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: Establishing a common Patient information Sheet /Leaflet and a Consent Form for biobanking of samples from patients with rare gynaecological tumours.

VM grant start and end date: 18/09/2021 **to** 18/10/2021

Grantee name: Dr Bridget Ellul

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

This virtual collaboration of COST members from Malta, Greece, Italy and Ireland, 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 (VM) grants, the members of this collaboration decided it would be more effective to produce one questionnaire rather than two, to avoid burnout by the responders. This report, prepared by myself, Dr Bridget Ellul (the grantee), is concerned with the ethical issues in research.

The questionnaire was developed to ascertain what information is included in the existing Patient Information Sheets/Leaflets (ISs) and Informed Consent Forms (ICFs), that are currently in use by different biobanks that collect samples and data from patients with rare gynaecological tumours. Clinical and scientific questions were not included as these are included in other surveys being prepared by other COST members.

The final questionnaire consists of 6 sections, where I, Dr Bridget Ellul (the grantee), was responsible for designing the first 4 sections, in virtual collabortation with the other members:

Section A: Biobank Profile
Questions relate to general information, including type of biobank (public or private), type of collections available, the type of legal entity and legislation regulating the biobank and contact details of the biobank.

Section B: Information Sheet
Questions relate to what information is included in the IS form – structure of biobank, potential benefits and risks to participants, storage details, patient rights (withdrawal of consent, data protection), use of and access to samples and data and return of results.

Section C: Informed Consent Form
Questions deal with the type of consent, re-contact, and re-consent.

Section D: Patient Engagement
There is one question on who was involved in preparing the forms.

The questionnaire has been approved by the team members and has been transferred to Google forms and is ready for submission for Ethics approval. It will be initially distributed to all the GYNOCARE COST members. They will be asked to target relevant biobanks that have collections of rare gynaecological tumours.

Response to the survey is expected to enable achievement of the main outcomes of this grant, which are to establish:

i) what documentation is available in the countries represented by the members of this COST Action; and
ii) whether it is fully compliant with GDPR and national legislation or if updates/ amendments are in progress

so that we can identify the ideal information that should be in these forms, with a view to harmonising collected information.

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

(max. 500 words)

This virtual mobility grant will generate knowledge of the current state of the art in biobanking, in the GYNOCARE COST Action members, from both EU and non-EU 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 disseminted to future members derived from NNC and IPC countries, through already existing links between members within the network.

The knowledge exchange will lead to recognition of best practices which can be introduced to the members. Identification of common ELSI issues that can form the basis for harmonised documents will lead to improvement in the quality of future collaborative research on biobanked rare gynaecological tumours.

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

The idea for this VM grant was put forward by Dr Sharon O'Toole (Ireland) in relation to discussions related to the VM grant *Harmonising a common dataset for biobanking of rare gynaecological cancers*. The collaborators of Working Group 2 on *Biobanking* agreed that knowledge of the currently employed ethical process of obtaining consent for biobanking of rare gynaecological tumours would be a useful adjunct to information on the clinical parameters being used for biobanking such samples. Since I, Dr Bridget Ellul (grantee), am a member of both Working Groups 2 and 3, I introduced the concept to Working Group 3 on *Legal and Regulatory Issues* and this led to the decision to also address the legal issues faced by biobankers. At this initial stage, WG3 members decided to apply for 2 separate VM grants but later on decided to join forces and produce one questionnaire (document supplied) to minimise stress to the partcipants and ensure more responses.

Virtual Meetings held throughout the period of the VM grant:
1 Skype Brainstorming meeting.
3 Skype/ Zoom meetings, including 1 with all collaborators – dealt with questionnaire related only to this grant - without legal aspects being addressed.
6 Skype/Zoom meetings, including 3 with all collaborators – dealt with Joint Questionnaire.
1 Virtual meeting organised by WG 2 with Prof. Simon Herrington to discuss classification of gynaecological tumours.

Following a brainstorming session with Dr Olga Tzortazou (14/09/2021), I prepared the first version of the questionnaire (24/09/2021) focussed entirely on ethical issues and shared this with Dr Sara Casati, an ethicist (Itlaly) and Dr Olga Tzortazou (Greece). 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 (28/09/2021) to produce a joint questionnaire, incorporating legal issues, Dr Olga Tzortazou provided the legal questions, which I incorporated into a new joint questionnaire, the first version being available on 4/10/2021 and an overview was outlined to all collaborators at a virtual meeting on the following day.

The content was extensively reviewed and revised by us three, Dr Sara, Dr Olga and myself, with new versions being submitted via email to all the collaborators, leading to a comprehensive version, presented to all collaborators on 12/10/2021. Feedback was positive but at 70 questions, the questionnaire was deemed to be too long and we three worked hard through virtual meetings, online via Skype and Zoom 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 (Malta).

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. It is important to focus on realistic objectives.
3. Zoom meetings were effective for large groups but Skype was better for small group meetings.
4. Use of a dropbox for shared documents proved less popular.
5. This virtual mobility gave the opportunity for flexibility to organise numerous online meetings as needed, at a time convenient for all the collaborators.