

Proposed exploration of institutions and processes for the design of trustworthy governance of emerging biotechnologies

The new Prime Minister showcased the bioeconomy as a key driver of innovation and growth for the UK and articulated a desire to reconsider the regulation of some biotechnologies in the light of Brexit and the new technological developments in the sector.

The many opportunities, potential risks and ethical issues raised by the different applications of biotechnologies (notably gene editing and modification of humans, animals and plants, synthetic biology, gene drives and industrial biotech) are being debated in many fora. However this new political dimension has added a level of urgency to this discussion and potentially requires immediate consideration of new approaches to governance.

Changing context for governance design

The UK has a good reputation globally for its ability to develop trusted processes to guide complex policy decisions and governance with a strong public interest element - such as the Warnock Commission in the 1980s, the subsequent design of the HFEA and the recent decisions on Mitochondrial Donation. However, most of the most respected initiatives were undertaken at a time when there was significant societal deference towards, and respect for, governance institutions and processes. It is arguable that these conditions no longer exist.

The empowerment of citizens through social media and distrust generated by missteps in other areas of governance and risk management, (notably BSE, GMOs, financial governance and Artificial Intelligence), appears to have undermined citizen's trust in institutions in general and some technologies and their governance in particular.

Many argue that this is also a function of the perceived and often real lack of trustworthiness of many of these systems, organisations and processes. Others, that despite genuine attempts to be trustworthy, distrust prevailed, putting this down to contextual, cultural, communications and other factors.

Furthermore, the application of the various biotechnologies often gives rise to challenges that standard governance processes are not necessarily equipped to deal with easily. Values and ethics issues, for example about food priorities, human enhancement or digitisation of living forms, embedding inequalities and many more require a different, more collaborative approach, potentially involving all actors, including citizens, in decision-making.

Other factors to take into consideration in governance design are the more complex governance arrangements which may be necessary for some applications of these new technologies, with oversight spanning multiple regulators. Also the often stark asymmetry of information and resources of business actors making trustworthy governance even more difficult to achieve.

Trust and governance and biotechnologies

Either way, the challenge now is to reinvent the governance design process to ensure effective appropriate governance despite these complexities, where all actors can play their part. But it is context where trust in institutions and processes is not automatically bestowed, but one where it has really to be earned.

"How can we restore trust?... is on everyone's lips.

The answer is pretty obvious:

First: **Be trustworthy**

Second: **Provide evidence of your trustworthiness**

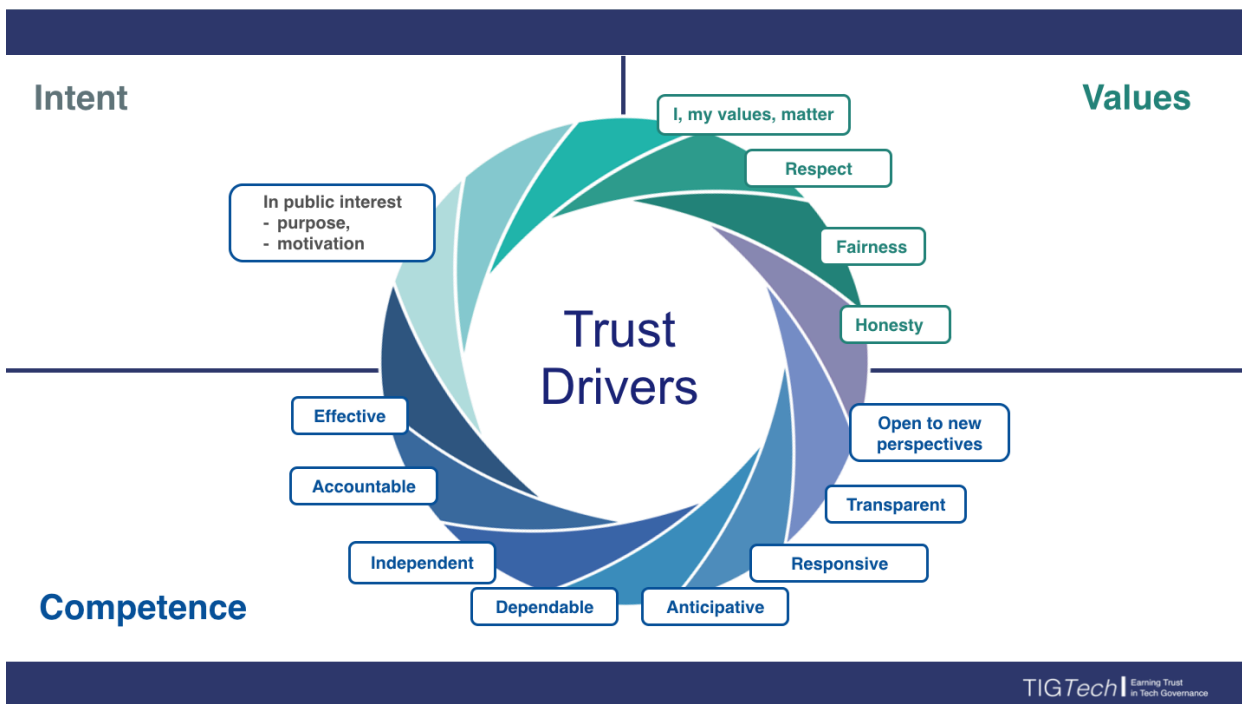
Baroness Onora O'Neill. Philosopher & winner of the 2017 Berggruen Prize for her work on trust & society.

Emerging biotechnologies inhabit a delicate political space. Historic distrust of GMOs, with pre-existing, deeply held, often polarised views, further complicates this aspiration. However it is widely agreed that the trustworthiness of the governance design and implementation is of significant importance in ensuring that biotechnologies can play their part in addressing some of our most pressing social, environmental and economic problems, address potential risks, social and ethical implications and anticipate and actively and positively shape societal impacts of the technologies in use and at scale.

Incorporating trust-based elements will be central to the development of effective and appropriate governance.¹ The demonstrable upholding of shared values, for example - such as fairness, inclusion, respect, responsiveness, and social purpose - are essential. These will need to be supported by clear competence in the effectiveness, accountability and legitimacy of the institutions, processes and outcomes.

We therefore proposed that a scoping study be undertaken to explore how these elements may underpin the design of trustworthy governance for biotechnologies, particularly where new applications and new regulation is under consideration.

Through a process of multi-stakeholder collaboration, co-creation and consultation, this study would articulate observations and recommendations to assist in the practical design of biotech governance which increases the chances of being seen as trustworthy and so earning societal and political trust.



OECD & TIGTech own research

Scoping Study - potential focus

- Explore, primarily through multi-stakeholder inquiry, the governance needs, concerns and issues arising regarding biotech laws post Brexit.
- Understand the drivers of trust and distrust in the governance of the various biotechnologies in the current context.

¹ OECD Trust and Public Policy and TIGTech unpublished research

- Include learnings from the GMO governance experience since the BSE crisis and the politicisation of biotech governance brought about by the recent government announcements.
- Explore options for current and potential institutional roles and arrangements, and their pros and cons, in being seen by all stakeholders, including citizens, as trustworthy for governance design, development and implementation.
- For example a statutory body such as the HFEA, House of Lords Sci & Tech Select Committee Inquiry, government institutions comparable to the Centre for Data Ethics and Innovation, arms length bodies eg Ofcom, independent organisations similar to Nuffield Council on Bioethics, Ada Lovelace Institute; Academic centres, not-for-profit organisations and others.
- Explore trustworthy design processes - be they traditional, or innovative - including potential new 'agile' approaches, which will be important in delivering the necessary competence and responsiveness to the speed and trajectory of biotech developments.
- Explore the potential for innovation in stakeholder and citizen involvement in the design of governance and the potential factors there which may contribute to trust or distrust.

Scoping study - output

- A report outlining observations and potentially recommendations on substantive governance elements that are important for the earning or losing of trust in the governance design and delivery of the various biotechnologies. In particular the need for new institutions, processes, laws and regulations, which may also include potential 'soft governance' elements.
- Cross-reference these to the various 'drivers of trust'.² For example:
 - How can and should alignment with societal purpose and values be incorporated and demonstrated?
 - How can and should fairness and respect be reflected and embedded to ensure that all actors can see that what matters to them has been considered and contributed.
 - How can and should transparency, which can be a driver of trust or distrust, be incorporated into design and implementation?
 - How can stakeholder and citizen inclusion be systematically incorporated, without undermining or duplicating democratically legitimized processes nor the separation of powers and similar fundamentals?
 - How do expected competencies such as effectiveness, accountability, responsiveness and integrity manifest themselves in these institutions and processes?
 - How does evidence of this aspiration to demonstrate trustworthiness best reach those who's trust is sought?

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