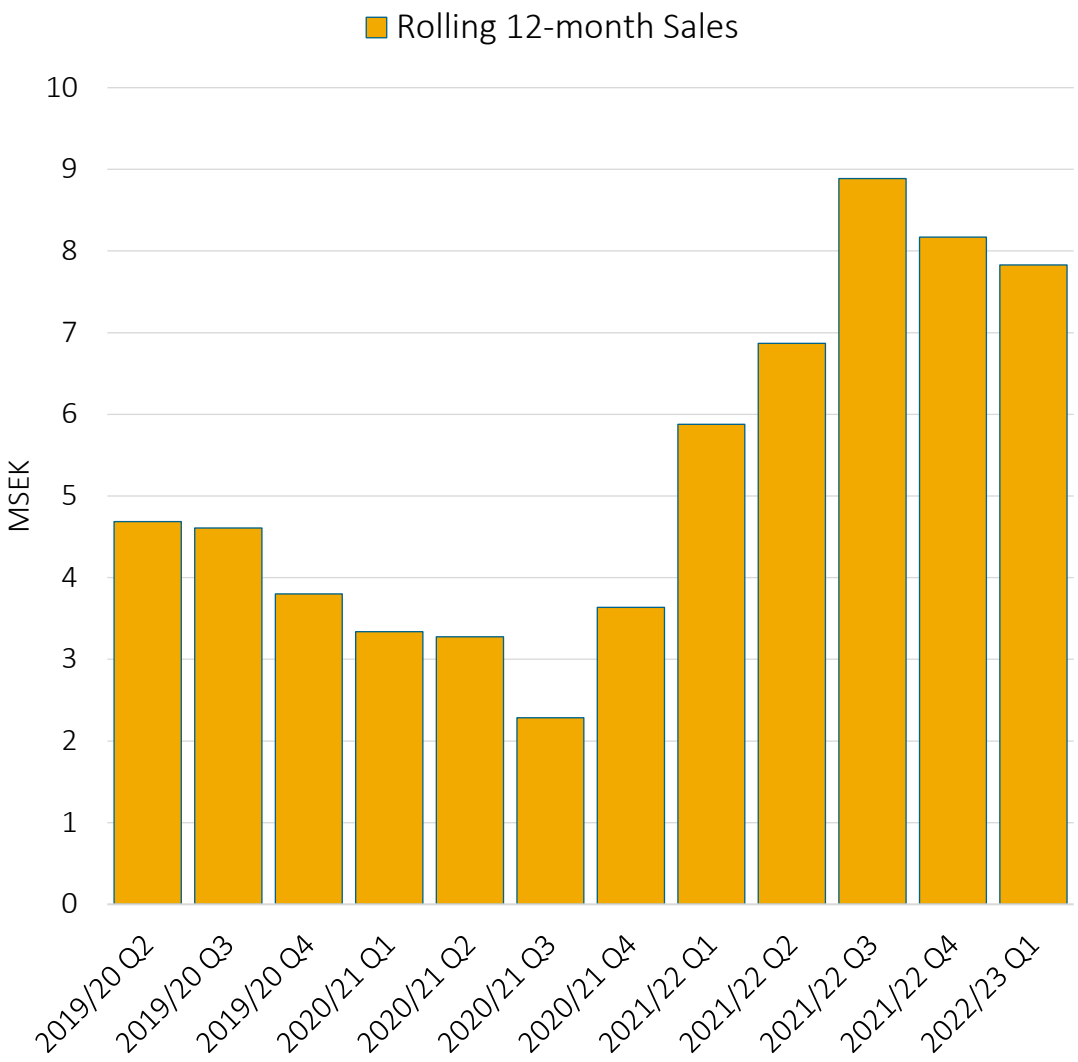
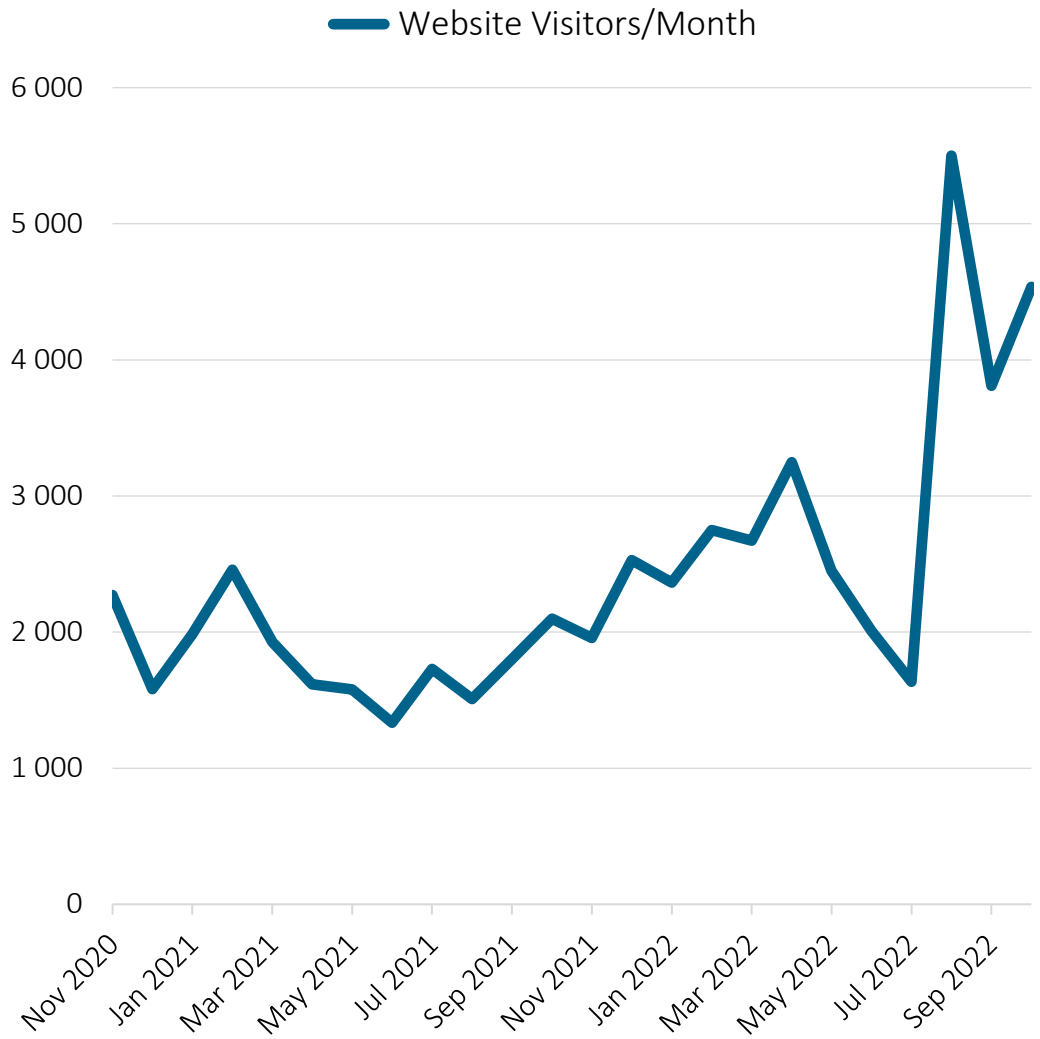
Årsstämma 2022/23

31 oktober 2022

SALES & MARKETING

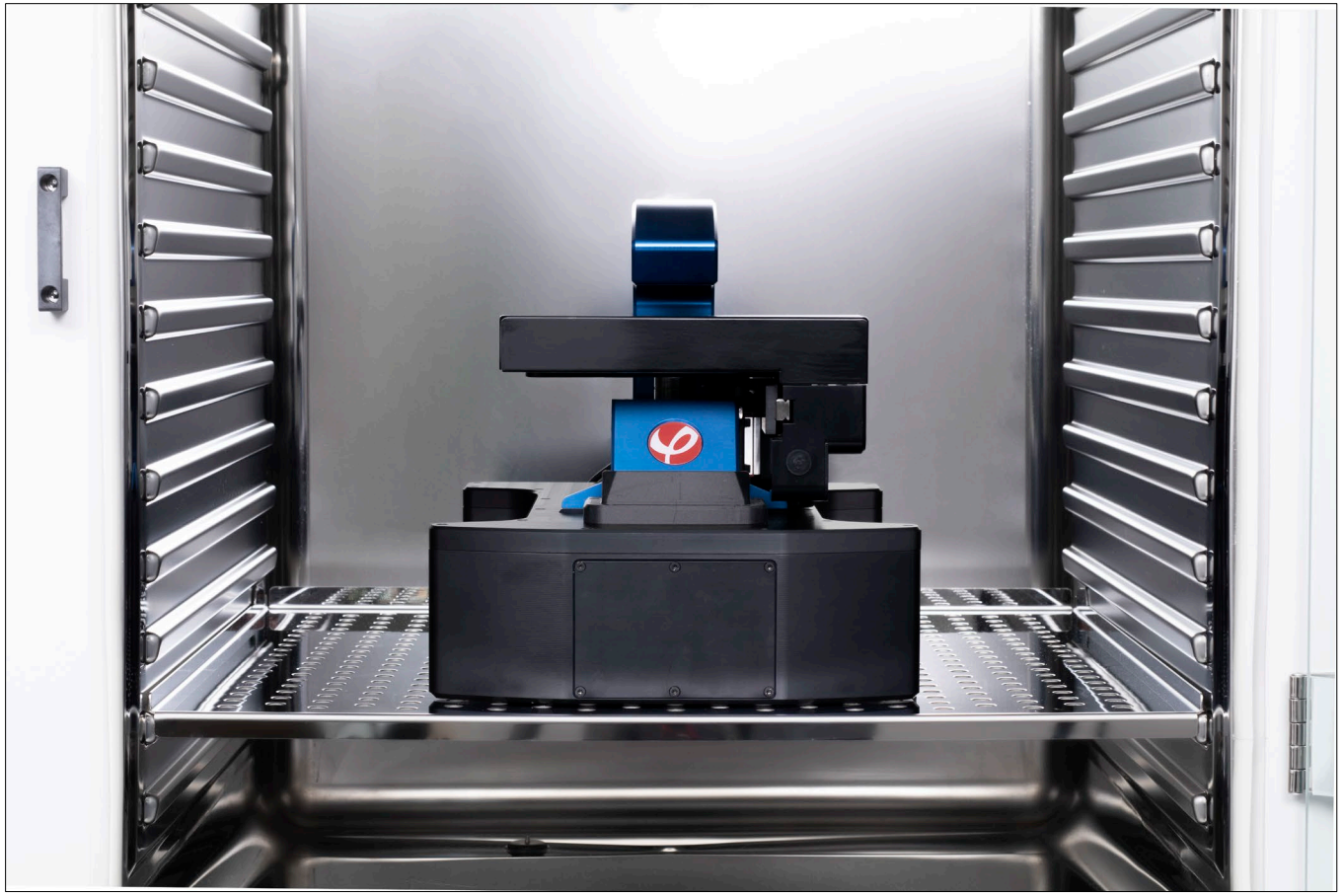




FLUORESCENCE UNIT

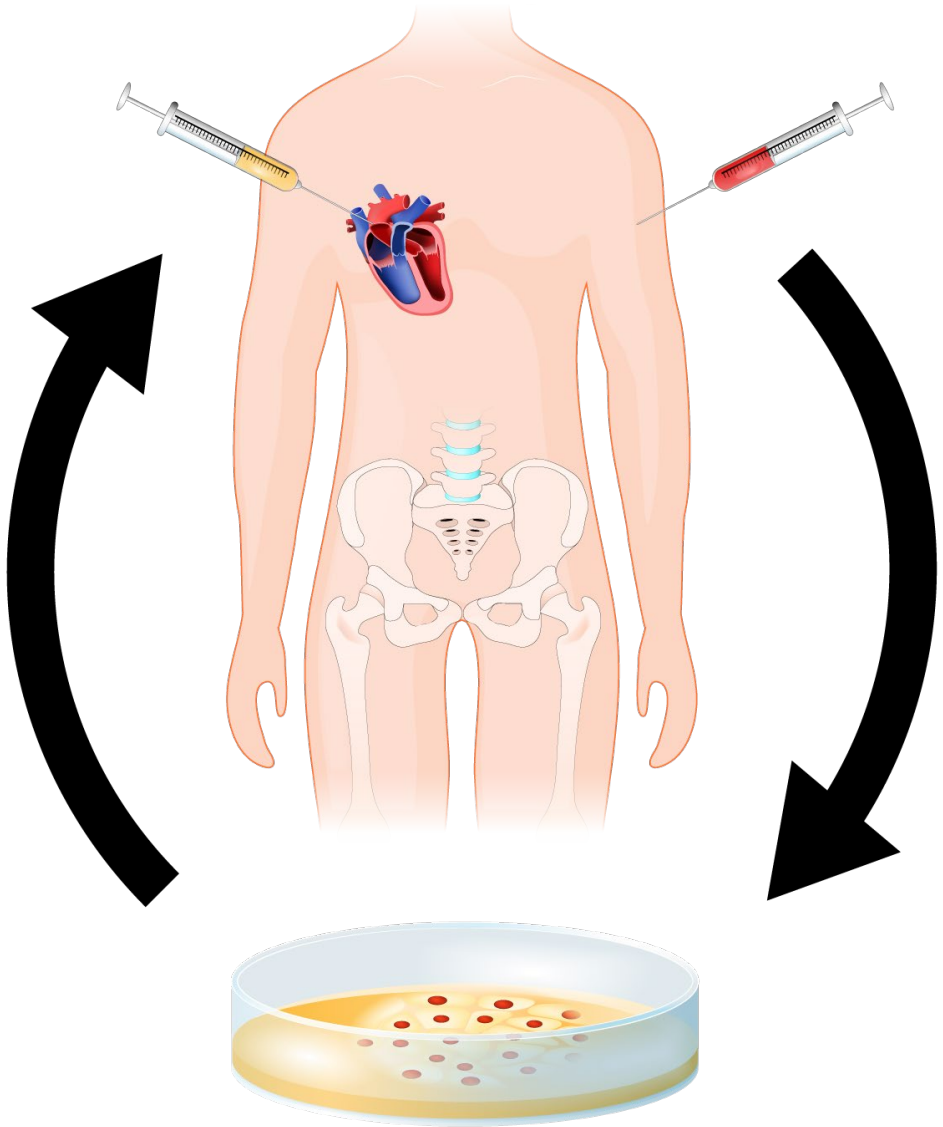
Life is Best Studied Alive

- Reduces the release of toxins to a minimum
- Reduces experimental cost and complexity as more data is obtained in an experiment with fewer fluorescent reagents
- During the autumn, units will be delivered to current customers who have expressed great interest in combining holography with fluorescence



REGENERATIVE MEDICINE

Basic Principle



- Promise to treat Alzheimer's, Parkinson's, diabetes, heart disease and many cancer forms
- +20 approved treatments
- 2 600 ongoing clinical trials
- Treatments today cost +100 000 USD
- Unlike traditional drugs, **the cells themselves are the treatment**
- **Must transition from craft to industry** to reduce costs and make treatments available to all

The Manufacturing Problem

- Traditionally, cell culturing is a small-scale research activity
- Accordingly, available tools are not suitable for large-scale biomanufacturing (right image)
- Neither do any standards exist

Cell culture quality control at a leading contract manufacturer of cell therapies

FEDERAL FOOD, DRUG AND COSMETIC ACT

- FDA shall in consultation with the National Institute of Standards and Technology (NIST) and stakeholders
- facilitate an effort to coordinate and prioritize the development of standards to, through regulatory predictability, support the development, evaluation and review of regenerative medicine therapies
- with respect to the manufacturing processes and controls of such products.

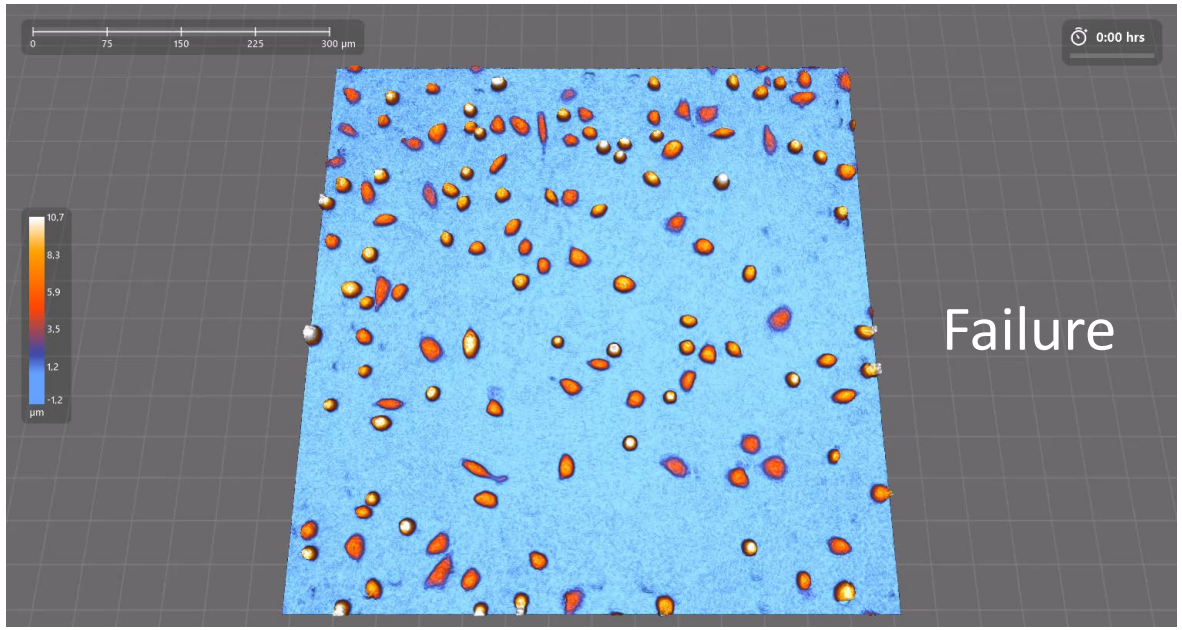
- The stakeholders are
  - regenerative medicine and advanced therapies manufacturers
  - clinical trial sponsors
  - contract manufacturers
  - academic institutions
  - practicing clinicians
  - regenerative medicine and advanced therapies industry organizations and
  - standard setting organizations

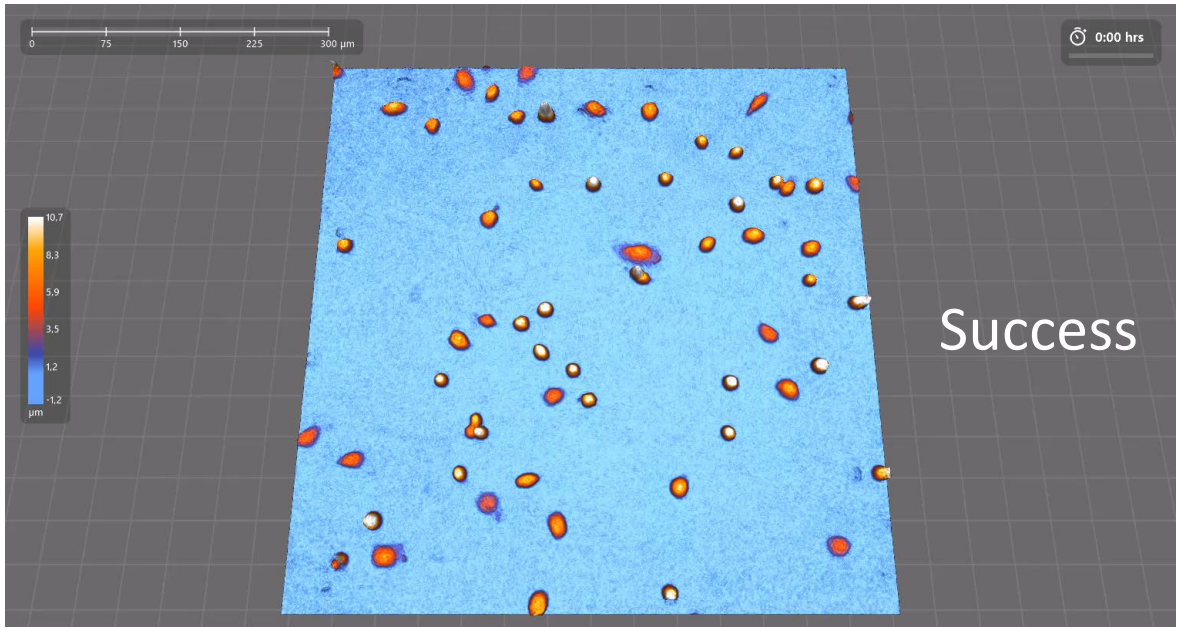
Source: 21 USC 356g : Standards for regenerative medicine and regenerative advanced therapies

In plain English, the US Congress has essentially ordered FDA to let the regenerative medicine players set the standards for how regenerative therapies shall be manufactured and regulated.

PREDICTING BIOMANUFACTURING

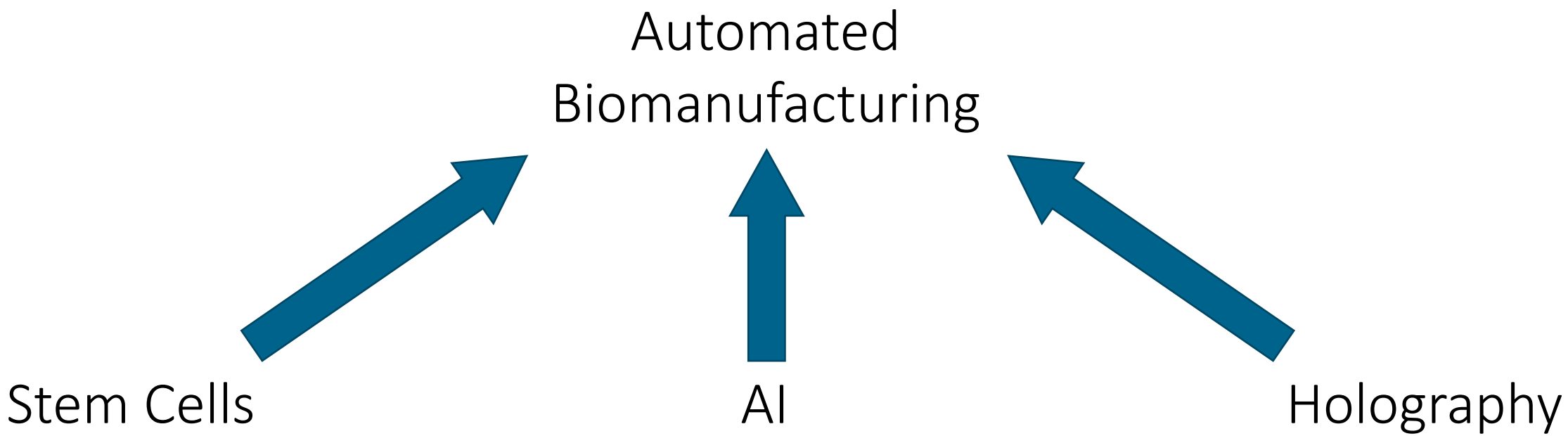
- The manufacturing of regenerative therapies can take up to several weeks
- Predicting the outcome at an early stage before cell death occurs is possible by quantifying cell morphology and failed divisions





It would be an invaluable tool for biomanufacturing!

ADVANCED BIOMANUFACTURING



- For the explained reasons, PHI and several companies associated with the Wake Forest Institute for Regenerative Medicine have come together to automate biomanufacturing
- Allowing cell-based therapies to be manufactured cost-effectively with superior efficacy and safety