

# Database for PROMS and Outcomes

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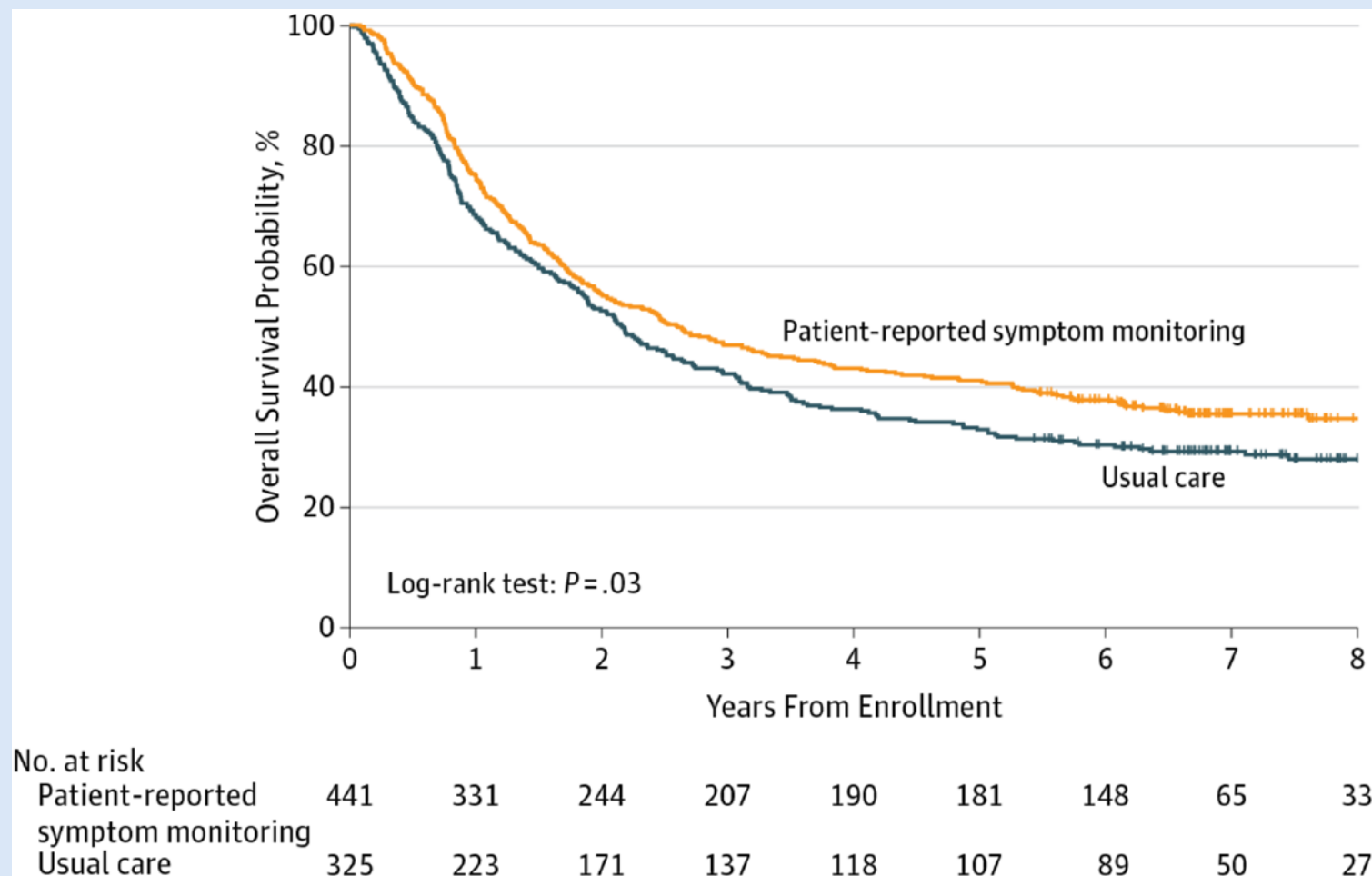
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# The value of PROMS

- To provide patients with the support they require
- To build up a body of evidence such that patients can incorporate QOL in decisions regarding their own management strategy
- NICE recommends that PROMS be used as secondary endpoints in future clinical trials regarding colorectal cancer

From: **Overall Survival Results of a Trial Assessing Patient-Reported Outcomes for Symptom Monitoring During Routine Cancer Treatment**

JAMA. 2017;318(2):197-198. doi:10.1001/jama.2017.7156



# Guildford Database

- National colorectal cancer database
- NICE recommended for all Papillon patients
- Use for planned organ preservation from decision to treat
- Can also be used for all colorectal cancer patients
  - Surgery, RT, chemo, palliation
- Collecting clinical outcomes

# Key Desired Features of Database

- Advance customisation of CRFs and rules
- Image upload into CRFs
- Input from multiple centres
  - Ability of each centre to pull their own data
  - Ability to analyse whole database
- Customisable graphical reports/summaries
- Customisable data exports
- Central area for document upload and 'blog' cases
- Security features
- Patient input mode (from home)

# URL

[www.colorectaldatabase.com](http://www.colorectaldatabase.com)

[www.papillondatabase.com](http://www.papillondatabase.com)



# CRFs – Tumour Assessment

## Rectal Brachy Database

Menu Admin Forum Help Logout Theme: Gray

Case Number: 00000019

### Tumour Assessment

Exit Data Entry

#### Forms

- Basic Data
- Images
- Patient Characteristics
- Physician Assessment
- Baseline Assessment
- Treatments
- Surgery
- Followups
- Adverse Events
- Death
- Archive/Delete

#### Instructions:

Each page has its own Save button. If you browse away without saving, your changes may be lost. [Reload](#)

Date of first biopsy: \*  
01/10/2014

#### Digital Rectal Examination \*

#### Endoscopy \*

#### MRI

#### CT

#### Endoluminal Ultrasound

#### Tumour Description (Digital Rectal Examination) \*

Distance between lower pole of tumour and anal margin 2 mm

Percentage of tumour circumferential extension 10 %

#### Tumour Measurements \*

Length 2 mm

Width 2 mm

Thickness 2 mm

Volume 0.008 cm<sup>3</sup>

Position in rectum 1 o'clock to 1 o'clock

#### Localisation in rectum \*

☒ Anterior

☐ Lateral left

☐ Postero lateral

☐ Posterior

☐ Lateral right

☐ Antero lateral

#### Digital Rectal Examination specific data \*

Mobility: \* TETHERED

Multiple  
diagnostics

#### Pathology \*

Histological type: \* ADENOCAR

Differentiation: \* MODERATE

#### Other histological characteristic \*

☒ Extra mural vascular invasion

☐ Colloid

☐ MST

#### Pathological Stage \*

☒ Vascular Invasion

☐ Nerve infiltration

Surgical Margin: \* R1

#### Tumour marker \*

☒ A CEA has been done

Date: \* 21/10/2014

Save

# CRFs – Treatments

## Rectal Brachy Database

Menu Admin Forum Help Logout Theme: Gray

Case Number: 00000019

### Treatments

Exit Data Entry

Local excision ☒

Date: 08/11/2014

Type: ENDOREC

Post operative complication: ☐

X-Ray Brachytherapy

Fraction 1 ☒

Date: 08/11/2014

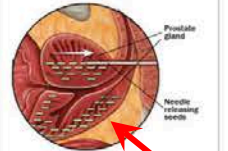
Applicator Size \*

3.0: ☒ 2.5: ☒ 2\_2: ☐

Dose 5 Gray \*

Image

Upload/Change Photo



Fraction 2 ☐

Date:

Applicator Size \*

3.0: ☐ 2.5: ☐ 2\_2: ☐

Dose Gray \*

Image

Upload/Change Photo

No Photo uploaded

Fraction 3 ☒

Date: 05/11/2014

Applicator Size \*

3.0: ☐ 2.5: ☒ 2\_2: ☐

Dose 5 Gray \*

Image

Upload/Change Photo

No Photo uploaded

☒ Is this the final overall radiotherapy treatment ?

Fraction 4 ☐

Date:

Applicator Size \*

3.0: ☐ 2.5: ☐ 2\_2: ☐

Dose Gray \*

Image

Upload/Change Photo

No Photo uploaded

☐ Is this the final overall radiotherapy treatment ?

External Beam Radio Therapy (EBRT) ☒

Date first fraction: 12/11/2014

Date last fraction: 14/11/2014

Technique: CONFORMAL 3D

Volume of PTV 5 cm<sup>3</sup> \*

Image Upload

Save

### Forms

Basic Data

Images

Patient Characteristics

Physician Assessment

Baseline Assessment

Treatments

Surgery

Followups

Adverse Events

Death

Archive/Delete

### Instructions:

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# CRFs – Bowel Surgery

[illegible]

# CRFs – Physician Assessment

## Rectal Brachy Database

Menu Admin Forum Help Logout Theme: Gray

Case Number: 00000019

### Baseline Bowel Function

Exit Data Entry

#### Forms

- Basic Data
- Images
- Patient Characteristics
- Physician Assessment
- Baseline Assessment
- Treatments
- Surgery
- Followups
- Adverse Events
- Death
- Archive/Delete

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Bowel function at time of first treatment

☒ Faecal Incontinence

☒ Faecal Leakage Leakage Type: Faeces

☒ Pads Number per day: 2

☒ Does bowel function affect normal activities

☒ Anti diarrhoeals Average per day: 2

Bowel opening per day: 2

☒ Bleeding

Severity: Weekly

☒ Regular Blood transfusions

☐ Iron suppliments

☐ Treatment argon (APC)/others

☒ Pain

Type: Intermittent

Analgesics: Simple

☒ Fistulas

Site: Recto Vesical

☒ Stricture

Type: Asymptomatic

☒ Dilation

☒ Stricture Surgery

Save button

Save

# CRFs – Follow ups

Follow ups are  
auto scheduled

You can reschedule  
all the follow ups  
using this button

ColoRectalDB - Version 1.0  
https://clinicaldb.royalsurrey.nhs.uk/coloRectalDB/

ColoRectal Database - 1.0  
Case Number: 00000086  
Exit Data Entry

Forms

- Basic Data
- Studies
- Images
- New Cancer Diagnosis
- Death
- Initial Cancer
  - Baseline Characteristics
  - Baseline Assessment
  - Baseline Bowel Function
  - Radiotherapy
  - Chemotherapy
  - Bowel Surgery
  - Metastatic Surgery
  - Synchronous Tumours
  - Final Treatment
  - Relapse
  - Followups
- PROMS
- Adverse Events
- MRIOCAP
- Administration
  - Archive/Delete
  - Reassign Case Number

Instructions:  
Each page has its own Save button. If you browse around without saving, your changes may be lost.

Scheduled Events (Diagnosis 1)

+ Add - Delete Reschedule Show Archived Events

Date	Range (Days)	Event	Bloods	MRI	Sigmoidoscopy	CT	Colonoscopy	Followup Status	Notes
18/12/2016	+/- 7 days	Onc OPA	✓	✓	✓	✓	✓	Overdue <a href="#">Enter Data</a>	
22/12/2016	+/- 14 days	Onc OPA	✓	✓	✓	✓	✓	Due <a href="#">Enter Data</a>	
16/03/2017	+/- 14 days	Onc OPA	✓	✓	✓	✓	✓	Not yet due	
17/06/2017	+/- 30 days	Onc OPA	✓	✓	✓	✓	✓	Not yet due	
17/09/2017	+/- 30 days	Onc OPA	✓	✓	✓	✓	✓	Not yet due	
17/11/2017	+/- 30 days	Onc OPA	✓	✓	✓	✓	✓	Not yet due	
14/02/2018	+/- 30 days	Onc OPA	✓	✓	✓	✓	✓	Not yet due	
17/05/2018	+/- 30 days	Onc OPA	✓	✓	✓	✓	✓	Not yet due	
17/08/2018	+/- 30 days	Onc OPA	✓	✓	✓	✓	✓	Not yet due	
17/11/2018	+/- 30 days	Onc OPA	✓	✓	✓	✓	✓	Not yet due	
17/05/2019	+/- 30 days	Onc OPA	✓	✓	✓	✓	✓	Not yet due	
17/11/2019	+/- 60 days	Onc OPA	✓	✓	✓	✓	✓	Not yet due	
17/05/2020	+/- 60 days	CNS OPA	✓	✓	✓	✓	✓	Not yet due	
17/11/2020	+/- 60 days	Onc OPA	✓	✓	✓	✓	✓	Not yet due	

You can add or delete follow ups

Follow up information can be entered here

You can reschedule a single follow up

# CRFs – Consultant Follow ups

Rectal Brachy Database

Menu Admin Forum Help Logout Theme: Gray

Case Consultant Follow up (00000019): 2014-11-19

Date of follow up: \*  
11/11/2014

Exam performed for staging

☒ Digital Rectal Examination Response: \* Clinical Complete re Biopsy Performed: ☐ Please specify

☐ Endoscopy Response: \*  Biopsy Performed: ☐ Please specify

☒ MRI Response: \* TRG 2

☐ PET CT Response: \*  Biopsy Performed: ☐ Please specify

☐ CT Scan Response: \*  Biopsy Performed: ☐ Please specify

☐ Other Other:  Response: \*  Biopsy Performed: ☐ Please specify

Performance Status: \*  
2

Other cancer evolution

☒ Perirectal tumour

☒ Lymph node

☒ Other pelvic metastasis

☒ Distant metastasis ☒ Lung ☐ Liver ☐ Other Specify:

Bowel Function

Pateint with a stoma: \*  
Yes

Date of stoma: \*  
20/11/2014

No Stoma

☐ Faecal Incontinence

Save & Close Cancel

# CRFs – Adverse Events

Rectal Brachy Database

Case Number: 00000019 <<

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ADVERSE EVENTS - Maximum adverse event grade evaluation by using CTCAE - V4.0

+ Add - Delete ? Help

Name of adverse event (AE)	Grade of AE	Date of ONSET	Outcome	Hospitalization required	Causality	Action Taken
	<div>Grade 3</div> <div>Grade 4</div> <div>Grade 5</div>					

Update Cancel

Data from CTCAE v4

# CRFs - PROMs

PROMS are  
auto scheduled

You can add or  
delete PROMS

PROMS can be  
entered here

You can  
reschedule a  
single PROM

ColoRectalDB - Version 1.0

https://clinicaldb.royalsurrey.nhs.uk/coloRectalDB

ColoRectal Database - 1.0

Case Number: 00000086

Exit Data Entry

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  - Synchronous Tumours
  - Final Treatment
  - Relapse
  - Followups
  - PROMS
- Adverse Events
- Administration
  - Archive/Delete
  - Reassign Case Number

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PROMS Events (Diagnosis 1)

+ Add - Delete Reschedule Dates Show Archived Events

Date	Descriptions	Patient Status	Notes
01/01/2017	Baseline	Overdue <a href="#">Enter Data</a>	
01/02/2017		Not yet due	
05/02/2017		Not yet due	
01/05/2017		Not yet due	
01/08/2017		Not yet due	
01/11/2017		Not yet due	
01/01/2018		Not yet due	
01/04/2018		Not yet due	
01/07/2018		Not yet due	
01/10/2018		Not yet due	
01/01/2019		Not yet due	
01/07/2019		Not yet due	
01/01/2020		Not yet due	
01/07/2020		Not yet due	

# Patient Input

All patient forms are customisable

## Rectal Brachy Database

Patient Follow up (00000019): 2014-11-19

How much do your bowel symptoms affect your quality of life?:




Not at all: 0: 1: 2: 3: 4: 5: 6: 7: 8: 9: 10: 11: 12: All the time:

Currently how often do you open your bowels?:

	What is the least often you have your bowels open?	What is the most you have your bowels open?
Less than once a week:	<input type="radio"/>	<input type="radio"/>
Once every 4-7 days:	<input type="radio"/>	<input type="radio"/>
Once every 2-4 days:	<input checked="" type="radio"/>	<input type="radio"/>
Once a day:	<input type="radio"/>	<input type="radio"/>
2-3 times a day:	<input type="radio"/>	<input type="radio"/>
4-6 times a day:	<input type="radio"/>	<input checked="" type="radio"/>
7 or more times a day:	<input type="radio"/>	<input type="radio"/>

Please tick the box(es) which best describe(s) the stool you pass:

### Bristol Stool Chart

- |        |   |   |                                     |
|--------|---|---|-------------------------------------|
| Type 1 |  | Separate hard lumps, like nuts (hard to pass) | <input checked="" type="checkbox"/> |
| Type 2 |  | Sausage-shaped but lumpy                      | <input type="checkbox"/>            |
| Type 3 |  | Like a sausage but with cracks on the surface | <input type="checkbox"/>            |

Save & Close

Cancel

# Which PROMS to collect?

- Wide variety of tools available
- Which are the best to choose?
- Rarely subjected to reliability to validity testing
- Patients apparently happy to enter up to half an hour of data in one sitting



- 6 monthly EORTC C30, SF36, CR38, LARS
- Interval questionnaires consider
  - Vaisey
  - Sexual function
  - Decision regret
  - G8 for over 65s (geriatric assessment)
  - GPAQ or MFI
  - Concise questions aimed at identifying symptom clusters

# Symptom Clusters

- Cluster analysis may enable early detection of patients who are experiencing poor QOL without significant individual toxicities
- 4 groups defined by Gosselin et al.
  - Minimally symptomatic
  - Tired and trouble sleeping
  - Moderately symptomatic
  - Highly symptomatic

# Complex Intervention Protocol

- Complex Intervention Protocol (CIP) study
  - Pilot study-PROMs collection via internet
  - Feasibility study-develop CIP and test
  - Full study-roll out CIP to all interested sites

# Possible Example of CIP

- PROMs defines that patient is experiencing regular rectal bleeding and excessive wind
  - Automatic referral for flexible sigmoidoscopy +/- local treatment
  - Low irritant fibre diet sheet and pelvic floor exercise advice sent in post
  - Telephone follow up with dietician to see whether would benefit from a fibre supplement

# Thank You For Your Attention

