



GlobalSurg 3 Validation Exercise

Frequently Asked Questions

Q: What is data validation and why do we need to do it?

A: The GlobalSurg dataset contains data on thousands of patients. It is extremely important that we demonstrate this data is robust and of high quality during the peer review process in order to enable the study to be published in a high impact medical journal.

The purpose of the validation exercise is to observe the primary dataset only. The original data will **not be corrected, updated or modified in any way**.

The validation exercise will **not be used to exclude any collaborators or centres** that have entered complete patient datasets from the study or any subsequent publications. Its purpose is to quantify the inherent uncertainty in data collection, not to exclude collaborators or remove data.

Q: When does the validation start?

A: Validator registration started on the 18th of September, 2018. The period for data checking will begin on October 8th, 2018. Validation for those centres collecting data in the final month of the project cannot take place until December (following entry of 30-day follow-up data collected in November). The validation study will stay open until February 2019 to allow validation at these centres.

Q: Who can work as a Validator?

A: The validator **cannot** be someone who has taken part in a primary data collection team.

The validator must work at a hospital contributing primary data to the study.

The validator must have access to hospital records

Q: Will it be possible to have two (2) validators at a big hospital?

A: We do not currently have systems for this. The validation methodology describes that we will only validate one (1) randomly selected, 4-week period at each hospital.

For hospitals that have collected all 7 months of data (from April to October), just one of these months will be selected at random for validation.

For hospitals that have collected only one (1) month of data, this is the month that will be validated.

As such, the workload will be the, regardless of hospital size. We can however discuss on a case-by-case basis if two (2) validators are required – please email enquiry@globalsurg.org



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

A: Validation will be focused on one 4-week data collection period, rather than a proportion of patients entered into the study. For example, if a hospital has collected only one (1) month of data, it will be all the patients whereas if a hospital has collected all seven (7) months, it will be one of the seventh of the patients – 1/7th.

Q: Will all patients collected during that month be validated?

A: Yes. It is all the patients entered during the 4-week data collection period; not a subset. However, not every variable for each patient will be validation.

Q: Are all data points to be validated for each patient?

A: No. There are five (5) data points to be validated. These are detailed in the validation user guide ([available here](#)). Only a small number of variables will be checked, to give a balance between robustness and over burdening data validators.

Q: In a case where there are only two (2) small hospitals taking part from a country, can a single validator validate both hospitals?

A: This may be possible. Please email enquiry@globalsurg.org to discuss this possibility. There are some technical challenges, such as when a validator logs in, they will see the data they need to validate, and it is only possible to see one hospital's data at once. We will look into finding 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 granted for the study will also cover the validation part of the study.

Q: Is validation mandatory?

A: Yes, validation should be considered mandatory. We do not wish to take a stance of removing un-validated 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: What if a validator cannot be found for a particular centre, will the primary data have to be removed from the final analyses?



A: It is extremely important that every centre is validated. Though there is no strict rule that un-validated data be removed, validation is essential and was one of the main reasons GlobalSurg 2 was accepted by a Lancet journal. It almost certainly would not have been accepted without validation. Therefore we need everyone to commit as much as possible to this aspect of the study

If you have further questions not covered here please email
enquiry@globalsurg.org