onetrust

## Assessment details

**ID** 122840

**Name** Italy_Study 309592 retrospective use of data_PIA

**Organization** Research & Development

**Date created** 04/15/2026 11:52 AM

**Deadline**

**Completed date** 04/23/2026 01:15 PM

**Date submitted** 04/21/2026 12:26 PM

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**Stage** Completed

**Approval stage**

**Status** Active

**Critical** 0

**High risks** 0

**Medium risks** 0

**Low risks** 0

**Total risks** 0

**Residual risk level** None

**Residual risk score** 0.0

**Result** Approved

**Primary record id** 7666

**Primary record name** Italy_Study 309592 retrospective use of data

**Template version** 20

**Open risk count** 0

**Open info request** 0

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## Assessment questions

### 1 General Information

1.1 **What is the name of the business activity processing personal information?**
*Please type the name of the activity in an understandable and recognisable way*

***Response***

Italy_Study 309592 retrospective use of data | Research & Development

***Justification***

None

1.2 **Please describe the business activity processing personal information, including the purpose.**
*Please describe the business activity in detail and how you intend to use the personal information of individuals to achieve your aims. Specifically:*

- *What do you want to achieve?*
- *How are you going to achieve this?*
- *How will personal information be used to do this?*
- *What is the benefit to GSK and to the individual?*

*Personal information is information that can be used to identify you directly or indirectly, on its own or when combined with other information.*

*Some examples of personal information are: Name / phone number / address / date of birth / bank account details / unique identifiers / social media posts / geotagging / staff number / IP address / video image*

***Response***

**Italy_Study 309592 retrospective use of data | Research & Development**

***Response***

This assessment concerns the processing of data, and in particular the secondary use of data for a multi-site, retrospective, non-interventional study.
The study is a multi-site retrospective, non-interventional secondary analysis study that uses existing clinical data captured in databases from participating sites, to analyze adult patients with chronic obstructive pulmonary disease (COPD) in Italy.
"Retrospective" means using data that were already collected in the past.
The primary objective of the study is to comprehensively describe the demographic, clinical, and treatment patterns of COPD patients, including subgroup analyses based on exacerbation history and blood eosinophil count (BEC). Secondary objectives focus on characterizing patients eligible for biologic therapy by analyzing their clinical features and comorbidities. The study also includes an exploratory analysis to estimate the rates of moderate-to-severe exacerbations among individuals receiving triple inhaled therapy with elevated BEC levels.
The study collects secondary, pseudonymized data from selected Italian sites, capturing variables such as demographics, clinical attributes, treatment patterns, lung function metrics, symptom scores, BEC levels, and exacerbation histories. Data handling processes involve securely transferring these pseudonymized datasets to servers operated by PPD Evidera within the EU, ensuring adherence to applicable data protection regulations, including the GDPR. Data not meeting minimum quality standards will be excluded from the analysis, with documentation provided for any exclusions. Results will be reported in aggregate form, and ethical and privacy safeguards, including institutional Ethics Committee approvals, will be put in place prior to study execution.
A protocol has been developed to ensure high standards of data integrity, privacy, and compliance while providing valuable insights into the demographics, clinical features, and treatment patterns of COPD patients, including those potentially eligible for biologic therapy.
The study does not impose a treatment protocol, any diagnostic or interventional procedures, or a visit schedule.
The study will collect data on approximately 1,000 patients from the clinical databases of the selected sites.
As this research involves the secondary use of existing clinical data and does not require direct patient contact, no primary data collection will be performed.
Data will be extracted retrospectively from the datasets at each site and transferred in a pseudonymized format. No directly identifiable personal data (such as names, initials, full dates of birth, addresses, or identification numbers) will be included in the study dataset provided to the contract research organization.
The pseudonymized data set will be stored on a secure, access-controlled, GDPR-compliant server located within the European Union. Access to the data will be restricted to authorized study personnel only within the European Union or the United Kingdom. Study results will be reported in aggregate form, and no individual subject will be identifiable in any publication or report.
With respect to informed consent, the study involves the secondary use of previously collected clinical data and does not entail additional procedures or interventions. A request for a waiver of informed consent is included in the relevant EC submission for review, in accordance with applicable regulatory provisions governing non-interventional research. The logistics involved in retrieving the contact information to reach all individuals eligible for this study and their guardians would be extremely difficult, if not impossible, given that the objective of the study is to collect and analyze data from approximately 1,000 people whose data were already gathered for research by participating sites. Furthermore, no patient-level data will be directly transferred to the study sponsor. This strengthens the legitimacy of using the instrument provided by Article 110 of Legislative Decree 196/2003. Obtaining consent from 1,000 people would be excessively burdensome. Without the instrument provided by Article 110, this study cannot be carried out.
The GSK legal entity sponsoring the study is GlaxoSmithKline SpA.
Following EC approval and site contracts, relevant pseudonymized data pertaining to the study variables will be extracted by site investigators or designated site personnel from the site registries and securely transferred to a server environment operated in accordance with applicable data protection requirements, located within the European Union and hosted by PPD™ Evidera™, Thermo Fisher Scientific (the designated contract research organization; hereafter referred to as PPD Evidera). No patient-level data will be directly transferred to the study sponsor.
Prior to data transfer, the site investigators or study personnel will remove all directly identifiable patient information and verify that the dataset is pseudonymized in accordance with applicable data protection requirements. No directly identifiable data will be transferred to the sponsor or the contract research organization.
Following receipt of the data, PPD Evidera will perform data quality control procedures to identify inconsistent, incomplete, or implausible records. Where feasible, queries will be addressed in collaboration with the registry team. Data that do not meet predefined minimum quality criteria and cannot be adequately resolved will be excluded from the relevant analyses, with documentation of the rationale.
Data management and statistical analyses will be conducted by PPD Evidera using validated statistical software. All analyses will be performed in accordance with the study objectives, PPD Evidera SOPs for data management, the approved protocol and study design document, and applicable regulatory and data protection requirements.
Data Management and Storage:
All extracted data are stored on secure servers, ensuring compliance with local or national regulations.
Findings will be disseminated through scientific publications and presentations in an aggregated, anonymous manner.
Timelines:
Start of data collection: Q2 2026
End of data collection: Q3 2026
Final report of study results: Q4 2026

***Justification***

None

1.3 **When is the expected start date of the activity?**

*Select the date that the activity is due to start or started if the date is in the past.*

***Response***

**Italy_Study 309592 retrospective use of data | Research & Development**

***Response***

12/18/2025

***Justification***

None

1.4 **When is the expected end date of the activity?**
*Select an end date if this is a one-off activity, project or initiative.*
*Select "Not Applicable" if this is an ongoing activity with no end date.*

***Response***

**Italy_Study 309592 retrospective use of data | Research & Development**

***Response***
12/31/2026

***Justification***
None

1.5 **Is this a global or a local activity?**
*A local activity involves one market.*

*A global activity will involve multiple (two or more) markets or personal Information of individuals located in multiple markets.*

***Response***

**Italy_Study 309592 retrospective use of data | Research & Development**

***Response***
Local

***Justification***
None

1.9 **Which country is the privacy contact reviewing this business activity responsible for?**
*Please only select one country.*

***Response***

**Italy_Study 309592 retrospective use of data | Research & Development**

***Response***
Italy

***Justification***
None

1.10 **Who decides why and how personal information is processed as part of this activity? Please select the appropriate GSK entity for this activity.**
*This is known as the controller in some jurisdictions.*

*If one entity is involved in determining the purpose and design of this business activity, please begin by typing the country it is associated with to filter the drop-down results.*

*If multiple entities are involved in determining the purpose and design of this business activity, please either select the specific entities or regions involved.*

*The regions available for selection are:*

- *Africa*
- *Asia-Pacific*
- *Australia*
- *Canada*
- *Central America/Caribbean/Mexico*
- *Europe*
- *Middle East*
- *South America*
- *United States*

*Please refer to guidance examples for controller and processor here.*

***Response***
ITALY GlaxoSmithKline S.p.A | Privacy | Italy

***Justification***
None

1.11 **Who processes personal information as part of this activity but is not involved in deciding why and how personal information is processed? Please select the appropriate GSK entity(ies) for this activity.**
*This is known as the controller in some jurisdictions.*

*If one entity is involved in determining the purpose and design of this business activity, please begin by typing the country it is associated with to filter the drop-down results.*

*If multiple entities are involved in determining the purpose and design of this business activity, please either select the specific entities or regions involved.*

*The regions available for selection are:*

- *Africa*
- *Asia-Pacific*
- *Australia*
- *Canada*
- *Central America/Caribbean/Mexico*
- *Europe*
- *Middle East*
- *South America*
- *United States*
- *Not Applicable*

*Please refer to guidance examples for controller and processor here.*

***Response***
Not applicable

***Justification***
None

1.12 **Does the activity consist of any of the following high risk features or is there any other reason a Privacy Impact Assessment (PIA) is required?**
*Some of these activities will trigger a PIA to be completed, others will only require a PIA when multiple activities are combined.*

*A Privacy Contact or Leader may ask you to complete a PIA in some circumstances where it is not automatically triggered.*

*Please hover over each option below to obtain a further explanation.*

***Response***

**Italy_Study 309592 retrospective use of data | Research & Development**

***Response***

PIA is required by the Data Privacy Authority | Processing of information concerning vulnerable individuals | Processing of sensitive personal information

***Justification***

None

## 2 Personal Data

2.1 **Please select the group(s) of individuals whose personal information will be processed. For each group, select the categories of information and individual data elements processed.**
*Remember that any information that GSK could identify an individual through, directly or indirectly, on its own or in combination with other personal information we hold, should be selected.*

*Please include all the personal data elements that you reasonably expect could be collected for this activity.*

***Response***

Research Subjects

Sensitive Elements

- Medical or Health Information
- Physical characteristics
- Lifestyle information

Restricted Elements

- Age or date of birth

Basic Elements

- Gender or Title

2.2 **How many individuals' personal information will be used to carry out this business activity?**
*Please estimate the number of individuals whose data is processed for this activity. If the activity does not have an end date, please provide an annual estimate.*

***Response***

**Italy_Study 309592 retrospective use of data | Research & Development**

***Response***

0-1000

***Justification***

None

2.3 **Where will the individuals be located whose personal information will be used for this business activity?**
*Please select all locations individuals are located, you can select multiple options.*

*In certain jurisdictions, individuals will be referred to as data subjects.*

***Response***

**Italy_Study 309592 retrospective use of data | Research & Development**

***Response***
Europe

***Justification***
None

2.4 **Please select the appropriate basis for processing the personal information.**
*You must have a valid basis to carry out your business activity. No single basis is 'better' or more important than the others – which basis is most appropriate to use will depend on your purpose and relationship with the individuals.*

*If consent is only used as an appropriate condition for processing sensitive personal information, and not as a lawful basis, please only select consent in the following question.*

*If selected, please explain the legal obligation in the justification box including name of statute or regulation and section references where possible.*

*If selected, please explain the contractual obligation in the justification box including name or reference for the related contract(s), where possible.*

***Response***

**Italy_Study 309592 retrospective use of data | Research & Development**

***Response***
Italian Privacy Code 101/2018 art. 110 and 110 bis. Garante's provision 10016146, dated 09May24

***Justification***
None

2.5 **Please select the appropriate condition for processing the sensitive personal information.**
*Sensitive personal information needs more protection because, due to its sensitivity, it poses a higher risk to individuals if it is misused.*

*You must determine an additional condition for processing sensitive information before you begin this processing.*

*Please hover over each option below to obtain a further explanation.*

***Response***

**Italy_Study 309592 retrospective use of data | Research & Development**

***Response***
Public health (with a basis in law)
Italian Privacy Code 101/2018 art. 110 and 110 bis. Garante's provision 10016146, dated 09May24

***Justification***
None

## 3 Necessity and Proportionality (of data)

3.1 **Describe the rationale for using the volume and categories of personal information selected**

*Please explain why the number of information types and numbers of individuals involved are relevant and necessary to achieve the aims of this activity.*

***Response***

The volume and categories of personal information used in this study are selected based to achieve the study's objectives effectively as described in the study protocol.
The study collects secondary, pseudonymized data from selected Italian sites, capturing variables such as demographics, clinical attributes, treatment patterns, lung function metrics, symptom scores, BEC levels, and exacerbation histories. Volume of data: The study will collect data on approximately 1,000 patients from the clinical databases of the selected sites.
As this research involves the secondary use of existing clinical data and does not require direct patient contact, no primary data collection will be performed. Data will be extracted retrospectively from the datasets at each site and transferred in a pseudonymized format. No directly identifiable personal data (such as names, initials, full dates of birth, addresses, or identification numbers) will be included in the study dataset provided to the contract research organization.
Volume of data: the data collected will provide patient phenotype information particularly among patients with elevated BEC and frequent exacerbations who are affected by COPD.

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**Comments**

**Filippo Montanari** *04/20/2026 02:27 PM*

Non viene spiegato il razionale del volume di dati

**Omar Shalby** *04/20/2026 06:32 PM*

aggiunto

3.2 **Could your objectives be achieved with less information from fewer individuals?**

*Remember you should only use the information that you need. Please consider whether the same results could be achieved with less information.*

*Please explain your rationale in the justification box below.*

***Response***

No

***Justification***

GSK ensures that only essential data is collected and processed. The data collected is limited to what is necessary to achieve the study objectives, in line with data minimization principles. The objectives of this study could not be effectively achieved with less information or fewer research subjects. Reducing the volume of data or the number of participants could compromise the validity and reliability of the study outcomes. By its nature, real-world data can be less complete and reliable, which is why often a larger population is needed to secure validity of the results.

3.3 **Is there any other way to achieve the purpose?**

*Consider the balance between business benefit and the privacy of individual. Could you achieve a similar benefit to the business in a way that gives greater privacy to the individual?*

*Please provide your rationale in the justification box below.*

***Response***

No

***Justification***

There are no alternative approaches that would achieve the same purpose without processing the personal data as currently done. The insights gained from the real world data are crucial and cannot be achieved without processing personal data. No directly identifiable personal data (such as names, initials, full dates of birth, addresses, or identification numbers) will be included in the study dataset provided to the contract research organization. The observational nature of the study relies on the collection and analysis of data to provide meaningful results.

3.4 **Is all the personal information collected necessary for the intended purpose?**

*You should avoid collecting or using information because it is an easier option or because you might need it in future.*

*Do you need to use each personal information type you are collecting for this business activity?*

*Please explain your rationale in the justification box below*

***Response***

Yes

***Justification***

Yes, GSK will ensure that each data element collected is essential for achieving the study objectives and ensuring the validity and reliability of the findings.

3.5 **Will the data collected be used for anything other than the specified purpose?**

*Personal information should only be used for the purposes (e.g. business activities) for which it was collected. it should only be used for other purposes if they are compatible with the original purpose for which it was collected.*

*Consider whether any other GSK colleagues or teams have access to the data and be able to use it for their own purposes. Are these purposes compatible with or similar to the purposes for which it was collected?*

*Please explain your rationale in the justification box below if you select 'Yes'.*

***Response***

No, the personal information will only be used for the purpose stated in question 1.2.

***Justification***

Personal data will be used according to the information provided in question 1.2

## 4 Consent

4.4 **What source do we obtain the personal information of individuals used in this processing activity from?**

*Select one or more that apply.*

*Please hover over the options to see more information.*

*Please add any further relevant information to the justification box below.*

***Response***

**Italy_Study 309592 retrospective use of data | Research & Development**

***Response***

Contracted third parties

***Justification***

None

4.5 **Which system collects the personal information?**

*Please select the system that collects the personal information from the individual, third party or other provider identified in response the previous question.*

*A GSK operated system/application in this context is one that supports information-related activities. This could include software systems, applications or databases.*

*If you can't find your system from the drop down list, please raise a ServiceNow ticket and this will be investigated for you.*

***Response***

Chrd Veeva Vault Etmf | Privacy | Unknown

***Justification***

None

4.6 **Please select the third party the personal information is collected from, from the drop down list.**

*If the third party is not available in the drop-down list, please select not sure and let your privacy lead or privacy contact know.*

***Response***

9910038064 - EVIDERA LTD | TPRM | Unknown

***Justification***

None

## 5 Individual Rights

5.1 **Can a copy of the personal information used for this activity be provided to an individual upon request?**

*An individual may have the right to request a copy of their personal information in certain countries. For example, under the GDPR this is called a Data Subject Access Request and we have one month to respond. Email, excel, word, pdf, etc is an acceptable format.*

*Please use the justification box below to provide a rationale if 'No' is selected.*

***Response***

Yes - information can be provided in a digital format (e.g. files, images, recordings, etc.)

***Justification***

In case of data collection by GSK, GSK has an Individual Rights Request (IRR) process in place. Data can potentially be provided in digital format, which can be requested at the study site. Furthermore, this is a secondary data analysis where the study sponsor will only receive the report in an aggregate form. We cannot fulfill the specific requests received since we only receive aggregated data.

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**Comments**

**Filippo Montanari** *04/20/2026 02:30 PM*

qui manca la parte in cui normalmente indichiamo che non possiamo evadere le richieste ricevute, ricevendo solo dati aggregati

**Omar Shalby** *04/20/2026 06:36 PM*

riportato

5.2 **Is there a mechanism or process to ensure the personal information is kept accurate and can be updated when required?**

*We must keep personal information accurate while we hold it. Please describe how we identify inaccurate personal information and correct it when it is inaccurate or out of date.*

***Response***

Yes

***Justification***

Data collection process involves a level of data validation. Built in mechanisms exist to correct typing errors, field verification, data formats, range checking. Study specific checks, which are specifically programmed to verify whether the inputted data is correct, are put in place.

5.4 **Is there a process in place for when an individual asks for GSK to stop using their information?**

*In some circumstances individuals may be able to ask us to restrict the use of their personal information. This means that GSK would be allowed to store the information but not use it.*

*Requests to restrict processing are most common when information is held longer than it should be or where there is a legal challenge.*

*If we had to stop using the personal information of one individual, could we continue the activity that their information was used for without impact?*

***Response***

Yes

***Justification***

The study gathers data from clinical datasets provided to a third party in pseudonymized form. GSK does not hold identifiers and cannot trace or isolate individual records. Any data subject rights, including requests to restrict processing, must be managed by the original data holders (participating study sites). Reachable patients may withdraw consent contacting the study physician. Any restriction on use would need to be applied by the data holder and, if necessary, reflected in the data provided to us.

## 6 Access/Transfers

6.1 **Where/who might the personal information be shared to/with?**

***Response***

**Italy_Study 309592 retrospective use of data | Research & Development**

***Response***

Regulatory Authorities and Ethical Committees

***Justification***

None

6.7 **Is personal information transferred from one country to another?**

*Personal information is transferred when it is transmitted from one country to another across jurisdictional borders.*

*Please note, a transfer does not mean the same as transit. If personal data is just electronically routed through Country B, but the transfer is actually from one organisation in Country A to another in Country A and there is no intention that this information will be access or used whilst transiting through Country B, then it is not considered a transfer to another country.*

***Response***

**Italy_Study 309592 retrospective use of data | Research & Development**

***Response***

No

***Justification***

None

## 7 Security

7.1 **What is the outcome of the Third Party Security Assessment?**

*A Third Party Security Assessment (i.e., TPSA) is performed by the cybersecurity team on a third party and/or on its applications, systems and platforms, when GSK's cybersecurity criteria are met.*

***Response***

**Italy_Study 309592 retrospective use of data | Research & Development**

***Response***

Reasonably Adequate

***Justification***

None

7.2 **Has a Risk and Compliance Assessment (R&CA) (previously known as a Smart Control Assessment) been completed and submitted?**

*Risk and Compliance Assessment (R&CA) (previously known as a Smart Control Assessment) are defined to ensure that technology systems meet GSK and Regulatory requirements (e.g., audit trails, access management, electronic records and signatures, validation, privacy) and allow GSK to manage its main technology risks.*

*They must be conducted for all systems and maintained through the life of the system.*

***Response***

**Italy_Study 309592 retrospective use of data | Research & Development**

***Response***

Yes

***Justification***

None

## 8 Transparency

8.1 **Have you or will you provide individuals with a privacy notice?**

*Where a third party is used to provide the privacy notice, please describe how GSK evidence that the privacy information has been given to the individual. For example, if an agency / health care partner / intermediary provide privacy notice to individuals on behalf of GSK.*

*If multiple options apply, please provide further information in the justification box below.*

***Response***

**Italy_Study 309592 retrospective use of data | Research & Development**

***Response***

We provide the individuals with a privacy notice at the time of collection

***Justification***

The notice will be published on GSK website

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**Comments**

**Filippo Montanari** *04/20/2026 02:33 PM*

la risposta non è corretta, la notice verrà pubblicata sul sito

**Omar Shalby** *04/20/2026 06:38 PM*

corretto

8.2 **Has the privacy notice been reviewed to ensure the processing covered?**

*The privacy notice is public facing and can be found on our websites.*

*If the activity being assessed is not covered by the existing wording, then the privacy notice may need to be updated before the activity can start.*

*If a third party is being used to provide a privacy notice, this should be reviewed to confirm that it includes the required information.*

*If you require further assistance, please speak to a Privacy Contact or Privacy Leader.*

***Response***

**Italy_Study 309592 retrospective use of data | Research & Development**

***Response***

Yes

***Justification***

None

## 9 Retention

9.1 **How long is the information held for?**

*Select the applicable GSK Global Retention Schedule(s) for each type of data subjects (you selected data subject types in question 2.1). If none of the GRS applies to your processing activity, please identify and mention the relevant retention period(s) in the justification box below.*

*As an example: Employees: employee records (GRS056 - 7 years after employment ends) HCP: Healthcare Events Programme Records (GRS101 - <10 years).*

*If you are unsure, please access the GSK Global Records Retention Schedule.*

***Response***

**Italy_Study 309592 retrospective use of data | Research & Development**

***Response***

10 years

***Justification***

None

9.2 **When does the retention period start from (trigger)?**

*This is the point from which the clock starts for deletion, this is often at the end of a relationship, closure of an account, the date a clinical trial ends.*

*For example, the period of retention for GSK employee personal information, only starts when an individual leaves employment. The trigger period, therefore, is when an employee ceases their employment with GSK.*

*Personal information will be kept for the length of the retention period from the trigger date, it will then be disposed of at the end of the retention period.*

***Response***

From CSR signature

9.4 **Is digital personal information automatically deleted and is hard copy personal information scheduled for deletion on a periodic basis?**

*Where information is used digitally, is there a process that destroys information (or puts in beyond use) without human input?*

*Where information is stored physically, for example in archive, is there a process to ensure that the information is destroyed regularly?*

*If the answer to either is No, please select No as the answer and provide an explanation.*

***Response***

(Yes)

***Justification***

GSK does not receive personal information, only aggregated data report. Third party vendor archives pseudonymized data for 5 years.

9.5 **Can you prevent automatic and/or scheduled deletion from taking place?**

*If we needed to, could automated deletion be paused or stopped? For example if we needed to keep information as part of a legal dispute, could it be kept longer than the original intended retention period?*

***Response***

(Yes)

***Justification***

Yes we could prevent the deletion of data, if necessary.

9.6 **How does GSK ensure personal information is managed in line with the retention period?**

*This is particularly important where retention and deletion processes are not automated or where information is not stored in a structured system.*

*Please describe the processes or controls that will help us understand how long information is being held for an will ensure that it is deleted at the right time*

***Response***

Pseudonymised patient data will be securely transferred from sites to the contracted research organisation at PPD Evidera, and stored at a structured, secure server. At project team members with the needs for data access and involved in data management and analysis will be granted data access. The retention period for the pseudonymised patient data is 5 years. Following which, the data will be deleted from PPD Evidera server.

9.7 **Can GSK delete the personal information on request?**

*In some countries individuals can ask for their information to be deleted, if we were asked to delete information by an individual, could their information be deleted? If information may not be deleted or there may be difficulties deleting it, please provide details.*

*If no is selected please provide a rationale in the justification box below.*

***Response***

(Yes)

***Justification***

The data used for this activity is pseudonymized and cannot be attributed to identifiable individual without additional information held separately by the participating study site personnel. Consequently, we cannot determine whether a specific individual is included in the dataset. Should GSK receive a deletion request from an individual, it will be forwarded to the appropriate data holder for action.

9.8 **Please provide the GSK Global Retention Schedule (GRS) number(s).**
*Please enter the relevant GRS numbers for the data elements collected for this processing activity. For more information on GRS numbers, you can consult the GSK Global Records Retention Schedule.*

***Response***

**Italy_Study 309592 retrospective use of data | Research & Development**

***Response***

Retention of 5 years for both data stored by GSK and by the TP vendor from the conclusion of the study.

GRS040 for GSK (Supportive Regulatory Information - Key records relating to obtaining and maintaining product registrations but not submitted to an agency or 3rd party).

GRS050 for TP (CRO) (Contracts / Agreements - Documentation detailing the legally binding terms and conditions of agreements between the Company and other people / organisations).

***Justification***

None

## 10 Consultations

10.1 **Who has been consulted as part of the activity?**
*It may be beneficial to seek opinion of others to fully consider risks and benefits. For example HR and/or Trade Union Representatives may be consulted for high risk change impacting GSK employees You can add links or upload output.*

***Response***

Country Privacy Advisor for Italy

## 11 Supporting Information

11.1 **(Optional) Please provide links to any documentation that may support the assessment**
*This is optional.*

*Examples of supporting documentation include data flow diagrams, system architecture diagrams, stakeholder consultation output, risk discussions/acceptance etc.*

***Response***

Not answered

## 12 For Privacy Contact / Privacy Lead

12.1 **Is it necessary to consult with the Data Protection Authority?**
*If a high risk has been identified and the risk cannot be mitigated, it may be necessary to consult with the Data Protection Authority*

***Response***

No

***Justification***

We need just to inform the Garante of Privacy

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**Comments**

**Filippo Montanari** *04/20/2026 02:35 PM*
risposta sbagliata. il garante va solo informato

**Omar Shalby** *04/20/2026 06:39 PM*
corretto

12.2 **(Optional) Additional Comments**

***Response***

Not answered

## 13 Risks

13.15 **Are there any other risks that you have identified?**
*If so, please detail them in the box below.*

***Response***
Not applicable

**Comments**

**Filippo Montanari** *04/20/2026 02:36 PM*
flaggare not applicable

**Omar Shalby** *04/20/2026 06:41 PM*
corretto

## Assessment notes

# Informativa sul trattamento dei dati personali

# Studio 309592

**Premessa**

I Suoi dati, in particolare quelli personali e quelli sulla salute e soltanto nella misura in cui sono indispensabili in relazione allo scopo dello studio, verranno trattati nel rispetto del Regolamento Generale sulla Protezione dei Dati Personali EU 679/2016 (GDPR) e il Decreto legislativo n. 196/2003 così come modificato dal D.lgs. 101/2018 e ss.mm. I documenti relativi ai partecipanti saranno custoditi in luogo sicuro e non riporteranno i nominativi in chiaro, noto solo ai ricercatori, ma solo un codice identificativo.

Il Regolamento Generale sulla Protezione dei Dati Personali (GDPR) dell'Unione Europea stabilisce che GSK e i Centri, in qualità di titolari autonomi del trattamento dei dati, devono indicare le basi legali del trattamento delle informazioni personali (Articolo 6.1). Le basi giuridiche seguite da GSK sono di seguito riportate:

| Tipo di informazioni personali | Base giuridica del GDPR |
|---|---|
| Informazioni sullo Studio (dati identificativi, dati sanitari)<br><br>Origine etnica | Coerente con il legittimo interesse del titolare del trattamento ai sensi dell'Articolo 6.1 (f), e ai sensi dell'articolo 9.2 (g) e (j), perché il trattamento di categorie speciali di dati è necessario per la ricerca scientifica per motivi di interesse pubblico rilevante e sulla base del diritto dell'Unione o degli Stati membri, nonché ex art. 110 e 110bis del d.lgs. 196/2003. |

Le Sue informazioni personali non saranno utilizzate per valutazioni eseguite mediante processi automatizzati senza coinvolgimento umano.

**Perché verranno raccolti i dati codificati?**

GSK utilizzerà i Suoi dati personali codificati per:

- Condurre e raggiungere lo scopo dello studio.
- Comprendere i risultati di questo studio.
- Progettare nuovi studi relativi al farmaco/vaccino in studio, alla malattia in studio e condizioni correlate.
- Pubblicare i risultati dello studio. Il Suo nome non apparirà in nessuna pubblicazione.

**Come vengono protetti i Suoi dati personali? Cosa succede quando i dati vengono trasferiti?**

Per proteggere i Suoi dati personali verranno adottate misure adeguate in accordo alle leggi applicabili in materia di protezione dei dati e di tutela della privacy.

I Suoi dati codificati (pseudonimizzati) potranno essere trasferiti in altri paesi a soggetti terzi che soddisfino requisiti di garanzia e che saranno contrattualmente vincolati alla protezione dei Suoi dati personali. In alcuni paesi le leggi sulla protezione dei dati potrebbero essere meno severe che in Italia. Qualora i dati personali siano trasferiti a un paese terzo o a un'organizzazione internazionale, saranno adottate tutte le garanzie previste dall'articolo 46 del GDPR 679/2016 relative al trasferimento.

Maggiori dettagli sulle misure di tutela sono consultabili agli indirizzi:

- https://commission.europa.eu/law/law-topic/data-protection/international-dimension-data-protection/standard-contractual-clauses-scc_en (Clausole contrattuali standard della Commissione europea per il trasferimento internazionale);
- https://ec.europa.eu/info/index_en
- https://www.gsk.com/en-gb/about-us/policies-codes-and-standards/binding-corporate-rules/ (GSK's Binding Corporate Rules)

**Quali sono i Suoi diritti relativi ai Suoi dati?**

Lei gode di alcuni diritti di cui riteniamo necessario informarLa. In alcune circostanze, alcuni Suoi diritti potrebbero essere limitati, ad esempio da requisiti legali per conservare una copia dei documenti di studio o per proteggere l'integrità scientifica di uno studio.

Lei ha il diritto:

- di conoscere con maggior dettaglio come vengono trattati i Suoi dati;
- una copia dei Suoi dati;
- di correggere le informazioni che Lei ritiene inesatte o incomplete;
- di richiedere la cancellazione dei Suoi dati;
- di chiedere l'invio dei Suoi dati ad un altro soggetto (ad esempio il Suo medico curante) per poterli riutilizzare.

Inoltre Lei potrà:

- opporsi al trattamento dei Suoi dati;
- sporgere reclamo all'autorità competente in caso di violazione dei Suoi diritti in materia di tutela di dati personali. In Italia l'autorità competente è il *Garante per la Protezione dei Dati Personali* (dati di contatto sul sito http://www.garanteprivacy.it);
- richiedere il risarcimento dei danni materiali o morali patiti in ragione di un trattamento illecito dei Suoi dati.

Per effettuare tali richieste, si consiglia di contattare prima la Sua regione di residenza. GSK non può rispondere a richieste pervenute direttamente da Lei, in quanto GSK non è in possesso dei dati identificativi dei pazienti e non è in grado di tracciare o isolare i singoli pazienti.

**Per quanto tempo saranno utilizzati i Suoi dati?**

I dati codificati saranno utilizzati esclusivamente per il periodo necessario allo svolgimento dello Studio, successivamente saranno cancellati trascorsi 10 anni dallo conclusione dello Studio.

**Chi raccoglierà e utilizzerà i Suoi dati?**

Il Titolare del Trattamento dei Dati raccoglie ed elabora i dati e stabilisce a quale scopo e come essi debbano essere elaborati. GSK e il Centro sono i Titolari autonomi del Trattamento dei Dati per questo Studio. Il Responsabile della Protezione dei Dati Personali (*Data Protection Officer*) di GSK può essere contattato all'indirizzo EU.DPO@gsk.com.

Per mantenere l'anonimato, La invitiamo in prima istanza a contattare il suo centro di riferimento. GSK non è in grado di rispondere a richieste ricevute direttamente in quanto non è in possesso dei dati identificativi dei partecipanti.

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