

Institution: University of Edinburgh		
Unit of Assessment: UoA 21 Sociology		
Title of case study: Innovation friendly regulation: Implementing proportionate and adaptive governance for innovation in technology in the UK(PAGIT)		
Period when the underpinning research was undertaken: 2007-2020		
Details of staff conducting the underpinning research from the submitting unit:		
Name(s):	Role(s) (e.g. job title):	Period(s) employed by submitting HEI:
Professor Joyce Tait	Director/Co-Director of the Innogen Centre and Institute	2002 - present
Dr. Geoff Banda	Research Fellow and Lecturer	2014 - present
Dr. Ann Bruce	Research Fellow, Lecture and Senior Lecturer	2002 - present
Dr. Michele Mastroeni	Research Fellow	2010 - 2013
Dr. James Mittra	Research Fellow, Lecturer and Senior Lecturer	2003 - present
Dr. Omid Omidvar	Research Fellow	2013 - 2014
Dr. Andrew Watkins	Research Fellow	2017 - 2019
Professor David Wield	Director/Co-Director of the Innogen Centre and Institute	2002 - present
Period when the claimed impact occurred: 2014-2020		
Is this case study continued from a case study submitted in 2014? N		
1. Summary of the impact (indicative maximum 100 words)		
<p>Innogen Institute research has demonstrated many flaws in today's regulatory systems for innovative technologies and developed a framework for their future governance (PAGIT) showing how the necessary adaptation could be achieved, leading to two significant research impacts.</p> <ul style="list-style-type: none"> • Tait led the Prime Minister's Council for Science and Technology initiative that culminated in publication of the White Paper on Regulation for the Fourth Industrial Revolution, setting up four government initiatives designed to deliver the necessary regulatory adaptation. • Funded by Innovate UK, the British Standards Institution commissioned Tait as technical author of a standard on Responsible Innovation to support responsible company behaviour in light of expected future changes in UK regulatory systems. 		
2. Underpinning research (indicative maximum 500 words)		
<p>Research by Tait and her colleagues at the Innogen Institute on the governance of innovative technologies covers both formal, legally-based regulation of the safety, quality and efficacy of new developments and their societal acceptance, particularly the need for responsible innovation (RI).</p>		

They demonstrated the extent to which today's regulatory systems are ill-adapted to the needs of innovative technologies, leading to abandonment of innovations that could meet pressing societal needs and, particularly in life science sectors, loss of the creative innovation potential that could come from small companies with the ability to develop transformative, path-breaking new developments (3.1, 3.2, 3.3). Their portfolio of research cases provided evidence on how and where regulatory systems are having these negative effects for: diagnostic devices; drug development; initiatives to overcome antimicrobial resistance; regenerative medicine and stem cell therapies; agricultural biotechnology; animal cloning; and industrial biotechnology. This research was based on social science research methods including literature reviews, policy and regulatory document analysis, interviews with senior regulators and industry managers, and analysis of company innovation strategies, following the Innogen Institute interdisciplinary methodology (3.4).

A parallel research strand on RI, given the societal requirement for innovative products to be developed responsibly, pointed to the emphasis of most social science studies on responsible *research* rather than innovation, and the lack of advice and guidance for companies on how to ensure that their business models are responsible, and how to demonstrate that responsibility, given competing commercial pressures to be first to market, to maintain necessary confidentiality and to raise private sector investment (3.5).

Tait was awarded a CBE for services to social science in 2005 and, based on the research programme, has taken a proactive role in informing and advising on UK regulation and governance of innovative technologies. She has been a member of 32 UK, EU and US advisory bodies and committees, averages 13 invited presentations per year to conferences and workshops, and has responded to numerous UK Parliament and House of Lords consultations. This approach to seeding these ideas in relevant policy and industry communities proved invaluable in enabling the impacts described in Section 4.

By 2015, this research had made a convincing case for the scale of the negative impact on innovative technologies by disproportionate and non-adaptive regulatory systems, and UK Government departments were looking for solutions to the problem. The UK Government Department of Business, Energy and Industrial Strategy (BEIS), through the British Standards Institution (BSI) funded two projects to develop a framework for *Proportionate and Adaptive Governance of Innovative Technologies* (PAGIT) (3.6), with a supplement from an Edinburgh University ESRC Impact Acceleration Account. The aim was to cover both regulatory and societal aspects of governance, including regulatory adaptation led by government bodies and assurance of responsible innovation led by companies.

The PAGIT framework delineates (i) creative roles for regulatory and standards bodies in devising future regulations, standards and guidelines to govern the development and adoption of a technology and (ii) the nature of the support needed by companies in order, first, to assure themselves that they are behaving responsibly and, second, to demonstrate that responsible behaviour to stakeholders.

Two key actions recommended by the PAGIT Report (3.6) were:

1. to explore opportunities to use the PAGIT Framework to optimise the UK's regulatory systems for innovative technologies; and
2. through BSI, to consider development of a standard on Responsible Innovation (RI).

3. References to the research (indicative maximum of six references)

3.1 Tait, J. and Wield, D. (2019) Policy Support for Disruptive Innovation in the Life Sciences. *Technology Analysis and Strategic Management*. DOI: [10.1080/09537325.2019.1631449](https://doi.org/10.1080/09537325.2019.1631449).

3.2 Mitra, J., Tait, J., Mastroeni, M., Turner, M., Mountford, J., Bruce, K. (2015) Identifying Viable Regulatory and Innovation Pathways for Regenerative Medicine: A Case Study of Cultured Red Blood Cells, *New Biotechnology*, 32 (1), 180-190.
DOI: [10.1016/j.nbt.2014.07.008](https://doi.org/10.1016/j.nbt.2014.07.008).

3.3 Tait, J., Bruce, A., Mitra, J., Purves J. and Scannell, J. (2014) *Independent review on anti-microbial resistance regulation/innovation interactions and the development of antimicrobial drugs and diagnostics for human and animal diseases: Main Report*. 14th Dec., 2014. Report to ESRC for the O'Neill Commission on Antimicrobial Resistance.
https://web.archive.org/web/20210114143211/http://www.innogen.ac.uk/sites/default/files/2019-04/AMR_Final_Report_141214_0.pdf

(Also published in Mitra, J., Bruce, A., Scannell, J.W. and Tait, J. (2019) Regulatory and market influences on innovation pathways for the development of new antimicrobial drugs. *Technology Analysis and Strategic Management*).
DOI: [10.1080/09537325.2019.1634253](https://doi.org/10.1080/09537325.2019.1634253).

3.4 Wield, D., Tait, J., Chataway, C., Mitra, J., and Mastroeni, M. (2016) Conceptualising and practising multiple knowledge interactions in the life sciences. *Technological Forecasting and Social Change*, 116, 308-315. DOI: [10.1016/j.techfore.2016.09.025](https://doi.org/10.1016/j.techfore.2016.09.025).

3.5 Tait, J. (2017) From Responsible Research (RR) to Responsible Innovation (RI): challenges in implementation. *Engineering Biology*, 1(1), 7-11. DOI: [10.1049/enb.2017.0010](https://doi.org/10.1049/enb.2017.0010).

3.6 Tait, J., Banda, G. and Watkins, A. (2017) *Proportionate and Adaptive Governance of Innovative Technologies (PAGIT): a framework to guide policy and regulatory decision making*. Innogen Institute Report to the British Standards Institution.
https://web.archive.org/web/20200530195125/http://www.innogen.ac.uk/sites/default/files/2019-04/PAGIT%20FrameworkReport-Final_170717.pdf

4. Details of the impact (indicative maximum 750 words)

The PAGIT Report, and in particular two of its key recommendations, had the following impacts on UK Government.

1. From PAGIT to the 'Fourth Industrial Revolution'

Following Tait's appointment to the Prime Minister's Council for Science and Technology (CST) in 2017, as outlined in the testimonial from the CST Secretary (5.1), she led the work on the CST project on 'Reforming the Governance of Technological Innovation'. The outcome of this project, informed by the PAGIT report, was a letter to the then Prime Minister, Theresa May, sent on 27th September 2018 (5.2) with recommendations on:

1. developing a regulatory horizon-scanning function ... in the Better Regulation Executive (BRE);
2. considering guidance, codes and standards alongside formal regulation as part of a more flexible and responsible approach to governing innovation;
3. providing a 'one-stop-shop' for UK regulatory enquiries; and
4. evaluating governance of innovation including setting up 'test beds' to try out emerging innovations safely.

PAGIT was central to this letter, as specified by CST: PAGIT was used "as a framework to guide policy and regulatory decision making. You presented the key concepts in the report for discussion with CST members, which helped to frame thinking on advice to the Prime Minister" (5.1, p. 1).

The Government's response was "unusually quick and robust" (5.1, p. 2): Greg Clark, then Secretary of State for Business, Energy and Industrial Strategy, responded on 12th October 2018 (5.3), confirming the government's intention to implement these recommendations. The resulting

White Paper on *Regulation for the Fourth Industrial Revolution* (5.4) commits the UK Government to the following:

1. Establishing a Regulatory Horizons Council to do horizon-scanning work and recommend priorities for regulatory reform to the Ministerial Working Group on Future Regulation (5.4 pp. 11-13) to which Tait was subsequently appointed and asked to take the lead role in advising Government on the future regulation of genomic technologies (5.5).
2. Improving use of regulatory guidance, codes of practice and industry standards, including piloting an innovation test to consider impact of legislation on innovation alongside working with bodies such as the BSI to review the use of standards (5.4, pp. 17-18);
3. Consulting on a digital Regulation Navigator for businesses to understand UK regulation, funding for specialist regulatory advisor services, encourage co-ordination between regulators (5.4, pp. 23-25).
4. Supporting experimentation through considering an extension of the £10M Regulators' Pioneer Fund, establishing a Regulators' Innovation Network (5.4, pp. 19-22).

CST noted that *"This would not have happened without your (Tait's) strong involvement in helping to develop recommendations and making yourself available to guide officials to bring these ideas to life"* (5.1, p. 2). The PAGIT Report is referenced in the White paper (5.4, p. 17) and many of its central ideas are evident, such as the flexible approach to regulation, consideration of how regulation can inhibit innovation, support to innovators, and the use of standards as alternatives to regulation (5.4, pp.17-18).

The White Paper has been welcomed by Lord Willetts in a recent report 'The Road to 2.4 per cent' (5.6, pp. 59-60), as important in enabling the UK to meet its commitment to spending 2.4% of GDP on research and development by 2027, and is discussed in the Better Regulation Annual Report (5.7, pp. 7-8).

2. A standard for Responsible Innovation

In response to the recommendation to develop a standard for responsible innovation, Innovate UK provided the necessary funding to the BSI and they commissioned Tait as Technical Author of the standard, a Publicly Available Specification (PAS). Development of the PAS involved: a survey of over 40 advanced technology companies to assess demand for such a standard; and four rounds of drafting, commenting and revision, the last two rounds involving a Steering Group (including technology-based companies, academic representatives, international agencies and policy bodies), and an open public consultation.

PAS 440 *Responsible Innovation – Guide* (5.8) was published in April 2020 and was downloaded from the BSI website over 1,000 times during the first 24 hours after the launch, a higher number than for any other standard launched by BSI (5.9). This take up indicates strong potential for the wider adoption across the sector as a full, accredited British Standard, and as part of the UK input to a European or International Standard. The Director of Standards Policy at the BSI writes that *"Professor Joyce Tait, and research that she had undertaken over the course of the past four years, has played a central role in informing BSI's thinking on the use of standards to design more adaptive and proportionate governance systems for innovate technologies"* and that *'contribution made by Prof Tait and the Innogen Institute both to BSI and to government policy formation has been extremely valuable'* (5.10). The Director of Responsible programmes in Innovate UK suggested that, *"Our view is that technologies are neither inherently good, nor inherently bad. It is how they are deployed that is important. Joyce made invaluable input as we sought to design and implement processes that would ensure that companies taking new and emerging technologies to market, in areas such as synthetic biology, did so in a responsible manner"* (5.9).

5. Sources to corroborate the impact (indicative maximum of 10 references)

5.1 Testimonial from Elizabeth Hogben, Secretary, Council for Science and Technology, Government Office for Science.

5.2 Sir Partick Vallance and Professor Dame Nancy Rothwell (2018) Letter to the Prime Minister from the Council for Science and Technology: Reforming the Governance of Technological Innovation.

https://web.archive.org/web/20200622032422/https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/750786/cst-reforming-the-governance-of-technological-innovation.pdf

5.3 The Rt. Hon. Greg Clark MP, Secy. Of State for Business, Energy and Industrial Strategy (2018), Response to the letter of 27th September to the Prime Minister on the governance of technological innovation in the UK.

https://web.archive.org/web/20200621195345/https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/750370/beis-reforming-the-governance-of-technological-innovation.pdf

5.4 HM Government (2019) Regulation for the Fourth Industrial Revolution, White Paper. June 2019, CP 111, p17.

https://web.archive.org/web/20200825190207/https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/807805/regulation-fourth-industrial-strategy-white-paper-print.pdf

5.5 Regulatory Horizon Council

<https://web.archive.org/web/20201020230209/https://www.gov.uk/government/groups/regulatory-horizons-council-rhc>

5.6 David Wilets (2019) The Road to 2.4 per cent: Transforming Britain's R&D Performance, December 2019, The Policy Institute, King's College London: pp 59-60.

<https://web.archive.org/web/20201201144044/https://www.kcl.ac.uk/policy-institute/assets/the-road-to-2.4-per-cent.pdf>

5.7 The Department for Business, Energy and Industrial Strategy (2020), Better Regulation: Government's Annual Report, 2018-2019, HC 80, February 2020, pp 7 – 8.

https://web.archive.org/web/20210115111224/https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/865807/hc-80-better-regulation-annual-report-2018-19-updated-february-2020.pdf

5.8 BSI (2020) *Responsible Innovation – Guide*. London: British Standards Institution, PAS 440:2020.

<https://web.archive.org/web/20201201144444/https://pages.bsigroup.com//35972/2020-03-17/2cgcnc1>

5.9 Testimonial from Director, Responsive Programmes, Innovate UK.

5.10 Testimonial from Director of Standards Policy, British Standards Institution.