TTV GUIDE
Torque Teno Virus
Based Immune Monitoring

Ethics and Governance Report on the inaugural meeting of the Ethical and Governance Council

Recommendations

The Ethical and Governance Council recommends:

- To ensure that all aspects of safety are considered, with special focus on long term organ rejection. Therefore, every effort must be made to ensure that trial participants risk for organ rejection or another serious adverse event during or after the 12 months after transplantation is not increased. It should be considered to assess the possibility of surveillance for patients after month 12. In addition, in the case of living donors, a potential rejection can increase the damage, because it will affect both the donor and the recipient. Due to that, the EGC recommends:
    - The living donors need to be aware about the possibility of trial participation of the recipient.
    - To clarify the procedure in case a participant has an organ rejection. Are these patients going to have priority because of their involvement in the RCT? To consider the inclusion in the informed consent document information regarding the risk of organ rejection, even if it may be a very unlikely event.
    - As a good practice, having a data bank for the surveillance of participants in the long term is highly recommended. This is one of the aspects that require attention to long term commitment to assess if some late rejections or other problems can appear.

- To clarify the responsibilities in case of adverse events.

- To ensure that all ethical requirements are met in the recruiting process and data management, and develop a checklist for each practice within all WPs to enhance transparency. It is a way in

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which all doubts and questions that may arise from the clinical trial are clearly communicated to all participants selected or not.

- To ensure that the informed consent process is clearly transmitted to all participants, with special emphasis on oral communication. Particularly, the issue about therapeutic misconception needs to be carefully addressed. Offering the clinicians some remarks or specific training before they start the recruiting process can increase the ethical quality of this practice and help to standardize the procedures between the participating clinics.

- To assess through questionnaires how the participants understand the informed consent, specially at the beginning of the recruiting process. To consider and assess if patient-physician gender can influence the informed consent process and participant's acceptance to be enrolled in the trial.

- As a good practice, the gender monitoring process is a minimum requirement. The EGC would require, once the half of the recruitment process starts, an intern report with statistics about participation dissociated by gender. In that case, measures should be undertaken to avoid

- To require safeguards to protect the privacy of personal health information. It is therefore necessary for a GDPR (regulation in EU law on data protection and privacy in EU) compliance implementation to be effective. GDPR recognises health data as a particular sensitive category of data.

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