IGNITE Summit 2020

Learnings from the Covid-19 pandemic to accelerate medical innovation

Foreword

By Professor Sir John Tooke and Dr Séamus O'Neill

Dr Séamus O'Neill

Professor
Sir John Tooke

The global Covid-19 pandemic has had a huge impact on us all. No sector has been spared. The existential threat posed by the infection precipitated accelerated medical innovation, with the development and deployment of novel diagnostics, repurposed therapies, novel ventilation devices, and most significantly vaccines in record time.

As we begin to emerge from the darkest days of the pandemic it is important to acknowledge the many other major health challenges that continue, all of which could benefit from the energy and smarter and more agile ways of working that underpinned much of the success in combating Covid-19.

The IGNITE summit series exists to enable established and emergent medical innovators to explore ways in which medical innovation might be accelerated and made more productive through a series of debates chaired by leading authorities in the field.

This, the fourth such summit, sought to capture the learnings from the experience of medical innovation in response to the pandemic.

An important positive legacy of the pandemic, in contrast to the personal tragedies and negative economic consequences, would be revisions to medical innovation that captured and systematised the beneficial approaches we were driven to adopt.

We applaud all those from academia, industry, the NHS, regulatory bodies, and citizens who made trials possible, for their collective contribution to address this scourge.

We hope that the insights gained through the summit will equip all concerned to rise to other health challenges with the same collaborative and entrepreneurial spirit.

IGNITE

NIHR | University College London Hospitals Biomedical Research Centre

casmi

UCL Academic Careers Office

nhsa Northern Health Science Alliance
A Health Partnership for Northern England

Executive summary

IGNITE is a medical innovation summit which in 2020 was jointly organised by the Collaboration for the Advancement of Sustainable Medical Innovation (CASMI), University College London, and the Northern Health Science Alliance (NHSA). The summit brought together a diverse group of leaders from across the country, and internationally, to focus on what the pandemic has taught us and how we can use that learning to optimise the UK's medical innovation system moving forward.

The summit is in its fourth year, with the first two iterations in London and the third one in South Africa with support from UK Research and Innovation (UKRI).

IGNITE enables established and emergent leaders from academia, NHS, industry and charity sectors to drive and accelerate change in their fields and across sectors. Under Chatham House rules, the IGNITE debate leads and participants discussed the challenges facing those engaged in medical innovation and the transformation required to address unmet clinical need faster and more efficiently.

The learning from four days of intensive discussion are presented in this report with the aim to help the UK develop and pursue transformative actions the pandemic has highlighted so that, where appropriate, they can be applied to other fields.

Findings

The Covid-19 crisis has had a seismic impact on the medical innovation ecosystem. A vaccine developed in nine months, transformation in the delivery of medical appointments and mass testing have demonstrated the power of the UK's health science system in tackling the worst global pandemic in a century.

But in a post-Brexit world there is still much to be done to build a resilient, prosperous and entrepreneurial world-leading health innovation system. The following areas were identified at the IGNITE summit as key game changers to help UK medical innovation to flourish:

1. Urgent breaking down of barriers in collaborative science, from devolved leadership to interdisciplinary awareness.

2. Intervention across the innovation pathway to cultivate an entrepreneurial culture, from responding positively to failure, to innovation governance and alignment of incentives.

3. A precise focus on needs awareness: accurate identification and articulation of unmet need in health and social care and optimising industry input.

4. State-supported life sciences cluster development to attract industry and external investment in medical innovation.

5. A focus on the Medicines and Healthcare Products Regulatory Agency (MHRA) in a post-Brexit era as a force to drive innovation.

1. Break down barriers to innovation and strengthen UK clusters

1.1 Create free space for innovation

- Invest in the multidisciplinary expertise needed to create a comprehensive pathway approach including in: applied behavioural science, sociology, anthropology, epidemiology, statistics and operational research to work alongside basic and translational scientists and clinicians.

- Stimulate and support innovation and research in NHS Trusts. Clinical professionals must have freedom to operate and there needs to be a collaborative working environment where all team members are able to contribute.

- Develop long-term funding streams to combat short-termism, 'staccato funding' requiring multiple re-applications and bureaucracy, and free up capacity to innovate.

- Current procedures are over-legislated, which stifles innovation.

- Look at removing regulation as a barrier to innovation.

EXAMPLE

Funding streams in the UK that focus on short-term outcomes stifle innovation and lead to failure. The North East's integrated healthcare record system, Great North Care Record, was founded five years ago with the NHSA's Department of Health funded organisation, Connected Health Cities.

It was deemed a success with health information exchanged 250,000 times a month during the pandemic. However, staccato funding led to a communication platform being shelved, which resulted in non-delivery of research consent and other patient engagement messages to 3.6 million citizens.

The public engagement system would have allowed the project to instantly communicate a test result to the patient, invaluable during the pandemic.

1.2 Cluster development

- Build on existing clusters such as the Northern Health Science Alliance and MedCity to deepen and strengthen national health innovation capability.
- Develop the UK's international health innovation position through its clusters, subjugating parochial or individual sector interests.
- Develop national incentives for multi-site collaborations and national resources in order to prevent silo working, which stifles innovation.

EXAMPLE

Partners in the COVID-19 National Diagnostic Research and Evaluation Platform (CONDOR) have been working together as a national platform but each partner may still compete against each other for funding and be judged against each other.

The pandemic precipitated a new dynamic around a collective goal and forced each partner to work more collaboratively to great success. This non-competitive behaviour is unlikely to be sustainable in the long-term without nationwide resources and incentives.

1.3 Join up innovation governance

- Develop a more joined up approach between funders and the NHS that provides additional funding for implementation and evaluation of innovation in the NHS.
- Replace intellectual property (IP) with fulfilment of purpose as the end goal in order to remove barriers to effective collaborations and to increase value.
- Make sure regulatory processes can deal effectively and efficiently with increasingly complex products that span therapeutic and diagnostic modalities and technologies.

EXAMPLE

A shortage of ventilators at the start of the pandemic brought individuals together from across University College London, University College London Hospitals NHS Foundation Trust and Mercedes-AMG High Performance Powertrains to build a new non-invasive ventilator (Ventura breathing aids).
This was achieved in just 100 hours from the initial meeting to production of the first device, with over 10,000 machines now operating around the world. Removing barriers between teams, in particular around intellectual property and contracts, was key to this.

The development of UCL Ventura breathing aids for Covid-19 patients demonstrated bringing together disciplines as diverse as mechanical engineering and medicine can provide innovative solutions.

Approaching the issue of the lack of appropriate breathing aids for Covid-19 patients with a problem solving/needs-led mentality helped to achieve a positive result. Getting quick regulatory approval by the Medicines and Healthcare products Regulatory Agency (MHRA) was possible because of direct engagement from UCL leadership directly with the regulator.

The same Ventura team were subsequently requested by the MHRA to support technical evaluation of similar projects.

1.4 Academia and industry bridge building

- Create specific deliverables to incentivise collaborative work in medical science between academia and industry.
- Devote more time and resource to match academic teams with commercial partners.
- Include innovation incentives in academic promotion criteria to support innovation.
- Facilitate smoother working between higher education institutions (HEIs) and commercial partners, particularly in regard to flexibility around funding cycles from HEIs and contracts from industry.

EXAMPLE

SMEs don't have respective technology transfer office (TTO) / translation research office (TRO) structure due to limited resources and struggle to make sense of the multiple streams of funding in the UK.

However, working in consortia can help tackle this issue. The UK BioIndustry Association (BIA) is a network of potential commercial partners that can interact easily with translational research.

IGNITE delegates questioned whether BIA was engaged sufficiently during the Covid-19 pandemic.

2. Develop and cultivate the UK's entrepreneurialism in Life Sciences

2.1 Developing an entrepreneurial culture

- Develop programmes that recognise the importance of leadership, attributes, and skills to equip those involved in research and innovation to optimise their contribution.
- Stimulate routes for engagement and for less established contributors who often have the brightest ideas.
- Put in place secondments between academia and SMEs which are beneficial for mutual learning and improved interactions aimed at innovation.
- Adopt an opt-in approach when it comes to identifying academic researchers with an entrepreneurial mindset with appropriate support.

EXAMPLE

The Experimental Medicine Initiative to Explore New Therapies (EMINENT), involving a few UK HEIs, identified there was a skills gap among clinicians around their understanding of the drug discovery pathway and translation into healthcare settings.

EMINENT addressed this by offering PhD studentships in which students were seconded to industrial partners and were able to move between both sectors through their PhD to create a more meaningful dialogue, enabling a subset of participants to think creatively about solving problems faced by both academia and industry.

2.2 Culture change and embracing failure as a path to innovation

- Adopt risk as a key factor in promoting innovation and accepting failure is part of that. The UK needs a funding structure and talent pool suitable for this mindset, which takes a more holistic approach to the innovation system rather than consider the individual parts separately.
- Identify and implement an acceptable/target failure rate for funders.
- Funders to support more innovative (and higher risk) ideas.
- Frame funding around grand challenges to help to increase the appetite for more innovative and higher risk research. Look at whether commercial milestones to incentivise spin offs and support for research teams increase the impact of grand challenge funding.
- Free space and create incentives for early career researchers to pursue entrepreneurial interests. Currently there are few incentives to develop entrepreneurial skills. Publication of papers is the imperative, rather than innovation.
- Adapt funding streams to support need. The pandemic freed up Innovate UK (IUK) to create a funding stream for SMEs which was quick and paid funding upfront. The virtual nature of the funding call helped to provide the speed needed to cope with the situation allowing flexibility for innovation.

INTERNATIONAL EXAMPLE

The Israeli Innovation Authority creates opportunities for SMEs to develop, even though many of those companies, backed by the Israeli Innovation Authority, eventually fail.
This experience is seen a useful training ground for entrepreneurs in Israel.

The most important element for a project in Israel is the team, with explicit reference to each person's skills and experience.
Conversely, in the UK pitching ideas has very little focus on the team behind them.
Betting on a good team has higher chance for success.
In Israel, individuals are asked to talk about their failures and learnings in job/panel interviews.

2.3 Innovate with needs awareness at the centre

- Focus on unmet need in health and social care to optimise industry input, harnessing research science and NHS adoption.
- Better adapt the NHS as a customer of innovation.
- Develop an NHS interface with entrepreneurs based on 'needs' and reorganise procurement based on innovation rather than standard commodities.
- Take a grand challenges approach to 'need' and create an incentive in the system similar to the needs presented by Covid-19.
- The imperative for 'need' should start with the end user/patient and evaluation and shouldn't be so reliant on large clinical trials.
- Real-world evidence might be more cost effective and hasten regulatory approval. We need to be open minded about the types of data for risk benefit calculation and select the methodology best suited to the research question.

EXAMPLE

The Covid-19 pandemic created a level of need that was self-explanatory allowing for quick innovation but NHS adoption remained an issue.

In developing Covid-19 testing, SMEs found it difficult to engage with the NHS for a number of reasons, including: accreditation, regulation and cash flow.

3. Enable the Medicines and Healthcare Products Regulatory Agency (MHRA) to drive innovation

3.1 Make the UK regulatory environment a global asset

- As the UK has left the European Union the MHRA is a sovereign regulatory agency outside of the European framework for pharmaceuticals, clinical trials and medical devices. The UK now has the ability to change regulation more quickly and, as the response to the Covid-19 pandemic has shown, we can act more effectively with regulation.
- Support the MHRA in creating opportunities for regulation of new products at pace without sacrificing safety.
- Position the UK as a high value, high trust environment for invention, evaluation and adoption.
- Under the pressure of Covid-19, the NHS has demonstrated its potential as an innovation asset for the UK, acting as a rapid response catalyst for large scale research. Previously, securing consent for trials in hospitals took longer than running the trial. The engagement with the public is much wider too, this should be continued post-Covid.
- There is still need for the MHRA to collaborate with agencies abroad and the UK must consider a global approach which also includes the EU.
- The MHRA system needs to be sufficiently flexible and responsive to deal with innovation.

EXAMPLE

The Clinical Trials Directive was approved in 2004 but was quickly recognised as unsuitable in some areas and needed reform.

It took until 2014 for the EU countries to reach agreement to replace it, despite widespread discontentment with the directive.

In total it took 17 years to reach implementation, which demonstrates the impact of a harmonised system. The long periods for changing regulation are not compatible with timescales of innovation.

The rate of innovation rapidly increases, including for new technologies, algorithms and software. The MHRA should provide oversight to protect the public but also support innovation.

3.2 Rethink how to measure risk and benefit

- Set up advisory groups that include experts in the field together with those directly involved in innovation.
- Make the UK a leader in gathering real-world data using AI to evaluate medicines post-launch.
- Develop a tailored approach to the specificity of each field or technology.
- Researchers and entrepreneurs should work with the MHRA from an early stage and take advantage of services such as the innovation office and innovation office scientific advice service (provided jointly with NICE).
- The MHRA should be adaptable in its interactions with the commercial sector according to the size of company.
- The NHS should be enabled to open up real-world evidence as a huge national asset to support patients and innovators.
- The UK approach to “cost-effectiveness” based on real-time assessment of real-world data (utilising AI) should be revised to include data on returning to work, feeling better, and other patient metrics beyond clinical data.

EXAMPLE

The development of the UCL Ventura breathing aid during the pandemic illustrates the advantages of engaging early on with the regulator.
There was a shared goal and an ability to take a shared risk with the MHRA for the innovation. This made contracts move quickly, aided by the commercial partner, Mercedes-Benz willing to take indemnity for the device.