

Introduction

The privacy of data is of paramount importance to Merge eClinical. As such, the organization subscribes to standards that instill confidence and comfort in our ability to satisfy customer data privacy requirements and will withstand the scrutiny of any data protection authority.

This statement is partially in response to the European Commission's Directive on Data Protection enacted in October 1998; which among other objectives includes requirements that prohibit the transfer of personal data to non-European Union nations that do not meet their standards for privacy protection. Merge eClinical complies with the U.S.-EU Safe Harbor Framework as set forth by the U.S. Department of Commerce regarding the collection, use, and retention of personal information from European Union member countries. The company has certified that it adheres to the Safe Harbor Privacy Principles of notice, choice, onward transfer, security, data integrity, access, and enforcement. Additional information regarding the Safe Harbor program, as well as a reference to the Merge eClinical certification, can be viewed at <http://www.export.gov/safeharbor/>. This statement is also in alignment with the Health Information Portability and Privacy Act of the United States and other similar data privacy laws in other nations.

Overview of Merge eClinical

Merge eClinical, a leading provider of eClinical software and services to pharmaceutical, biotechnology, medical device, and contract research organizations (CROs) offers adaptive, Web-based tools that work together to coordinate data capture, logistics, patient interaction and trial management—turning data into intelligence and shortening the pathway to an actionable study endpoint.

Merge eClinical acts as a processor of data collected and stored in secure databases on behalf of its clients, who are the data controllers of the information. The information is key-coded and is generally not personally identifiable to Merge eClinical. Merge eClinical does not analyze the information or otherwise use it in any way beyond client instruction.

At the end of each clinical trial study, copies of the data are transferred to the client and the individual sites that originally collected that data. Client notification occurs prior to the destruction of the data at the end of the retention period.

Notice

Merge eClinical relies upon the assurances of its clients on whose behalf it processes personal information that those individuals about whom the personal information concerns have been fully informed about the purposes for which the information is collected and used, including the types of non-agent third parties to which that information is disclosed, if any, and the choices and means offered individuals for limiting the use and disclosure of their personal information.

Upon client instruction, Merge eClinical will inform individuals about the purposes for which Merge eClinical clients collect and use personal information. If so instructed, Merge eClinical also will disclose the types of non-agent third parties, if any, to which Merge eClinical discloses this information and the choices and means offered individuals for limiting the use and disclosure of their personal information.

Merge eClinical will require that this notice be provided in clear language in a conspicuous manner at the same time individuals are first asked to provide personal information, or as soon as possible thereafter, and in any event before Merge eClinical uses or discloses information for a purpose other than that for which it was originally collected.

Choice

In accordance with client instructions, Merge eClinical will work with clients to provide individuals with the opportunity to choose (opt out) whether personal information is disclosed to a third party agent used by Merge eClinical; or to be used for a purpose other than the purpose originally authorized.

For sensitive personal information (e.g., personal information that pertains to racial or ethnic origin, political or religious beliefs, health condition or sexual orientation) or use of personal information for a purpose other than the purpose originally authorized, in accordance with client instructions, Merge eClinical will work with clients to ensure that information is disclosed to a third party agent only after an individual explicitly consents (opts in) to the disclosure.

Transfers to Third Parties

Merge eClinical will transfer personal information received from the EU to a third party consistent with client instruction.

Merge eClinical will enter into a written agreement or contract to ensure that agents, third party providers, and independent entities to which Merge eClinical transfers personal information adhere to the same level of privacy protection as Merge eClinical.

When Merge eClinical has knowledge that a third party is using or sharing this personal information in a way contrary to this policy, Merge eClinical will take reasonable steps to prevent or stop such processing or use.

Access and Security

Upon request and in accordance with client instructions, Merge eClinical will allow individuals access to personal information that it holds.

Individuals can correct, amend, or delete information that is inaccurate; except in certain cases where providing this access would be disproportionate to the risks to the individual's privacy or where rights of other individuals would be violated.

Access will not be provided to personal information relating to medical or pharmaceutical clinical trials to the extent that access, disclosure, deletion or alteration of the personal information would jeopardize the integrity of the trial or if contrary to regulatory requirements.

Merge eClinical takes precautions to protect personal information from loss, misuse and unauthorized access, disclosure, alteration, and destruction. These precautions include data redundancy and the implementation of physical and logical controls.

Data Integrity

Merge eClinical relies upon assurances from its clients that the personal information Merge eClinical possesses is relevant for the purposes for which it is to be used. Merge eClinical uses the data in accordance with client instruction.

Merge eClinical will take reasonable steps to ensure that personal information entered onto its platforms retains its original relevance, accuracy completeness and currency.

The Merge eClinical Compliance department will periodically review and conduct compliance audits of the relevant privacy practices to verify adherence.

Merge eClinical management will remedy issues arising out of any failure to comply with this policy.



Merge eClinical Data Privacy Statement

Dispute Resolution

Merge eClinical employees or external parties will direct any issues, concerns, or questions arising from the use or disclosure of personal information to the Merge eClinical Senior Management.

Enforcement

Merge eClinical will cooperate with the Data Protection Authorities (“DPAs”) of EU Member States where it has operations in the investigation and resolution of complaints and comply with advice given by the DPAs.

Any employee that Merge eClinical determines is in violation of this policy will be subject to disciplinary action, up to and including termination.

Geoff Kabel
Director of Compliance