

## GlobalSurg 3 National Leads online Meeting Minutes and Validation Information - September 18<sup>th</sup> 2018

Welcome to everyone on the call and thank you joining

GlobalSurg 3 is progressing extremely well and everyone should be extremely pleased with progress to date – thank you all!

### GlobalSurg 3 General update:

Countries now registered to take part = 93; a big increase compared to GS2  
Teams = 990, at 517 hospitals,  
Data entry = 4475 patient records started; 2856 complete so far  
Live updates are always available at [data.globalsurg.org](http://data.globalsurg.org)

Important to note that many countries have yet to start data entry – so far, approximately 60 out of 93 countries have begun data entry; this is 234 out of 517 registered hospitals, and 370/990 teams

We are aiming for >10,000 patients; we believe we're on track for this target based on data entry trajectory and we know some teams have data on paper forms not yet submitted to REDCap.

It's really important to encourage as many teams as possible to collect and enter data into REDCap – please help them to convert their initial enthusiasm into data entry

October will be the final month of data collection – all 4 week data collection periods should be completed by Oct 31<sup>st</sup>. 30-day follow-up data for patients collected in October will be collected in November, but no new patients should be collected after 31<sup>st</sup> October. For any hospitals still completing ethics approvals etc, remember the teams need to start data collection by the first week of October if they are to have chance to take part

Please encourage collaborators to complete the Data Collection Completion form in the authorship project of REDCap – this provides information essential to the analyses and prepares data periods for validation by confirming the data entry for the team's period is complete

Further instructions on doing this can be found at these links

<http://globalsurg.org/additional-guides-to-using-redcap-in-globalsurg-3/>

REDCap user guide 4: data collection & entry completion

<http://globalsurg.org/globalsurg-3-protocol-project-documentation/>

Email reminders will be sent to collaborators with these instruments

Essential for all National Leads not in a data collection team to send us their ORCID ID and details for the purposes of the authorship list. A REDCap survey to collect national lead ORCID IDs has been circulated previously; a reminder to those who have not yet completed will be emailed in the next few days

## GlobalSurg 3 Validation Exercise

The purpose of validation exercise is to demonstrate that GlobalSurg data collection processes and the primary dataset are robust and reliable. It's essential to the success of the study. It is an observation of the dataset; the purpose is not to remove, modify or correct the primary dataset

Validator registration will begin from today; the period for data checking will begin Oct 8<sup>th</sup>

Over the next month we need to register 1 validator at each participating hospital that has been collecting primary data.

You may know individuals who wished to take part in the study and were not able to do so; this is a good opportunity for them to take part. All validators will receive authorship as primary data collectors do.

**The validator can not be someone who has taken part in a primary data collection team;** they need to be independent of the team

Validator App:

<https://argoshare.is.ed.ac.uk/validation/>

This dashboard will show hospitals where validators are needed and where a validator has already registered. It will update every minute or so throughout the process.

We would like National Leads, helped by Hospital leads, to identify a validator at each hospital.

When you have identified a validator please forward them the link supplied separately.

This will allow them to register as a validator at their hospital.

In the next newsletter to be circulated after the meeting, we will issue a call for validators. Interested collaborators will be asked to contact their National Lead via the contact form on our website so you may notice an increase in emails received via this form.

Please first check if a validator is registered at the hospital the emailer is interested in validating using the Validator App above; if a validator is still required, please forward them the link to register as a validator for GS3.

The validation study has 2 main aims:

1. Case ascertainment – to ensure all the patients that should have been included at a given hospital have been, and to sure no patients that should have been excluded have been included
2. Check a small number of variable are entered correctly – please see validation guide for details of the variables to be checked

This should be relatively straightforward and we hope the processes are more streamlined than was used in GlobalSurg 2.

Once a validator has registered, they will receive a log in for a REDCap account that will contain all the data they need to validate. There is a facility for validators to tell us additional information such as there is no reason to believe the data is wrong but we can no longer find the records, for example if they are on a patient-held record.

We understand this part of the study is difficult for everyone, but we are blazing the trail with validation of this type of large cohort study and journals are beginnined to recognize this. GS2 almost certainly would not have been accepted by a Lancet journal without the validation exercise.

The validation user guide will be circulated to all National Leads after the meeting. It is currently only available in English – it has not been translated into the 12 languages the main protocol is available in. If translational would help, please let us know and we will look into having the user guide translated.

Validator log in details will not be available immediately after registration forms are received. There may be a delay of a few weeks. We anticipate that the first validator accounts will be available from October 8<sup>th</sup>

Please let us know how we can help you achieve the validation study – it is the most difficult aspect of the study and we are very aware of this! For example, if you have feedback or questions on the National Leads app – any extra information you need to see on the app let us know. We can also help support National Leads with many registrations in their country for example, combining all the email addresses of the teams to ease communications.

Thank you again for everyone for all your hard work on GlobalSurg 3 and good luck with validation study. We will organize the next National leads meeting soon and in the mean time please send us any questions to [enquiry@globalsurg.org](mailto:enquiry@globalsurg.org)

### **Questions arising from the meeting**

Q: *I it possible to have 2 validators at a big hospital?*

A: We do not currently have systems for this. The validation methodology describes that we will only validate 1, randomly selected, 4-week period at each hospital. If a hospital has collected all 7 months of data from April to October, just one of these months will be

selected for validation; for hospitals only collecting 1 month of data, that is the month that will be validated.

Therefore, the workload should be similar despite the hospital size – ie 1 month of data for checking.

However, we can discuss on a case-by-case basis if 2 validators are required

Q: *What is the proportion of patients that will be validated?*

A: It is 1 month, rather than a portion. If the hospital has only collected 1 month, it will be all patients; if they have collected all 7 months, it will be 1/7<sup>th</sup>

Q: *Will all patients collected during that month be checked?*

A: Yes – it's all of the patients rather than a subset. But not every variable for each patient

Q: *Are all data points to be validated?*

A: No – there are 5 data points to be validated. These are detailed in the validation user guide. Only a small number of variable will be checked to give a balance robustness and making the process overly burdensome for validators

Q: *We have only 2 small hospitals taking part in my country; can a single validator validate both hospitals?*

A: This may be possible. Please email [enquiry@globalsurg.org](mailto:enquiry@globalsurg.org) to discuss this possibility. There are some technical challenges as when the validator logs in they will see the data they need to validate and it's only possible to see one hospital's data at once. We will look for a solution in this scenario

Q: *Will records need to be accessed again? Will we need to re-apply for separate ethics?*

A: The validation study is described in the protocol, there is no separate validation study protocol, therefore it is anticipated that ethics approvals for the study will also cover the validation part of the study.

Q: *If a validator can't be found for a particular centre, will the primary data have to be removed from the final analyses?*

A: It's really important that **every** centre is validated. We haven't made it a strict rule that un-validated data will be removed, but please consider that validation is essential as described in the protocol.

We are aware it is very difficult and generates more work at the end of the study. However, it was one of the main reasons GlobalSurg 2 was accepted by a Lancet journal and almost certainly would not have been accepted without validation

Q: *When will validation take place?*

A: Validation registration will take place from September 18<sup>th</sup>. Validation accounts containing data will be available from Oct 8<sup>th</sup>. Validation for those centres collecting data in the final month of the project can not take place until Dec (following entry of 30-day follow-up data collected in Nov). The validation study will remain open until February 2019 to allow validation at these centres

Q: *Is validation mandatory?*

A: Yes, please consider validation mandatory. We do not wish to take a stance of removing un-validated data but we really need everyone to aim to validate data at every participating centre. If validation is genuinely not possible, we would not wish to penalize teams or hospitals by removing data from the dataset

Q: *Can we enter data collected in a previous month?*

A: Yes, you can enter data collected previously collected on paper this can be entered into REDCap provided the team that collected is registered to take part

Q: *Is there a specific time the validators should be working?*

A: The validators for those hospitals that have collected data early on in the project can begin validation from Oct 8<sup>th</sup>. Those hospitals joining the study in September and October, will have to wait until the primary data collection team have completed their data completion form in the authorship project on REDCap

Q: *Is there a way for National Leads to check the completion status of the teams in their country*

A: Please use the National Leads online tool and select the patients tab. Records started will show in light pink, completed records in dark pink. It won't show if teams have collected data on paper but have not yet begun entering data into REDCap. But it will be a start to show teams with zero patient entry that leads can then follow up with to check if they are collecting data on paper or whether they are no longer participating.

<https://argonaut.is.ed.ac.uk/shiny/private/g3reg/>

Username: countrylead

Password is supplied separately

If there is any feedback on the online tool or if anyone would like to be able to see additional information please let us know.