

A Flexible workflow for continuously monitoring the ProBio platform trial

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Conclusions

- We have developed a flexible workflow for constantly monitoring the progress of the ProBio platform trial.
- The dynamic report with interim results on treatment efficacy and adverse events is valuable for reviewers in the Data Safety Monitoring Board.
- The workflow ensures data protection, version history, and blinding of the study results.

Introduction

Platform trials are adaptive designs which utilize the accumulated results for modifying trial's components in a prespecified way. It is therefore essential to continuously monitor the progress of the trial and to keep track of outcome data, adverse events and other components.

ProBio is an ongoing platform trial to evaluate the effectiveness of genetic biomarkers for treatment selection of advanced prostate cancer patients. More info can be found at <http://probio.se/>.

Aims

To develop a flexible workflow for constantly monitoring the progress of the ProBio study.

Methods

The flexible workflow includes the automatization of the following tasks:

1. Fetching the data from a database server;
2. Manipulating and cleaning the raw data;
3. Analyzing and summarizing the transformed data;
4. Creating reports with different level of details.

The procedure needs to run automatically everyday, ensure database versioning, guarantee data safety and blinding of specific results from the trial.

```
+ Enrollment status by participating centers
+ Follow-up data
  - flowchart and swimmer plot
+ Baseline variables
  - table 1 comparing treatment vs control patients
+ Genetic biomarker data
  - prevalence of mutations and biomarker signatures
+ Number of events (tumor progression)
+ Treatment evaluation
  - Heatmaps and density plots
+ Adverse events
  - case reports and comparison treatment vs control
```

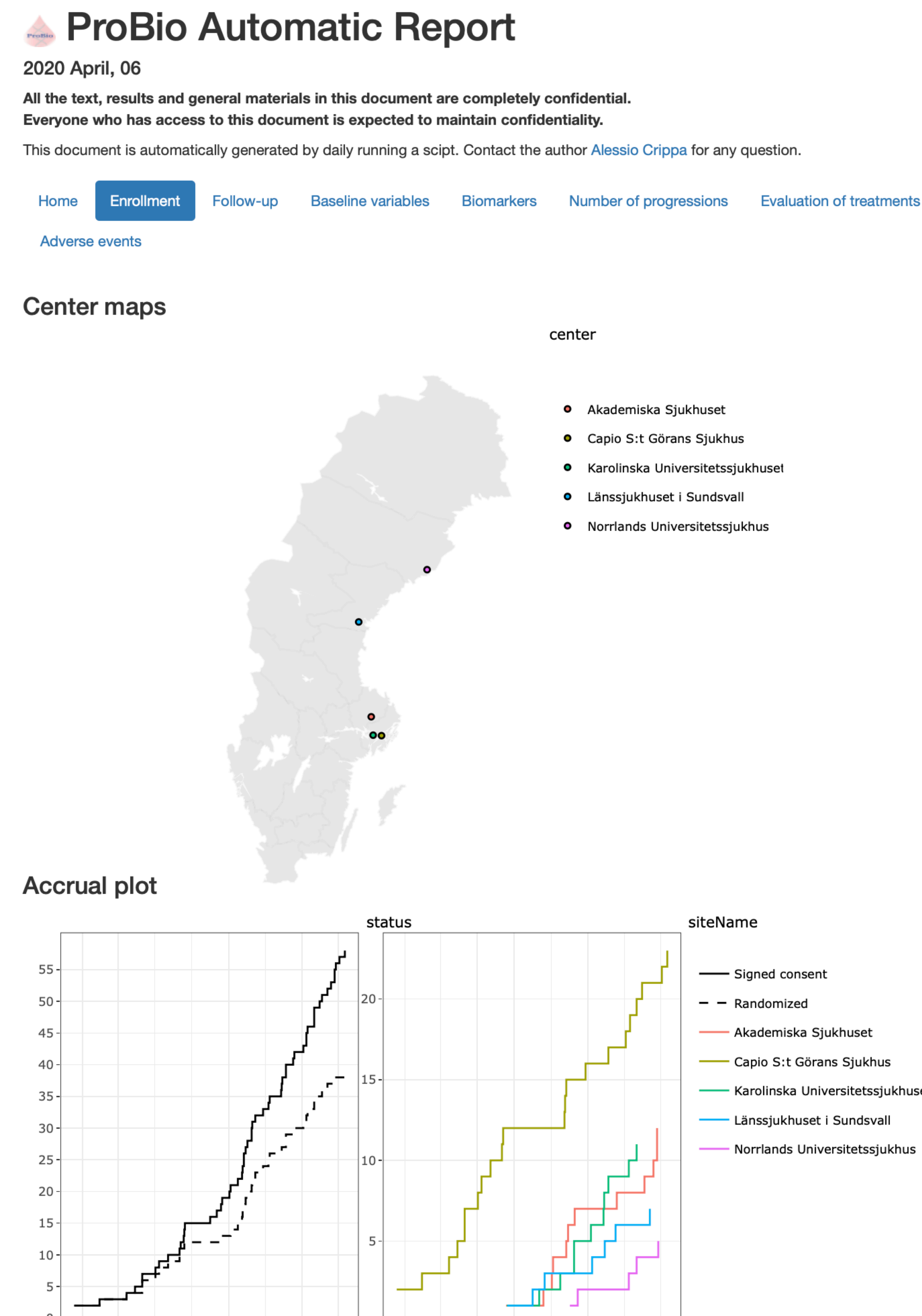
Figure 1. Information available in different panels in the ProBio Automatic Report

Results

The different tasks are addressed in 4 different Rscripts. The first implements an API interface for fetching the data in R from the [SMART-TRIAL](#) database. Two sync R scripts are dedicated for manipulating, cleaning, analyzing and summarizing data. A final .Rmd file produces a dynamic html webpage with interactive graphs (plotly) and informative tables and widgets.

The structure of the automatic report together with the key figure components is presented in Figure 1. The multitude of results and number of details in the figure makes a html report more convenient than a dashboard for assessing key components of the trial.

The sourcing of the different Rscripts is included in a shell script. This is run daily as a scheduled job in cron.



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