Johnson&Johnson Innovative Medicine	**Data Sharing Request Due Diligence Assessment**

General Information	
YODA Project (Protocol) ID:	2025-0884
Date Proposal Received by YODA Project:	12-DEC-2025
Product Name(s):	Esketamine
Condition(s) Studied:	Depressive Disorder, Major Depressive Disorder, Treatment-Resistant
	1. NCT04599855 - **54135419TRD4005** A Randomized, Double-blind, Multicenter, Placebo-controlled Study to Evaluate the Efficacy, Safety, and Tolerability of Esketamine Nasal Spray, Administered as Monotherapy, in Adult Participants With Treatment-resistant Depression 2. NCT04338321 - **54135419TRD3013** A Long-term Comparison of Esketamine Nasal Spray Versus Quetiapine Extended Release, Both in Combination With a Selective Serotonin Reuptake Inhibitor/Serotonin-Norepinephrine Reuptake Inhibitor, in Participants With Treatment Resistant Major Depressive Disorder (ESCAPE-TRD) 3. NCT03434041 - **ESKETINTRD3006** A Randomized, Double-blind, Multicenter Active-controlled Study to Evaluate the Efficacy, Pharmacokinetics, Safety and Tolerability of Flexible Doses of Intranasal Esketamine Plus an Oral Antidepressant in Adult Subjects With Treatment-resistant Depression 4. NCT02497287 - **ESKETINTRD3004** An Open-label, Long-term, Safety and Efficacy Study of Intranasal Esketamine in Treatment-resistant Depression 5. NCT02493868 - **ESKETINTRD3003** A Randomized, Double-blind, Multicenter, Active-Controlled Study of Intranasal Esketamine Plus an Oral Antidepressant for Relapse Prevention in Treatment-resistant Depression **6.** NCT01998958 - **ESKETINTRD2003** A Double-Blind, Doubly-Randomized, Placebo-Controlled Study of Intranasal Esketamine in an Adaptive Treatment Protocol to Assess Safety and Efficacy in Treatment-Resistant Depression (SYNAPSE) 7. NCT02918318 - **54135419TRD2005** A Randomized, Double-blind, Multicenter, Placebo-controlled Study to Evaluate the Efficacy, Safety and Tolerability of Fixed Doses of Intranasal Esketamine in Japanese Subjects With Treatment Resistant Depression

	8. NCT01627782 - **KETIVTRD2002** A Double-blind, Randomized, Placebo-controlled, Parallel Group, Dose Frequency Study of Ketamine in Subjects With Treatment-resistant Depression 9. NCT01640080 - **ESKETIVTRD2001** A Double-Blind, Double-Randomization, Placebo-Controlled Study of the Efficacy of Intravenous Esketamine in Adult Subjects With Treatment-Resistant Depression 10. NCT03097133 **- 54135419SUI3002** A Double-blind, Randomized, Placebo-controlled Study to Evaluate the Efficacy and Safety of Intranasal Esketamine in Addition to Comprehensive Standard of Care for the Rapid Reduction of the Symptoms of Major Depressive Disorder, Including Suicidal Ideation, in Adult Subjects Assessed to be at Imminent Risk for Suicide 11. NCT02133001 - **ESKETINSUI2001** A Double-blind, Randomized, Placebo Controlled Study to Evaluate the Efficacy and Safety of Intranasal Esketamine for the Rapid Reduction of the Symptoms of Major Depressive Disorder, Including Suicidal Ideation, in Subjects Who Are Assessed to be at Imminent Risk for Suicide 12. NCT03039192 - **54135419SUI3001** A Double-blind, Randomized, Placebo-controlled Study to Evaluate the Efficacy and Safety of Intranasal Esketamine in Addition to Comprehensive Standard of Care for the Rapid Reduction of the Symptoms of Major Depressive Disorder, Including Suicidal Ideation, in Adult Subjects Assessed to be at Imminent Risk for Suicide 13. NCT02422186 - **ESKETINTRD3005** A Randomized, Double-blind, Multicenter, Active-controlled Study to Evaluate the Efficacy, Safety, and Tolerability of Intranasal Esketamine Plus an Oral Antidepressant in Elderly Subjects With Treatment-resistant Depression 14. NCT02418585 - **ESKETINTRD3002** A Randomized, Double-blind, Multicenter, Active-controlled Study to Evaluate the Efficacy, Safety, and Tolerability of Flexible Doses of Intranasal Esketamine Plus an Oral Antidepressant in Adult Subjects With Treatment-resistant Depression **15.** NCT02417064 - **ESKETINTRD3001** A Randomized, Double-blind, Multicenter, Active-controlled Study to Evaluate the Efficacy, Safety, and Tolerability of Fixed Doses of

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	Intranasal Esketamine Plus an Oral Antidepressant in Adult Subjects With Treatment-resistant Depression

Proposal Review	
Question 1: The clinical trial data from the study/studies listed above were previously identified and approved as being available for a data sharing request. **Is there any reason why the study/studies listed should no longer be shared?**	No
Comments if 'Yes':	
Question 2: On review of the proposal, is there any data that has been requested that may be **missing** from the clinical database?	Yes
Comments if 'Yes':	
Question 3: Is a similar analysis underway, or completed and pending disclosure by J&J?	Yes
Comments if 'Yes':	