Improving Gastrointestinal and Liver Care through Research

The Clinical Research Strategy of the British Society of Gastroenterology
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Dear Colleague/Member

On behalf of the Research Committee of the BSG I am delighted to be able to introduce the updated BSG Clinical Research Strategy for 2018. Professor Mark Hull developed an ambitious and comprehensive strategy document in 2010, which has been helpful in many ways in shaping the face of current gastroenterology and hepatology research. Since 2010 there have been a number of changes to the Research Committee and its sub-groups, in particular the re-structuring of the Clinical Research Groups (CRGs) from their original Clinical Studies Groups. This document will provide members with:

1. An overview of the changes which have taken place in gastrointestinal and liver research over the past 8 years
2. A report on the successes of the previous strategy document, including case studies
3. A summary of the roles and remits of the committees and groups
4. A broad scope of future priorities for the CRG

This Research Strategy will help to inform funding bodies, charity partners and patient groups about our research plans and priorities over the next 5 years. It will act as a mechanism for supporting research-active gastroenterologists, gastrointestinal nurses and scientists, stimulating research ideas and proposals for external funding. It will allow us to better engage our trainee and nurse membership, to assist in delivery of research in early careers and to support colleagues to become engaged if they have not been before.

The CRGs and the Research Committee have consulted widely during the development of the Strategy and I would like to take this opportunity to thank all of the BSG colleagues who have contributed to the CRGs and formulation of research priorities. Continuing development of research ideas leading to successful trial proposals and funding will be the best sign of success emerging from the Strategy.

BSG Research Committee always welcomes new ideas and input from any BSG member or partner organisation and can be contacted easily at research@bsg.org.uk. I look forward to being able to report an increase in successful research applications and active trials when we update the strategy in the future.

Yours sincerely

Professor Matthew Brookes
Chair, BSG Research Committee

The four chairs of the clinical research groups who have contributed to the research strategy development are Colin Rees, Steve Ryder, John McLaughlin, John Mansfield
The best of UK gastroenterology and hepatology

Programme highlights:
53 symposia, covering all aspects of GI and liver care, exploring the latest developments in gastroenterology with hundreds of original abstracts to be presented.

Attend the Monday Masterclass:
What to do when the evidence is unclear? These sessions will feature presentations from experts in the field on topics such as: “Delivering high quality colonoscopy”, “Managing severe alcoholic hepatitis” and “Severe steroid-resistant ulcerative colitis”.

Join us for live endoscopy:
On Thursday 7 June, a day of live endoscopy education will take place. Cases from leading endoscopists will be streamed from Aintree University Hospital. This day will focus on delivering excellence in endoscopy.

Key speakers include:
Jaques Devière
Erasme University Hospital, Belgium

Gert van Assche
University Hospitals of Leuven, Belgium

Elliot Tapper
University of Michigan, USA

Register now online at www.bsg2018.org
The British Society of Gastroenterology (BSG) is committed to improving treatment and prevention of gastro-intestinal (GI) and liver diseases in the UK through high-quality basic and clinical research. The Clinical Research Strategy of the BSG was developed through a process of wide consultation with BSG members and our Clinical Research Groups (CRGs), building on their successes from the previous Research Strategy (2010). We have consulted with the relevant National Institute for Health Research (NIHR) Specialty Groups (Gastroenterology and Hepatology) and external stakeholders, including other professional societies, charities and patient groups.

In this document, we have also taken the opportunity to review the current landscape for research activity funding across the BSG membership. This has enabled us to highlight opportunities to promote the need for sessional funding and support for all membership groups at the BSG. In particular we have set out a number of specific and measurable objectives over the next 5 years to promote the research activities of all of our membership groups.

We have identified that our specialty, which is pivotal for all acute services in the UK, has a central role in diagnosis of almost one third of all cancers in the UK, and has a significant cohort of patients with chronic disease burden, is under-represented in research activity and funding awards.

The outlined strategy is designed to highlight specific and measurable objectives which can be delivered by the Research Committee and research-active BSG members over the next 5 years. The Strategy (which will be renewed every 5 years) makes clear the research priorities of the BSG to Governments, the Department of Health (and devolved equivalents), other funding bodies and agencies, patient groups and the public, with a view to improving the quality and quantity of basic and clinical research into GI and liver diseases in the UK. There are two principal aims for this strategy:

1. To align with the BSG’s strategic objective to set “a collaborative and pioneering agenda and priorities in scientific and clinical research that will benefit patients and clinical practice nationally and internationally”.

2. To redress the imbalance between research spend and activity compared with the burden of GI and liver disease in the UK.

Finally, the research strategy also outlines newer opportunities to promote research activity within our speciality, introducing the concept of Big Data and illustrating the accessible datasets currently available or in development for our membership.
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| 3d Food and function        | 1. Reconstitute membership  
2. Priority setting partnership  
3. Development of thematic projects | 1. Appoint new chair  
2. Renew membership  
3. Develop PSP outline                                                          |
| 3e Cancer prevention and diagnosis | 1. Develop strong collaboration between relevant CRGs and the NCRI CSG  
2. Develop a future research active endoscopy/cancer workforce  
3. Ensure under-represented GI cancers are appropriately represente | 1. Progress collaborative early diagnosis/prevention project to grant application to CRUK  
2. Database of regional endoscopy research champions and links to endoscopy trainees  
3. Work with charities to highlight and promote priority setting |
|                             |                                                                                       | 1. Funded large scale cancer prevention and/or early diagnosis trial  
2. Network of trainees and research champions actively engaged  
3. Evidence of published priorities for under-represented GI cancers |
| 4 Promote research sessions | 1. Develop a network of regional mentors/research champions  
2. Develop a national trainee research network  
3. Good clinical practice (GCP) training for all trainees  
4. Promote and foster links with commercial research partners | 1. Database of regional research champions  
2. Illustrate successful trainee networks  
3. Increase proportion of GCP trainees  
4. Host national collaborative meeting with industry |
|                             |                                                                                       | 1. Demonstrate an increase in principle and chief investigators  
2. Show at least 1 nationally delivered trainee led research project  
3. Include GCP training on mandatory training record  
4. Demonstrate increase in number of investigator initiated commercial studies |
| 5a Gastroenterology health data set research | Promote research using Gastroenterology big databases | Set up an oversight/custodian group for database research access |
|                             |                                                                                       | Illustrate successful delivery of at least 1 project from each database |

*Table 1 Strategic objectives and measurable outcomes*
“... we encourage all consultants, trainees and nurses to undertake good clinical practice (GCP) training as part of their continuing professional development...”
The GI and liver research ‘landscape’ in the UK

Gastrointestinal and liver diseases are major causes of morbidity and mortality in the UK but clinical research in these areas is traditionally under-funded compared with oncology (UK Clinical Research Collaboration (CRC) UK Health Research Analysis 2014) [1]. The UK CRC has highlighted a growth in overall research funding between 2004 and 2009 of 8.2%, but little difference in total funding in real terms between 2009 and 2014 (1.4%). It is estimated that a total of £8.5bn was spent on health-relevant research and development in the UK in 2014, a real term decrease of £780m from the revised estimate for 2009/10 (after adjustment for 2014 prices), largely due to a decrease in pharmaceutical company spend in this area [1]. They have also highlighted a shift in funding priorities from the basic towards translational research and illustrated a regional variation in funding distribution across the UK [1].

Most of the health categories were seen to have an increase in real terms funding in research between 2004 and 2014. A smaller proportion saw a decrease in funding and in Oral and Gastrointestinal increases of 0.49% (compared to 2004) and 0.07% (compared to 2009/10) were seen (Figure 1; [1]).

Figure 1 Proportion of combined spend by health category for 2004/05, 2009/10 and 2014 from UKCRC, with Oral and Gastrointestinal receiving approximately 2% [1].
According to the UKCRC, the research spend on oral, gastrointestinal and liver diseases by the DoH, Research Councils and large charities (e.g. Wellcome Trust, Cancer Research UK) is still only approximately 2% of the total spend (Figure 1) and is less than 50% of the estimated percentage of Disability Adjusted Life Years (DALY) accounted for by these conditions (Figure 2). By comparison, almost a third of other specialties have spending on research which exceeds their DALYs. Our specialties fall into the lowest funded groups alongside respiratory, renal and musculoskeletal [1]. However, these data may need to be interpreted with caution as some gastrointestinal and liver funding could be aligned under other speciality banners e.g. Cancer.

Prior to the publication of the last BSG research strategy document there were 46 and 17 studies respectively in England which were in an active recruitment phase in the Gastrointestinal and Hepatology Portfolios [2]. This has dramatically increased, with 79 and 55 non-commercial studies respectively in an active recruitment phase in the Gastrointestinal and Hepatology Portfolios [3].

While there has been good progress since the last BSG Research Strategy there is still a significant gap to close to ensure patients with gastrointestinal and liver diseases benefit from the resources and advances that many other specialties enjoy.

Figure 2 Comparison of Disability Adjusted Life Years (DALY) rates for the UK in 2012 and proportion of UK Health Research Analysis 2014 combined spend by health category in 2014 taken from UKCRC [1].
2b. Aims of the National Clinical Research Strategy

There are two principal aims for this strategy:

1. To align with the BSG’s strategic objective to set “a collaborative and pioneering agenda and priorities in scientific and clinical research that will benefit patients and clinical practice nationally and internationally”.

2. To redress the imbalance between research spend and activity compared with the burden of GI and liver disease in the UK.

A Clinical Research Strategy has been developed (through processes outlined in Appendix 1) with the intention of increasing the quantity of high-quality clinical gastrointestinal and hepatology research performed nationally. We will do this by:

- identifying barriers and levers to research activities amongst BSG members
- further increasing the number of BSG members actively involved in research & development work in parallel with increased clinical trial activity by BSG members in National Institute for Health Research (NIHR) Local Clinical Research Networks
- encouraging on-going funding for research sessional activities by BSG members
- informing funding bodies what we consider to be the most important research questions and priorities for funding in order to improve disease understanding and healthcare
- identifying research funding awards to meet the requirements of the identified priorities
- increasing interaction with the public, patient groups and CORE (Guts UK! charity)
- determining mechanisms to support engagement with research by trainees, nurses and other allied healthcare professionals e.g. physiologists

Whilst this strategy is set out to support clinical research activity we would emphasise that the BSG is supportive of all academic, basic science and clinical science research.

Originally six Clinical Studies Groups (CSGs) were formed, covering a broad spectrum of sub-specialty areas within gastroenterology and hepatology; however, these have now been consolidated into four Clinical Research Groups (CRGs) and the strategy detail is laid out for each of these:

- Endoscopy
- Inflammatory Bowel Disease
- Liver
- Food and Function

These four areas are at different stages of development in term of their research activity and this is reflected in their outline strategies. In addition to these CRG-based research themes, we acknowledge that early diagnosis and cancer prevention is a central issue for our specialities and is of relevance to our patients. In this regard the Clinical Studies Group (CSG) cancer function is performed by the National Cancer Research Institute (NCRI). The BSG Research Committee will work closely with these well established CSGs to promote research into early diagnosis and cancer prevention.
There are two principal aims for this strategy:

1. To align with the BSG’s strategic objective to set “a collaborative and pioneering agenda and priorities in scientific and clinical research that will benefit patients and clinical practice nationally and internationally”.

2. To redress the imbalance between research spend and activity compared with the burden of GI and liver disease in the UK.
It is important to highlight the work done by our CRGs, in particular their work on obtaining research funding and assisting in the setting of priorities for future research into areas of unmet need. The importance of the latter has been recently exemplified by the NIHR consultation - ‘Health Futures’ 20 year forward view. Although the outcomes from this process have not yet been published, they will no doubt be essential to our research planning over the next 5 years. The NIHR consultation was focusing on identifying what health challenges in England will be like in 20-30 years’ time, and how they will differ from today. The project has been developed by the NIHR to inform strategic thinking and importantly to assess the perceived impact of provision of healthcare based on socio-economic and/or geographic groups. The outcomes of this project will need to be incorporated into the CRGs’ approach to funding particularly for research grants submitted through the NIHR. The BSG Research Committee response to this consultation was submitted in May 2017 and is outlined in Appendix 2.

3a. Endoscopy CRG

A review of current and recent research activity was undertaken and the following are some of the highlights:

Major trials delivered
- Discard 2 (Detect InSpect ChAracterise Resect and Discard 2) 1731 patients were recruited to optical diagnosis trial
- ADENOMA (Accuracy of Detection using ENdocuff Optimisation of Mucosal Abnormalities) 1772 patients were recruited through the device trial
- seAFOod (Systematic Evaluation of Aspirin and Fish Oil) Polyp Prevention Trial – first and only Clinical Trial of an Investigational Medicinal Product (CTIMP) in the English Bowel Cancer Screening Programme (BCSP). Funded by the NIHR Efficacy and Mechanisms Evaluation (EME) / Medical Research Council (MRC), it had truly national coverage for recruiting sites from the Northeast to Cornwall. Sites were led by BCSP specialist screening practitioners (SSPs) performing research duties. Recruited 709 high-risk patients needing annual surveillance colonoscopy. Major trial biobank for future genetic and biomarker studies.
- ENDCaP-C (Enhanced Neoplasia Detection and Cancer Prevention in Chronic Colitis) – 818 patients were recruited to medical device trial
- FIND UC – delivery to international IBD surveillance trial.

Management of large non pedunculated colorectal polyps and polyp cancers

Current trials
- B-ADENOMA (BowelScope: Accuracy of Detection Using ENdocuff Optimisation of Mucosal Abnormalities) – 3222 patients were recruited to BowelScope trial.
• HALT-IT (Haemorrhage alleviation with tranexamic acid-intestinal system) – major UK lower GI bleeding trial.
• WASH trial (Water Assisted Sigmoidoscopy in NHS BowelScope Screening Programme: A Randomised Multicentre Study) funded by NIHR Research for Patient Benefit (RPB) funding stream.
• Trials of pancreatic endotherapy and endoscopic ultrasound.

In addition to delivery of trials, the infrastructure for development and delivery of high quality research in the UK has been bolstered by further engagement and activity in our endoscopy units. Some of these activities are listed:

• Quality in endoscopy, specifically strengthening the evidence underpinning key performance indicators (KPIs)
• Current work refining surveillance strategies: post-polyp adenoma surveillance (in development) and management of hereditary GI cancer, focusing on colonoscopic surveillance
• Use of Big Data in endoscopy research – specifically the National Endoscopy Database (NED). This will be a rich source of data for service evaluation and research purposes. NED automatically uploads a minimum dataset for individual endoscopic procedures from compliant endoscopy reporting systems (further details see Section 5a(ii) and Appendix 3). Preparatory meetings have developed an initial framework for research priorities using NED data. Particular areas of research potential include measuring and improving endoscopic quality, developing training interventions and linkage with other databases. It is envisaged that NED data will be available for research purposes through a governance structure involving peer-review of research applications (see Appendix 3).
• Developing collaborative research groups with the aim of promoting early diagnosis and prevention of GI cancer e.g. Colorectal Cancer Screening, Prevention, Endoscopy and Early Diagnosis (COLO-SPEED; see Section 3e).

From this survey of current activity the following statements can be justified:

• The UK is now seen as a major player in international endoscopy research.
• The UK now delivers many large endoscopy randomised controlled trials.
• Several large UK grants have been delivered for endoscopy research.
• UK endoscopy research now publishes widely in high quality journals.
• The UK now has several strong academic endoscopy teams with a number of academic chairs.
• UK endoscopists are recipients of major research prizes and awards.
• Development of Endoscopy quality improvement programme (EQIP).

A long list of research questions and priorities was devised and posed to the Endoscopy CRG (Appendix 4).

The endoscopy CRG members were given the opportunity to vote for their top 4-5 research priorities from the long list for delivery over the next 5 years. The four priorities that were selected will be promoted to funders and the CRG members will seek to deliver these within the outlined timelines.

1. How do we develop the best multimodality approach to optimally use resources to detect and prevent colorectal cancer (CRC)?
2. How can we improve the quality of upper GI endoscopy, ERCP and EUS using lessons learned from colonoscopy?
3. How can we use minimally invasive tests to stratify GI cancer risk?
4. What is the role of bariatric endoscopy in treating patients with obesity and diabetes?
Crohn’s disease (CD) and ulcerative colitis (UC) are chronic inflammatory bowel diseases (IBD) of high prevalence in the United Kingdom (1 in 200). The cause of these diseases is as yet unclear.

Presently, only very crude measures are available to identify which patients are at risk of experiencing a more aggressive disease course (e.g. early-onset disease). Identifying these patients is of great importance to enable appropriate targeting of intensive early combined immunosuppressive therapy.

Similarly, evidence is very crude at predicting response to newer biologic therapies [4,5]. There are no robust biomarkers to predict non-responders to these biological agents which is problematic because biological agents incur a considerable financial burden while exposing patients to the risk of adverse events.

Patients with UC and Crohn’s colitis are at an increased risk of CRC and despite endoscopic surveillance as many as 50% of cases progress to invasive cancer before neoplasia is detected. There is a pressing need to enhance the effectiveness of surveillance and early selection for prophylactic resection.

Further work on the use of genetic, serological or radiological biomarkers is needed to help improve personalised choices in medicine.

The UK IBD Genetics Consortium has now been at the forefront of complex disease genetics for more than 10 years and has exposed the genetic architecture of IBD and the relationship between CD and UC. This has illuminated a number of new pathogenic mechanisms and potential drug targets [6-21]. A large national patient resource platform (such as those outlined below; IBD platforms) would enable a number of studies and would facilitate research to answer the questions posed in this document.

**IBD-RELATED SUCCESS FROM THE BSG RESEARCH STRATEGY IN 2010**

Various aims were set out in 2010, most of which were studies that have been completed or are now funded and started recruiting. An overview of these successes follows:

**ASTIC** (Autologous Stem Cell Transplantation for Crohn’s Disease Trial) (https://nottingham.ac.uk/research/groups/giandliverdiseases/nndcd-clinical-trials/astic-trial/index.aspx). This pivotal trial recruited 45 patients and involved an international collaboration [22]. A UK collaboration has now submitted an application to NIHR EME for a further trial of haemopoetic stem cell transplantation (HSCT) in refractory CD; ‘ASTIClite’ will see 96 patients with CD being randomised to low-intensity mobilisation and immediate HSCT or best conventional care.

**TOPPIC** (Trial of Prevention of Post-operative Crohn’s Disease) TOPPIC was a UK-wide randomised controlled trial investigating the efficacy of 6-mercaptopurine (6MP) in the prevention of recurrence of CD-related bowel resection. No significant difference in the post-operative outcomes was observed in the study population, with a signal of increased efficacy noted in smokers.

**CONSTRUCT** (Comparison of Infliximab and ciclosporin in STeroid Resistant Ulcerative Colitis: a Trial) The overall aim was to compare the clinical and cost effectiveness of infliximab and ciclosporin for patients with steroid resistant UC. This was a pragmatic UK-wide study funded through the NIHR HTA (Health Technology Assessment) funding stream [23].
IBD PLATFORMS

**IBD Registry (IBDR; see also Section 5a and Appendix 5)**
The IBD Registry is the first UK-wide collection of anonymised adult and paediatric IBD data for prospective audit and research.

**IBD BioResource (see also Section 5a and Appendix 5)**
A major new platform to drive clinical translation of the new genetics knowledge is the IBD Bio Resource, funded by the MRC, Open Targets, Wellcome Trust, NIHR and Crohn’s and Colitis UK. This is recruiting 25,000 patients with IBD to facilitate studies in stratified medicine and is making personalised medicine a reality. More than 9,000 patients have already been recruited.

CURRENT STUDIES

**PROFILE**
This is a £4.5 million Wellcome Trust funded biomarker-stratified study of top-down vs step-up therapy in CD. The biomarker is based on genetic work carried out in Cambridge using transcriptomic profiling in CD8+ T cells [24]. PROFILE will be run in 40 centres UK-wide and will be complete by 2020.

**PANTS and PRED4**
These studies are led by the Exeter IBD and Pharmacogenetics Research Group. The current projects included five retrospective studies, predicting serious drug side effects in gastroenterology (PRED4), and a prospective observational study looking to personalise anti-TNF therapy in CD (PANTS).

**GEM**
GEM is a $20m (Canadian) observational cohort study originating in Toronto, Canada to investigate the causes of CD. This now internationals cohort study recruited 5,000 young (6-35 years) healthy first-degree relatives of patients with confirmed CD and will allow unbiased comparison of environmental baseline factors in those subjects who develop CD versus those who do not.

**ENDCaP-C**
The ENDCaP-C (Enhanced Neoplasia Detection and Cancer Prevention in Chronic Colitis) study prospectively evaluated the ability of a methylation assay to detect pre-cancerous lesions (dysplasia) missed by histology within a surveillance programme for colitis associated neoplasia.

**IASO**
The IASO trial is a multicentre randomised double-blind placebo-controlled trial to test the hypothesis that interleukin (IL)-1 blockade using anakinra can improve outcomes when given as initial therapy in acute severe UC. Funding has been provided by the NIHR and MRC through the EME programme, Wellcome Trust and Swedish Orphan Biovitrum AB, totaling £1.6m. Main trial recruitment will run from 2018-2021 across 20 centres.

**MOTILITY**
MOTILITY is investigating the hypothesis that segmental small bowel motility measured using multiparametric MRI at 12-14 weeks after initiation of anti-TNF (tumour necrosis factor) better predicts long-term response than current standard clinical tools. This study will be run in up to 10 NHS academic centres supported through the NIHR EME.

**The PREdiCt study**
PREdiCt (PRognostic effect of Environmental stimuli in Crohn’s and Colitis) will examine the effect of the gut microbiota and diet on disease outcomes in CD and UC.

**STOP COLITIS**
This is a double-blind randomised controlled trial to investigate the efficacy of faecal microbiota transplantation in achieving and maintaining remission in patients with UC.
KEY STUDIES IN COLLABORATION WITH ECCO

SPARE
SPARE (A proSpective randomized controlled trial comParing infliximAb-antimetabolites combination therapy to anti-metabolites monotheRapy and infliximAb monoThErapy in Crohn’s disease patients in sustained steroid-free remission on combination therapy) aims to demonstrate that scheduled infliximab maintenance with or without antimetabolites is superior to treatment with antimetabolites alone.

i-CARE
i-CARE (Ibd Cancer and serious infections in Europe) is an ECCO-funded study designed to assess prospectively the presence and risk of developing cancers (especially lymphoma) and the risk of developing serious infections when IBD patients are treated with anti-TNF alone or in combination with thiopurines.

IBD RESEARCH PRIORITIES
In 2012, an IBD Priority Setting Partnership (PSP) was set up between the BSG, the James Lind Alliance (JLA) and relevant patient and clinical representatives across the UK to help set research priorities. The top 10 research priorities were informally published in 2015 and then formally in 2017 [25].

The IBD CRG has overseen a significant increase in the volume of active research projects undertaken by BSG members over the past 10 years. The current research landscape is healthy in IBD, but there remain a number of key underfunded research priorities. Although the JLA PSP identified a top ten priority list in 2015, several of these priorities have now been funded or have received commissioned calls. As such, the following are the current top five priorities identified for the next 5 years in the field of IBD:

1. What are the optimal markers/ combinations of markers to decide the optimal treatment strategy?
2. What are the optimal markers/ combinations of markers for stratification of patients with regards to a) disease course and b) monitoring disease activity c) disease prognosis?
3. What is the optimal dietary therapy (liquid enteral diet and/or reintroduction diet) and duration to achieve mucosal healing in active IBD and/or remission either as a primary or adjunctive treatment? Is there a difference between adults and children?
4. Does influencing the gut microbiota influence the course of IBD?
5. What is an optimal treatment strategy for perianal Crohn’s Disease and what individual factors determine this?
Since the publication of the first BSG research strategy, hepatology research in the UK has grown in strength. Hepatology studies on the NIHR portfolio have increased both in number and in breadth, with most areas of liver and biliary diseases being the focus of clinical studies.

**HOW IS BSG HELPING?**

The BSG provides a coordinating function: the Liver CRG meeting (chaired by Dr Stephen Ryder, research lead for the British Association for the Study of the Liver (BASL)) links directly with the NIHR Clinical Research Network (CRN) Hepatology National Specialty Group meeting (NSG, chaired by Prof William Rosenberg). The group is informal, with any researcher able to bring protocols for discussion or input. The Liver CRG and Hepatology NSG have worked with BASL (Prof Matthew Cramp President (2017-2019)) to align the Special Interest Groups led by BASL and BSG with the objectives of the Hepatology NSG to ensure that studies in development will find a natural location within the NIHR delivery network.

**CLINICAL AREAS AND SUCCESS**

**Autoimmune liver diseases.** A strong UK-wide collaborative group has been established with MRC and charity funding for cohort studies open to all in primary biliary cirrhosis (PBC), primary sclerosing cholangitis (PSC) and autoimmune hepatitis. The PBC cohort has recruited from every NHS secondary care provider. PBC UK and its nested cohort studies have pioneered a regional recruitment structure: eligible patients are identified in the PBC UK database and approached and recruited in regional research centres for more interventional studies, including those for new therapeutics.

**Viral hepatitis.** The UK was a significant player in the therapeutic marvel that was hepatitis C virus (HCV) therapy, with establishment of the HCV UK cohort and many industry partnerships for trials of new agents, particularly in genotype 3 disease.

**Fatty liver disease.** The commercial portfolio has grown considerably in the last 3 years with both investigator-led and commercial studies entering the portfolio.

**Alcohol related liver disease (ArLD).** BSG co-hosted the JLA PSP for research into ArLD. The top 10 questions where research answers are required were published in 2016 [26]. This list will provide the basis for grant applications and calls to address the leading cause of mortality in the UK from liver disease. The STOPAH study (STeroids Or Pentoxifyline for Alcoholic Hepatitis) has been completed and published [27]; 60 UK centres participated. This trial provided the foundations for a £5 million 5-year stratified medicine programme grant commencing in April 2018, covering clinical trials and an observational cohort study. The programme aims to minimise mortality from alcoholic hepatitis.

**Portal hypertension/complications of cirrhosis.** The group responded to an HTA call for beta blockers in portal hypertension. In late 2017, the HTA awarded £2.3 million to Liver CRG members to investigate the role of beta blockers and variceal band ligation in preventing bleeding in patients with cirrhosis and medium/large varices. Another bid (small varices) has been shortlisted by the HTA to submit a full proposal for consideration.

**Biomarkers.** The enhanced liver fibrosis (ELF) test for hepatic fibrosis has now translated into clinical practice with incorporation into NICE guidelines.

**PLANS**

The Liver CRG plans to formalise membership and roles for each of its previously informal groups. It is hoped this will encourage new members to join and clarify the process for those intending to develop grant applications. BASL plans to enhance support for the Liver CRG with central coordination and links between the BSG and BASL websites.

BASL and BSG are working with the Hepatology NSG to develop a training programme for hepatology trainees. The programme will ensure that all trainees emerging into the consultant grade have been trained in the skills...
necessary for them to function as principal or chief investigators on NIHR portfolio studies, thus contributing to the NHS’s research agenda. Further examples of coordinated strategic input can be seen in the work being done by the NIHR Hepatology Specialty Group, which is developing a clear offer to industry, focussing on early translation of new treatments and tests that might benefit patients and the NHS.

Also, BASL has raised funds to support HCC UK in establishing a national research group with data collection on HCC from all MDTs. It is hoped this will provide a strong basis for future studies.

Studies which then come through the CRG will receive BASL/BSG approval and endorsement as part of submission.

The current research priorities for the Liver CRG are the ones identified by the JLA PSP in ArLD:

1. What are the most effective ways to help people with alcohol-related liver disease stop drinking?

2. What are the most effective ways of delivering healthcare education and information about excessive alcohol consumption, the warning signs and the risks of alcohol-related liver disease to different demographics (including young people)?

3. What is the most effective model of community-based care for patients with alcohol-related liver disease?

4. What is the patient’s experience of alcohol-related liver disease?

5. Do attitudes to perceived ‘self-induced illness’ amongst healthcare professionals affect treatment, care provision and compassion for individuals with alcohol-related liver disease?

6. What are the most effective strategies to reduce the risk of alcohol-related liver disease in heavy drinkers?

7. Does the stigma associated with alcohol misuse affect the willingness of people with alcohol-related liver disease to ask for help?

8. What interventions improve survival in individuals with complications of advanced alcohol-related cirrhosis?

9. How should depression be managed in the context of alcohol-related liver disease?

10. What models of involvement of palliative care services in advanced alcohol-related liver disease are most beneficial?
The gut is a complex physiological system with multiple functions, principally the provision of nutrition and the excretion of waste products of digestion. When these physiological functions do not operate correctly, gastrointestinal symptoms or adverse nutritional consequences result. This can be in the presence or absence of the specific structural or inflammatory disorders that are the main focus of mainstream clinical gastroenterology, and which are readily amenable to diagnostic approaches such as endoscopy and imaging.

In contrast, our ability to study disorders of digestive function and thereby understand them is limited, in spite of them representing the most common issues in our patients in both community and hospital settings. Irritable bowel syndrome (IBS) is one of the most commonly diagnosed conditions within our speciality. Despite recommendations from the National Institute for Health and Care Excellence (NICE) in 2008 (updated 2017) for further research in key areas of the treatment of IBS, limited funding has been awarded. To develop and advocate for key strategic topics in this particularly underfunded and poorly understood domain, the Food and Function CRG has been formed, by fusing the neurogastroenterology, motility, small bowel and nutrition research communities. The CRG’s work is especially timely given recent MRC and Biotechnology and Biological Sciences Research Council (BBSRC) strategic focus on nutritional research, diet and health.

**NUTRITION RESEARCH**

Symptoms are very commonly driven by components of diet, which also play a role in the pathogenesis of gastrointestinal and systemic diseases. The gut microbiome is also of importance in this arena. Therefore the CRG needs to be a multidisciplinary alliance of experts equipped to drive strategy, deliver a step change in prioritisation for funding, and enhance understanding of the field for both patient and professional communities. The recent MRC review of nutrition and human health research identified, through a series of stakeholder workshops, the gaps in basic through to applied health research in this field. The review identified the crucial role of diet in individual health, public health and disease, allowing us to better understand the health resources that are needed at a strategic level within the UK and globally to promote research into nutrition. The review highlighted the importance of nutrition-related research: both under-nutrition and obesity are pivotal in many infectious and chronic disease processes. It remains a concern that 3 million people are malnourished in the UK (25% of in-hospital patients). These problems have a wider economic significance, with £6 billion being currently invested on the medical costs related to obesity [30].

The MRC review highlighted opportunities for funding in the field of nutrition research as well as highlighting several grand challenges [29]. These will form the framework for our CRG priority areas and include:

- Complexity of growth and relationship with health and disease
- Maximising human potential through nutrition
- Metabolic homeostasis and the biology of transition

The review provides an excellent overview of the limitations of the current evidence base and issues pertaining to undertaking nutrition research in the UK. It highlights a number of strategic opportunities, which the BSG Research Strategy supports. An integrated and collaborative approach is relevant to several areas of the current BSG Research Strategy, not just nutrition. The themed list in Appendix 6 includes an overview of those areas most relevant to BSG members.
FUNCTION

Irritable Bowel Syndrome (IBS) is the most common disease diagnosed by gastroenterologists and one of the most common disorders seen by primary care physicians. Despite some advances, the pathophysiology of the condition remains uncharacterised and treatments are sub-optimal. In recent years the UK neurogastroenterology community have been successful at collaborative development of high profile NIHR-funded research programmes. These include:

**CapaCITY:** £1.9 million Programme Grant for Applied Research. This programme has four work-streams; the first three are studying the effectiveness of biofeedback, rectal irrigation and laparoscopic ventral rectopexy, and the fourth is an evidence synthesis workstream. The recruitment phase is nearly closed and the programme has already produced 14 publications with significant impact.

**TRITON:** This is a £2.1 million NIHR/MRC EME-funded randomised controlled trial, with clinical and mechanistic endpoints, of titrated ondansetron versus placebo for the treatment of IBS with diarrhoea in secondary care. TRITON is a multi-centre study being conducted in England and Scotland, and will recruit 400 patients.

**ATLANTIS:** This is a £1.8 million NIHR HTA-funded randomised controlled trial of amitriptyline versus placebo for the treatment of irritable bowel syndrome in primary care. The study will recruit over 500 patients from 75 general practices in three geographical regions in England.

**EXCITES:** £900k MRC project grant exploring the effects of cerebellar stimulation on dysphagic stroke.

**FICUS:** £990k Academic Health Science Network (AHSN) Small Business Research Initiative (SBRI) phase 2 grant. Developing An-I-sys, a novel device for assessing faecal incontinence.

**FICUS extension:** £350K Innovate UK Biomedical Catalyst grant. This is a co application with Lucid: Designing a novel approach to biofeedback in Faecal Incontinence.

In the past, recruitment to studies of functional bowel disorders has been challenging as the majority of patients with these conditions are not under regular follow-up. This has affected the ability of the UK to attract industry studies in this field. The neurogastroenterology community have faced this challenge with a collaborative approach to set-up and delivery, producing successful delivery of LINACLOTIDE IV and a coordinated multi-site set-up for RELIEVE-IBSd. A national registry (ContactME-IBS) has been launched to further enhance patient engagement.

A collaborative approach will be a core value in moving forward, underpinning strong engagement with our patients, effective relationships between researchers, and partnerships with industry and third sector. Our vision is to oversee a strong and growing programme of research in IBS and other functional gut conditions.

CONCLUSIONS

The CRG will soon be reconstituted through election. The CRG and the wider BSG membership, in partnership with key professional groups (dietetics, nutrition scientists, physiologists) and CORE (Guts UK! charity), will be engaged to highlight the key food and function research priorities. Subsequently, collaborative groups will be developed to take forward these research questions into the development of thematic projects. An example of such an approach is outlined below.

1. Promote the need for funding in the field of functional GI disorders
2. A PSP will be developed to identify research priorities
3. BSG and Food and Function CRG members will work towards developing an NIHR Cochrane systematic review grant application in the field of nutrition research directed at the themed list in this field (Appendix 6) [29].
4. The highlighted knowledge gaps will lead to the relevant development of research sub-groups within the BSG who will then work collaboratively to develop appropriate funding applications.
3e Cancer Prevention & Early Diagnosis

In 2010, the BSG Clinical Research Strategy highlighted several priority research areas which were subsequently successfully funded:

- Aspirin Chemoprevention for Everybody (ACE) Study
- CRC chemoprevention studies using ‘natural’ agents (funded by EME); recruitment completed and in follow up (http://www.seafood-trial.co.uk)
- BEAT (Barrett’s oesophagus ablation trial)
- Development of a non-endoscopic immunocytology screening test for Barrett’s oesophagus – BEST 2/3 trials funded by CRUK and recruitment ongoing (https://www.best3trial.org/the-best3-trial)

Although our understanding of the causes of GI cancer has expanded, unnecessary deaths continue to occur. The UK has lower survival rates than many other developed countries and this is in large part due to later stage of diagnosis. Historically, cancer research has been seen as the domain of oncologists and surgeons and the emphasis has been on treatment of cancer rather than prevention or early diagnosis. This must change in order to significantly improve outcomes for GI cancer. Early diagnosis, prevention and screening are areas where gastroenterologists have major input. The advent of screening programmes and early diagnosis interventions in the UK has opened up this area significantly. Work has been undertaken with major funders to prioritise research in these areas. Some progress has been made by the BSG CRGs, particularly the endoscopy CRG, which has led the development of a collaborative research group (COLO-SPEED: Colorectal Cancer Screening, Prevention, Endoscopy and Early Diagnosis). Gastroenterologists, surgeons, epidemiologists, geneticists, behavioural scientists, and methodologists are working with charities, stakeholders and industry to deliver a paradigm shift in research on colorectal cancer (CRC) prevention and early diagnosis. Continued momentum and significant investment is still required, however, to shift the emphasis of cancer research towards prevention and early diagnosis.

In addition to these areas, several GI cancers are relatively under-funded internationally: pancreatic, hepatobiliary, oesophageal and gastric [31]. Opportunities to promote these areas to research funders through BSG members working with priority-setting groups, such as the recent PSP for Barrett’s oesophagus and gastro-oesophageal reflux disease [32], should be encouraged. Through these opportunities we will be able to highlight the key outstanding research questions in these under-represented fields. Barrett’s oesophagus is the main precursor to oesophageal adenocarcinoma and the partnership highlighted both the poor prognosis and the burden of these diseases on patients and health-care resources. The BSG research community looks forward to being able to promote opportunities aligned to these research priorities.

Furthermore, attention is also turning to the relevance of the GI consequences of living with and beyond cancer and its treatment. This is one of the focuses of an ongoing JLA PSP [33]. The BSG will be interested in and supportive of outcomes from this PSP, which has the potential to identify additional areas where research funding should be invested.

Although cancer prevention and early diagnosis are priority research areas for the BSG, the Clinical Studies Group (CSG) function is now performed by the National Cancer Research Institute (NCRI) CSGs, which include well-established groups for the upper GI tract, colorectum, hepatobiliary tract and pancreas (Appendix 7). In the case of CRC, the NCRI CSG has a dedicated subgroup for Screening, Prevention and Early Diagnosis (SPED), over and above the ‘generic’ SPED CSG that spans all the cancers, recognising the importance and strength of this area of research in the UK. BSG members are encouraged to contribute to these groups.
CONCLUSIONS

Early diagnosis, prevention and screening are key areas where gastroenterologists have major input. Screening programmes and early diagnosis offer gastroenterologists strategic opportunities to develop interventions, particularly those in the specialities relevant to diagnosis (Endoscopy CRG). The BSG will therefore promote collaboration between the relevant BSG CRGs and the NCRI CSGs, with a view to development of funding applications and delivery of clinical trials in the key areas of early diagnosis and prevention of not only common GI cancers, but also the under-represented GI cancers (e.g. pancreatic, hepatobiliary, gastric and oesophageal cancers), to encourage more funding and resources for these areas.

STRATEGY

1. Develop strong collaboration between relevant CRGs and the NCRI CSG to progress to submission of project grant submission to relevant funders (e.g. CRUK).
2. Develop a research-active endoscopy/cancer early diagnosis workforce.
3. Ensure under-represented GI cancers are appropriately represented.

“COLO-SPEED aims to transform endoscopy units into CRC research recruitment centres, building the world’s largest ‘experimental platform’ for CRC prevention and research. COLO-SPEED Hubs of research expertise across the UK will support endoscopy units and catalyse trans-disciplinary work and innovation, removing silos between disciplines and between research and clinical practice. This will accelerate the translation of research into practice and revolutionise prevention strategies with the aim of reducing unnecessary deaths from CRC.” Colin Rees, Chair of COLO-SPEED Steering Committee and Chair of the Screening and Prevention NCRI CSG sub group.”
The Research Committee and CRGs are aware of the importance of promoting research activity amongst all BSG members across all areas of the membership; indeed, we encourage all consultants, trainees and nurses to undertake good clinical practice (GCP) training as part of their continuing professional development and (as mentioned in Section 3c) we are developing a research training pilot programme for hepatology trainees. This section outlines the importance of research activity in gastroenterology and hepatology and the relevance of participation from each membership group. We also highlight, following consultation with each of the membership sections, those strategies most likely to increase the membership’s research activity and engagement. Whilst this strategy focuses on clinical research and science we are keen to emphasise the importance and relevance of academic and basic science research in gastroenterology and hepatology.

BSG council members at 2017 annual meeting with President Martin Lombard and CEO Richard Gardner.
4a. The relevance of research to BSG members

The Royal College of Physicians’ (RCP) report “Research for all” [34] highlighted several aspects of the importance of research in the modern-day NHS. Research activity is of particular importance in keeping knowledge of the causes and treatments of disease up to date, to enable development of new treatments and ways of working, and thus to improve the health and quality of life of patients. Consultants participating in research are also able to improve knowledge of current literature, interpret and communicate benefit and risk, and develop professional skills such as team-working, mentoring and communication [34].

The RCP have highlighted that patients in research-active institutions have better outcomes than those in other institutions and are more likely to benefit from earlier access to new treatments, technologies and approaches [34,35]. In addition, recent data suggest that institutions with higher research funding have lower standardised mortality and lower in-patient mortality rates [36]. Translational research has allowed clinicians to develop a closer interest in research directed at immediate patient benefit and this “bedside” research activity allows patients access to new therapies and improved outcomes [34]. This had been exemplified by the recent work by Downing et al, which illustrated a strong independent association between survival and participation in interventional clinical studies for all patients with CRC [37]. This relationship was further shown to increase with the levels and years of ongoing research participation by the hospital, with improved outcomes seen sooner in patients being treated in research-active hospitals with sustained interventional research participation [37].

Industry-supported research is important to the NHS; this was highlighted in a report commissioned by the NIHR [38] from KPMG’s Economics team. This document highlighted the economic impact of the NIHR CRN’s activities and has for the first time clearly linked the financial value to NHS Trusts of participating in commercial studies.

These benefits have highlighted the importance of more physicians engaging in research, so that future patients can benefit from novel therapies and improved healthcare. The additional benefits, direct to consultants, are likely to include a more rewarding clinical career, a point highlighted in the 2015 survey reported by the RCP [34]. A benefit to the BSG is that a widely engaged, research-active community will likely enhance job satisfaction and encourage recruitment to and retention by the specialty.

The RCP suggest that there’s a place for everyone in research – whether that is pursuing a career as a clinical academic, contributing to large collaborative projects, recruiting into other people’s trials, or contributing to quality improvement and audit research. It is clear that clinical doctors, and in particular consultants, have a role in the process of research. Clinicians are well placed to understand the needs of the patients they care for and can therefore highlight the key research priorities. Clinicians are also crucial to understanding what clinical trials are deliverable and to understanding how and where these could be best implemented in an NHS setting [34]. In the current NHS this is likely to be of benefit to all stakeholders and emphasises the importance of the BSG’s support for research-active members and the imperative to encourage and foster new researchers within the specialty and the wider NHS.
4b. Barriers to engagement

The RCP survey [34] showed that a large amount of unrecognized and informal research activity is being undertaken and that researchers and clinicians are keen to deliver more research activities within their job plans. The biggest reported barrier to delivery of research was lack of protected time and funding. This finding is supported by previous publications which have highlighted these as major barriers to delivery of research within the UK [39,40]. The BSG must support its membership to ensure that current dedicated time and funding for research (Appendix 8) should be ring-fenced and that, in the future, institutions should support additional funding of research sessions for those clinicians who express a desire. As discussed in Section 4a, this should be encouraged specifically because of the potential to:

1. Enhance patient experience
2. Reduce mortality and morbidity rates
3. Improve patient access to drug therapy/interventions
4. Improve job satisfaction
5. Improve recruitment and retention of staff

“The BSG must support its membership to ensure that current dedicated time and funding for research should be ring-fenced and that, in the future, institutions should support additional funding of research sessions for those clinicians who express a desire.”
4c. Funding time for research

We must ensure that the future of gastroenterology research is protected by supporting the ongoing research activities of our members. It is clear that many Consultants express a desire to do research but find barriers that are insurmountable. The funding of research sessions for clinical gastroenterologists across the UK and indeed across regions themselves is complex and unclear and the BSG’s knowledge of the total support that consultants receive for their research activities (outside of dedicated academic appointments) is not comprehensive (Appendix 8).

The RCP survey [34] showed that Research & Development (R&D) departments are an essential component of medical research infrastructure, playing a crucial role in enabling doctors to carry out research safely. Having said that, the support offered by R&D departments to physicians varies widely. Where these units work well they can promote involvement in research, and are an important source of expertise and intelligence on all aspects of the research system – from information on funding opportunities, to access to support services. It may be that a process of best-practice sharing, regarding how gastroenterology Consultants can work successfully with R&D departments, would enable us to increase funding across institutions and regions. In the short term, best-practice sharing between institutions and a process of mentorship and support for newly appointed Consultants may encourage ongoing research activities by clinical researchers. We should also encourage the idea that all institutional and regional research funding should be performance-managed to ensure that “value” for this funding is being obtained.

Another route to funding time for research is through closer collaboration with industry to generate investigator-led and -initiated commercial funding for key priority areas. Such links have already been shown to bring value to NHS institutions [38]. In late 2016, BSG representatives held a meeting with key industry partners to explore common future goals for education and research within gastroenterology. This was followed with an internal (BSG-CRN) meeting in January 2018 to focus on research, and further events are will take place over the coming years to help develop these industry links and collaborations further. Research funding can also be achieved by encouraging applications to national funding bodies such as those shown in Figure 3.

Figure 3 Highlighted funding bodies that support GI research.
4d. Other BSG support for research involvement

The BSG is well placed to offer support to established academic and non-academic clinical researchers, even if this is by way of an expression of support to them locally or by organisational support for the RCP report “Research for all” [34], and by highlighting this support to members and their institutions.

Integration of research activity into the specialty training programme is a medium- to long-term target to encourage clinicians to become and remain research-active. Research-confident and -active trainees are likely to be able to transfer their skills into consultant posts, which will have a promotional effect on research engagement and recruitment in the medium to long term. Current attitudes to research are mixed and the BSG Research Committee’s 2016 survey (article in preparation) highlighted a number of factors that could influence trainees’ engagement, which are outlined in Section 4e(i).

Opportunities to support research activity and enhance performance could potentially be achieved through:

1. Mentorship of new Consultant appointees by linking them to research-active clinicians in the same region. This could be facilitated through discussion and collaboration with the CRN and specifically coordinated by the local CRN (LCRN) leads. The BSG Research Committee will identify and highlight a database of regional research champions to help support this initiative.

2. Developing trainee research networks to enable collaborative recruitment to trainee-led projects across regional and/or national networks. Work in the area has already begun: the first BSG-supported national trainee research network symposium was held in March 2017 in Birmingham. Further such events will take place to continue to support these networks.

3. Engagement of trainees with the NIHR CRNs, perhaps by having a nominated regional trainee who shadows the LCRN lead for that region (attending national and regional meetings). With support from the BSG (for the idea and to advertise and collect applications), both the Hepatology and GI CRNs already have appointed Trainee members.

4. Facilitating research networks through the BSG website and offering peer support and review at BSG conferences.
“Clinicians are well placed to understand the needs of the patients they care for and can therefore highlight the key research priorities.”
4e Supporting non-consultant BSG membership in research active careers

Support should be developed to address optimising research activity in each of the major membership cohorts; the shapes of these support systems may be different according to individual group needs. Part of the strategic development of supporting the membership should include workshops to specify these research-support systems, to develop networks and to facilitate future engagement with research. Here we outline the training pathways for trainees, but it is important to emphasise that the BSG supports and encourages research and postgraduate study for all our membership, whether academic or not.

4e (I) TRAINEES

Academic trainees

The members of the Academic Development Committee (ADC) are well placed to provide specific support to academic pathway trainees (Appendix 9). The ADC is in a position to forge and maintain academic links with other organisations, collate and report on strategic issues and their impact in academic medicine and provide advice to BSG Council, and provide both individual support to trainees and forums for discussion, all of which support the BSG’s strategy of building gastroenterology research capacity and profile in the UK. Development of mentorship networks for these academic trainees could support their progression to academic Consultants. Mentors could provide support to early career clinical academic pathway trainees (Figure 4), sharing their experiences and information on career progression, research and funding opportunities. Mentoring networks could be developed around the BSG annual meeting, where mentors and mentees could initially meet and develop a future mentorship pairing. Contact should be encouraged several times in the year to discuss:

- developing the mentees’ research interests
- career planning/tracking to help ensure the mentee is proceeding as required to achieve their goals
- getting the most out of conferences and meetings
- understanding career pathways and the funding landscape

Figure 4 The integrated academic training pathway
For academic trainees who have already obtained their MD or PhD, a dedicated mentorship system already exists outside of the BSG through the Academy of Medical Sciences (AMS). The AMS’s programme should be promoted and links established more closely for this particular cohort of senior academic trainees. The engagement of academic trainees with this mentorship system should be monitored to ensure maximal exposure.

**Clinical trainees**

Mentoring, it is increasingly clear, has an important role to play in the NHS as well as in academia. However, there are a wide range of views and assumptions about what it means to mentor someone and precisely what activities are involved. For non-academic pathway trainees who express an interest in a research-active career, opportunities should be developed to encourage contact between them and NHS clinical researchers who can offer mentorship and advice. In this regard, work has already begun, as mentioned in Section 4d.

Clinical trainees should be encouraged to consider going out of programme for clinical experience (OOPE) in its various forms (further information can be found in [41]). The current cohort of trainees is well engaged with OOPE, but limited data exist to determine whether out of programme research (OOPR) in training is positively correlated with more research activity as a clinical consultant. The specialist trainees (ST) cohort survey in 2016 (manuscript in preparation) demonstrated that 85% had the intention to undertake OOPE during their training. The most commonly cited reasons for participating in OOPE were to improve career prospects, academic interest and educational benefits. Specifically cited reasons, which trainees felt discouraged OOPE, were...
intense funding competition and personal choice. It was also reassuring to see that almost 40% of respondents wished to maintain research activity into their consultant careers. Additional data show that 64.2% had published within the last 2 years and 47.3% had recruited patients into a CRN portfolio study.

The BSG Research Committee is currently engaged with a number of developing regional trainee research networks that are planning to develop large volume studies. These groups are currently in their inception and the BSG should support these groups to deliver large projects which eventually recruit from many NHS institutions and allow trainees to experience collaborative working. Trainees are ideally placed to deliver this model as they work in a rotational pattern through several hospitals, are in regular contact with each other, are motivated, and require formalised evidence of research and audit. Similar networks of trainees have been very successful in other speciality groups (Figure 5; [42]) and we should encourage BSG trainee members to mirror these groups. Aligned to this we should promote charitable funding to allow these networks to flourish such as those streams of funding supported by BSG via CORE. If trainee research network studies have been funded by CRN-approved funding streams, such as CORE (Guts UK!), then the studies would be eligible for inclusion in the Gastroenterology and Hepatology CRN portfolios, which would have additional benefits to our speciality.

To further facilitate research activity and training for our speciality’s trainees the BSG should look to embed good clinical practice (GCP) training [43] into the trainees’ core curriculum competencies. The BSG will work with the SAC and BSG training committee to achieve this.

4e (II) BSG NURSES

This section has been prepared in dialogue with the BSG Nurses Association (BSGNA). BSG nurse members have a unique expertise to understand the needs of patients and the potential benefits of patients’ participation in research. They are well placed to support, deliver and recruit to high-quality research in gastroenterology. Nurse participation in research has been promoted by the NIHR in its strategic priorities for the clinical research nurse workforce [44].

The BSG Research Committee would be keen to promote research activities and access for our nurse members in several areas outlined below, some of which are aligned with the NIHR strategies. Over the next 5 years we intend to:

1. Support nurses by enabling or developing meetings/symposia at national or regional meetings to demonstrate what research is happening in gastroenterology currently and future plans. We aim to facilitate the development of training through the BSG nurse’s sessions at the annual meeting in collaboration with the BSGNA section committee.

2. Develop better links with the funded clinical research nurses in gastroenterology departments and encourage them to join BSG and share their experiences with clinical nurse members.

3. Encourage development of local principle investigators from the current BSG nurse membership or from the Gastroenterology and Hepatology CRN research nurses.

4. Host a session at the BSG annual meeting and produce an article from a current nurse principal or chief investigator – “How I got into research”.

5. Encourage additional funding for secondment opportunities for clinical nurses (IBD/endoscopy/ward based) to work with CRN research nurses for a period to support research. The aim is to develop better understanding of research processes and pathways and their importance in GI and hepatology clinical nursing. We believe that full-time clinical nurses who have experienced research first-hand are more likely to identify potential recruits for research.
4f Four nations research strategy statements

This document has focused around principles which may be useful to engage in research practice in UK gastroenterology. Some aspects of the strategy and some components of the research infrastructure vary between the nations in which BSG members work. Details of these differences can be found in Appendix 10 but do not affect the BSG’s overall research strategy.
Optimising research activities for BSG members in special situations

5a. Using Big Data

This section was prepared following a multi-stakeholder meeting funded by the BSG Research Committee and chaired by Professor John McLaughlin. In recent years there has been an increase in the use of digital databases to facilitate ‘Big Data’ research. Information gleaned from population science employing large datasets has perpetuated a shift in mechanisms for defining and investigating health and disease in the individual patient [45]. We are now better at understanding the profound value of these broad data sets and the integration of diverse data to describe individuals to sufficient depths for discerning clinical outcomes. There is an increasing need to transform ‘big data’ into intelligible scientific facts but such a transition into this digital era of medicine holds great promise for advancing our fundamental knowledge in biology and driving personalised medicine. It should remain a focus of the activity of BSG researchers to use the healthcare Big Data ecosystem to advance biomedical research and health outcomes in our specialty.

There are a number of important factors about defining big data, and these should be used to consider data that can:

1. be useful and reused,
2. accumulate value over time, and
3. innovate a multi-dimensional, systems-level understanding. [46]

Many challenges are seen in the use of Big Data for biomedical research and these should be considered when investigating the source of data and the potential research project:

1. Data heterogeneity (accuracy, format);
2. Data fragmentation (multiple databases, multiple owners/stakeholders);
3. Data availability (protection for commercial or cultural reasons, or related to personal privacy);
4. Data handling (management, access, quality, querying, sharing);
5. Data privacy and integrity, in particular the need for consent from participants in any dataset which is remotely identifiable. Anonymisation of data goes some way to prevent this and protect participants and is a factor in several of the gastroenterology databases; and
6. Data conceptualisation (ontologies).

5a (I) NATIONAL HEALTH DATA SETS

In the UK a number of accessible databases are already being utilised by BSG members to facilitate population-based studies. These databases are not unique to gastroenterology but allow access to data records through a number of different databases linked to NHS Digital. The complexities and number of different datasets have led to a centralisation of these resources through the development of the Health Data Finder For Research website (http://www.hdf.nihr [47]. This tool enables researchers to find information about the UK healthcare datasets that are available and directly relevant to their work. Their role is to streamline access through the complex health data landscape.

The Health Data Finder for Research includes the Metadata Catalogue, which describes the datasets available for research and contains information about these datasets, including coverage, provenance, attributes, spatiality and temporality. The BSG research strategy team has taken the opportunity to highlight a number of these key databases for developing and undertaking Big Data research projects in Appendix 11.

5a (II) NATIONAL DEDICATED GASTROENTEROLOGY HEALTH DATA SETS

More specific to gastroenterology are a number of newly developed resources which should be utilised to benefit big data research in our specialty in the future. A number of these databases are in their early stages of development, and have been supported throughout development by the...
BSG. These databases will allow access to specific datasets in a population of our patients with specific diagnoses or who have had specific procedures. Access to the datasets for research purposes will be determined by appropriate governance processes and peer review. These databases include the National Endoscopy Database (NED), UK Inflammatory Bowel Disease Registry (IBDR), Improving Quality in Liver Services (IQILS) and IBD BioResource.

1. The National Endoscopy Database (NED) is a central database containing each unique endoscopy record, automatically uploaded from each hospital’s Endoscopy Reporting System. NED will likely be fully established in 2018; the vision is that data will be uploaded from every endoscopy facility in the UK. The data will be anonymised in its first iteration, but will allow researchers to access records from all endoscopy institutions. Researcher access to data will likely be through a peer-review process. The project leads for NED (Endoscopy CRG members) have highlighted examples of potential future research tools in relation to general endoscopy research and more specifically in relation to endoscopy training (Appendix 3).

2. The UK Inflammatory Bowel Disease Registry (IBDR) was supported by the BSG through its instigation and development and has recently been incorporated into its own independent entity governed by BSG, RCP and Crohn’s and Colitis UK (CCUK) as joint partnership organisations. Patient data are entered by clinicians at point of care (fully identifiable at Trust level) but are pseudo-anonymised on export to NHS Digital, allowing identification of patients affected by rare events and providing a powerful tool for pharmacovigilance. The dataset will inform health care delivery and facilitate UK-wide research and audit for the benefit of IBD patients. Access to data for purposes of research is yet to be fully defined but the IBDR offers BSG members the opportunity to participate in research and develop and/or answer research questions. Additional detail is available in Appendix 5.

3. LiverQuEST – This pilot project has now been developed into a full accreditation programme, Improving Quality in Liver Services (IQILS), through a collaboration with the RCP, BSG, BASL and others. IQILS aims to support teams working in Liver Services to improve service quality, care and safety for patients accessing and undergoing treatment for liver disease. Assessment against standards offers the opportunity to better understand services and to share knowledge and best practice. Although in its current format this project will not be ready to develop or answer Big Data research projects, it is envisaged that over the next 5 years it will have the potential to do so. As a dataset it will most likely be able to address research into service evaluation, quality improvement and assessment.

4. The IBD BioResource is a nationwide initiative (led by an IBD CRG member) designed to promote IBD research by any investigator from science or industry. Originally conceived as a vehicle to drive the translation of recent IBD genetics advances (by allowing recall of patients with specific genotypes for further sampling and study), in reality it can be used to drive recruitment for anything from surveys to interventional trials. Researchers wishing to access data apply through IBD BioResource’s system. Patients with eligible history, phenotype and/or genotype can be notified of relevant studies and invited to participate. This by-passes one of the major bottlenecks in IBD research, and should dramatically accelerate recruitment and sample gathering. Further details are available in Appendix 5.

5a (III) BIG DATA SUMMARY

Harnessing the potential of Big Data represents an opportunity to transform biomedical science, leading to new discoveries and better healthcare. One of the biggest hurdles relates to the issue of patient confidentiality and the re-use of data for purposes other than that for which it was gathered originally.

Data-sharing protocols and inter-operability of databases are being developed on a number of national databases and this will enable the evolution of knowledge networks. BSG members need to be able to access these resources to enable the optimisation of outcomes from these large
datasets, but with the development of more dedicated datasets access procedures will likely evolve over time. The newer BSG-supported datasets should allow us to see a new series of resources develop to support Big Data research over the next 5 years.

As part of the initial outcomes from this strategy, BSG Executive Committee and Council will seek to approve documents which will outline the regulation of databases/registries/bio-banks (DRB-banks) for which the BSG has been asked for sponsorship, endorsement or other support. Such a resource is usually run by other organisations, individuals or companies, who request BSG endorsement to lend professional credibility or integrity to the enterprise or project. As such, BSG has an interest in protecting the value and governance of such assets for its members and for the object of its charitable status. This statement (Appendix 12) will set out the conditions under which BSG would support setting up, maintaining or involvement in this area and also highlights the management of data access requests. The guidance in this statement has been drawn from that published by the UK Biobank.

5b Working with CORE (Guts UK!) to align strategic 5-year plans

The Chair of the BSG Research Committee sits on the Board of Trustees of CORE and works with their Research Awards Committee. CORE recently developed an ambitious 5-year strategic operational view that includes their new research strategy, which is highlighted below by their Head of Research.

CORE’s vision is of a world where digestive disorders are better understood, better treated and where everyone who lives with one gets the support they need. CORE has emphasised its commitment to be a patient-centric organisation. Research is an integral part of this plan.

The new CORE research strategy will take a four-fold approach.

1. We will support research that can make a difference to patients affected by digestive disorders. This will include research on the management of neglected symptoms such as gut pain, bloating and diarrhoea across a range of conditions. Research priorities will be identified in consultation with patients and other research users, such as via PSPs. CORE will also support research on the role of diet, nutrition and the microbiome in digestive disorders and will continue its commitments to pancreatitis, upper GI disorders and paediatric gastroenterology.

2. We will support the research and training aims of the BSG’s CRGs. This includes supporting research priorities that aim to optimise the prevention, screening and early diagnosis of gastrointestinal cancers. It also includes encouraging involvement in research for specialty trainees and other health professionals.

3. We will continue to support the development of the future leaders in academic gastroenterology. CORE will do this by funding research training fellowships for clinicians and non-clinical scientists and by providing small awards to academic trainees to underpin their pilot work.

4. We will encourage research that draws on innovation and achievements of other fields to speed up progress in gastroenterology.

In addition to supporting research, CORE will also direct resources to raising awareness, campaigning, providing expert information and giving patients a voice. On occasions, when they might be more effective at delivering its aims, CORE might prioritise these activities over directly funding research. CORE will also seek collaborations with other organisations that can help it meet its aims sooner.
Introducing...

After 13 years as Core, we’re planning a rebrand so we can make even more impact, transform the levels of research into gastroenterology and be the leader in information services for people affected by digestive conditions.

Why the change?
Core was adopted as the working name for the Digestive Disorders Foundation charity in 2004, however, this name doesn’t state clearly who we are and what we do. We need an easily recognisable name so people can access our services and support our vision.

The charity conducted some market research from November 2016 to April 2017. We surveyed 158 stakeholders and 787 patients and carers to inform the charity’s decisions about the new direction of the organisation. The majority of people (73%) had not heard of Core before the survey.

Introducing Guts UK!

We have worked with a brand specialist agency Toucan to develop a new look. Creative partner, Kevin Frost, is a Core supporter following the loss of his brother, Stephen, to pancreatitis. He and his team really understand what we are trying to achieve.

When our survey asked patients and carers how their digestive health affects their lives, their responses were incredibly personal, honest, brave and bold. And Toucan used these values to come up with three different approaches to a new name. We then tested these again, putting patients and our loyal supporters right at the heart of our decision making. The clear winner was a dynamic, bold, ‘say-what-it-does-on-the-tin’ name, and Guts UK! was born.

What will Guts UK! stand for?
We believe it’s time for the guts to get the attention they deserve. Guts UK! will help people get expert information and enable them to ask the right questions. This will then speed up diagnosis, treatment and effective self management.

Research into our guts is woefully underfunded and has been for decades. We should rival levels of investment into heart and cancer research.

With our new name and improved outreach, Guts UK! will be the voice for those who feel their digestive condition is not well understood or taken seriously enough.

Guts UK! will raise the banner for all digestive disorders to remove stigma, raise awareness and talk free from fear, shame and embarrassment.

By bringing the urgency of the patient need alongside the expertise of health professionals, together we can understand more and help others.

What do you think?
We’re always listening, and we’d love to know what you think about the rebrand. Turn to the back page to find out how to get in touch with your thoughts.
5c Working in partnership with patients and public

Patient and public involvement (PPI) is the creation of a partnership between patients, carers, the public and researchers, to try to make the research process more effective and representative of their needs.

It is considered good practice to involve patients, carers and the public in research. INVOLVE is part of the NIHR; its role is to support active public involvement in NHS, public health and social care research, as their involvement can lead to the development of more relevant research questions. PPI is now a key component for many funding applications, not just those made to the NIHR.

Good examples of PPI in research include:

- Review of research proposals/applications
- Inclusion as co-applicants on a research project/grant
- Involvement in identifying research priorities either directly or through partnerships including the JLA
- Membership of a project steering group
- Developing patient information leaflets or other materials

The BSG Research Committee intends to ensure that working in partnership with patients and public is a major part of our 5-year strategic objectives. In order to deliver this we intend to involve patients and public in the following:

1. Working alongside our relevant funding partners to encourage relevant patient and public input.
2. Partnerships in all aspects of our priority setting.
3. Developing and supporting patient and public educational events, in collaboration with charitable organisations, to promote research engagement.
4. Incorporating representation on relevant research committees at the BSG (CRGs for example).

An example of points 1 and 3 above is the IBD PPI workshop being held in May 2018, which is being supported by CCUK, BSG and BDRF.
5d BSG membership engagement with the Research Excellence Framework 2021 (REF); drivers for action

The REF is the system for assessing the quality of research in UK higher education institutions. It was first carried out in 2014 after replacing the former system, the Research Assessment Exercise. Its purpose is to “secure the continuation of a world-class, dynamic and responsive research base” in academia, by ensuring accountability, benchmarking and an information base for allocating funds. BSG members are therefore encouraged to apply for membership on the assessment panels as well as to contribute to the academic activities that are incorporated into their institution’s REF submission. The BSG membership is encouraged to engage wherever possible with their local institutions to support these submissions, which consist of three distinct elements: the quality of outputs (e.g. publications, performances, and exhibitions), their impact beyond academia, and the environment that supports research. An overview of this process is provided in Appendix 13.

CONCLUSION

The BSG has achieved many of its 2010 strategic goals: we have increased clinical research in prevention, screening and diagnosis, and disease management, for example, as well as informing funding bodies what we consider to be the most important research questions and priorities. We have developed ‘Clinical Studies Groups’ (now CRGs), which have acted as stimuli for development, review and submission of collaborative research proposals. We are working to increase the number of BSG members actively involved in research at all levels (trainees, nurses and consultants) and to involve them in local, regional and national networks such as UKCRN and trials networks. We are also increasing our interaction with the public and with patient groups through PSPs. As mentioned above, many trials have been completed or are underway, increasing the visibility of GI and liver research in the UK. The BSG has moved further towards achieving its goal of training the next generation of clinical and academic researchers through its workshops and collaborative efforts with other organisations. The next 5 years will be an exciting time for GI and liver research in the UK.
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Acknowledgements

Catherine Stansfield, Karen Kemp, Julie Duncan, Isobel Mason and the BSG nurses committee for their input into the strategy and the BSG nurses section.

Colin Rees, Endoscopy CRG chairman and member responsible for writing the endoscopy CRG section.

Fiona Veira and Julie Harrington provided the CORE strategy section.

Gordon Moran, IBD CRG member responsible for writing the IBD section.

Janusz Jankowski, responsible for writing Appendix 13 (Research Excellence Framework).

John McLaughlin, Food and Function CRG chairman and member responsible for writing this section and for contributions to the Big Data section. Additional contributions were made by Yan Yiannakou and Alex Ford.

Julie Solomon, BSG Head of Research & Learning, for editing, editorial review and input.

Mark Hull for providing review on behalf of the Gastroenterology CRN Committee.

Martin Lombard, President BSG, for editorial review and input and for co-writing Appendices 1 and 12.

Matt Rutter, Clinical Lead for NED, for contributing to section on National Endoscopy Database and reviewing section on Big Data.

Neil Hawkes, Chair JAG Quality Assurance for Training Working Group, contributed to training research outputs from NED.

Paul Dunckley, Clinical Lead for the JETS e-portfolio and NED Working Group member, contributed to training research outputs from NED.

Rebecca Fitzgerald and Simon Leedham, Academic Development Committee, contributed to the academic training section and mentorship.

Research Committee membership 2016-2018, BSG Council and Executive Committee for reviewing draft documents and approving final version.

Richard Gardner, CEO BSG, for editorial review and input.

Steve Ryder, Hepatology CRG chairman and member responsible for writing the liver CRG section.

Stuart Bloom contributed to the section on Big Data and the IBD Registry.

William Rosenberg for providing review on behalf of the Hepatology CRN Committee and for his contribution to the liver CRG section.
“The BSG must support its membership to ensure that current dedicated time and funding for research should be ring-fenced and that, in the future, institutions should support additional funding of research sessions for those clinicians who express a desire.”
Appendix 1 - How the strategy was developed

BSG Council agreed to support the Research Committee to develop a Clinical Research Strategy based on the work of the existing Clinical Research Groups (CRG) and with an imperative to increase the research activity of the membership. The CRGs hold up-to 4 regular annual meetings per year to determine investigator-led projects, analyse and respond to priorities which have been set and support, through peer review, responses to commissioned calls from funders. We utilised the expertise in these subgroups through nomination of a representative by the respective chair of each group. These representatives were involved in the Research Strategy working group, which was formed to advise and structure the working strategy document. Input and representation was also sought from the national Gastroenterology & Hepatology Clinical Research Network (CRN) groups and the Academic Development Committee of the BSG.

FORMAT AND CONTENT OF THE BSG CLINICAL RESEARCH STRATEGY

CRGs were requested to submit a document outlining the key successes from the 2010 research strategy document, identify between 3 and 6 priority research areas and research questions or unmet clinical needs pertinent to their disease area, stating for each:

- The impact of the problem
- Investigator interest
- Competing, similar studies
- Methodology to be used
- Feasibility including patient availability

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<td>Dr Nick Thompson</td>
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<td>Prof Mark Hull</td>
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<td>Dr Stephen Ryder</td>
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<td>Dr Shaji Sebastian</td>
<td>Adolescent &amp; Young Persons</td>
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<td>Ms Gemma Pickering</td>
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<td>Dr Matthew Banks</td>
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<td>Prof Barry Campbell</td>
<td>Scientists in Gastroenterology</td>
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Current research committee membership who have reviewed and contributed to the development of this strategy.
Appendix 2 - BSG response to the National Institute for Health Research (NIHR) strategy ‘Health Futures’ 20 year forward view (May 2017)

BSG is the main professional organisation for Gastroenterology & Hepatology (3000 clinicians), involved with >80% of gastrointestinal cancer diagnosis and >50% of their treatment. Gastrointestinal cancers in turn accounts for 1/4 of all cancers and gastrointestinal disease accounts for ~10% of all GP consultations and approximately 40% population at some point have gastrointestinal symptoms.

As with many medical specialties we have increasing workforce issues which include training & recruitment. With this and the need for escalating demand for diagnostic and therapeutic services it is important to focus our future research strategy around increasingly efficient diagnosis and treatment i.e. right test/treatment first time and personalised diagnostics and therapeutics.

In relation to your area of interest (discipline or geography), what differences do you foresee in the state of health and provision of healthcare in England in 20-30 years’ time? In your answer, please consider if/how these changes might affect some populations (within England) differently to others, i.e. socioeconomic, ethnic groups and/or geographic groups.

At the BSG we focus our research into key areas stratified broadly into four main clinical research groups. The broad highlights in the state of health and provision of healthcare that we foresee are thus structured under these four sub-groups.

1. **Endoscopy CRG** – increasing need to diagnostic and fast-track and/or open access to endoscopy procedures to enable early diagnoses. Particularly in cancer, around established screening programmes. Pressures on waiting time and manpower issues make delivery of diagnostic and therapeutic endoscopy services increasingly difficult. Opportunities to undertake research into prioritisation through biomarker, genetics, or other personalised strategic risk profiling will help us to try to get the right procedures done for the right patients efficiently. It is also important to highlight that many of these priority disease areas are more prevalent in lower socioeconomic populations. These populations are also seen to be less likely to participate in screening programmes to identify early disease process and are less likely to access healthcare. Improving early diagnosis in endoscopy through the use of new optical technology.

2. **Food and function CRG**
   - **Obesity and well-being** – alternative strategies for treatment. Promoting health and well-being through better nutrition and minimizing risk of associated complications through better prevention. Treating obesity through modulation of microbiome or newer signaling pathways within the gut. Newer endoscopic procedures may allow us to reverse obesity and diabetes without the need for surgical procedures.
   - **Barrett’s Oesophagus** – a disease associated with an increasingly prevalent cancer (oesophageal adenocarcinoma). Important future areas of focused work may include enhancing early detection of disease and dysplasia through novel techniques, outside of traditional endoscopy.
   - **Gut microbiome** – an area of increasing interest in many gastrointestinal and non-gastrointestinal diseases. Microbiome dysbiosis is associated with many diseases in Gastroenterology and other areas including Diabetes, endocrinology, cancer and...
infection. Mechanisms to modify the abnormal dysbiosis could in the future offer a new strategy to treat these conditions.

3. **Inflammatory bowel disease CRG** – A disease of increasing prevalence with specific increases in certain demographics – ethnic and socioeconomic JLA PSP. In 2013, an IBD PSP was set up between the JLA and clinical representatives across the UK to help set research priorities. Other focuses in IBD will include the introduction of cost-saving biosimilar drugs and their role in disease treatment.

4. **Liver CRG** - Alcohol liver disease - Alcohol will contribute to more deaths and cancer than smoking over the next 20 years. BSG co-hosted the JLA PSP for research into ArLD. The top 10 questions where research answers are required are published (http://www.jla.nihr.ac.uk/priority-setting-partnerships/alcohol-related-liver-disease/top-10-priorities.htm).

What do you think will be the key drivers of the changes you have described?

Research into these areas to effectively improve access to diagnostics and treatment and to streamline healthcare access pathways will be key. Several of these areas have been through research PSPs (JLA, charitable organisations) but more work into these priority areas are needed in Gastroenterology. We also hope to see increases in commissioned funding calls for these priority research areas in the future, which will allow to fund and undertake the necessary work to improve healthcare access and treatment in the future. Indeed, in this regard the BSG has recently undertaken a research strategy process, which will outline how we aim to promote research into key areas in Gastroenterology over the next 5 years. We will aim to complete this document in July 2017 and would be happy to share this broader outline of improving healthcare in Gastroenterology through research with any relevant stakeholders, including the RCP. The revised research strategy for Gastroenterology will be further reviewed on a 5-yearly cycle and updated.

In your view, what will be the major trends in health and healthcare in England over the next 20-30 years? (Going beyond your immediate area and expertise).

Beyond Gastroenterology and the outlined areas above, we feel that obesity and associated complications will form a major trend in healthcare and provision of such care in the future. This will likely link into further increases in prevalence of Gastrointestinal diseases as well including, non-alcohol fatty liver, increases in GI cancers, cirrhosis. In addition, treatment and management options to tackle obesity will likely increase and these will most likely include novel endoscopic therapies which may replace current surgical anti-obesity strategies. These newer endoscopic therapies will need to be embedded into UK clinical practice, which will need training and funding to be in place.

Are there any commonly discussed issues related to the future of health and healthcare in England which you believe to be overstated? If so, why do you believe them to be overstated?

In Gastroenterology, we feel that there are no real areas of overstated healthcare. Indeed, for many years we have felt that several diseases have been under-represented particularly within the research funding charities. Gastrointestinal and liver diseases are major causes of morbidity and mortality in the UK but clinical research in these areas is traditionally under-funded compared with Oncology (UK Clinical Research Collaboration (CRC) UK Health Research Analysis 2014). The UK CRC has highlighted a growth in overall research funding between 2004 and 2009 of 8.2%, but little difference in total funding in real terms between 2009 and 2014. It is estimated that a total of £8.5bn was spent on health relevant research and development in the UK in 2014, a real terms decrease of £780m from the revised estimate for 2009/10, largely due to a decrease in pharmaceutical company spend in this area. This project has also highlighted a shift in funding priorities towards translational research from the laboratory to the clinic areas and also highlights a regional variation in funding flow across the UK.

Most of the health categories were seen to have an increase in real terms funding in research between 2004 and 2014. A smaller proportion saw a decrease in funding and in Oral and Gastrointestinal increase of 0.49%
(compared to 2004) and 0.07% (compared to 2009/10).
The research spend on oral, gastrointestinal and liver
diseases by the DoH, Research Councils and large
Charities (Wellcome Trust, Cancer Research UK) is still
approximately 2% of the total spend and is less than
50% of the estimated percentage of Disability Adjusted
Life Years (DALY) accounted for by these conditions. By
comparison, over half of the other specialities have a
spend on research which exceeds their DALYs and our
specialities fall into the lowest funded groups alongside
respiratory, renal and musculoskeletal.

*Are there any issues that are underrepresented in the
debates around the future of health and healthcare in
England? If so, please describe them and explain why you
think they merit greater attention.*

In addition to obesity, as outlined above, alcohol will be
a major cause of mortality with deaths exceeding those
linked to cigarette smoking within the next 20 years.
Forming alliances with appropriate specialist groups
which are relevant to the delivery of new services will
be key here. For example, alliances with our healthcare
partners in addiction, pharmacologic treatment services
and potentially psychology services may be required; a
better researched understanding of how that would be
effective is likely to be necessary.

Antibiotic over-usage is an area of further potential
interest, through its potential to create a dysbiosis in
the micro-biome and the potential impacts this might
have on future risk of specific diseases. There remains a
lack of clear or specific understanding of the relationship
between microbiome, health physiology.

Future of Health publication available at
[https://www.rand.org/pubs/research_reports/RR2147.html](https://www.rand.org/pubs/research_reports/RR2147.html)
Appendix 3 - Research opportunities from National Endoscopy Database

A. TRAINING RELATED RESEARCH POTENTIAL FROM NATIONAL ENDOSCOPY DATABASE

BACKGROUND
The last 12 years has seen a marked transformation in the way endoscopy is trained in the UK. The multi-stakeholder organisation Joint Advisory Group (JAG) for endoscopy has been responsible for developing robust processes for quality assurance of endoscopy and endoscopy training. JAG endeavours to ensure that trainees are exposed to high quality training and that they reach certain standards by the time that they are signed off (certified) for independent practice. In order to streamline these processes JAG developed the JAG Endoscopy Training System (JETS), a web-based portfolio which enables trainees to record their endoscopic experience, demonstrate their experience and apply for JAG certification. JETS is now used by all training endoscopy units in the UK and since its release in 2009 has had 1.8 million procedures logged onto it. Trainees are required to record all their endoscopic procedures on JETS during their training. On completion of their training, there is no requirement to continue using the system. Responsibility for the quality assurance of endoscopists then passes to the units in which they are working.

JETS has some limitations:
1. Trainees submit their own data. Incomplete data submission could result in inaccurate calculations of endoscopy performance
2. Once a trainee is appointed into an independent endoscopist post (consultant, non-medical endoscopist, etc) then there is no requirement to continue recording their endoscopic experience in JETS

3. There is no link between trainer performance and trainee development

The National Endoscopy Database (NED) project is developing upload methodology to allow data to be extracted from endoscopy reporting tools into both its own database as well as the JETS database thereby creating a database of all endoscopy performed in the UK.

PROPOSED STUDIES
Once NED has achieved 100% roll out, it will within its database have a complete record of endoscopic practice in the UK. Furthermore, NED and JETS databases will be interlinked. This provides a unique opportunity to study:

- Training influences on independent practice performance
- Impact of training on patient experience
- Impact of trainer experience/performance on training
- Comparing unit performance with endoscopist/training performance

TRAINING INFLUENCES ON INDEPENDENT PRACTICE PERFORMANCE
Trainees develop endoscopic skills at different rates [1,2]. There are multiple factors that are likely to influence this including innate ability, access to training and the quality of training. The result, however, is that at the end of their training period, trainees will perform endoscopy with differing levels of expertise. Whilst JAG have introduced a JAG certification process designed to ensure that a minimum standard of performance is achieved by sign off, experience and performance remains variable at the point of certification (personal observation). The
“In the short term, best-practice sharing between institutions and a process of mentorship and support for newly appointed Consultants may encourage ongoing research activities by clinical researchers.”
The impact of this variation in practice is currently unknown; however, it is a logical hypothesis that trainees with less experience/skill will result in independent practitioners with less experience/skill. Patients may therefore be exposed to endoscopies of varying standard. Identifying measures in training that predict the standard subsequent independent practice will allow the development of processes to support endoscopists during the transition from training to independent practice and potentially improve patient experience/outcomes.

**IMPACT OF TRAINING ON PATIENT EXPERIENCE**

There is very little data to show the impact of having a trainee perform an endoscopic procedure has on a patient. Having a less experienced endoscopist perform the procedure may result in increased discomfort for the patient and potentially an incomplete test. However, a single site analysis of patients undergoing colonoscopy performed by a trainee has suggested that the opposite may be true [3]. Understanding the impact of having a training procedure will help patients make informed decisions when consenting for a procedure on a training list.

An endoscopist-controlled study of several factors would be performed for different trainee groups at different stages of training:

- Patient comfort
- Key endoscopic performance indicators
- Patient outcomes (post colonoscopy CRC rates, post gastroscopy gastric cancer rates, complications)

**IMPACT OF TRAINER EXPERIENCE/PERFORMANCE ON TRAINING**

There is variation in the standard of endoscopy performed in the UK [4]. Effective training is dependent on the competence of the trainer at performing that procedure. Trainers with poor technique will tend to teach poor technique. Furthermore, it is likely that the training ability/competence of an endoscopist is also likely to affect the quality of a training episode. The degree of this impact and how it influences trainee progression is unknown. Having a greater understanding of these factors will allow endoscopy/training leads to allocate trainees to appropriate trainers and support underperforming trainers. Identifying endoscopy units who accelerate trainee development will also enable training programme directors to direct trainee to the most appropriate trainers/units.

**COMPARING UNIT PERFORMANCE WITH ENDOSCOPIST/TRAINING PERFORMANCE**

Data from NED will be compared with data from the JAG Unit Accreditation database. The JAG accreditation base stores endoscopy units’ performance over several domains (including clinical quality, workforce and training domains). Comparisons will be made between performance of units, performance of the trainers and the rate of skills acquisition of the trainees. Scores on the GRS accreditation system are rated between “A” and “D” according to the unit’s performance. High performing units (scoring As and Bs) will be compared with low performing units (scoring Cs and Ds).

**FURTHER UTILISATION OF THE NATIONAL ENDOSCOPY DATABASE FOR TRAINING STUDIES**

NED will be able to provide baseline and post intervention performance data for training interventions. For example, randomised controlled trials studying longitudinal training interventions (programmes) will be possible. The coverage and numbers of procedures/interventions included will allow for high powered studies to answer key questions in endoscopy training.
B. WIDER RESEARCH THEMES FOR THE POTENTIAL RESEARCH OUTPUT PROJECTS FOR NATIONAL ENDOSCOPY DATABASE.

- Service evaluation & improvement
- Quality improvement
- Quality assessment

REFERENCES


Appendix 4 - Long list of endoscopy research questions proposed by Endoscopy CRG and prioritised (Strategy Section 3a)

**IMPROVING DIAGNOSIS**

a. Early diagnosis, screening and prevention of bowel cancer – how we use multi-modality approach to prevent and diagnose colorectal cancer and optimally use resources?

b. Optical diagnosis – e.g. how can we implement a discard policy into clinical practice using Infrared / spectroscopy / laser / Image enhancement / CAD / Generalisability?

c. Which devices can be used to enhance colonoscopic diagnosis?

d. How can we use minimally invasive tests to stratify risk e.g. Cytosponge / EG Scan / Ultrathin scopes / Breath testing / faecal immunohistochemical testing in diagnosis?

e. Endoscopic risk stratification for Mucosal healing in Inflammatory bowel disease.

f. Defining the role of spyglass EHL for biliary stone disease.

g. How do we screen more effectively?

h. How do we optimise surveillance?

i. How do we optimise surveillance?

j. Optical diagnosis - there are numerous optical diagnostic systems in the upper GI and this is confusing. We need a simple unified system across all technologies otherwise this will not be used in general practice.

k. We need to move away from random biopsies for all areas, in particular Barrett’s, pre-malignant stomach. The Sydney classification is dated and there needs to be an optical solution to targeted biopsies.

l. There are good data for Barrett’s and squamous but the practice of optical diagnosis is still limited to a few large centres – again a simple, reproducible recognition system is required.

m. Robotic platforms are evolving but there are no trials as yet – pilot studies are required for the prototypes.

n. Artificial intelligence / deep learning image analysis is going to be a major change in our practice in the next 5 years - we have to engage and set up well characterised high quality video cohorts.

**IMPROVING PATIENT FACTORS AND QUALITY**

a. How do we optimally prepare GI tract for endoscopy E.g. Correct prep colon, N-acetylcycteine, Acetic acid, MMX?

b. How do we optimally sedate patients?

c. What devices and drugs can we use to reduce post procedural complications?

d. How do we optimally deliver quality improvement and how do we do for upper gastrointestinal endoscopy and endoscopic retrograde cholangiopancreatography what we have done for quality improvement in colonoscopy?

**IMPROVING THERAPIES**


b. How can delivery minimally invasive therapy e.g. endoscopic submucosal dissection, endoscopic mucosal resection, Robotic platforms, Anti-reflux devices?

c. Defining the role of endoscopic ultrasound guided biliary drainage/access.

d. Device assisted therapy: new injectates, blood or other device stabilisation, counter traction, better knives, endoscopic mucosal resection haemostats etc.
Appendix 5 - IBD platforms

**IBD REGISTRY**
These are like-minded organisations with similar visions and values who share an ambition of promoting, developing and sustaining the IBD Registry to ensure that there is a safe, efficient and secure electronic system for recording and accessing key demographic and clinical data on patients with inflammatory bowel disease. This registry allows entry of relevant data by clinicians at the point of contact via a number of different platforms. The registry data platforms include a dedicated software platform, a webtool and a mechanism for importing data from existing "legacy" systems. Data is uploaded into a national registry on a quarterly basis and can be used to inform and refine HES data.

**IBD BIORESOURCE**
The goal is to recruit 25,000 patients with detailed phenotype data, all of whom will undergo whole genome sequencing at the Sanger Institute. DNA, serum and plasma are stored for all recruits, with more detailed sampling on a subset of 1000 newly diagnosed patients. Phenotype and genotype data will be held on the NIHR Bioresource server. Patients can then be notified of research projects for which they are eligible (for example based on their specific IBD phenotypes, drug history, genotype or any combination of parameters) (blood, stool etc) from homogenous sub-groups of IBD patients - the latter being key to driving high quality research. Interested investigators should contact ibd@bioresource.nihr.ac.uk.
Appendix 6 - Food and function goals

1. To promote and facilitate high-quality research in the UK
2. To identify areas of research and prioritise research projects (including engaging in dialogue with NETSCC and other bodies)
3. To engage with the patient community to understand their needs and priorities
4. To support the design, implementation and delivery of multi-centre trials
5. To inform and implement the Research Strategy of the British Society of Gastroenterology
6. To offer expert peer review and support for funding applications from the Food and Function research community

An example of how the BSG and the Food and Function CRG have acted on goals 2 and 3 in the list above was the recent support provided to Coeliac UK’s JLA PSP, which resulted in a list of priorities being published in March 2018.

Themed research areas identified in the MRC review [29] relevant to BSG members

MOLECULAR/CELLULAR NUTRITION
- nutrient sensing and cellular decision making
- host-microbe mutualism – the need to fully understand the interplay between nutrition, immunology/mucosal immunity and the microbiome – particularly in terms of shaping the normal immune response and resilience to infection and other diseases, as well as the relationship of component parts in dysbiosis; the therapeutic potential of targeting the microbiome and the human microbiome as a reservoir of antimicrobial resistance
- the effect of biological rhythms on nutritional response
- the use of nanotechnology and specific nutrients to manipulate molecular pathways
- the role of nuclear factors in immune-metabolic regulation
- epigenetic memory and the role of nutritional components in transcriptional (dys) regulation (eg role of non-coding RNAs)
- interplay between nutrients and regulatory networks controlling energy homeostasis

STRATIFIED/PERSOANLISED NUTRITION
- stratified medicine approaches to understand differing nutritional needs and responses to interventions
- interplay between poor nutrition and predisposition to disease
- personalised nutrition for health – interplay between diet and genetics; nutritional regulation of genes/transcription

NUTRITION ACROSS THE LIFE COURSE
- key time points in developmental programming (including adolescence and high risk/vulnerable stages/populations) where susceptibility to poor nutrition has long term consequences
- interplay between nutrition and cognition/brain ageing
- interaction between nutrition and physical activity across the life course
- special nutrient needs in relation to ageing (eg effect of nutrition in relation to cellular and tissue homeostasis, cell senescence and loss); polypharmacy – understanding of the interaction of nutrition and drug exposure and the effects on appetite, taste, smell etc
“These benefits have highlighted the importance of more physicians engaging in research, so that future patients can benefit from novel therapies and improved healthcare. The additional benefits, direct to consultants, are likely to include a more rewarding clinical career...”
Appendix 7 - NCRI groups

Gastroenterology and hepatology are traditionally very well represented on the NCRI CSGs. There are strong links with the BCSP Research Committees across the Home Nations.

The current structure of these groups, relevant to BSG members, is outlined below:

**UPPER GASTROINTESTINAL CSG (INCLUDES SUBGROUPS HIGHLIGHTED BELOW)**
- Hepatobiliary
- Pancreatic
- Oesophagogastric
- Neuroendocrine

**COLORECTAL CANCER CSG (INCLUDES SUBGROUPS HIGHLIGHTED BELOW)**
- Surgical
- Screening & Prevention
- Advanced & Adjuvant
- Anorectal Cancer

BSG members should also consider engaging with the advisory group for Screening, Prevention and Early Diagnosis (SPED) for any relevant projects for which they wish to receive feedback on. This can be achieved through either attendance at one of their relevant workshops, or through submission of projects online through an outline proforma (http://csg.ncri.org.uk/news-and-events/newsfeed/).

Appendix 8 - Current research-funding streams

Although we do not have a specific understanding of the sources of all clinical Consultant research-session funding, it is likely that time for research will be funded from one or more of these sources:

1. Investigator-led support for chief/principle investigators from programme grants funded through major funding bodies (NIHR, CRUK, Wellcome, MRC).
2. Investigator-led support for chief/principle investigators from project grants funded through funding bodies (Figure 1; NIHR, CRUK, Wellcome, MRC) or more dedicated gastrointestinal research funding bodies (Figure 1 examples include CORE (Guts UK! charity), Bowel Disease Research Foundation (BDRF), Bowel and Cancer Research (BACR), Bowel Cancer UK, Coeliac UK, Crohns and Colitis UK (CCUK), British Liver Trust, Foundation for Liver Research).
3. Investigator-initiated support for chief/principle investigators from industry funding.
4. Clinical research specialty leads’ support from the NIHR CRNs.
5. Regional clinical research networks for principle investigators recruiting to commercial and non-commercial portfolio studies.
6. R&D Departments or gastroenterology departments to support investigators within their host institution.
Appendix 9 - The roles of the Academic Development Committee

The ADC provides the current roles:

a. academic links between the BSG and clinical academic organisations (both national and international), to ensure effective representation of the academic needs of the BSG. In particular;

1. representation of academic issues of the BSG on the RCP Academic Committee and the Specialist Advisory Committee (SAC) in Gastroenterology
2. establishing contact with academic groups in sister clinical professional medical organisations to establish and share best practice, e.g. British Specialist Societies, American Gastroenterology Association (AGA), European Societies

b. annual reports of strategic issues in academic medicine and their likely impact on the BSG, using information obtained from Research Councils, NIHR, Association of Medical Research Charities (AMRC), Charities etc.,

c. advice on specific academic issues as required by BSG Council.

d. To provide (for clinical academic trainees and research fellows) support for their career development needs and engage their close involvement in the processes by which such needs are identified and met. In particular:

1. an online advice centre
2. a mentoring programme
3. a database of academic trainees and research training opportunities
4. a forum for trainees in academic gastroenterology to meet at the annual meeting of the BSG and to link with mentors

e. To provide for academics in the Society;

1. a forum for discussion of academic issues
2. a forum for clinician academics to meet at the annual meeting of the BSG

Rebecca Fitzgerald, current chair of the Academic Development Committee 2018.
Appendix 10 - An outline of the current differences in the research infrastructure between the four nations

**ENGLAND**

In England, the NIHR provides the infrastructure to support health care research, particularly for clinical projects. The NIHR coordinates a range of support staff within various centres, units, and networks, which in turn work together to conduct a nationwide research delivery system for our patients.

The NIHR research network is called the Clinical Research Network (CRN) and is composed of 15 local clinical research networks (LCRNs) that support clinical research across 30 clinical specialty groups, which include two represented by BSG members (Hepatology and Gastroenterology).

Other aspects of the English research infrastructure which might provide helpful in establishing yourself as a researcher include:

- Biomedical Research Centres and Units conduct and support translational research.
- NIHR Collaborations for Leadership in Applied Health Research and Care (CLAHRCs) participate in applied health research. There are 13 NIHR CLAHRCs which focus on research in chronic disease and public health interventions.
- Translational Research Partnerships develop collaborations between researchers and the life sciences industry in the development of drugs and interventions. Their role is to ensure that scientific research is directed towards patient need.
- The Patient Safety Translational Research Centres support research focused on improving the safety, quality and effectiveness of NHS services.
- Clinical Research Facilities for Experimental Medicine, of which there are 19, support research collaborations between basic and clinical scientists and promote the development of translational interventions directed towards improving healthcare.
  - Experimental Cancer Medicine Centres promote cancer drug development and the search for relevant cancer biomarkers.
  - The Rare Diseases Translational Research Collaboration supports research into rare diseases and has specific subgroups, including those representing hepatology and gastroenterology.
  - The Medical Research Council / NIHR National Phenome Centre undertakes research into how the environment and genes affect biochemical processes and disease.
  - The NIHR BioResource consists of volunteers who are willing to be approached to participate in research studies.
  - The NIHR National Biosample Centre provides a biosample processing and storage service.
  - The NIHR Health Informatics Collaborative consists of five leading NHS trusts with large NIHR Biomedical Research Centres that allow clinical data to be accessible to researchers, industry and the NHS.

**SCOTLAND**

The Chief Scientist Office in Scotland supports health research through the Scottish clinical research networks and provides a number of funding opportunities and fellowships.

Funding awards include Researcher Initiated Grant Scheme, Scottish Government Policy Priorities and Catalytic Research Grants Scheme.
The Chief Scientist Office also funds several Research Units, the most relevant of which are listed:

- Health Services Research Unit
- Health Economics Research Unit
- Nursing, Midwifery and Allied Health Professions Research Unit
- Social and Public Health Sciences Unit
- Scottish Collaboration for Public Health Research and Policy

The charity Medical Research Scotland also has a range of funding opportunities.

**NORTHERN IRELAND**

The Health and Social Care R&D Office of Northern Ireland supports the Northern Ireland Clinical Research Network (NICRN), which provides research infrastructure as part of the UK CRN. The NICRN coordinates clinical research across trusts and academic organisations, maintains a portfolio of network studies and assists with all aspects of study delivery. The network coordinating centre is based at the Royal Victoria Hospital in Belfast, and it coordinates 10 NICRN interest groups (gastroenterology, cardiovascular, primary care, children’s, respiratory, critical care, stroke, dementia, diabetes and vision). In gastroenterology there are currently two specialty leads who co-chair this research network.

**WALES**

Health and Care Research Wales supports the design and delivery of high-quality research through Clinical Research Collaboration Cymru. Additional support for researchers can also be found through the following:

- five Biomedical Research Centres
- three Biomedical Research Units
- three Infrastructure Support Groups
- three Clinical Trials Units
- School for Social Care Research.
Appendix 11 – General health-related national databases

1. Hospital episodes' statistics (HES) processes over 125 million records per year. HES is a data warehouse containing details of all admissions, outpatient appointments and A&E attendances at NHS hospitals in England. This data is collected during a patient's time at their NHS hospital and is designed to enable secondary uses which include accesses for researchers. Access to these datasets can be obtained through the data access request service (DARS) via an application process which includes five stages [1].

2. Clinical Practice Research Data link (CPRD) is the English NHS observational data and interventional research service. CPRD services are designed to maximise the way anonymised NHS clinical data can be linked to enable many types of research. These include observational studies that look at the records of large numbers of people to see if there are any links between lifestyle, diet, family history and particular illnesses. Access to CPRD databases is through an online application process through the independent scientific advisory committee for MHRA database research [2].

3. Death Registration data from the Office for National Statistics (ONS) can be obtained by applying though the office of national statics to become an approved researcher [3]. This data set will allow researchers to access deaths registration data in the United Kingdom and can include data on demographics, regional mortality data and other measures (numbers, rates and standardised mortality rates).

4. National Cancer Registration and Analysis Service (NCRAS) is run by Public Health England and is responsible for cancer registration in England only. In the UK, collection of NHS cancer data is managed individually by each of the devolved nations. In Scotland, data is collected by the Information Service Division (ISD), the Welsh Cancer Intelligence and Surveillance Unit (WCISU) manages collection across Wales and in Northern Ireland, it is the responsibility of the Northern Irish Cancer Registry (NICR). Every year NCRAS provides data on over 300,000 cases of cancer to ONS on new cancer cases and cancer survival. They also provide data on incident cases of cancer in the population and trends and geographical distributions. An outline of the application process to access this data for research purposes can be accessed through the National Cancer Research Institutes [4].

REFERENCES

Appendix 12 - BSG statement on access to databases/registries/bio-banks

This statement pertains to information databases/registries/bio-banks (DRB-banks) for which the BSG has been asked for sponsorship, endorsement or otherwise support. Such a Resource, usually run by other organisations or companies, ask for support to lend professional credibility or integrity to the enterprise or project. As such, BSG has an interest in protecting the value of its own integrity as an asset for its members and for the object of its charitable status*. This statement sets out the conditions under which BSG would support setting up, maintaining or involvement in this area. The guidance in the statement is based upon that published by the UK Biobank**.

PRINCIPLES OF GOVERNANCE

• An oversight group should be the custodians for the DRB-bank.

• The custodian group should be independent of the day-to-day operations and should not have members who have any interest in gaining access to the material, and preferably lay members.

• The custodian group*** should write clear parameters setting out:
  a. the purpose of the DRB-bank (usually for research as alternative arrangements are in place for care and clinical management of individuals)
  b. the governance arrangement for maintaining and protecting the material
  c. the principles, criteria and requirements for access
  d. the future sustainability of the enterprise

• Any data or material pertaining to individuals must be collected, collated, stored or be given access in accordance with the relevant statutory requirements including consent and data protection etc.

• The custodian group should be responsive to queries, meet regularly and have a rapid decision process

PRINCIPLES OF ACCESS

• BSG endorsement or support will be dependent with the aims and governance of the DRB-bank being consistent with BSG values and charitable objects

• The DRB-bank must actively seek engagement with participants and researchers throughout the Resource's lifetime, in particular regarding the research that is being conducted on it and the research findings that emerge.

• All applications to use the Resource will be checked to ensure that they are consistent with the Access Procedures, Withdrawal Protocol, the Ethics & Governance Framework, and the consent that was provided by the participants, and that they have any relevant ethics approval that is required

• The Resource is available to all bona fide researchers for all types of health-related research that is in the public interest, without preferential or exclusive access for any person or group of individuals. All researchers, whether in universities, charities, government agencies or commercial companies, and whether based in the UK or abroad, will be subject to the same application process and approval criteria which will be conducted independently by the custodian group.

Access to the biological samples that are limited and depletable will be carefully controlled and coordinated. The quantity of sample that is required will be judged against the potential benefits of the research project, with advice from appropriate experts when required

• Safeguards will be maintained to ensure the anonymity and confidentiality of participants' data and samples. Researchers will enter a legal agreement not to make any attempt to identify participants, and the data and/or samples provided to researchers will not identify any particular participant (i.e. they will be “anonymised”).

• Applicants may be expected to pay for access to
the Resource on a cost-recovery basis, with a fixed charge for managing the application review process and a variable charge depending on how many samples, tests and/or data are required for the approved research project

- BSG will not be the owner of the database and samples, and will have no financial claim over any inventions that are developed by researchers using the Resource
- All users will be required to publish their findings, including negative results, so that they are available for other researchers to use for health-related research that is in the public interest
- Upon the request of DRB custodians return, delete or otherwise permanently dispose of all copies of the data in the dataset that are in their possession
- If reposting the dataset or a subset of the dataset, require that third-party users of the data adhere to the same conditions above
- By using these data, you signify your agreement to comply with the conditions stated above. Continued access to these data is dependent upon compliance with such conditions.

**PRELIMINARY APPLICATION: MINIMUM REQUIRED**

- Non-technical short description of aims and methods
- How it meets the DRB-bank purpose
- Approx. number of participants included
- Data, samples, re-contact of participants requested
- List of collaborators
- Payment of any relevant admin fee

**DRB-BANK MINIMUM DETERMINATION**

- Is it of scientific public health interest?
- Is it feasible?
- Does it require samples or re-contact of participants?
- What is the provisional cost? Main Application What is required?
- More detailed methods
- Supporting documents, if applicable
- Evidence of funding
- Methods of how data will be stored securely
- Plans for reporting results and publication

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**UK Biobank was established by the Wellcome Trust medical charity, Medical Research Council, Department of Health, Scottish Government and the Northwest Regional Development Agency. It has also had funding from the Welsh Government, British Heart Foundation, Cancer Research UK and Diabetes UK. UK Biobank is supported by the National Health Service (NHS). UK Biobank is open to bona fide researchers anywhere in the world, including those funded by academia and industry. The medical research project is a non-profit charity which had initial funding of about £62 million. [http://www.ukbiobank.ac.uk/wp-content/uploads/2014/06/1000-Naomi-Allen-10am-data-and-access.pdf](http://www.ukbiobank.ac.uk/wp-content/uploads/2014/06/1000-Naomi-Allen-10am-data-and-access.pdf)**

*** Custodian group constitution and terms of reference are being developed in a separate document***
Appendix 13 - Overview of the Research Excellence Framework (REF) and its processes

REF submissions consist of three distinct elements: the quality of outputs (e.g. publications, performances, and exhibitions) from the higher education institute, their impact beyond academia, and the environment that supports research. The Quality Reward for good outputs following the REF is approximately £1.7billion/year in funding to the Higher Education Institutions, although the 24 Russell Group Universities receive over 50% of this. In this way the REF acts as an evidence-based way for institutions to optimise their research strategy based on strengths and weaknesses. It also allows the Government to have a structure of accountability on previous investments. However, it also has forward looking implications in that it acts within institutions as a performance incentive as well as a reputational benchmark when dealing with outside institutions in forming partnerships. It may also allow researchers to hold back for better quality publications (one impactful world-class paper is much better than many mediocre publications).

It is important to emphasise that there are opportunities for the successful clinical researcher to become partially employed by Medical Schools and Universities. In this regard, prospective academics should be funded to a minimum of 0.2 FTE by the academic host institution in order to be submitted as an academic to the REF. Advice would therefore be to aim as high as possible for 4-star world-class papers as this could lead to underwriting of clinical sessions by prospective Universities.

RESOURCES NEEDED TO SUPPORT REF

Resources (approximately £4,800 per academic submitted, of which 60% is borne by the host institution) are needed to fund administrative support for the entire process. Creating transformational cultures and environments and designing staff progression and retention processes are essential early and mid-way through the REF cycle, but other factors come into play closer to the REF submission period. By far the most impactful aspect to the home institution is getting good-quality peer review by external experienced researchers on the planned submission to the REF.

REF TIMETABLE.

Final structure and assembly of the relevant committees judging institutional submissions to REF 2021 will take place in 2018, with final submissions for REF due in October 2020 and decisions made at the end of 2021.

UNITS OF ASSESSMENT

In REF 2021 there are 34 Units of Assessment (UoA) for submission purposes. For most gastroenterologists it is likely they will be classified as UoA1 Clinical Medicine, UoA2 Public Health, UoA3 Allied Health Professions and more rarely UoA4 Psychology, UoA5 Biological Sciences, UoA20 Social Work and Social Policy or UoA23 Education. The individual will become less important and the focus will increase onto the institutional submission. There will be a decoupling of staff and outputs so that any new staff should be employed on their potential to achieve good outputs rather than their previous track record of outputs. There will be a minimum of 1 case study for each UoA; any others added will be a bonus.

OUTPUTS

The number of outputs will also vary, with 1-6 for each staff member, with a multiple of x2 used for each full-time equivalent staff member (FTE) in each UoA. Therefore 10 FTEs will need 10 outputs and 30 FTEs will need 60 outputs. However, advice is needed for the weighting of authorship (e.g. first and last position are the most impactful, position in the first 3 and last 3 is useful, but other authorship positions are less helpful unless the relevant article has been specially cited in the publication).
Experience from HEFCE indicates that creating the research environments may be slow at first but then the process improves as relationships thaw when the disparate groups understand each other’s skills and abilities. However, you need the best people with open minds and a vested interest to make true high-quality interdisciplinary research work.

**IMPACTS**

These should be broad, for example, in academic understanding, policy, industry, public engagement, cultural life, teaching and even outside the field in question. In addition to the UoA environment statement, there will be an Institutional statement about core facilities and culture i.e. some form of greater societal/public benefit.

Surrogates of output quality are citation metrics, data sharing, commercial uses and impacts. The Post-92 Universities do much better in rankings in UoAs of sport, leisure, creative industries and architecture i.e. translational or applied research.
“... it is important to emphasise that the BSG supports and encourages research and postgraduate study for all our membership...”