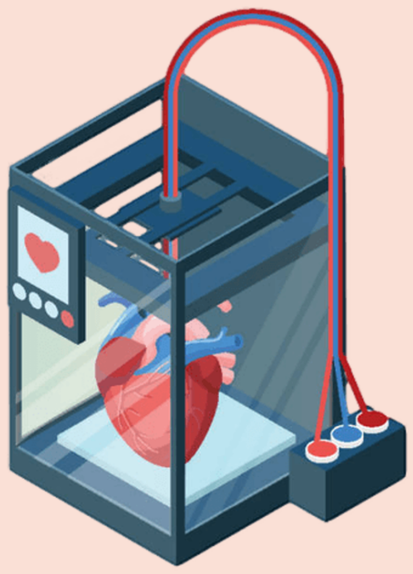
3D-bioprinted hearts: an affordable solution to the scarcity of human donors in the EU



An innovative technique:

- 3D-bioprinting enables the production of materials called bioinks, which can support tissue cells in their development and proliferation.

An imperative need:

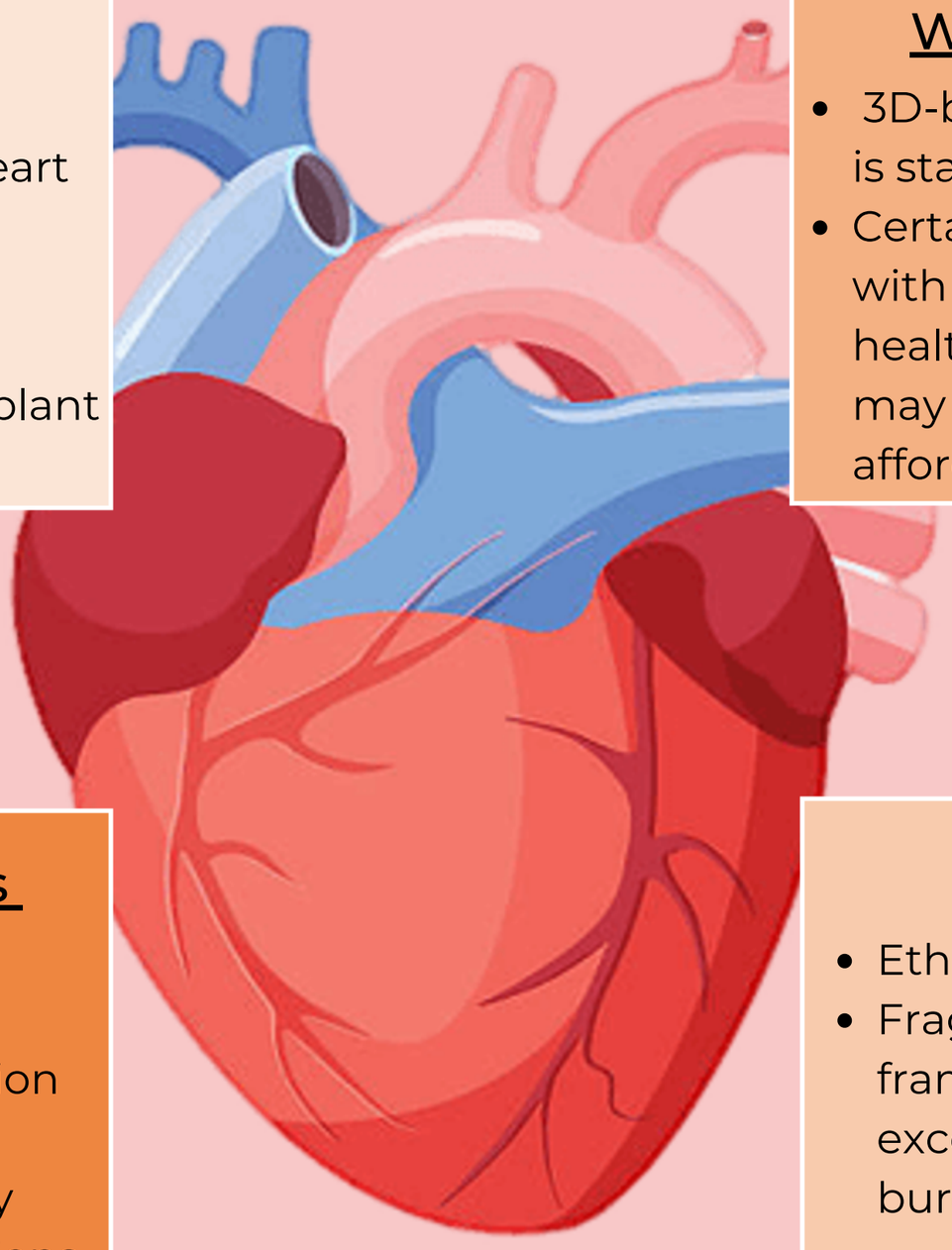
- Cardiovascular diseases account for 1/3 of all European deaths (Eurostat, 2020).
- The supply of human donor hearts for transplants does not fulfill patients´ demand.
- The exhausting process of heart transplants has led to depression and a lack of productivity. An economic burden has been placed on Europe's institutions.

Strengths

- Decrease of time spent on donor heart waiting list
- Decrease in labor productivity loss
- Decrease of transplant rejection risk

Weaknesses

- 3D-bioprinted heart is static
- Certain EU countries with overburdened health care systems may struggle to afford spending on it



Opportunities

- Building of associations for efficient distribution
- Once 3D is fully devloped, 4D may overcome limitations
- Tailor-made laws

Threats

- Ethical challenges
- Fragmented legal framework and excessive regulatory burden in the EU

Regulation

- 3D-bioprinted hearts will be classified as 'Combined Advanced Therapy Medicinal Products' under EU Regulation Regulation (EC) No 1394/2007.
- EU-wide market authorisation must be obtained through the European Medicines Agency following approval by the EU Commission.

Funding

- 30 USD return on investment for each USD spent on cardiovascular research suggests the need for higher 3D-bioprinting research spending (Cutler & Kadiyala, 2003).
- Cooperation between government-funded academic institutions and corporations to facilitate rapid innovation.

Logistics

- Regional transplant associations, such as Scandiatransplant, should act as mediators between donor hospitals and transplant centers.
- A centralized approach through university hospitals should be initially implemented.

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Honours+