

Data Privacy and Security Policy for the Infosario Registry Platform:

The privacy and security of personal data and health information are of primary concern to Outcome Sciences, LLC, a QuintilesIMS company (“QuintilesIMS”). QuintilesIMS carefully protects the confidential personal and health information provided to it by business partners and volunteer research subjects, healthcare professionals and health care institutions that maintain data. QuintilesIMS is committed to following applicable laws, rules and regulations in our use, collection and disclosure of such information. This Data Privacy and Security Policy is a dynamic document, which will reflect our continuing vigilance to properly handle and secure information that we are trusted to maintain.

For more information about QuintilesIMS’ commitment to privacy, please visit <https://www.quintilesims.com/en/corporate/privacy-commitment>.

I. For users located in the United States, the terms of this Section I shall apply:

The Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) and the rules and regulations implemented under HIPAA were enacted for Covered Entities to protect the privacy, security and distribution of individually identifiable health information, that is, Protected Health Information (“PHI”). Healthcare organizations, which include health plans and health care providers, as Covered Entities, must comply with HIPAA or face significant sanctions from the U.S. Department of Health and Human Services, the government agency authorized to enforce HIPAA. Compliance with HIPAA is of wide-ranging importance because HIPAA specifies legal, regulatory, process, security, and technology requirements imposed on healthcare organizations that handle PHI.

Although QuintilesIMS is not a HIPAA Covered Entity, certain of HIPAA’s duties and obligations apply to QuintilesIMS when we serve as a Business Associate (as defined under HIPAA) of healthcare organizations that are covered entities, such as when QuintilesIMS facilitates the conduct of quality improvement programs at various healthcare sites, which involve the use and disclosure of PHI. QuintilesIMS is committed to handling PHI in a manner consistent with U.S. federal laws and regulations relating to the security and electronic handling of protected health information, including but not limited to applicable HIPAA requirements relating to security and electronic transfer and any other legal mandates.

All of QuintilesIMS’ post-marketing research solutions are consistent with HIPAA and mesh with healthcare organizations’ existing HIPAA protocols. QuintilesIMS has extensive experience in customizing products for healthcare organizations and pharmaceutical companies, and has worked closely with them to facilitate healthcare organizations’ HIPAA compliance.

QuintilesIMS has implemented administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of electronic protected health information. QuintilesIMS manages security through both physical and logical methods. Our systems and databases are maintained in a secure, access-controlled and monitored facility. The mechanisms we employ include encryption, authentication, intrusion detection, user-identification, secure storage and back-up, data redacting, and non-modifiable audit trails. In addition, external assessments of system security are routinely performed by an independent, expert third party.

In summary, QuintilesIMS’ systems are maintained according to high standards of health care information collection, handling and transmission. We regularly monitor technological, procedural and statutory changes which affect the protection of protected health information.

II. For users located in the European Union, the terms set forth in the following link shall apply:

<http://www.quintiles.com/privacy/privacy-policy-statement/>.

III. For users located outside of the United States and outside of the European Union, the terms of this Section III shall apply:

It is QuintilesIMS' intention to ensure that all personal data provided to it, from anywhere in the world, is protected by its standard practices and procedures with regard to the collection, use and disclosure of personal data and complies with local data protection laws, where applicable. Pursuant to appropriate laws and regulations, all personal data is stored on a secure database.

All QuintilesIMS staff handling personal data receive privacy training. QuintilesIMS is committed to ensuring that personal data is appropriately protected; however, personal data may be disclosed to regulatory authorities as necessary for the purposes of obtaining approvals or otherwise to comply with applicable legal requirements. Personal data may also be disclosed to certain third parties consistent with the terms of unambiguous informed consent obtained from data subjects whose personal data may be used for research activities, or as otherwise permitted by other appropriate rules. Personal data may, at times, also be key-coded in accordance with applicable laws, regulations and standards.

Where QuintilesIMS collects personal data directly from individuals throughout the world, we will inform them about the purposes for which we collect and use personal data about them, namely the conduct of research that may involve their personal data and any other relevant purposes. QuintilesIMS will provide information only to third party agents for the purposes of providing QuintilesIMS' services in a manner consistent with the principles described above. QuintilesIMS may transfer personal data to its United States offices, and those offices will hold such data in accordance with this policy. QuintilesIMS may also transfer personal information to agents, from whom appropriate assurances will be sought that the personal information will be handled in accordance with applicable laws and standards.

QuintilesIMS recognizes the importance of maintaining the privacy of information collected and/or stored online and has systems in place that protect personal data collected and/or stored online or via an electronic database. QuintilesIMS has implemented administrative, physical and technical safeguards to protect electronic personal data from loss, misuse and unauthorized access.

In order to maintain our information collection and transmission system to appropriate standards, QuintilesIMS monitors developments in respect of technological, regulatory and legislative standards relating to the privacy and security of personal data.