APPENDIX 1

Novel interventions for GORD and their mechanism of action

Novel Interventions for GORD

LINX	Magnetic Sphincter Augmentation	Ethicon, Somerville, NJ, USA
Stretta	Radio-frequency stimulation of Lower Oesophageal Sphincter	Restech, Houston, TX, USA
EsophyX	Transoral/Endoscopic Incisionless Fundoplication	EndoGastricSolutions, Redmond, WA, USA
IM RefluxStop	Implant to augment angle of His	Implantica, Baar, Switzerland

APPENDIX 2

Details of clinical recommendations considered for inclusion as audit standards and reasons for exclusion where applicable.

Audit Standard	Included as audit measure	Reason for exclusion
ICARUS Guidelines[24]		
ARS can be considered for patients with typical symptoms of heartburn, with a good response to PPI.	No	Measures of patient selection for ARS not being collected as part of ARROW.
Patients with functional heartburn and patients with eosinophilic oesophagitis are poor candidates for ARS.	No	Measures of patient selection for ARS not being collected as part of ARROW.
Patients with morbid obesity and patients with substance abuse are not excluded from ARS.	No	Measures of patient selection for ARS not being collected as part of ARROW.
Endoscopy (during the last year) is mandatory prior to referral for ARS.	Yes	N/A
Patients with GORD symptoms and a hiatal hernia, Barrett's oesophagus or erosive oesophagitis grade B or higher at endoscopy are good candidates for ARS.	No	Measures of patient selection for ARS not being collected as part of ARROW.
Patients without erosive oesophagitis are not excluded from ARS.	No	Measures of patient selection for ARS not being collected as part of ARROW.
There is no need to obtain routine biopsies of the distal oesophagus in patients considered for ARS.	No	Not possible to develop audit standard to measure adherence against.
A barium X-ray should be obtained in patients with a suspicion of a hiatal hernia or short oesophagus when considered for ARS.	No	Potential subjective interpretation of guidelines would make measurement of audit standard potentially inaccurate.
Patients with GORD symptoms and a hiatal hernia on X-ray are good candidates for ARS.	No	Measures of patient selection for ARS not being collected as part of ARROW.
Patients with GORD symptoms and a para-oesophageal hernia on X-ray are good candidates for ARS in addition to para-oesophageal hernia repair.	No	Measures of patient selection for ARS not being collected as part of ARROW.
A short oesophagus on barium X-ray does not preclude the patient from ARS.	No	Measures of patient selection for ARS not being collected as part of ARROW.
Oesophageal manometry and oesophageal pH monitoring	Yes	N/A

(±impedance) are mandatory prior to referral for ARS.		
Patients with normal pH-monitoring off PPI are poor candidates for ARS.	No	Measures of patient selection for ARS not being collected as part of ARROW.
Response to baclofen does not enhance patient eligibility to ARS.	No	Measures of patient selection for ARS not being collected as part of ARROW.
There is no need to asses gastric emptying rate in patients considered for ARS.	No	Not possible to develop audit standard to measure adherence against.
British Society of Gastroenterology (BSG) Guidelines[23]		
Any staff member performing manometry or reflux monitoring should either be fully trained or accredited by the AGIP in this procedure or supervised by a fully trained and accredited practitioner.	No	Oesophageal physiology quality measures beyond the scope of ARROW study.
All patients undergoing manometry for the investigation of dysphagia should undergo at least one form of adjunctive testing (eg: larger volumes of water, solid/viscous swallows or a test meal).	No	Oesophageal physiology quality measures beyond the scope of ARROW study.
All patients undergoing manometry to investigate dysphagia should have previously undergone endoscopy and mucosal biopsy.	No	Only patients with reflux symptoms (rather than dysphagia alone) included and performance of endoscopy prior to ARS captured separately.
All patients undergoing reflux monitoring should have manometry to guide probe placement	No	Oesophageal physiology quality measures beyond the scope of ARROW study.
All patients undergoing ARS should have manometry to exclude major oesophageal motility disorders.	Yes	N/A
All impedance recordings should be manually edited to ensure accurate reflux symptom association	No	Oesophageal physiology quality measures beyond the scope of ARROW study.
All patients should have at least two methods of symptom association assessed (eg: SAP and SI).	No	Oesophageal physiology quality measures beyond the scope of ARROW study.
All patients should undergo reflux monitoring prior to ARS.	Yes	N/A

The Provision Of Services For Upper Gastrointestinal Surgery Association of Upper GI Surgeons (AUGIS)[22]		
Unit rate of conversion to open surgery during ARS of <5%	Yes	N/A
Unit readmission rate following ARS of <10% within 30 days of surgery	Yes	N/A
Unit re-operation rate at 30 days following ARS of <5%	Yes	N/A
Laparoscopic ARS minimum activity per surgeon of >5 per annum	No.	Important to gain accurate clinical representation of current United Kingdom practice in this audit which units will voluntarily participate in. Therefore necessary to also include any potential low-volume clinical centres for ARS.

APPENDIX 3

Surgeon Survey

Registration

Name of surgeon:

Email address:

Please enter all hospitals the surgeon works for and select the main one:

- Hospital name …
- County …
- Main one: ☐

Surgeon Survey

Date completed …

Please select job role:

- Consultant ☐
- Associate Specialist ☐

Year first appointed as a consultant/associate specialist:

Primary practice:

- Benign upper GI ☐
- Bariatric ☐
- OG resectional ☐
- HPB resectional ☐
- General Surgery ☐
- Colorectal ☐

Please estimate how many anti-reflux surgery cases you perform per year:

- NHS …
- Private …

Which preoperative investigations would you consider **compulsory** for anti-reflux surgery:

Tick all that apply

- OGD ☐
- Upper GI contrast study ☐
- CT ☐
- 24-hour pH monitoring ☐
- Wireless pH monitoring (BRAVO) ☐
- 24-hour impedance monitoring ☐
- High resolution manometry ☐
- Standard resolution manometry ☐
- Other ☐

Where is your oesophageal physiology testing (including pH monitoring, manometry and impedance) performed?

- NHS laboratory situated within your Trust ☐
- NHS laboratory at another hospital Trust ☐
- External laboratory ☐
- Not sure ☐

Which of the following procedures do you undertake for GORD?

- Fundoplication: ☐
- LINX: ☐
- Stretta: ☐
- EsophyX: ☐
- Roux-en-Y gastric bypass ☐
- RefluxStop™ ☐
- Other: (please name) ☐

Which of the following procedures do you perform when doing a fundoplication?

- Nissen posterior 360º ☐
- Toupet posterior 270º ☐
- Toupet posterior 180º ☐
- Dor anterior 180º ☐
- Watson anterior 120º ☐
- Partial anterior 90º ☐
- Collis: ☐
- Other ☐

Do you tailor the type of wrap performed for each individual?

- Yes, based on manometry findings ☐
- Yes, based on clinical symptoms ☐
- Never ☐

Which procedures do you perform as an intended day-case?

- Fundoplication: ☐
- LINX: ☐
- Stretta: ☐
- EsophyX: ☐
- Roux-en-Y gastric bypass ☐
- None performed as intended day case procedure: ☐
- Other: (please name) ☐

What criteria do you apply for same-day discharge following anti-reflux surgery (other than standard requirements for day-case surgery)?

- Tolerance of solid oral intake ☐
- Tolerance of liquid oral intake ☐
- Proximity of patient residence from hospital ☐
- Surgery completed by a specific time ☐
- Not performed as intended day case procedure: ☐
- Other (please give details): _____

Do you divide the short-gastric vessels?

- Routinely ☐
- Selectively ☐
- Never ☐

Do you perform an anterior cruroplasty?

- Routinely ☐
- Selectively ☐
- Never ☐

Do you perform a posterior cruroplasty?

- Routinely ☐
- Selectively ☐
- Never ☐

Do you perform a Collis oesophageal lengthening procedure?

- Routinely ☐
- Selectively ☐
- Never ☐

Do you repair over a bougie or orogastric tube?

- Routinely ☐
- Selectively ☐
- Never ☐

Do you maintain a prospective database of your anti-reflux surgery practice?

- Yes ☐
- No ☐

Do you record severity/symptom or quality of life scores pre-operatively?

- Routinely ☐
- Selectively ☐
- Never ☐

Do you record severity/symptom or quality of life scores post-operatively?

- Routinely ☐
- Selectively ☐
- Never ☐

Post-Op workup: Do you carry out a routine post-operative assessment of the wrap with:

OGD

- Yes ☐
- No ☐

Upper GI contrast study

- Yes ☐
- No ☐

Do you believe anti-reflux surgery (other than gastric bypass for reflux disease) is effective for patients with obesity?

- Yes ☐
- No ☐

What is the upper limit of a patient's BMI that you would perform anti-reflux surgery (other than gastric bypass for reflux disease)?

- <25 ☐
- <30 ☐
- <32 ☐
- <35 ☐
- <40 ☐
- <45 ☐
- <50 ☐
- No limit ☐
- Alternative criteria used ☐

Do you request patients with obesity complete a pre-operative liver shrinkage diet prior to surgery?

- Yes ☐
- No ☐
- Selectively ☐

If yes do you use specific clinical or BMI criteria for advising patients to complete this?

- Do not utilise ☐
- BMI>32 ☐
- BMI>35 ☐
- BMI>40 ☐
- BMI>45 ☐
- BMI>50 ☐
- Central pattern obesity ☐
- Clinical examination of abdominal wall stiffness in RUQ ☐
- Alternative criteria used ☐
- No specific criteria ☐

Do you discharge patients home with an anti-emetic?

- Yes ☐
- No ☐
- Selectively ☐

Do you discharge patients home with opioid analgesia?

- Yes ☐
- No ☐
- Selectively ☐

Are you the lead surgeon for the Arrow Audit at any institution?

- Yes ☐
- No ☐

(if Yes opens Institutional survey)

Institutional survey

Estimated number of cases of anti-reflux surgery performed annually at your institution …

Number of surgeons completing anti-reflux surgery at your institution: …

Is oesophago-gastric resectional surgery performed at your institution?

- Yes ☐
- No ☐

Is bariatric surgery performed at your institution?

- Yes ☐
- No ☐

Does your institution have set funding criteria for anti-reflux procedures? If so, please describe or supply a copy of funding criteria?

- Yes ☐
- No ☐
- Details: _____

Is your institution required to apply to the local Clinical Commissioning Group for funding of anti-reflux surgery on an individual patient basis?

- Yes ☐
- No ☐

Preop workup: Which of the following does your institution have access to for the investigation of reflux:

- OGD ☐
- Upper GI contrast study ☐
- CT ☐
- 24-hour pH monitoring ☐
- Wireless pH monitoring (eg. BRAVO™) ☐
- 24-hour impedance monitoring ☐
- High resolution oesophageal manometry ☐
- Standard resolution oesophageal manometry ☐

Does your institution maintain a prospective database of anti-reflux surgery practice?

- Yes ☐
- No ☐

Does your institution have access to a benign UGI MDT to discuss patients prior to anti-reflux surgery?

- Routinely ☐
- Selectively ☐
- Only prior to revision surgery ☐
- Never ☐

If your institution holds a benign UGI MDT is this held:

- Locally ☐
- Regionally (in person) ☐
- Regionally (via tele-link) ☐

If your institution holds a benign MDT who are your core members?

- UGI Surgeons ☐
- Gastroenterologists ☐
- Radiologist ☐
- Physiologist ☐
- UGI Nurse Specialist ☐
- Other (details below) ☐
- Details of other team members: _____

Does your institution give a standardised pre-operative information sheet/booklet to patients?

- Yes ☐
- No ☐

Does your institution have a standardised advice sheet for post-operative diet?

- Yes ☐
- No ☐

Do all surgeons in your institution follow the same post-operative diet protocol?

- Yes ☐
- No ☐

What routine clinical follow up does your institution perform?

- In-person clinic appointment (doctor) ☐
- In-person clinic appointment (nurse) ☐
- Telephone clinic (doctor) ☐
- Telephone clinic (nurse) ☐
- None ☐

APPENDIX 4

Go straight to content.

MRC Medical Research Council

NHS Health Research Authority

Is my study research?

To print your result with title and IRAS Project ID please enter your details below:

Title of your research:

A multicentre prospective cohort study to investigate the current management of patients undergoing anti-reflux surgery in the United Kingdom: ARROW (Audit & Review of Anti-Reflux Operations & Workup)

IRAS Project ID (if available):

You selected:

- **'No'** - Are the participants in your study randomised to different groups?
- **'No'** - Does your study protocol demand changing treatment/ patient care from accepted standards for any of the patients involved?
- **'No'** - Are your findings going to be generalisable?

Your study would NOT be considered Research by the NHS.

You may still need other approvals.

Researchers requiring further advice (e.g. those not confident with the outcome of this tool) should contact their R&D office or sponsor in the first instance, or the HRA to discuss your study. If contacting the HRA for advice, do this by sending an outline of the project (maximum one page), summarising its purpose, methodology, type of participant and planned location as well as a copy of this results page and a summary of the aspects of the decision(s) that you need further advice on to the HRA Queries Line at **HRA.Queries@nhs.net**.

For more information please visit the **Defining Research** table.

Follow this link to start again.

Print This Page

NOTE: If using Internet Explorer please use browser print function.

A**PPENDIX 5**

Case Report Form (CRF)
[Completed via online portal through ALEA]

1. Registration

Patient Initials: _____

Date of birth: _ _/_ _/_ _ _ _

2. Patient History

2.1 Demographics

Sex: Male ☐
Female ☐

ASA: I ☐
II ☐
III ☐
IV ☐
V ☐

Height: _____ metres

Weight: ____ Kg

OR

BMI (derived): _____

Previous Thoracic Surgery: Yes ☐
No ☐
Unknown ☐

If Yes Thoracoscopic ☐
Open ☐
Both ☐
No ☐
Unknown ☐

Previous abdominal surgery: Yes ☐
No ☐
Unknown ☐

If yes: Laparoscopic ☐
Open ☐
Both ☐
Unknown ☐

Any Co-morbidities: Yes ☐
No ☐
Unknown ☐

If yes:
Charlson comorbidity index:

Acute myocardial infarction	☐
Cancer	☐
Cerebral vascular accident	☐
Congestive heart failure	☐
Connective tissue disorder	☐
Dementia	☐
Diabetes	☐
Diabetes complications	☐
HIV	☐
Liver disease	☐
Metastatic cancer	☐
Paraplegia	☐
Peptic ulcer	☐
Peripheral vascular disease	☐
Pulmonary disease	☐
Renal disease	☐
Severe liver disease	☐

Total score: ____

Smoking status:

Current smoker	☐
Ex-smoker	☐
Never smoked	☐
Unknown	☐

Vaping status:

Current vaper	☐
Ex- vaper	☐
Never vaped	☐
Unknown	☐

2.2 Referrals

Date of referral:

Source of referral:
- GP/Primary care ☐
- Gastroenterology ☐
- ENT ☐
- Respiratory ☐
- Transplant ☐
- Other hospital specialist ☐
- Unknown ☐

If not primary care:
Was this referral from:
- The same hospital ☐
- Other hospital ☐

Duration of symptoms at referral:
- 0 - 6 months ☐
- 6 - 12 months ☐
- 1 - 2 years ☐
- 2 - 5 years ☐
- > 5 years ☐
- > 10 years ☐

Current use of PPI:
- Yes (continuous) ☐
- Yes (intermittent) ☐
- No ☐
- Unknown ☐

Current use of H_2 Antagonist (eg Ranitidine):
- Yes (continuous) ☐
- Yes (intermittent) ☐
- No ☐
- Unknown ☐

2.3 Symptoms

Heartburn

Daytime heartburn:
- Yes ☐
- No ☐
- Unknown ☐

Nocturnal heartburn:
- Yes ☐
- No ☐
- Unknown ☐

Positional heartburn: Yes ☐ No ☐ Unknown ☐

Regurgitation

Daytime regurgitation: Yes ☐ No ☐ Unknown ☐

Nocturnal regurgitation: Yes ☐ No ☐ Unknown ☐

Positional regurgitation: Yes ☐ No ☐ Unknown ☐

Other Symptoms

Epigastric/chest pain: Yes ☐ No ☐ Unknown ☐

Sleep disturbance: Yes ☐ No ☐ Unknown ☐

Dysphagia: Yes ☐ No ☐ Unknown ☐

Chronic cough: Yes ☐ No ☐ Unknown ☐

Chronic laryngitis: Yes ☐ No ☐ Unknown ☐

Dental erosions: Yes ☐ No ☐ Unknown ☐

2.4 Workup

OGD performed: Yes ☐ No ☐ Unknown ☐

Date of most recent OGD: …

OGD findings:

Barrett's Oesophagus: Yes ☐ No ☐ Unknown ☐

Oesophagitis: No ☐ Yes - Grade A ☐ Yes - Grade B ☐ Yes - Grade C ☐ Yes - Grade D ☐ Yes - Grade Unknown ☐ Unknown ☐

Stricture: Yes ☐ No ☐ Unknown ☐

Hiatus Hernia: Yes ☐ No ☐

Hiatus Hernia Size: Small<2cm ☐ Medium 2-5cm ☐ Large >5cm ☐ >50% intrathoracic Stomach ☐ Total intrathoracic Stomach ☐

Other intra-abdominal organs within hiatus hernia
None ☐ Colon ☐ Pancreas ☐ Spleen ☐ Other ☐

24h pH monitoring performed: Yes ☐
No ☐
Incomplete ☐

Total time pH <4 ….hrs ….mins or ….%
Symptom Correlation Index ….% or value 0-1
Symptom Association Probability ….% or value 0-1

DeMeester Score ….

Impedance monitoring performed Yes ☐
No ☐
Incomplete ☐

Manometry performed: Yes ☐
No ☐
Incomplete ☐

If yes: High resolution ☐
Standard resolution ☐

Peristalsis:

Normal ☐

Weak ☐

Absent ☐

Lower Oesophageal Sphincter Pressure: …
Integrated Relaxation Pressure IRP: …

Contrast swallow performed: Yes ☐
No ☐

CT performed: Yes (oral contrast) ☐
Yes (no contrast) ☐
No ☐

Other investigation performed: [Details] _____

3. Surgery

3.1 – Revisional surgery

Is this a revisional procedure?

Yes ☐
No ☐

If Yes:
How long ago was the primary procedure?

< 6 months ☐
6-12 months ☐
1-5 years ☐
>5 years ☐
>10 years ☐

What was the primary procedure?

Fundoplication ☐
LINX ☐
EsophyX ☐
Stretta ☐
Gastric bypass ☐
Other – please specify

Has this patient had previous revisions?

Yes ☐
No ☐

Indication for this revision:

Recurrence of symptoms ☐
Dysphagia ☐

3.2 Primary Indication for Surgery

What is the primary indication for surgery? (Tick one only)

- Symptoms not sufficiently controlled by PPI ☐
- Not compliant with PPI ☐
- Side effects with PPI ☐
- Symptoms adequately controlled but patient prefers surgical management: ☐
- Intra-oesophageal complications of GORD: ☐
- Lung transplant patient ☐
- Non-oesophageal symptoms/complications of GORD: ☐
  - Info: Chronic cough, dental erosions, aspiration pneumonia etc.
- Other: [Details] _____

3.3 Surgery

Date of operation: _ _/_ _/_ _ _ _

Grade of primary surgeon:
- ST3-6 ☐
- ST7-8 ☐
- Staff Grade ☐
- Associate Specialist ☐
- Post CCT Fellow ☐
- Consultant ☐

Was the procedure a training case:
- Yes(in part) ☐
- Yes(in full) ☐
- No ☐
- Unknown ☐

Procedure performed:
- Fundoplication ☐
- LINX ☐
- EsophyX ☐
- Stretta ☐
- Gastric bypass ☐
- Other – please specify

Was the operation as part of an unplanned admission:
- Yes ☐
- No ☐
- Unknown ☐

Was the planned procedure performed:
- Yes ☐
- No ☐
- Unknown ☐

If No: Procedure planned:
- Fundoplication ☐
- LINX ☐
- EsoPhyx ☐
- Stretta ☐
- Gastric bypass ☐
- Other – please specify

Was the procedure planned as a day case:
- Yes ☐
- No ☐
- Unknown ☐

Procedure Specific Details

Procedure Duration:
- <1hr ☐
- 1-2hrs ☐
- 2-3hrs ☐
- 3-4hrs ☐
- >4hrs ☐

Fundoplication intra-operative details [Additional drop-down menu]

Approach:
- Open ☐
- Laparoscopic ☐
- Robotic ☐
- Endoscopic ☐
- Lap converted to open ☐
- Robotic converted to lap ☐
- Robotic converted to open ☐
- Endo converted to lap ☐
- Endo converted to open ☐

Posterior cruroplasty:
- Yes ☐
- No ☐

Anterior cruroplasty:
- Yes ☐
- No ☐

Suture material:
- Absorbable ☐
- Non-absorbable ☐

Sizing of repair:
- Bougie/OG tube ☐
- Visual ☐

Mesh used:
- No ☐
- Biologic ☐
- Synthetic – non-absorbable ☐
- Synthetic – absorbable ☐
- Composite – synthetic ☐
- Composite – synthetic + biological ☐

If mesh used:

Mesh fixation:
- Absorbable sutures ☐
- Non-absorbable sutures ☐
- Metal tacks ☐
- Non-metal tacks – absorbable ☐
- Non-metal tacks – non-absorbable ☐

Hepatic vagal fibres preserved:	Yes	☐
	No	☐
Anterior vagus preserved:	Yes	☐
	No	☐
Posterior vagus preserved:	Yes	☐
	No	☐
Division of short gastrics:	Yes	☐
	No	☐
Wrap anterior/posterior:	Anterior	☐
	Posterior	☐
Wrap 180/270/360:	90	☐
	120	☐
	180	☐
	270	☐
	360	☐
Oesophageal stitch:	Yes	☐
	No	☐
Diaphragmatic stitch:	Yes	☐
	No	☐
Collis (oesophageal lengthening procedure):	Yes	☐
	No	☐
Other modifications: [Details]	…	

Roux-en-Y Gastric Bypass:

Alimentary limb length	…
Biliary limb length	…

LINX intra-operative details [Additional drop-down menu]

LINX Size:	10	☐
	11	☐
	12	☐
	13	☐
	14	☐
	15	☐
	16	☐
	17	☐
	18	☐

All Procedures:

Intraoperative complications:	Yes	☐
	No	☐
Pneumothorax (requiring drain):	Yes	☐
	No	☐
Major visceral injury:	No	☐
	Oesophagus	☐
	Stomach	☐
	Spleen	☐
	Liver	☐
	Colon	☐
	Small Bowel	☐
	Heart/ Pericardium	☐
	Other	…
Major vascular injury:	No	☐
	Aorta	☐
	Inferior Vena Cava	☐
	Other	…
Estimated blood loss:		
	Minimal	☐
	100-500ml	☐
	500-1000ml	☐
	1-2l	☐
	>2l	☐

3.3 Post-Operative

Date of discharge:	…	
Delayed discharge?	Yes	☐
	No	☐
If yes: Reason:	Dysphagia	☐
	Inadequate oral intake	☐
	Vomiting	☐
	Pain	☐
	Pneumonia	☐
	Pneumothorax	☐
	Urinary retention	☐
	Social	☐
	Other – please specify	

Investigations:

- None ☐
- Laparoscopy ☐
- Contrast swallow ☐
- CT ☐
- OGD ☐
- CXR ☐
- Other – please specify

(able to select multiple options)

Interventions:

- None ☐
- Antibiotics ☐
- Chest drain ☐
- Return to theatre ☐
  - If ticked – please specify ….
    - Date of operation …
- Pneumatic dilatation ☐
- Other – please specify

(able to select multiple options)

Complications?

- Yes ☐
- No ☐

If yes: Number of Complications (per Clavien Dindo):
(on index admission)

- Grade 1 …
- Grade 2 …
- Grade 3a …
- Grade 3b …
- Grade 4a …
- Grade 4b …
- Grade 5 …

Readmission within 90 days? (Including admission for day case procedure/investigation)

- No ☐
- Yes ☐

If yes:

Date of readmission …

Date of discharge from readmission …

Reason:

- Dysphagia ☐
- Inadequate oral intake ☐
- Vomiting ☐
- Pain ☐
- Pneumonia ☐
- Pneumothorax ☐
- Urinary retention ☐
- Social ☐
- Other – please specify

Investigations:

- None ☐
- Laparoscopy ☐
- Contrast swallow ☐
- CT ☐
- OGD ☐
- CXR ☐
- Other – please specify

(able to select multiple options)

Interventions:

- None ☐
- Antibiotics ☐
- Chest drain ☐
- Return to theatre ☐
  - If ticked – please specify ….
    - Date of operation …
- Pneumatic dilatation ☐
- Other – please specify

(able to select multiple options)

Complications?

- Yes ☐
- No ☐

If yes:

Number of Complications (per Clavien Dindo):
(on index admission)

- Grade 1 …
- Grade 2 …
- Grade 3a …
- Grade 3b …
- Grade 4a …
- Grade 4b …
- Grade 5 …

4. Outcomes

Follow-up within 90 days of operation:

Routine Outpatient-Doctor	☐
Routine Outpatient-Nurse	☐
Unplanned re-presentation	☐
Telephone - Doctor	☐
Telephone - Nurse	☐
No follow-up planned	☐
Did not attend follow-up	☐

If followed up:

Date of first follow-up: _ _/_ _/_ _ _ _

Discharged after first follow-up:

Yes	☐
No	☐

Any Patient Reported Outcome Measures used:

No	☐
GERDQ	☐
GSFQ	☐
Other – please specify	

Resolution of symptoms?

Yes	☐
No	☐
Partial	☐

Ongoing PPI used:

Yes	☐
No	☐

APPENDIX 6

Data storage technical details

ALEA eCRF is an electronic Case Report Forms service for the data collection in clinical trials. It provides a comprehensive, user friendly forms service which can be used with a standard browser running on any computer connected to the internet. The system has been validated and has been certified by registered auditors to be in compliance with regulation, such as the FDA's CFR 21 Part 11.

ALEA consists of a study design (SD) component and a data management (DM) component. During setup and maintenance of the study, the SD component is used to create or modify the design of the study. The DM component exists on a test/development, acceptance and production instance. The test/development instance provides an environment to test the setup and modifications for the CIRU programmers while the acceptance instance is used by the client for user acceptance testing. The production instance is used once the study is live. These environments are physically isolated, and do not share data and accounts.

SD and the test/development environment of data management are hosted in Amsterdam. The acceptance and production environments of DM are hosted in Den Bosch. This location is a secured, ISO 27001 certified data centre operated by InterConnect BV in Den Bosch, the Netherlands. FormsVisions' Quality Assurance includes formal disaster management procedures for management of issues related to the operational environment. Measurements include failover, local data recovery, and site recovery. Each physical server is equipped with RAID5 disk redundancy, redundant power supply and redundant network connectivity. The server facilities in Den Bosch include both hot standby and cold standby servers. Hot standby servers (DBSHV3 and DBSSQL2) allow for near-instant failover to a running server in case

of physical server failure. In case of logical server failure, cold standby servers (DBSHV4, DBSHV5) provide local data recovery in case the site is operational. In case of site failure, the disaster recovery procedure provides transfer of all operational services to our hosting facilities in Amsterdam.

APPENDIX 7

Definitions

Gastro-Oesophageal Reflux Disease	A condition which develops when the reflux of stomach contents causes troublesome symptoms and/or complications[1].
Heartburn	A burning sensation in the retrosternal area (behind the breastbone) [1].
Regurgitation	The perception of flow of refluxed gastric content into the mouth or hypopharynx[1].
Typical Reflux Syndrome	Heartburn and regurgitation are the characteristic symptoms of the typical reflux syndrome[1].
Nonerosive Reflux disease	The presence of troublesome reflux-associated symptoms and the absence of mucosal breaks at endoscopy[1].
Reflux Oesophagitis	Defined endoscopically by visible breaks of the distal esophageal mucosa[1].
Reflux Stricture	A persistent luminal narrowing of the esophagus caused by GORD[1].
Dysphagia	A perceived impairment of the passage of food from the mouth into the stomach[1].
Lower Oesophageal Sphincter	A specialized thickened region of the circular muscle layer of the distal oesophagus

1. Vakil, N; van Zanten, S; Kahrilas, P; Dent, J; Jones R. The Montreal Definition and Classification of Gastroesophageal Reflux Disease: A Global Evidence-Based ConsensusCMEThe Montreal Definition and Classification of GERD. Am J Gastroenterol. 2006 (101):1900–20.