Proportionate and adaptive governance of innovative technologies

The role of regulations, guidelines and standards

Joyce Tait and Geoffrey Banda
Innogen Institute, University of Edinburgh

bsi.

Department for Business Innovation & Skills

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1. Introduction: Governance and its impact on innovation

The concept of governance has three dimensions: authority, decision-making and accountability – determining who has power, who makes decisions, how other players make their voices heard and how accountability is rendered. It is increasingly recognized that the governance framework that is in place for an industry sector has a significant impact on its capacity to innovate. For example, the more onerous, time-consuming and expensive the regulatory system for an industry sector, the more it is dominated by the business models of large multinational companies and the more difficult it becomes for a small company to gain long-term competitive advantage. The landscape will also be dominated by incremental innovation, rather than the more disruptive innovation that could deliver significant benefits to national and regional economies.[1]

In the UK and the EU there are concerns that the prevailing regulatory systems have become unnecessarily precautionary and disproportionate to the nature and extent of the risks presented by many technologies, and are hindering competitiveness and the development of a vibrant economy. There is a new emphasis on adaptation in current regulatory regimes, along with appropriate design incorporating proportionality in future regulatory regimes, the scale of the challenge being greater for more disruptive innovation.

The premise of this report is that the facilitation of innovation has much to gain from a formal consideration of the complementary roles that regulations, guidelines and standards could play in delivering the more proportionate and adaptive governance approach needed to support commercialization of scientific research.

The value of standards in supporting innovation and emerging technologies lies partly in their diversity and ability to cope with a broad range of circumstances (e.g. covering products, processes, manufacturing and organizational behaviour); partly in their flexibility and adaptability to cope with rapidly changing understanding of opportunities and risks; partly in their ability to incorporate in their development the perspectives of a broad range of stakeholders; and in the fact that their use, although voluntary, is motivated by the desire of innovators to speed up and facilitate the path to commercial application.

This report considers the required elements of a governance framework to support development of innovative technologies, in general and for three case studies.

1. Personalized medicine manufacture for autologous cell therapies
2. Industrial biotechnology/synthetic biology
3. Financial technology (FinTech)

The focus is on where guidelines or standards could contribute most effectively to the proportionate and adaptive implementation of regulations, to support the speedy and effective delivery of innovation that safely meets public needs and desires, and where appropriate, contribute to the development of a thriving innovation environment in the UK.

This area is terminologically complex and the report uses the key terms as follows:

- Regulation: legally based instrument, backed up and enforced by a government authority.
- Guideline: issued under the aegis of a regulatory system to help those being regulated to understand what is expected of them by the regulator.
- Standard: an agreed way of doing something (making a product, managing a process, delivering a service or supplying materials), incorporating the distilled wisdom of people with expertise in their subject matter, who know the needs of the organizations they represent (manufacturers, sellers, buyers, customers, trade associations, users, academics or regulators).
- Consensus (in relation to standards): having general agreement, characterized by the absence of sustained opposition to substantial issues by any important part of the concerned interests and by a process that involves seeking to take into account the views of all parties involved and to reconcile any conflicting arguments. Consensus need not imply unanimity.

1. Incremental innovation will fit well with the business model of a firm, enabling it to continue to innovate around current business practices, generating competitive advantage relative to other companies in its sector through more efficient use of resources, or elimination of wasteful or environmentally damaging practices. It is less likely to generate stakeholder concerns, is more likely to have a pre-existing regulatory framework in place, but is much less likely to lead to sectoral transformations with significant commercial and societal benefits.

   Disruptive innovation involves discontinuities in innovation pathways, requires new areas of R&D, development of new markets and new modes of production, and (in some areas) potentially leads to stakeholder concerns at an early stage of development. Also, for a disruptive innovation there may be no obvious regulatory precedent to govern potential human and environmental safety issues.

Table 1 – Differences between standards and regulations/guidelines

Standards	Regulations/Guidelines
Based on recommendations	Based on legislation
Adoption is usually voluntary	Adoption is mandatory for regulations and potentially so for guidelines (soft law)
Established by consensus of all parties concerned, including relevant industry sectors	Developed by a regulatory authority, usually involving consultation
Based on consolidated results of science, technology and experience	Guidelines provide technical specifications either directly or by reference, e.g. to standards
Approved and published by recognized standardization body	Adopted by a legal authority
Oversight by independent third party certification	Oversight by formal government-appointed regulatory bodies

See also Allen and Sriram, (2000), Langlois and Savage (2001)[2]

Table 2 – Relative advantages of standards and regulations/guidelines

Advantages of standards	Advantages of regulations/guidelines
Standards can act as infrastructures for coordination; a common language for interoperability and compatibility	Regulations have the force of law, and compliance is compulsory and enforceable
Standards as routines (usually internal standards) can govern behaviour required for certain activities/routines	Easier to diffuse through inter-country, regional or international treaties and conventions
Standards as technology can reduce variety and enhance economies of scale thereby reducing transaction costs	Regulations are prescriptive, and sometimes are linked to specific guidelines and/or standards which, if adhered to, constitute compliance
Standards can be an innovation to achieve market dominance	

See also Allen and Sriram, (2000), Langlois and Savage (2001)[2]

2. Current regulatory experience and future opportunities

2.1 The need for a new governance approach

This report proposes an approach to judging how to deliver proportionate and adaptive governance of innovative technologies for different degrees and types of innovation, across different industry sectors with widely differing histories and experiences of regulation. It could unlock greater commercial potential from emerging technologies while also addressing regulatory and public concerns about risk, safety, quality and efficacy. The research found the following:

- Current governance systems for innovative technologies lack coherence and are in need of a new approach to guide more effective decision making.
- Different governance approaches will be required for disruptive and incremental innovation.
- The relevant elements of a governance approach that need to be addressed will differ across sectors.

2. Allen, R.H. and Sriram, R.D. (2000) The role of standards in innovation. *Technological Forecasting and Social Change*. 64, pp. 171–181

Langlois, R.N. and Savage, D.A. (2001) Standards, modularity, and innovation: The case of medical practice, in R. Garud and P. Karnøe (eds), *Path Dependence and Path Creation*. Lawrence Erlbaum: Hillsdale, NJ, pp. 149–168

- It is a relatively common experience that when a regulatory system is imposed in the early stages of development of an innovative technology, it requires subsequent adaptation but proves difficult to adapt.
- Where guidelines and standards exceed the minimum requirements of a regulation or go beyond reasonable societal expectations ('gold plating'), this can have serious negative impacts on innovation.
- Where standards are employed with the intention to reduce variety, this may lead to different outcomes for disruptive and incremental innovation. For an incremental innovation, reduction of variety can help to create viable markets. In the early stages of development of a disruptive innovation, it may be desirable to retain as much variety as possible until it becomes clear what the winning technology will be.
- No general conclusions can be drawn on whether either standards or regulations/guidelines are more consultative with stakeholders during their development as there is considerable variation across sectors. However, there will be inevitable differences in style and outcome where the regulator is in charge (regulations/guidelines) and where BSI takes a leading role in convening a broad spectrum of stakeholders, including industry players.

2.2 Responsible research and innovation (RRI)

RRI is increasingly seen by policymakers, government bodies and research funders as an important component of governance systems for advanced innovative technologies. The emphasis in current versions of RRI is mainly on stakeholder engagement as the key requirement to deliver 'responsibility', but future development of the concept needs to consider the wider governance system and to shift attention beyond the conduct of basic research to include innovation processes.

So far there is little coordination across organizations tasked with implementing an RRI approach, and no consensus around what should constitute such an approach. As currently implemented through EU-funded research projects, 'responsible behaviour' requires scientists and innovators to undertake effective public engagement about planned research and future innovative developments and then to adapt them where necessary to comply with European values and ethics related to gender equality, science education and open access. The absence of any reference to innovation or the societal benefits it may be able to deliver is notable, as is the assumption that there will be a societal consensus around the values on which to base such policies.

These RRI-related pressures are real and cannot be ignored. However, there is a need for such pressures to be moderated by a better understanding of: (i) current governance systems, including the roles of standards and guidelines, and how they could shape industry sectors and determine the range of innovative developments that can be delivered; and (ii) the reasoning behind pressures for regulatory systems to be more adaptive and proportionate. The industry sectors expected to be involved in RRI will have a legitimate role to play in its development, but this process has not yet begun in any formal sense. The development of a framework standard is proposed here as an appropriate mechanism to address this policy gap.

3. Economic benefits of standards

This report discusses the economic benefits of standards, with the proviso that, given the very different roles of standards in different industry sectors, it would not be appropriate to uniformly apply economic benefits across sectors or across different stages in the development of an innovative technology.

Given the broad range of benefits conferred by standards, it is clear that they could have a substantial economic impact on the nations and industry sectors to which they contribute, boosting productivity and innovation, opening up new markets and linking UK companies to global supply chains, and reducing technical barriers to trade. However, it is also clear from interviews that inappropriate, poorly specified or insufficiently adaptive standards can have negative impacts on innovation and the economic competitiveness of companies and countries and this factor is generally not covered in published economic analyses.

The framework and approach proposed here could greatly augment the economic benefits currently attributed to standards by removing some of the countervailing disbenefits that we have identified. Future economic analyses should be encouraged to take these factors into account.

Table 3 – Types of standard and their effect on innovation

Type of standard	Positive effects	Negative effects
Comparability and interoperability		
• Process standards • Product standards	• Network externalities • Avoiding lock-in of old technologies • Increasing variety of system products • Efficiency in supply chains	• Monopoly power • Lock-in of old technologies in case of strong network externalities • Path dependence if chosen standard came from a non-optimal selection process (see Variety reduction)
Minimum quality and safety		
• Product standards • Process standards • Organizational behavioural standards	• Avoiding adverse selection • Creating trust • Reducing transaction costs	• Raising rivals' costs • Competitive barrier to entry for new resource-poor entrants due to 'gold plating' of standards by incumbents
Variety reduction		
• Process standards • Product standards	• Economies of scale • Critical mass in emerging technologies and industries	• Reducing choice • Market concentration • Premature selection of technologies • Stifling alternative development (innovation) pathways
Information		
• Product standards • Process standards	• Providing codified knowledge	• Barrier if codified knowledge is proprietary or expensive to incorporate
Framework		
• Aspirational/behavioural standard	• Delivering equitable relationships across companies and sectors • Contributing to 'responsible' company behaviour	• Can be seen as a barrier to trade

Source: Adapted from Blind (2009); Steedman (2013)[3]

3. Blind, K. (2009) *Standardisation: A catalyst for innovation.* Inaugural Address Series: Research in Management. Erasmus University, Rotterdam. (http://repub.eur.nl/pub/17558/)

   Steedman, S. (2013) *Standards and synthetic biology: Structuring knowledge to accelerate innovation.* EU Workshop in Synthetic Biology, 11 Oct 2013

4. Stakeholder views

The results of a telephone survey and workshop to gauge stakeholder views on the proposals outlined earlier found considerable differences in the policy environment experienced for different sectors, comparing cell therapies, synthetic biology and FinTech.

4.1 Personalized medicine

Innovation in personalized medicine manufacturing for autologous cell therapies is disruptive at all levels e.g. scientific research and early development phases, manufacturing and translational development, and at the market level where it will, if effective, undermine some of the multinational pharmaceutical markets. Other sector-specific factors include the following:

- Difficulties experienced in adapting a chemicals-based regulatory system to govern biological products.
- The need to protect patients from harmful procedures using a clinical trial-related process enshrined in regulation.
- Difficulties in developing standards and guidelines for cell manufacturing.
- Absence of a governance system for some cell therapy applications.
- Different expertise-related perceptions of the openness of the regulators to adaptation of regulatory systems.
- The European Pharmacopoeia standards (equivalent to guidelines) perform an important role in medical regulatory systems, including cell therapies, but the system was criticized by some as being expensive and bureaucratic, and sometimes duplicating standards developed by others.
- The competitive nature of the industry and difficulty in persuading companies to collaborate, e.g. to develop a consensus standard, and risks to patients caused by the delays this might entail.

4.2 Industrial biotechnology/synthetic biology

Industrial biotechnology/synthetic biology innovation can be seen so far as mainly incremental, building on the now routine development of GM-related[4] technologies, at least in countries outside the sphere of influence of the EU. Relative to GM technologies, industrial biotechnology is incremental at the research and early development stage and at the final marketing stage where the companies will mainly be using the new techniques to replace chemicals-based manufacturing processes, delivering to existing markets. However, replacing the manufacturing process will be a disruptive change for the industrial biotechnology companies concerned, requiring new facilities and new skills in the workforce. Additional relevant sector-specific issues include the following:

- The choice of GM regulatory systems as the precedent for these technologies should be unproblematic, except for the extent to which the EU regulatory system is influenced by political advocacy. This leads to pressure for adaptation of the EU regulatory system, so far to no effect.
- Standards are playing an important role in developments in synthetic biology, for example, to develop a common language that will be needed for the development of any future guidelines or regulations.
- There is a need for adaptation in the regulatory systems for the manufacturing of complex protein molecules where it is prohibitively expensive to change the organism used even if new, more efficient processes have been developed.
- Some proposals to use biological containment as a risk mitigation measure for relatively safe organisms used in industrial processes will amount to 'gold plating', will be difficult to adapt in future, and could make these techniques less useful where they are needed for seriously hazardous organisms.
- Given the enormous potential of cell factories, for example, to enable the manufacturing of complex molecules that would otherwise be prohibitively expensive or impossible to make, the process of standardization to facilitate innovation is moving too slowly and is too focused on definitions and images; the most important challenge is to develop measurement standards for proteins.

4. Genetic modification (or genetically modified, depending on the context)

- It will be important not to impose standards and guidelines prematurely so as to avoid constraining innovation; it is better to wait until the direction of innovation becomes clear.
- There was nervousness about political issues stemming from an association between synthetic biology and GM technologies.
- Interviewees working in GM-related areas found it difficult to engage with regulators to discuss compliance with current regulations or future regulatory initiatives, or regulatory adaptation, unlike the situation in medicine-related sectors.

4.3 FinTech

Innovation in the FinTech sector was regarded as likely to be disruptive at all stages of the innovation process (basic research and early development phases, translational development, and at the market level), for example, disrupting the way financial services markets operate to make them more efficient for the benefit of consumers. However, the regulatory environment for the technologies likely to be displaced by it is very different from the other two cases, and the relevant risks are financial and reputational. Relevant sector-specific issues include the following:

- There was a strong appreciation of the potential benefits of FinTech among financial sector regulators and a much stronger emphasis on regulators' interactions with innovators to avoid inhibiting FinTech innovation and to support SMEs.
- There was a focus on 'principle-based' rather than 'prescriptive' regulation, implying a move away from detailed, prescriptive rules towards high-level, broadly stated principles to set the standards for regulated firms in conducting their business.
- Mainstream financial services find it difficult to deal with FinTech, but FinTech needs access to bank accounts and bank systems and standards will be a key component of the integration.
- Important types of standard will be based around compatibility, interoperability, data protection, customer security, and the use of technology for automated risk assessment (RegTech).
- The regulator is alert to the fact that big companies favour heavy regulation as it acts as a barrier to entry – if virtual currencies were regulated through basic FCA[5] standards, a few large companies would dominate the scene, going against the competition imperative for the FCA.
- A range of projects is targeted on assisting new firms to navigate regulatory challenges, e.g. the regulatory sandbox.

5. The proposed Framework for Proportionate and Adaptive Governance of Innovative Technologies and its use

Our proposed framework (see Figure 1) can be seen as a way of conceptualizing the potential roles of standards, guidelines and regulations in enabling the delivery of more proportionate and adaptive governance for innovative technologies across a range of sectors, in supporting decisions by companies, regulators and policymakers. The arrow on the left of the figure represents the value chain for an innovative technology including a notional timescale from early stage R&D, through beginning and late stage translational development, to marketing. The rest of the figure explains how the regulations, guidelines and standards relevant to the technology could be adopted in different ways at different stages in the innovation process, and for different types of innovative technology, to facilitate more proportionate and adaptive governance.

At the different stages along the development of the value chain, standards, guidelines and regulations will play different roles, and some may not need to be involved at all at some stages. Standards, guidelines and regulations, as shown in the central portion of the figure, are categorized somewhat simplistically as 'soft', 'firm' and 'hard' law, and where human and environmental hazards are involved, the governance system will move towards hard law (formal regulation) as the product reaches market-readiness. The standards and guidelines at the bottom of the chain are those that will support firms in compliance with the regulatory system, for example, to ensure quality and safety of products, or good manufacturing practice. The broken line under guidelines in the central part of the figure indicates

5. Financial Conduct Authority

that, for some technologies, relatively firm guidelines may prove a sufficient basis for governance with no need to move to a legally based regulatory system. Some aspects of FinTech may be in this category.

Interviewees and stakeholders were generally in favour of couching legally binding regulations in very general terms, and including detailed procedures, specifications and expectations in the guidelines and standards that are subservient to the regulations. To summarize how proportionality could be achieved for a disruptive innovation for which there is no existing regulatory precedent, interviewees generally agreed with the proposed approach as embodied in the framework:

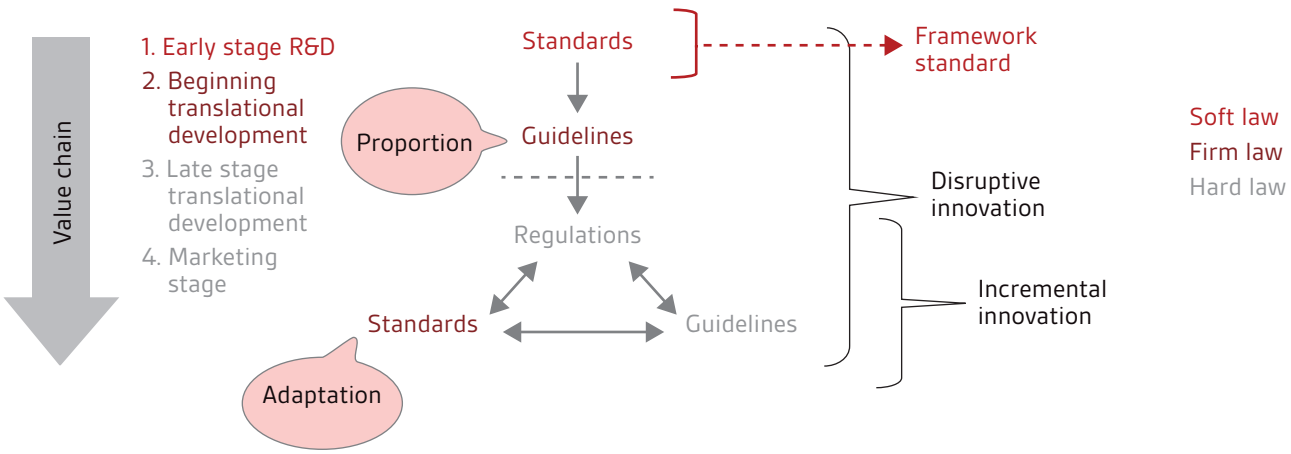
1. In the earliest stage of developing the technology, focus, for example, on PASs[6] and/or consensus standards devised in collaboration with companies and scientists with expertise in the area.
2. As experience is gained and the likely future nature of the emerging innovative products and processes becomes clear, adapt the initial standards and begin to formalize them as guidelines that could then form the basis of a future regulatory system (this stage involving companies and scientists and also regulators and policymakers).
3. Based on the guidelines, involving all interested stakeholders, develop legally binding regulations, couched in general terms relating to the desired outcome of the regulation.
4. Also in an open democratic process involving all interested stakeholders, devise standards and guidelines to support compliance by those engaged in developing the new technology.

For incremental innovation, beginning at stage 3, there will be a continuing need for guidelines and standards to support innovators in compliance with current regulatory systems. Also, where there is evidence of lack of adaptation of current regulatory systems in the face of innovation-related pressures, industry-promoted adaptation of standards or guidelines can very effectively release new innovation potential. This was the case for the development of new antimicrobial drugs, where a change in regulatory guidelines for the conduct of clinical trials had a dramatic impact on innovation-related incentives, potentially reducing the cost of developing a new antimicrobial by 50%.[7]

Proportionality can be delivered most effectively if it is built into regulations from their earliest stages of development, and the suggestion to progress from standards to guidelines and then to regulations could be an effective means to deliver this objective. Also, standards can play a role in the adaptation of existing regulations and guidelines to the needs of an innovative technology after they have been implemented, as illustrated at the bottom of the figure.

Different, but equally valuable, roles for standards and guidelines (as specified earlier) are therefore envisaged in contributing to proportionate and adaptive regulation of innovative technologies, both disruptive and incremental.

Figure 1 – Framework for proportionate and adaptive governance of innovative technologies



6. Publicly Available Specifications
7. Tait, J. et al. (2014) *Independent review on anti-microbial resistance – Regulation/innovation interactions and the development of antimicrobial drugs and diagnostics for human and animal diseases.* Innogen, Edinburgh (http://www.innogen.ac.uk/reports/946)

In some cases new relationships will need to be built between regulators and standards bodies and further research will be needed to explore how these roles should be developed in different sectoral contexts and in collaboration with different sets of actors.

Given the more wide-ranging potential of this framework and approach, further analysis and development would be justified to build on the three case studies described here to cover a broader range of innovative technology sectors, bringing in additional key actors, and where appropriate considering the economic benefits that could accrue from implementation of this approach.

Additional target areas (not a comprehensive list) could be:

- new approaches to the development of pharmaceuticals in the context of the questions being raised about the long term viability of blockbuster drug value chains, for example, developing new antimicrobial drugs to meet the antimicrobial resistance problem;
- the development of novel diagnostic tools, particularly in the context of stratified or personalized medicines;
- new plant and microbial biotechnologies with a potential to deliver a range of contributions including nutraceuticals and other novel foods, pharmaceutical products such as vaccines, feedstocks for other industry sectors from food production to perfumes and flavours;
- biological pesticides;
- unconventional fuels; and/or
- robotics.

5.1 Impact of an innovation mandate

In the UK and the EU there is a range of initiatives designed to focus the attention of regulators on the need to support innovation as a contribution to national and regional prosperity and competitiveness. This resonated well with the agendas of innovators and regulators working in health and FinTech related areas interviewed for this project, but has had much less influence on the industrial biotechnology/synthetic biology area. These circumstances would warrant further research on the extent of the success of an innovation mandate in areas where it does appear to be influential, and the reasons for lack of success in other areas. For both types of outcome, there is an opportunity for further investigation on context-specific mechanisms to facilitate such adaptation, including a potential role for standards.

5.2 A new approach to RRI

A more integrated approach is proposed here to incorporating RRI (as desired by a range of stakeholders and citizens) within the overall approach to governance of innovative technologies. Given that stakeholder concerns are most likely to focus on innovations considered disruptive (and therefore most potentially valuable to the economy and society), development of a standard for RRI could be an effective means to address this question.

As illustrated in the framework, there is an opening for development of a standard, beginning in the earliest stages of R&D for a potentially disruptive innovation, which encompasses appropriate forms of stakeholder dialogue at different stages in the development of an innovative technology and addresses issues related to proportionality and adaptation in governance systems.

Notably, throughout all discussions and recommendations on RRI, the focus is on the need for scientists and innovators to behave responsibly. Based on the ethical principle of equitable treatment of all stakeholders, the field is open for a new approach to RRI that also includes the desirability of responsible behaviour by regulators/policymakers (in being proportionate and adaptive in their regulatory decisions) and by stakeholders and citizens (in engaging 'responsibly' with other stakeholders).

Given BSI's experience in the development of consensus standards with the involvement of a broad range of stakeholders, it would be well placed to take the lead in supporting the development of a new standard for RRI that provides a more equitable basis for the allocation of responsibility across a range of actors, organizations and sectors. One potential format could be an umbrella aspirational framework standard that takes into account the various expectations and needs of all stakeholders, and development under that umbrella of specific consensus standards for the needs of different industry sectors and a broad range of actors, including regulators, policymakers and citizens/stakeholders.

6. Recommended next steps

This project has given rise to the following recommendations.

1. The proposed Framework for Proportionate and Adaptive Governance of Innovative Technologies needs to be tested in a broader range of sectors with a broader range of stakeholders.
2. A new dialogue needs to be opened between regulators and standards developers on the overall governance of advanced innovative technologies, covering the following issues:
   (i) Ensuring proportionality of regulatory systems in different sectors.
   (ii) Facilitating adaptation of existing regulatory systems to the needs of innovative technologies.
   (iii) Tailoring governance systems to the differing needs of disruptive and incremental innovation in different industry sectors.
   (iv) Meeting the expectations of an innovation mandate while ensuring compliance with expected safety, quality and efficacy requirements.
   (v) Delivering a level playing field across sectors in the extent of involvement of all key actors (including scientists, industry, regulators, standards bodies, and citizen representatives) in governance-related decisions.
   (vi) Stimulating learning across sectors in different innovation and sectoral contexts.
3. The development of an overall aspirational framework standard should be considered on the Governance of Innovative Technologies, incorporating elements (consensus standards) related to responsible innovation, responsible regulation and responsible stakeholder engagement.

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For more information, please contact Alberto Garcia-Mogollon, Emerging Technologies and Innovation: alberto.mogollon@bsigroup.com.

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Innogen Institute
The Innogen Institute (formerly the ESRC Innogen Centre) has a mission to support the delivery of innovative impacts that are profitable, safe and societally useful, building on advanced research relevant to a broad range of technologies. Its research covers: evidence-based knowledge of business models; value systems and industrial dynamics, linked to a pragmatic understanding of stakeholder perspectives and in-depth knowledge of regulatory requirements; science and innovation policy; funding models; intellectual property and standards related issues; and market-related incentives and constraints. This unique combination of cross-disciplinary insight and expertise enables the Innogen Institute to support company and policy decision-making based on a unique level of understanding of what will and will not work in the diverse sectors developing advanced innovative technologies.

Professor Joyce Tait
With an interdisciplinary background covering both natural and social sciences, Joyce has specialized in innovation–governance–stakeholder interactions in life science and related areas, including cell therapies and regenerative medicine, synthetic biology, GM technologies, drug development, stratified medicine, and biofuels, for example:

- strategic and management decision making in companies and public bodies;
- policy analysis, risk assessment and regulation;
- stakeholder attitudes, science and risk communication;
- evaluation and application of interdisciplinary research; and
- sustainable development.

Dr Geoffrey Banda
Geoff has an interdisciplinary background spanning biotechnology, quality assurance, food safety, and manufacturing, as well as professional experience in financial services covering retail, corporate and transactional banking. He is currently working on an ESRC-funded project on regenerative medicine focusing on business models, value chains and innovation ecosystems surrounding the commercialization of cell therapies in the UK.

BSI Group Headquarters
389, Chiswick High Road
London W4 4AL
United Kingdom

T: +44 (0) 845 086 9001
E: cservices@bsigroup.com
bsigroup.com

BSI UK
Kitemark Court
Davy Avenue
Knowlhill
Milton Keynes MK5 8PP
United Kingdom

T: +44 (0) 845 080 9000
E: MK.customerservices@bsigroup.com
bsigroup.com

BSI Group America Inc
12950 Worldgate Drive
8th Floor Monument II
Herndon
VA 20170
USA

T: +1 800 862 4977 / 703 437 9000
E: inquiry.msamericas@bsigroup.com
bsiamerica.com