

**Appendix A.** Correspondence regarding obtaining individual patient level data for serious adverse events (SAEs) that occurred during TADS from Duke University for RIAT reanalysis, which also includes correspondence regarding the provision of documents related to the general analysis.

Table A1. An index of correspondence regarding obtaining individual patient level data from TADS. Items are listed in chronological order, where each row provides the date of correspondence in day/month/year format (where ~ approximates the day), sender, primary recipient(s), a brief description of the subject matter, any associated attachments ('Att'), and the total number of pages of the linked document. Hyperlinks, and personal and contact details have been redacted from all correspondence for privacy reasons.

Item	Date	Sender	Recipient(s)	Brief description of correspondence	Number of pages
1.	04/06/2018	Jon Jureidini (University of Adelaide)	John March (TADS primary investigator, Duke University)	Jureidini informing March of the RIAT call to action for TADS.	1
2.	18/7/18	Jon Jureidini	John March	Jureidini requesting TADS data collection or case record forms. <b>Att:</b> Email confirmation of Approval to Access TADS/SOFTAD in the NIMH Data Archive.	2
3.	24/7/18	Jon Jureidini	Graham Emslie (TADS co-investigator, Duke University)	Request for SAE narratives from TADS. <b>Att:</b> Confirmation of Approval from the NIMH Data Archive.	2
4.	27/7/18	Jon Jureidini	Mark Lane (University of Texas, Southwestern)	Contacting Emslie. <b>Att:</b> Jureidini's email to Emslie sent 24/7/18.	3
5.	4/8/18	Jon Jureidini	Duke Clinical Research Institute (DCRI)	Attempt to contact March.	2
6.	~8/18	DCRI	Jon Jureidini	No forwarding address for Dr March available.	1
7.	11/8/18	Jon Jureidini	DCRI	Requesting contact for TADS, reiteration of RIAT effort.	2
8.	06/02/2019	Jon Jureidini	John Curry (TADS co-investigator/ data custodian, Duke University)	Request for de-identified, individual patient data. <b>Att:</b> letter confirming scope of RIAT reanalysis.	3

<b>Item</b>	<b>Date</b>	<b>Sender</b>	<b>Recipient(s)</b>	<b>Brief description of correspondence</b>	<b>Number of pages</b>
9.	09/02/2019	John Curry	Jon Jureidini	Curry will contact Jureidini if requires further information.	1
10.	11/3/19	Jon Jureidini	John Curry	Request for update on progress.	1
11.	14/3/19	John Curry	Jon Jureidini	Estimates an updated response by the weekend.	1
12.	20/3/19	John Curry	Jon Jureidini	Update on the status of the request, including establishing available files, de-identification process and approval from IRB regarding consent.	1
13.	20/3/19	Jon Jureidini	John Curry	Thanking Curry for update.	1
14.	18/4/19	Jon Jureidini	John Curry	Request for update.	1
15.	18/4/19	John Curry	Jon Jureidini	Curry still trying to locate CRFs at storage facility.	1
16.	30/4/19	Natalie Aboustate (University of Adelaide)	John Curry	Inquiring whether CRFs were provided to Lilly.	2
17.	1/5/19	John Curry	Natalie Aboustate	Curry will look for records of SAE reports sent to Lilly.	1
18.	2/5/19	Natalie Aboustate	John Curry	Thanking Curry.	1
19.	14/5/19	John Curry	Jon Jureidini	TADS individual CRFs were destroyed but there are SAE reports (approximately 70), offer to work out a plan with IRB to de-identify and share the SAE reports.	1
20.	16/5/19	Jon Jureidini	John Curry	Inquiring whether other adverse event reports were preserved, request for SAE reports, inventory of destroyed boxes and reason why some archived boxes were destroyed and others not.	1
21.	23/5/19	John Curry	Jon Jureidini	No other adverse event reports preserved, there were approximately 70 SAE reports for 66 SAEs, will provide the archive inventories, unsure about varied destruction dates.	1

Item	Date	Sender	Recipient(s)	Brief description of correspondence	Number of pages
22.	28/5/19	John Curry	Jon Jureidini	Inventory of TADS archive. <b>Att:</b> Excel files listing available inventory reviewed by Curry; Excel file listing destroyed inventory. Attachments not reproduced at Duke's request.	3
23.	15/6/19	John Curry	Jon Jureidini	Format of subject IDs from NIH dataset provided to Jureidini, organising de-identification of SAE forms.	1
24.	17/6/19	Jon Jureidini	John Curry	Querying de-identification process and sample of subject IDs from NIH dataset.	1
25.	17/6/19	John Curry	Jon Jureidini	De-identification process for NIH data, where IDs vary from those on TADS SAE forms. Curry will try to link original IDs to the de-identified ones.	1
26.	18/6/19	Jon Jureidini	John Curry	Thanking Curry and inquiring whether list of queries regarding inventory can be sent through.	1
27.	19/6/19	John Curry	Jon Jureidini	Agrees to be sent a list of queries regarding inventory.	1
28.	20/6/19	Jon Jureidini	John Curry	Additional datasheet regarding subject IDs from NIH dataset. <b>Att:</b> Excel spreadsheet of subject IDs from NIH dataset. Attachment not reproduced due to data access agreement.	2
29.	27/6/19	John Curry	Jon Jureidini	Found master list linking original IDs to the de-identified ones from the NIH dataset, will file for IRB approval of data transfer agreement which will be associated with a cost.	1
30.	27/6/19	Jon Jureidini	John Curry	Request for cost estimate.	1
31.	4/07/19	Natalie Aboustate	John Curry	Questions regarding TADS' archived inventory. <b>Att:</b> Document containing questions regarding TADS' archived inventory.	3
32.	4/7/19	John Curry	Natalie Aboustate	Out of office reply.	1

Item	Date	Sender	Recipient(s)	Brief description of correspondence	Number of pages
33.	8/7/19	John Curry	Natalie Aboustate & Jon Jureidini	Response to questions regarding TADS' archived inventory. <b>Att:</b> Document of responses to Aboustate's questions regarding TADS' archived inventory. Attachment not reproduced at Duke's request.	2
34.	8/7/19	Jon Jureidini	John Curry & Natalie Aboustate	Thanking Curry.	1
35.	9/7/19	John Curry	Natalie Aboustate & Jon Jureidini	Update on contract process.	1
36.	31/7/19	Natalie Aboustate	Susan Silva (TADS statistician, Duke University)	Request for study syntax. <b>Att:</b> emails between Jureidini and Curry regarding the data request; TADS publication regarding its acute phase (2004; attachment not reproduced due to copyright); and TADS publication regarding its follow up phase (2007; attachment not reproduced due to copyright).	7
37.	31/7/19	Natalie Aboustate	John Curry	Request for update.	1
38.	31/7/19	John Curry	Natalie Aboustate	Contracting group are working on it.	1
39.	5/8/19	Natalie Aboustate	John Curry	Thanking Curry.	1
40.	11/8/19	Susan Silva	Natalie Aboustate	Redacted at Duke's request.	-
41.	11/8/19	Susan Silva	Natalie Aboustate	Redacted at Duke's request.	-
42.	14/8/19	John Curry	Natalie Aboustate & Jon Jureidini	DCRI estimate of charges for work to de-identify SAE forms. <b>Att:</b> Draft proposal of charges for de-identifying SAE forms.	4
43.	20/8/19	Jon Jureidini	John Curry	Request for itemisation of charges to de-identify SAE forms.	1
44.	21/8/19	John Curry	Jon Jureidini	Curry will organise itemisation of charges, request for IRB approval from Jureidini.	1
45.	22/8/19	Alka Srivastava (Contracts	Jon Jureidini	Draft data transfer agreement for the provision of de-identified SAE forms.	3

Item	Date	Sender	Recipient(s)	Brief description of correspondence	Number of pages
		management, Duke University)		<b>Att:</b> Draft Data Transfer agreement.	
46.	25/8/19	Jon Jureidini	John Curry	The University of Adelaide legal team will need time to review the Data Transfer Agreement.	1
47.	5/9/19	Alka Srivastava	Jon Jureidini	Request for an update on the University of Adelaide's review of the Data Transfer Agreement.	1
48.	5/6/19	Jon Jureidini	Alka Srivastava	Data Transfer Agreement is being reviewed by the University of Adelaide's legal team, will follow up.	1
49.	10/9/19	Jon Jureidini	John Curry	University of Adelaide's IRB certificate of exemption from ethical review. <b>Att:</b> letter of exemption explaining that the project is only using de-identifiable data and carries only negligible risk.	2
50.	10/9/19	Natalie Aboustate	Susan Silva	Thanking Silva for syntax and asking whether Silva would agree to answer follow up questions.	2
51.	11/9/19	John Curry	Jon Jureidini	Thanking Curry.	1
52.	12/9/19	Lawillette Wilkins (Strategic business development, Duke University)	Jon Jureidini & John Curry	Revised scope and itemised list for de-identification of SAE forms. <b>Att:</b> Revised itemised scope for de-identification of SAE forms.	4
53.	14/9/19	Jon Jureidini	Lawillette Wilkins & John Curry	Clarification of the nature of the 1128 forms when there were fewer than 100 SAEs, requesting a sample SAE form to illustrate this.	1
54.	17/9/19	Lawillette Wilkins	Jon Jureidini & John Curry	Wilkins informing Jureidini that McClanahan-Crowder is out of office currently but will respond upon return.	1
55.	18/9/19	Michelle McClanahan-Crowder (Data solutions, Duke University)	Lawillette Wilkins, Jon Jureidini & John Curry	Confirming there are 68 patient SAE folders, some patients having more than one SAE that would also have supporting documents.	1
56.	18/9/19	Alka Srivastava	Jon Jureidini	Request for update regarding legal review of the Data Transfer Agreement.	1

Item	Date	Sender	Recipient(s)	Brief description of correspondence	Number of pages
57.	20/9/19	Jon Jureidini	Alka Srivastava	Jureidini will follow up with legal team today.	1
58.	20/9/19	Jon Jureidini	Michelle McClanahan-Crowder, Lawillette Wilkins & John Curry	Seeking clarification of whether each SAE form is a single page.	1
59.	20/9/19	Michelle McClanahan-Crowder	Jon Jureidini, Lawillette Wilkins & John Curry	Confirmation that each SAE form is a single page.	1
60.	21/9/19	Jon Jureidini	Alka Srivastava	Provision of Data Transfer Agreement executed by University of Adelaide parties. <b>Att:</b> Data Transfer Agreement executed by University of Adelaide parties.	3
61.	22/9/19	Jon Jureidini	Michelle McClanahan-Crowder	Request for payment reduction for de-identification process.	1
62.	27/9/19	Alka Srivastava	Jon Jureidini & Jerry Kirchner (Duke University)	Provision of Data Transfer Agreement executed by all parties. <b>Att:</b> Data Transfer Agreement executed by all parties.	3
63.	28/9/19	Jerry Kirchner	Alka Srivastava & Jon Jureidini	Kirchner will upload agreement to Duke IRB system.	1
64.	28/9/19	Jon Jureidini	Michelle McClanahan-Crowder	Reminder of request to consider payment reduction for de-identification process.	1
65.	28/9/19	Michelle McClanahan-Crowder	Jon Jureidini	McClanahan-Crowder has requested to run proposal for payment reduction at government instead of industry rate and will update Jureidini by Monday.	1
66.	1/10/19	Lawillette Wilkins	Jon Jureidini; Michelle McClanahan-	Proposal for de-identification process at revised cost. <b>Att:</b> Revised itemised proposal for de-identification of SAE forms.	4

Item	Date	Sender	Recipient(s)	Brief description of correspondence	Number of pages
			Crowder; John Curry; Jerry Kirchner		
67.	4/10/19	Jon Jureidini	Lawillette Wilkins; Michelle McClanahan-Crowder; John Curry; Jerry Kirchner	Acceptance of revised quote for de-identification of SAE forms, request to proceed with agreed work. <b>Att:</b> Revised itemised proposal for de-identification of SAE forms.	4
68.	14/10/19	Jon Jureidini	Lawillette Wilkins; Michelle McClanahan-Crowder; John Curry; Jerry Kirchner	Request for timeline of obtaining de-identified SAE forms.	1
69.	14/10/19	Michelle McClanahan-Crowder	Jon Jureidini; Lawillette Wilkins; John Curry; Jerry Kirchner	Resources available to complete de-identification of SAE forms in November.	1
70.	20/11/19	John Curry	Jon Jureidini	Declining the provision of de-identified SAE forms.	1
71.	20/11/19	Jon Jureidini	John Curry	Reiterating the importance of SAE reporting in conducting a RIAT reanalysis and suggesting the execution of a Data Use Agreement to reassure confidentiality.	1
72.	20/11/19	Jon Jureidini	John Curry	Adding Peter Doshi (University of Maryland/ Restoring Invisible and Abandoned Trials Center) to conversation.	1
73.	21/11/19	John Curry	Jon Jureidini	Reiterating that Curry will not send the SAE reports for reasons outlined in previous email.	1
74.	22/11/19	Peter Doshi	John Curry	Explanation of RIAT analyses, reiteration of the suggestion to execute a Data Use Agreement, discussion regarding considerations of confidentiality.	1

Item	Date	Sender	Recipient(s)	Brief description of correspondence	Number of pages
75.	2/12/19	Peter Doshi	John Curry	Re-sending previous email in case it did not reach Curry.	1
76.	3/12/19	John Curry	Peter Doshi	Redacted at Duke's request.	-
77.	3/12/19	Peter Doshi	John Curry	Request for further details on final decision.	1
78.	5/12/19	Ann Bradley (Legal counsel, Duke University)	Peter Doshi	Redacted at Duke's request.	-
79.	5/12/19	Peter Doshi	Ann Bradley	Reiterating confidentiality is not breached, arguing all data should be able to be de-identified. Offer to discuss over the telephone.	1
80.	5/12/19	Ann Bradley	Peter Doshi	Redacted at Duke's request.	-
81.	5/12/19	Peter Doshi	Ann Bradley	Offering discussion with legal scholars regarding legal pathways to reassure confidentiality.	1
82.	5/12/19	Ann Bradley	Peter Doshi	Redacted at Duke's request.	-
83.	13/12/19	Peter Doshi	Ann Bradley	Request to clarify which aspect of SAE forms are difficult to de-identify, comparison with other trials' publication of SAE reports, querying whether this decision also referred to the opinion of the de-identification service. <b>Att:</b> Revised itemised proposal for de-identification of SAEs.	4
84.	13/12/19	Ann Bradley	Peter Doshi	Redacted at Duke's request.	-
85.	13/12/19	Peter Doshi	Ann Bradley	Link and screenshot of example of SAE reports from FDA public archive.	2
86.	13/12/19	Ann Bradley	Peter Doshi	Redacted at Duke's request.	-
87.	13/12/19	Peter Doshi	Ann Bradley	Asking to clarify term used in previous email.	1
88.	13/12/19	Ann Bradley	Peter Doshi	Redacted at Duke's request.	-
89.	13/12/19	Peter Doshi	Ann Bradley	Doshi will ask Jureidini for sample of SAE report from GSK trial, inquiring whether the de-identification service also concluded that de-identification of SAE forms was not possible.	1
90.	13/12/19	Ann Bradley	Peter Doshi	Redacted at Duke's request.	-
91.	13/12/19	Peter Doshi	Ann Bradley	De-identification work was meant to be done as per quote sent by DCRI. <b>Att:</b> Revised itemised proposal for de-identification of SAE forms.	4
92.	13/12/19	Ann Bradley	Peter Doshi	Redacted at Duke's request.	-



Item	Date	Sender	Recipient(s)	Brief description of correspondence	Number of pages
93.	13/12/19	Peter Doshi	Ann Bradley	Asking whether de-identification experts had also been consulted to confirm SAE narratives cannot be de-identified.	1
94.	13/12/19	Ann Bradley	Peter Doshi	Redacted at Duke's request.	-
95.	13/12/19	Peter Doshi	Ann Bradley	Clarifying whether de-identification experts themselves said they could not de-identify narratives.	1
96.	13/12/19	Ann Bradley	Peter Doshi	Redacted at Duke's request.	-
97.	13/12/19	Peter Doshi	Ann Bradley	Request to clarify de-identification issue over the telephone.	1
98.	13/12/19	Ann Bradley	Peter Doshi	Redacted at Duke's request.	-
99.	13/12/19	Peter Doshi	Ann Bradley	Organising a time to speak over the telephone.	1
100.	18/12/19	Peter Doshi	Ann Bradley	Link to example of SAE reports from GSK and inquiring whether they compare to TADS SAE forms.	1
101.	20/12/19	Ann Bradley	Peter Doshi	Redacted at Duke's request.	-
102.	21/12/19	Peter Doshi	Ann Bradley	Thanking Bradley for her work.	1
103.	21/1/20	Natalie Aboustate	Kelly Posner Gerstenhaber (The Columbia Lighthouse Project)	Inquiring whether Columbia received any SAE reports. <b>Att:</b> Data use agreement between Jureidini and NIMH; Blank TADS SAE form. Attachment not reproduced for copyright reasons.	14
104.	4/2/20	Natalie Aboustate	Kelly Posner Gerstenhaber	Requesting acknowledgement of receipt of previous email. <b>Att:</b> Data use agreement between Jureidini and NIMH; Blank TADS SAE form. Attachment not reproduced for copyright reasons.	15
105.	25/6/20	Bijan Esfandiari (Baum Hedlund Aristei Goldman Consumer Attorneys)	Ann Bradley	Letter containing legal arguments and demanding Duke adhere to the terms of the executed Data Transfer Agreement.	5
106.	~/6/20	Ann Bradley	Bijan Esfandiari	Redacted at Duke's request.	-
107.	22/7/20	Natalie Aboustate	The Columbia Lighthouse Project	Contact submission form requesting contact with Posner Gerstenhaber for information about TADS SAEs.	2
108.	7/8/20	Natalie Aboustate	John Curry	Seeking TADS procedural documents that were not made available online despite apparently being published.	2

Item	Date	Sender	Recipient(s)	Brief description of correspondence	Number of pages
				<b>Att:</b> TADS publication regarding methodology (2003). Attachment not reproduced for copyright reasons.	
109.	8/8/20	Ann Bradley	Jon Jureidini	Redacted at Duke's request.	-
110.	14/8/20	Jon Jureidini	Ann Bradley	Baum, Hedland, Aristei, Goldman PC are not taking further action.	1
111.	14/8/20	Ann Bradley	Jon Jureidini	Redacted at Duke's request.	-
112.	15/8/20	John Curry	Natalie Aboustate	Provision of requested documents and explanation regarding those missing. <b>Att:</b> CBTA form; TADS publication policy; TADS suicide prevention manual; TADS Independent Evaluator manual; CBT quality assurance document; Formulation and treatment plan form. Attachments not reproduced at Curry's request.	7
113.	15/8/20	John Curry	Natalie Aboustate	Description of TADS in-service manual that should be included in the NIMH's public access data use package.	1
114.	17/8/20	John Curry	Natalie Aboustate	Request to confirm that the TADS documents Curry sent on 15/8/20 will not be disseminated.	1
115.	18/8/20	Natalie Aboustate	John Curry	Aboustate confirming that the TADS documents Curry sent on 15/8/20 will not be disseminated.	1
116.	8/10/20	Ann Bradley	Natalie Aboustate; Jon Jureidini	Redacted at Duke's request.	-
117.	10/10/20	Ann Bradley	Natalie Aboustate; Jon Jureidini	Redacted at Duke's request.	-
118.	12/10/20	Natalie Aboustate	Ann Bradley	Accepting revised text for manuscript and plan to publish correspondence.	1
119.	12/10/20	Ann Bradley	Natalie Aboustate; Jon Jureidini	Redacted at Duke's request.	-
120.	13/10/20	Natalie Aboustate	Ann Bradley	Provision of email correspondence received from Duke for planned publication.	1

Item	Date	Sender	Recipient(s)	Brief description of correspondence	Number of pages
				<b>Att:</b> pdf versions of correspondence received from Duke. Attachment not reproduced for brevity's sake and/ or due to lack of permission received from Duke.	
121.	20/10/20	Ann Bradley	Natalie Aboustate	Redacted at Duke's request.	-
122.	20/10/20	Natalie Aboustate	Ann Bradley	Explanation of correspondence for planned inclusion or exclusion. <b>Att:</b> pdf versions of correspondence received from Duke. Attachment not reproduced for brevity's sake and/ or due to lack of permission received from Duke.	1
123.	21/10/20	Ann Bradley	Natalie Aboustate	Redacted at Duke's request.	-
124.	21/10/20	Natalie Aboustate	Ann Bradley	Confirming emails to Doshi will not be included.	1
125.	21/10/20	Ann Bradley	Natalie Aboustate	Redacted at Duke's request.	-
126.	22/10/20	Natalie Aboustate	Ann Bradley	Reaffirming emails to Doshi will not be included.	1
127.	12/11/20	Natalie Aboustate	Ann Bradley	Request to review one item of correspondence missing from initial review by Bradley. <b>Att:</b> pdf version of Appendix A, item 38. Attachment not reproduced for brevity's sake.	1
128.	12/11/20	Ann Bradley	Natalie Aboustate	Redacted at Duke's request.	-
129.	12/11/20	Natalie Aboustate	Ann Bradley	Thanking Bradley.	1
130.	24/11/20	Natalie Aboustate	John Curry	Proposing Duke analyse the SAE reports and write up the data, as SAEs are not completely reported by TADS literature. Request for more detailed electronic records or databases that contain the timing of medication administration in association with adverse events.	2
131.	4/12/20	Natalie Aboustate	John Curry	Asking whether Curry will consider the proposal and suggesting that Aboustate send through only specific TADS patient IDs that have missing data for medication at the time of their adverse events.	1

Item	Date	Sender	Recipient(s)	Brief description of correspondence	Number of pages
132.	8/12/20	Ann Bradley	Natalie Aboustate	Redacted at Duke's request.	-
133.	8/12/20	Natalie Aboustate	Ann Bradley	Thanking Bradley.	1
134.	16/12/20	Ann Bradley	Natalie Aboustate	Redacted at Duke's request.	-
135.	23/12/20	Natalie Aboustate	Ann Bradley	Questions about the SAE report recently sent by Bradley regarding concomitant medications, linking case IDs, unreportable SAEs, sharing safety reports and requesting permission to report on this document.	1
136.	7/1/21	Ann Bradley	Natalie Aboustate	Redacted at Duke's request.	-
137.	10/1/21	Natalie Aboustate	Ann Bradley	Requesting confirmation of whether Duke will write up the SAE data, and questions about: the timing of concomitant medication administration, whether the IRB violation invalidates data on outcomes, nature of confidentiality agreement with the NIMH and FDA, RIAT reporting on SAEs. <b>Att:</b> template TADS treatment log form TADS. Attachment not reproduced for copyright reasons.	1
138.	21/1/21	Ann Bradley	Natalie Aboustate	Redacted at Duke's request.	-
139.	27/1/21	Natalie Aboustate	Ann Bradley	Follow up questions about the SAE report sent by Bradley regarding timing of concomitant medications, confirming report will not be redistributed and inquiring whether correspondence to date can also be published. <b>Att:</b> template TADS concomitant medication log form. Attachment not reproduced for copyright reasons.	3
140.	5/2/21	Natalie Aboustate	Ann Bradley	Setting deadline for response from Duke.	1
141.	5/2/21	Ann Bradley	Natalie Aboustate; Jon Jureidini	Redacted at Duke's request.	-
142.	17/2/21	Natalie Aboustate	Ann Bradley	Response to rescission of approval to publish certain correspondence and confirmation of correspondence to be published.	1

<b>Item</b>	<b>Date</b>	<b>Sender</b>	<b>Recipient(s)</b>	<b>Brief description of correspondence</b>	<b>Number of pages</b>
143.	17/2/21	Ann Bradley	Natalie Aboustate	Redacted at Duke's request.	-
144.	17/2/21	Natalie Aboustate	Ann Bradley	Reiteration of correspondence previously approved for publication by Duke.	1

**Appendix B.** Correspondence regarding obtaining individual patient level data for serious adverse events (SAEs) that occurred during TADS from Eli Lilly & Company for RIAT reanalysis.

Table B1. An index of correspondence regarding obtaining individual patient level data from TADS. Items are listed in chronological order, where each row provides the date of correspondence in day/month/year format, sender, primary recipient(s), a brief description of the subject matter, any associated attachments ('Att'), and the total number of pages of the published document. Hyperlinks, and personal and contact details have been redacted from all correspondence for privacy reasons.

Item	Date	Sender	Recipient(s)	Brief description of subject matter	Number of pages
1.	05/7/2018	Medical Information (Lilly)	Jon Jureidini	Redacted at Lilly's request.	-
2.	08/07/18	Jon Jureidini	Medical Information (Lilly)	Reiterating request for TADS SAE narratives on grounds that the TADS protocol mandated reporting to Lilly.	1
3.	18/9/18	Jon Jureidini	Medical Information (Lilly)	Jureidini requesting response to email sent 08/07/18.	1
4.	25/09/18	Medical Information (Lilly)	Jon Jureidini	Redacted at Lilly's request.	-
5.	02/11/18	Jon Jureidini	Eli Lilly Australia	Excerpt from TADS study protocol reiterating that Lilly must have received SAE reports.	1
6.	5/11/18	Medical Information (Lilly)	Jon Jureidini	Redacted at Lilly's request.	-
7.	20/1/20	Natalie Aboustate	Medical Information (Lilly)	Reiteration of Jureidini's contact in 2018, request for SAE narratives given the study protocol's instructions and FDA's post-marketing requirements for fluoxetine. <b>Att:</b> FDA publicly available letter from 2013 regarding fluoxetine's supplemental approval, TADS blank SAE form, TADS protocol excerpt regarding adverse event reporting, TADS AE and ASAP Manual. Attachments are not reproduced for copyright reasons.	6
8.	4/2/20	Natalie Aboustate	Medical Information (Lilly)	Requesting acknowledgement of receipt of email sent 20/1/20. <b>Att:</b> FDA publicly available letter from 2013 regarding fluoxetine's supplemental approval, TADS blank SAE	5

				form, TADS protocol excerpt regarding adverse event reporting, TADS AE and ASAP Manual. Attachments are not reproduced for copyright reasons.	
9.	4/2/20	Medical Information (Lilly)	Natalie Aboustate	Redacted at Lilly's request.	-
10.	4/2/20	Natalie Aboustate	Medical Information (Lilly)	Thanking Lilly.	1
11.	5/2/20	Medical Information (Lilly)	Natalie Aboustate	Redacted at Lilly's request.	-
12.	5/2/20	Natalie Aboustate	Medical Information (Lilly)	Reiteration of request for SAE reports given that TADS protocol and SAE forms state that SAE reports must be sent to Lilly. <b>Att:</b> TADS blank SAE form, TADS protocol excerpt regarding adverse event reporting, TADS AE and ASAP Manual. Attachments are not reproduced for copyright reasons.	5
13.	10/2/20	Peter Doshi	Medical Information (Lilly)	Request for data given that protocol said Lilly should receive these data.	1

**Appendix C.** Correspondence with the US Food and Drug Administration (FDA) and its affiliates (former and current) regarding obtaining information on SAEs that occurred during TADS for RIAT reanalysis.

Table C1. An index of correspondence regarding obtaining information on SAEs that occurred during TADS for RIAT reanalysis. Items are listed in chronological order, where each row provides the date of correspondence in day/month/year format, sender, primary recipient(s), a brief description of the subject matter, any associated attachments ('Att'), and the total number of pages of the published document. Hyperlinks, and personal and contact details have been redacted from all correspondence for privacy reasons.

<b>Item</b>	<b>Date</b>	<b>Sender</b>	<b>Recipient</b>	<b>Brief description of subject matter</b>	<b>Number of pages</b>
NA	Early 2019	Jon Jureidini/ Natalie Aboustate (University of Adelaide)	Freedom of Information Act (FOIA) Division	<i>Online submission form, not reproduced as our record has been lost.</i>	-
1.	8/5/19	Sarah Kotler (Division of Freedom of Information)	Natalie Aboustate	Denying expedited processing of abovementioned FOIA request for TADS data.	2
2.	18/7/19	Natalie Aboustate	Marieann Brill (Office of the Commissioner/ Office of Pediatric Therapeutics)	Request for any records or data pertaining TADS submitted to the FDA. <b>Att:</b> letter from Aboustate outlining details of this request; emails outlining approval of data access request; Publication regarding RIAT reanalysis efforts (2013; not reproduced for copyright reasons); BMJ publication outlining Call to Action for the RIAT reanalysis of TADS (2013; not reproduced for copyright reasons); executed Data use agreement with the NIMH.	20
3.	20/7/19	Marieann Brill	Natalie Aboustate	Provision of link to submit request through FOIA.	1



Item	Date	Sender	Recipient	Brief description of subject matter	Number of pages
4.	20/7/19	Center for Drug Evaluation and Research (CDER) Drug Info	Natalie Aboustate	CDER SBIA to provide further information upon consultation with additional experts. <b>Att:</b> letter from Aboustate outlining details of this request; emails outlining approval of data access request; Publication regarding RIAT reanalysis efforts (2013; not reproduced for copyright reasons); BMJ publication outlining Call to Action for the RIAT reanalysis of TADS (2013; not reproduced for copyright reasons); executed Data use agreement with the NIMH.	19
5.	30/7/19	FDA	Natalie Aboustate	Confirmation receipt of request.	1
6.	30/7/19	Natalie Aboustate	CDER Drug Info	Thanking the CDER and informing of submission through FOIA link supplied by Brill.	1
7.	1/8/19	FOIA Division	Natalie Aboustate	Confirming receipt of request.	2
8.	9/9/19	Natalie Aboustate	FOIA Division	Request for list of contents or description of any data related to TADS held by the FDA.	2
9.	4/10/19	Natalie Aboustate	CDER Drug Info	Request for contents or description of any data related to TADS held by the FDA.	2
10.	10/10/19	CDER Small Business & Industry Assistance (SBIA)	Natalie Aboustate	No additional information from subject matter experts, referral to FOI team.	1
11.	14/10/19	Natalie Aboustate	FOIA Division	Letter of request for contents or description of any data related to TADS held by the FDA. <b>Att:</b> letter of request; executed NIMH Data Use Agreement; emails outlining approval of data access request.	17
12.	19/10/19	FOIA Division	Natalie Aboustate; Sudarshini Satchi (FOI team, CDER)	Request assignment to CDER. <b>Att:</b> letter of request; emails outlining approval of data access request.	5
13.	22/10/19	Natalie Aboustate	FOIA Division; Sudarshini Satchi	Thanking FDA FOIA and Satchi.	1

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14.	7/2/20	Natalie Aboustate	Sudarshini Satchi; FOIA Division	Request for update on request for contents or description of any data related to TADS held by the FDA.	1
15.	7/2/20	Sudarshini Satchi	Natalie Aboustate	Out of office reply.	1
16.	23/3/20	Jon Jureidini	FOIA Division	FDA FOIA online request form not working, providing letter of request instead. <b>Att:</b> Letter from Jureidini seeking documentation of all SAEs related to TADS.	2
17.	29/4/20	Natalie Aboustate	Tarek Hammad	Noting that Hammad reanalysed TADS data and asking whether Duke provided deidentified data to the FDA for the purposes of the reanalysis.	1
18.	29/4/20	Tarek Hammad (former FDA affiliate)	Natalie Aboustate	Redacted at Hammad's request.	-
19.	30/4/20	Natalie Aboustate	Tarek Hammad	Thanking Hammad for this information, request for contact at Columbia University.	1
20.	30/4/20	Tarek Hammad	Natalie Aboustate	Redacted at Hammad's request.	-
21.	7/5/20	Natalie Aboustate	Tarek Hammad	Thanking Hammad.	1
22.	7/5/20	Natalie Aboustate	[Recipient redacted]	Request to confirm whether FDA received patient level data from TADS regarding SAEs for RIAT reanalysis.	4
23.	7/5/20	Natalie Aboustate	Andrew Mosholder	Noting that Mosholder reanalysed TADS data and asking whether Duke provided deidentified data to the FDA for the purposes of the reanalysis.	2
24.	8/5/20	Andrew Mosholder (CDER)	Natalie Aboustate	Redacted at Mosholder's request.	-
25.	14/5/20	Natalie Aboustate	Andrew Mosholder	Thanking Mosholder.	1
26.	31/7/20	Natalie Aboustate	Sudarshini Satchi; FOIA Division	Request for update on request for contents or description of any data related to TADS held by the FDA.	1
27.	4/8/20	Sudarshini Satchi	Natalie Aboustate	Request is tagged as complex and will, on average, take at least 2 years to process.	1