Bridging the innovation funding gap:

Maximising proof of concept success

Medical Technologies

INNOVATION AND KNOWLEDGE CENTRE

Contents

A note to knowledge exchange and commercialisation leaders and practitioners

This good practice guide is for knowledge exchange and commercialisation practitioners, and will be useful for anyone with an interest in innovation or research translation based in a higher education or research institution.

In this guide, we explain how to source and select the most promising research projects for proof of concept funding and how to support those projects to ensure a maximum chance of success.

Proof of concept projects bridge the gap between academic grants and commercial funding. They can be used effectively to take a project through to Technology Readiness Level 5, so it is better positioned for industry investment or commercialisation.

Our extensive experience in translation has been developed through the Medical Technologies Innovation and Knowledge Centre (IKC) established by the University of Leeds in 2009, and through Grow MedTech, a consortium of six universities set up in 2018.

Through these programmes, and working with our industry partners, we've progressed over 250 projects (proof of concept or technology development and demonstration), of which 84 have been taken beyond Technology Readiness Level (TRL) 4 – with over 50 products or services reaching the market.

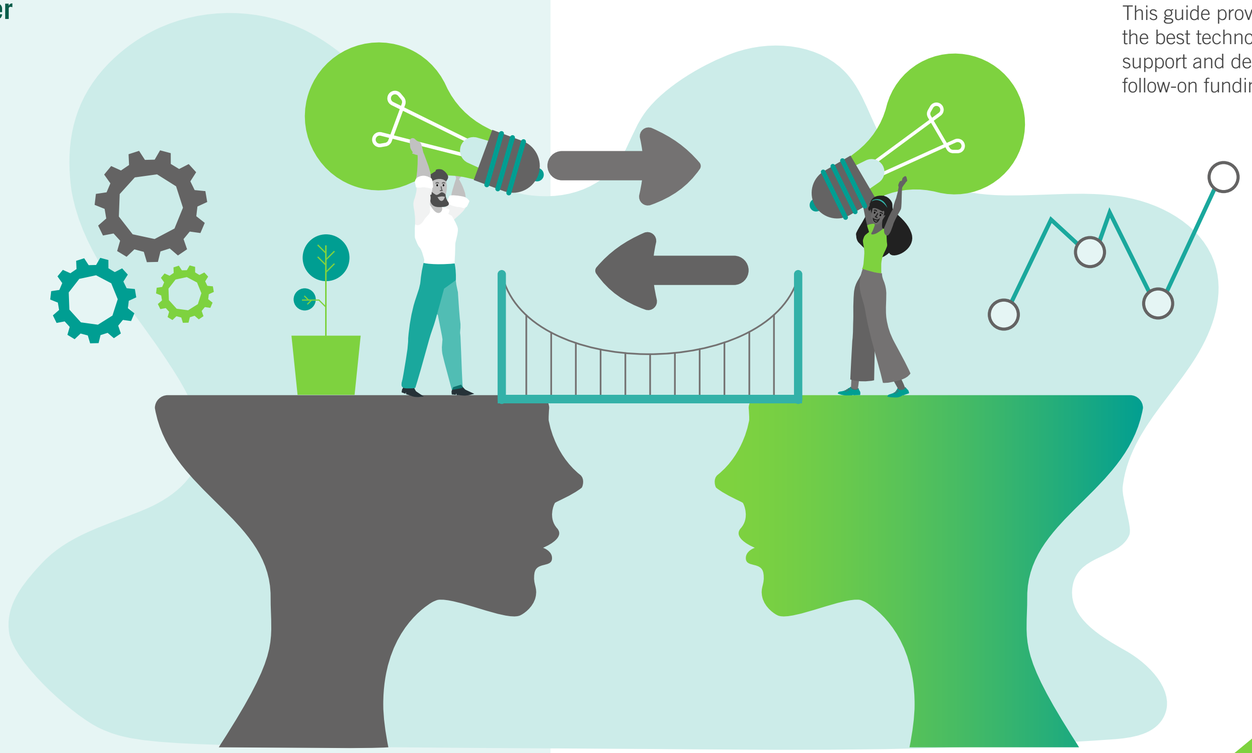
While our approach was developed for the commercialisation of medical technologies, it is relevant to other sectors too. It centred around a strong network of stakeholders, including industry and clinicians; a team of experienced sector-specific innovation managers; and a process and infrastructure that supports and enables academics to take their research forward to commercial application.

Bridge

the gap between academic grants and commercial funding

How this guide can help you

The job of a knowledge exchange and commercialisation practitioner is never straightforward. With limited time and resources, you're expected to help identify the most promising projects for translation from a portfolio of potential opportunities. These are likely to span a number of research disciplines and sectors, each with their own translational and regulatory challenges.



The academics you work with are often heavily invested in their ideas and technologies and excited about their potential applications and impact. But in reality, you know only a fraction of those ideas will be successfully progressed and adopted by industry.

Our *Fail fast or prove it early* guide to proof of market funding, published by Grow MedTech, explains how to test the viability of projects at a very early stage. Our *Ten steps to building an effective consortium* guide shows how to build a strong team with the necessary skills and expertise to take an idea forward.

After progressing through those early stages, technologies inevitably reach a point where academic funding is no longer available, but they are still not ready for innovation funding or industry investment. Proof of concept grants can help to bridge that gap. Their purpose is to advance a technology through to Technology Readiness Level (TRL) 5 and above to make it ready for commercial investment and commercialisation. For that reason, they are usually more substantial awards, often up to £100k and last for one to two years.

This guide provides practical advice to help you source and select the best technologies for proof of concept funding. It will help you to support and develop projects to maximise their chance of success and follow-on funding.

Advance
a technology through to Technology Readiness Level (TRL) 5 and above

What makes our proof of concept funding different?

Our proof of concept funding is much more than just money – it is a holistic approach we developed within the Medical Technologies IKC and further evolved through Grow MedTech. The grants provide much needed resources to help bridge a gap, but the process that academics follow to apply for funding and the support we provide are equally important.

Firstly, we make sure that we're selecting from the best possible pool of projects. We map the research strengths we can draw on, scout for potential projects and bring researchers from different disciplines together in innovation workshops to spark ideas. Then we run funding calls that encourage additional researchers to come to us.

We run a two-stage application process, asking first for expressions of interest and then choosing the strongest projects for a full application.

The application process is quite involved, but this is where our experienced, sector-specific Technology Innovation Managers step in. They have a wealth of expertise in medtech innovation, with backgrounds in academia, industry and knowledge exchange. They work with the researchers to complete their applications, helping them to think about their project not just as academic research, but as a commercialisation opportunity.

The full applications are reviewed by an expert panel, which includes internal and external expertise and end user representatives. All applications – including the unsuccessful ones – are given detailed feedback to refine their proposition and help them improve their future chances of success.

The relationships built during this process continue after a proof of concept grant is awarded. Our Technology Innovation Managers provide project management, meeting regularly with the research team, ensuring they keep on track and helping them adapt as required.

The Technology Innovation Managers tap into our national medtech network, involving businesses, clinicians, patients and academics, to bring the right expertise together for each project. Once the proof of concept project is successfully completed, the Technology Innovation Managers also help the researchers to identify and apply for further funding or industry co-development.

Experienced
sector specific Technology Innovation Manager support

How to maximise value from your proof of concept call

1 Ask the right questions

Asking for detailed information even at expression of interest stage helps ensure the quality of applications.

Our expression of interest (EoI) form includes:

- Project aims, objectives and plan
- Professional user needs (for us this means clinical and healthcare professionals)
- End user needs (for us, this means patient benefit)
- Industry engagement (for us, the medtech sector and other related industries, such as digital)
- End user involvement (for us, this meant patient and public involvement)
- Competitor analysis
- Intellectual property (IP)
- Route to commercialisation
- Likelihood of success

We ask for more detail on these areas in full applications, including a full proposal plan with work packages, milestones and deliverables, a financial breakdown and a product development roadmap.

In our experience…

Many academics initially need convincing of the value of the detail required on our application forms. The detail is intentional: by completing the forms, the researchers are effectively putting together an initial business case for their technology. But we don't expect them to do that on their own – many researchers won't have the necessary expertise and may not know where to source the information they need.

Our Technology Innovation Managers work closely with them to develop their applications, bringing the necessary sector-specific innovation and translation expertise to fill the gaps. And once this relationship is established, it continues throughout the project, providing support and advice and keeping things on track.

2 Make your review process robust

Carrying out a paper review first, scoring each application based on clear criteria, helps to streamline the decision process at panel review meetings. The criteria we use includes:

3 Select high quality projects

Find the best research

Scout for projects that address unmet needs or market opportunities, run innovation workshops, run funding calls

Co-develop expressions of interest

Technology Innovation Managers work with academics to develop business case

Review on paper

Score applications based on clear criteria

Run EoI panel

Technology Innovation Managers present applications and hear full panel discussion

Co-develop full application

Technology Innovation Managers work with academics and bring in other parties

Review on paper

Score applications based on similar criteria to EoI

Run full panel

Technology Innovation Managers attend, but academics present their project, followed by a Q&A and both hear the full panel discussion

Panel makes decision

Invite for full application, decline, ask for more info, direct to other funding

Panel makes decision

Fund, fund with clarification, decline, direct to other funding

In our experience…

We've found that combining internal and external expertise on our review panels helped ensure that the selection process was fair and robust. Our expression of interest panels for Grow MedTech included representatives from each of the six universities involved in the consortium – heads of either Technology Transfer Offices or Research and Innovation – plus three external members with medtech innovation expertise. Our full application panels for Grow MedTech were made up purely of external partners, bringing together medtech innovation experts, IP experts, an innovation funding body and a patient representative.

4 Support the delivery of funded projects

Ensure your projects have the best chance of success by remaining involved after funding has been awarded, through proactive project management.

- Run a kick-off meeting with all involved – including external partners
- Set out roles and responsibilities, aims and objectives
- Ensure everyone understands the project plan and reporting requirements
- Ask for monthly project update reports
- Use simple, time efficient reporting, such as RAG traffic lights to communicate progress
- Run quarterly project meetings, involving all partners
- Keep all stakeholders involved
- Address bottlenecks and delays
- Work with the team on a project final report
- Ensure there is follow-on planning
- Track outputs and outcomes to drive impact

5 Gather critical sector insights

Close working with industry partners is critical for successful innovation, translation and commercialisation of proof of concept projects.

This is particularly true in the medical technologies sector, where there is increasing regulation to be navigated. Commercial partners are often closer to user needs and bring critically important regulation and market insights which go beyond standard proof of market studies. These are vital both to inspire project opportunities and to enable a project to reach TRL5.

Industry partners play a critical role as research collaborators, commercial or investment partners, through start-up or spin-out companies or licensing agreements.

A successful approach to proof of concept

Since 2009, the University of Leeds has been working with UK HEIs to accelerate technologies closer to market through the Medical Technologies Innovation and Knowledge Centre (IKC), funded by the Engineering and Physical Sciences Research Council. Over the years, we have developed a unique innovation infrastructure, a team of experienced professional innovation and IP managers, and successful innovation and evaluation methods to advance medical technologies and reduce uncertainty and risk.

Our approach has enabled us to deliver a large portfolio of proof of concept projects. By de-risking technologies at an early stage, we've opened the door to over £200m private sector investment to progress technologies towards commercialisation. Most of this investment – £148m – has supported seven start-up companies established to take the technologies forward, while the remainder has supported work by established industry partners. This investment has enabled new products to be developed and manufacturing facilities to be established in the UK, the European Union, Switzerland and the USA.

Other organisations, including the medical charity Versus Arthritis, have also partnered with us, to apply our approach to their research funding programmes.

In 2018, the IKC team were awarded funding from Research England's Connecting Capability Fund to evolve our approach as part of a consortium of six universities in the Leeds and Sheffield City Regions, called Grow MedTech.

The IKC and Grow MedTech both focused on medical technologies, but our approach to research translation and commercialisation, outlined in this and other guides, is relevant to any sector.

Our successful approach to innovation

7

spinout and start-up companies created and supported

Enabled

£200m

downstream private sector investment into the private sector

267

technology development and demonstration projects

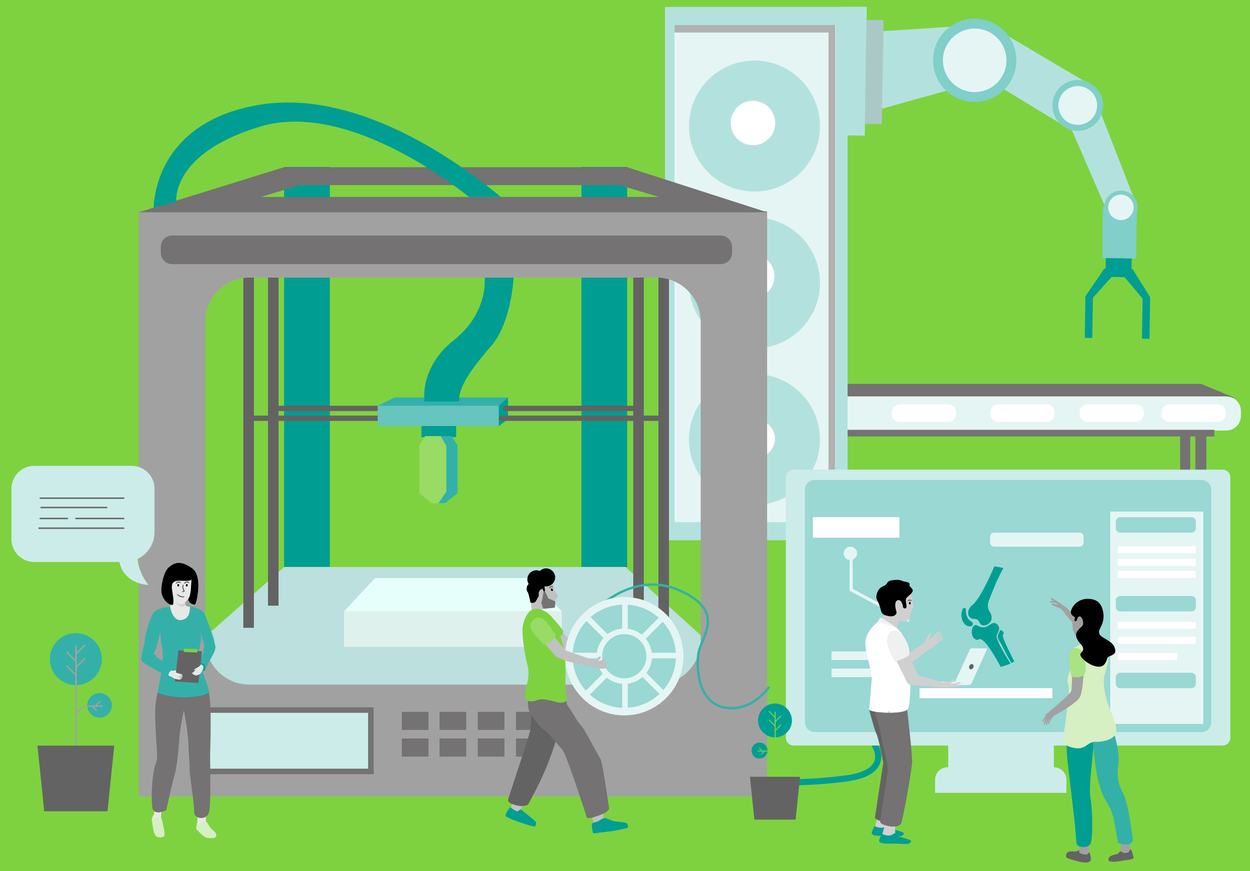
84

have progressed beyond TRL 4

50+

different products and services reaching the market

Case studies



1

Funding to de-risk ‘joint’ innovation

As people live longer and remain active into their later years, even following joint replacements, they are demanding more and more from their new hips and knees.

New and innovative designs are needed to meet these demands, and reliable testing of designs at an early stage is crucial to de-risk the innovation process. Taking forward designs that later fail in clinical trials is extremely costly.

“The new standard operating procedures have become part of the international standards.”

IKC proof of concept funding has supported co-development projects between the University of Leeds and simulator manufacturer, Simulation Solutions, to help de-risk innovation in total joint replacements.

Professor Louise Jennings leads the University’s world-leading joint simulation facility and is a member of the core IKC team. As such, she is both the lead academic and the TIM for her proof of concept projects, while gaining translational development support and training through her IKC involvement. The IKC also enabled her to tap into a wider network, notably through presenting her research at the IKC’s annual conference.

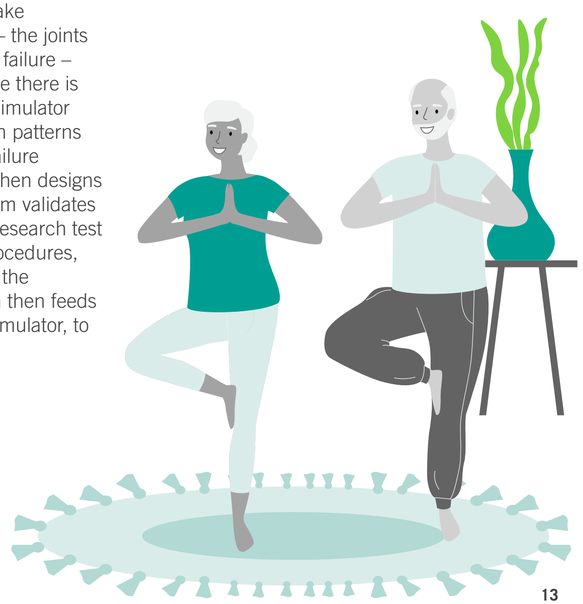
She describes the work with Simulations Solutions as a ‘loop’, which benefits the company, the wider orthopaedic industry and, most importantly due to the better joint replacements designed as a result, patients.

Professor Jennings and her team take information from clinical retrievals – the joints that need replacing again following failure – to see what’s gone wrong and where there is uneven wear. They then specify a simulator able to replicate loading and motion patterns that can reproduce these clinical failure mechanisms, which the company then designs and builds. Professor Jennings’ team validates the new simulator and develops a research test method and standard operating procedures, making it a marketable product for the company. The knowledge they gain then feeds into the specification for the next simulator, to begin the process again.

And this led to...

The new standard operating procedures have become part of the international standards, enabling Simulation Solutions to market their machines across the world and providing a reliable basis on which orthopaedic companies can design and test new joints.

The proof of concept funding from the IKC has also been the catalyst for other industry collaborations to develop new simulation methods and procedures.



Innovative technology that led to a global company

2

Since the inception of the UKRI EPSRC Medical Technologies IKC, it has supported and advanced technologies in regenerative medicine that have been commercialised through University of Leeds spin-out Tissue Regenix, one of the most successful medical technology companies from any UK university.

“Decellularised dermis repair technology is currently being used in NHS hospitals to treat chronic leg and foot ulcers.”

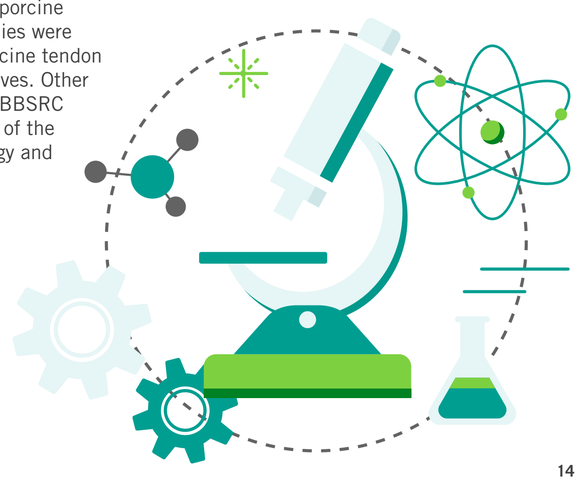
In the late 1990s, Professor Eileen Ingham’s team in the Institute for Medical & Biological Engineering at the University of Leeds, along with her colleague, medical engineering Professor John Fisher, developed a ‘deceullarisation’ process – removing cellular and DNA material from donated human or animal tissue, but leaving a tissue frame or ‘scaffold’ behind. The scaffold could be used as an implant to replace or restore diseased or injured tissue and support the growth of new tissue, using the patients’ own cells. As well as reducing the chances of rejection, this innovation – later trade marked as ‘dCELL®’ – proved to be clinically effective with relatively short development times and costs compared to cell and molecular-level therapies.

Medical Technologies IKC supported Tissue Regenix following its spin out from the University of Leeds in 2006. Since 2009, Tissue Regenix and the IKC have worked together on proof of concept and co-development projects. A co-development project with IKC funding, matched by the industry partner, was run in the University of Leeds which developed industry standard test methodologies for dCELL® porcine meniscus. Proof of concept studies were conducted on decellularised porcine tendon and porcine pulmonary heart valves. Other funding from UKRI EPSRC and BBSRC has supported the advancement of the underpinning dCELL® technology and the extensive patent portfolio.

The UKRI EPSRC IKC was also instrumental in supporting the development of the tissue scaffold decellularisation technology with the National Health Service’s Blood and Transplant Tissue & Eye Services, which is developing human tissue derived dCELL® scaffolds for use in the NHS. Decellularised dermis repair technology is currently being used in NHS hospitals to treat chronic leg and foot ulcers.

And this led to...

Tissue Regenix, a University of Leeds spinout, was listed on the London Stock Exchange’s Alternative Investment Market in 2010. It now has a portfolio of 12 commercial products on the market, involving different tissue types and for a range of patient conditions, and has also moved into natural bone regeneration. It employs 77 people across three global manufacturing facilities, annual revenue of £13 million and has over the last decade had a Market capital value estimated at between £30 million and £140 million.



From virtual to clinical trial

3

Funding from Versus Arthritis, provided in partnership with the IKC, enabled the first ever 'virtual' trial of an orthopaedic device. The funding, and IKC support, has helped the technology gain MHRA approval and progress to clinical trials.

Tailored Osteotomy Knee Alignment (TOKA) aims to improve outcomes for high tibial osteotomy (HTO) operations. These are used in younger osteoarthritis patients, to realign the knee and take pressure off damaged areas of the knee joint. Correct alignment during surgery is vital, but often difficult to obtain, particularly using standardised metal plates to hold the tibia in place.

"The IKC supported the team to further develop and patent the technology and helped in their applications for further funding."

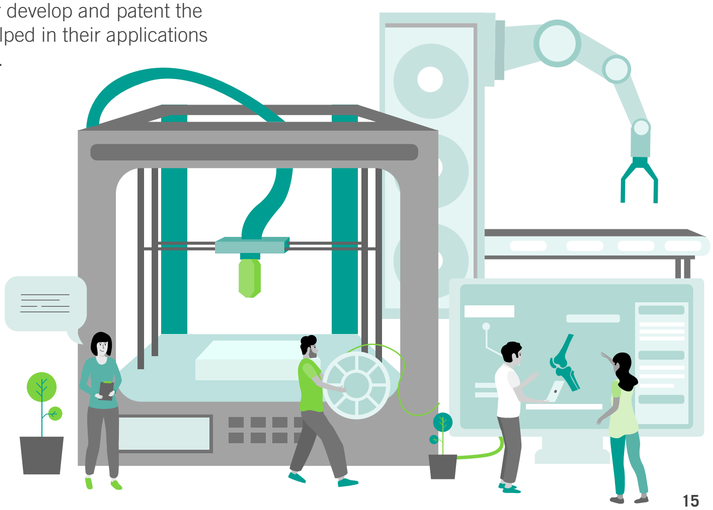
The new technology uses the patient's CT scans to print a 3D personalised surgery guide for each patient and create a bespoke 3D printed titanium plate. TOKA was developed by Professor Richie Gill and Dr Alisdair Macleod from the University of Bath, knee surgeons from the Royal Devon & Exeter Hospital and Alberto Casonato from 3D Metal Printing Ltd.

Unlike most orthopaedic devices, each TOKA implant is unique, which makes the regulatory process more complex. The team used IKC proof of concept funding to create computer models of different tibias based on CT scans from osteoarthritis patients. They used these models to assess how a standard HTO and a TOKA plate would behave if implanted into the same tibia – a 'virtual' or 'in silico' trial. The results were analysed alongside mechanical stress testing on the titanium material used in the 3D printed TOKA plates, proving that fatigue and wear in the standard HTO and the TOKA plates were very similar. This helped the team gain MHRA approval and was a critical component of their bids for clinical trial funding. The IKC supported the team to further develop and patent the technology and helped in their applications for further funding.

And this led to...

3D Metal Printing, the SME partner which developed the product for market, won UK government small business funding to run the first clinical trial which tested the technology in 25 patients in Italy. Initial findings were very positive.

Further funding from Versus Arthritis is supporting a larger randomised controlled trial in 88 patients, due to start in 2022, which will compare the outcomes of TOKA to standard HTO.



Read more case studies on our successful approach to innovation: https://medical-technologies.co.uk/case-studies/

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