

Bioclinica TopCo LP  
510 Madison Avenue New York, NY 10022  
USA

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Caseworker  
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## Decision by the Danish Data Protection Agency approving Controller Binding Corporate Rules of Bioclinica Group

**The Danish Data  
Protection Agency**  
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1. Having regard to Article 47(1) of the EU General Data Protection Regulation 2016/679 (GDPR), the Danish Data Protection Agency shall approve Binding Corporate Rules (BCRs) provided they meet the requirements set out under this Article.

Whereas:

2. In accordance with the cooperation procedure as set out in the Working Document WP263.rev.01, the Controller BCRs application of Bioclinica Group was reviewed by the Danish Data Protection Agency as the competent supervisory authority for the BCRs (BCR Lead) and by the Romanian Supervisory Authority and the Lithuanian Supervisory Authority acting as co-reviewers. The application was also reviewed by the supervisory authorities of the EEA countries, to which the BCRs were communicated as part of the cooperation procedure.
3. The review concluded that the Controller BCRs of Bioclinica Group comply with the requirements set out by Article 47(1) of the GDPR as well as the Working Document WP256.rev.01 and in particular that the aforementioned BCRs:
  - i) Are legally binding and contain a clear duty for each participating member of the Group including their employees to respect the BCRs by;  
  
requiring all members of the Bioclinica Group to enter into signed contracts with Bioclinica Topco LP, which is the headquarter of the Bioclinica Group (See Annex 1, Appendix 2 for a list of the participating entities and section 2 in Annex 2, appendix 2 - BCR Controller Agreement for the obligation to comply with the BCRs); and  
  
requiring that the BCRs are incorporated in relevant group policies and procedures, and that all employees are informed of the BCRs and possible disciplinary sanctions in case of violation of the BCRs (see section 4 of the Application Form)
  - ii) Expressly confer enforceable third party beneficiary rights to data subjects with regard to the processing of their personal data as part of the BCRs (see section 20 of the BCR Policy and section 3 of Annex 2, Appendix 2 - BCR Controller Agreement);

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4. The EDPB provided its opinion 08/2022 in accordance with Article 64(1) (f) of the GDPR. The Danish Data Protection Agency took utmost account of this opinion.

DECIDES AS FOLLOWING:

5. The Controller BCRs of Bioclinica Group provide appropriate safeguards for the transfer of personal data in accordance with Article 46 (1) and (2) (b) and Article 47 (1) and (2) GDPR, and the Danish Data Protection Agency hereby approves the Controller BCRs of Bioclinica Group.
6. However, before making use of these BCRs it is the responsibility of the data exporter in a Member State, if needed with the help of the data importer, to assess whether the level of protection required by EU law is respected in the third country of destination, including onward transfer situations. This assessment has to be conducted in order to determine if the guarantees provided by the BCRs can be complied with in practice, in light of the circumstances of the possible impingement created by the third country legislation with the fundamental rights and the circumstances surrounding the transfer. If this is not the case, the data exporter in a Member State, if needed with the help of the data importer, should assess whether it can provide supplementary measures to ensure an essentially equivalent level of protection as provided in the EU.
7. Where the data exporter in a Member State is not able to implement the supplementary measures necessary to ensure an essentially equivalent level of protection as provided in the EU, personal data cannot be lawfully transferred to a third country under these BCRs. Therefore, the data exporter is required to suspend or end the transfer of personal data.
8. The approved BCRs will not require any specific authorization from the concerned supervisory authorities.
9. In accordance with Article 58 (2) (j) GDPR, each concerned supervisory authority maintains the power to order the suspension of data flows to a recipient in a third country or to an international organization whenever the appropriate safeguards envisaged by the Controller BCRs of Bioclinica Group are not respected.

ANNEX TO THE DECISION

The Controller BCRs of Bioclinica Group that are hereby approved cover the following:

a. Scope

Only members of Bioclinica Group acting as Controllers that are legally bound by these BCRs.

*(A list of members of the Bioclinica Group covered by these BCRs is available in Annex 1, Appendix 2)*

b. EEA countries from which transfers are to be made (*See Annex 1, Appendix 2*)

- c. Third countries to which transfers are to be made (*See Annex 1, Appendix 2*)
- d. Purposes of the transfer (*See section 2.3.2 of the BCR Policy and section 2 and 7 of the Application Form*)
- e. Categories of data subjects concerned by the transfer (*See section 1.2 of the BCR Policy, section 2 and 7 of the Application Form, and Annex 1, Appendix 1*)
- f. Categories of personal data transferred (*See section 2.3.1 of the BCR Policy, section 2 and 7 of the Application Form, and Annex 1, Appendix 1*)

On behalf of the Danish Data Protection Agency,

Anna Carolina Jensen

RELEVANT DOCUMENTATION TO BE ATTACHED WHEN SUBMITTING THE DRAFT DECISION TO THE EDPB VIA IMI AS

1. WP256.rev.01 referential completed with corresponding sections in Controller BCRs of Bioclinica Group, showing that they meet all requirements
2. The BCRs, their annexes and any other relevant documents supporting the SA's analysis under the draft decision (including the ones relating to any objection or concern raised by the concerned Supervisory Authorities, which has not been fully addressed by the applicant).

Kind regards

[SAGSBEHANDLER]