Publication of results of clinical trials by investigation centres pursuant to Section 42b German Medicinal Products Act (Arzneimittelgesetz, AMG)

Joint information from the
Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM), the
German Institute of Medical Documentation and Information (Deutsches Institut für Medizinische Dokumentation und Information, DIMDI) and the
Paul-Ehrlich-Institut (PEI)

as of 17 June 2014

Based on the announcement of the Federal Ministry of Health dated 3 August 2011[1] and Section 42b AMG, the minimum information to be provided in the results of clinical trials must include all investigators and investigation centres. Since uncertainties have been expressed with regard to the handling of personal data, the competent authorities BfArM, DIMDI, and PEI have published the explanations below concerning the type and scope of the information to be published on investigators and investigation centres.

1. Content

Pharmaceutical companies and/or sponsor are informed that they are responsible for checking that the consent mentioned below is available in conformity with Section 4a Federal Data Protection Act (Bundesdatenschutzgesetz, BDSG) and that the regulations related to data protection law are observed in connection with the results to be submitted or already submitted.

With regard to specifying the investigator and investigation centre, two case scenarios must be distinguished:

a) Consent for specifying personal data has been given

If the investigator has given his or her consent to the publication of his or her personal data pursuant to Section 4a BDSG, the first name, last name, academic title, if any, and the name of the investigation centre and its postal address must be specified. This applies to both German and international investigation centres.

b) Consent for specifying personal data has <u>not</u> been given

[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

If the consent pursuant to Section 4a BDSG has not been given, no personal data must be contained in the report on the results. Furthermore, mentioning the name of the investigation centre is not permitted, if this made it possible to draw conclusions from the information as to the identity of individuals since the investigation centre and the investigator are identical and publish the names of their doctor's offices or companies in legal communication:

I. Hospitals and centres of medical treatment
If the investigation centre is a hospital or a major medical treatment centre which does not bear the name of the investigator in its name, both the name of the hospital and its postal address must be specified. However, personal data must not be specified.

Examples:
Kreiskrankenhaus Musterstadt, Abt. Innere Medizin, Musterstraße 1, 12345 Musterstadt
Onkologisches Zentrum Musterstadt, Klinikum Musterstadt, Musterstraße 1, 12345 Musterstadt
General Hospital, Dept. of Medicine, 123 Sample Street, Anytown USA, 12345

II. Doctor's offices
For doctor's offices which include the name of the investigator in the names of their offices, only the location and the type of specialist physician must be indicated as the "investigator's name". The last two digits of the postal code may be blacked out to prevent a direct identification of the investigator on the basis of the postal code. If the direct specification of the location permits the identification of the investigator, the name of the district (in Germany: "Kreis") can be used instead of the place name. For doctor's offices outside Germany, the type of specialisation shall also be indicated, if available. Otherwise, this information can be dispensed with.

Examples:
Facharztpraxis Innere Medizin, 123xx Musterstadt
General Practice, Anytown USA, 123xx

2. Coming into force

The above mentioned regulations shall come into force as of the joint publication on the internet pages of the senior federal authorities and PharmNet.Bund (*17 June 2014*).

For reports which have already been submitted but not yet published at PharmNet.Bund, the competent senior federal authorities will check whether investigators and investigation centres have been explicitly specified in compliance with the requirements set forth above. Where only cumulative specifications have been made in the results reported on clinical trials in the individual countries, the information described above must be supplied. However, if the description of the specialist physician is the sole piece of information that is missing in the reports already submitted, this information need not be supplied.