Data Protection Impact Assessment

Step 1: Project Administration

Trust Name: Sherwood Forest Hospitals NHS Foundation Trust

Project Title: OnCoRe - Oncological Outcomes after Clinical Complete Response in Patients with Rectal Cancer

Senior Responsible Officer for the Project: Alison Steel, Head of Research and Innovation and Information Asset Owner

Step 2: Project Details

2.1 What are the full details and rationale of the project?

Supporting CAG documentation.


IRAS_232110_SupplDoc_CAG_Cover_Letter_


OnCoRe Research Database IRAS Applic


Oncological Outcomes after Clinica

Data already held: - Data has already been collected for 1,126 patients through three audits registered and approved within The Christie NHS Foundation Trust [Ref No: 11/638 (start year: 2011; N = 663); 10/643 (start year: 2010; N = 180); and CE14/1274 (start year: 2014; N = 283)]. The data is currently held within secure, password protected, onsite databases at The Christie that can only be accessed by designated personnel.

Further data collection: - Future data will retain the same format – namely routinely collected data, but will include individual patient research consent for any new patients added to the database. We aim to maintain this database with new patient data added prospectively from September 2017 until August 2022.

Personal data: - demographic data will be collected in this database. Patients will not be required to provide any additional data that is not collected during the course of their standard treatment pathway for inclusion into this database.

Special categories of personal data: - diagnosis, treatment and outcome (for example, deaths, local regrowth, metastasis) will be collected in this database.

There are approximately 16,000 new cases of rectal cancer in the UK per year. Surgery is the mainstay of treatment which is associated with peri-operative mortality and long-term morbidity. Locally advanced disease is treated initially with preoperative radiotherapy, in the main using long-course chemo-radiotherapy (LCCRT) at 45 to 50 Gy, followed by major surgery 8 to 15 weeks later (referred to in this protocol as standard surgical pathway) or selectively by short course radiotherapy (SCRT) at 25 Gy, traditionally followed by major surgery within 10 days, but based on modern trial results, increasingly major surgery is being delayed for 6 to 8 weeks.

In 10% to 20% of cases, chemo-radiotherapy (CRT) may result in a complete disappearance of the rectal tumour. In patients without residual tumour on imaging and endoscopy (clinical complete response [cCR]), a watch-and-wait (W&W) policy (omission of surgery with follow-up) might be considered as an alternate to major resection. This represents a new paradigm for treating rectal cancer. But there are concerns that this approach is oncologically unsafe outside published series from selected specialised centres. In the largest comparative analysis to-date, we addressed the above concern in 129 patients with cCR and demonstrated that W&W is oncologically equivalent to standard surgical pathway. However, most published series worldwide are small (as cCR is an uncommon occurrence) – by example, in a recently reported meta-analysis of 23 studies, only five studies had sample sizes greater than 50 patients.

While randomised trials would represent the ideal way to evaluate the natural history and efficiency of W&W in patients with cCR, there is a general international option that such trials are “unlikely” and that investigators have observed that “many patients.... express a strong preference not to undergo major surgery”.

Thus, there is a continuing need:

(i) to prospectively collect clinical data in a standardised manner to monitor the natural history of patients with CCR managed by W&W

(ii) to collect clinical data on related pathological sub-groups of patients, such as those with pathological complete response following (chemo)-radiotherapy (which occurs in 15% to 27% of patients undergoing major resection)

(iii) to collect clinical data on related clinical sub-groups of patients, such as those with clinical near-complete complete response following (chemo)-radiotherapy (the exact proportion of these is unknown – but in a Dutch study of 100 patients managed by avoidance of surgery there were 15 cases with near-complete response)

(iv) to scale-up and collaborate with international groups (for example, through individual participant data (IPD) metaCAG form IRAS Version 5.5.1 Date: 5 232110/1120163/11/149 analysis, to identify how factors influence and predict patients who have beneficial oncological outcomes from W&W versus those less likely to do well. Currently, there are no molecular markers to predict outcome.

(v) beyond these oncological outcomes, there is a need to address other major research questions, for example, such as functional outcome studies, patient quality of life (QoL) studies, and patient preference studies. To-date, there is a near total paucity of this type of research in this field – the only sizeable analysis has been the assessment of faecal incontinence in 29 of the 100 patients reported by the Dutch research team. The proposed database (under research ethics) will give an opportunity to have a unique dataset to address the above needs.

2.2 What is the name of the system / application to be used?

Rectal Cancer Oncological Complete Response Database

2.3 Is the system / application being used in any similar organisation to this, and if so, which? (See also Q3.5.)

The Christie NHS Foundation Trust

The following questions (11 – 16) are to be answered if we are using a third party ie supplier

2.4 Is the supplier registered with the ICO? Please check the register	**Yes**	**No**
	X Z7091213	

2.5 Has the supplier received ICO Enforcement? Please check the register	**Yes**	**No**
		x

2.6 Has the supplier received ICO Decision Notice? Please check the register	**Yes**	**No**
		x

14. Has the supplier received an ICO Audit? Please check the register	**Yes**	**No**
		x

2.7 Has the supplier completed a Data Security and Protection Toolkit, please check the register and provide the following details	**Completed: Yes/No**	**Date submitted**	**Standard Met/Not Met**
	Yes	30th June 2021	Standards Met

2.8 Can the supplier demonstrate compliance with any of the following standards? If YES please provide further information e.g. date achieved and a copy of the certificates		
	Yes	**No**
Cyber Essentials Plus		x
ISO 15489 Records Management		x
ISO 27001 Information Security Standards		x
ISO 9001 Quality Management Systems		x

Step 3: Risk Assessment Yes, unauthorised access to information or disclosure. The user will be

3.1 Are there any risks to the **Confidentiality** of personal data? Confidentiality is defined as unauthorised disclosure of, or access to, personal data.

All patient clinical data is separated from personal identifiable data and held on a password protected encrypted database within The Christie's secure servers. All patient identifiable information (NHS Number) will be stored in a separate table within the database with Unique codes (e.g. CR00001) linking back to the table holding the pseudonymised data. Only fully anonymised data, with no link-able ID number or any identifiable information, will be shared for any research projects or collaborations.

Risk - Data is accessed inappropriately due to lack of access controls. Movers and leavers access not removed. Data is inappropriately processed and/or disclosed.

Mitigation - Username and password controls in place and access is managed by The Christie NHS Foundation Trust.

3.2 Are there any risks to the **Integrity** of personal data? Integrity is defined as unauthorised or accidental alteration of personal data.

All patient clinical data is separated from personal identifiable data and held on a password protected encrypted database within The Christie NHS Foundation Trust secure servers. All patient identifiable information (NHS Number) will be stored in a separate table within the database with Unique codes (e.g. CR00001) linking back to the table holding the pseudonymised data. Only fully anonymised data, with no link-able ID number or any identifiable information, will be shared for any research projects or collaborations.

Risk - Data is accessed inappropriately due to lack of access controls. Movers and leavers access not removed. Data is inappropriately processed and/or disclosed.

Mitigation - Username and password controls in place and access is managed by The Christie NHS Foundation Trust.

3.3 Are there any risks to the **Availability** of personal data? *Availability is defined as unauthorised or accidental loss of access to, or destruction of personal data.*

Only the Colorectal Research Team based at The Christie NHS Foundation Trust will have access to the data together with the codes for identifying individuals. The data will all be held on a secure HSCN server. Regular backups of the database will be completed.

Risk - Loss of system data due to system failure and/or backup failure either via NHIS or 3rd party supplier. This could result in the service being disrupted or unavailable. The consequences of this could be patient harm, financial penalties and reputational damage to the Trust.

Mitigation - Full system back-up processes in place with NHIS and The Christie NHS Foundation Trust.

3.4 Are there any known or immediate technical / IT / Information Security / Cyber Security concerns?

No

3.5 If the answer is “Yes” to 3.1, 3.2, 3.3 or 3.4 how are these to be Reduced or Mitigated?

Answered above

3.6 Once the mitigations in 3.5 are implemented, how would you score any remaining risk in the following Risk Assessment? If you consider that there are no remaining risks give a value of 1 for both Likelihood and Severity.

Likelihood *(please tick)*				**Severity** *(please tick)*				
1		Rare		**1**	x	Negligible		
2		Unlikely		**2**		Minor		
3	X	Possible	**x**	**3**		Moderate	**=**	3
4		Likely		**4**		Major		
5		Almost certain		**5**		Catastrophic		

Any risks scoring above 6 will need to be reviewed by either the Trusts’ Senior Information Risk Owner), Data Protection Officer or a Directorial member of staff (depending on availability during the outbreak).

Step 4: Project Sign-Off

Sign-off can be given by a Senior Manager for any DPIAs scoring up to 6 in Q3.6, a copy of which must be emailed to the IG Team. For those scoring above this it must be from the Trusts’ Senior Information Risk Owner), Data Protection Officer or a Directorial member of staff (depending on availability during the outbreak), demonstrating that risks have been acknowledged and accepted for the duration of the pandemic, and will be added to the Trust’s Risk Register.

Name: Alison Steel
Job title: Head of Research and Innovation
Date: 24th June 2022

Name: Jacquie Widdowson
Job title: Data Protection Officer and Information Governance Manager
Date: 15th September 2022