The State Commissioner for
DATA PROTECTION and
FREEDOM OF INFORMATION
Rhineland-Palatinate

The State Commissioner for Data Protection and Freedom of Information RLP
PO Box 3040, 55020 Mainz

Boehringer Ingelheim International GmbH
Data Protection Office Germany
Mr. Timo Ahland
Binger Straße 173
55216 Ingelheim
Germany

Hintere Bleiche 34, 55116 Mainz
PO Box 3040, 55020 Mainz

Phone +49 (0) 6131 208-2449
Fax +49 (0) 6131 208-2497

poststelle@datenschutz.rlp.de
www.datenschutz.rlp.de

Your reference	Your letter dated	Reference number	Direct dial	Date
		8.08:0001	22 26	16.03.2018

Boehringer Ingelheim International GmbH (BI) concept for the anonymisation of studies within the scope of disclosure requirements pursuant to Art. 81 EU 2014/536

1. Meeting BI/ State Commissioner for Data Protection and Freedom of Information (LfDI) on 18.08.2017
2. Glyxambi anonymisation report (status 01.09.2017) / presentation of the implementation of EMA Policy 0070 (mail dated 08.09.2017)

Dear Mr. Ahland,

Within the scope of its jurisdiction as data protection supervisory authority pursuant to Sec. 38 (1) of the Federal Data Protection Act (BDSG) in conjunction with Sec. 24 (1) Clause 2 of the State Data Protection Act (LDSG), the LfDI Rhineland-Palatinate, with focus on the requirements set by the European Medicines Agency, was requested to provide a response on the implementation of EMA Policy 0070 by Boehringer Ingelheim International GmbH (BI) with regard to the anonymisation of studies in line with the disclosure requirement pursuant to Art. 81 EU 2014/536.

In the above meeting (reference no. 1), the concept intended for this purpose was presented to the LfDI and the approaches that have changed to some extent compared to the previous procedures were explained. The future BI concept was implemented in the Glyxambi anonymisation report by way of example (reference no. 2). Below, this is made reference to, in order to assess the anonymisation concept in general.

I. Preliminary remark:

The following response of the LfDI RLP focuses exclusively on issues of anonymisation of protected personal data (PPD). By disclosing study data, other legally protected or legitimate interests of third parties can also be affected, such as commercially confidential information (CCI) as well as interests and expectations of contracting parties. These are not the object of this examination.

The response focuses on the implementation of EMA Policy 0070 for the anonymisation of study data and the procedures used in the process.

II. Response

The information about clinical trials conveyed to the European Medicines Agency within the scope of an approval procedure are entered in a publicly accessible database. In this context, in October 2014, the European Medicines Agency (EMA) has published Policy 0070 on the publication of clinical data about medicinal products for human use[1]. For the disclosure of clinical trials discussed therein, the EMA published additionally in April 2017 the External guidance on the implementation of the European Medicines Agency policy on the publication of clinical data for medicinal products for human use[2]. The EMA guideline explains the procedures and requirements for the submission of documents in line with Policy 0070 in more detail. Both documents constitute the basis for the procedures for the anonymisation of clinical study data examined below.

In addition to Policy 0070, Art. 81 CTR was also used as a basis in this present case, which stipulates a publicly accessible portal after coming into force. This has not been set up at present. Policy 0070 and Art. 81 CTR will differ in terms of content and involve physically separate databases.

With regard to the criteria relevant for anonymisation, the guidelines refer to the orientation guide of Art. 29 Data Protection Working Party on anonymisation techniques (Working Paper WP216) and establish two alternatives for assessing the efficacy of anonymisation[3]:

a. oriented to the possibility of identifying single individuals in a data pool (singling out), linking different data sets of an individual (linkability) as well as inferring to a specific individual from available information (inference),
b. based on the methodological assessment of the existing re-identification risk.

For b), the EMA Guideline stipulates either an analytical approach based on the analysis of individual data or a non-analytical approach.
The latter is based on the concept of anonymisation selected by BI[4]. With regard to the issue of the potential allocation of data to individuals, it takes direct identifiers that can be used alone or together with other information to positively identify a person (e.g. name, ID number, contact data) as well as quasi-identifiers which make the re-identification of a data set possible (e.g. date of birth, gender, ethnicity, diagnoses, time of treatment). BI hereby follows the relevant specifications of the EMA Guidelines[5].

Within the scope of a qualitative risk assessment, identifiers and quasi-identifiers are assessed in terms of the risk of re-identification as well as the risk of damage[6]. Hereby, it is seen favourably that beyond the specifications of the EMA Policy, BI also explicitly takes into account violation of the obligatory EMA terms of use during risk assessment. This is based on a worst-case scenario where an offender knows an individual in the data pool and thus has extended possibilities for re-identification, if applicable.

In extending the previous study classifications (</> 25 participants; single centre/multicentre), BI henceforth uses three study categories as basis for risk assessment:

Category 1	(high risk)	< 100 participants/rare disease / one trial site
Category 2	(moderate risk)	100 to 1000 participants/possibly several trial sites
Category 3	(low risk)	> 1000 participants

If the risk of re-identification seems possible taking into account the type of identifiers/quasi-identifiers, the study category as well as the risk scenario, the respective date will be deleted/redacted within the

[1] EMA/240810/2013
[2] EMA/90915/2016
[3] Compare EMA Guideline, MN 3.2.1 / WP216, MN 3
[4] See Glyxambi anonymisation report, P. 4
[5] EMA/90915/216, MN 5.3.2.1 and 5.3.2.2
[6] See Glyxambi anonymisation report, MN 2.1.2, P. 7

scope of an editorial process[7]. BI hereby complies with the recommendations of WP216[8]. Complete redaction is performed even if only partial redaction would have been possible[9]. In this respect, BI gives precedence to data protection.

Due to the fact that after the redaction, data can no longer be linked to a specific or identifiable natural person or only with a disproportionately large amount of time and effort, cost and manpower, the specifications of Sec 3 (6) Federal Data Protection Act (BDSG) on anonymisation are met.

In addition to the actual study data from clinical trials, narratives as well as listings are relevant for the assessment of the re-identification risk. Here, it is stipulated to fully redact descriptions related to participants as well as listings for all study categories. Exceptions are listings of deaths and other serious and significant adverse events from which PPD are redacted in all study categories. Descriptions related to participants that appear in the course of the text, will be fully redacted in category 1 studies, and personal data (PPD) in all category 2 and 3 studies[10].

Conclusion:

The concept of anonymisation presented by Boehringer Ingelheim International GmbH, exemplified in the Glyxambi anonymisation report, is consistent with the specifications of EMA Policy 0070. With regard to the criteria for effective anonymisation, risk assessment and methodology, it takes into account the relevant specifications of the guideline for the implementation of EMA Policies (EMA/90915/2016) as well as the relevant recommendations of the data protection officers of the European Member States (Working Paper WP216).

If the criteria and procedures defined in the concept are implemented properly, the specifications from Sec 3 (6) BDSG for effective anonymisation are met.

The competent data protection supervisory authority therefore has no objections against the concept of anonymisation presented here.

The response was issued on the basis of the current factual and legal position. Since the state of the art in science and technology is in constant development in the area of clinical study data, the concept should undergo an evaluation at regular intervals, not least in view of the specifications of the future European General Data Protection Regulation (DSGVO) for the regular review, assessment and evaluation of measures[11].

Yours sincerely,
On behalf of

[signature]
Helmut Eiermann

[7] See Glyxambi anonymisation report, MN 2.2.1, P. 9
[8] WP216, MN 5.2, P. 25
[9] See Glyxambi anonymisation report, MN 2.2.4, P. 11, MN 2.2.5, P. 12
[10] See Glyxambi anonymisation report, MN 2.2.8, P. 16
[11] Art. 32 (1) lit d) DS-GVO