

March 2019



# Perspectives

Legal updates for the world of higher education

Dear Colleague

As the eleventh hour political debates over the UK's scheduled departure from the EU continue, this edition of Perspectives looks at some of the future opportunities and challenges for the Higher Education sector. I examine the importance of education and research in the Government's industrial strategy and also the OfS' new approach to widening Access and Participation. Partner James Fry considers the challenges that the sector has been addressing in clinical trials with reference to Brexit. Real estate partner Christian Bull looks at the potential challenges and opportunities for institutions and their estates teams making decisions about buildings and real estate as universities, technology and society continue to evolve. As ever, the sector has plenty to consider.

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“the way we live continues to be transformed by the technological advances of what is a fourth industrial revolution.”

# UK Industrial Strategy

## The importance of higher education and research

As the UK prepares to leave membership of the European Union, we review the UK Industrial Strategy which was set out in the Government’s White Paper in November 2017 - “Building a Britain fit for the future” - and consider the importance of the role played by the UK higher education and research sector.

Launching the Industrial Strategy, Business Secretary Greg Clark said:

“The way we earn and live our lives as workers, citizens and consumers is being transformed by new technologies. The UK is well-placed to benefit from this new industrial revolution and we start from a position of significant strength. We have a thriving research and science base and are home to a wide range of innovative sectors, from advanced manufacturing and life sciences, to fintech and creative industries. The Industrial Strategy is an unashamedly ambitious vision for the future of our country, laying out how we tackle our productivity challenge, earn our way in the future, and improve living standards across the country.”

### Four Grand Challenges

In December 2018, a one year review of progress was published - ‘Forging our Future’ - which reminded us of the four Grand Challenges set by the Industrial Strategy:

#### Artificial intelligence and data

- “We will put the UK at the forefront of the AI and data revolution.”
- mission: to use data, artificial intelligence and innovation to transform the prevention, early diagnosis and treatment of chronic disease by 2030.

#### Clean growth

- “The move to cleaner economic growth – through low carbon technologies and the efficient use of resources – is one of the greatest industrial opportunities of our time.”
- missions:
  - \* at least halve the energy use of new buildings by 2030
  - \* establish the world’s first net-zero carbon industrial cluster by 2040 and at least 1 low-carbon cluster by 2030.

#### The future of mobility

- “We will become a world leader in the way people, goods and services move.”
- mission: put the UK at the forefront of the design and manufacturing of zero emission vehicles, with all new cars and vans effectively zero emission by 2040.

#### The ageing society

- “We will harness the power of innovation to help meet the needs of an ageing society.”
- mission: ensure that people can enjoy at least 5 extra healthy, independent years of life by 2035, while narrowing the gap between the experience of the richest and poorest.

## Six Sector Deals

To support the Industrial Strategy and the grand challenges, the Government has so far agreed six Sector Deals in the following areas:

- life sciences
- automotive
- creative industries
- AI
- nuclear
- construction

Three more Sector Deals have been promised as next in line: aerospace; rail; and, food and drink manufacturing.

Each of the Sector Deals is designed to build on the five foundations which have been identified as necessary for success: ideas; people; a business environment; infrastructure and places.

## Batteries and the Faraday Institution

The 'Forging the Future' review of progress highlights a significant project involving the Birmingham Centre for Strategic Elements and Critical Materials (BCSECM) at Birmingham University. This is the Recycling of Lithium-Ion Batteries (ReLiB) project which is being funded by the Faraday Institution, an independent national battery research institute established following the launch of the UK Industrial Strategy.

The ReLiB project is a collaborative activity between Birmingham University, University of Leicester, University of Newcastle, Cardiff University, University of Liverpool, Oxford Brookes University, University of Edinburgh and 13 industrial partners.

The Faraday Institution is also funding 3 other significant projects involving consortia on other important aspects of battery research: extending battery life (led by the University of Cambridge), battery system remodelling (led by Imperial College London) and next-generation solid-state batteries (led by Oxford University).

The Faraday Institution has seven founding universities: Oxford University, University College London, Warwick University, Cambridge University, Imperial College London, Newcastle University and Southampton University. Its projects involve 30 industry partners and 20 universities.

## Artificial Intelligence and the Turing Institute

Higher Education and Research institutions are to play an integral role in the AI Sector Deal as illustrated by some of the Government commitments set out below.

In terms of 'ideas':

- £93m investment from the Industrial Strategy Challenge Fund into the robotics and AI in extreme environments programme.

In terms of 'people':

- support for the prestigious Turing Fellowship programme to attract and retain research talent from around the world.
- support for 1,000 PhDs in AI and related disciplines by 2025.

In terms of 'infrastructure':

- the Alan Turing Institute and the Information Commissioner's Office to work together to develop guidance to assist in explaining AI decisions.
- In terms of 'business environment':
- a new AI Council to include leading figures from industry and academia to come together with Government to identify opportunities and issues.

In terms of 'places':

- support for the Alan Turing Institute's plans for expansion to become the national academic institute for artificial intelligence and data science.

"As our Industrial Strategy acknowledges, the way we live continues to be transformed by the technological advances of what is a fourth industrial revolution." – Forging our Future, December 2018.

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# Clinical trials and Brexit

The close integration of the UK’s regulatory and research environment with that of the European Union is of particular significance in biomedical fields. This alignment is relevant in areas such as the regulation of medicines, medical devices and clinical trials and provides consistency of approach across EU member states over the approval of new biomedical products. This article highlights a number of areas that need to be considered in the context of clinical trials in light of Brexit.

Many UK universities participate in the conduct of clinical trials concerning investigational medicinal products where the trial is being conducted in the UK and at least one other EU member state. An institution may be:

- a “sponsor” of a trial (the lead organisation managing the trial and having overall oversight);
- a “co-sponsor” with another organisation (such as with a hospital trust); or
- a participant i.e. the sponsor or sponsors of the trial being another organisation.

## Regulatory framework

EU clinical trials are currently governed by the EU Clinical Trial Directive (2001/20/EC) (CTD). The CTD is due to be replaced, at EU-level, by the Clinical Trial Regulation No 536/2014 (CTR). The CTR is aimed at harmonising further the rules applying to clinical trials across all EU member states and will bring in changes, including some which will streamline process e.g. around the obtaining of approvals, and reporting requirements.

The CTR is not likely to be law by the time Brexit happens, however, the UK government has indicated that it plans to adopt the CTR such that regulatory alignment on trials between the UK and EU continues. UK institutions participating in EU trials will still need to ensure that they comply with EU laws post-Brexit in relation to any trial being conducted in an EU member state and UK laws where that trial is also being performed in the UK.



## Sponsor status

One of the specific issues caused by Brexit is that the “sponsor” of an EU trial must be established in the EU. A UK institution may have operations in the EU (e.g. through an overseas campus) or it could look to establish an EU entity who could become the sponsor however there are no developed guidelines around what “establishment” means in the context of a clinical trial and there is likely to be some uncertainty as to whether, after Brexit, a UK institution would be regarded as being “established”.

An alternative solution is for an institution to appoint a legal representative established in the EU. A legal representative is required to ensure that the sponsor complies with the relevant regulations and also acts as the addressee on communications with regulators (such as the European Medicines Agency).

Setting up a legal representative arrangement is relatively straightforward but involves putting in place a contract to ensure that regulatory requirements continue to be met. The legal representative could be an EU-based institution or another organisation. However given that the legal representative is to maintain oversight on compliance, it should have experience of managing trials. Any institution looking to appoint a legal representative over EU trials that it is sponsoring going forward should carry out due diligence and be satisfied that the representative has the resources and capability to ensure ongoing compliance.

Relevant sections of the CTD and CTR read as follows:


CTD: This Directive is without prejudice to the civil and criminal liability of the sponsor or the investigator. To this end, the sponsor or a legal representative of the sponsor must be established in the Community.

CTR: In order to ensure that enforcement action may be taken by Member States and that legal proceedings may be brought in appropriate cases, it is appropriate to provide that sponsors that are not established in the Union should be represented by a legal representative in the Union.

## Clinical trial agreements

Clinical trial agreements will be in place between the sponsor and other trial participants, including industry participants. These will need to be reviewed to assess the impact of Brexit e.g. does the agreement allow for costs to be reviewed in the light of Brexit, either expressly or by implication?

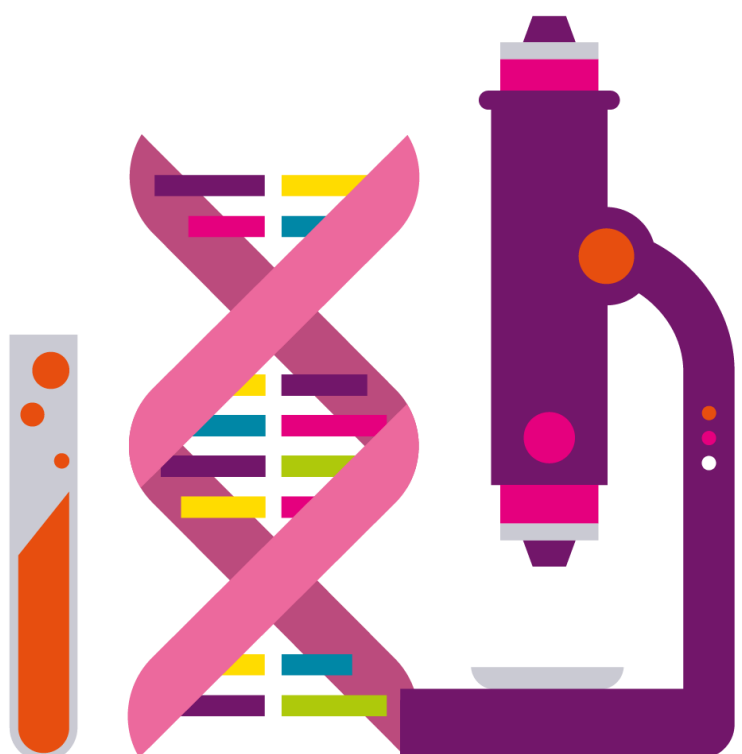
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“Alongside funding pressures, the other challenge and change affecting HEIs’ estates is the digital revolution, where the flow of information will impact on the delivery of teaching and research.”

## Change, challenge... and opportunity.... are coming to the real estate landscape in HE

Universities and their estates teams are facing some of the biggest challenges in recent memory spanning:

- budgetary pressures involving growing revenue versus expenditure tensions at some institutions;
- skills and workforce shortages (possibly compounded by concerns over a post-EU UK and potential limits on free movement);
- constant change (legislative and governmental initiatives eg, TEF, REF, the Augar review, OfS requirements, forthcoming changes to the accounting rules, further health and safety laws following the Grenfell tragedy etc);
- fluctuating student numbers;
- growing competition;
- rapid technological growth;
- inefficient use of buildings and facilities;
- uncertainty surrounding Brexit (it had to be mentioned!)

### **Given these challenges, how will the property landscape in HE change and need to evolve?**

There are some emerging trends and predictions, largely driven by financial pressures and speedy technological change:

- a potential reduction in full-time undergraduate “traditional” student numbers – but possibly seeing more part-time, lifelong, online, flexible learning, apprenticeships and teaching at/from, possibly fewer, universities;
- higher education may become more employer-driven involving teaching by companies, particularly technology organisations and larger employers. Employers may look to alternative models to the conventional undergraduate

degree. With the rise of AI, falling job security and a growth in micro-businesses, is HE and its estate responding quickly enough?

- the re-purposing of parts of the existing estate/facilities at certain universities e.g., for offices, co-living/working spaces and mixed use schemes. This doesn’t mean institutions will necessarily lose their identity and autonomy – it’s just a broader, more open and different way of thinking by focussing on being able to adapt the estate quickly and flexibly to make (and generate) money and resources go further;
- how universities spend money on their estate needs to be re-imagined. There will continue to be increased pressure on costs (the Augar review in England could have a real impact on affordability) and hence quality of service and facilities to students. Flexibility is therefore key. This may not involve universities always building or managing their own estate and the “traditional” model of having costly (new) buildings in fixed locations for fixed purposes may no longer always be desirable. The way learners are working is changing and universities’ estates need to evolve to reflect this. Students have a growing preference for, and expectations of, a “study anytime, anywhere” approach. This increasingly involves group study on a 24/7 basis and informal learning. It should be remembered that universities’ buildings and facilities are part of the student appeal, they provide a sense of belonging and play an important role in students’ overall life experience at university. There will be more smaller buildings, flexible floor spaces, further mixed use schemes involving co-located facilities and collaboration areas with third parties. Essentially, there will be a greater focus on the return on capital investment: academic faculties will increasingly have to provide robust business

cases for new builds/significant re-purposing schemes. Such cases should include ongoing maintenance costs and a focus on maximising occupancy and utilisation. Advances in data collection, analysis and technology will help with this and will assist in assessing (and responding to) students' evolving working styles and preferences;

- universities shouldn't always automatically respond to financial challenges by selling land and buildings. Overall rises in land values, particularly in certain city centre locations, could mean that once land has gone, it's gone. It may be prohibitively, and disproportionately, expensive if institutions need to buy (back) land in the future.

### The future campus

Although there will always be a need to continue to invest in the university estate to meet competition and attract the best learners, staff, partners and funding, what that investment will look like will change. It won't always involve large-scale, expensive single-use new builds. Expansion of the estate isn't always right or desirable – if the above challenges require a temporary “pause and reflect” approach amongst estates directors and senior university management, then that isn't necessarily a bad thing.

### Broadening of estates strategies


University estates teams regularly mention a lack of interdisciplinary research and collaboration as a real problem to address. Institutions' estates masterplans not only need to be linked to universities' wider strategies. They should also increasingly involve others such as the NHS, combined authorities etc, not least to access/share funding but also to foster greater partnership working for the benefit of the university, its students, staff and stakeholders. This will also help to develop and enhance universities' civic mission and promote the valuable role institutions play in our local, national and increasingly international communities.

### Technology and the estate

Alongside funding pressures, the other challenge and change affecting HEIs' estates is the digital revolution, where the flow of information will impact on the delivery of teaching and research. Overseas students in particular are “digitally dependent and expectant”. Many competing universities from abroad already have “smart” campuses where people, place and technology are integrated. Students have a growing global outlook and expect universities' IT to be personalised, contextualised (to facilitate social interaction, be data location specific and with 5G) and measured, to both assess occupancy and help to enhance the student experience. The growth of the virtual lecture theatre (already featured at Harvard and Stanford universities) will continue. Are UK universities doing enough to create “smart” campuses by blending the physical and digital?

British universities are one of the UK's “crown jewels”, with their estate and facilities being their most visible shopfront. By recognising and adapting to the above changes and challenges they can retain and enhance their strong global reputation, quality, desirability, respect and brand whilst also being financially sustainable.

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“it is not only about individuals from underrepresented groups getting into higher education but also about individuals achieving, progressing and succeeding in their time in higher education.”

## Fair access to higher education

Many will remember the publication of the National Committee of Inquiry into Higher Education in 1997 which was chaired by Lord Dearing. Chapter 7 focused on widening participation and was introduced as follows:

“Looking back, there is much to celebrate: there have been some remarkable achievements. But substantial problems remain and improvements are required as a matter of priority. For the reasons set out in the previous chapter (Chapter 6), increasing participation in higher education is a necessary and desirable objective of national policy over the next 20 years. This must be accompanied by the objective of reducing the disparities in participation in higher education between groups and ensuring that higher education is responsive to the aspirations and distinctive abilities of individuals.”

The reasons for increasing participation given in Chapter 6 of the National Committee of Inquiry - ‘Higher Education in the Learning Society’ - included the following:

- the changing structure of the national economy
- the changing requirements of the labour market
- the economic benefits to individuals participating in higher education
- the economic benefits to society for participation in higher education

These broad reasons would appear to remain valid, although the needs of the national economy and the labour market may well be quite different in 2019 as the UK prepares to leave membership of the European Union. Perhaps one might also give greater weight now to the imperative of social justice and fairness.

Looking at the legal and regulatory landscape in 2019, we now have the Office for Students (OfS) which was

established under the Higher Education and Research Act 2017. We also now have a Director of Fair Access and Participation which has replaced the previous Director of Fair Access, emphasising that it is not only about individuals from underrepresented groups getting into higher education but also about individuals achieving, progressing and succeeding in their time in higher education.

Following a consultation towards the end of 2018, the OfS has now set ambitious targets for the higher education sector which are to eliminate the gaps in access and student success within the next 20 years, namely:

- the gap in entry rates at higher tariff providers between the most and least represented groups
- the gap in non-continuation between the most and least represented groups
- the gap in degree outcomes between white and black students
- the gap in degree outcomes between disabled and non-disabled students

Each institution which is on the Register of English Higher Education Providers and wishes to charge the higher fee to under-graduate students (currently £9250 pa) must submit their Access and Participation Plan to the OfS for approval. The new approach adopted by OfS will apply to Access and Participation Plans from academic year 2020-21. A new Regulatory Notice was issued by OfS on 28 February 2019 which sets out the new regulatory landscape:

- all Access and Participation Plans are required to “demonstrate clear long-term ambitions for how providers will achieve significant reductions in the gaps in access, success and progression over five years from when the plan commences”;
- an annual impact report will need to be submitted



each year to enable the OfS to monitor an institution and identify “early warning signs that there is an increased risk that a provider may not be able to satisfy its ongoing conditions of registration”.

Underrepresented groups have been defined by the OfS to include “all groups of potential or current students where the OfS can identify gaps in equality of opportunity in different parts of the student lifecycle” and, for the purposes of Access and Participations Plans, to include students with the following characteristics:

- students from areas of lower higher education participation, lower household income and/or lower socioeconomic status groups
- some black, Asian and minority ethnic (BAME) students
- mature students
- disabled students (those in receipt of disabled students allowance (DSA) and those who have declared a disability but are not in receipt of DSA)
- care leavers

The OfS goes on to note in the new Regulatory Notice:

“We aim in all our work to be evidence-based and never lose sight of the individuality of each student. Therefore the OfS expects providers to consider the way in which these characteristics combine to increase underrepresentation. For example white British men and women from lower socioeconomic backgrounds are among the most underrepresented groups in higher education. Therefore, within its definition, the OfS includes male and female students in combination with the characteristics above. In addition there is a wider set of student groups where the national data indicates there are particular equality gaps and support needs that can be addressed in access and participation plans. These are also included in the OfS definition of underrepresented groups:

- carers
- people estranged from their families
- people from Gypsy, Roma and Traveller communities
- refugees
- children of military families”

In addition to the Access and Participation Plan, institutions are required to submit to the OfS two

spreadsheets which set out the institution’s a) targets and investment plan and b) fee information. These will be considered as part of the evidence when the OfS considers whether to approve an institution’s Plan. The OfS sets out its requirements in respect of targets and investment in the new Regulatory Notice.

The OfS rightly reminds higher education institutions in the Regulatory Notice that higher education institutions have duties under the Equality Act 2010. Those which are classified as ‘public authorities’ for these purposes are subject to the Public Sector Equality Duty. This legal duty is set out in section 149 of the Equality Act 2010 and requires that public authorities have due regard, in the exercise of their functions, to the need to:

- eliminate discrimination, harassment, victimisation and any other conduct that is prohibited by or under the Act;
- advance equality of opportunity between persons who share a relevant protected characteristic and persons who do not share that characteristic;
- foster good relations between persons who share a relevant protected characteristic and persons who do not share that characteristic.

In addition to the Public Sector Equality Duty, Part 6 of the Equality Act 2010 specifically applies to the provision of education. Section 91(1), for example, requires a higher education institution not to discriminate against a person:

- in the arrangements it makes for deciding who is offered admission as a student;
- as to the terms on which it offers to admit the person as a student;
- by not admitting the person as a student.

The protected characteristics under Part 6 of the Equality Act 2010 relating to the provision of education are: age, disability, gender reassignment, pregnancy and maternity, race, religion or belief, sex and sexual orientation.

The OfS says that its ambition of enabling equal opportunity for all is “necessarily a long-term goal, but we are clear that to achieve it, the higher education sector needs to make significant progress over the five-year period for which the next round of access and participation plans (APPs) will operate, through to 2024-25.”

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# About Mills & Reeve

Mills & Reeve offers a deep knowledge of the higher education sector and the commercial strength of one of the UK's leading national law firms.

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