



ANSYS, Inc.

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To Whom It May Concern:

Ansys values the protection of personal data and strives to comply with applicable legal requirements and obligations regarding data protection and privacy. Ansys is continually expanding its operation, including into the healthcare industry. Therefore, we anticipate questions about potential data privacy implications of our operations, such as whether Ansys receives access to health personal data.

This letter offers an explanation of our company's processing activities when providing its products and services to its customers in the healthcare industry (collectively "Services"). This letter is being provided to you as a courtesy, and it is not meant to provide legal advice. If you have legal questions in this regard, please consult your attorney.

What's new?

Modeling and simulation are proven ways to address the high and unsustainable costs and time required for the design and regulatory approval of increasingly complex healthcare solutions. In silico medicine is set to drastically change the way engineers approach healthcare solutions. This approach maximizes patient safety while making healthcare more affordable. Applying engineering simulation throughout development and the regulatory approval process accelerates innovation, reduces cost, and shortens time to market, while meeting safety standards and product deadlines. These solutions serve the entire healthcare industry (i.e., medical devices, pharma and biopharma, and clinical applications) and can be used during discovery and ideation, invention and prototyping, pre-clinical, clinical, and regulatory decision-making. Examples of applications include optimization of orthopedic and cardiovascular implants, respiratory devices, hospital equipment and drug manufacturing and delivery.

Ansys aspires to be an effective partner to stakeholders in the healthcare ecosystem by generating insights and by adapting its simulation technologies to participate in existing health data platforms. Ansys' current work revolves around building a forward-looking simulation to predict response to an event, a clinical intervention, therapy, etc. Customers may be wondering whether these simulation solutions are built on or entail any processing of personal data and in particular health data.



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What is “personal data” and “health data”?

According to the Regulation (EU) 2016/679 (“GDPR”), “personal data” means any information relating to an identified or identifiable natural person; an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person. Other applicable data privacy laws and regulations across the globe adopt similar definitions. According to the GDPR “data concerning health” or “health data” means personal data related to the physical or mental health of a natural person, including the provision of health care services, which reveal information about his or her health status.

According to the US Health Insurance Portability and Accountability Act (“HIPAA”), “health data” means any information, including genetic information, that is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual.

In most jurisdictions, health data constitutes sensitive data and entails special treatment and additional protection.

What is “clinical data,” does it constitute “health data,” and does Ansys process “health data”?

Clinical data is commonly defined as data related to patient diagnosis, patient care, and clinical trial programs, and may include demographics, exposures, laboratory tests, medical device information etc. You may see Ansys referring to “clinical data” via its website, during presentations, or when promoting or demonstrating its Services. Currently at Ansys, clinical data: (i) does not mean or contain personal data, including health data; and (ii) includes only the following information: patient’s age at the time of data collection (not the exact birthday), gender, known diseases, lab results, images (X-ray, CT, MRI, Ultrasound) (collectively “Clinical Data”). At Ansys, Clinical Data does not include identifiers that can be related to an identifiable individual and thereby does not constitute personal data or health data, according to applicable legal definitions.



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While it is the customer's sole responsibility to ensure that its datasets do not contain any personal data before sharing, Ansys has taken additional measures to minimize the risk of any unwanted disclosure, including, where applicable, adding contractual terms that prohibit customers from sharing any health/ sensitive data.

Given that Ansys and customer do not exchange any patient personal data, an analysis of further data privacy requirements, such as the roles of the parties and their respective obligations, is not relevant.

Other resources

For general information about how Ansys handles personal data, please read [Ansys Global Privacy Notice](#). For customer-specific information, please refer to [Ansys Customer Letter on Data Privacy](#). If you have more questions about how Ansys treats personal data, please contact privacy@ansys.com. For other information, please contact your account representative at Ansys.