

Privacy Policy

(applicable to European data processors and European data subjects)

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Privacy Policy

1. Scope

- Compliance with European data protection regulations.
- All processing activities with regard to personal data as conducted by staff working for all Byondis Holding B.V. and its affiliated companies, including but not limited to Byondis B.V.
- All processing activities with regard to personal data as conducted by external parties under responsibility of Byondis.

2. Background

Byondis is committed to process personal data necessary for its business processes in a reliable and secure way.

Privacy is a universal human right protected by many laws throughout the countries in which Byondis operates, including the General Data Protection Regulation (“GDPR”) within the European Economic Area (“EEA”). These laws are also applicable to Byondis.

Pharmaceutical legislation and regulations (e.g. via WHO, EMA and FDA) provide strict standards and guidelines on how to deal with personal data in respect to medical health care.

While Byondis is committed to complying with laws in all countries in which it operates, the implementation of the GDPR requires special attention to privacy laws in the European Economic Area (EEA).

3. Purpose

This policy applies to the processing of personal data by Byondis Holding B.V. and all its affiliated companies (collectively “Byondis”) in the context of their activities and irrespective of the domicile of the data subjects.

This policy further applies to all parties processing data on behalf of Byondis.

This policy relates to the collection, recording, organization, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction (collectively “processing”) of information relating to an identified or identifiable natural person (“personal data”).

The purpose of this policy is to clarify to all our stakeholders, including employees, customers, suppliers, contracted service providers and clinical trial participants, that Byondis is committed to ensure that personal data are processed in accordance with all international, national, federal, state, provincial and local laws, statutes, codes, rules, regulations, ordinances, orders, decrees or other pronouncements or requirements of any governmental, administrative or judicial authority with the EEA having the effect of law that govern such activities (“applicable law”).

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This policy provides a framework, directives and guidelines for affiliates, business units, departments and individual employees to collect, process, maintain, store and destroy personal data in a way that is compliant with applicable law.

4. Responsibilities

Byondis Holding B.V. is responsible to ensure that Byondis complies with all applicable law, including but not limited to the General Data Protection Regulation (GDPR), which governs Byondis' activities within the EEA. The level of protection of applicable laws in a specific country within the EEA might differ, in which case the most restrictive rulings will be applied to the operations in such country.

The Board of Directors of Byondis Holding B.V. is ultimately responsible for ensuring compliance with this policy. All employees are responsible for complying with this policy. Violations of this policy could lead to irreparable harm, liability for any damages caused and loss of reputation by Byondis as well as high administrative fines as imposed by governmental bodies. Byondis may consider disciplinary action, including possible dismissal, in case of violation of this policy.

5. Policy

Byondis is committed to processing personal data of identifiable natural persons, including employees, patients and volunteers participating in clinical trials, ("data subjects") in such a way as to protect personal data and enable personal rights in accordance with applicable law.

Byondis attaches great importance to a careful balance between the responsibilities related to the development, manufacture and marketing of medicines on the one hand and the protection of personal data on the other hand.

Byondis is committed, legally and morally responsible and accountable for compliance with this privacy policy and the principles stated below. In order to safeguard this, the following measurements will be implemented:

This policy will be accessible to all stakeholders;

- Each relevant affiliate or department processing personal data will have procedures in place describing the guidelines and specific measurements to handle personal data they process. All employees involved in the processing of personal data should be familiar with this policy and the relevant procedures of affiliates and departments;
- Such departmental procedures will be compliant with this overall Privacy Policy and applicable law;
- Each relevant department will assign a responsible person for conducting, implementing and checking the actual operation of this procedure(s) and being the contact person for any questions relating to this policy and procedures;
- All procedures will be stored in a central, secure, electronic document management system with a defined review cycle;
- An adequate mechanism will be in place to check compliance, test the major internal controls and the accuracy and propriety of execution of the policies and procedures;
- An adequate mechanism will be in place to keep abreast of actual developments in applicable law and inform internal responsible employees and stakeholders about this;

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- Byondis will designate a responsible person for informing and advising Byondis and its employees on the applicable law relating to the protection of personal data within the EEA and Byondis' obligations under applicable law, monitoring compliancy as well as the impact of new and existing processing activities of personal data and to cooperate with stakeholders and authorities when applicable;
- Byondis will keep personal data for as long as it is needed for the relevant purpose and in accordance with business needs and any legal requirements or to comply with Byondis contractual obligations, respond to queries and resolve any disputes, to meet our legitimate interests and to enforce our rights.

5.1. Privacy Policy principles

These Privacy Policy principles are based upon the Fair Information Principles from the Organization for Economic Cooperation and Development, an intergovernmental economic organization with 35 member countries, founded in 1961 to stimulate economic progress and world trade (www.OECD.org), and the General Data Protection Regulation.

Byondis will impose limits to the collection of personal data and any personal data should be obtained by lawful and fair means and, to the extent required by applicable law, with the knowledge or consent of the data subject.

All personal data processed by or on behalf of Byondis should be relevant to the purposes for which they are to be used and to the extent necessary for those purposes. The data should be accurate, complete and up-to-date.

The purposes for which personal data are collected will be specified not later than at the time of data collection and the subsequent use will be limited to the fulfilment of those purposes or such others as are not incompatible with those purpose and as are specified on each occasion of change of purpose.

Personal data will not be disclosed, made available or otherwise used for purposes other than those specified in accordance with the purpose except: a) with the consent of the data subject; b) if required by Byondis to fulfil its contractual or other obligations; or c) in accordance with or as required by applicable law.

Personal data will not be transferred to a country or territory outside the EEA if such transfer is in violation of applicable law unless that country or territory ensures an adequate level of protection for the rights and freedoms of data subjects as may be required by such applicable law in relation to the processing of personal data. Transfer of personal data between affiliated companies within Byondis shall be done in accordance with appropriate safeguards the protection personal data in accordance with applicable laws.

Personal data will be protected by adequate security safeguards against such risks as loss or unauthorized access, destruction, use, modification or disclosure of data.

There will be a general attitude of openness about developments, practices and policies with respect to personal data. Means will be readily available of establishing the existence and nature of personal data and the main purposes of their use.

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Data subjects whose personal data are or may be processed by Byondis will have the right:

- To obtain confirmation from Byondis whether or not Byondis has personal data relating to such data subject;
- To have communicated to the data subject, personal data relating to him/her within a reasonable time, free of charge, if any, that is not excessive in a reasonable manner; and in a form that is readily intelligible to the data subject;
- To be given reasons if a request made under (a) or (b) is denied, and to be able to challenge such denial; and to challenge data relating to the data subject and, if the challenge is successful to have the personal data erased, rectified, completed or amended, unless Byondis is required to retain such personal data to fulfil its obligations under applicable law (e.g. obligations under tax laws, relating to the retention of clinical data or otherwise).
- To assurance Personal data processed for any purpose or purposes will not be kept for longer than is necessary or required for that purpose or those purposes.

5.2. Communication

Any external communication about matters relating to the protection of personal data will be done in accordance with the Byondis External Communication Policy.

6. Related policies, guidelines and procedures

- Legal Affairs Policy
- External Communication Policy
- Corporate Environment, Health and Safety (EHS) Policy statement

7. Communication of issues

For questions relating to this policy and the implementation thereof, please contact Byondis' privacy officer at dataprivacy@byondis.com or via telephone at +31 (0)24 679 5100.

8. Template History

Template History

Version	Part	Change
1.0	NA	New template; replacement of Synthon privacy policy in effect as from May 25, 2018 as revised on July 9, 2018. Effective as of April 16, 2020
2.0		New template; change Arcory into Byondis Holding; add last bullet art 4 Policy