onetrust

Assessment details

ID 121559

Name Italy_Study 300718 retrospective use of data_PIA

Organization Research & Development

Description
This document is a redacted version of the DPIA 121559 carried out on the OneTrust platform

Completed date 01/21/2026

Date submitted 01/20/2026

Last updated 01/21/2026

Result Approved

Primary record name Italy_Study 300718 retrospective use of data

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 300718 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 300718 retrospective use of data | Research & Development

The business activity is to conduct a multi-country, retrospective vaccine effectiveness and impact study of 4CMenB in infants, children and adolescents including the use of regional surveillance data in Italy (secondary use).

Purpose: To evaluate real-world vaccine effectiveness (VE) and real-world impact of the 4CMenB vaccine against invasive meningococcal disease (IMD) caused by Neisseria meningitidis serogroup B in vaccine-eligible infants, children and adolescents.
To generate evidence to inform public health policy and demonstrate vaccine value for GSK.

Study overview and scope: This is a retrospective, observational, secondary-use epidemiologic analysis using existing regional surveillance and registry data (no interventional procedures). The geographic scope is multi-country (Czechia, Italy, Portugal); the following describes the Italian data sources and processes. Data sources include regional vaccination registries and regional reference laboratory databases for notifiable diseases (laboratory-confirmed IMD with serotyping). Data subjects comprise individuals in the study regions who are eligible or not eligible for 4CMenB during the study period, including laboratory-confirmed IMD cases and comparator non-cases. Only routinely collected data are used; no patient recontact or study visits will be imposed.

Data access and parties involved: Regional public health authorities and regional reference laboratories hold the primary surveillance datasets. Principal investigators (PIs) at regional healthcare/research institutions act as data custodians and provide pseudonymized datasets or enable secure remote analysis. Where local secure remote analysis is not feasible, pseudonymized datasets will be transferred to a secure accredited analysis environment managed by the contracted data processor (PPD/Thermo Fisher). GSK scientists will receive aggregated, non-identifiable analysis outputs only; no direct identifiers will be transferred to GSK.

Data extraction and linkage: PIs (or authorized site staff) extract relevant fields from vaccination registries, laboratory reports and hospitalization records and perform local linkage using a pseudonym or local linkage key. Direct identifiers are not included in transferred analytic datasets. Where linking requires identifiers, linkage will be performed at source or by the PI; a pseudonym will be used for the analytic dataset. Day of birth will be masked (month and year retained) to enable eligibility determination while reducing re-identification risk.

Personal data processed and purpose:
Vaccination records (vaccine type, date(s)): determine exposure and coverage.
Laboratory results and serotype: identify IMD cases (serogroup B) and non-cases.
Dates of diagnosis/hospitalization: establish timing and person-time at risk.
Age (month/year of birth; day masked): determine eligibility and stratify age cohorts.
Immunocompromised status / key clinical covariates (if available): subgroup analyses and confounding adjustment.
Minimal geographical information and sex
Administrative linkage key/pseudonym: link datasets without transferring identifiers. Direct identifiers (full name, exact date of birth, national ID, address, phone) will not be transferred to GSK or the processor.

Analysis, outputs and dissemination Individual-level pseudonymized data will be analyzed in secure environments. Outputs will be aggregated and disclosure-checked (suppression/aggregation for small counts) before release and any publication.

Benefits to GSK and to individuals/public health
Generates robust, real-world evidence of vaccine effectiveness and impact to support public health engagement, value communication, and product strategy.
Provides data to support market access, reimbursement discussions and policy engagement.
Inform policymakers and clinicians about vaccine benefits, potentially increasing appropriate vaccine uptake.
Support reduction in IMD incidence, morbidity and mortality through evidence-based vaccination policy.

Legal and regulatory considerations
Secondary use of routinely collected surveillance and laboratory data will be conducted in accordance with applicable data protection laws and regional privacy rules.
Local legal/regulatory requirements and approvals (e.g., data access agreements, ethics approvals, supervisory authority notifications) will be obtained as required by region

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 300718 retrospective use of data | Research & Development

Response
02/02/2026

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 300718 retrospective use of data | Research & Development

Response
11/30/2027

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 300718 retrospective use of data | Research & Development

Response
Local

Justification
None

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

Response

Italy_Study 300718 retrospective use of data | Research & Development

Response
Italy

Justification
None

1.7 **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
BELGIUM GlaxoSmithKline Biologicals SA | Privacy | Belgium

Justification
None

1.8 **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

1.9 **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 300718 retrospective use of data | Research & Development

Response

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

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

Patients

Restricted Elements

Home contact details | Age or date of birth | Key Coded Data

Basic Elements

Gender or Title | First / Last name

Sensitive Elements

Medical or Health Information

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 300718 retrospective use of data | Research & Development

Response
10M - 100M

Justification
None

Comments

Pavo Marijic *12/18/2025*

We will be utilizing health data from 5 regions in Italy (approximately 17–18M: Tuscany 3.7M, Sicily 4.8M, Veneto 4.9M, Puglia 3.9M, Liguria 1.5M), with 13% under age 15 (~2.3M). Individual-level information will be requested from the vaccine registries. We will use date jittering for each of the vaccine dates and immunocompromised condition dates to reduce the risk of re-identification and will restrict the data requested to a minimum to undertake the analysis (month/year of birth, vaccine dates, gender, immunocompromised condition, date of immunocompromised condition).

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 300718 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 300718 retrospective use of data | Research & Development

Response
It is necessary for compliance with a legal obligation

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

It is necessary for the performance of a task carried out in the public interest

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 300718 retrospective use of data | Research & Development

Response
Public health (with a basis in law)

The lawful basis for processing resides in the EU Regulation 2016/679 art 9, comma j, art. 89.1, as well as in the provisions of the Italian Privacy Code 101/2018 art. 110 and 110 bis and in the Garante's provision 10016146, dated 09May24.

Archiving, research and statistics (with a basis in law)

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 categories and volume of personal information selected are strictly necessary to achieve the scientific objectives of the study. Each data element directly supports the analysis of vaccine effectiveness and duration of protection across subpopulations. The inclusion of a large population pool ensures statistical robustness and representativeness, which is critical for informing public health policy. Sensitive attributes are limited to those essential for the research questions. Data will be pseudonymized and processed with appropriate safeguards to minimize risk.

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

In this study, variables are limited to those essential for the research questions; sensitive attributes are included only when analytically required and justified.

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

It is not possible to achieve the study objectives with less granular or aggregated data because individual-level linkage of vaccination history to IMD outcomes is essential for accurately estimating vaccine effectiveness and duration of protection. These analyses require the specific data elements and volume proposed; any reduction would compromise validity and scientific integrity.

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, all personal information collected is necessary for the intended purpose. Each data element is directly required to link vaccination history with disease outcomes and perform subgroup analyses. No additional or non-essential data is included, and sensitive attributes are limited to those analytically justified.

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

The data will only be used for the specified purposes.

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 300718 retrospective use of data | Research & Development

Response

Contracted third parties

Justification

The Regions, as independent data controllers, collect the surveillance data during vaccination programs and from hospitals on meningococcal disease cases. As part of the Study, the Regions will ensure that all patient identifiable information is removed and that the data is pseudonymized before transferring the data to the CSO (Evidera PPD).

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

Evidera | 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

The data used for this activity is pseudonymized and cannot be attributed to an identifiable individual without additional information held separately by the relevant regional health authorities. Consequently, we cannot determine whether a specific individual is included in the dataset. Should we receive a request from an individual seeking a copy of their personal information, we will forward that request to the appropriate data holders (i.e., the respective regional health authority).

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

Yes. The data originates from official regional vaccination registries and national disease surveillance systems, which maintain accuracy through established processes. Additionally, within the study, standard data quality checks are applied to identify inconsistencies or anomalies and ensure the dataset remains accurate for analysis.

5.3 **Can the activity continue if 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 their information was part of without impact?

For example, an individual wishes to withdraw from a clinical trial midway through and asks us to restrict the use of their information, but not delete it. Could the clinical trial continue without using the information?

Response

Yes

Justification

The study uses secondary data collected for public health surveillance and provided to the third party in pseudonymized form. We do 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 (regional health authorities). As a result, GSK and the third party cannot selectively stop using a specific individual's data within the dataset; any restriction on use would need to be applied by the data holder and, if necessary, reflected in the data provided to us.

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

If a request is received, this would be forwarded to the Data Holders (ie. Regional Health Authority) as the GSK or PPD study team does not have access to identifiers.

6 Access/Transfers

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

Response

Italy_Study 300718 retrospective use of data | Research & Development

Response

Third Parties

Justification

The Italian Principal Investigators will ensure that all patient identifiable information is removed and that the data is pseudonymised before transferring the data to Evidera|PPD.

Evidera will store the data on a cloud-based data storage and computing infrastructure restricted to programmers in the Nordic countries in Europe: Microsoft Azure Sweden Central, located in Gävle, Sweden. This data center is a physical infrastructure hosting facility managed by Microsoft and is covered by ISO 27001, FedRAMP, SOC 1 and SOC 2 certifications. It also complies with applicable data privacy laws and data localization requirements.

6.3 **Please select any third party(ies) with whom the personal information is shared with?**

Is the personal information disclosed, shared, sent to or accessed by any additional 3rd party vendors or service providers for this activity?

Select the third party from the drop-down menu. If you don't find the third party in the drop-down menu, please let your privacy contact or lead know, who may liaise with TPRM.

Response

Evidera | TPRM | Unknown

Justification

None

6.4 **Is a contract or agreement in place with the third party?**

If we are sharing personal information, a contract or data processing agreement will set standards and help everyone involved understand their roles and responsibilities to protect information.

Response

Italy_Study 300718 retrospective use of data | Research & Development

Response

Yes - includes data protection schedule/clauses

Justification

None

6.5 **Where else may the personal information be sent to?**

Response

Italy_Study 300718 retrospective use of data | Research & Development

Response

Not applicable

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 300718 retrospective use of data | Research & Development

Response

Yes

Justification

Evidera will store the data on a cloud-based data storage and computing infrastructure restricted to programmers in the Nordic countries in Europe: Microsoft Azure Sweden Central, located in Gävle, Sweden. This data center is a physical infrastructure hosting facility managed by Microsoft and is covered by ISO 27001, FedRAMP, SOC 1 and SOC 2 certifications

6.8 **Is personal information transferred out of EEA, Switzerland or the UK?**

The EU and UK GDPRs contain specific requirements regarding the transfer of personal data collected in the EU or UK.

To determine whether specific requirements are needed, please confirm whether any personal data collected in the EU or UK is being transferred to a country outside the EU or UK.

Here is the EU official list of European Economic Area (EEA) countries (europa.eu)

Response

Italy_Study 300718 retrospective use of data | Research & Development

Response

No

Justification

None

6.9 **Which country/ies is the personal information transferred to?**
Please select any and all countries that the personal information may be transferred to.

This could include:

where the personal information is sent to to be stored
where other GSK departments are accessing the personal information from another country, for example in an off-shore operations centre
where personal information is shared with a service provider who accesses or stores this in another country

Response

Italy_Study 300718 retrospective use of data | Research & Development

Response

Sweden

Justification

Evidera will store the data on a cloud-based data storage and computing infrastructure restricted to programmers in the Nordic countries in Europe: Microsoft Azure Sweden Central, located in Gävle, Sweden. This data center is a physical infrastructure hosting facility managed by Microsoft and is covered by ISO 27001, FedRAMP, SOC 1 and SOC 2 certifications

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 300718 retrospective use of data | Research & Development

Response

Evidera latest TPRM renewal assessment on 3 Sep 2025 (pre-screening ID 5472), expiring on 11 Sep 2028 - approved, medium risk.

Justification

risk score 2, medium, previous assessment no: 83278 and 13815971

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 300718 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 300718 retrospective use of data | Research & Development

Response

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

Justification

The Privacy Notice will be published on the website.

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 300718 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 300718 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
Personal Information is not received by GSK, only pseudonymized data report. Third party vendor archives pseudonymized data for 10 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 would be able to prevent deletion of data from taken place if needed.

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
Third party vendor archives pseudonymized data for 10 years from the conclusion of the study. GSK is notified when data is deleted.

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 an identifiable individual without additional information held separately by the relevant regional health authorities. Consequently, we cannot determine whether a specific individual is included in the dataset. Should we receive a deletion request from an individual, we will forward it to the appropriate data holders (i.e., the respective regional health authority) 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 300718 retrospective use of data | Research & Development

Response
GRS040

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

Asset Lawyer for ICF waiver

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

ICF waiver already provided

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

Yes

Justification

This is a requirement for Italy

12.2 **(Optional) Additional Comments**

Response

no additional comments

13 Risks

13.15 **Are there any other risks that you have identified?**

If so, please detail them in the box below.

Response

No other risks have been identified.

Assessment notes

GlaxoSmithKline S.p.A. unipersonale
Sede legale
Direzione e Uffici
Viale dell'Agricoltura, 7
37135 Verona - Italia

Tel. + 39 (0) 45 7741111
Fax + 39 (0) 45 4859009
PEC gsk@gsk.legalmail.it

www.gsk.it

Informativa sul trattamento dei dati personali

Studio 300718

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 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 dalla 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 la Sua regione di residenza. GSK non è in grado di rispondere a richieste ricevute direttamente in quanto non è in possesso dei dati identificativi dei partecipanti.

Ultimo aggiornamento 22/01/2026