

General Information	
YODA Project (Protocol) ID:	2025-0352
Date Proposal Received by YODA Project:	8-SEP-2025
Product Name(s):	Bapineuzumab, Bosentan, Canagliflozin, Esketamine, Galantamine, Guselkumab, Infliximab, Macitentan, Mebendazole, Methylphenidate HCl, Paliperidone, Risperidone, Selexipag, Topiramate, Toreforant, Ustekinumab
Condition(s) Studied:	Alzheimer Disease; Pulmonary Arterial Hypertension; Diabetes Mellitus, Type 2; Depressive Disorder, Major; Psoriasis; Bipolar Disorder; Schizophrenia; Anxiety Disorders; Dementia; Hypertension, Obesity; Partial Seizure Disorder; Multiple Sclerosis
NCT Numbers(s), Protocol Number(s) and Title(s):	<ol style="list-style-type: none"> 1. NCT00575055 - ELN115727-302 2. NCT00574132 - ELN115727-301 3. NCT00253201 - GAL-USA-1 4. NCT00304629 - GAL-USA-3 5. NCT00253227 - GAL-INT-2 6. NO NCT# - GAL-INT-3 7. NO NCT# - GAL-INT-7 8. NCT00261573 - GAL-INT-6 9. NCT00253188 - GAL-INT-1 10. NCT00253214 - GAL-INT-10 11. NCT00236574 - CR003145 // GAL-INT-11 12. NCT00236431 - GAL-INT-18 13. NO NCT# - GAL-MVD-302 14. NCT00679627 - GALALZ3005 15. NCT00216593 - GAL-ALZ-302 (PMID # 19042161-CR003940) 16. NCT00645190 - GAL-CHN-T100 17. NO NCT# - GAL-USA-10 18. NO NCT# - GAL-93-01 19. NO NCT# - RIS-INT-83 20. NCT00034762 - RIS-USA-232/CR002764 21. NCT00086112 - RIS-ANX-301 22. NCT00299715 - R076477-BIM-3001 23. NCT00309699 - R076477-BIM-3002 24. NCT00309686 - R076477-BIM-3003 25. NCT00490971 - R076477BIM3004 26. NCT00391222 - RISBMN3001 27. NCT00076115 - RIS-BIM-301 28. NCT00132678 - RISBIM3003 29. NCT00094926 - RIS-BIP-302 30. NCT00253162 - RIS-INT-69 31. NCT00249236 - RIS-IND-2/CR006064 32. NCT00250367 - RIS-INT-46/CR006058

33. NCT00253149 - RIS-USA-102/CR006040
34. NCT00257075 - RIS-USA-239/CR006052
35. NO NCT# - RIS-USA-240
36. NCT00246246 - RIS-BIP-301
37. NCT00237289 - CR002653 (CAPSS-168)
38. NCT00240721 - TOPMAT-PDMD-005 (CR002248)
39. NCT00037674 - TOPMAT-PDMD-004
40. NCT00035230 - TOPMAT-PDMD-008
41. NO NCT# - TOPMAT-PDMD-006
42. NCT00249158 - RIS-AUS-5/CR006010
43. NO NCT# - RIS-BEL-14
44. NCT00249145 - RIS-INT-24/CR006046
45. NCT00253123 - RIS-USA-63/CR006022
46. NO NCT - RIS-USA-70 (EXTENSION OF RIS-USA-63)
CR003361, RIS-USA-T216
47. NCT02417064 - ESKETINTRD3001
48. NCT02418585 - ESKETINTRD3002
49. NCT02422186 - ESKETINTRD3005
50. NCT02497287 - ESKETINTRD3004
51. NCT02493868 - ESKETINTRD3003
52. NCT02133001 - ESKETINSUI2001
53. NCT03039192 - 54135419SUI3001
54. NCT03097133 - 54135419SUI3002
55. NCT02918318 - 54135419TRD2005
56. NCT01627782 - KETIVTRD2002
57. NCT01640080 - ESKETIVTRD2001
58. NCT00246233 - 42603MDD3001 (CON-CAN-3)
59. NCT00044681 - RIS-INT-93
60. NCT00095134 - RIS-DEP-401
61. NCT01998958 - ESKETINTRD2003
62. NCT03434041 - ESKETINTRD3006
63. NCT00642278 - 28431754DIA2001
64. NCT01106625 - 28431754DIA3002
65. NCT01064414 - 28431754DIA3004
66. NCT01081834 - 28431754DIA3005
67. NCT01106677 - 28431754DIA3006
68. NCT00968812 - 28431754DIA3009
69. NCT01106651 - 28431754DIA3010
70. NCT01106690 - 28431754DIA3012
71. NCT01137812 - 28431754DIA3015
72. NCT01809327 - 28431754DIA3011
73. NCT01381900 - 28431754DIA3014
74. NCT01340664 - 28431754DIA2003
75. NCT02025907 - 28431754DIA4004
76. NCT01032629 - 28431754DIA3008
77. NCT01989754 - 28431754DIA4003
78. NCT02065791 - 28431754DNE3001
79. NCT03267576 - 28431754DIA4026

80. NCT00231530 - TOPMAT-OBDM-003
81. NCT00231673 - TOPMAT-NP-005
82. NCT01173562 - MEBENDAZOLGAI3002
83. NCT00236665 - TOPMAT-OBHT-001
84. NCT00207727 - C0743T06
85. NCT00113815 - TOPMATPEP3001
86. NCT01483599 - CNTO1959PSO2001
87. NCT02203032 - CNTO1959PSO3003
88. NCT02207231 - CNTO1959PSO3001
89. NCT02207244 - CNTO1959PSO3002
90. NCT02905331 - CNTO1959PSO3006
91. NCT02325219 - CNTO1959PSO3004
92. NCT02951533 - CNTO1959PSO3008
93. NCT03090100 - CNTO1959PSO3009
94. NCT00106834 - CR003130 / C0168T38
95. NCT00230529 - CR003124 / C0168T31
96. NCT02295865 - 38518168PSO2001
97. NCT01009086 - CNTO1275PSA3001 /// PSUMMIT I
98. NCT01077362 - CNTO1275PSA3002 /// PSUMMIT II
99. NCT00267969 - C0743T08
100. NCT00307437 - C0743T09
101. NCT01550744 - CNTO1275PSO3009
102. NCT00723528 - JNS009-JPN-02
103. NCT00320216 - C0379T04
104. NCT00454584 - C0743T12
105. NCT00747344 - C0743T25
106. NCT01008995 - C0743T23
107. NCT01059773 - CNTO1275PSO4004
108. NCT01090427 - CNTO1275PSO3006
109. NCT02698475 - CNTO1275PSO3013
110. NCT00319111 - AC-052-370 (BENEFIT OL)
111. NCT00303459 - AC-052-414 (COMPASS-2)
112. NCT00433329 - AC-052-419
113. NCT00091715 - AC-052-364
114. NCT00319267 - AC-052-365
115. NCT00313222 - AC-052-366
116. NCT00319020 - AC-052-367
117. NCT01223352 - AC-052-373
118. NCT01338415 - AC-052-374
119. NCT00660179 - AC-055-302
120. NCT01743001 - AC-055-305
121. NCT02070991 - AC-055G201
122. NCT02382016 - AC-055-404
123. NCT03359291 - AC-055-122
124. NCT01106014 - AC-065A302
125. NCT02471183 - AC-065A304
126. NCT03078907 - AC-065A404
127. NCT00488319 - R076477PSZ3002

	128.	NCT01009047 - R076477PSZ3003
	129.	NCT00645099 - R076477SCH3020
	130.	NCT00518323 - R076477PSZ3001
	131.	NCT00334126 - R076477SCH3015
	132.	NCT00086320 - R076477-SCH-301
	133.	NCT00650793 - R076477-SCH-703
	134.	NCT00397033 - R076477SCA3001
	135.	NCT00412373 - R076477SCA3002
	136.	NCT00752427 - R076477-SCH-702
	137.	NCT00077714 - R076477-SCH-304
	138.	NCT00083668 - R076477-SCH-305
	139.	NCT00078039 - R076477-SCH-303
	140.	NCT00085748 - R076477-SCH-302
	141.	NCT01662310 - R076477-SCH-3041
	142.	NCT00524043 - R076477SCH4012
	143.	NCT00105326 - R076477-SCH-1010/CR002281
	144.	NCT00645307 - R076477-SCH-701
	145.	NCT00460512 - R076477SCH3017
	146.	NCT00566631 - R076477SCH3018
	147.	NCT00668837 - R076477-SCH-705
	148.	NCT00589914 - R092670PSY3006
	149.	NCT00604279 - R092670PSY3008
	150.	NCT00590577 - R092670PSY3007
	151.	NCT00111189 - R092670PSY3001
	152.	NCT00210717 - R092670PSY3002
	153.	NCT00119756 - R092670PSY3005
	154.	NCT00210548 - R092670PSY3003
	155.	NCT00101634 - R092670PSY3004
	156.	NCT00074477 - R092670-SCH-201
	157.	NCT01529515 - R092670PSY3012
	158.	NCT01193153 - R092670SCA3004
	159.	NCT01157351 - R092670SCH3006
	160.	NCT01081769 - R092670SCH3005
	161.	NCT01281527 - R092670SCH3010
	162.	NCT01051531 - R092670SCH3009
	163.	NCT01527305 - R092670SCH4009
	164.	NCT01299389 - PALM-JPN-4
	165.	NCT01258920 - PALM-JPN-5
	166.	NCT01515423 - R092670PSY3011
	167.	NCT02713282 - R092670SCH3015
	168.	NCT03345342 - R092670PSY3015
	169.	NCT01559272 - R092670PSY1005
	170.	NCT00034749 - RIS-USA-231
	171.	NCT00249132 - RIS-INT-3
	172.	NCT00216476 - RISSCH3001
	173.	NCT00378092 - CR011992, RISSCH3024
	174.	NCT00088075 - RIS-SCH-302/CR003370
	175.	NO NCT# - RIS-USA-1 (RIS-USA-9001)

Data Sharing Request Due Diligence Assessment

	176. NCT00253136 - RIS-USA-121/CR006055 177. NO NCT# - RIS-USA-72 178. NCT00249223 - RIS-INT-61 179. NCT00216671 - RISSCH4045 180. NCT00369239 - RISSCH4043 181. NCT00216632 - RISSCH4026 182. NCT00236379 - RIS-USA-275 183. NCT01050582 - RISNAP4022 184. NCT00216528 - RIS-KOR-66 185. NCT00269919 - RIS-KOR-64 186. NCT00992407 - RISSCH4178 187. NCT00236353 - RIS-USA-305 188. NCT00495118 - RIS-INT-80 189. NCT00236457 - RIS-INT-62 190. NCT00236587 - RIS-USA-265 191. NCT00297388 - RIS-SCH-401 192. NCT00821600 - RIS-SCH-1012 193. NCT00299702 - RISSCH4060 194. NCT00526877 - RISSCH4119 (RISC-TWN-MA10) 195. NCT00061802 - RIS-SCP-402 196. NO NCT# - RIS-INT-85 197. NCT00034775 - RIS-USA-259
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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':	

EFRM-0005440 Legacy: TV-eFRM-01723 v1	Data Availability Inquiry Due Diligence Assessment
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Part 1: General Information	
Date:	08-Apr-2024
Product Name:	Motrin
Therapeutic Area:	Pain, Inflammation, Fever
Product Class:	Nonsteroidal Anti-inflammatory Drugs (NSAIDs)
Condition(s) Studied:	None: Healthy Volunteer Study
Protocol Number(s) and Title(s):	97-024 Multiple-Dose Pharmacokinetic Study of an Ibuprofen-Pseudoephedrine HCl Suspension in Children. Aug 1999.
Part 2: Data Availability	
Question:	Response:
Data Holder has authority to provide clinical trial data or development partner has agreed to share clinical trial data.	Yes
Comments:	
Data Holder has sharable electronic clinical trial data or data can be converted to electronic format.	Yes
Comments:	
De-identification and redaction of clinical trial data in accordance with current HIPAA and European Union (EU) criteria allows protection of participant privacy and confidentiality.	Yes
Comments:	
The product and relevant indication studied has either been approved by regulators in the US and EU, or terminated from development.	Yes
Comments:	
Data Holder has completed the clinical trial and trial has been completed for a period of at least 18 months (or results published in peer-reviewed biomedical literature).	Yes
Comments:	
Part 3: Data Availability Summary	
Based on the responses to the above Data Availability questions, the identified clinical trial data are available for a data sharing request.	Yes

Please refer to the following page for Kenvue Functional Approval

Compound Development Team Leader (or delegate)

Date

EFRM-0005440 Legacy: TV-eFRM-01723 v1	Data Availability Inquiry Due Diligence Assessment
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Mark Watt

*Electronically signed by: Mark Watt
Reason: I am approving this document
Date: Apr 16, 2024 19:41 GMT+1*

Clinical Research Need State Lead (or delegate)	Date
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Robert Pineda

*Electronically signed by: Robert Pineda
Reason: I have reviewed this document
Date: Apr 16, 2024 13:59 EDT*

Brand Regulatory Lawyer (or delegate)	Date
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Leigh Vincent

*Electronically signed by: Leigh Vincent
Reason: I am approving this document
Date: Apr 23, 2024 12:01 EDT*

Brand Patent Lawyer (or delegate)	Date
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EFRM-0005440 Legacy: TV-eFRM-01723 v1	Data Availability Inquiry Due Diligence Assessment
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Part 1: General Information	
Date:	08-Apr-2024
Product Name:	TYLENOL®
Therapeutic Area:	Pain, Inflammation, Fever
Product Class:	Nonsteroidal Anti-inflammatory Drugs (NSAIDs)
Condition(s) Studied:	None: Healthy Volunteer Study
Protocol Number(s) and Title(s):	02-161 Tolerability and Multiple-Dose Pharmacokinetics of Acetaminophen (Paracetamol) At and Above the Currently Recommended Maximum Daily Dose
Part 2: Data Availability	
Question:	Response:
Data Holder has authority to provide clinical trial data or development partner has agreed to share clinical trial data.	Yes
Comments:	
Data Holder has sharable electronic clinical trial data or data can be converted to electronic format.	Yes
Comments:	
De-identification and redaction of clinical trial data in accordance with current HIPAA and European Union (EU) criteria allows protection of participant privacy and confidentiality.	Yes
Comments:	
The product and relevant indication studied has either been approved by regulators in the US and EU, or terminated from development.	Yes
Comments:	
Data Holder has completed the clinical trial and trial has been completed for a period of at least 18 months (or results published in peer-reviewed biomedical literature).	Yes
Comments:	
Part 3: Data Availability Summary	
Based on the responses to the above Data Availability questions, the identified clinical trial data are available for a data sharing request.	Yes

Please refer to the following page for Kenvue Functional Approval

Compound Development Team Leader (or delegate)

Date

EFRM-0005440 Legacy: TV-eFRM-01723 v1	Data Availability Inquiry Due Diligence Assessment
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Mark Watt

*Electronically signed by: Mark Watt
Reason: I am approving this document
Date: Apr 16, 2024 19:39 GMT+1*

Clinical Research Need State Lead (or delegate)	Date
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Robert Pineda

*Electronically signed by: Robert Pineda
Reason: I have reviewed this document
Date: Apr 16, 2024 13:33 EDT*

Brand Regulatory Lawyer (or delegate)	Date
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Leigh Vincent

*Electronically signed by: Leigh Vincent
Reason: I am approving this document
Date: Apr 18, 2024 11:42 EDT*

Brand Patent Lawyer (or delegate)	Date
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