The Office of Data Protection and Freedom of Information of the State of Rhineland-Palatinate

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The Office of Data Protection and Freedom of Information of the State of Rhineland-Palatinate RLP
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Mr. Timo Ahland
Data Protection Officer
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Boehringer Ingelheim Pharma GmbH & Co. KG A Recht Ingelheim

17 Feb. 2014
(Signature)

Your ref.:	Your message of:	Reference no.:	Telephone extension:	Date:
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Dear Mr. Ahland,
Dear Sir/Madam,

Acting within its competence as the data protection authority, specified in the German Federal Data Protection Act (BDSG), section 38.1, in conjunction with the State Data Protection Act, section 24.1, sentence 2, our Office has been asked to provide advice and support for Boehringer Ingelheim Pharma GmbH & Co. KG in setting up a policy on the transparency of Boehringer Ingelheim's clinical trial data.

For this purpose Boehringer Ingelheim submitted to us its draft corporate policy on creating transparency for trial data from clinical studies ("Transparency of Data from Boehringer Ingelheim's Clinical Studies – Anonymisation and Data Protection Procedures"). Other documents that were studied for this purpose were the publicly accessible website "BI Transparency Policy" (http://trials.boehringer-ingelheim.com/transparency_policy.html) and the publicly accessible website "Clinical Study – Data Request" (https://clinicalstudydatarequest.com/Studv-Sponsors-BI-Details.aspx).

Two in-depth meetings were held in which this data protection policy was presented to our Office and explained in detail. Any specific issues that were raised on this occasion were explained intelligibly and comprehensively.

On this basis, the Office of Data Protection and Freedom of Information of the State of Rhineland-Palatinate wishes to comment as follows:

The task of making data from clinical studies accessible to a (scientifically knowledgeable) public and at the same time to ensure that information meets data protection requirements is a complex task

for data protection purposes. The policy that was submitted to us in this connection was found by us to be convincing.

The procedure is divided into three stages: anonymisation of personal details prior to being sent to the Multi-Sponsor Analysis System (MAS), control of access to MAS, and the security policy of MAS. This procedure was explained in an understandable manner, divided into manageable sub-segments, with individual steps that are consistent and which adequately meet data protection criteria.

As a background, it must be considered that the issue of anonymising personal details (BDSG section 3.6) is subject to changes in understanding by supervisory authorities and that, from a legal perspective, anonymisation can no longer be regarded as an "absolute" guarantee for compliance with data protection regulations (see, for instance, Wolff/Brink/Schild, *Datenschutzrecht in Bund und Ländern*, 2013, section 3, recitals 94 ff., 96 f.). With this in mind, a consistent concatenation has been applied, with the deletion of personal details and with formal stages of anonymisation, accompanied by two mutually independent quality checks. As a result, a security standard has been achieved which is so high that we do not expect any danger to a patient's self-determination rights concerning the use of sensitive personal details which are under special legal protection (BDSG section 3.9).

Nevertheless, we do recommend that the relevant unit continues to review its data protection procedures at regular intervals in the future, so that its high standard of anonymisation will not be undermined by ongoing progress in networking or by any further technical development of information processing options. Our Office will continue to offer its support.

We also discussed with the relevant unit the measures it had taken to control access to MAS and the underlying security policy. We did not raise any concerns on this issue, neither did we have concerns about the selection of a platform for MAS outside Europe. The high standard of anonymisation eliminates any data protection concerns towards the appointment of service providers outside European data protection with its high standards (see BDSG section 3.8 in conjunction with section 4b).

In all, we therefore welcome the endeavours made by Boehringer Ingelheim to provide data protection security under its transparency policy for trial data from clinical studies. The large effort that is made by the relevant unit in this connection convincingly safeguards respondents' self-determination rights concerning their data in the relevant clinical studies.

Yours sincerely,

p.p.

(Signature)
Dr. Stefan Brink