

Assessment details

ID 122945

Name Italy_Study 308920 retrospective use of data_PIA

Organization Research & Development

Description

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Respondent Omar Shalby,Michaela Tutone

Template PIA Questionnaire (2023)

Workflow DPO Review

Creator Massimo Zuppini

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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

Result comments

Under Review (Massimo Zuppini - Approved) ; (Filippo Montanari - Approved) ;

DPO Review (Massimo Zuppini - Approved) ; (FELIX CZWIKLA - Approved) ; (Filippo Montanari - Approved) ;

Primary record id 7793

Primary record name Italy_Study 308920 retrospective use of data

Template version 21

Open risk count 0

Open info request 0

Tags

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

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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

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Response

This assessment regards 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 leverages real-world data (RWD) from routine medical records to analyze adult patients with advanced epithelial ovarian cancer who received niraparib per standard of care.

"Retrospective" means using data that was already collected in the past.

The study aims to characterize Long-Term Responder patients with epithelial ovarian cancer to 1L maintenance treatment with niraparib. This ambispective study will retrospectively collect data on diagnosis, surgical management, first-line platinum-based chemotherapy, chemotherapy response assessment and niraparib first-line maintenance and will prospectively follow patients at one and two years after the end of niraparib treatment.

The key study events and periods are as follows:

- Index date: This will be defined as the date when patients initiated 1LM niraparib monotherapy for advanced epithelial OC during the eligibility period.
- Eligibility period: This will be defined as the period within which the index date must fall for the patient to be included in the study. The planned eligibility period will start on 01 January 2022 and end on 31 August 2023. Those who initiated 1LM niraparib monotherapy during this eligibility period and with a PFS > 12 months from the first niraparib dose will be eligible for enrollment.
- Study period: This will be defined as the period during which the data required to address the study objectives will be collected from patient medical records. For each patient, the study period will be composed of retrospective and prospective period data collection:
 - Retrospective period: the retrospective data collection will cover the period from initial diagnosis, through primary surgery and first line chemotherapy (pre-index date), until start (index date) and completion (or discontinuation) of niraparib 1LM therapy (post index date). These information pertaining to patient care will already be documented in patient medical charts at the time of the start of the study.
 - Prospective period: The prospective data collection will be limited to outcome assessment. Standardized follow up assessments will be performed at approximately 1 year and 2 years (post index date) after the end of niraparib treatment if available (or at the closest routine visit).

The study does not impose a treatment protocol, any diagnostic/interventional procedure, or a visit schedule.

Eligible patients satisfying eligibility criteria written in the protocol, will be included in the study.

The study will collect data of approximately 200 patients from 20 Italian sites.

Written informed consent will be obtained from all patients before enrolment into the study.

The name of the GSK legal entity who is sponsor for the study is GlaxoSmithKline SpA.

The process flow 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): Clinical.net 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 OPIS 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: Q2 2026

End of data collection: Q3 2028

Final report of study results: Q4 2028

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 (OPIS) appointed as data processor ex art. 28 GDPR: 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.

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

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Response

05/03/2026

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

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Response

12/31/2028

Justification

None

1.5 Who is the accountable business owner for this activity?

Please list all accountable Business Owner(s). If there is more than one Business Owner please list all their names.

This should be the individual accountable for the business activity and processing of personal information, for example the Senior Director who is responsible and the ultimate decision-maker/accountable for the business activity.

Response

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Response

Michaela Tutone

Justification

None

1.6 Who is the back-up business owner in case accountable business owner is not available?

The back-up business owner information is important so that if the business owner is not available or leaves the firm we are able to contact another individual to identify who ownership of this activity should transfer to.

Response

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Response

omar.x.shalby@gsk.com

Justification

None

1.7 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

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Response

Local

Justification

None

1.9 Which country is the privacy contact reviewing this business activity responsible for?

Please only select one country.

Response

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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

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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

Genetic information

Ethnicity or Race

Medical or Health Information

Lifestyle information

Physical characteristics

Restricted Elements

Age or date of birth

Key Coded Data

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

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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

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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

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Response

Consent of the individual

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

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Response

Explicit consent

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 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 advanced epithelial ovarian cancer as detailed in the study protocol. Volume of data: based on patients who initiated niraparib monotherapy maintenance between 1 January 2022 and 31 August 2023, following completion of 1L platinum – based chemotherapy, deemed sufficient to have insights of long-term responder patients characterization with advanced epithelial ovarian cancer.

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. 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

4.1 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

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Response

Opt-in

Justification

None

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

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Response

Yes

Justification

None

4.3 How can the individual change their consent preferences?

Response

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Response

Preference centre

Justification

None

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

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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

9910018128 - OPIS SRL | 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. 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

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 electronic medical records 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

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Response

Regulatory Authorities and Ethics 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

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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

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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

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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

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Response

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

Justification

None

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

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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

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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 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, 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 and 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 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

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Response

Retention of 10 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

Data protection authority must only be informed

12.2 (Optional) Additional Comments

Response

Not answered

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.

Questions answered that triggered risk:

Have you or will you provide individuals with a privacy notice? Answer: We are not required to provide individuals with a privacy notice for this activity.

or

Have you or will you provide individuals with a privacy notice? Answer: We rely on a third party to provide the individuals with a privacy notice.

or

Has the privacy notice been reviewed to ensure the processing is covered? Answer: No

Have you or will you put in place any actions to mitigate the risk? Select Yes and use the justification box below to detail any mitigating actions taken. If No, use the justification box below to detail how this risk was accepted or closed.

Response

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Response

No

Justification

The privacy notice will be published on GSK public website, available for all individuals

13.15 Are there any other risks that you have identified?

If so, please detail them in the box below.

Response

Not applicable

Assessment notes