Johnson&Johnson	[redacted]

[redacted]

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[redacted]

Table of Contents

Johnson&Johnson	[redacted]		
	[redacted]	[redacted]	[redacted]

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Johnson&Johnson	[redacted]		

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[redacted]	[redacted]	
[redacted]	[redacted]	

3 Data Protection Impact Assessment Regions and Associated Protocols

3.1 Protocols

[redacted]

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

3.2 Janssen Global Sponsor(s) and Regulatory Roles

Roles per the Clinical Trials Directive / Regulation

[redacted]

Johnson&Johnson	[redacted]		
	[redacted]	[redacted]	[redacted]

Global Sponsor:	Not Applicable
☒ Sponsor in EU/EEA:	Janssen Cilag International NV Turnhoutseweg 30 B-2340 Beerse, Belgium
☐ Representative in EU/EEA:	

Roles per the General Data Protection Regulation

Data Controller:	Janssen Pharmaceutica NV. Turnhoutseweg 30 B-2340, Beerse, Belgium
☐ Data Controllers Representative in EU/EEA:	N/A

Is this a registrational study?

☐ Yes ☒ No

Are all Countries and Clinical Sites listed in CTMS?

☒ Yes ☐ No, provide comment

[redacted]

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: :

[redacted]

- 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 ☐ Political Opinions

☐ Data concerning a natural person's sex life or sexual orientation ☐ Racial or Ethnic Origin

☒ Data concerning health ☐ Religious or Philosophical Beliefs

☒ Genetic Data ☐ Trade Union Membership

☒ Other: Sex will be collected

- 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)
No study specific risks identified. For general risks and mitigations please refer to the Genera DPIA document. Data safeguards of the eCRF system Medidata RAVE are included in a separate document (Medidata White paper – Information Security).			

3.5 Systems

System Name			
iDARTs			
LSAF			
Medidata Rave			

Johnson&Johnson	[redacted]		
MFT (MBOXSDX) Managed File Transfer Platform		[redacted]	[redacted]
V-TMF		[redacted]	[redacted]
GSS	[redacted]	[redacted]	
SPACE		[redacted]	[redacted]
Pinnacle 21		[redacted]	[redacted]

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	[redacted]	[redacted]	[redacted]	[redacted]
IQVIA_Durham, NC, USA	[redacted]	[redacted]	[redacted]	[redacted]

4 Cross-Border Transfer and Data Localization

General statement on cross border transfers.

[redacted]

- 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.
  - [redacted]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

   [redacted]Measures for Cross-Border Transfer–Clinical Studies been filed in the Trial Master File?

   ☒ Yes, [redacted] ☐ 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.