

## VIRTUAL MOBILITY (VM) GRANT REPORT

This report is submitted by the VM grantee to VNS Manager, who will coordinate the approval on behalf of the Action MC.

Action number: CA18117

VM grant title: Biobanking of Rare Gynaecological Tumours: The Legal Aspects

VM grant start and end date: 04/10/2021 to 24/10/2021

Grantee name: Dr Olga Tzortzatou

**Description of the outcomes and achieved outputs (including any specific Action objective and deliverables, or publications resulting from the Virtual Mobility).**

*(max. 500 words)*

This virtual collaboration of COST members from Greece, Malta and Italy, has developed a joint questionnaire to cover the ethical and legal issues faced by biobankers of rare gynaecological tumours. Although these issues are covered by two separate Virtual Mobility grants, the members decided it would be more effective to produce one Questionnaire rather than two, to avoid survey fatigue. This report, prepared by myself the grantee, Dr Olga Tzortazou from Greece, will cover the legal aspects.

From the clinical point of view, high-quality protocols can be performed in the different European countries, however from the legal point of view, each country has to prepare country specific appendices to fulfil the national law request. The main objectives of this Virtual Mobility Grant has been to map the national legislation regarding the General Data Protection Regulation (GDPR) and its implementation with regards to biobanking of samples from patients with rare gynaecological tumours. This online survey which has been written up as part of this virtual collaboration has now been finalised and transferred to Googleforms (see attached pdf). The next step is that it will be submitted for Ethics approval and then sent out to representatives from all the countries involved in the GYNOCARE COST Action, and beyond.

The final questionnaire consists of 6 sections, the last 2 of which (Sections E and F) were co-ordinated by myself as the grantee, while giving direct contribution also to the compilation of Sections A to D:

**Section A: Biobank Profile**

**Section B: Information Sheet**

**Section C: Informed Consent Form**

**Section D: Patient Engagement**

**Section E: Legal Issues**

The legal issues targeted concern legislation related to copyright, patents and innovative knowledge.

**Section F: Request for Forms and Legislation**

This section is asking for forms and legislation to be submitted.

Response to the survey is expected to enable achievement of one of the main outcomes of this grant, which is to establish whether it is fully compliant with GDPR and national legislation or if updates/ amendments are in progress. The expected output of this grant is to collect all current information dealing with the national legislation related to GDPR and the country specific requirements, if any.

This is in keeping with the objectives of Working Group 3 of the GYNOCARE COST Action. These objectives include coordination of knowledge and best practices needed for biobanking and the creation of Standard Operating Procedures (SOPs) for legal requirements to support research, including clinical trials on rare cancers. (<https://gynocare.net/working-group-3/>). This will form the basis for the development, in future, of harmonized relevant documents, to minimize the need for country specific appendices to be added to cover the legal requirements in different countries, thus facilitating collaborative research.

**Description of the benefits to the COST Action Strategy (what and how).**

*(max. 500 words)*

The introduction in Europe of GDPR, has introduced the concept of 'consent as a legal basis for processing of personal data' in Article 6(1)(a) of the GDPR and provides for exemptions other than such explicit consent, as well as mandatory provisions to protect the rights of data subjects, e.g. right to information on data processed.

This has led to revisions and/or updates of available documents to ensure they comply with the GDPR requirements. However the implementation of GDPR provisions varies in European countries, and we are aware that such documents may also vary.

This collaborative initiative has resulted in a detailed questionnaire and the results will lead to comparison of the content of the documents, particularly to analyse if legal requirements are different in countries because they reflect the specific national legislation regulating research and in particular biobanking.

The plan is that in the future, the data collected will be analysed so that within the next COST Grant period, there can be the development of protocols, agreements, contracts, standard operating procedures (SOPs) and other relevant legal/operational documents related to the network considering all the legal peculiarities of the different countries so that countries specific appendices can be omitted. This is in line with the subobjectives of WG3 This virtual mobility grant will generate knowledge of the current state of the art in biobanking, in the COST Action members, from both EU and non EU European countries, as well as Israel, a cooperating member. This is fully in line with the GYNOCARE COST Action Strategy.

This grant will generate a consensus on the crucial ELSI issues that must be addressed in Patient Information Sheets and Consent Forms to satisfy ethical and legal/regulatory requirements for biobanking, specific to rare gynaecological cancers. This consensus

can eventually be disseminated to future members derived from NNC and IPC countries, through already existing links between members within the network.

**Description of the virtual collaboration (including constructive reflection on activities undertaken, identified successful practices and lessons learned).**

*(max. 500 words)*

The virtual mobility grant was led by myself Dr Olga Tzortzatou as the chair of Working Group 3, in virtual collaboration with Dr Bridget Ellul from Malta and Dr. Sara Casati from Italy and another Greek member, Mrs. Spatha Pepi.

**Virtual Meetings**

2 Skype Brainstorming meetings;

4 Skype/ Zoom meetings, with all collaborators – dealt with questionnaire related only to this grant, specifically addressing the legal aspects.

6 Skype/Zoom meetings, including 3 with all collaborators – dealing with the Joint Questionnaire.

Following a brainstorming session with Dr Bridget Ellul, I prepared the first version of the Questionnaire focussed entirely on the legal issues and shared this with Dr Sara Casati, an ethicist and Dr Bridget Ellul. The three of us were mainly responsible for the development of the questionnaire although we also received useful suggestions and recommendations from the collaborators and these were included in the revised versions.

Following the decision to produce a joint questionnaire, incorporating legal issues, I, Dr Olga Tzortazou provided the legal questions, which were incorporated into a new joint questionnaire.

The content was extensively reviewed and revised by us three, Dr Sara, Dr Bridget and myself, with new versions being submitted via email to all the collaborators, leading to a comprehensive version, presented to all collaborators. Feedback was positive but at 70 questions, the questionnaire was too long and we three worked hard through virtual meetings, on line corrections and emails to reduce the questionnaire to a reasonable length (47 questions), with questions focussed on the objectives of the grants. Group discussion led to a decision to use Google Forms and this was undertaken by, Prof Charles Savona-Ventura.

**Lessons learnt**

1. It was extremely helpful to have collaborators with different expertise in biobanking, which was fruitful in producing a concise questionnaire with emphasis on important issues.
2. Given that all the meetings were held virtually, this work could be carried out effectively and in a timely manner, in spite of the ongoing busy schedule of work back home, including personal travel. Effective communication on pre-set time

schedules allowed us to meet up frequently, even if in different time-zones. It is unlikely that we would have achieved such a huge amount of work in such a short time, had there not been the support of this virtual mobility grant.