
The World: External Factors
Our World: The Community
My World: Individual

Synthetic Biology

- **Scientists have been attempting to understand the basic units of life - from DNA which makes up the genetic code to the bio molecules which make up the structure and metabolism- of a number of organisms ranging from simple bacteria to more complex life forms including humans.**

- **Certain groups have been trying to use what they have learnt to design these basic units to perform a specific job.**

- **Synthetic biology is a new area of biological research that attempts to combine <u>science</u> and <u>engineering</u>. It attempts to use these basic units like building blocks – assembling things from scratch. For example, in the same way that new engineering parts are made to give a car different functions, scientists want to make biological 'components' to give microbes new properties.**

- **Work is at a very early stage and there are lots of uncertainties – for instance these basic units may have more than one function or interact in ways that can't be predicted.**

- **Overall, the goal is to design and build new biological parts, devices or systems for different uses.**

- **Like any technology, the potential uses of synthetic biology may be perceived as being good or bad (or somewhere in between). It could be used to make medicines. It could be used to produce fuels. It could also be used for military purposes and for bioterrorism. There may be unforeseen or unintended consequences of use – or social and ethical issues around particular applications.**

- **We will be exploring these issues in more detail in the next workshops.**

Actors Script: A scientist viewpoint

Q: How would you define synthetic biology?

At this stage there isn't a firm definition of what makes someone a synthetic biologist - but I would sum it all up as trying to design and build biological devices for useful purposes.

It's all made possible by the application of engineering principles to biology – understanding and controlling the building blocks of life.

Q: What sorts of approaches are there?

One approach being looked at is how to manufacture a range of standardised biological parts called bio-bricks, all with different functions. These could then be mixed and matched to create biological devices with a specific purpose. But we still need to understand how all the parts interact and get them to the point where they work together in a predictable way without altering each other.

Q: So where do you think it's going?

There's still a lot we don't know, but with time and money there is the potential to produce everything from industrial chemicals and biofuels, to bacteria clean up oil slicks, to new drugs, vaccines and ways to diagnose illness. We are a good few years away from producing the finished products just yet though; what draws people to the field is that the science itself is fascinating and there are still big juicy questions to be answered about how life actually works.

So far there has been quite a lot of hype around the field and there is certainly a growing interest from the research councils and governments. I think it's important for the UK to invest in this research; we don't want to get left behind. This could be an important area for the economy and with the right incentives we can encourage businesses working on synthetic biology to set up in the UK and provide high skilled jobs.

Q: What about the regulation and control of synthetic biology?

We do need to consider how to regulate the technology develops - and what security and safety procedures are put in place. While synthetic biology is done in a safe and totally controlled environment, we do have to consider the whole issue of bio safety and the potential risk it could poses to ecosystems or people without adequate bio-safety protocols.

With areas like this it can sometimes seem that things are developing faster than the regulations can keep track. I think people need to be assured that there's some regulatory framework there that ensure scientists act responsibly. I think we need to explain why we want to do these things and what the benefits are likely to be.

Actors Script: A commercial viewpoint

Q: So what do you think about synthetic biology?

You know, I think synthetic biology is tremendously important. It could be applied to resolving some of the pressing energy and medical problems that are going to beset the world. I see endless opportunities in this field, where we will continue to find organisms that can produce new products. It has the potential to be one of the single most transformative technologies in the next 20-30 years with the capacity for doing tremendous good.

Q: And are there any downsides?

People often flag up the downsides, but I think the social and ethical issues are about not using synthetic biology effectively. I think that's a grave crime. What's the alternative: that we ration the allocation of things like energy to our kids? I struggle to see who will be harmed by synthetic biology unless you have some sort of fear that we're going to get superbugs.

Q: What is the role of business in synthetic biology?

I believe that ultimately if you want development in this area, you need to get business to invest it. Syn bio needs to be profitable. We would not be investing in research programmes if we didn't think that we would be able to get a benefit from that as a company. I would not be able to get the money to invest from my shareholders.

And if you want business to invest you need to allow them to take it in-house. Openness around developments and funding could act as significant barrier. We've been doing a lot of work with companies around synthetic biology on a new product - it could make us a lot of money. There is no way that I would have wanted to announce to the world that that's what we were doing.

Q: What about the regulation and control of synthetic biology?

I am glad you asked me that. If anything, the UK has a chronic set of regulatory obstructions which prevent the effective deployment of synthetic biology. Our academic effort is fragmented and we have a government that is over influenced by the voices of NGO's. As an investor, there is no sense for me putting money either into the technology or production facilities in the UK if its will be undermined by the attitudes and opinions of pressure groups.

Sure markets shouldn't run completely free. We need to make sure that mechanisms exist so that synthetic biology can be applied where it is going to be needed most. There will be times when market signals alone aren't sufficient to provide that guidance. But if we wait forever - if we are over cautious - others will get there before us.

Actors Script: A social science and ethics viewpoint

Q: How would you define synthetic biology?

Well synthetic biology is at a very, very early stage, and it is an ill defined field. I guess the overarching idea is to make biology as useful as things like chemistry have become to us - so that we can synthesise whatever products we need from biological components. At the moment scientists are asking 'can we do it', you know, it's kind of like trying to climb Mount Everest.

Q: Where do you think its going?

As for me, I am sceptical about how quickly applications in synthetic biology are going to come to fruition. It is being driven by a sort of vision of industrial applications around food and energy production which are primarily going to benefit large corporations.

Even though the applications are far off, issues are a bunch of big issues for this area: what might the technology lead to; who is going to gain; who drives the technology; and who should take responsibility for it.

Q: So what do you think some of the wider implications are?
One concern is that synthetic biology could alter the production of certain drugs or food, removing the benefit from local producers, and widening the gap between rich and poor nations. Also broad patenting of the developments that emerge from synthetic biology may lead to the creation of commercial monopolies or restrict research.

There is also the question of creating life. As much as asking whether creating life is right or wrong - I'd also like to know what people think makes something alive or not. Is there a difference between creating small micro-organisms and more complex organisms? Though total science fiction at this time, if we do create new life forms what sort of respect and treatment should we accord it?

There is also the issue of bio security. In the long run that it may be possible to recreate the polio and smallpox virus – though I guess in reality there may be easier ways of going about terrorism.

Q: What about the control of the area?
What is interesting is that the majority of scientists know little about the potential implications of the work they are doing or how it might be governed. So I think the real problem is trying to get the scientific community to be aware of the potential issues around their own work in general and to take greater responsibility.

Actors Script: An NGO viewpoint

Q: So what do you think about synthetic biology?

I think it's extremely interesting the way that computing, engineering and biology are being brought together in this field. But I do worry about issues arising from this mix of disciplines; engineering and computing are not the same as biology.

I mean in engineering if you build a new piece of equipment, it generally performs one job and you can modify it if it doesn't quite work. But in biology there is still so much to learn, genetics is incredibly complex, genes interact in different ways. Essentially, the biology aspect makes the engineering side of things much less predictable.

Q: Who might benefit or be harmed from synthetic biology?

We work to monitor new and emerging fields of science and technology and the ways in which they might impact on society. I think our primary role is to say: here's what might be done with this technology; is it useful or not useful; who owns and controls it; and here are some of the health, environmental and intellectual property issues around it.

And it's complicated. If we ask: who will potentially benefit from synthetic biology and who might be harmed - there is no simple answer. We have to consider the potential knock-on effects of the technology. For example: one of the major areas being talked about is energy and how we can use custom built organisms to produce a new generation of renewable bio-fuels. The idea is that you're transforming plants into fuels and plastics and so forth using synthetic bacteria.

On an industrial scale that means that you're either having large scale monoculture crops, which are competing for land with food production, or you're looking at destroying forest land or grasslands in developing countries to create space. There is also the question of what happens with these organisms if they are deliberately or accidentally released into the wider environment.

Q: What about the regulation and control of synthetic biology?

Well that's a big one. We are pretty sceptical about the idea of voluntary regulation, there is a lot of pressure to move forward as quickly as possible, release commercial products and recoup the money invested in research. How can the field be regulated in a way that protects people and the natural world while allowing scientists to move forward and increase their understanding?

Handout A: Key Points on Synthetic Biology

Synthetic biologists seek to design and engineer new biological systems, or redesign existing ones.

It involves the application of engineering principles to biology – attempting to build life for a specific purpose.

It aims to use standard procedures that can be replicated – designing biological parts in the same way that an engineer would make parts for a car. These biological parts or systems don’t exist in the natural world

In one example, synthetic biology aims to produce an anti-malarial drug called artemisinin. In this case scientists are using synthetic biology to engineer genes from a plant which produces this anti-malarial drug into a bacterium. The bacteria can then produce a chemical component of the anti-malarial drug.

Handout A: Key Considerations

It is not as easy as assembling a car

The building blocks of life are not like the parts of a car. They have not all been tested to demonstrate what they can do – or they may exhibit properties or functions that change under different conditions.

Living organisms are unpredictable

Even if the function of each part can be defined, when you put them all together they may not work as expected. Living organisms are complex and unpredictable. Biological parts used in synthetic biology could be incompatible.

The living systems may not function reliably

Living organisms are prone to random changes and fluctuations. Complex synthetic biological systems could develop functions that differ from those that were initially intended. These unintended consequences could be beneficial, benign or harmful.

Handout B: Overview of the Social and Ethical Considerations

Uncontrolled Release:
One concern is that these organisms could evolve, proliferate and have unexpected interactions with existing ecosystems.

Bioterrorism:
Another concern is that synthetic biology could be used to design organisms which would be hostile to humans

Trade and Global Justice:
Synthetic biology could alter the production of certain drugs or food, removing the benefit from previous local producers, potentially maintaining the discrepancy of wealth and health between rich and poor nations.

Patenting and creation of monopolies:
Broad patenting of the developments that emerge from synthetic biology may lead to the creation of commercial monopolies or restrict research.

Tolerable Risk
Can we balance the risks presented by synthetic biology with the benefits it offers?

Creating artificial life
An aim of synthetic biology is to create novel organisms or to modify existing organisms for our own purposes. This raises concerns that scientists could 'play God', or that they can apply 'design' to organisms in the way which evolution has never done before.

Issues of not investing in synthetic biology
There are a number of proposed benefits from synthetic biology – new ways to make fuels or medicines. If we were not to fund the field, future generations could lose out.

Handout C: The Research Councils

In the UK, most of the public funding of basic research in synthetic biology comes from the Research Councils - in particular, the Biotechnology and Biological Sciences Research Council (BBSRC) and the Engineering and Physical Sciences Research Council (EPSRC).

In 2007/8, the Research Councils spent approximately £20million on synthetic biology research of an overall budget of £2.7billion. The estimated expenditure for 2008/9 is £33million – of an overall budget of £2.9billion.

Most research is funded through 'responsive mode'. Here an academic will have an idea and will apply to a Research Council for funding. Under this mode, the direction of the basic science is driven by researchers.

An expert panel will review an application and make a judgment about which proposals should be funded – the decision is primarily based on excellence in science or engineering.

When applying for funding, researchers also need to provide an impact statement for their work (e.g. its use to society or how it would be commercialised) as well as flag up any ethical concerns. The research councils look to ensure that some thought has been given to these issues in the application – though they are generally not used for funding purposes, except when judging two proposals of equal merit.

In the case of BBSRC, if social and ethical issues are thought to be significant, applications will be flagged up to a separate 'science in society' committee. Each year approximately 8 proposals are referred in this regard. The science in society committee works with applicants to help them consider the social or ethical issues raised by their proposal or to resolve specific problems.

EPSRC has a senior advisory panel who reports directly to the Chief Executive and its governing Council and which provides strategic advice about the potential societal and ethical impacts of EPSRC sponsored research and training.

There is no further requirement for researchers to report on impact, social or ethical issues other than at then end of the grant. However, researchers are expected to engage with the public about their research throughout the duration of their grant.
Both Councils have made synthetic biology a strategic priority area. Councils can also fund under specific research initiatives - synthetic biology applications for energy for instance. Under this mode, the direction of the science would be driven by research councils.

Beyond trying to ensure that researchers consider the issues around the research, the Research Councils also work at a higher level to consider those issues , by conducting public dialogues for example.

Handout D: Commercialising Research

To create wealth for the UK, the research councils encourage the commercial exploitation of the research they sponsor. There has been increasing efforts by government to ensure there is a return on investment in university research over the past few years.

Academics value the exchange of ideas and the open communication of results is an inherent part of science and engineering research. There are some concerns that the commercialisation of research will decrease openness and transparency.

For instance, if commercialising research, researchers are encouraged to delay the announcement of results or the publication of papers to ensure that ownership of the 'intellectual property' (IP) has been secured. Granting a patent to protect IP can take 3-4 years in the UK – and the patent typically lasts for 20 years from the time of application.

Research institutions, or spin out companies from universities, will often go into partnership with industry to make money from ideas – either giving them ownership of IP or granting them an 'exclusive exploitation agreement' in return for a fee.

Conflicts of interest may also arise whenever researchers' commercial interests have the potential to compromise their professional judgment – for instance disclosure of negative results.

However, it is also argued that protecting IP is essential to commercialisation and synthetic biology has potential to help create jobs and money in the UK. Without sufficient incentives for the private sector investment will go elsewhere and other countries will get there first. In 2008, the global synthetic biology market was estimated to be $234M– this s expected to grow to $2.4bn by 2013.

Handout E: Synthetic Biology and Regulation

Regulation will play an important role in the development of synthetic biology. The official view in the UK is that the majority of synthetic biology research will be covered by current regulations that apply to genetically modified organisms, and that there is no need for any new regulations relating specifically to synthetic biology at present. In the future it is possible that new regulations will be needed and this situation is kept under review.

At present all synthetic biology is being developed under laboratory conditions. In the UK this is regulated by the Health and Safety Executive. A thorough risk assessment is carried out before research can begin. If approval is given appropriate steps must be taken to prevent release to the environment.

With further development synthetic biology applications may be ready for use outside the laboratory, for example in medicine or agriculture. Depending on the use, this would be regulated by different bodies, who currently assess the safety of other products for human health or the environment.

Most of the challenges faced in regulating synthetic biology involve how best to protect the environment and human health in light of the uncertainties surrounding a new technology. How can regulations keep pace with the technology without stifling its development? How best can we deal with risks when there are still so many unknowns? History has taught us that risks are not always obvious and can take years to emerge, consider examples such as the BSE crisis, Asbestos and Thalidomide.

Who should be responsible for regulation? Should it be the remit of government, an independent body, or indeed scientists or industry themselves? Would regulations be effective without the setting up of international standards?

The potential for "garage" synthetic biology – where people can order parts on line and potentially do the science in their own back yard – may present further complications for effective regulation of synthetic biology.

The need for specialised equipment and facilities might limit the likelihood of such home uses. However, if individuals were to choose to work in their homes on private projects how could this be regulated and monitored both to protect their own health and that of the wider public and environment? As well as uncontrolled release, there are also potential bioterrorism risks in this regard.

Note: there were originally images included in this stimulus material; however these have been removed due to copyright restrictions.

Workshop 2: Brief Overview

- After W2, general **more enthusiastic** towards synthetic biology however the discussions also raised questions and some **concern regarding what the science was aiming for and who would benefit from it**. General desire to discuss **applications in more depth**.

- A key consideration was what constitutes **trustworthiness** in the different stakeholders involved in synthetic biology.

- Some points around **regulating** synthetic biology, **bioterrorism issue**, how much of a possibility that actually is and how could it be **controlled**.

- Certain amount of concern expressed at the potential for **"garage" synthetic biology** – where people can order parts on line and potentially do the science in their own back yard – how would **access to this be regulated** and while the possibility is limited at this stage, would that raise concerns around **security.**

- Consideration of how synthetic biology would be **funded** and how this was translated into a **particular direction** for the science and society in general.

A: Current Energy Research: Bio fuels

Concern over climate change is helping stimulate investment in renewable energy sources such as bio fuels.

Developers hope to make bio fuels from use the component of crops that cannot be used for food (for example stems, some leaves and husks) or use whole plants that are not used in the human food chain.

These components typically contain tough woody material (cellulose or lignin) and are difficult to break down into fuel. Recently scientists have synthesised enzymes that can break down cellulose into sugar which can then be converted into a number or renewable fuels and chemicals.

This was achieved by inserting designer DNA into yeast cells.

B: Other Ways to Address Energy Needs

1. Bio fuels can be produced by non-GM or synthetic biology pathways
2. Other ways to power vehicles could be explored – for instance the use of hydrogen cells, the by-product from which is water. This would require a complete change in a transport infrastructure to achieve this goal.
3. People could be encouraged to be less reliant on the car. This could include ‘sticks’ (road user charging/ green taxes) and ‘carrots’ (subsidised public transport)
4. Improving engine efficiency could also make a significant impact on the demand for fuel

C: Energy Applications: Regulation

Regulations for synthetic organisms involved in fuel production would fall under contained use which implies that measures have been taken to limit contact between the organism and people or the environment. In these cases it would be done through closed industrial production processes.

Monitored by the Health and Safety Executive, any contained use requires a risk assessment as well as appropriate containment of the organism.

D: Possible Future Energy Scenario

With the political pressure to address climate change increasing, a few years back there was a major push on bio fuels. Your new car runs partly on bio diesel. The planes you take for your holidays also use bio aviation fuel. The UK decided to grow crops for fuel: to become less dependent on imports and ensure security of fuel supply – the oil strikes of 10 years ago almost brought the country to a halt. Global demand has also meant developing countries are cutting down pristine forest to make way for 'the green gold'.

In the UK, a great deal of arable land now grows perennial crops such as grasses - with the biomass broken down in huge processing and refining plants by synthetically engineered E. coli bacteria. There is debate as to how much this has led to carbon reductions – and the water needed to grow the crops has created shortages in places like East Anglia. Nonetheless, fuel prices have fallen and there has been a blossoming of the UK's energy industry – creating much needed work in rural areas.

E: Energy Applications: Environmental Social and Ethical considerations

Impact on food security: One concern is that bio fuel crops may compete for land and water with food crops. More broadly, there is a limit to the amount of biomass the earth can produce for fuel purposes.

Environmental risks: synthetically engineered crops may interact in the environment in ways that can't be predicted. Seeds may be able to germinate and spread beyond the farm. A great deal of land may be needed to meet the demands of fuel.

Water shortages: Crops – whether for food or fuels – require water. While crops in the UK are predominantly rain fed, globally it is estimated that as much as 70% of water is already used for crops. Climate change may exacerbate these pressures.

Impact: there is some evidence that other greenhouse gases - such as nitrous oxide - produced when refining bio fuels may offset much of the proposed CO2 reduction.

Patenting and creation of monopolies: Broad patenting of the developments that emerge from synthetic biology may lead to the creation of commercial monopolies or restrict research.

Issues of not investing in synthetic biology: It offers a means to address our fuel needs and promote fuel security. Certain groups argue that without investing in this area, alongside other technologies, we may hit a fuel or energy shortage

A: Current Environmental Research: Bioremediation

Bioremediation is the use of biological systems to treat environmental contaminants such as oil spills.

Researchers are using their knowledge of natural processes to develop microbes that can take up the pollutant in contaminated sites and break it down into less harmful substances.

This involves creating new microbes that can survive outside of a laboratory.

B: Other Ways to Clean Up Pollution

1. Bioremediation can use microbes that occur naturally in the soil rather than synthetically engineered ones
2. Soil and water can be cleaned through other means – digging it up or pumping it out for disposal for instance. However, this is expensive option.
3. Thermal remediation – essentially heating up the soil - can also be used for certain volatile pollutants

C: Environmental Applications: Regulation

European laws cover the release of GMOs into the environment which would also apply to the release of most synthetic organisms.

Applications to release synthetic organisms would be assessed on a case by case basis and only be authorised if it is considered they pose no unacceptable health and environmental risks

No technology or practice is risk free. While some risks are known, others may only become known later when it is widely used, especially if adverse events are rare.

Before release public consultation is compulsory under EU laws

Following release monitoring of any impacts would be required and the authorisation modified, suspended or terminated if new information became available.

D: Possible Future Environment Scenario

There has been a growth in the development of biosensors to detect a whole host of things – from arsenic in drinking water to traces of explosives in airports. Some of these sensors have been coupled synthetically engineered bacteria – which not only help detect but also clean up pollution - digesting and neutralising toxins and heavy metals. The bacteria are now routinely used in the natural world and are claimed to be safe. Scientists also claim to have engineered them to die off after use.

Building on successes in environmental applications, other industries are also looking at the potential for synthetically engineered ‘good’ bacteria to digest ‘bad’ bacteria. This ranges from dental products to clean teeth and address bad breath, to facial scrubs for acne.

E: Environmental Applications: Environmental, Social and Ethical Considerations

Environmental risks: synthetically engineered organisms may interact in the environment in ways that can't be predicted. This could create new environmental pollutants which nature may not be equipped to deal with or new micro-organisms which could compete with existing life forms.

Release risks: Can a modified organism be retrieved from an environment once released? Will it stay where it is meant to?

Who benefits: What happens if the environmental applications can only be accessed by certain organisations or countries?

Personal/Industrial responsibility: should people/industries be encouraged to be more responsible in terms of pollutants?

Patenting and creation of monopolies: Broad patenting of the developments that emerge from synthetic biology may lead to the creation of commercial monopolies or restrict research.

Issues of not investing in synthetic biology: In some cases cleaning up pollutants is difficult with existing technology. Synthetic biology may offer a new means to address pollutants in our environment – though research needs to be done to establish its effectiveness.

A: Current Crop Research: Crop Modification

A potential focus for synthetic biology research is modifying plant components and metabolism with the aim of:

Increasing the resistance of crops to pests

Using plants for the remediation of pollutants

Increasing yields and nutritional value of plants

B: Other ways to Increase Crop Yields and Nutritional Value

1. There are other ways to improve yield and nutrition through selecting existing crop traits (rather than engineering them)– from traditional cross breeding to the more advanced use of molecular markers.

2. Producing less meat would increase availability of grain currently eaten by animals for people to eat

3. It is agued by certain groups that food production is not the major issue - it is distribution

4. Increasing the resistance of crops to pests may not always work- like other conventionally farmed crops, pests may become resistant to the pesticides used.

C: Crop/Food Applications: Regulation

Food applications are reviewed on a case-by-case basis, including a consideration given to potential for toxic, nutritional and allergenic effects.

Foods produced through a synthetic biology pathway may only be authorised for sale if they are judged not to present a risk to health, not to mislead consumers, and not to be of less nutritional value than the foods they are intended to replace.

Any risk of growing the crop would also be assessed including, for example, the risk of it pollinating wild plants. Release of the crop would only be authorised if it posed no environmental or health risks beyond those of the conventional crop

D: Possible Future Food Scenario

With the growing population and the increasing competition for land to grow food and fuel, scientists have attempted to make crops more productive. Specifically, using synthetic biology processes, they claim to have redesigned crops to grow bigger with less water and on poorer soil. There have also synthetically engineered pesticides – which claim to cause less damage to the environment. After changes to regulations surrounding the modification of organisms and plants a few years ago, applications in this area have flourished. However, it is now harder and more expensive to source food that is certified as organic.

There has also been an increase in food that has been designed to offer greater nutritional and health benefits. While this trend started off designing fortified food for developing countries – for instance placing extra vitamins into rice; over time this has led to an increase in so-called functional foods for the West. These foods now claim to do everything from helping to lower cholesterol, to promoting weight loss and boosting IQ. Many landowners are now large agribusinesses - running both production facilities for food as well as fuel refineries.

E: Crop/Food Applications: Environmental, Social and Ethical Considerations

Environmental risks: synthetically engineered organisms may interact in the environment in ways that can’t be predicted. This could create new environmental pollutants which nature may not be equipped to deal with or new micro-organisms which could compete with existing life forms.

Gene transfer: There may be ways for synthetically engineered crops to transfer their genes to plants – with the potential to create super weeds or contaminate other crops.

Trade and Global Justice: Synthetic biology could alter the production of food and associated trade. The technology provides benefits and risks for different sorts of farmers in different parts of the world, potentially impacting on traditional farming practices and on the wealth and health of nations.

Patenting and creation of monopolies: Broad patenting of the developments that emerge from synthetic biology may lead to the creation of commercial monopolies on food, however expensive research needs to offer incentives. How can the right balance be struck?

Environmental impact: Insect-resistant crops may harm species that are not their target. On the other hand, the insects that GM crops are designed to kill could develop resistance to those crops, ultimately requiring farmers to use more aggressive control measures, such as increased use of chemical sprays.

Functional foods: it may be possible to design all sorts of consumer benefits into foods. What are the ethics of having synthetically produced foods that could increase your IQ or improve your physical performance?

A: Current Medical Research: Artemisinin

Malaria is one of the three biggest killer diseases worldwide. One treatment uses a chemical derived from the plant Artemisia Annua called artemisinin.

The benefits of this plant have long been known in Asia but it costs too much to extract enough artemisinin to treat the world's malaria sufferers.

Synthetic biologists have found out how the plant makes artemisinin and have engineered this ability into bacteria and yeast.

This makes them produce a chemical which can be turned into artemisinin in large quantities so that it could be used more broadly as an anti-malarial drug.

B: Other ways to address malaria

There are a number of other ways to combat malaria. These include:

1. Use of insect repellent and wearing long clothes
2. The use of mosquito nets impregnated with insect repellent
3. The drainage of waterlogged land
4. Other anti-malarial medicines such as Proguanil and Chloroquine
5. Developing research into natural occurring pheromones to repel mosquitoes
6. Genetic engineering of mosquitoes to alter the transmission of the parasite

Finally it should be noted that malaria parasite can become drug resistant – all drugs will suffer from this. Parasites resistant to artemisinin were found in Cambodia in 2009.

C: Medical Applications: Regulation

Medical regulations are complex and relate to whether the application is for a medicine, medical device or therapy.

Regulations generally examine a product's safety, quality and performance.

No medical product is risk free. Many decisions involve weighing risks to human health and the environment.

If a product is available for use, its risks, and proposed measures to address the risk must be acceptable.

Some risks are known when a product goes on the market but others will only become known later when it is widely used, especially if adverse events are rare.

D: Possible Future Health Scenario

You wake up feeling awful – the bad pains you have had in your stomach over the past few days are getting worse. You make it down to the hospital and it's not good. Tests reveal that you have a type of inflammatory bowel disease - with ulcers developing in your lower gut. Those years of poor eating, smoking and little exercise are starting to hit home. They prescribe a new drug made by a synthetic organism - it has only recently come out and trials have been promising. The alternative treatment - anti-inflammatory drugs and immunosuppressants - is believed to be less effective and can lead to complications.

While the problem is likely to clear up - the doctor flags up that people with this condition have about a 1 in 40 risk of developing a bowel cancer – much higher than the normal. They would like to permanently insert a biosensor in you - a genetically engineered machine that will detect the cancer and then manufacture a drug to kill it off. Given your weight and poor health they would also like to insert in you a synthetically engineered device to enhance your immune system. They also believe there may be a genetic predisposition to the condition – and would like to do a genetic test on your kids. If they are also susceptible, they would also like them to have implanted devices.

E: Medical Applications: Environmental, Social and Ethical Considerations

Misuse: Learning developed from healthcare uses of synthetic biology could be used to design organisms which would be hostile to humans, for instance the flu virus could be modified.

Trade and Global Justice: Synthetic biology could alter the production of certain drugs – with research focusing on diseases of the West (such as cancers).

Patenting and creation of monopolies: Broad patenting of the developments that emerge from synthetic biology may lead to the creation of commercial monopolies or restrict research so that it does not benefit the people that need it most.

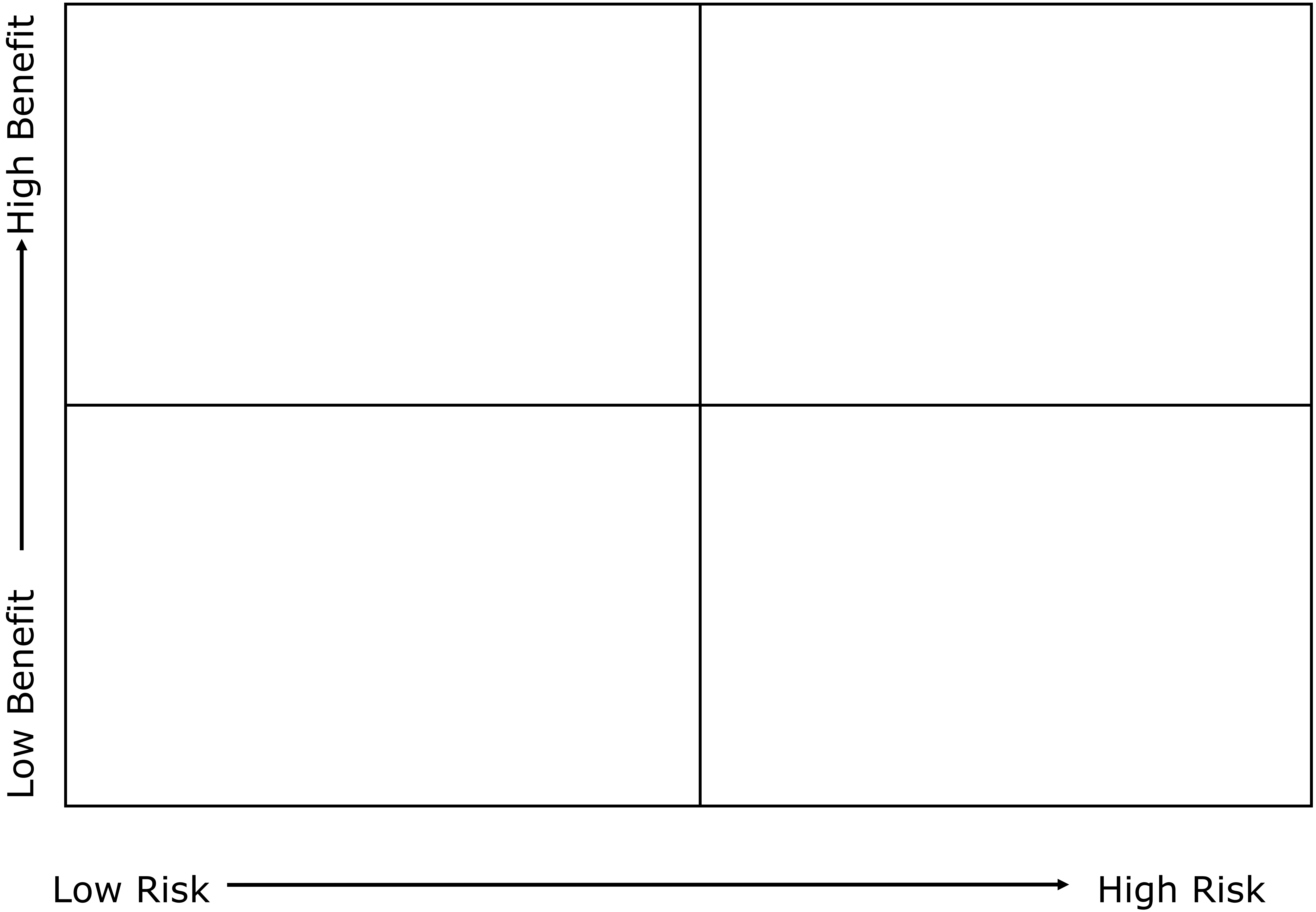
Investing in synthetic biology: There are a number of proposed healthcare applications of synthetic biology – not researching this area could impact on the development of treatments for patients with serious diseases. Conversely, funding synthetic biology takes resources away from other research.

Risks: How would a device such as a biosensor interact with your body? Could it be retrieved? Would it stay where it is meant to?

Enhancement: What if such devices were used for human enhancement processes – for instance to boost physical performance or IQ?

Who benefits: What happens if companies only end up developing drugs for those whose genetic profile can make them the most money?

Personal responsibility: should people be encouraged to look after their own health – or if they pay taxes, should they be able to get treatments for diseases that may be predominantly related to lifestyle?


High Benefit
Low Benefit
Low Risk
High Risk