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

General Information	
YODA Project (Protocol) ID:	2025-0544
Date Proposal Received by YODA Project:	25-JUL-2025
Product Name(s):	Esketamine/SPRAVATO
Condition(s) Studied:	Major Depressive Disorder, including Suicidal Ideation/Treatment Resistant Depression
NCT Numbers(s), Protocol Number(s) and Title(s):	**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. **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. **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. **NCT01640080/ESKETIVTRD2001:** A Double-Blind, Double-Randomized, Placebo-Controlled Study of the Efficacy of Intravenous Esketamine in Adult Subjects with Treatment Resistant Depression. **NCT01998958/ESKETINTRD2003**: A Double-Blind, Double-Randomized, Placebo-Controlled Study of Intranasal Esketamine in an Adaptive Treatment Protocol to Assess Safety and Efficacy in Treatment Resistant Depression (SYNAPSE). **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. **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.

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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?	No
Comments if 'Yes':	
Question 3: Is a similar analysis underway, or completed and pending disclosure by J&J?	No
Comments if 'Yes':	