Clinical evaluation and post market clinical follow up of medical devices

Dr. Heike Wachenhausen
Lützeler Klümper Wachenhausen,
Partnerschaft von Rechtsanwälten
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Abstract

- The regulatory framework for the evaluation and post market surveillance of medical devices is still fragmented. Developers and manufacturers of medical devices are often faced with practical and legal hurdles regarding the planning and conduct of clinical studies with medical devices. The diversity of medical devices requires adapted and customized types of studies. Developers, manufactures but also clinical investigators need adequate legal guidance and technical standards in order to achieve patient safety, a constant improvement of medical devices and overall an ethical environment.
Annex X of 93/42/EEC

- General provisions for a clinical evaluation
  - The confirmation of conformity with the requirements concerning the characteristics and performances under the normal conditions of use of the device and the evaluation of the undesirable side-effects must be based on clinical data
  - the adequacy of the clinical data must be based on:
    - either a compilation of the relevant scientific literature currently available on the intended purpose of the device and the techniques employed as well as, if appropriate, a written report containing a critical evaluation of this compilation
    - or the results of all the clinical investigations made
Clinical Investigation

- Legally not defined yet, but
  - ISO 14155 (harmonised standard), Section 3.6 = "Systematic investigation in one or more human subjects, undertaken to assess the safety or performance of a medical device"
  - Proposal for Regulation
    "clinical investigation’ means any systematic investigation in one or more human subjects, undertaken to assess the safety and/or performance of a device"

- Is reference to the system of clinical trials with medicinal products advisable?
Clinical investigation

- Current practical hurdles
  - Clinical investigations with medical devices and medicinal products – which provisions are applicable?
  - When is a clinical investigation necessary?
  - Design of clinical investigations – risk-benefit-assessment?
  - Commercial and non-commercial research – demarcation and rules? (IITs)
Post market clinical follow up

- The clinical evaluation does not end with the CE-mark – PMCF is essential
  - Important after CE-marking/essential part of the technical documentation
  - Direct impact on product liability
  - Interventional and non-interventional measures possible
  - Quality assurance and implementation of measures
  - Contract management and cooperation with clinical investigators and medical institutions necessary
Questions

- Is there a need for more detailed definitions and guidance by the legislator?
- Are harmonised standards (such as ISO 14155) adequate in order to plan and conduct clinical investigations?
- Do we need more standards for single medical device categories?
- Do we need more surveillance by Notified Bodies and competent authorities?
- May scandals be avoided (e.g. PIP breast implants) by more clinical investigations or PMCF measures?
Heike Wachenhausen

Contact:
• wachenhausen@gerricus.com
• +49.(0)451.31702600

Heike provides advice across the full range of regulatory matters relating to medicinal products and medical devices on German and European level with particular focus on clinical trials, marketing authorisation and pharmacovigilance.

Heike has been working as a pharma lawyer for twelve years. She started her career in the practice group “Healthcare, Life Sciences and Chemicals” in the Düsseldorf office of Clifford Chance. She then joined law firm Sträter in Bonn before she became Head Legal Regulatory & Development in the legal department of Novartis AG based in Basel, Switzerland. In 2011, Heike joined Lützeler und Partner and the firm was renamed to Lützeler Klümper Wachenhausen Rechtsanwälte. Heike holds a PhD in law. Her doctoral thesis deals with clinical trials with persons incapable of giving legal consent. She is fluent in English.

Heike is co-editor of the German Medical Device Journal. She has widely published on matters relating to authorisation of medicinal products and medical devices. Heike regularly holds seminars and presents papers at symposia.