Bundesinstitut für Arzneimittel und Medizinprodukte

Paul-Ehrlich-Institut

Publication of trial sites in result reports of clinical trials pursuant to Section 42b German Medicinal Products Act (Arzneimittelgesetz, AMG)

– Amended version of 19 June 2020 –

Updated joint information from the
Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM) and the
Paul-Ehrlich-Institut,
Federal Institute for Vaccines and Biomedicines (Bundesinstitut für Impfstoffe und biomedizinische Arzneimittel, PEI)

as of 19 June 2020

Based on the announcement of the Federal Ministry of Health dated 3 August 2011[1], the minimum information to be provided in the results of clinical trials pursuant to Section 42b German Medicinal Products Act (Arzneimittelgesetz, AMG) must include all investigators and all investigation centres. Since uncertainties had been expressed with regard to the handling of personal data, the competent authorities responsible at that time, the Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM), the Paul-Ehrlich-Institut, Federal Institute for Vaccines and Biomedicines (Bundesinstitut für Impfstoffe und biomedizinische Arzneimittel, PEI) and the former German Institute of Documentation and Information (Deutsches Institut für Dokumentation und Information, DIMDI) published joint information on their websites and on that of PharmNet-Bund on 17 June 2014 detailing how to handle the specification of names and addresses of the investigators concerned.

With the entry into force of the German Act for More Safety in the Provision of Medicinal Products (Gesetz für mehr Sicherheit in der Arzneimittelversorgung, GSAV) on 16 August 2019, the wording of Section 42b sub-section 3 AMG was altered in that the names and addresses of investigators continue to be listed in the results of clinical trials pursuant to sub-section 1, but that this no longer requires prior consent from the investigators concerned in accordance with the Federal Data Protection Act (Bundesdatenschutzgesetz, BDSG). Explicit consent from the investigators concerned to having their names and addresses specified in the results pursuant to Section 42b AMG is thus no longer required since the coming into force of the amendment of Section 42b sub-section 3 AMG.

[1] Federal Ministry of Health: Announcement concerning the publication of results of clinical trials pursuant to Section 42b Medicinal Products Act (Arzneimittelgesetz, AMG) of 3 August 2011, published in Federal Gazette No 127 of 24 August 2011, p. 2975

Based on this adjusted wording in Section 42b sub-section 3 AMG, the differentiation between investigators having given their consent and those who did not give this prior consent, described in the aforementioned publication of 17 June 2014 is no longer required. Thus, the specification of names and addresses of all investigators must be included in all results of clinical trials pursuant to Section 42b AMG submitted as of 16 August 2019.

The procedure described in the publication by BfArM, DIMDI and PEI of 17 June 2014 is therefore no longer valid; the original publication is hereby repealed.