COST Action: GYNOCARE

European Network for Gynaecological Rare Cancer research: From Concept to Cure CA18117

Establishing a common Patient Information Sheet/Leaflet and a Consent Form for Biobanking of Samples from Patients with Rare Gynaecological Tumours

COLLABORATOR COUNTRIES:

Malta (Dr Bridget Ellul lead for ethical questions); Greece (Dr Olga Tzortazou lead for legal questions), Italy, Ireland

OBJECTIVES

To establish a common Patient Information Sheet /Leaflet and a Consent Form for biobanking of samples from patients with rare gynaecological tumours.

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.

Main contributors: Dr Bridget Ellul, Dr Olga Tzortazou, Dr Sara Casati

26th October 2021

METHODOLOGY

1. Develop a Questionnaire to ascertain what information is included in existing Patient Information Sheets/Leaflets (ISs) and Informed Consent Forms (ICFs)
2. Distribute via Google Forms to COST members
3. Analyse responses
4. Possible future re-contact
5. Possible future wider distribution

Basis for future development of harmonized documents, to minimize the need for country specific appendices to be added to cover the legal requirements in different countries, thus facilitating collaborative research.

EXPECTED OUTPUT

1. collect all current documentation dealing with Patient Information Sheets and Consent Forms;
2. compare the themes covered and analyse these in relation to the national legislation;
3. establish if content has been approved by the national Data Protection Authorities; and
4. establish whether the expectations of patients and lay organisations are fulfilled.

Questionnaire

Section A: Biobank Profile
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
information included in form - structure of biobank, potential benefits & risks to participants, storage details, patient rights (withdrawal of consent, data protection), use of & access to samples and data, return of results

Section C:Informed Consent Form
information on type of consent, re-contact, and re-consent

Section D: Patient Engagement
one question to ask who was involved in preparing the forms

Section E: Legal Issues (another VM grant)
legislation related to copyright, patents and innovative knowledge

Section F: Request for Forms and Legislation