

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 of 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
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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 argued 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?

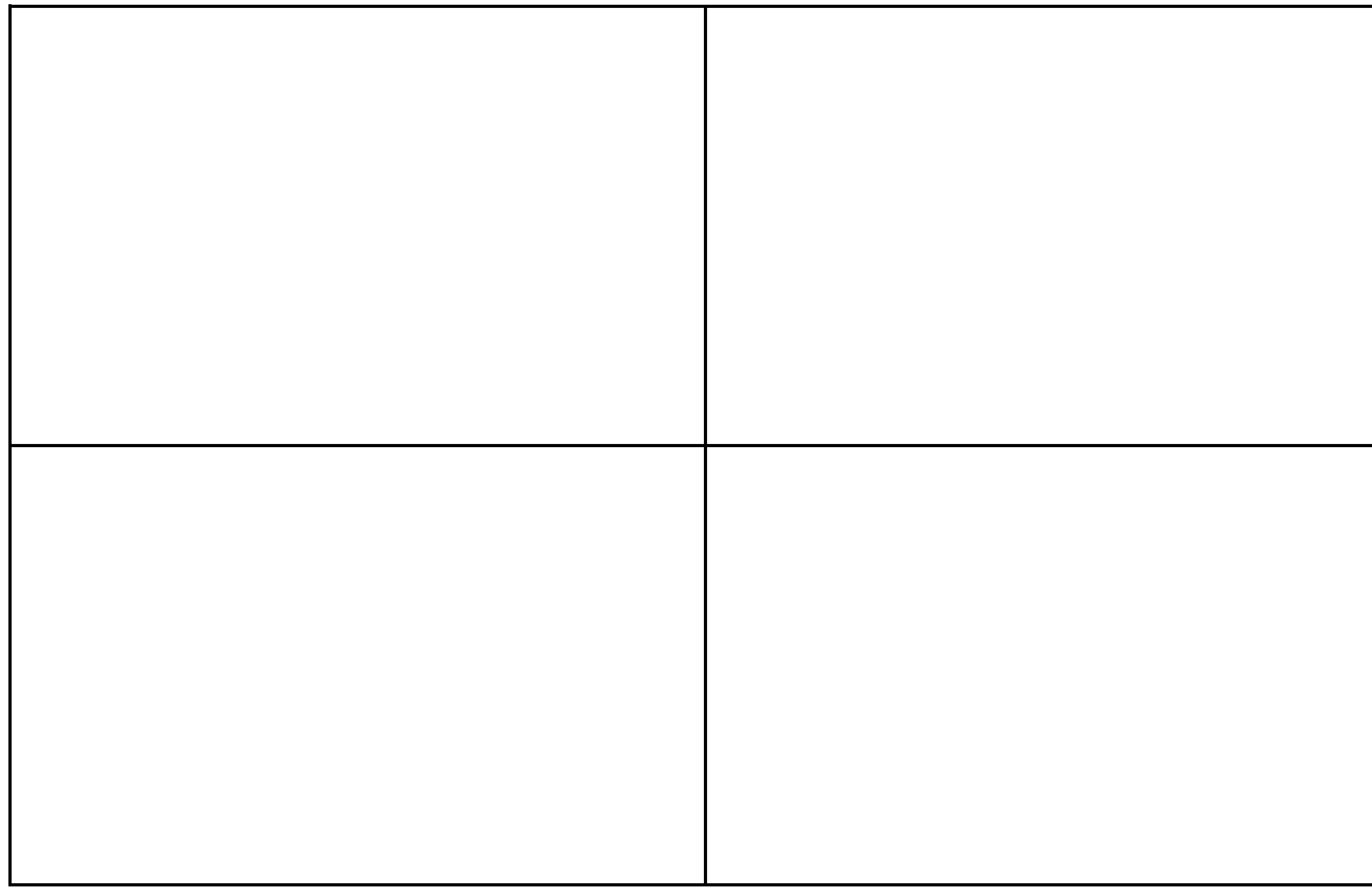
Who benefits: What happens if companies only end up developing drugs for those whose genetic profile can make them the most money?

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