



HELLO



Laura Saville (left) & Lindsay Pliskin (right) at the Data Coordinating Centre in Liverpool

Speech Meetings

The last speech meeting in March 2016 was a huge success! The next TOPS 12-month speech rating meeting will be **November 14th –17th 2016, Manchester UK.**

The Core Speech and Language Therapy Team also plan to visit our Bauru site to rate 12 month recordings October 3rd-7th 2016. We now invite all TOPS Speech and Language Therapists to a meeting **March 6th-8th, 2017, Midland Hotel Manchester UK.**

New TOPS Team Members!

The Data Coordinating Centre in Liverpool has welcomed a new Trial Coordinator, Lindsay Pliskin.

Laura Saville also joined the TOPS team as Data Manager alongside Paul Tate. Both Laura and Lindsay started work on TOPS in mid-April 2016.

At the Administrative Centre in Manchester, Reetu Child has joined the TOPS Trial alongside Phil Eyres.

We're making the rounds again!

The TOPS Trial Management Group are planning for site visits to all participating sites and will be in touch soon!

If there is anything you think your site needs specific guidance or help with, please contact Lindsay Pliskin at the TOPS email account.

It would be great to hear your opinion!

Data Queries Have Changed

You will notice in the near future that the old Data Query Form has had a makeover.

The new Data Clarification Form condenses multiple queries onto just one page and you only have to sign it off once.

If you have any questions about the Data Clarification Form or any data queries in general, email Paul Tate at tops.trial@liv.ac.uk



Who's best to answer my question?

Data Coordinating Centre

Lindsay Pliskin:
+44 (0)151 282 4727
tops.trial@liv.ac.uk

General trial inquiries
TOPS website
Safety reporting
Site visits

Paul Tate:
+44 (0) 151 282 4725
tops.trial@liv.ac.uk

Data Queries
CRF questions and guidance
USB questions

Laura Saville:
+44 (0) 151 282 4705
tops.trial@liv.ac.uk
Speech recordings
Surgical and five-year photographs

Administrative Centre

Linda Norman:
+44 (0) 161 275 6783
linda.norman@manchester.ac.uk

Travel and conference arrangements
Materials and equipment for sites
Translations of trial documents
Invoices and reimbursements

Phil Eyres:
+44 (0) 161 275 6809
phil.eyres@manchester.ac.uk
Maxillary arch and dental impressions

Dieter Weichart:
+44 (0) 161 275 6792
d.weichart@manchester.ac.uk

Contracts and other legal matters
Finances: budgets and invoices
Planning of trial meetings
Ethics approvals outside the UK

When do we follow up?

The first TOPS patients are now returning for their five year visits. As this visit is when the primary outcome of speech is assessed, as many patients as possible (unless parents have explicitly withdrawn their consent) should be encouraged to attend.

Please complete as many assessments as possible. Email Lindsay Pliskin if you are not sure or have questions.

Protocol Amendment Status

The TOPS protocol amendment which includes the Intelligibility in Context Assessment at age 5 together with approval to contact local Speech and Language Therapists about local therapy has been approved and rolled out across all UK and Swedish sites.

Approval and rollout at Brazilian, Danish and Norwegian sites are pending country specific approvals.

TOPS Financial Annual Award Received

As expected, and as each year so far, the annual funding award has now been confirmed and the budgets are set until the end of June 2017. In line with the US annual budget, the NIH provide the project budgets on an annual basis, depending on acceptance of our reports. This is great news, once again, and we send a huge thank you to all for your continued hard work on TOPS!

Data Transmission Guidance

CRF forms should only be sent via fax or by post.

If you would like additional information on Data Transmission procedures for TOPS, please find the guidance document on the TOPS website on the researchers page in "other forms."