

---

## Plan Overview

*A Data Management Plan created using DMPonline*

**Title:** Role of pre-operative inflammatory markers as predictors of lymph node positivity and disease recurrence in well-differentiated pancreatic neuroendocrine tumours.

**Creator:**Lulu Tanno

**Principal Investigator:** Lulu Tanno

**Data Manager:** Lulu Tanno

**Affiliation:** University of Southampton

**Template:** DCC Template

### **Project abstract:**

Pancreatic neuroendocrine tumours are a rare and slightly unusual type of cancer. Sometimes these cancers can be difficult to see on scans patient's have before surgery. When we are planning for an operation, it is very important to know if a lymph node near the cancer is normal or if the cancer has spread into it. If the lymph node has cancer or does not look normal then it must be removed during surgery. However, in neuroendocrine tumours we cannot always tell this before surgery. We understand that patients are often worried before surgery, and having lots of unnecessary scans and tests can be scary. We want to find a test that can be used instead that is less stressful. There have been reports that high white blood cells in the blood test before surgery are associated with neuroendocrine tumours that are more aggressive. If we could use blood tests that patients normally have before surgery to see if lymph nodes are normal or not, this would be an ideal test. In this study, we want to see if high white blood cell count is something that is also linked with cancer spread in the lymph node. Because if we can predict this before surgery, it will ensure that patients will have the correct operation and have all cancer removed. This study will answer this question, by selecting patients who had surgery and looking at their blood results before surgery, and then looking at the report of the removed cancers and lymph node spread. This will help us see if high white cell counts are linked with cancer spread in the lymph node or not.

**ID:** 46513

**Last modified:** 11-10-2019

### **Copyright information:**

The above plan creator(s) have agreed that others may use as much of the text of this plan as they would like in their own plans, and customise it as necessary. You do not need to credit the creator(s) as the source of the language used, but using any of the plan's text does not imply that the creator(s) endorse, or have any relationship to, your project or proposal

# **Role of pre-operative inflammatory markers as predictors of lymph node positivity and disease recurrence in well-differentiated pancreatic neuroendocrine tumours.**

---

## **Data Collection**

### **What data will you collect or create?**

Data capture will be performed by each centre. Most centres who are registered European Neuroendocrine Tumours Centres of Excellence (ENETs) will have a pre-existing prospectively collected database which will be used to retrieve relevant information for this project. We are expecting roughly around 100-200 patients to be included per centres.

Data collected will include

Basic demographics: sex, age at diagnosis, date of diagnosis

Pre-operative haematological and biochemical results

Surgical information: date and type of surgery

Pathological data: differentiation, ki67, grade of tumour, neurovascular involvement, resection margin, total number of lymph node examined, number of lymph nodes involved

All the data can also be used for future research in some form, subject to appropriate measures being implemented to protect participant confidentiality. Digital and physical outputs will be made available to bonafide researchers for health-related research, irrespective of their institution (university, charity, government, commercial) or location (UK or elsewhere).

### **How will the data be collected or created?**

We would expect most ENETs centres to already have a database which would contain the majority of data already. They may need to lookup certain parameters such as haematological and biochemical values for some or all patients.

However, for the purpose of the study, we have formulated a data collection sheet with clear headings for each column (with further comments and information on the second sheet) and with dropdown boxes to ensure the ease and consistency of the data. We have chosen an excel spreadsheet for collection of the data as most clinicians, nurses, or research technicians would be familiar with the file format.

The excel files will be saved with dates (i.e. 01\_Jan\_2019) so that the versions and updates of files will be recorded.

## **Documentation and Metadata**

### **What documentation and metadata will accompany the data?**

Definition of terms, explanations of values are included in our data collection sheets, some as added comments on the heading columns and also as a separate information sheet (sheet2) of the data

collection excel file.

## **Ethics and Legal Compliance**

### **How will you manage any ethical issues?**

We ask all the centres to anonymise the patients prior to sending the file to the primary investigator. This is simply done by adding a number and initials of the centre (i.e. university hospital southampton patient no 3 = UHS3).

Health Research Authority (HRA) in the UK states that a database containing non-identifiable patient information does not require HRA approval nor ethical approval. (<https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/research-tissue-banks-and-research-databases/>)

However, individual centres participating in this study are advised to register the study with the appropriate department within their institution.

### **How will you manage copyright and Intellectual Property Rights (IPR) issues?**

The University of Southampton will hold copyright in the primary data generated by the research throughout the project. The University will also hold the copyright in any database created to collate already published data, however if necessary, consent will be sought and acknowledgement will be provided to third parties who may retain rights over some of the data used.

## **Storage and Backup**

### **How will the data be stored and backed up during the research?**

All data generated will immediately be transferred and stored in the University of Southampton iSolutions secure research data storage service. The data stored within this facility is regularly backed up and a copy of the back-up, regularly off-sited to a secure location for disaster recovery purposes.

Only authorised users can access data stored within this facility and it is managed under the governance of the University of Southampton Research Data Management Policy (<http://www.calendar.soton.ac.uk/sectionIV/research-data-management.html>).

The analysis and storage of the data will also be performed on the university laptop by the chief investigator (Lulu Tanno)

### **How will you manage access and security?**

All data generated will immediately be transferred and stored in the University of Southampton

iSolutions secure research data storage service. The data stored within this facility is regularly backed up and a copy of the back-up, regularly off-sited to a secure location for disaster recovery purposes.

Only authorised users can access data stored within this facility and it is managed under the governance of the University of Southampton Research Data Management Policy (<http://www.calendar.soton.ac.uk/sectionIV/research-data-management.html>).

Data will be transferred from other trust using the NHS or university email addresses (encrypted) rather than via personal emails such as gmail and hotmail accounts. The collaborators can access the data upon request if it required.

## **Selection and Preservation**

### **Which data are of long-term value and should be retained, shared, and/or preserved?**

As this is a retrospective data, it is unlikely that the data will be have long-term value. Unless the data collected could be used for another study.

Metadata records for the data (and published outputs) will also be maintained on the University of Southampton Institutional Research Repository. In accordance with the University's Data policy, the data will be archived from a minimum of ten years after publication or last access, whichever is longer (see<http://www.calendar.soton.ac.uk/sectionIV/research-data-management.html>). DOIs will be issued for the dataset and data subsets as per the University's DOI policy (see<http://library.soton.ac.uk/identifiers/doipolicy>).

Future users of the data will be bound by data sharing agreements. Where suitable a licence (currently Creative Commons) can be applied to data deposited in the repository.

### **What is the long-term preservation plan for the dataset?**

The database will be kept for ten years after publication. However, the data will be stored in the university repository and will be available for other researchers.

Metadata records for the data (and published outputs) will also be maintained on the University of Southampton Institutional Research Repository. In accordance with the University's Data policy, the data will be archived from a minimum of ten years after publication or last access, whichever is longer (see<http://www.calendar.soton.ac.uk/sectionIV/research-data-management.html>). DOIs will be issued for the dataset and data subsets as per the University's DOI policy (see<http://library.soton.ac.uk/identifiers/doipolicy>).

Future users of the data will be bound by data sharing agreements. Where suitable a licence (currently Creative Commons) can be applied to data deposited in the repository.

## **Data Sharing**

### **How will you share the data?**

The data will be transferred between the primary investigator and other hospitals using the SafeSend system via university of Southampton. All files are transferred across the network securely encrypted. All access to data is very tightly and strictly controlled by the University. All accesses to data on SafeSend are logged and can be easily checked if you are ever concerned that a 3rd party might have gained access to your data.

Furthermore, uploaded data is only held on SafeSend for a maximum of 32 days, after which time it is automatically deleted. There is no "undelete" facility available at all. No backups are taken of the uploaded data (it's only a transitory stopping point), so no uploaded data ever moves off SafeSend itself onto other equipment or media such as backup tapes. After an uploaded file has been deleted, there is no way of recovering the file.

### **Are any restrictions on data sharing required?**

There will be a restriction on the data sharing during the data analysis phase of this project, and until the publication. After this, the data can be shared.

## **Responsibilities and Resources**

### **Who will be responsible for data management?**

Overall responsibility of the data management will be with the primary investigator (Lulu Tanno). PI will be responsible for checking the data quality, storage and backup, archiving the data.

During the data collection phase, each centres collecting the data should be responsible for their data caption and anonymisation of the data.

### **What resources will you require to deliver your plan?**

None specific is required