

From: [Anneka Tomlinson](#)
To: [Yale Open Data Access Project](#)
Cc: [Samuele Cortese](#); [Samuele Cortese](#)
Subject: Re: Follow Up RE: Final Signed DUA (YODA Project Protocol #2022-4930)
Date: Friday, October 3, 2025 5:55:33 AM
Attachments: [image001.png](#)
[image003\[11\].png](#)
[image004\[18\].png](#)

Dear Jessica

I hope you are well.

We just wanted to update you on additional analyses we wish to carry out, I copy below for transparency the correspondence with Vivli. Please do let us know if you require any further information:

Dear Vivli Team,

We are contacting you to request clarification regarding the following.

As per your protocol, we will conduct an IPD NMA that will determine the effect size of ADHD medications, as well as potential moderators. In discussions with peers, it became clear that a potential critique by reviewers—based on previously published papers (e.g., <https://pubmed.ncbi.nlm.nih.gov/26608309/>)—may question the accuracy of effect sizes due to possible unblinding from medication side effects. For instance, Storebo et al (<https://pubmed.ncbi.nlm.nih.gov/26608309/>) assert that it is not possible to fully trust effect sizes in meta-analyses of RCTs because participants may guess the allocation due to side effects. However, this has never been empirically proven.

We would therefore like to use the efficacy and safety data from placebo-controlled stimulant RCTs in children and adults to examine whether the effect sizes (within and between groups) differ between those with and without side effects. Although this analysis was not explicitly stated in our protocol, we consider it necessary to better estimate the accuracy of the conclusions of our main analyses in the portal.

We would greatly appreciate your feedback as to whether this would be an allowable use of the data.

Thank you Anneka and Samuele

Dear Dr. Tomlinson,

Thank you for reaching out to us and noting that you would like to perform additional analysis. Please note that according to Vivli policy any changes to the Statistical Analysis Plan will require that data contributors have the opportunity to re-review your data request and have it go through their entire approval process.

Given that your request is in the Data upload stage, we will reach out to the Data Contributor Teams with your request. The Data Contributors can approve this or they may request a formal review of your proposal in a separate application. Either way, you can have access to the existing data. We will let you know when we receive a reply to your request and advise on next steps. Thank you.

Please note that you will also need to reach out to YODA and follow their process for making changes to your YODA request. Any changes made to the YODA request will need to be reflected in your Vivli request and vice versa. We will need you to provide a new approval email from them as well.

Regards,
The Vivli team

Dr Anneka Tomlinson, BSc(hons), MPhil, BM BCh(oxon), PhD, MRCPsych

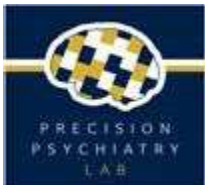
*Academic Clinical Fellow, Department of Psychiatry, University of Oxford
Teaching Associate, Green Templeton College, University of Oxford*

[Department of Psychiatry,](#)

University of Oxford,

Warneford Hospital, Oxford OX3 7JX, UK

Email: anneka.tomlinson@psych.ox.ac.uk; Anneka.tomlinson@oxfordhealth.nhs.uk



From: Yale Open Data Access Project <yodap@yale.edu>

Date: Wednesday, 13 August 2025 at 18:46

To: Anneka Tomlinson <anneka.tomlinson@psych.ox.ac.uk>

Cc: Samuele Cortese <Samuele.Cortese@soton.ac.uk>, Amrutha (Vivli User Support) <support@vivli.org>

Subject: RE: Follow Up RE: Final Signed DUA (YODA Project Protocol #2022-4930)

Hi Anneka,

Thank you for letting us know. We have added these trials to your data request and it is approved on our end.

Regards,
Molly
On behalf of the YODA Project

From: Anneka Tomlinson <anneka.tomlinson@psych.ox.ac.uk>
Sent: Wednesday, August 13, 2025 11:53 AM
To: Yale Open Data Access Project <yodap@yale.edu>
Cc: Samuele Cortese <Samuele.Cortese@soton.ac.uk>
Subject: Re: Follow Up RE: Final Signed DUA (YODA Project Protocol #2022-4930)

Dear Jessica

I hope you are well

We just wanted to update you (as per vivli policy) that we have applied for access to data to 4 additional trials:

- NCT02466425
- NCT03325881
- ID 1306A3122
- ID 1411A3223

Vivli have kindly asked for you to send a letter of approval, stating that you are happy for us to proceed with the inclusion of these trials.

Thank you
Anneka and Samuele

Dr Anneka Tomlinson, BSc (hons), BM BCh, PhD, MRCPsych

*Academic Clinical Fellow, Department of Psychiatry, University of Oxford
Teaching Associate, Green Templeton College, University of Oxford*

[Department of Psychiatry,](#)
University of Oxford,
Warneford Hospital, Oxford OX3 7JX, UK

Email: anneka.tomlinson@psych.ox.ac.uk; anneka.tomlinson1@nhs.net

From: Yale Open Data Access Project <yodap@yale.edu>
Sent: Tuesday, May 20, 2025 3:13:17 PM
To: Anneka Tomlinson <anneka.tomlinson@psych.ox.ac.uk>
Cc: Samuele Cortese <Samuele.Cortese@soton.ac.uk>
Subject: RE: Follow Up RE: Final Signed DUA (YODA Project Protocol #2022-4930)

Dear Dr Tomlinson,

If Dr. Efthimiou needs access to the Janssen data on Vivli, please have them complete our [DUA Training](#) as soon as possible. If they do not need access, please let Vivli know.

Thank you,
Jessica
On behalf of the YODA Project

From: Yale Open Data Access Project <yodap@yale.edu>
Sent: Friday, March 21, 2025 8:12 AM
To: Anneka Tomlinson <anneka.tomlinson@psych.ox.ac.uk>
Cc: Samuele Cortese <Samuele.Cortese@soton.ac.uk>
Subject: RE: Follow Up RE: Final Signed DUA (YODA Project Protocol #2022-4930)

Hi Dr Tomlinson,

Apologies for the second email- if Dr. Efthimiou needs access to the data on Vivli, please have them complete our [DUA Training](#) as soon as possible.

Thank you,
Jessica
On behalf of the YODA Project

From: Anneka Tomlinson <anneka.tomlinson@psych.ox.ac.uk>
Sent: Thursday, March 20, 2025 3:17 PM
To: Yale Open Data Access Project <yodap@yale.edu>; Samuele Cortese <Samuele.Cortese@soton.ac.uk>
Subject: Re: Follow Up RE: Final Signed DUA (YODA Project Protocol #2022-4930)

Dear Team

the correct affiliation is - University of Bern

This has been updated on Vivli too

BW

Dr Anneka Tomlinson, BSc (hons), BM BCh, PhD, MRCPsych

*Academic Clinical Fellow, Department of Psychiatry, University of Oxford
Teaching Associate, Green Templeton College, University of Oxford*

[Department of Psychiatry,](#)

University of Oxford,

Warneford Hospital, Oxford OX3 7JX, UK

Email: anneka.tomlinson@psych.ox.ac.uk; anneka.tomlinson1@nhs.net

From: Yale Open Data Access Project <yodap@yale.edu>

Sent: Thursday, March 20, 2025 7:15:18 PM

To: Samuele Cortese <Samuele.Cortese@soton.ac.uk>; Anneka Tomlinson
<anneka.tomlinson@psych.ox.ac.uk>

Subject: RE: Follow Up RE: Final Signed DUA (YODA Project Protocol #2022-4930)

Hi Dr. Cortese,

Do you still need to update the affiliation of Dr. Orestis Efthimiou as well?

Thank you,

Jessica

On behalf of the YODA Project

From: Samuele Cortese <Samuele.Cortese@soton.ac.uk>

Sent: Wednesday, March 5, 2025 12:59 PM

To: Yale Open Data Access Project <yodap@yale.edu>; Anneka Tomlinson
<anneka.tomlinson@psych.ox.ac.uk>

Subject: Re: Follow Up RE: Final Signed DUA (YODA Project Protocol #2022-4930)

Dear Jessica, many thanks- we will action this ASAP

all the best

s

Samuele Cortese, M.D., Ph.D.

NIHR Research Professor

Full Professor of Child and Adolescent Psychiatry, University of Southampton, UK

Honorary Consultant Child and Adolescent Psychiatrist, Solent NHS Trust, UK

Full Professor of Child and Adolescent Neuropsychiatry, University of Bari "Aldo Moro", Italy

Adjunct Full Professor, Department of Child and Adolescent Psychiatry, NYU Grossman School of Medicine, New York, USA

<https://www.southampton.ac.uk/people/5xf5yj/professor-samuele-cortese>

Research Administrator: Tanya Palmer, tep@soton.ac.uk



From: Yale Open Data Access Project <yodap@yale.edu>

Sent: 04 March 2025 19:58

To: Samuele Cortese <Samuele.Cortese@soton.ac.uk>

Subject: Follow Up RE: Final Signed DUA (YODA Project Protocol #2022-4930)

CAUTION: This e-mail originated outside the University of Southampton.

Hi Dr. Cortese,

Vivli let us know you need to change the affiliation of Dr. Orestis Efthimiou- can you please provide their updated information? If they require data access, please have them complete the [DUA training](#).

If you have any new team members, please have them complete the [COI Form](#) and [DUA training](#) (if they require access).

Regards,
Jessica
On behalf of the YODA Project

From: Yale Open Data Access Project
Sent: Wednesday, February 5, 2025 12:28 PM
To: Cortese S. <Samuele.Cortese@soton.ac.uk>
Subject: RE: Final Signed DUA (YODA Project Protocol #2022-4930)

Hi Dr. Cortese,

Vivli let us know you need to change the affiliation of your statistician can you please provide their updated information?

Regards,
Jessica
On behalf of the YODA Project

From: Yale Open Data Access Project
Sent: Friday, January 17, 2025 1:44 PM
To: Cortese S. <Samuele.Cortese@soton.ac.uk>
Cc: Amrutha (Vivli User Support) <support@vivli.org>
Subject: Final Signed DUA (YODA Project Protocol #2022-4930)

Dear Dr. Cortese,

I am happy to share the attached final DUA, signed by Yale University, for access to the data requested in YODA Project Protocol #2022-4930/Vivli#7846. Please keep this for your records. The DUA expiration date is 1/14/26.

The data will not be made available on the Vivli platform until Vivli notifies the YODA Project that the full multi-sponsor data request has been approved. Data access is approved for you and Dr. Cipriani.

If any new team members require data access, please notify the YODA Project to complete additional steps for access approval. Per your DUA, credentials cannot be shared.

Thank you again for your interest in this project. As always, please contact the YODA Project at yodap@yale.edu with any questions.

Regards,
Jessica

On behalf of the YODA Project