Johnson&Johnson	**Study Specific Data Protection Impact Assessment (DPIA)**

NOTE TO AUTHORS: To see general and in-text instructions turn on hidden text as follows: Click on the ¶ symbol in the Paragraph section of the Home Ribbon.

Protocol Number: 64007957MMY4004 Version Number: V2.0
Last Revision Date of DPIA: 23-May-2024
Created by: Caroline Verrijcken, Global Trial Leader

Filing: Refer to the study-specific TV-FRM-10860: Filing and Archiving Plan and TV-FRM-06254: TMF Content Map.

Table of Contents

1 Revision History

Version	Date	Description of Change(s)
1.0	03-Oct-2023	Initial version DPIA V2.0
2.0	23-May-2024	DPIA update needed as V3.0 available

2 Approvals

Function/Role	Name	Signature
Global Trial Leader	Caroline Verrijcken	caroline verrijcken Digitally signed by caroline verrijcken Date: 2024.05.28 08:56:53 +02'00'
☐ Global Privacy Representative		

3 Data Protection Impact Assessment Regions and Associated Protocols

3.1 Protocols

This form should be completed after review of the General DPIA

Protocol Version(s)	Protocol Date
V1.0	22-Aug-2023
V2.0	26-Apr-2024

3.2 Janssen Global Sponsor(s) and Regulatory Roles

Roles per the Clinical Trials Directive / Regulation

Global Sponsor:	NA
☐ Sponsor in EU/EEA:	Janssen Cilag International Turnhoutseweg 30, 2340 Beerse, Belgium
☐ Representative in EU/EEA:	NA

Roles per the General Data Protection Regulation

Data Controller:	Janssen Cilag International Turnhoutseweg 30, 2340 Beerse, Belgium
	NA

☐ Data Controllers Representative in EU/EEA:	

Is this a registrational study?

☐ Yes ☒ No

Are all Countries and Clinical Sites listed in CTMS?

☒ Yes ☐ No, provide comment

Comment:

3.3 Types of Individuals and Collection of Special Categories of Personal Information

- Does the study involve data concerning study participants that belongs to the following categories of individuals?

☒ Trial participants - treatment population
☐ Trial participants - healthy volunteers
☐ Children (e.g., if the study is a pediatric study)
☐ Other: :

- Special Categories of Personal Information are data that reveal racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, and the processing of genetic data, biometric data for the purpose of uniquely identifying a natural person, data concerning health or data concerning a natural person's sex life or sexual orientation.

☐ Biometric Data for the purpose of uniquely identifying a natural person
☐ Data concerning a natural person's sex life or sexual orientation
☒ Data concerning health
☐ Genetic Data
☒ Other: Race/Ethnic Origin is collected in countries where allowed. In this study Race/Ethnic Origin is not collected in France, even though considered to be overall relevant
☐ Political Opinions
☒ Racial or Ethnic Origin
☐ Religious or Philosophical Beliefs
☐ Trade Union Membership

- Are the Special Categories of Personal Information indicated above required to be collected in accordance with the study protocol **and** does the protocol include a scientific rationale justifying the need for collecting the data?

☒ Yes

☐ No, provide rationale why the collection of the data is necessary

Rationale:

3.4 Study Specific Risks Relating to Processing of Personal Information

- Identify risks which are specific for the study.
- Common risks related to the processing of personal information are included in the General DPIA. Consideration should be given to specific processes in a study which may pose additional risk or a higher likelihood of disclosure e.g., review by the sponsor of a document which is less likely to be redacted such as a pathology report of biopsied tissue.
- Study-specific risks may include, but are not limited to, risks identified in the General DPIA **where mitigation / controls are addressed differently** and risks not identified in the General DPIA. Specific attention should be given to risks related to process, disclosure, or transfer of directly identifiable study participant data.
- In the table below Residual Risk means risk remaining after mitigation and controls have been put in place.
- If a risk is identified, it will then be discussed with the stakeholders to resolve or determine if a privacy officer needs to be brought in for further guidance.

Are there any study specific risks that have been identified?

☒ No ☐ Yes, complete the table below

If "NO" is checked above, the table below does not apply and will remain blank

Risk Description / Scenario	Potential Impact to data subject (Study Participant)	Mitigation / Controls reducing the risk	Residual Risk (Low, Medium, High)
Example: Patient's personal information may be collected in error on Pathology forms submitted to central lab supplier	*Example: Sites are instructed to redact patient's personal information on pathology reports prior to submission but risk that data is not fully redacted*	*Example: Supplier to have QC process to identify any privacy issues and agreed action plan. Monitoring guidelines to direct SMs to check redacted copies filed in site files*	*Low*

3.5 Systems

The privacy assessment of systems used in clinical studies sponsored by Janssen Research and Development is governed by TV-SOP-48974: Data Protection Impact Assessments for clinical studies sponsored by Janssen Research & Development. Where required, in accordance with TV-SOP-48974: a specific system Data Protection Impact Assessment is performed.

For systems that are not included in the List of R&D Systems assessed by Privacy, contact the Business Application Owner and Privacy to initiate such an assessment.

- Systems, which may be associated with a high risk to individuals' personally identifiable information are assessed in accordance with TV-SOP-19006: Global Privacy Impact Assessment and TV-SOP-48974: Data Protection Impact Assessments for clinical studies sponsored by Janssen Research & Development.

System Name	System Specific DPIA ID#	Included in the List of R&D Systems assessed by Privacy?	If no System Specific DPIA #, summarize assessments to protect privacy or provide rationale why DPIA # was not considered necessary
iDARTs	2414/ NA	Yes	No technology specific DPIA is required: See assessment ID: 6603.
LSAF	2420/ NA	Yes	No technology specific DPIA is required: See assessment ID: 6603.
Medidata Rave	2428/ 4195	Yes	
MFT (MBOX-SDX) Managed File Transfer Platform	3021/ NA	Yes	No technology specific DPIA is required: See assessment ID: 6603.
V-TMF	2439/ NA	Yes	No technology specific DPIA is required: See assessment ID: 6603.

3.6 External Service Providers

The privacy assessment of external service providers or suppliers used in clinical studies sponsored by Janssen Research and Development is governed by TV-SOP-48974. Ensuring inspection readiness requires that we document all suppliers / external service providers that access, process and view patient data.

☒ Confirm all study suppliers accessing or processing study participant level data are on the List of Suppliers assessed to process personal data in clinical studies sponsored by Janssen Research & Development (see location above). Include the suppliers in the table below.

☐ Other Service Providers not listed, add them to the table below and provide information about the privacy qualification performed and countries in scope, as applicable.

If the Privacy Qualification conditions are not met, contact the Global Privacy group via the mailbox before finalizing the DPIA.

Name of External Service Provider / Third Party Supplier	Business Partner Risk Assessment	Approved Supplier List	Privacy Group Assessment Complete	Comments (e.g., Country Scope)
IQVIA	Yes	Yes	Yes	CRO
Medidata Solutions, Inc._New York, NY, USA	Yes	Yes	Yes	Computerized Systems
Parexel International Limited_Dublin, Ireland	Yes	Yes	Yes	Data Management

Name of External Service Provider / Third Party Supplier	Business Partner Risk Assessment	Approved Supplier List	Privacy Group Assessment Complete	Comments (e.g., Country Scope)
SAS Institute Inc.	Yes	Yes	Yes	Computerized Systems
Veeva Systems Inc._Pleasanton, CA, USA	Yes	Yes	Yes	Computerized Systems

4 Cross-Border Transfer and Data Localization

General statement on cross border transfers.

- Cross-border transfer from the European Economic Area (EEA), UK and Switzerland.
  - The data protection laws in the EEA, UK, and Switzerland require that contractual and other safeguards be put into place when personal data is transferred to countries which do not have adequate data protection laws as determined by the European Commission and government authorities in UK and Switzerland. Individuals in the countries referenced have rights to receive information about how their personal data is protected when transferred.
  - To address the above, TV-eFRM-15277: Measures for Cross Border Transfer–Clinical Studies, summarizes the measures for cross-border transfer of personal data, including key-coded data that are transferred in Clinical Research in accordance with GDPR CHAPTER V, Transfers of personal data to third countries or international organizations.
- Other cross-border transfer and/or data localization requirements.
  - Countries other than the EEA, UK, and Switzerland may be subject to cross-border transfer restrictions and data localization requirements. Common examples include China and Russia. Identify cross-border transfer restrictions and localization requirements for the study and confirm adequate mitigation controls are in place.

1. Does this study have clinical sites in the EEA, UK, or Switzerland?

   ☒ Yes, see details below ☐ No, go to Question 2

   If "Yes," has a completed TV-eFRM-15277: Measures for Cross-Border Transfer–Clinical Studies been filed in the Trial Master File?

   ☐ Yes, V-TMF reference number[.] ☒ No, The Cross Border Transfer document must be created before First Site Opened in the EEA, UK, or Switzerland.

2. Have other cross-border transfer or data localization risks been identified for the study?

   ☐ Yes, see below for mitigation controls in place. ☒ No

Mitigation controls:

5 Legal

The Clinical Trial Agreements language is drafted following applicable Standard Operating Procedures (SOPs), which requires the most up to date approved templates are used to protect clinical trial data.