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## **ESRC Genomics Scenarios Project:**

### **5. Genomics and Society: Four Scenarios for 2015**

A Project for the  
Economic & Social Research Council



# **Genomics and Society: Four Scenarios for 2015**

<b>Introduction .....</b>	<b>3</b>
<b>Scenario 1: Genomics, Inc.....</b>	<b>5</b>
<b>Scenario 2: Broken Promises.....</b>	<b>7</b>
<b>Scenario 3: Out of Our Control.....</b>	<b>9</b>
<b>Scenario 4: Genomics for All .....</b>	<b>11</b>
<b>Highlights of Genomics Drivers in Four Scenarios of Genomics and Society: 2015.....</b>	<b>12</b>
<b>Progress in Genomics Technologies in the Four Scenarios .</b>	<b>14</b>

## Introduction

Genomics is surrounded by a high degree of uncertainty – about its applications and even more about its effects. The following four scenarios bound that uncertainty by providing four divergent pathways to 2015.

The scenarios integrate many of the forecasts identified through the key drivers of genomics in the previous section. Scenario 1, “Genomics, Inc.”, is a “best guess extrapolation” of key drivers shaping genomics. Scenario 2, “Broken Promises”, explores hard times for genomics. Scenario 3, “Out of Our Control” combines both challenges and failures for some genomic applications with success in others. Scenario 4, “Genomics for All”, in the spirit of the World Health Organization’s vision of *Health for All*, explores successful and visionary development of genomics.

These scenarios provide different images of 2015. Use these images to check and to stimulate your thinking. First take the scenario as given and consider the implications. For this project consider the implications for social science research of the each scenario. After using the scenarios this way, consider how you would adjust these scenarios or add others that you think either more likely or more challenging.

For each scenario, consider what would be the most important issues for social science research, given the conditions in the scenario.

### **Abstracts of the Four Genomics Scenarios:**

#### **Scenario 1, Genomics, Inc.**

Genomics gains more public acceptance as better safety standards and new applications demonstrate the value of genomics. Mergers and alliances create a handful of “Life-Science” conglomerates that operate on a global scale. Many individuals use genomics to identify their unique health risks and sensitivities.

#### **Scenario 2, Broken Promises**

Genomics applications prove more difficult to develop than expected, and several prominent genomics accidents turn public opinion against genomic technology. Activists mobilize for stronger measures against the industry and further reduce public demand. Liability lawsuits severely diminish the industry and force genomic patents into the public domain.

#### **Scenario 3, Out of Our Control**

Genomic breakthroughs accelerate and the costs of research decline; throughout the developed world, applications are delayed in approval processes. In the meantime, developing nations use unregulated field trials to

rapidly advance and develop genomics applications. Miracle products create widespread public acceptance, despite genomic accidents and uncertainties.

**Scenario 4, Genomics for All**

Genomics is successfully implemented, with wise and participatory management of the risks and side effects. A consensus emerges not only on how genomics should be implemented, but also on the type of society that genomics should serve. Genomics plays an important role in building a global society dedicated to improving equity and sustainability.

## Scenario 1: Genomics, Inc.

*As better safety standards and new applications demonstrate the value of genomics, it gains acceptance among the public. By 2015, mergers and alliances create a handful of “Life Science” conglomerates that operate on a global scale, and many individuals use genomics to identify their unique health risks and sensitivities.*

At the turn of the 21<sup>st</sup> century, the field of genomics seemed to contain unlimited promise, with the prospect of decoding the secrets locked deep within the coils of DNA and of gaining access to the fundamental codes of life itself. With the codes of DNA cracked, it seemed as if the only limitation on genomics was our willingness to embrace the vast and novel opportunities of genomic technology. By 2015, genomics has, for the most part, lived up to the dreams expressed in its adolescence, but as more genomic technology moved out of the lab and into the marketplace, the early enthusiasm was tempered by a healthy dose of reality.

### A Healthy Dose of Reality

The genomics industry flourished as marketable applications flowed from experimental trials and regulatory testing. Many health and environmental fears about genomics proved to be overblown as systematic research allowed testable fact to replace fear of the unknown. Public demand for new genomic medical products was high, since these new products were effective in preventing and curing diseases. Successful genomic products for the bioremediation of polluted land and water further enhanced support from the public.

Start-up genomics companies found it increasingly difficult to shoulder the financial costs of long product approval processes. These small independent genomics companies followed their biotech counterparts in partnering, or being acquired by, more traditional agricultural, chemical, and pharmaceutical companies. Over time, the genomics industry became tightly integrated with more traditional industries in an ongoing process of industry consolidation.

### Industry Consolidation

By 2015, there are seven multinational conglomerates dominating the “Life Sciences” sector globally. They use their scale and resources to spread out operations to all corners of the globe, conducting high-value research and technological development in developed nations, and using developing nations as low-cost testing grounds for new products.

Pressures from the WTO and affiliated institutions facilitated the globalisation of genomics by strengthening intellectual property protections. This was an important factor in preserving corporate return on investment. However, it also enabled global companies to patent products developed by modifying indigenous biological products, often with little or no compensation to the communities contributing to the knowledge and products.

### Globalisation of Genomics

Reform of the regulatory systems of genomics risk assessment also made a great difference in smoothing the way for the genomics industry. Previous regulatory indecision created an uncertain environment for development of genomic products, and only exacerbated public fears. New research, personal and environmental monitoring, and new computer risk models for assessing genomic contamination reduced much of the uncertainty about the impacts of genetically modified plants and animals. These models were able to simulate the extent to which genetic modifications would upset the balance of ecosystems, and allow rapid identification of potential hazards such as super-weeds and dangerous transgenic animals.

The adoption of reformed safety standards for genomics allayed the worst public fears and helped stabilize the product development path. Public concerns about genomics have declined significantly. Public activism supporting genomics is most visible with friends and families of patients affected with diseases and their organizations seeking the acceleration of research, approval processes, and coverage by NHS.

### Public Acceptance

While the basic safety concerns of genomic applications have been addressed, some members of the public feel a lingering suspicion about the potential for negative long-term health impacts. Organic food remains popular for some, while others have embraced the better flavour, appearance and enhanced nutritional value successfully being designed into genetically modified foods. The labelling of genomic products has expanded to keep pace with the expanding range of GM and non-GM food products. The millions of people who avoid GM foods provide a control group for monitoring long-term effects.

Low-cost biochips have made it much easier to assess and monitor potential problems arising from genetic modifications. Biosensor technology allows food to be screened by inspectors for transgenic contamination and is commonly used by companies to find genetic intellectual property violations. Individuals are able to test their own sensitivities to genetically modified foods, and many use biochips to screen out foods to which they have dangerous sensitivities.

For health services, individual choice and control plays a critical role in patient health. Most individuals have their DNA profile in their NHS medical record, and are aware of their genetic predispositions for disease. High-risk patients are encouraged to do more intensive bio-monitoring that can catch diseases in the earliest stages. A remarkable array of treatments exists but they remain costly, only partially covered by the NHS, and well out of reach of most poor countries.

## Scenario 2: Broken Promises

*Genomics applications prove more difficult to develop than expected, and several prominent genomics accidents turn public opinion against genomic technology. Activists mobilize for stronger measures against the industry and further reduce public demand. Liability lawsuits severely diminish the industry and force genomic patents into the public domain.*

At the turn of the 21<sup>st</sup> century, the allure of genomics was so strong that gene-crimes like Dolly the cloned sheep, and stem cell embryocide, triggered only mild debate and some doubt about the morality of genomic research. Since then, many have rejected the power, arrogance, and quick fixes that come from rewriting nature's code and disturbing the souls of humans and animals.

The European insistence on providing hazard labelling for genetically modified foods was one of the first signs that genomic technologies could be subjected to social pressures. Although the United States brought considerable pressure to bear on the European Union to allow imports of GM agricultural products, the EU decided to use its economic and regulatory solidarity to directly confront US hegemony. With the strengthening of the Euro against the US dollar, enacting stronger EU import standards for GM foods helped to protect more traditional European farming practices from American agribusiness.

### Hegemony Challenged

Developing nations began to grow increasingly sceptical of genomic solutions to their agricultural issues. Monsanto's experiments with "terminator genes" were one bit of evidence that benefits from agricultural genomics were coming with strings attached. The widespread corporate patenting of plant compounds derived from indigenous cultures was a stronger sign that the developing world was going to be on the wrong end of the genomics revolution. In response, many developing countries began exploring in depth non-genomic methods of increasing agricultural productivity, such as more effective use of hybrid seeds, crop rotation, and natural pest control.

On the medical front, genomics apologists who claimed that miracle cures for various diseases were around the corner began to have trouble explaining why so many purported cures never seemed to make it to market. In some cases, unravelling the genomic mysteries of life proved to be a bit more complicated than initially expected. In other cases, the experimental drugs turned out to have reduced efficacy, or unforeseen side effects. The torrent of supposed genomics miracle cures turned out to be a trickle of uncertain and expensive medications.

### Genomics Unravelling

In 2005, a series of genomics-related accidents changed many perceptions about the real promise and perils of genomics. The first incident involved a genetically modified plant pathogen – a form of oak blight – that was accidentally released from its research lab and spread rapidly through the surrounding countryside. Images of dying oak trees were featured prominently in television reporting, providing an enduring symbol of the hazards of genomic research.

The other accident of 2005 involved an experimental gene therapy for haemophilia that had tragic consequences. The trials involved a new delivery mechanism for the supplemental genetic information. Halfway into the trial, 40 of the subjects began to suffer severe side effects and soon perished from complications that were the direct result of the gene therapy. The dramatic nature of this medical disaster gave rise to an even larger whirlwind of media coverage and contentious public hearings. The issue was further inflamed when it was revealed that the inserted genetic material had crossed into the sperm and egg cells of many of the trial participants. What began as a tragic experiment had crossed the line into the modification of the human germline. Gene therapy trials were halted, and the affected survivors were strongly pressured not to have children.

### Public Inflamed

These incidents shocked the conscience of the public. Activists increased their efforts against genomics applications of every variety. Much like earlier anti-globalisation protestors, the anti-genomics movement used the Internet and other communication technologies to coordinate their activities. Participants found the activist websites, educated themselves on the relevant issues, and used online discussion forums to connect with like-minded activists. By working with allied NGOs, activists brought considerable pressure to bear on the genomics industry.

Students on college campuses began demanding colleges divest themselves from companies pursuing and funding genomic research. Activists blockaded the entrances to genomic research facilities. Mass boycotts were organized against GM products, exploiting GM labelling laws for the purposes of political action. A stringent interpretation of the precautionary principle became a means to prevent these disasters from happening again.

With genomics experiments under greater public scrutiny, other unsuccessful experiments with less drastic side effects began to surface. In several countries, lawsuits were brought against genomics companies alleging that they had not performed adequate risk assessment on the technologies and failed to effectively communicate the risks to the public. Massive punitive damage awards against US genomics companies put much of the genomics industry on the verge of bankruptcy. With minimal public demand for genomic products, the companies had little ability to pay large cash settlements. In a comprehensive settlement in 2014, many genomics patents on genes and organisms were stripped from companies and placed into the public domain for the benefit of all researchers.

### Scenario 3: Out of Our Control

*Genomic breakthroughs accelerate and costs of research decline while applications are delayed in approval processes. Developing nations use unregulated field trials to rapidly advance and develop genomics applications. In health care, several real breakthrough products create widespread public acceptance, despite genomic accidents and uncertainties.*

In the first few years of the 21st century, proponents and opponents of genomic technologies retreated into their fixed rhetorical positions of progress versus safety on issues ranging from therapeutic cloning to transgenic organisms. This stalemate led regulators to take a cautious approach to experimental applications of the technology. Approval processes stretched from months to years.

In the meantime, the technological infrastructure of genomics was accelerating rapidly. Computing power was following Moore's law and doubling every 18 months, making each new generation of bioinformatic computers more powerful and less expensive. Gene-chips began a similar process of accelerating in power while simultaneously dropping in costs. The rapid automation of testing, sequencing, and computer analysis allowed researchers to swiftly piece together the complex patterns of gene expression in humans, plants and animals.

#### Rapid Development

Faced with rapid population growth, moderate economic growth, and declining natural resources, developing nations eyed developments in genomics with a mixture of hope and envy. Several developing nations – especially China and Brazil – began crash programs to create national genomics industries. The declining costs of research made these initiatives financially feasible, allowing new players to outfit their research facilities with leading edge equipment.

To tap into the expertise of western genomics companies, these national initiatives used lax regulatory and testing requirements to attract mainstream companies. Most genomics companies followed their competitors into testing in these countries. Secret agreements forged between western corporations and national genomics initiatives gave China, Brazil and several developing nations direct access to advanced genomic technology and expertise, while allowing genomics companies to quietly refine their innovations with minimal restrictions.

In many cases, these tests were conducted successfully and without incident. Not every trial went as well – in several areas GM plants began to dominate their ecosystems, GM animals on the loose threatened several species with extinction, and participants in germline gene therapy experiments were passing their genetic fixes onto their children.

### Times of Trial

While international awareness of the full magnitude of these testing programs was slow to build, by 2010 the EU and US began pressuring developing countries to rein in rogue research programs. They pushed for the adoption of international standards defining the limits of acceptable genomic research. Their diplomatic efforts were decisively rebuffed by China, which had the economic clout in 2010 to resist international pressure. China's intransigence led other developing nations to reject the international agreements governing genomics, shattering the prospects for a global system of genomic regulation and control.

Years of regulatory gridlock in the US and Europe had allowed China and other developing nations to take the lead in developing real-world genomics applications. With dim prospects for further global agreements, developed nations moved rapidly to streamline their safety testing processes, accelerating the introduction of many sought after but still controversial forms of gene therapy.

With the genomics genie out of the bottle, the public is beginning to accept a world where genomics technologies are developing as fast as technology allows. Environmental changes due to GM plants and animals are a matter of some concern, and there remain many ethical concerns about the wanton manipulation of animal and human genetic codes - and the new life forms produced.

### Genomics Uncorked

The critics of genomics say that society has traded away both its conscience and the balance of nature for the benefits from a range of enhanced foods and medical cures. Stem cell therapies are now available to treat diabetes, Parkinson's, and Alzheimer's – a welcome development for aging populations in industrialized countries. A wide variety of gene defects are now treatable with relatively inexpensive gene therapies. These tangible benefits have made people more accepting of the risks that go with advanced genomic research.

The genomics industry is highly competitive and flexible, with innovative firms of all sizes and from all corners of the globe actively competing to further develop and disseminate genomics technologies. Simultaneously, black-market genomic technologies have emerged. It's rumoured that confidential clinics already perform prenatal genetic enhancements for wealthy clients. And bio-weapons based on genetically modified infectious agents have become the favourite of some terrorist and cult groups.

In many cases, more genomics technology may prove to be the solution to existing GM-induced problems. In one experiment, biological diversity was restored to a GM-plant monoculture infestation by artificially introducing new genetic variations into the affected plants. By the end of the experiment, the field showed more genetic diversity than in its "natural" state. Now that genomics technologies have been unleashed to reach their full potential, there is no going back to the old mechanical mindset of regulation and control.

## Scenario 4: Genomics for All

*Genomics is successfully implemented, with wise and participatory management of the risks and side effects. A larger consensus emerges, not only on how genomics should be implemented, but also on the type of society that genomics should serve. Genomics plays an important role in building a global society dedicated to improving equity and sustainability.*

In the first few years of the twenty-first century, rapid breakthroughs in embryonic cloning and enhanced in-vitro fertilization (IVF) treatments created ethical conundrums that were explored by evolving media coverage. These discussions fed into other ongoing debates about the proper role for the precautionary principle in the regulation of potentially dangerous technologies.

Scientists and regulators worked to develop standards of safety and guidelines that defined the scope – and limits – of safety testing. As these standards were crafted, it became clear that the public needed an explicit role in assessing the new technology and in setting permissible limits. Innovative experiments in developing informed public input were conducted, including deliberative polling, electronic town meetings, and citizen juries. These processes allowed groups of citizens to substantively engage these issues, and give knowledgeable answers reflecting their preferred vision for genomic technologies.

Successes in citizen participation were reinforced by a subculture of citizens that placed greater emphasis on sustainable lifestyles, the win-win resolution of conflicts, and greater tolerance for alternative value-systems. These “cultural creatives” (90 million in Europe in 2000), steered away from more traditional orientations towards family values, and more modern orientations towards material success. Instead, their values focused on enhancing quality of life, personal growth, and giving back to the community. Even though these “cultural creatives” were a significant percentage in the population, they often failed to recognize their distinctive values and lacked a cohesive group identity.

### Values Defined

In 2005, a radical Islamic terrorist group used a genetically modified bio-weapon to attack the European Parliament in Brussels. The attack targeted the gathering for a final vote on an agreement that would bring tighter integration between Israel and the European Union. The toxic agent, engineered to cause nerve damage by degrading the myelin sheath of neurons, was delivered through aerosol sprays hidden in several areas of the facility. This stab at the heart of the European Union caused close to 900 deaths and over 1,500 casualties; all suffered permanent neurological damage from exposure to the toxic compounds. The graphic horror of the attack triggered international revulsion, and brought entirely new leaders into the top positions of the European Union.

In the aftermath, a new international bio-weapon convention placed strict limits on the development of offensive, defensive, and non-lethal bio-weapons. The convention was enhanced with provisions for international inspections of commercial genomic research facilities, and restrictions on lines of research with potential dual-use applications as bio-weapons.

The horror of the Brussels attack crystallized public opinion, and brought to the surface public yearnings for a more sustainable and equitable world that could work for all. These deep social impulses were channelled into the new forms of electronically enhanced democracy, giving citizens concerned with the common good a stronger voice in policy discussions. Global disparities in basic health and well-being came to be identified as a root cause of terrorism, global instability, and environmental degradation. New forms of political participation allowed citizens to play a critical role in steering the direction of society, demanding more proactive remedies for social and economic problems. “Cultural Creatives” came together as a social force, realizing that millions of others shared their core social values.

#### Public Engaged

The genomics industry was one of the first to be transformed by participatory decision-making processes. The public began to look unfavourably on efforts to develop expensive genomic medical treatments and high-margin genomic food products. Instead, genomics companies were urged by the public and vocal, effective advocacy groups to devote research resources towards developing cost-effective nutritional enhancement of foods, bio-engineering organisms for environmental remediation, and diverse strains of locally adapted crops to boost productivity and biodiversity. Genomics companies were attentive to this shift in the public mood, and reoriented research lines to explore new genomic products that provided more equity and sustainability-enhancing opportunities.

#### Equity Embraced

Reform of the intellectual property system curbed the use of broad and non-specific gene sequence patents. New stricter standards for genomics patents limited them to specific implementations of genetic expression, rather than speculative patents based on marginal research. To create an equitable international system of intellectual property rights, exemptions on patents for genomic and health products were extended to countries facing food shortages and medical crises. The biological knowledge of indigenous peoples is protected by tribal trusts that licensed access to traditional biological knowledge, allowing indigenous peoples to share the wealth gleaned from their cultural heritage.

By 2013, the new international agenda for equity, sustainability, and genomic justice was codified in a United Nations Declaration of Genomic Rights and Responsibilities. This broad statement of intent established global standards for animal rights, ethical boundaries for genomic research, criteria for genetic discrimination, principles of environmental sustainability, and goals for social equity. The UN, NGOs, and several countries began to craft policy incentives

to steer nations and the global economy towards a preferred future designed to alleviate the disparities in the global sociopolitical system.

## 5. Genomics and Society: Four Scenarios for 2015

<b>Highlights of Genomics Drivers in Four Scenarios of Genomics and Society: 2015</b>				
	<b>Genomics, Inc.</b>	<b>Broken Promises</b>	<b>Out of Our Control</b>	<b>Genomics for All</b>
<b>Business Forces</b>	Consolidation of ag, pharma, and chemical companies into 7 global life science corporations; successful small players absorbed	Decline and fall of genomic applications in industry as failures emerge	Range of competitors, with Chinese and Indian companies playing significant roles	Broad spectrum of companies, large and small; operate with greater collaboration with competitors and regulators; more clarity on multiple bottom lines
<b>Demand</b>	Cautious acceptance of GM foods; high demand for health applications	Increasing public rejection of GM products	High demand for breakthroughs, and low cost advances	Strong demand, focusing on products that enhance equity and sustainability
<b>Environment</b>	Modest decline, with localized improvements from bioremediation	Generally stable, but localized contamination from GM organisms	Major threats, especially in China and India, from widespread GM deployment	Low level of genomic caused degradation; Improvements from bioremediation
<b>Geopolitics</b>	China and India become more important; Global corporations remain US and Euro dominated	Developing world increasingly pursues non-genomic solutions	China and India become major players	Global and equity focus driven by consumers; Post crisis integration of genomics regulation
<b>Governance of Knowledge</b>	Strong intellectual property protections; research results readily available	Increasing public oversight, right to genomic data shifted to public domain	Diminished governance as rogue researchers lead the agenda	Equitable intellectual property reform; indigenous knowledge better protected; scientists reconstitute their trust

## 5. Genomics and Society: Four Scenarios for 2015

	<b>Genomics, Inc.</b>	<b>Broken Promises</b>	<b>Out of Our Control</b>	<b>Genomics for All</b>
<b>Risk</b>	More objective risk models with increasing use of education and individual preferences; supported by personal genomic data	Risks perceived to outweigh benefits; precautionary principle embraced	Risks prove significant but widely distributed; high benefits balanced with risks	Advanced citizen assessment of risk; prudent use of the Precautionary Principle, with strong commitment to use genomics to make improvements in areas of greatest need
<b>Social Attitudes</b>	Increasing comfort with genomics	Fear and anger towards genomics; active opposition, limited public support	Mixed, widespread support for successful cures, criticism of mistakes	Mixed, but active citizen input in genomics decision-making leads to wide support for genomics applied to enhance equity and sustainability
<b>Social Mobilization</b>	Much of the public is disengaged; environmental opponents and disease group supporters are major advocacy groups	Internet enabled activists “swarm” effectively in opposition to genomics	Sporadically effective groups, working to meet the social challenges posed by radical genomic change	Enhanced infrastructure of civil society, more effective large NGOs, general public want genomics done right; support global monitoring
<b>Functionality of Genomics</b>	Works well with minor side effects	Several dramatic accidental failures	Dramatic successes, dramatic failures; periodic terrorist uses	Wide range of applications that support broader values with minimal side effects; terrorist use diminished

## 5. Genomics and Society: Four Scenarios for 2015

Progress in Genomics Technologies in the Four Scenarios				
	Genomics, Inc.	Broken Promises	Out of Our Control	Genomics for All
<b>Health Care</b>				
Biomonitor	* Widespread biosensor use	* Active biosensor use	* Active biosensor use	* Biosensors support sustainability & equity
Genetic profiles	* Individual genetic profiles used for predictive med	* Genetic profiles available, but not effectively used	* Genetic profiles used	* Genetic profiles also support equity
Tailored med Rx	* Tailored drug Rx	* Tailored drug RX, but few new tailored drugs	* Many tailored drugs	* Focused tailored drug development
Genomics based cures	* Genomic based cures – i.e. Parkinson’s & some cancers * “Designer babies” available	* Only 2 gene therapies on market; most genetic based drugs still in R&D	* Many advanced therapies; aggressive use * “Designer babies” & manipulations available	* Medical genomics focused on addressing diseases of global importance – infectious, heart disease, diabetes, cancer
<b>Agriculture &amp; Food</b>				
	* Many GM plants, animals & fish with range of beneficial properties	* A few GM plants & animals; lack of public acceptance limits R&D	* Well developed GM industry with many benefits for developing world	* GM plants, animals & fish cautiously used with focus on sustainability & equity – especially in developing world
<b>Other Uses</b>				
Environment	* Active biomonitoring & bioremediation	* Use traditional methods	* Delayed development with some use	* Active development & use of biomonitoring & bioremediation
Biomaterials			* Fairly common	
Biofuels	* Widespread	* Common	* Low use	* Widespread
Biomanufacturing	* Low use	* Little use		* Aggressive development
	* Slowly being adopted	* Not economical; low use	* Lack of interest, investment & reg. support	* Actively pursued with early commercial adoption