

## Clinical Reports now Shall be Written According to MEDDEV 2.7.1 Guideline

As detailed in the Med-Info issue 12/2003, the MEDDEV 2.7.1 was published by the European Commission in April 2003, replacing the previous recommendations of the Notified Bodies.

### 1. Clinical report according to MEDDEV 2.7.1

Based on our experience with these new rules, and to alleviate the compilation of an adequate clinical report, the following aspects, which are generally checked during the in-house review process of a clinical report provided by the customer, shall be reflected adequately:

- Relevance of background and expertise of the author of the clinical report in relation to the particular device and/or medical procedure involved (in case of doubt by checking the curriculum vitae, or comparable documentation).
- Acknowledged state of the art presented in the clinical report, which is documented by a systematic review of relevant literature according to MEDDEV 2.7.1. A protocol for the identification, selection, collation, and review of the literature, including search databases, search terms, selection criteria, and rationale shall be contained. Reasons for believing that all relevant references were taken into account, both favorable and unfavorable, shall be presented.
- Acceptability of publications quoted: reviewed journal, publication year, qualification of the author.
- Verification of the provided literature research.
- Availability of the citation index of the referenced literature.
- Adequate technical description of the device.
- Intended use/indications/contraindications conclusive in the different parts of the documentation.
- Correspondence of clinically relevant information provided in the clinical data package.
- Availability as well as adequacy of assessment criteria for the evaluation of safety and performance.
- Availability as well as adequacy of market experience (in case there are comparable or predecessor devices).
- Availability as well as adequacy of bench test and pre-clinical results.

- Adequacy of estimation of the associated risks of each identified hazard by characterizing:
  - the severity of the hazard
  - the probability of occurrence of the harm
  - the selection of adequate testing to evaluate each identified risk
  - the decision on the acceptability of risks in relation to each identified hazard
- Availability of assessment of device-related and medical procedure-related risks.
- Availability of clinical overall risk-to-benefit analysis.
- Demonstration of performance and safety of the device by the provided documentation.
- Substantiation of the author's conclusions by the available data.
- Substantiation of the claimed intended use/ indications/contraindications by the provided clinical data.
- Demonstration of the equivalence of the device under assessment with the current state of the art.
- Statement that any information clinically relevant for the risk-to-benefit assessment of the device and available at the date of compilation of the report, was included.

**The following items shall also be reflected in detail if the "literature route" is chosen:**

- Transferability of the data from literature to the device under assessment.
- Assessment of method used in the quoted clinical studies.

**The following items shall be additionally reflected in detail if the "clinical investigation route" is chosen:**

- Correspondence of the Clinical Investigation Plan (CIP) and the study report.
- Correspondence of the CIP to EN 14155-2.
- Fulfillment of the requirements of EN 14155-1.
- Adequacy of study duration regarding the evaluation of safety and performance.
- Adequacy of primary and secondary objectives regarding the evaluation of safety and performance.
- Adequacy of inclusion/exclusion criteria regarding the evaluation of safety and performance.
- Adequacy of statistical methods (including sample size estimation).
- Intent-to-treat and per-protocol analysis.

## 2. MEDDEV 2.12-2

The recent "Guidelines on Post Market Clinical Follow-up" (May 2004) provide guidance on how to fulfill the requirements of the Directives regarding post market surveillance obligations. This MEDDEV emphasizes the limitations of premarket conformity assessments, in that infrequent complications may not be detected. Adequate post-marketing strategies are therefore to be regarded as of utmost importance.

Due to the fact that the "literature route" to demonstrate safety and performance of a medical device prior to CE marking is particularly associated with major limitations (i.e. transferability of clinical data to the device under assessment), a rigorous post market surveillance has to be regarded as essential.

Please take into account that:

- in general, the intended post market clinical follow up (PMCF) concept shall be part of the clinical documentation;
- if the "literature route" is chosen, a PMCF shall be performed as a registry or as a prospective study. The protocol shall be part of the clinical documentation. In addition, the report on the results of the PMCF shall be submitted for evaluation at an appointed date after market release.

This ruling takes effect immediately.

## 3. Modes of the review process

The last Med-Info also introduced an additional service of Clinical Affairs offering an accelerated review of clinical data in cases of shortage of time on the way to market.

If an accelerated review is desired by the customer, i.e. the result of a review should be available at a certain point of time, the accelerated mode may be adequate. Prerequisite for this option is an arrangement of the date for review six to eight weeks prior to the desired date. If the full documentation is not available to us at the agreed date, one further arrangement can be made after a waiting period of three weeks. Further details have been outlined in our last Med-Info.

It should be taken into account that switching between the routine and the accelerated mode during the review process as well as acceleration during a routine mode-review is not feasible.

## 4. Miscellaneous

- Since there have obviously been some misunderstandings in the past regarding the design of clinical investigations, it should be noted that Clinical Affairs offers a preassessment of clinical investigation protocols prior to starting the review process, to avoid later delays during the "hot" phase of the clinical data review.
- In general, documents for review shall be provided as hard copies.



[www.tuev-sued.com/mhs](http://www.tuev-sued.com/mhs)

**Your contact partner at TÜV SÜD Product Service can give you further information:**

TÜV SÜD Product Service GmbH • [www.tuev-sued.com/mhs](http://www.tuev-sued.com/mhs)

Dr. Roland Prestel • Ridlerstr. 65 • D-80339 Munich

Tel.: + 49 89/50 08-44 21 • Fax: + 49 89/50 08-44 03

TÜV Product Service Ltd. • Octagon House • Concorde Way

Segensworth North • Fareham • Hampshire • PO15 5RL

Phone: +44 (0) 1489 558100 • Email: [info@tuvps.co.uk](mailto:info@tuvps.co.uk)

This Med-Info can be ordered at: [www.tuev-sued.com/mhs](http://www.tuev-sued.com/mhs)

