

Surgical MedTech Co-operative





In England:

- ◆ 4.7 million hospital admissions involve surgical care per year.
- ◆ 1.3 million procedures annually in general surgery.
- ◆ 27% increase in number of surgical procedures performed over 10 years.
- ◆ 1/3 of all hospital admissions are for surgical procedures.

In the UK:

- ◆ Major abdominal surgery: 30 – 50% of patients suffer complications.
- ◆ Surgical devices market set to grow 8% by 2020.
- ◆ Less than 1% of new surgical devices are widely adopted.

Globally, only 9.8% of new surgical devices reach clinical trials.

The NIHR Surgical MedTech Co-operative

The NIHR Surgical MedTech Co-operative is creating the premier national network for improving surgical care through technological innovation. Our aim is to ensure patients in need of surgical care have access to new technologies that have been rigorously tested to ensure they are safe, effective, and represent value for money to the NHS.

We support the development of new technologies in the fields of colorectal, vascular and hepatopancreaticobiliary (liver, gall bladder and pancreas) surgery, improving both healthcare and quality of life for patients.

Through our nationwide network of clinicians, engineers, scientists, industry and patients, we identify new areas in need of innovation, support research to address these clinical problems, and provide a resource for evaluating new surgical technologies within the NHS, helping them to move into clinical practice.

We run events that bring together partners from different fields to share expertise and develop new ideas. We provide seed corn funding to kick start research that can turn these ideas into reality. And our Surgical Technology Testbed provides specialist surgical trial systems and protocol development to ensure new technologies benefit from rapid, but affordable, clinical evaluation and adoption.

We are hosted by Leeds Teaching Hospitals NHS Trust, the second biggest healthcare provider in the UK, working closely with the University of Leeds, a leading UK University with strengths in biomedical research.

Working together to address unmet clinical needs

Clinical themes

Our work will focus on three important areas within general surgery:

Colorectal



Led by Professor David Jayne, Honorary Consultant Surgeon and Clinical Director of the NIHR Surgical MedTech Co-operative

This theme covers surgery for colorectal cancer and diverticular disease, which is more common in elderly patients. It also covers chronic conditions such as inflammatory bowel disease, benign anorectal conditions and pelvic floor disorders, which mostly affect younger patients.

Vascular



Led by Professor Julian Scott, Consultant Vascular and Trauma Surgeon

This theme covers surgery to treat peripheral arterial disease, which is becoming more prevalent due to an ageing population and rising levels of obesity and type II diabetes. It will tackle the conditions which ensue from this disease, such as abdominal or thoracic aortic aneurysm, lower limb ischaemia, diabetic foot ulcers and other wound management.

Liver, pancreas, biliary



Led by Professor Giles Toogood, Consultant Hepatobiliary Surgeon

This theme covers surgery for primary and secondary liver cancer and other, less common, hepatopancreaticobiliary (HPB) cancers, such as hepatocellular and pancreatic cancer, for which there has been little improvement in prognosis for decades. It also covers surgery for benign conditions, including gall stone disease and its complications, and for pancreatitis, which is increasing in prevalence due to alcohol abuse.

Supporting expertise

Our three clinical themes will be supported by five areas of expertise that will help us develop surgical innovations and assess their benefit in clinical practice:

Physics and Engineering

Led by Professor Steve Evans (Physics), Assoc Professor Peter Culmer (Engineering) and Professor Pietro Valdastrì (Robotics) of the University of Leeds

The engineering sciences and physics are fundamental to the development of minimally invasive therapies, providing expertise in instrument/device technology, nanotechnology, material and surface sciences, imaging, and computer and robotic assistance.

Pathology

Led by Dr Nick West, Academic Consultant Histopathologist at Leeds Teaching Hospitals

With pathology at Leeds Teaching Hospitals now fully digitised, we can draw on the latest developments in the field, using pathology expertise to inform clinical practice and aid diagnosis and treatment decisions, particularly in cancer surgery.

Clinical Trials

Led by Professor Julia Brown of the Clinical Trials Research Unit

The highly experienced team at CTRU have developed research protocols specific to surgical trials, ensuring that surgical studies carried out with us receive the appropriate regulatory approvals.

Health Economics

Led by Dr Bethany Shinkins, Head of the Test Evaluation Group at the University of Leeds

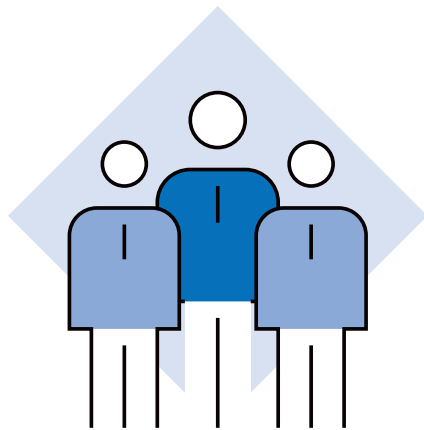
Our experienced health economics team have developed a formal model for evaluation that has been designed specifically for surgical innovations, helping to provide the economic case to underpin clinical take-up and commercialisation.

Business Development and Commercialisation

Led by Dr Chris Herbert, Director of Operations, Research and Innovation at Leeds Teaching Hospitals

We will work with our industrial partners, developing networks covering all stages of the innovation pathway and enabling a route for industry-driven projects through the NIHR Surgical MedTech Co-operative.

How we work

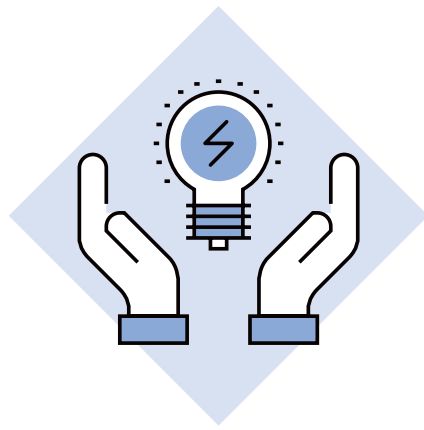


Step 1

Our strategy follows a five-step innovation cycle to develop new surgical technologies and bring them into clinical practice. Partners can join at any stage.

Identify unmet clinical needs

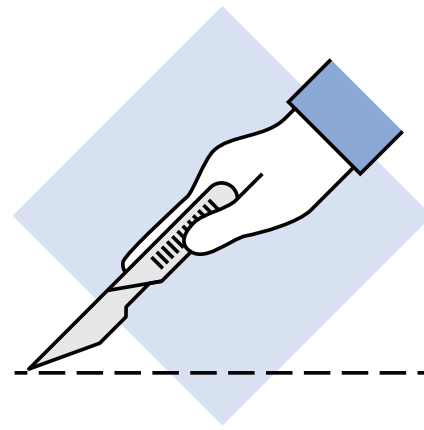
We bring academic researchers, clinicians, patients and industry together to identify areas where new technology is needed to overcome a clinical problem. Through these events we identify projects to support the development of new surgical technologies.



Step 2

Technology development

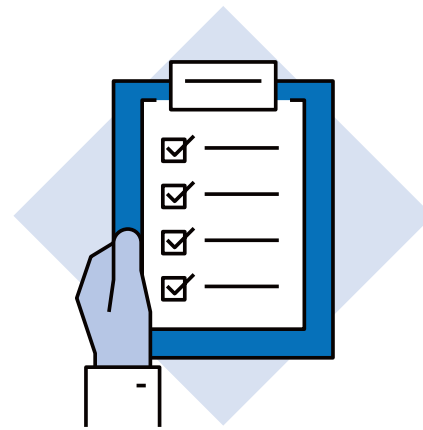
We use pump-prime and incubator funding to build consortia and collaborations that can take projects forward to proof-of-concept, enabling applications for larger grants.



Step 3

Show clinical efficacy

Our surgical test bed (see page 8) provides fast and low cost clinical evaluation and evidence generation for new technologies, either developed through our programme or directly by our industrial partners.



Step 4

Clinical validation

Multicentre randomised controlled trials, using new models of trials designed specifically for surgical technologies, are used alongside health economics evaluations and regulatory approval, to provide an evidence base to support adoption within the NHS.



Step 5

Demonstrate value

Our work – and the value it creates – will be widely disseminated through our industry networks, stakeholder events, and through the partnerships we build with patient organisations and dedicated Patient and Public Involvement (PPI) groups.

Surgical Technology Testbed

The Surgical Technology Testbed offers medical technology companies a rapid and affordable route to early and late phase evaluation of surgical technologies, providing robust evidence for progression to CE marking, commercialisation and NHS adoption. This can include technologies:

- ◆ for use in a surgical environment that do not directly impact on patients.
- ◆ that use patient data but are not used in treatment.
- ◆ that are CE-marked but with minor adaptations.
- ◆ that are completely new and require full clinical testing on patients.

Companies will benefit from (as appropriate):

- ◆ Off-the-shelf trial designs.
- ◆ Clinical and cost-effectiveness assessment in a real-world setting.
- ◆ Clinical trial design and regulatory support through the Leeds Clinical Trials Research Unit (CTRU).
- ◆ Access to multiple clinical sites through the STT partner NHS Trusts in Leeds, Bradford, Sheffield and Hull to enable rapid evaluation.
- ◆ Health economics assessments.
- ◆ Transparent and affordable fees, based on a pay-per-patient system.
- ◆ Coordination and management through the CTRU and NIHR Surgical MedTech Co-operative.

The MedTech Foundation Supporting early career innovators

The MedTech Foundation (MTF) is a national student and trainee driven medical technology and innovation collaborative network, enabling early career interdisciplinary professionals from science, engineering and healthcare to get involved in research and innovation training.

The MTF helps university students, clinical trainees and early career researchers build their CV, skills and experience through national collaboration, workshops and access to exclusive MedTech research projects.

Established in 2015 as an affiliation of the then NIHR Colorectal Therapies Healthcare Technology Cooperative, the MTF is now a key part of the NIHR Surgical MedTech Cooperative, as part of our support for early career innovators.

The MTF's core activities include the annual educational Innovation Programme, involving a series of workshops covering the skills needed in interdisciplinary collaboration to

develop and translate novel innovations into patient benefit. Participants form multidisciplinary teams to develop ideas to solve unmet clinical needs whilst learning from experts in academia, industry and healthcare. After the Innovation Programme, these teams are supporting in sourcing research internships to develop their ideas further. These internships are provided within academia and industry as well as international exchanges with our overseas partners. The MTF also delivers a series of inspirational talks on a range of current topics in the medical technology landscape known as MEDx talks.

Realising the benefits of the work of the MTF, the NIHR has supported the group to expand their activities across the MIC

network and there are now MTF spokes in Birmingham, Cambridge and Edinburgh. Each spoke is supported to deliver their own Innovation Programme and activities. The MTF hopes to continue to grow and provide a national offer for innovators across the country.

To find out more about the MTF, please visit the website and follow on social media:

www.surgicalmic.nihr.ac.uk/medtechfoundation

[facebook.com/MedTechFoundation](https://www.facebook.com/MedTechFoundation)
[@MIC_Foundation](https://twitter.com/MIC_Foundation)

Involving patients and the public

We want to ensure that technological innovation is focused on patient and clinical needs from an early stage, and our new PPI group will bring the patient perspective to all our work.

We are developing strategic partnerships with national patient organisations across our three clinical themes, including Colostomy UK for colorectal surgery, the Circulation Foundation for vascular surgery and the British Liver Trust for HBP surgery. Representatives from these groups will sit on our Management Steering Committee.

We are also working with local patient groups, including Leeds Vascular Patient Interest Group, Healthwatch Leeds and Leeds Irritable Bowel Disease panel. Representatives from these and the national organisations are invited to our sandpit events, workshops and to advisory groups for our research projects, to help us in the identification of unmet clinical needs.

Our PPI groups also have a say in the commissioning and prioritisation of research, including decisions on pump-prime funding. They are involved in surgical technology evaluations, advising on effective recruitment strategies for our surgical test bed and clinical trials.

A partnership between:



Our wider network:



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