onetrust

Assessment Details

ID 112749

Name Italy_Study 222965 retrospective use of data_PIA

Organization Research & Development

Description –
This document is a redacted version of the DPIA ID112749 carried out on the OneTrust platform

Completed Date 07/07/2025 05:10 PM

Date Submitted 07/03/2025 05:32 PM

Last Updated 07/07/2025 05:10 PM

Stage Completed

Result Approved

Result Comments

This DPIA serves to demonstrate compliance to the Italian legal requirements and Garante's provision for the re-use of patients' personal information.
For Italy, lawful basis for processing is the consent for the patients that are reachable.
If patients are not reachable or deceased, we shall complete the tasks mandated by the Italian Privacy Code 101/2018 art. 110 and 110 bis and the Garante's provision 10016146, dated 09May24.

Primary Record Name Italy_Study 222965 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 222965 retrospective use of data | Research & Development

1.2 Please describe the business activity processing personal information, including the purpose.

Response

This assessment regards the processing of data, and particularly the processing of data for non reachable patients for a multi-site retrospective, non- interventional study.
The study is a multi-site retrospective, non-interventional chart review study that uses longitudinal, RWD from routine medical records, leveraging real-world data (RWD) from routine medical records to analyze patients with untreated stage II/III dMMR/MSI-H locally advanced rectal cancer (LARC). "Retrospective" means using data that was already collected in the past.
The objectives of this study are to understand the characteristics of patients with previously untreated stage II/III dMMR/MSI-H Locally Advanced Rectal Cancer, to characterize the current standard of care (SOC) treatment landscape and its associated outcomes, and to help benchmark the results of the single-arm AZUR-1 trial of dostarlimab (JEMPERLI™)
In addition, this study aims to understand the disease characteristics of locally advanced rectal cancer (LARC) patients, healthcare resource utilization, and to evaluate the prevalence of patients with dMMR/MSI-H LARC in Italy.
The study does not impose a treatment protocol, any diagnostic/interventional procedure, or a visit schedule. Individual-level data on patients with previously untreated stage II/III dMMR/MSI-H rectal cancer will be analyzed.

Eligible patients from EU countries including France, Germany, Italy, Spain, as well as the UK will be included in the study. Approximately 2000 Italian patients will be enrolled, with data collected from 15 sites within the STAR network.
Written informed consent (if required based on local regulatory and legal country requirements) will be obtained from all patients before enrolment into the study. Written informed consent may be obtained from family members of deceased patients, if allowed according to the regulatory and legal country-specific requirements of the participating site.

The name of the GSK legal entity who is sponsor for the study is GlaxoSmithKline Research and Development Ltd. The GSK legal entity is based in the UK. The process flows from chart review to data entry in the Electronic Data Capture (EDC) system involves the following steps and parties:
Chart Review and Data Extraction:
Site Investigators or designated site personnel review patient medical records to extract relevant data, including baseline characteristics, study outcomes, and other pertinent information. The medical record serves as the source document for this information.
Data Entry into Electronic Data Capture (EDC): - Medidata Rave is the database used
De-identified data (pseudo-anonymous to non-site staff) is transferred from the patient's medical record into the electronic Case Report Form (eCRF) within the EDC system. The EDC system is designed to minimize errors with built-in logic checks to prevent missing or illogical data.
Verification and Quality Assurance:
Site Investigators are responsible for ensuring the accuracy and timeliness of data entry.
Study monitors from the vendor PPD perform remote visits to confirm that data entered into the eCRF is accurate, complete, and verifiable from source documents.
Data Management and Storage:
All data extracted is 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 global: Q1 2025

Start of data collection for Italy: 30 September 2025 End of data collection: Q4 2025

Final report of study results: Q3 2026

The level of access to personal information (PI) for different study roles is as follows:
Study Staff:
Full access to personally identifiable information (PI) such as name, address, phone number, and health insurance number. Responsible for collecting and storing PI securely at the study site.

CRO (PPD):
Access to coded data only.
Does not have access to direct identifiers like name or contact details. GSK Team:
Access to coded data only.
Coded data is anonymized once the code list is destroyed, ensuring no linkage to the participant. IRBs/IECs and Regulatory Authorities:
May review study records, including PI, to ensure compliance with legal and quality requirements. Appropriate measures are taken to protect PI, and direct identifiers are never sent to GSK or CROs.
This questionnaire and the subsequent PIA are necessary to assess the feasibility to collect data for the Italian patients that are either deceased or not reachable and so their consent cannot be obtained, in compliance in particular to the Italian Privacy Code 101/2018 articles 110 and 110 bis

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

Italy_Study 222965 retrospective use of data | Research & Development

Response
03/21/2025
Justification
None

Comments
Start date for global study is 21 March 2025. Expected start date for Italy is 30 September 2025

1.4 When is the expected end date of the activity?

Response

Italy_Study 222965 retrospective use of data | Research & Development

Response
02/16/2026

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 222965 retrospective use of data | Research & Development

Response
Global

1.6 Which regions carry out this activity?
Please select all regions that are involved in carrying out

this activity. ***Response***

Italy_Study 222965 retrospective use of data | Research & Development

Response
Europe

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 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*
  Canada
- *Central*
- *America/Caribbean/Mexico*
  Europe
- *Middle East*
- *South*
- *America*
  United States

Response
UK GSK | Privacy | United Kingdom

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 processor in some jurisdictions.

If multiple entities are involved, please either select the specific entities or regions involved. Please provide a response if applicable, otherwise please select the Not Applicable entry.

The regions available for selection are:

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

Response

UNITED STATES GSK | Privacy | United States

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?**

Response

Italy_Study 222965 retrospective use of data | Research & Development

Response

PIA is required by the Data Privacy Authority | 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.**

Response

Patients

Basic Elements

First / Last name

Gender or Title

Restricted Elements

Key Coded Data

Age or date of birth

Personal contact details

Sensitive Elements

Ethnicity or Race

Medical or Health Information

2.2 How many individuals' personal information will be used to carry out this business activity?

Response

Italy_Study 222965 retrospective use of data | Research & Development

Response

1000-10,000

Justification

None

2.3 Where will the individuals be located whose personal information will be used for this business activity?

Response

Italy_Study 222965 retrospective use of data | Research & Development

Response

Europe

Justification

None

2.4 Please select the appropriate basis for processing the personal information.

Response

Italy_Study 222965 retrospective use of data | Research & Development

Response

Consent of the individual

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

Justification

lawful basis for processing is the consent for the patients that are reachable.
For those subjects that are not reachable or deceased, the lawful basis for processing resides in the provisions of the Italian Privacy Code 101/2018 art. 110 and 110 bis and the Garante's provision 10016146, dated 09May24

2.5 Please select the appropriate condition for processing the sensitive personal information.

Response

Italy_Study 222965 retrospective use of data | Research & Development

Response

Explicit consent

Art. 110 and 110bis Italian Privacy Code; Garante's provision 10016146 of 09May24; GDPR: art 9.j and 89.1

Justification

None

Comments

The lawful basis for processing of reachable patients is the explicit consent of the individual. For the patients who are not reachable or deceased, 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 09 May 24

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 to achieve the study's objectives effectively as described in the study protocol.

The study will be collecting relevant data from medical records for patients with rectal cancer as detailed in the study protocol.
Volume of data: A sufficiently large volume of data is necessary to ensure statistical validity and reliability of the study results to ensure a understanding of the prevalence of the disease in Italy.

3.2 Could your objectives be achieved with less information from fewer individuals?
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 minimisation principles.
The objectives of this study could not be effectively achieved with less information or fewer research subjects. The nature of these studies requires comprehensive data to ensure that the findings are statistically significant and applicable to a broad population.
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?

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 real world data are crucial and cannot be achieved without processing personal data. The observational nature of NI studies 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?
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.

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

4.1 How do individuals provide consent for their information to be collected?

Opt-in consent *requires user action to confirm they do want their data included and processed in this way, with data not processed unless confirmation provided. Examples of opt-in are:*

- *Signature box*
- *Tick box asks user to select to confirm they want their personal data used*
- *for this activity Verbal agreement (documented by GSK)*

Opt-out consent *tells individuals that their consent is deemed to have been given, unless there is user action to notify GSK that they do not want their data included in the activity, with data not processed only if notification provided. Examples of opt-out are:*

- *Tick box asks for user to select if they do not want their personal information used for this activity.*

Continuing without objection *is where an individual is deemed to have given consent unless they tell us*

- *otherwise. Examples include: Continuing to use a website after seeing a cookie pop up. (this would not be acceptable under the GDPR)*
- *"By using this site / continuing with this form you consent to..."*

Response

Italy_Study 222965 retrospective use of data | Research & Development

Response

Opt-in

Justification

For patients who are not reachable or deceased, the lawful basis for processing their data 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 09 May 2024.

4.2 Can individuals change their consent preferences, for example withdraw their consent, at any time?

Most privacy laws require that if an individual provides consent, they should be able to withdraw their consent in a way that is as easy as those for giving consent.

If individuals cannot change their consent preferences, please provide a rationale for why this is acceptable or an alternate approach to managing consent in the justification box below.

Response

Italy_Study 222965 retrospective use of data | Research & Development

Response

Yes

Justification

Reachable patients may withdraw consent; for those patients that are no longer reachable, we are assessing it with a DPIA as per the Italian DPA provision. For patients who are not reachable or deceased, the lawful basis for processing their data 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 09 May 2024.

4.3 How can the individual change their consent preferences?

Response

Italy_Study 222965 retrospective use of data | Research & Development

Response

Preference centre

Justification

None

Comments

Patients are instructed to contact primarily their site staff/ physician

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. Moreover, for study records, patients are invited (as specified in the ICF and privacy consent form) to contact their study staff. Data can potentially be provided in digital format. For

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

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, etc. Study specific checks, which are specifically programmed to verify whether the inputted data is correct.

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

Response

Yes

Justification

Reachable patients may withdraw consent contacting the study physician.
For deceased patients or patients that cannot be reached, we are assessing it this DPIA as per the Italian DPA's provision.

6 Access/Transfers

6.1 Please select any systems/applications which the personal information is shared with / sent to?

.

Response

Medidata Rave Edc | Privacy | Unknown

Justification

None

Comments

MEDIDATA RAVE EDC

6.2 Where else may the personal information be sent to?

Response

Italy_Study 222965 retrospective use of data | Research & Development

Response

Authorities (government agencies, tax authorities, law enforcement, regulators)

Other companies in GSK

Other organisations that provide services for us (e.g., vendors, suppliers, contracting agencies, advisers etc)

Justification

1. Authorities (government agencies, tax authorities, law enforcement, regulators): Personal information may be sent to authorities such as government agencies, law enforcement, and regulators to comply with legal obligations and regulatory requirements. This includes reporting for public health purposes, responding to law enforcement requests, and adhering to regulatory standards for NI Studies (NI Studies can be part of regulatory package) and pharmaceutical operations. Sharing data with authorities is often mandated by law and is necessary to ensure compliance with statutory obligations and to support public interest activities.
2. Other Companies in GSK:
   Personal information may be shared with other companies within the GSK corporate group to facilitate global operations, ensure consistency in research practices, and support collaborative projects. This internal sharing is governed by Intra Group Agreements that ensure compliance with data protection standards across all GSK entities. Sharing within the corporate group allows GSK to leverage resources and expertise from different entities while maintaining a high level of data protection.
3. Other organizations that provide services for GSK (e.g., vendors, suppliers, contracting agencies, advisers, etc.): These organizations are typically engaged under contractual agreements that include data protection clauses to ensure compliance with data protection laws. Sharing data with service providers is necessary to support various operational activities, including clinical trials, research, and business functions. It allows GSK to access specialized expertise and resources while ensuring that personal data is handled securely and responsibly.

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?

Response

9910049873 - PPD DEVELOPMENT LP | TPRM | Unknown

Justification

None

6.4 Please select any GSK legal entity(ies) with whom the personal information is shared?

Response

UNITED STATES GSK | Privacy | United States

Justification

None

6.5 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 222965 retrospective use of data | Research & Development

Response

- Intra Group Agreement (between GSK businesses)

Yes - includes data protection Yes schedule/clauses

Justification

An Intra Group Agreement (IGA) is in place to facilitate the sharing of personal data between different GSK entities. This agreement ensures that all GSK businesses adhere to consistent data protection standards and practices, regardless of geographical location. The IGA typically includes provisions that align with the General Data Protection Regulation (GDPR) and other relevant data protection laws, ensuring that personal data is processed lawfully, fairly, and transparently within the corporate group. This agreement helps maintain a high level of data protection and compliance across all GSK entities.
Contracts with third parties include specific data protection schedules or clauses to ensure compliance with data protection laws, including the GDPR. These clauses outline the responsibilities and obligations of both parties regarding the processing of personal data, including data security measures, data subject rights, and breach notification procedures. By including these clauses, GSK ensures that third parties handle personal data in a manner that is consistent with GSK's data protection policies and legal requirements. This contractual approach helps mitigate risks associated with data sharing and ensures that third parties are accountable for protecting personal data.

6.6 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.

Response

Italy_Study 222965 retrospective use of data | Research & Development

Response

Yes

Justification

None

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

Response

Italy_Study 222965 retrospective use of data | Research & Development

Response

Yes

Justification

GSK US R&D team

6.8 Which country/ies is the personal information transferred to?

Please select any and all countries that the personal information may be transferred to.

Response

Italy_Study 222965 retrospective use of data | Research & Development

Response

United States

Justification

GSK R&D US team will access K-coded data.
Findings will be disseminated through scientific publications and presentations in an aggregated, anonymous manner.

6.9 What suitable safeguards are applied to the international transfer?

For personal information collected in the EEA, Switzerland or the UK a safeguard might not be required if the transferred is going to a country within the adequacy list. The list of countries that the European Commission has so far recognised as adequate can be found here.

Response

Italy_Study 222965 retrospective use of data | Research & Development

Response

Standard Data Protection Clauses adopted by the EU commission

Binding Corporate Rules

Justification

None

6.10 Does the third party subcontract the processing of GSK personal information to an organisation based outside UK, Switzerland, or EEA?

Please indicate whether any third parties involved in this activity use any sub-processors to process our information on their behalf.

This includes anyone acting on behalf of the third party including sub-contractors or affiliates or third parties, or other organisations to which the third party may transfer the personal information.

Response

No

Justification

No subcontractors involved by PPD

6.11 Supplementary Measures

Response

Italy_Study 222965 retrospective use of data | Research & Development

Response

Data security and privacy policies in place

Pseudonymization

Encryption in transit (key accessible to data importer)

Training in relation to data protection, security, and confidentiality of data.

Data importer personnel are subject to binding duties of confidentiality.

Justification

GSK carries out a Third Party Risk Management assessment of any Third Party they work with. During this risk assessment, any risks identified are mitigated often through specific contractual agreements with the Third Party.
GSK has standard contractual clauses that deal with risks surrounding data, particularly to data security and privacy. These clauses set requirements that the Third Party will manage data privacy to comply with any local or international privacy regulations through adoption of industry best practices.
GSK's expectations of data encryption are formalized in individual contractual agreements with Third Parties. In general, GSK would expect our Third Parties to encrypt data at rest and in transit. Cyber Security standardized requirements are in GSK's standard cyber security contractual clauses.
The Third Party would also be required to carry out due diligence on any subcontractors that would process GSK Study data, to ensure they also meet data privacy and security standards applicable to appropriate regulations. GSK requires any subcontractors used by the Third Party to be disclosed to GSK.
GSK also expects that the Third Parties can evidence that appropriate training has been taken by their teams involved in data handling in their training record and that employees are aware of their responsibilities and compliance with any confidentiality implicit in the contractual arrangement with GSK.
Any data processed by Third Parties on behalf of GSK will be either in a pseudonymized data format or in a de-identified format. This applies to data provided by GSK under licensing agreement with the data owners, data from clinical trials owned by GSK or data processed by the Third Party as a result of primary data collection in line with the aims of a GSK study.

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 222965 retrospective use of data | Research & Development

Response

Satisfactory

Justification

Satisfactory outcome for PPD Development LP. Clinical study sites are out of scope for TPRM/TPSA.

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 222965 retrospective use of data | Research & Development

Response

Yes

Justification

Medidata Rave EDC

onetrust

8 Transparency

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

Response

Italy_Study 222965 retrospective use of data | Research & Development

Response

We rely on a third party to provide the individuals with a privacy notice

Justification

The Informed Consent Form and the Privacy Notice for the concerned PI processing will be provided to the patients by the study staff. For deceased or not reachable patients the privacy notice will be published in a dedicated GSK website

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

Response

Italy_Study 222965 retrospective use of data | Research & Development

Response

Yes

Justification

It has been reviewed as per SOP VQD-SOP-044229

9 Retention

9.1 How long is the information held for?

Response

Italy_Study 222965 retrospective use of data | Research & Development

Response

10 years

Justification

10 years for non-Good Clinical Practice (GCP) or non-regulatory data filed in GSK TMF systems : For Non-interventional studies, it has been have determined a nominal retention period of 10 years.

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.

Response

The retention period starts from the end of the study (finalisation of the final study report).

9.3 How is the personal information removed when it is no longer needed?

Please select the option that

applies. ***Response***

Medidata Rave Edc | Privacy | Unknown

Response

Anonymisation

Justification

Coded data is anonymized once the code list is destroyed, ensuring no linkage to the participant.
Data retained by GSK is deleted in line with GSK standard practices, once the data retention period has completed. In some systems this is automated.

Primary data collected as the result of NI studies will be stored by GSK in secure file management systems and then deleted at the end of the retention period.

Technical deletion is documented in GSK's Asset Management Standard, which details controls to ensure secure media sanitization and disposal processes to protect sensitive information. Media must undergo documented sanitization procedures aligned with regulatory standards, with methods tailored to the security classification of the data. Disposal must be conducted by authorized personnel, tracked in a centralized register, and reviewed periodically. Sensitive media must be irreversibly destroyed prior to disposal, ensuring complete data erasure. Vendors handling SaaS data or providing disposal services must comply with security requirements and provide proof of secure disposal. These measures mitigate risks and ensure compliance with privacy and security standards.

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

Response

Yes

Justification

Hard copy not retained.
Digital: Deletion depends on the system used.
Technical deletion is documented in GSK's Asset Management Standard, which details controls to ensure secure media sanitization and disposal processes to protect sensitive information. Media must undergo documented sanitization procedures aligned with regulatory standards, with methods tailored to the security classification of the data. Disposal must be conducted by authorized personnel, tracked in a centralized register, and reviewed periodically. Sensitive media must be irreversibly destroyed prior to disposal, ensuring complete data erasure. Vendors handling SaaS data or providing disposal services must comply with security requirements and provide proof of secure disposal. These measures mitigate risks and ensure compliance with privacy and security standards.

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

The used systems have the required features to manage records both in line with the Global Retention schedule and as required for litigation holds.

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

Response

The used systems have the required features to manage records both in line with the Global Retention schedule and as required for litigation holds.

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

No

Justification

To ensure quality and data integrity of the study and of scientific in general, we cannot delete the data. In case of an individual withdrawing from the study we will stop the processing of data. Data shall anyway be retained according to NIS retention

10 Consultations

10.1 **Who has been consulted as part of the activity?**

Response

N/A

11 Supporting Information

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

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

Response

Global assessment on general Non-interventional studies have been linked to this assessment that is specific for Italy on the use-reuse of PI for deceased/non reachable patients as mandated by the Italian Privacy Code (Legislative decree 101/2018 and the Garante's provision).
89178 Global_Non-Interventional Study (NIS)_IQ
107188 Global_Non-Interventional Study (NIS)_PIA

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

Consultation is not required.
The PIA (with proper redaction) will be communicated to the Garante, according to the Italian legal requirements

12.2 (Optional) Additional Comments

Response

N/A

13 Risks

13.2 **Based on the answers provided, there is a risk that individuals are not informed about how GSK use their information and their rights in relation to the information, or that the activity is unexpected.**

Have you or will you put in place any actions to mitigate the risk?
Response

Italy_Study 222965 retrospective use of data | Research & Development

Response

Yes

Justification

Contractual arrangements with the third parties will cover data processing by third parties in accordance with privacy regulations and industry practice. This includes provision of the study Informed Consent Form and the study privacy notice to be provided to the patients by the study staff, prior to their participation to the study.
For non reachable patients, the Privacy notice will be published on a dedicated GSK web site.

13.13 **Based on the answers provided, there is a risk that data may not be deleted when it should be, either when it comes to the end of its retention period or where we have been asked to remove the information by the individual.**

Have you or will you put in place any actions to mitigate the risk?

Response

Italy_Study 222965 retrospective use of data | Research & Development

Response

No

Justification

To ensure quality of research we cannot delete the data. In case of an individual withdrawing from the study we will stop the processing of data.
Data retained by GSK is deleted in line with GSK standard practices, once the data retention period has completed. In some systems this is automated. Primary data collected as the result of NI studies will be stored by GSK in secure file management systems and then deleted at the end of the retention period.

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

If so, please detail them in the box below.

Response

N/A