

Instructions on how to create, modify and share study protocols

# Protocol creation

Do you have an idea of a study you would like to conduct using EBMT registry? These are the steps you should follow:

* Obtain the TCWP protocol template. If you don’t have it, you can ask to any member of the TCWP and they will provide it to you (their names and contact details are in the protocol template).
* Construct your protocol by editing all yellow parts of the template.
  + If you don’t know which Sub-Committee to choose, the TCWP Chair will assign it for you.
  + Don’t forget to add your personal details at the beginning of the protocol.
  + Should you have any questions about how to complete the protocol, please contact the TCWP Secretary.
* Modify the Document changes tracker following these rules:
  + Each protocol version written before the Working Party approval should have a 0.x number. Each new version is incremented by 0.1.
  + The first draft of your protocol will always be v0.1. The first WP approved version will always be v1.0.
  + Put the date of your last modification before sending it to other WP members.
  + Don’t forget to put your name and a brief summary of your modifications.
  + Here is an example:

|  |  |  |  |
| --- | --- | --- | --- |
| Version | Date | Name | Brief summary of modifications |
| v0.1 | 01/01/2018 | PI | First draft of proposal sent to TCWP chair |
| … | … | … | … |
| v0.6 | 02/15/2018 | Alenca Harrington | Data feasibility checked |
| … | … | … | … |
| v0.8 | 03/04/2018 | Christophe Peczynski | Statistical part written – Submitted to PI and chair |
| … | … | … | … |
| v1.0 | 03/25/2018 | PI | Final WP approval |

* Name your file using the following items in order:
  + Name of the Principal Investigator
  + Study short title (acronym or 3-5 words)
  + Last version
  + Last modification date

Example: “Penack EASIX to predict alloSCT outcome v1.0 2018\_01\_19.docx”

* You are ready to send your protocol to the TCWP Chair and Secretary!

# Protocol modification

Each time you want to modify the protocol before TCWP final approval, please follow these rules:

* Be sure to use the latest protocol version.
* After your modifications, don’t forget to update the Document changes tracker.
* Send your new version to each person involved in your study. This includes at least TCWP Chair, Sub-Committee Chair, Secretary, Study Coordinator and Biostatistician.

It’s preferable not to make any modifications after the final TCWP approval. An amendment can be made if necessary but the protocol will have to be validated again by each person involved in the study (follow the previous rules).