

Johnson & Johnson Innovative Medicine	Data Sharing Request Due Diligence Assessment
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General Information	
YODA Project (Protocol) ID:	2025-0280
Date Proposal Received by YODA Project:	16-May-2025
Product Name(s):	Esketamine (SPRAVATO®)
Condition(s) Studied:	Depressive Disorder, Major
NCT Numbers(s), Protocol Number(s) and Title(s):	<p>1. NCT02417064 - ESKETINTRD3001 A Randomized, Double-blind, Multicenter, Active-controlled Study to Evaluate the Efficacy, Safety, and Tolerability of Fixed Doses of Intranasal Esketamine Plus an Oral Antidepressant in Adult Subjects With Treatment-resistant Depression</p> <p>2. 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</p>
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':	