Database for PROMS and Outcomes

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The value of PROMS

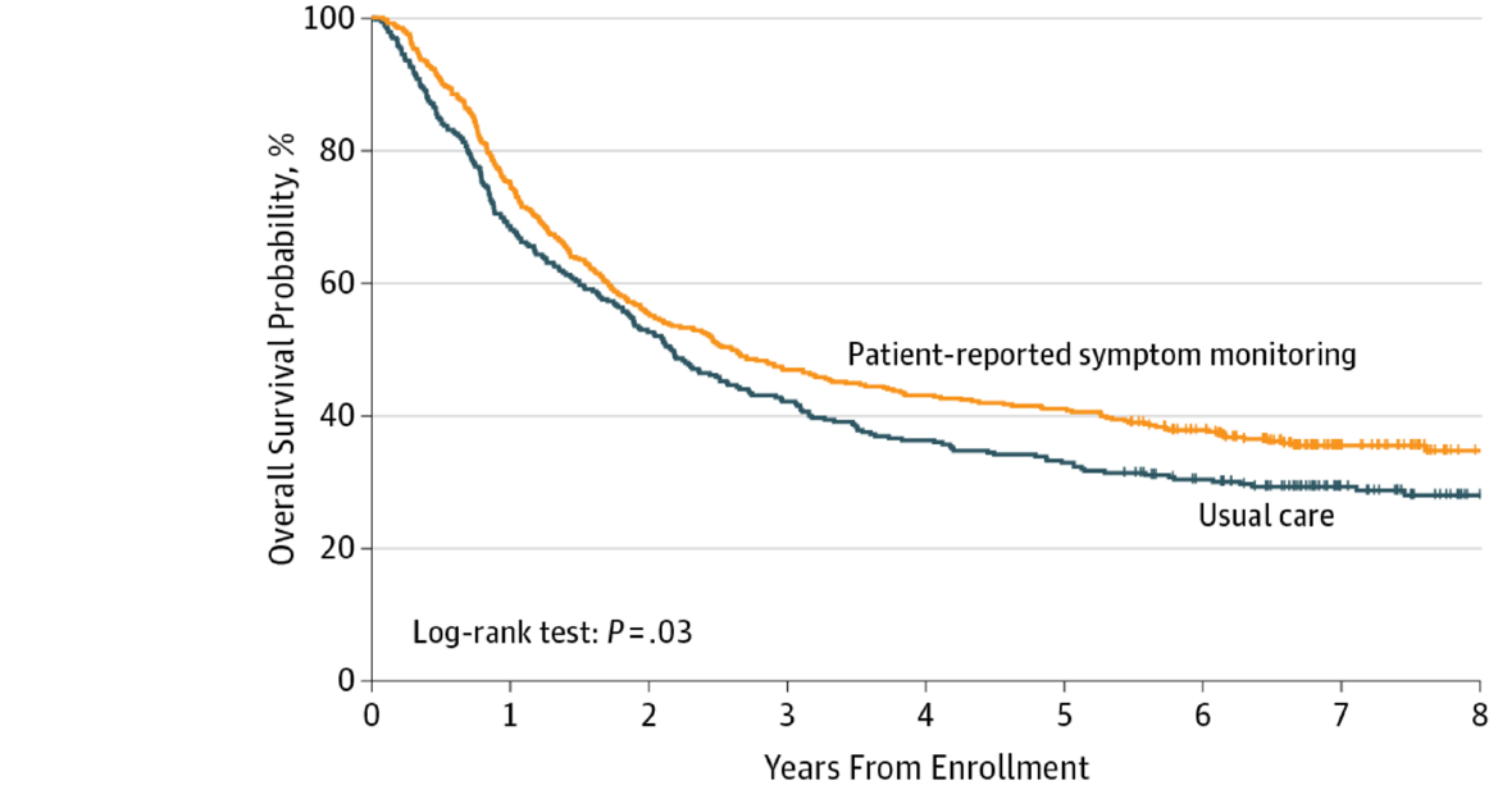
- To provide patients with the support they require
- To build up a body of evidence such that patients can incorporate QOL in decisions regarding their own management strategy

- NICE recommends that PROMS be used as secondary endpoints in future clinical trials regarding colorectal cancer

The JAMA Network

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



No. at risk

Patient-reported symptom monitoring	441	331	244	207	190	181	148	65	33
Usual care	325	223	171	137	118	107	89	50	27

Date of download: 11/20/2017

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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

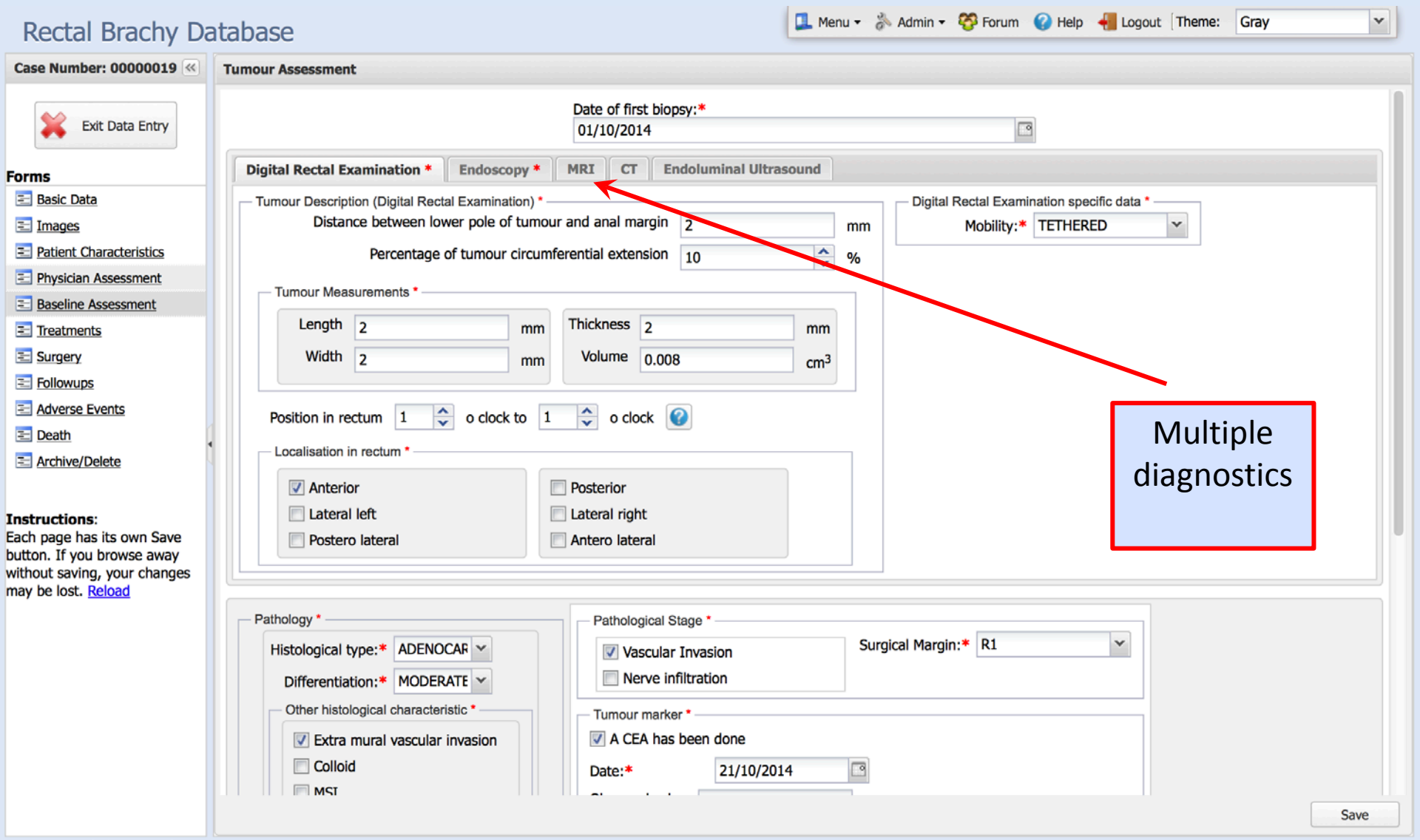
Key Desired Features of Database

- 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)

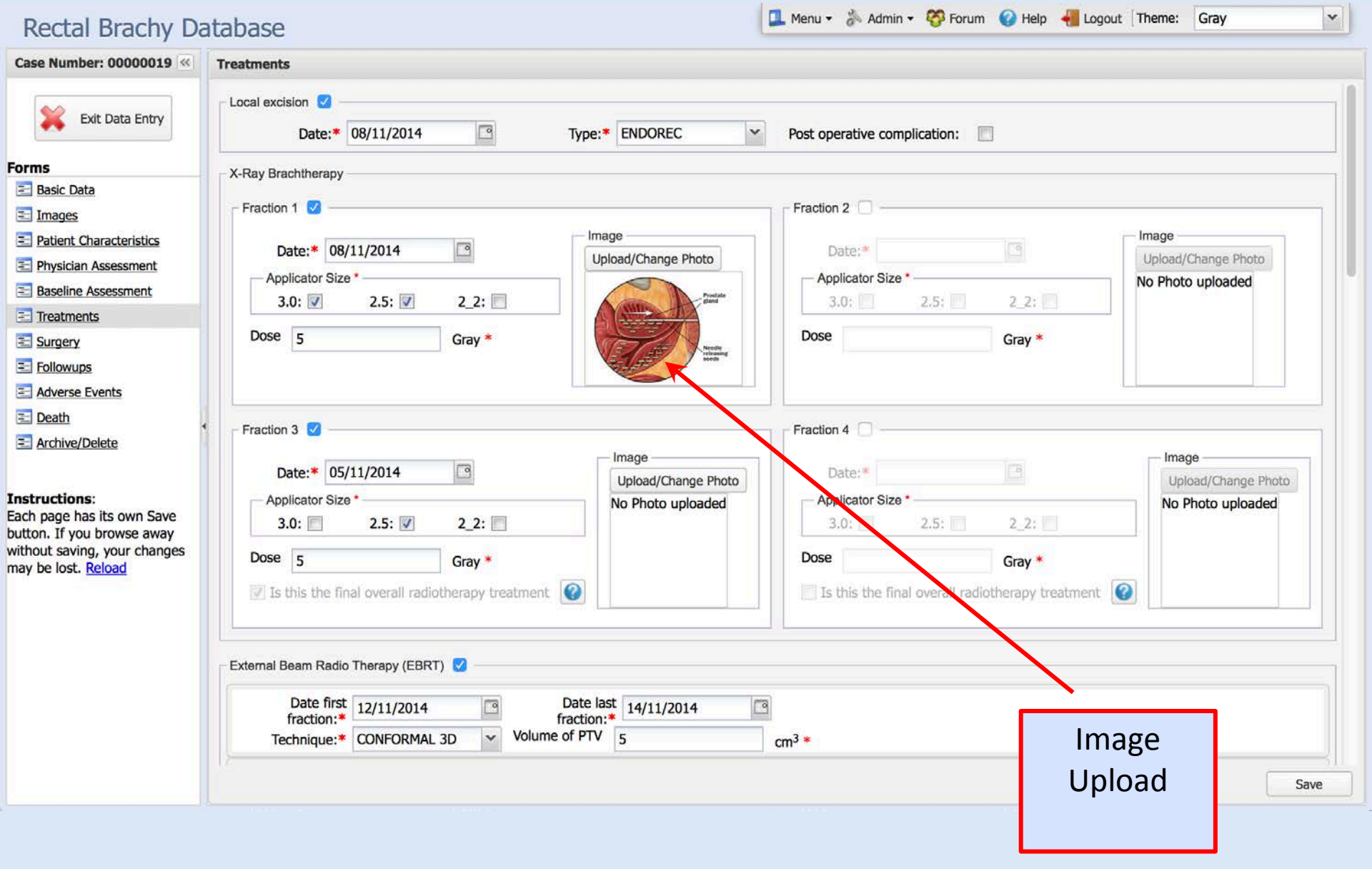
URL

www.colorectaldatabase.com
www.papillondatabase.com

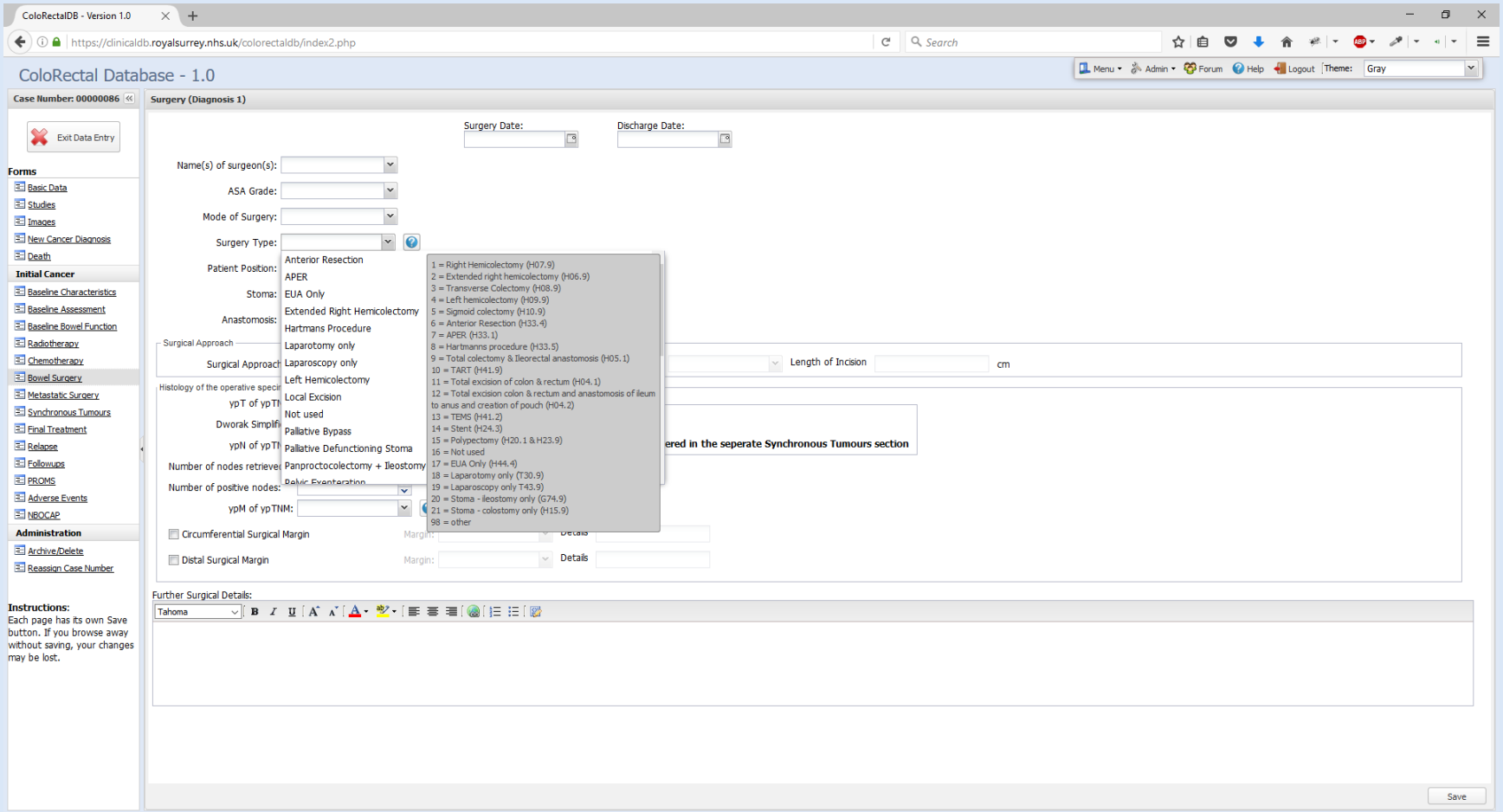
CRFs – Tumour Assessment



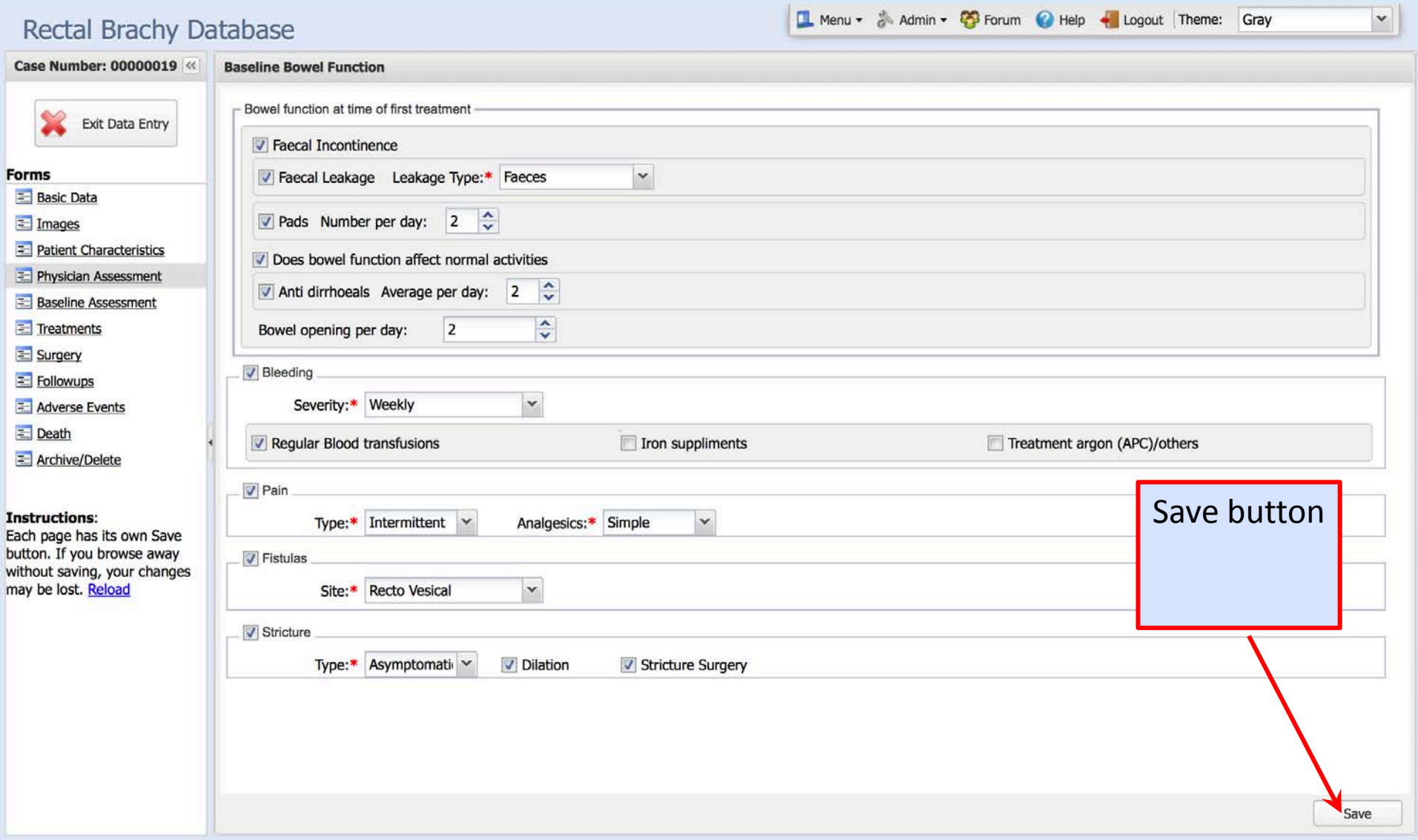
CRFs – Treatments



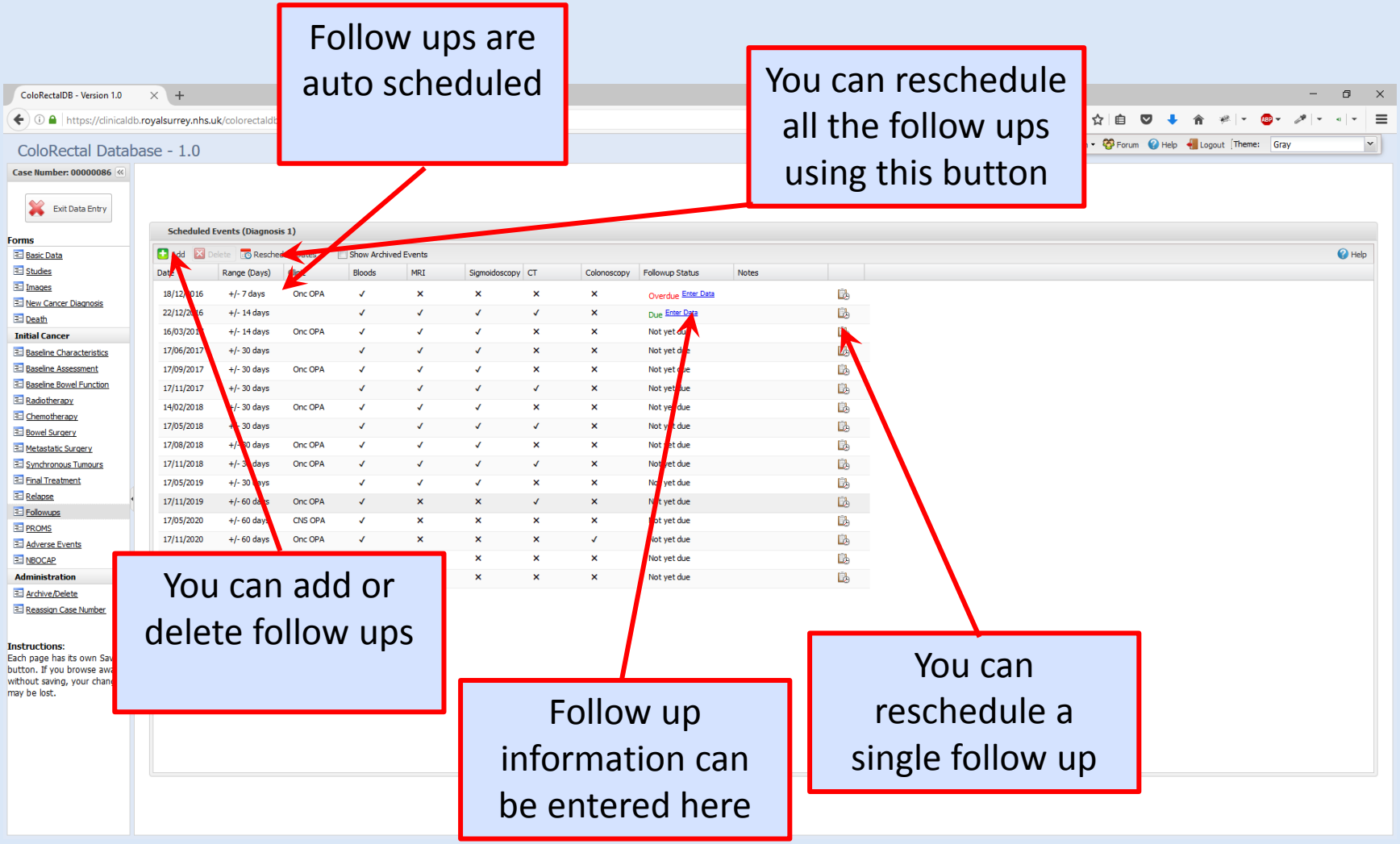
CRFs – Bowel Surgery



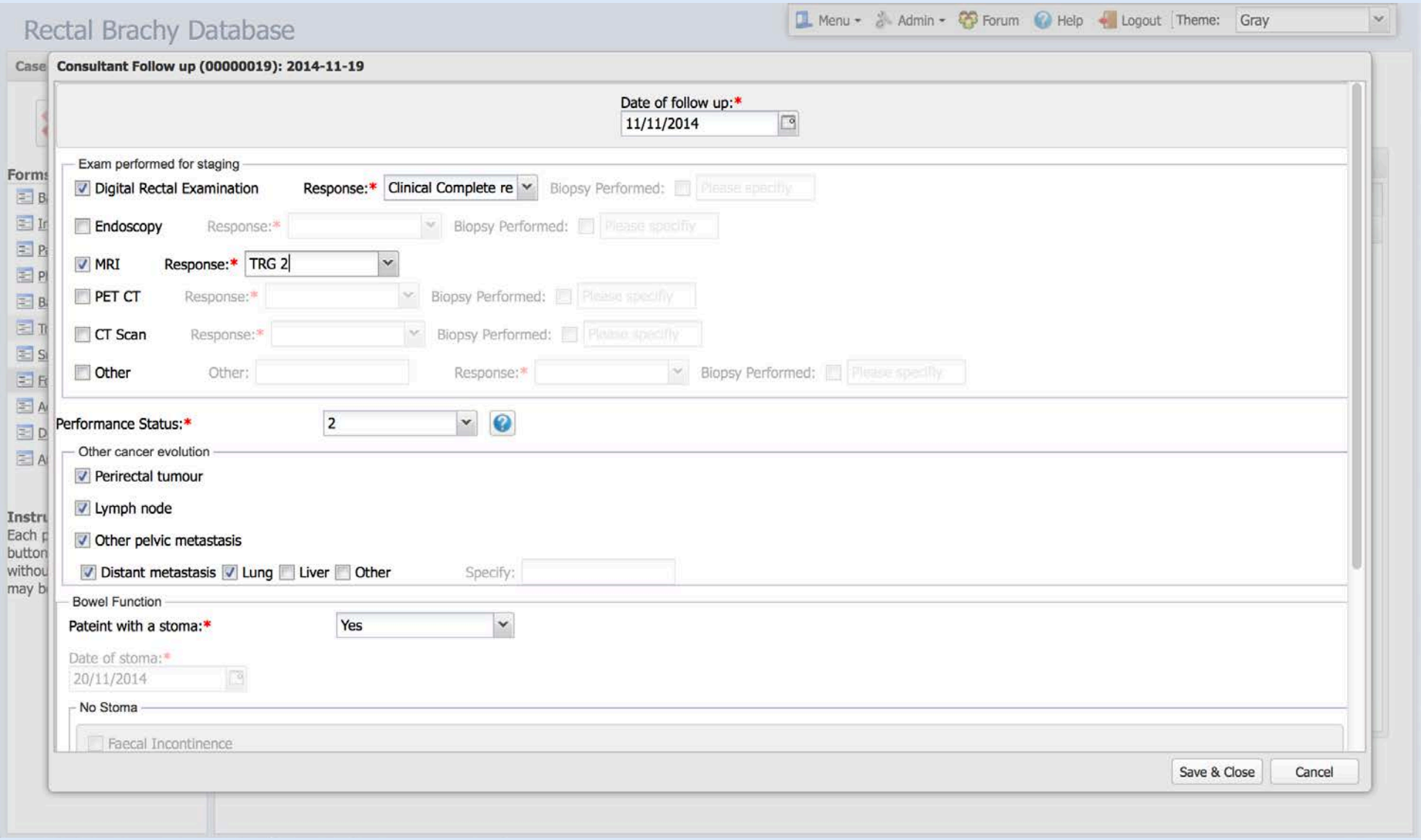
CRFs – Physician Assessment



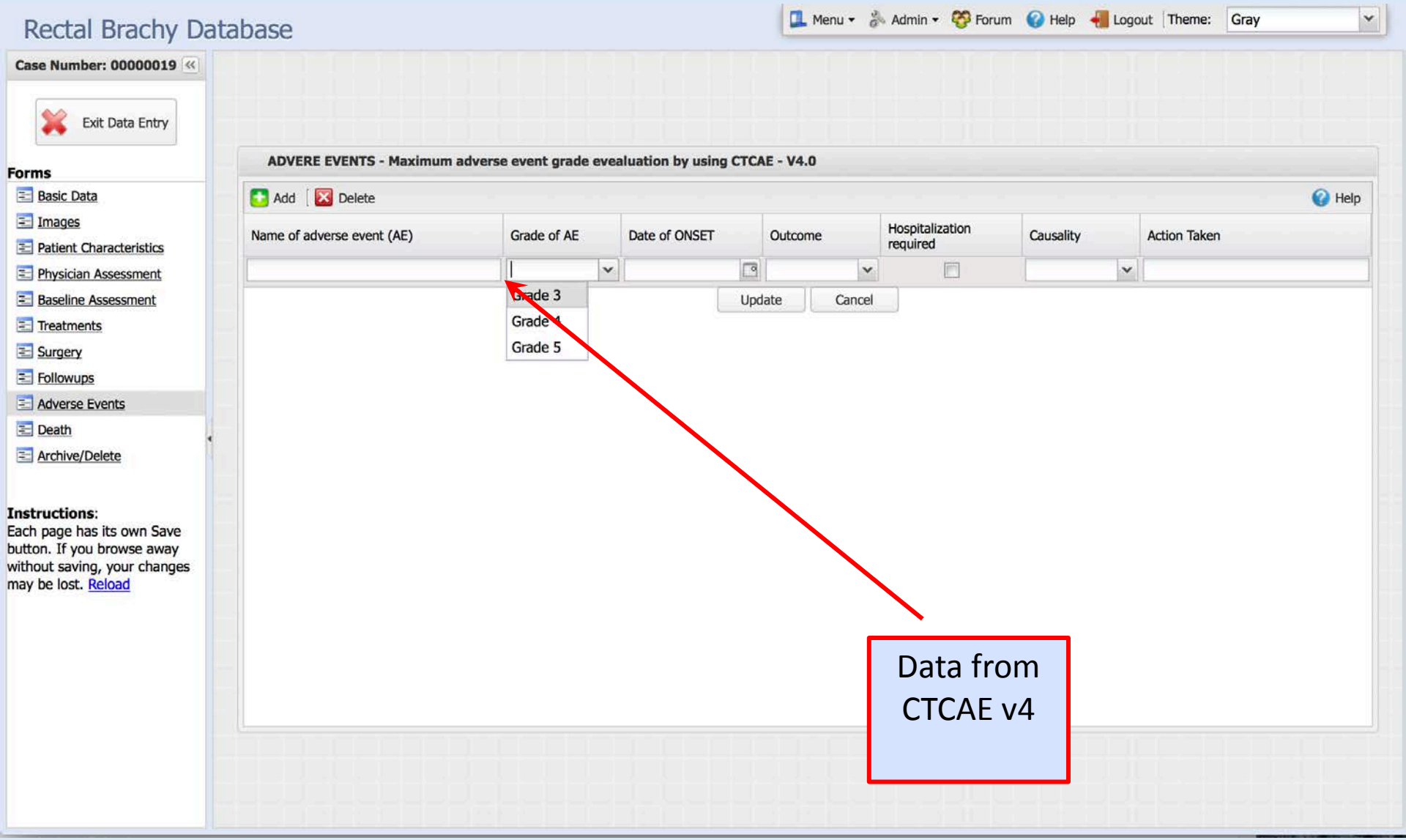
CRFs – Follow ups



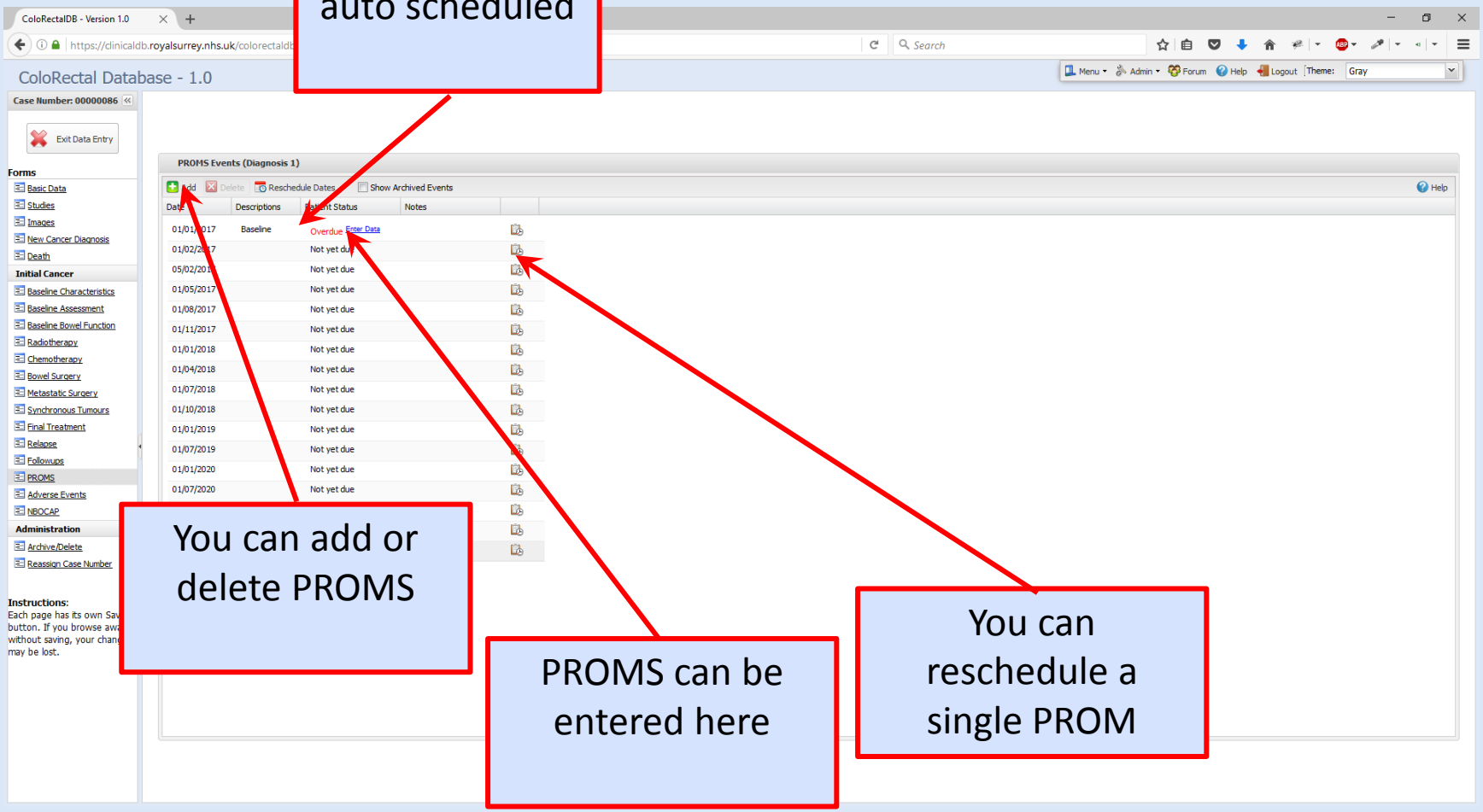
CRFs – Consultant Follow ups



CRFs – Adverse Events

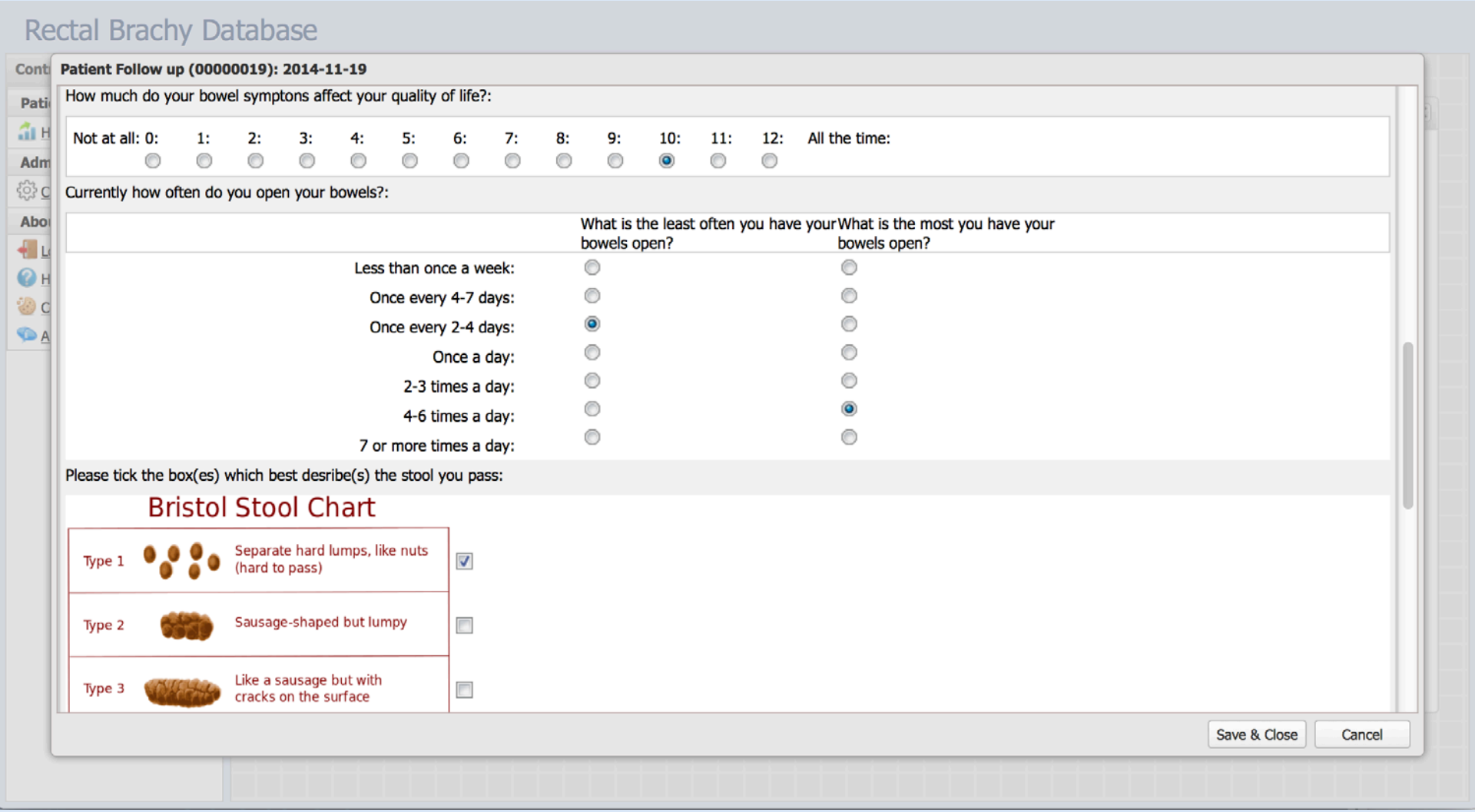


CRFs - PROMs


PROMS are auto scheduled
ColoRectalDB - Version 1.0
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
NBOCAP
Administration
Archive/Delete
Reassign Case Number
Instructions:
PROMS Events (Diagnosis 1)
Add
Delete
Reschedule Dates
Show Archived Events
Help
Date
Descriptions
Recruitment Status
Notes
01/01/2017
Baseline
Overdue
Enter Data
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
You can add or delete PROMS
PROMS can be entered here
You can reschedule a single PROM

Patient Input

All patient forms are customisable



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

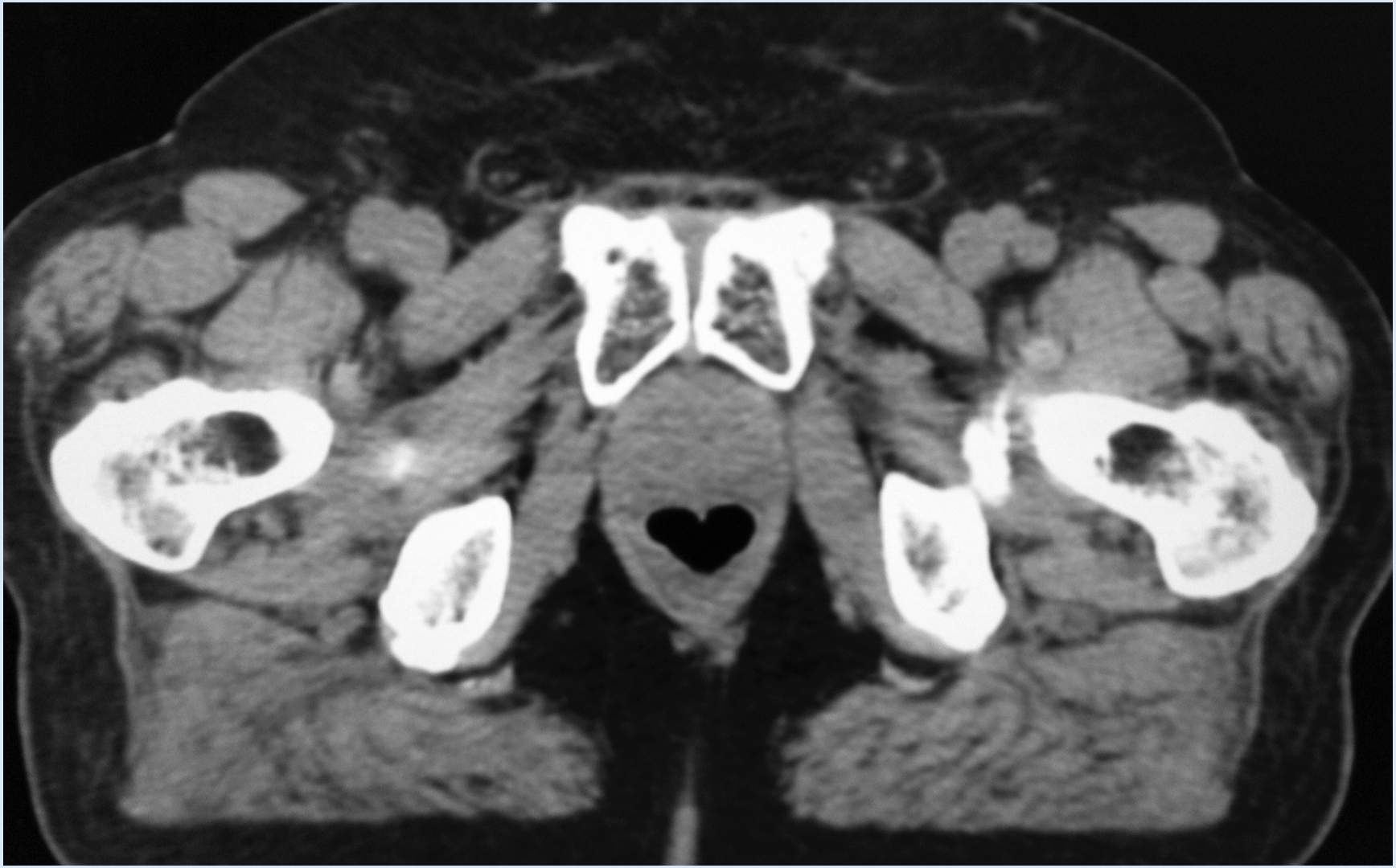
- Cluster analysis may enable early detection of patients who are experiencing poor QOL without significant individual toxicities

- 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