



Ameliorated subjects

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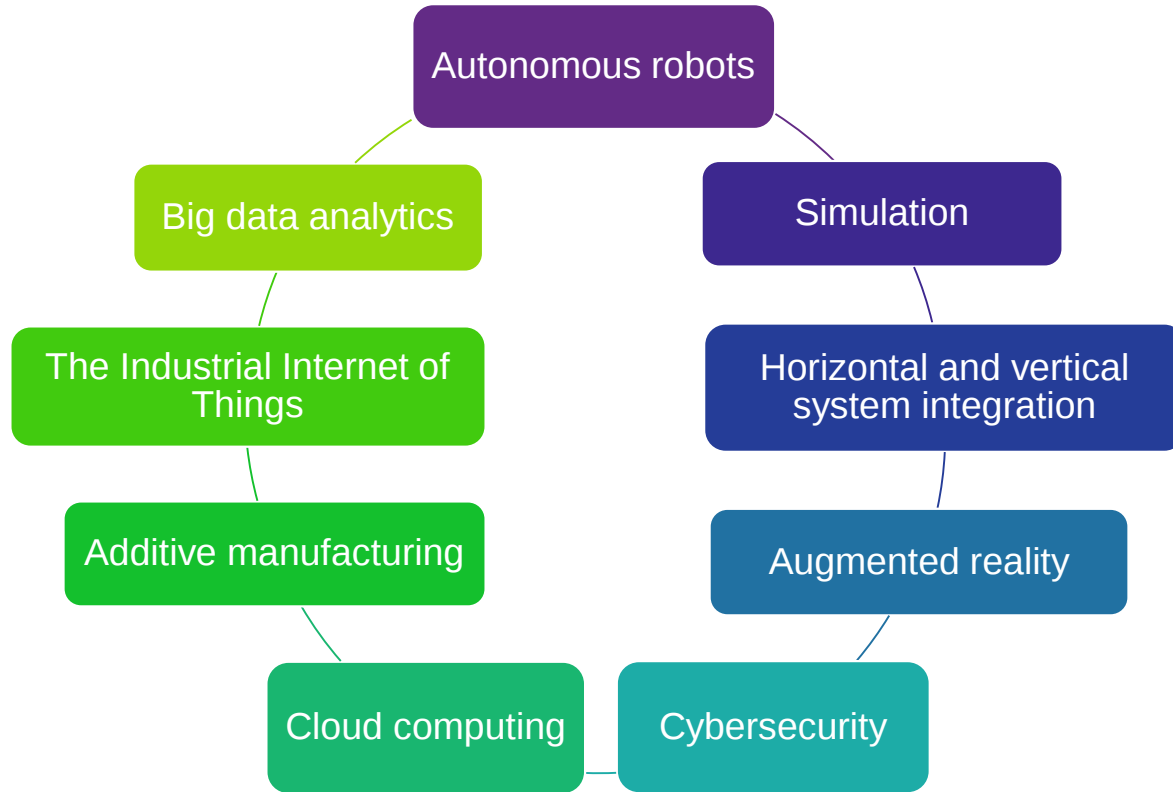
Index

- Background
 - Industry 4.0
 - The bigger picture
 - Virtual Biology
 - What is *In-Silico*?
- Pros vs Cons
- Regulatory authorities and Ethics
- Yesterday
- Today
- Tomorrow
- Conclusion

Background

Background

Industry 4.0



Background

The bigger picture

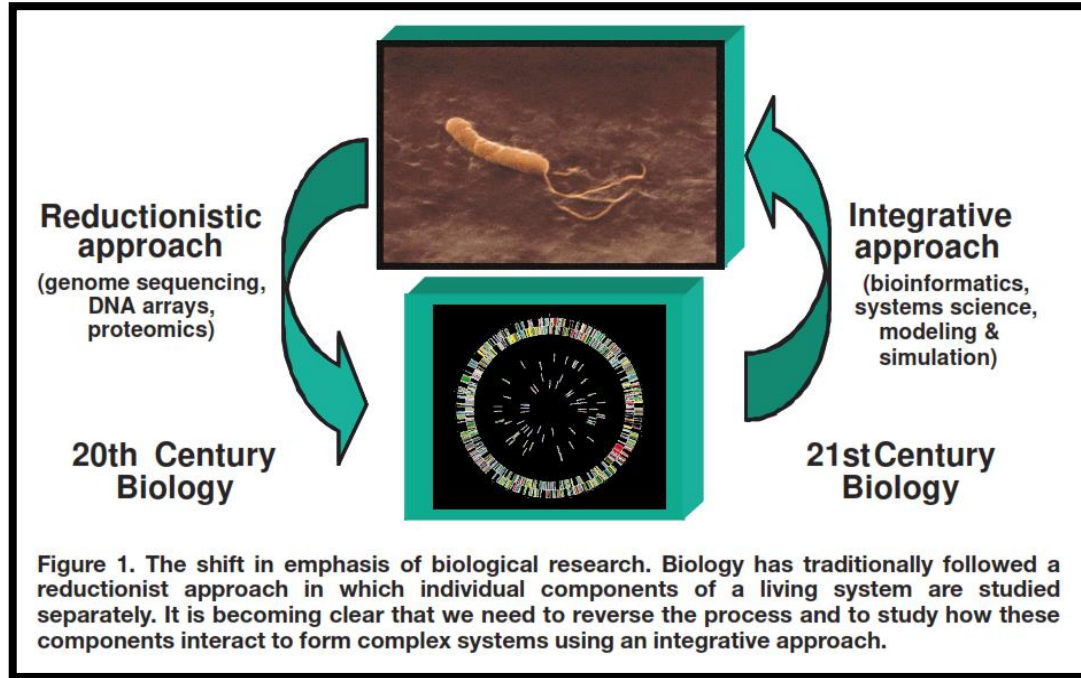


Figure by Palsson, B., 2000

Background

Virtual Biology



Figure by Shutterstock.com

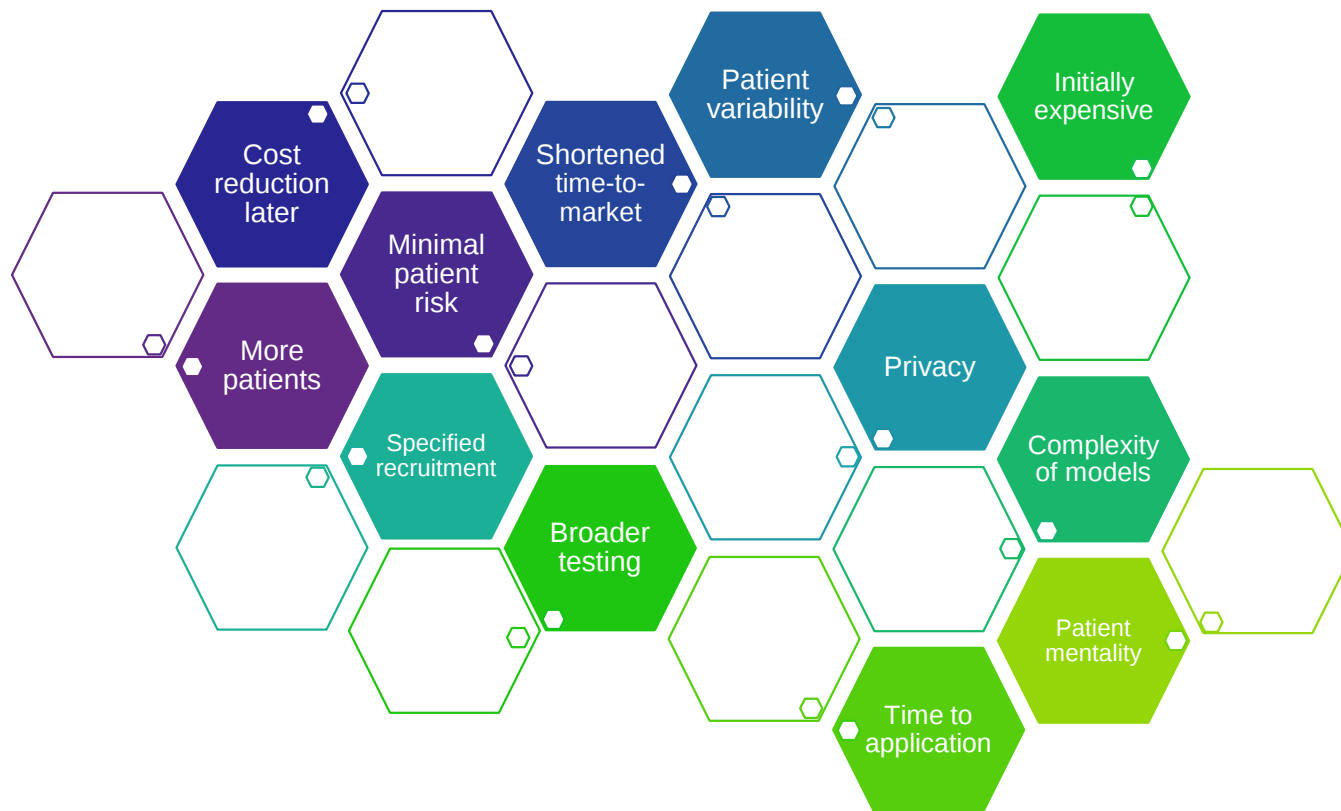
Background

What is *In-Silico*?

- *In-Silico*: by means of computer modelling or computer simulation.
- *In-Silico* clinical trials: The use of individualised computer simulation in the development or regulatory evaluation of a medicinal product, medical device, or medical intervention. It is a subdomain of '*In-Silico* medicine', the discipline that encompasses the use of individualised computer simulations in all aspects of the prevention, diagnosis, prognostic assessment, and treatment of disease (Viceconti, M., et al., 2016).

Pros vs Cons

Pros/Cons



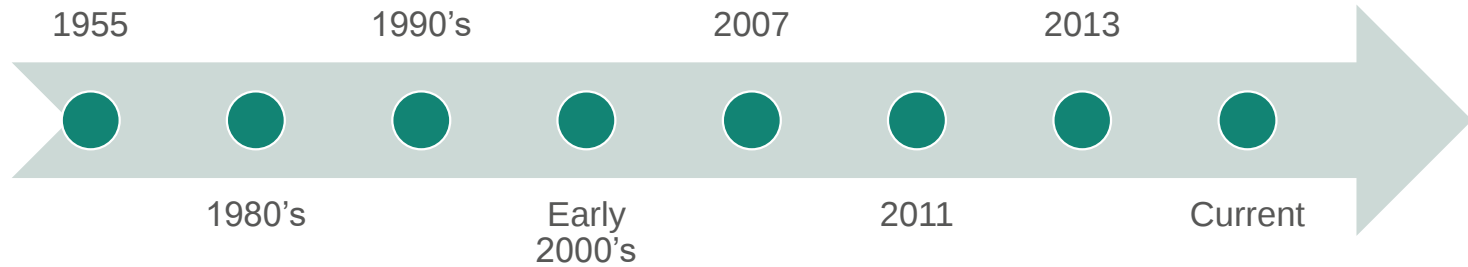
Regulatory authorities and Ethics

Regulatory authorities and Ethics



Yesterday

Yesterday



Today

Today

HumMod

National Cancer Institute database

In-Silico ADME-Tox prediction

VIRTUheart™ project

Tomorrow

Tomorrow

Oncosimulator project

Paediatric patients

HumMod

Patient-specific modelling

Conclusion

Conclusion

Ameliorated subjects, the way forward.

References

- [1] Algahtani, S., 2017. *In-Silico ADME-Tox modeling: progress and prospects*. Expert Opinion Drug Metab. Toxicology, Vol. 11, p. 1147-1158.
- [2] Chakraborty, S., 2014. *In-Silico analysis identifies genes common between five primary gastrointestinal cancer sites with potential clinical application*. Ann Gastroenterol, Vol. 27, p. 231-236.
- [3] Galbusera, F., et al., 2018. *Exploring the Potential of Generative Adversarial networks for Synthesizing Radiological Images of the Spine to be Used in In-Silico Trials*. Frontiers in Bioengineering Biotechnology, Vol. 6.
- [4] Gallatly, N. & Sewell, F., 2019. *Regulatory acceptance of In-Silico approaches for the safety assessment of cosmetic-related substances*. Computational Toxicology, Vol. 11, p. 82-89.
- [5] Läer, S., et al., 2009. *The In-Silico Child: Using Simulation to Guide Pediatric Drug Development and Manage Pediatric Pharmacotherapy*. The Journal of Clinical Pharmacology, Vol. 49, p. 889-904.
- [6] Lee, J., et al., 2014. *Service innovation and smart analytics for Industry 4.0 and big data environment*. Procedia CIRP, Vol. 16, p. 3-8.
- [7] Lee, J., et al., 2015. *A Cyber-Physical Systems architecture for Industry 4.0-based manufacturing systems*. Manufacturing Letters, Vol. 3, p. 18-23.
- [8] Marchal, T., 2015. *IN VIVO, IN VITRO, In-Silico!* ANSYS ADVANTAGE, Vol. IX, p. 6-10.

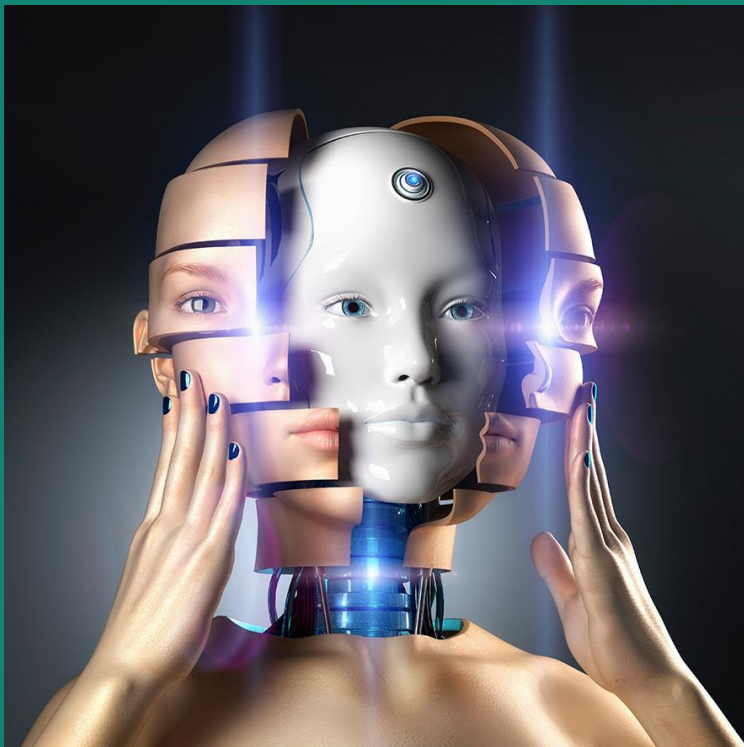
References

- [9] Mesko, B., 2019. *For how long will we test drugs on patients?* Available at <https://medicalfuturist.com/future-of-clinical-trials/>
- [10] Morrison, T., *Advancing In Silico Medicine at FDA: Perspectives in Simulation in Medical Devices*. Available at <http://www.omgwiki.org/MBSE/lib/exe/fetch.php?media=mbse:patterns:incose2018--morrison.pdf>
- [11] Pallson, B., 2000. *The challenges of In-Silico biology: Moving from a reductionist paradigm to one that views cells as systems will necessitate changes in both the culture and the practice of research*. Nature Biotechnology, Vol. 18, p. 1147-1150.
- [12] Pirogova, E., et al., 2009. *Investigating the interaction between Oncogene and Tumor Suppressor Protein*. IEEE Transactions on Information Technology in Biomedicine, Vol. 13, p. 10-15.
- [13] Rüßmann, M., et al., 2015. *Industry 4.0: The Future of Productivity and Growth in Manufacturing Industries*. Available at https://www.bcg.com/publications/2015/engineered_products_project_business_industry_4_future_productivity_growth_manufacturing_industries.aspx
- [14] Saeidnia, S, et al., 2013. *The Pros and Cons of the In-silico Pharmaco-technicology in Drug Discovery and Development*. Internation Journal of Pharmacology, Vol. 9, p. 176-181.
- [15] Tian,S, et al., 2015. *The application of In-Silico drug-likeness predictions in pharmaceutical research*. Advanced Drug Delivery Reviews, Vol. 86, p. 2-10.

References

- [16] Vekris A., et al., 2004. *Molecular Determinants of the Cytotoxicity of Platinum Compounds*. Experimental Therapeutics, Molecular Targets, and Chemical Biology, Vol. 64, p. 356-362.
- [17] Viceconti, M., et al., 2016. *In silico clinical trials: how computer simulation will transform the biomedical industry*. Available at <https://www.ijclinicaltrials.com/index.php/ijct/article/view/105/72>
- [18] Viceconti, M., et al., 2018. *In silico clinical trials: concepts and early adoptions*. Briefings in Bioinformatics, bby043, <https://doi.org/10.1093/bib/bby043>
- [19] Vincent, B., 2019. *The agency is looking for a computational model of a whole human heart for simulated device testing*. Available at <https://www.nextgov.com/emerging-tech/2019/08/fda-seeks-virtual-heart-test-medical-devices/158946/>
- [20] Wadood, A., et al., 2013. *In-silico drug design: An approach which revolutionarised the drug discovery process*. OA Drug Design & Deliver, Vol. 1.

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