State Data Protection and Freedom of Information Officer for Rhineland Palatinate

Der Landesbeauftragte für den Datenschutz und die Informationsfreiheit RLP
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Your reference:	Your email of:	Reference no.:	Extension no.:	Date:
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Dear Mr. Ahland,
Dear Sir or Madam,

As part of his duties as Data Protection Officer according to § 38, para.1 of the BDSG (Federal Data Protection Act) in conjunction with § 24, para.1 sentence 2 of the LDSG (State Data Protection Act), the Rhineland-Palatinate State Commissioner for Data Protection and Freedom of Information (LfDI RLP) was called upon to provide advice and support to Boehringer Ingelheim Pharma GmbH & Co. KG in the drafting of a guideline on the transparency of Boehringer Ingelheim's clinical study data. Generally, the State Data Protection and Freedom of Information Officer had already responded to this with the correspondence dated February 10, 2014.

Since then, the original draft of Boehringer Ingelheim's corporate guidelines on providing transparency in study data from clinical trials ("Transparency of Data from Clinical Studies by Boehringer Ingelheim – Anonymization and Data Protection Procedures") has been developed further, whereby individual changes have been made. Those individual changes have been presented and explained in detail to the State Data Protection and Freedom of Information Officer (LfDI) in a meeting. Specific questions raised in this regard have all been understandably and comprehensibly addressed.

The changes made appear to be significant enough to require another opinion from the LfDI. They are partly based on a unifying standardization of the formats and nomenclature according to the CSDR (Clinical Study Data Request.com), thus taking into account the international standard that is currently emerging. As such those changes are logical and reasonable. Specifically, the terms "direct/indirect personal identifiers" were removed and replaced by the internationally used term "personally identifiable information (PII)," which comes from the Anglo-American legal sphere. This does not appear to have had any negative impact on the draft from February 2014 in terms of data protection law.

Likewise, a re-arrangement in the quality inspection seems to be non-critical: this was originally planned as a two-part quality inspection, however, it will now be combined as a single quality assessment that is materially more comprehensive and covers the core of the technical anonymization process.

However, a more problematic aspect is that in future, the classification of data from an entire study or certain data variables from a study as "high risk sensitive data" will be removed from the technical anonymization process. This is because the technical anonymization process is designed to protect against re-identification. By contrast, the classification of data or data variables as "high risk sensitive" requires medical and data-protection law expertise taking into account the entire study context. In particular, the subject of "high risk sensitive data" – if applicable - may be discussed and clarified as part of the study approval process by the competent ethical committees and regulatory authorities, with the trial clinical monitor. As an external topic, this discussion is not reflected in the sponsor’s

clinical study database. Boehringer Ingelheim has taken this aspect into account, in that the classification of "high risk sensitive data" has now been assigned to the competent medical director from the relevant therapeutic area in which the respective study was conducted and to the company's Data Protection Officer (DPO). With this change, the process of deciding whether all the data of a clinical study or individual data variables of a study is even admissible accessible to anonymization, and can subsequently be made accessible to third parties or not, has also been brought forward into the phase prior to the technical anonymization.

This modification is significant, but with regard to assessment classification of the present concept it does not change my position from February 10, 2014. The modified concept also achieves the task of making data from clinical studies accessible to a (scientifically qualified) public in a convincing way that complies with data protection.

Further to my statement of February 10, 2014, the competent authority is additionally advised to enable the medical directors from the affected therapeutic areas, through sufficient material resources and through assignment of a corresponding procedural position, to make informed decisions and implement them properly. In this regard, it must be ensured that the company's Data Protection Officer can be adequately involved while carrying out his duties independently. The Data Protection and Freedom of Information Officer (LfDI) also offers the medical director from the relevant therapeutic area or the DPO his future support in this.

With regard to the statement by the Data Protection Officers from Berlin and Hessen from 2002 regarding data protection in science and research (http://www.datenschutz-berlin.de/attachments/47/Materialien28.pdf?1166527077), which was recently discussed again, the letter from the LfDI dated February 10, 2014 is to be expanded to include the question of whether the anonymization of databases should not also be regarded as data usage within the meaning of § 4, para. 1 BDSG and therefore must be justified by consent or legislation. The LfDI considers the answer to be no (as also shown in: Wolff/Brink, Datenschutzrecht, 2013, § 3, point 65; Plath, BDSG, § 3, point 38; open or unclear Gola/Schomerus, BDSG, 11th edition, § 3, point 31; Dammann in: Simitis, BDSG, 7th edition, § 3, point 131). At any rate, in cases such as this one, where the anonymization of personal data does not result in its loss by the person affected, since the clinical dataset is maintained and anonymized copies of this data are only produced to create transparency, anonymization cannot be equated with deletion of data, which requires a legal basis. According to the protective purpose of the BDSG, which is expressed particularly in the data minimization and avoidance requirement of § 3a BDSG, it is instead to be assumed that the BDSG is fundamentally open to the anonymization of personal data (cf. especially § 3a, sentence 2 BDSG).

If individual data protection supervisory authorities demand a legal basis in this regard, they therefore consider – according to the statement concerning the LfDI – there to be relevant legal grounds, according to § 40 of the Federal Data Protection Act (BDSG), for anonymization in the context of research projects for non-public bodies.

Overall, the LfDI continues to welcome Boehringer Ingelheim's efforts to safeguard its transparency policy for data from clinical studies in terms of data protection law; the great effort made by the responsible body in this regard convincingly protects the informational self-determination right of participants of the respective/applicable clinical studies.

Sincerely,

p.p.a.

[Signature]
Dr. Stefan Brink