



## Timing Of Primary Surgery for Cleft Palate

# NEWSLETTER

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### TOPS 12 MONTH ASSESSMENTS NOW COMPLETE!

Following the success of our March 2016 speech meeting, our Core Speech and Language Therapy team travelled to our TOPS site in Bauru, Brazil in October to carry on with the 12 month recording assessments. This was a great success and laid the foundations for completing the 12 month recording assessments during the Manchester speech meeting in November.



Season's Greetings



With the successful return of all expected 12 month recordings, many of our Speech and Language Therapists joined us in Manchester November 14-18 to assess the remaining 12 month recordings. This went extremely well and even included a sing-a-long after dinner one night!

Between sing-a-longs and a walking tour of Manchester city centre, each of our dedicated SLTs were able to complete assessments for at least twenty-one patients each in just four days!

The next stop for many of the TOPS team will be India.

Best of luck and safe travels to those of you attending the International Cleft Conference in Chennai, India in February.

Following the Holiday Season, we hope to see all of our Speech and Language Therapy Team in Manchester in March 2017. The next big TOPS meeting is at The Midland Hotel. The meeting will take place between Sunday 5th March (arrival day for most residential delegates) and Wednesday 8th March 2017.

The actual meeting will start on the morning of Monday 6th March and finish at lunchtime on Wednesday 8th March. Beth Conroy (DCC Statistician) and Lindsay Pliskin (DCC Trial Coordinator) will also be attending the meeting to discuss any issues or answer any questions you may have.



Please contact Linda Norman with any questions regarding the meeting.



**We're trying to reduce the number of data queries we send out!**

The DCC are currently working through each of the CRF forms with our Chief Investigator while keeping patient safety and primary outcome data at the forefront. However, we have been able to identify some areas that do not affect either of these things and therefore could be removed from the list of items that we ask sites to clarify. Therefore, you may start to notice a reduction in the amount of data queries received from the DCC very soon.

Something to smile about this holiday season.

The fruits of our labour are really paying off; all eligibility, screening and genetics forms for 12 months have been completed and returned. Brilliant work!

We are also very close to obtaining all of the surgical forms and the rest of the 12 month forms!

## Protocol Amendment Update

After receiving ethical approval in late November, our Brazilian colleagues are the latest members of the TOPS team to start working to Protocol Version 4.0 and associated documents. This means everyone in England, Scotland, Wales, Northern Ireland, Sweden, Norway and Brazil are finally on the same version of the protocol and should be obtaining the additional consent from patients which allows the ICS (Intelligibility in Context Scale) questionnaire and the letter to local speech therapists at five years.

Hang in there, Danish colleagues; we expect an ethical approval letter which covers Århus and Copenhagen on the amendment very soon too!

## TOPS Additional Information and Consent, please try to remember...



When TOPS concludes, we should have two consent forms for most of our patients; the original consent form and the additional consent that came into action with ethical approval of protocol version 4.0 in each country. The only patients for whom we will have just one consent (only the original) will be the few that completed all TOPS visits before Protocol amendment 4.0 was approved in your country. Once your country has had ethical approval for protocol version 4.0 and associated documents, TOPS Additional Information and Informed Consent can be completed at any time. It affects our permission to contact local SLTs at three years and five years and to do the ICS questionnaire at five years.

-Children who have already completed three year visits and will now be attending for five year visits: The additional consent can be filled in any time before or during the five year visit. This allows us to do the ICS questionnaire and contact their local SLT at five years.

-For Children coming in for three year visits now: The additional consent form can be filled in at any time before or during the three year visit. This allows us to contact local SLTs at three years and then we have it on file so we can contact local SLTs and to do the ICS questionnaire at five years when they come back (this does not require them to fill out the additional consent form again.)



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