options have already been excluded through the selection of a previous option, these no longer appear in the following documentation sections, thus minimizing the risk of incorrect entries. This also contributes to the quality of data documentation.

The team of the Be-Up trial wish to thank GE ViewPoint for the marvellous support given to the Be-Up Study. GE ViewPoint incorporated the team's requests and suggestions for creating the Be-Up forms very carefully and attentively so that we found the cooperation with GE Healthcare to be extremely productive.

[1] *ICH Harmonised Tripartite Guideline: Guideline for Good Clinical Practice E6. International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH E6, 1 May 1996)*

Imagination at work

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