



DIRECT

DIABETES RESEARCH ON PATIENT STRATIFICATION

STANDARD OPERATING PROCEDURE (SOP)

Diabetes Research on Patient Stratification (DIRECT) All Work Packages

PROCEDURE FOR SUBMITTING DATA TO THE DATABASE

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APPROVED BY (1):

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DATE APPROVED:

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DATA SUBMISSION CHECKLIST

SUBMITTING FOREGROUND DATA		
Task	Notes	Date Completed
Check with work package lead / centre lead whether [REDACTED] have been informed that you need access to the database	The work package lead / centre lead is responsible for providing a list to [REDACTED]	
Contact [REDACTED] to inquire whether the appropriate user interface exists for data submission. If not, provide [REDACTED] with a written spec. Please note that implementation and testing of new modules can take up to several months.		
Make sure personnel requiring access to the database have had [REDACTED] training	[REDACTED] will contact you to arrange training	
Upload data onto the database		
Check uploaded data is accurate	You will be able to see a summary of data uploaded to ensure it is correct	
Inform [REDACTED] immediately if any changes to personnel responsible for uploading data		

SUBMITTING DATA (BOTH FOREGROUND AND BACKGROUND) FROM ANOTHER DATABASE		
Task	Notes	Date Completed
Complete Data Submission Form	Include contact information for all personnel responsible for uploading data	
Submit the form to [REDACTED]	[REDACTED] may require you to provide your data in a certain format.	
Make sure personnel requiring access to the database have had [REDACTED] training	[REDACTED] will contact you to arrange training	
Provide data for [REDACTED] to upload onto the database	Contact [REDACTED] if have questions on appropriate format	
Inform [REDACTED] immediately if any changes to personnel responsible for uploading data		

Procedure for submitting data to the database for use in the DIRECT Consortium

1. Purpose

The purpose of this SOP is to outline the procedure for submitting data to the database for use within the DIRECT consortium.

2. Applicability

This SOP applies to: all personnel involved in the DIRECT consortium; all work packages.

3. Procedure

Data will be uploaded onto the DIRECT database at various points throughout the programme. These data fall into the following categories:

1. Data that are prospective and are collected as part of a DIRECT work package (Foreground data);
2. Data that have been previously collected within a non-DIRECT study and whose use is dictated by the consents obtained for those studies (Background data).

In order to make sure there is a transparent system in place to move data across the consortium, and to keep oversight of the data that is available to the consortium, the following processes are needed to submit data to the database.

For more information relating to the policy for data submission, please refer to section 2 of the Data Access Policy.

Foreground data:

This will include eCRF data, records of patient visits, sample registration, ie individual level data.

To submit Foreground data to the database, you need to:

- Get in touch with the work package / centre lead to let them know that you need to upload data onto the database
- The work package / centre lead notifies ██████████ of all researchers needing access to the database to upload foreground data
- The work package / centre lead contacts ██████████ to inquire whether the appropriate user interface exists for data submission. If not, provide ██████████ with a written spec. Please note that implementation and testing of new modules can take up to several months.
- ██████████ organises training for researchers who will need to access the database
- ██████████ provides access to trained researchers, and will notify you when this access has been granted
- You can then start to upload data onto the database as trained.

In instances where prospective data is being added from a different database, either as a specific data file, or in another format other than as individual level data, a submission

form must be filled in as described below to submit Background data. This is because the data is grouped in such a way that the consortium needs a more detailed record of what it includes, so that it is clear what is available.

Background / Retrospective data (and to upload grouped Foreground data)

This will include data from other studies outside DIRECT and Foreground data that is being transferred as a grouped dataset from another database.

In order to submit Background data to the database, you will need to:

- Complete a data submission form providing detail of the data that needs to be submitted, including the format it is in
- Submit the submission form to [REDACTED]
- [REDACTED] may require you to provide your data in a certain format.
- [REDACTED] considers and approves submissions
- [REDACTED] provides training for researchers who need to access the database
- You can then send your data to the database to be uploaded by [REDACTED] (please contact [REDACTED] if you have any questions about the appropriate format or how to send it).

The database includes a section that summarises the data that has been uploaded onto it already.

Background data are usually directly uploaded to the database by [REDACTED] and the person submitting data does not usually have the opportunity to review the data after submission.