

SECRETO Newsletter

February 2020

Happy New Decade 2020!

Many thanks for all your efforts over the past decade. Our goal for the first year of this decade is to complete the recruitment of the SECRETO Study.

An abstract on the preliminary results of Lupus anticoagulant analysis was submitted to ESOC 2020 in January, with a decision regarding its acceptance awaited in March. Laboratory analysis of coagulation assays will continue in April this year. Furthermore, we have begun doing basic analyses on the plasma samples, including lipids, glycemia, renal function, and hs-CRP.

Recruitment status

In the end of January 2020, **460 patients** and **339 controls** have been enrolled. That means 77 % of the target number of patients and 57 % of the target number of controls. There are still centers that have recruited no controls to date. Please make all efforts to activate recruitment of controls as well, as it is highly important to achieve a balanced 1:1 case-control ratio for the main analyses.

Data monitoring

Data consistency checks have begun by the Database Committee. You may have already received an Excel file summarizing your site's data entry status and comments if any concerns have arisen.

Please make sure to keep your patients in systematic follow-up and prospectively maintain up to date data in the database at all times.

Tips for working with your data in OpenClinica

Working with missing data. If data for an eCRF is entirely missing or not available, complete the eCRF by selecting 'no information' for all entries and tick the 'Mark CRF Complete' tickbox. By doing so, the eCRF turns from yellow to green and we know that data for that eCRF have been checked.

Forcing Event status from 'Data entry started' to 'Completed'. If all eCRFs of an Event are completed (green) and the Event does not turn from yellow to green, you can manually change the event status in the View Subject view, i.e. in the overview view of all eCRFs or in the Subject Matrix view. Simply click the Event icon and select Edit. On the Update Study Event window, select 'Completed' from the Status dropdown menu and submit changes.

Working with queries. In case of inconsistent data entries or missing data etc. you may have received one or more queries. Please review SOP-04 for details. Also queries should be managed in a timely manner.



- ◆ Keep up the good pace in recruiting patients and controls!
- ◆ Take good care of your data in the database!
- ◆ Keep on sending images timely to core labs and update OpenClinica accordingly!