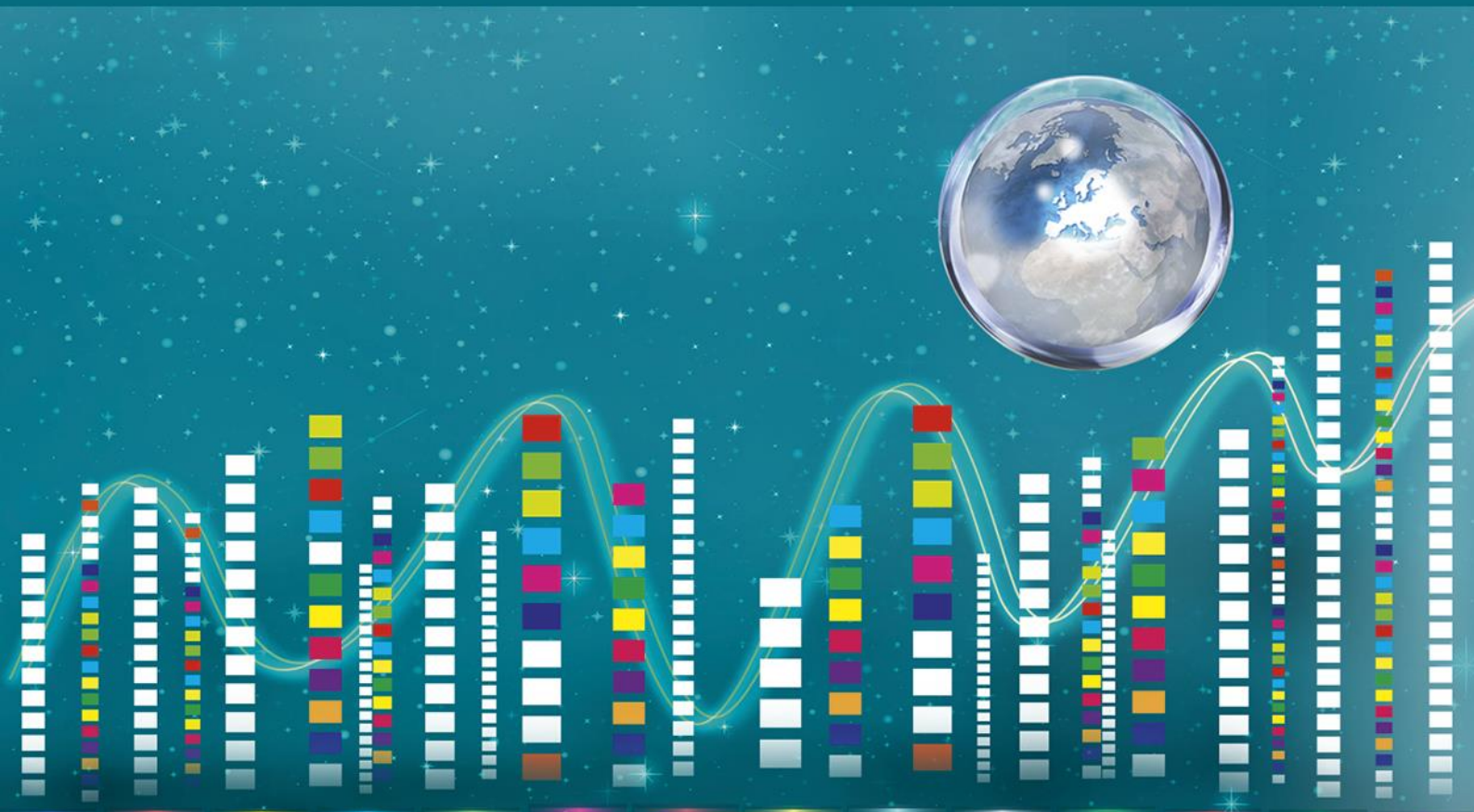
European Commission

Foresight

Human Organ Replacement

Targeted scenario N°8

Glimpses of the future from the BOHEMIA study



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Research and Innovation

EN

***Human Organ Replacement* - Targeted scenario N°8**

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Manuscript completed in March 2018

Luxembourg: Publications Office of the European Union, 2018

PDF ISBN 978-92-79-81041-1 doi: 10.2777/37898 KI-04-18-271-EN-N

EUROPEAN COMMISSION

Human Organ Replacement

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Glimpses of the future

from the BOHEMIA study

Directorate-General for Research and Innovation

2018

About BOHEMIA

BOHEMIA is a foresight study (contract N° Contract PP-03021-2015) designed specifically to support the preparation of the next framework programme.

The study put forward policy recommendations for the next framework programme, based on a foresight processes involving scenario development, a Delphi survey and an online consultation.

As part of its recommendations, the study identified 19 likely future scenarios with disruptive implications and associated priority directions for EU research and innovation.

The full range of the results of the study is available at https://ec.europa.eu/research/foresight

Targeted scenario N° 8

Human Organ Replacement

Summary

It is 2040. Most human organs and tissues can be replaced. The majority of organs and tissues are bio-printed, produced by additive manufacturing or breeding (e.g. organoids). Human organ or tissue replacement is accessible and affordable for all European citizens so that the average life expectancy increases.

UN Sustainable Development Goals (SDGs) most relevant to this scenario:

The scenario

It is 2040. Artificial organs have become a widely used option in medical treatment. Many human organs exist in artificial versions, on chips or as organoids and can be reproduced and replaced at least once. Not all organs are yet replaceable - some are too complex. Organoids and in-silico models can be used to quickly develop effective treatments for existing organs; other solutions are based on genetic engineering or require therapeutic cloning and breeding (i.e. Xenotransplantation). The bio-printing of organic tissues presents a third avenue for human tissue replacement.

Suitability, durability and minimising side effects are key concerns for replacement of human tissues. Organ replacement is no longer considered a solution of last resort. Preventive transplants have been increasing for a while. There is still scepticism even though people are already used to some of the organ replacements. Organs and other parts of the body are replaced in ordinary 'surgeries'. But human enhancement is still a divisive issue.

In some countries, private health insurers co-operate with the medical devices industry to develop new and better generations of artificial organs. Those are first used among well-off people who can afford to pay for the latest solutions available on the global market.

But organ transplantation has become far less burdensome for the patients and more mainstream in the medical profession. It is costly, but affordable, and as costs fall, artificial organs become an increasingly attractive option for financially constrained public health systems. After an accident or an illness that is indicated on the list of 'follow-up for transplants", the costs for the artificial organ as such and the surgery (personnel costs) are taken over by the health insurances in Europe. Costs are not borne by the health insurance system in circumstances where artificial organs are aimed to improve lifestyle, or to prolong life in general. An age-limit of 90 years is set for this kind of surgery. For the early adopters life span has already increased dramatically and a life expectancy of 120 years is in sight.

Relevance for Europe

We are facing a continuously increasing demand for human organs. Markets for human organs, often illicit, emerge with dire ethical consequences. Trafficking for organ transplantation is a worldwide problem.[1] Many patients die waiting for a transplant that could save their life. The numbers differ from country to country, depending on the regulation. But the number of human organ donors is not increasing very much – and is limited.

Replacing the 'market' for human organs with a market for artificial organs that involve less side-effects and have better performance is an important vision for the medical devices industry, an industry in which Europe is very strong.

Contribution towards the UN Sustainable Development Goals (SDGs)

Human organ replacement is directly relevant to SDG 3, which aims to ensure healthy lives and promote well-being for all, at all ages. Because of the significance it has for people's lives, it is important to align its deployment with SDG 10 "Reduce inequality within and among countries", including developing the economic conditions so as to offer access of all people to organ replacement, where necessary.

[1] Joint Council of Europe/United Nations Study, 'Trafficking in organs, tissues and cells and trafficking in human beings for the purpose of the removal of organs" (Strasbourg, 2009), https://www.edqm.eu/sites/default/files/medias/fichiers/Joint_Council_of_EuropeUnited_Nations_Study_on_tra1.pdf

Implications for EU policy

Cost, functionality and medicines regulation have been issues that affect the development of artificial human organs. EU health policy can promote regulatory improvements and insurance systems' reforms that would be more conducive to innovations in this field.

Ethical considerations and new regulations are also paramount. For example issues of population control in the context of longer lifespans and the definition of possible age limits for certain transplantations may well be needed.

Regulation in the health insurance systems are necessary, especially about the question if the treatments should be available and affordable for everyone. In this context, the relationship with human enhancement may be challenging for insurance systems - but the development already started. Ethical considerations have to be part of the EU policy.

Future Directions for EU R&I policy recommended by the public consultation

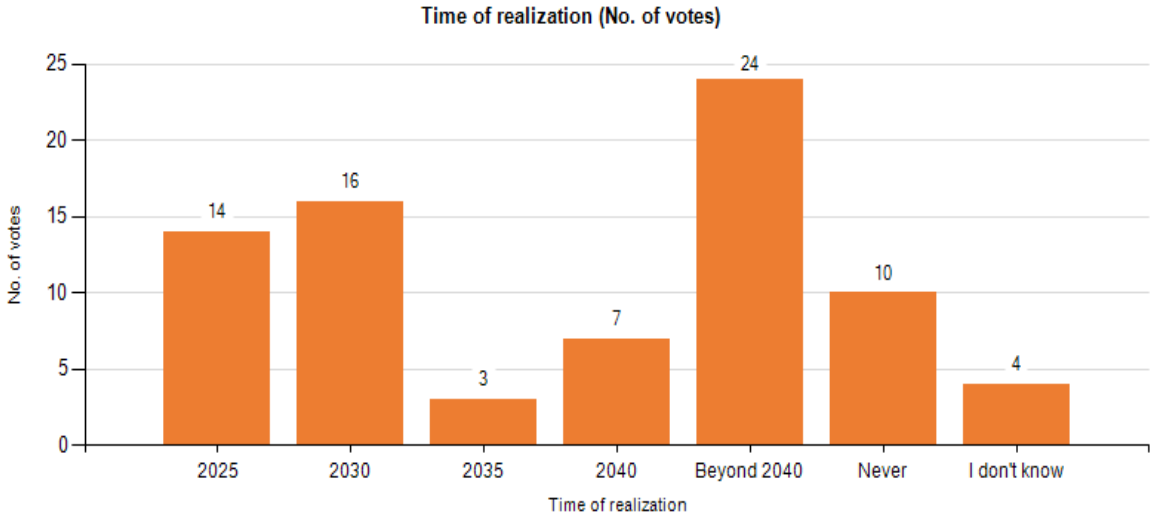
- **Breeding of tissues and organs (theory and practice)**
- **Avoiding immune reactions to organ replacement**
- **Solving ethical dilemmas regarding human enhancement (e.g. age limits for organ exchange)**
- **Providing and controlling product safety/ toxicity**
- **Using epigenetics and genetic engineering for creating organs**
- **Developing new gene technologies for human organs**
- **3D and (later) 4D printing of human organs**
- **Creating pathways to ensure non-discriminatory access for all people to future artificial organs and organ replacement procedures**

Annex: Relevant Data from the Delphi Survey

The Delphi survey of the BOHEMIA study asked experts about the time of realization of 143 statements about the future, and about the relevance of Research and Innovation for that realization, or about the relevance of the realization for Research and Innovation policy. The experts were asked to justify their judgements with arguments. The whole data set has been published and can be found at: https://ec.europa.eu/research/foresight

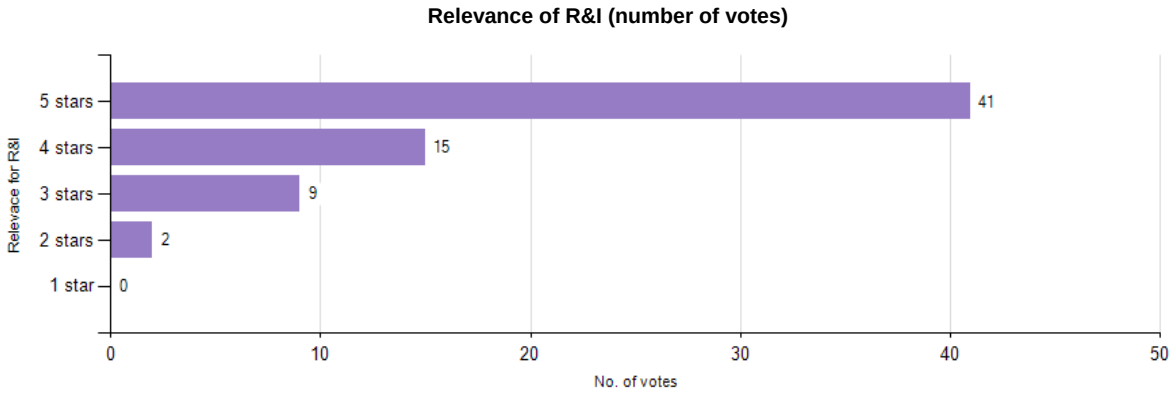
This annex includes the parts of the data set that are relevant to this scenario.

It is possible to replace any human organ



Number of respondents : 76

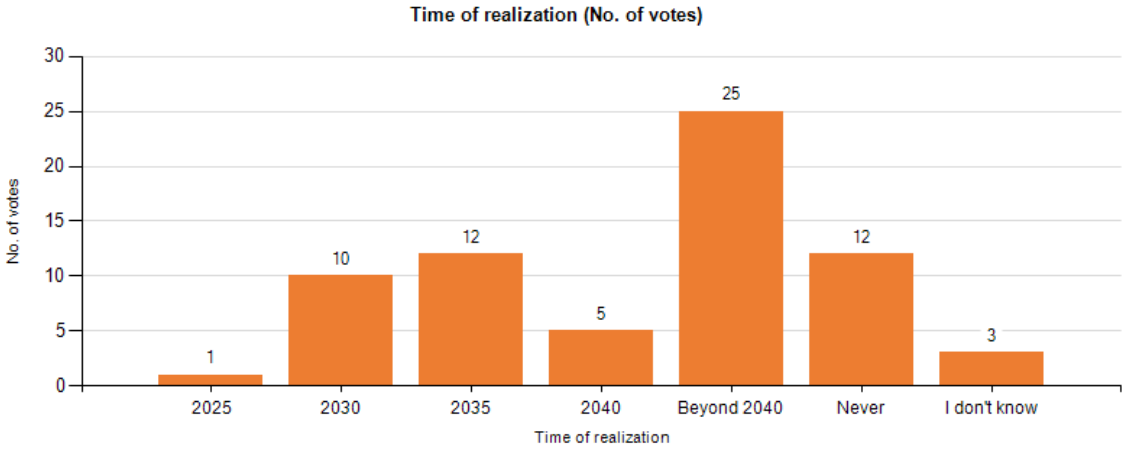
Arguments regarding the time of realization	**No. of votes**
"Any human organ" is too ambitious, but some of them may be replaced by synthetic/ artificial organs in the near future.	88
Some of the human organs have been transplanted for a long time now, but to replace them all with artificial organs or to transplant intestine or brain will remain impossible.	47
We will make great progress in stopping and reversing the deterioration of organs with regenerative medicine, replacement instead will be much harder to achieve.	45
Is this an ambition humanity want to aim at, clear ethical questions must be answered now.	31
The possibility of replacing an organ does not indicate that such replacement would be practiced. Replacement may seem possible, but serious flaws may be undetectable for years.	7
Bio 3D printing is very promising for replacements of organs by own-stem cell-grown organs.	4
Yes, with the growth and innovation of growing cells from human blood. All organs consist of a skeleton and cells growing on it.	3



Average: 4.42 **Dispersion:** 0.67

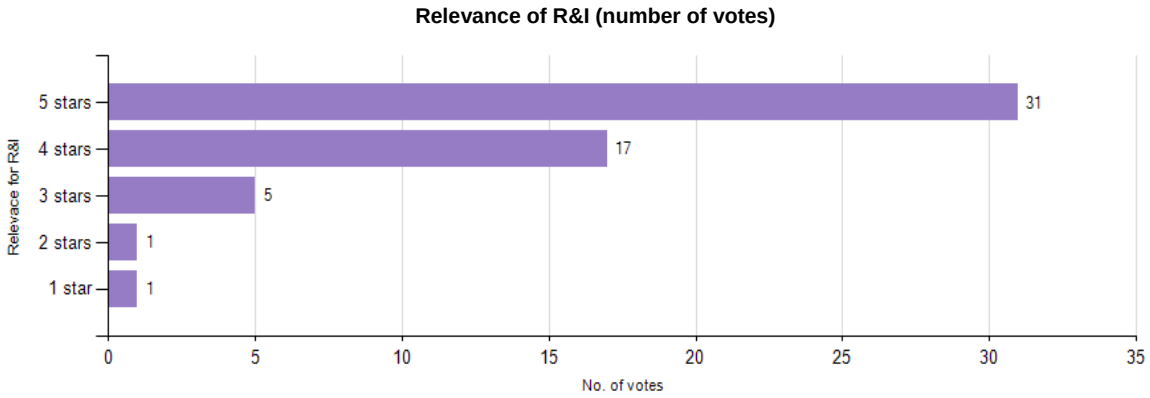
Arguments regarding the relevance of R&I	**No. of votes**
R&I is fundamental, as major investment is needed in a range of 'auxillary' fields to realise the ambition.	50
Ethical issues are still highly problematic if stem cells are to be used.	40
Growing human organs in host animals still needs consistent research - for now, the resulting human-animal chimeras don’t grow well, and few human cells survive.	34
Artificial organs are a realistic option using sensing and actuating systems or by engineering advanced materials e.g. the artificial pancreas.	29
Due to the enormous risk and the limited know-how protection I do not yet see industry as the driver in this field.	4

All of the vital organs and parts of the human body can be reproduced



Number of respondents : 66

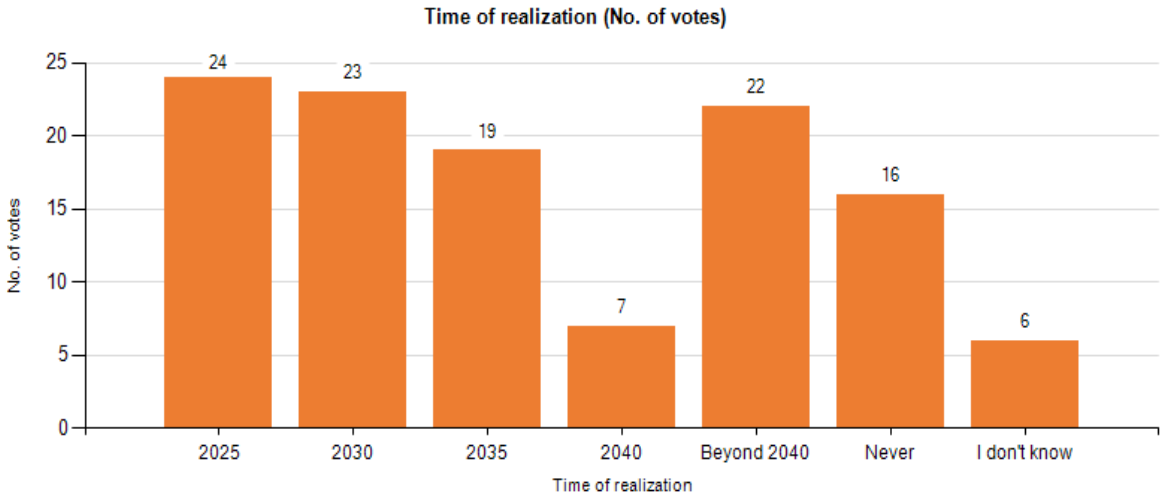
Arguments regarding the time of realization	**No. of votes**
Even if certain functions of the human brain might be possible to achieve by reproducing this vital organ, other essential function will not be possible to restore in this way.	54
Regenerating organs will require a much deeper basic understanding of developmental biology and its application to re-development.	53
New technologies are required that combine cell biology with advanced material in biohybrid systems.	38
The 3D printing of some organs has already been achieved	18
Regenerating organs will require a much deeper understanding of developmental biology and synthetic biology to be able to re-develop a functional new organ.	13
Europe must know if it wants to invest into human cloning for therapeutic purposes, it might not be the priority, other options should be explored.	9
Reproducing the brain is unlikely to enable reproduction of mind which may be subject to quantum decoherence. The intestinal tract may have analogous limits including harmonization of the microbiome.	7
All organs will not be possible - too complex, e.g., liver.	5
A clear decision has to be made on which technologies (e.g. therapeutic cloning) might be used to achieve that goal.	4
Research into human cloning for therapeutic purposes has come to a halt in the United States.	3



Average: 4.38 **Dispersion:** 0.76

Arguments regarding the relevance of R&I	**No. of votes**
More support of the biology of organ development is needed	49
3D printing of organs is still an evolving technology, and needs a substantial investment of research to succeed.	37
Further ethical research is necessary.	26
Approaches should look beyond what is already known today	14
Due to ethical reasons such research shall be funded and thereby transparent for the legislators	2

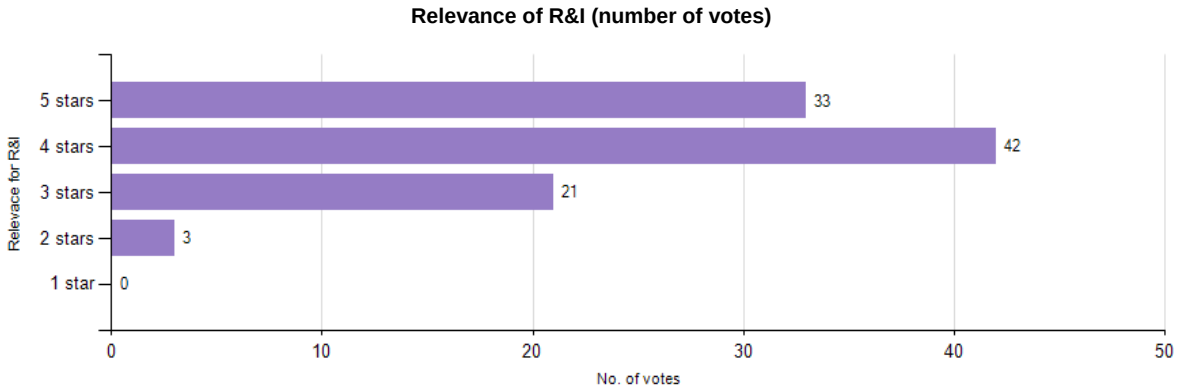
With the introduction of new technologies such as 3D printing, a significant proportion of manufacturing is decentralised and carried out either by consumers or local businesses. As a result, industrial floor-space in Europe shrinks by 50% (compared to 2016)



Number of respondents : 113

Arguments regarding the time of realization	**No. of votes**
Current 3D printers have limited capabilities and can only print with a limited number of molecules. To improve the range of outputs will require a lot of time.	61
Producers have already begun printing spare parts and small parts - this is a challenge for suppliers in the very near future and will decrease their floor-space.	51
3D printing is used for component production only. Large parts of the floor space in Europe is used for assembly and process industries which will never be replaced by 3D printing.	36
It will be used for special applications, e.g., medical (tailor-made) or prototypes. However, it will be difficult for it to compete with large-scale production.	35
In every city, 3D printers can already be found - the Maker Movement supports the application of this technology. Therefore, these changes will be very rapid.	21
Industrialization of 3D printing requires a seamless integration of 3D printing within the shop floor, shop floor systems and post-processing.	19
New technology requires much longer time than 30 years to catch up with traditional technologies - in 2040, Tech Business will use 3D-printing but in narrow, specialized fields.	16
3D printing has advantages for a selected range of products with complex shapes. For mass production 3D is unsuitable and too costly.	11
3D printing will be used within the manufacturing steps rather than substitute existing production processes. This will allow achieving new features, mechanical and functional, on existing products.	11
3D printing will become the new industrial floor-space.	10
The main issue for additive processes: seamless integration with subtractive processes based on an interoperable numerical control program and metallic material, currently proposed by hybrid machines.	8
Large floor space for storage will shrink but the amount of decentralized floor space is likely to increase as	4

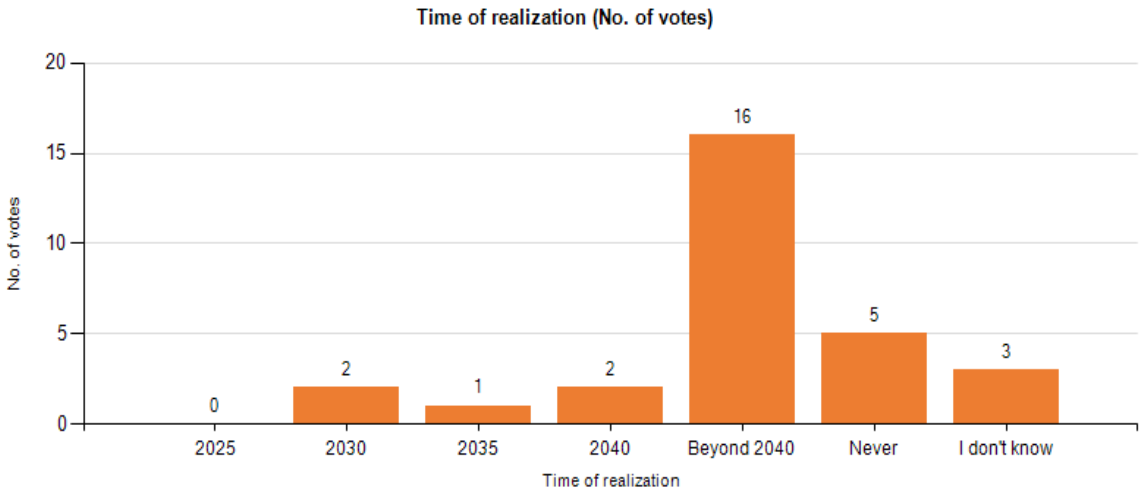
business looks to optimize overall operations. May have greater impact on warehousing.	
3D printing enables very rapid product change and adaptation to local conditions significantly reducing packaging and shipping costs.	3
The roles will change. Suppliers will be seen more and more as a developer for the OEMs, and will therefore be responsible for the 3D printing at the OEMs' assembly.	3
Industrial floor-space in Europe is needed also for locally 3D-manufactured products targeted for European markets. Decentralisation of manufacturing will happen also in US and Asia.	2
3D printing allows manufacturing of components with higher mechanical properties and lower weight replacing very soon the present spare parts and rethinking structures (plane, cars, etc.).	2
True. But changing technologies will also change the concept of industrial floor space, which will remain fundamental in Europe, as it is vital for maintaining the world leadership of our community	2
3D printing has lot of limitations like the support for cantilever structures and compatibility to use multiple extruder noses.	1
In many areas 3D printing will reduce process chains and floor-space significantly, but not by 50%, because floor space is a function of product dimensions, too.	1
Floorspace reduction has another cause and for disassembly we need the floorspace that is made free due to integrated flexible hybrid (additive/substractive) multiprinter-multimaterial flowlines.	1



Average: 4.06 **Dispersion:** 0.67

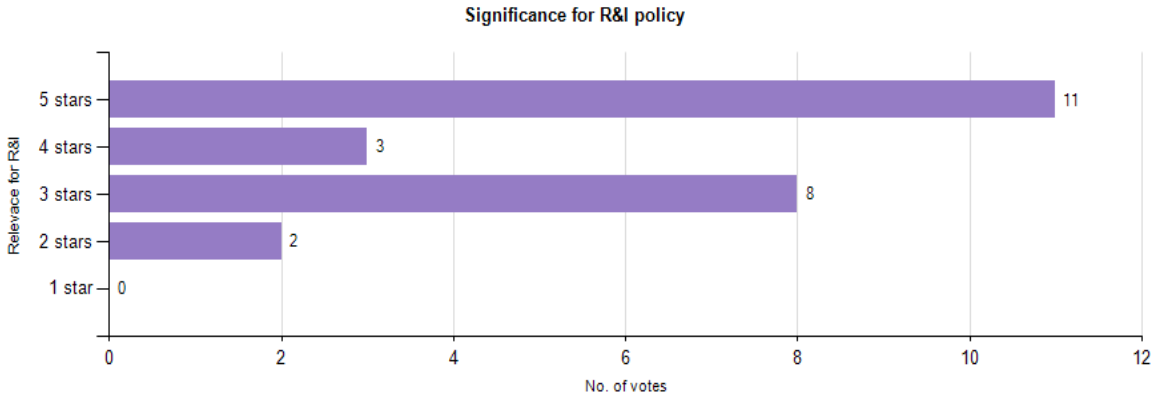
Arguments regarding the relevance of R&I	**No. of votes**
Research is still necessary regarding the possibilities for the use of different and more complex molecules, modules, as well as the creation of larger parts.	94
Research should focus on both new, small-scale production processes and on their implications for the workers.	32
Rethink the design process: take additive manufacturing into account and the product as a whole, rather than assembling parts	26
3D printing research must go beyond aspects related to the 3D printing process and machine to encompass a full production chain.	25
For large volume markets, create components as a replacement of normal production, might not be the most sustainable way. Placing material only to add value to lower cost preforms shall be considered	16
A lot of research is still needed to prevent people from printing with toxic materials, or from over-exposure to toxic emissions when printing.	13
The integration of 3D printing within existing manufacturing processes should be easy, flexible and automized. This is needed particularly for powder-based methods for metal printing.	8
To capture the added value of 3D printing - integration of novel functions and complexity at no cost - engineering systems must enable a cost-effective design of one-off products for applications	6
It requires lot-size-1 for mass production costprice, zero-defect manufacturing, and Blockchain type of automated quotation/ording/shipping/billing processes, all to be developed at higher levels	4
3D printing is already dealing with a great variety of materials : metals, polymers, concrete, food, etc...creating a wide range of all new businesses.	2
Total cost of ownership and cost with hybrid process to compete with only CNC and injection-molding manufacturing.	2

EU citizens have a life expectancy of 120 years on average



Number of respondents: 29

Arguments for time of realization	**No. of votes**
Experts assume a limit of human life around 120 to 140 years, therefore 120 years is rather long.	17
Life expectancy is still increasing in an average of 3 months per year. Without any additional effects, 120 years is possible, but long-term.	14
To become true, this requires a dramatic shift of lifestyle for all members of a population (no smoking, way less sugar and fat), regular exercise.	12
To become true, this requires a paradigm shift on medical research (rejuvenation, nanomedicine...). Stakeholders must realize that it is now thinkable to considerably delay aging through biotechs.	10
Because of the unhealthy lifestyle in the industrialized countries, this will not be possible. In developed countries, the increase of life expectancy seems to already be slowing (i.e. UK).	10
The fiscal crisis in public healthcare will create an age limit for patients to get life-extension treatments.	2



Average: 3.96 **Dispersion:** 1.11

Arguments regarding the significance for R&I policy	**No. of votes**
Policies in R&I also need to support the quality of life for all ages - particularly in elderly populations. This is as important as prolonging life.	26
It will be necessary to reconsider completely the distinction between working life and retirement, between working time and training time.	11
There need to be policy ideas for funding retirement. The official retirement age has to increase, too.	10
There needs to be policies considering political participation - the elderly people will have much more political power if they are so numerous.	6
If average lifespans are 120 active working life for most people would be 100 or more. Increasing opportunities for career renewal increasingly important.	2
Funding for training or retirement must be considered within the broader framework of a Universal Income.	1
Increasingly functions will be amplified through prosthetics to the degree where age no longer matters for most functions.	1

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It is 2040. Most human organs and tissues can be replaced. The majority of organs and tissues are bio-printed, produced by additive manufacturing or breeding (e.g. organoids). Human organ or tissue replacement is accessible and affordable for all European citizens so that the average life expectancy increases.

Studies and reports