

Biotechnology Industry introduction

What is biotechnology?

- Broad range of activities which exploit living organisms and biological processes for industrial and scientific purposes
- Industry characterised by innovation and a strong research and development focus
- Plays a critical role in pioneering scientific, medical and technological advances including novel strategies for diagnosis, disease monitoring, treatment and prevention

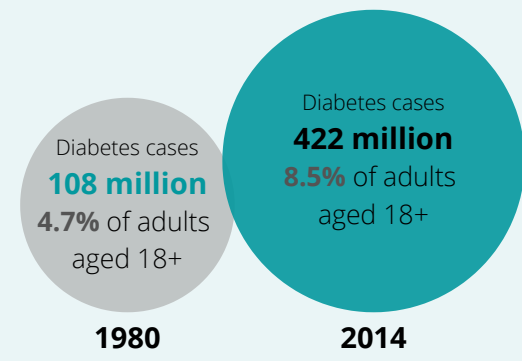
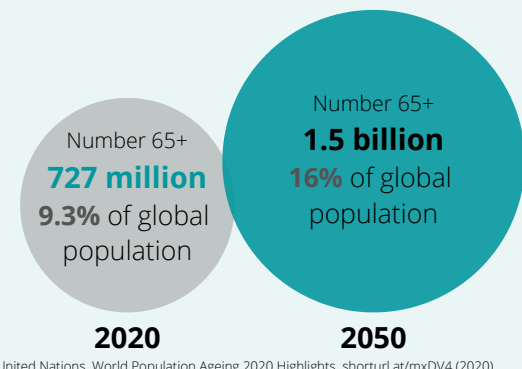
Categories

- Red** **Medical technology & pharmaceuticals:** vaccines, antibiotics, drug discovery, regenerative therapies, artificial organs, diagnostics
- Green** **Agricultural:** increased food production, disease and insect resistance, environmentally friendly fertilisers, biopesticides, biofortification (nutrition)
- White** **Industrial:** biocatalysis, biodegradable and 'Smart' polymers, renewable energy, enzymes and microorganisms
- Gold** **Bioinformatics & chip technology**
- Blue** **Marine & aquatic**
- Purple** **Legal, ethical & philosophic issues**
- Dark** **Bioterrorism & biological weapons**

Red biotechnology

Industry Drivers

- **Ageing populations** - the number of over 65's is expected to more than double in the next 30 years
- **Increasing burden of chronic and infectious diseases** leading to increased healthcare spending
 - Cardiovascular diseases (CVDs) - leading cause of death globally
 - Cancer - second leading cause of death globally
 - Diabetes & obesity - increasing prevalence

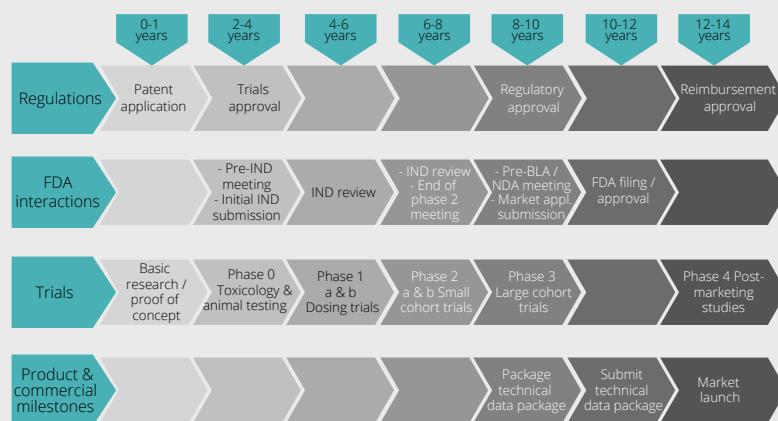


Development Pipeline

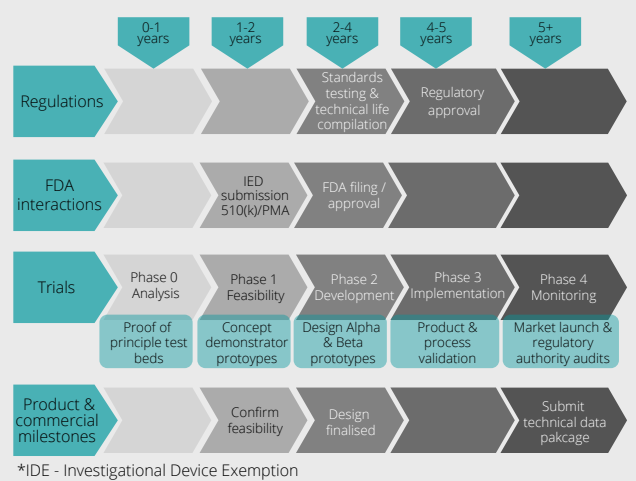
- The life cycle for products in the red biotechnology sector differs from many other sectors & industries
- Bringing a new vaccine or medicine (drug) to market may involve:
 - 10 to 15 years of development
 - US\$1.5 – 2.6 billion, on a risk-adjusted average basis
- Bringing a medical technology product to market may be shorter (~4 to 10 years) with costs of US\$30 – 150 million
- Numerous local and/or international processes & regulations must be followed and satisfied in the development and commercialisation of products in the red biotechnology sector - see alongside
- To bring a drug or medical device to market requires regulatory approval from the relevant country authority - pathway set out by the FDA, the regulatory authority in the USA, is the most common pathway used
- Drug development - The FDA requires non-human (animal) toxicology studies and a 'trials approval' step followed by successful completion of three phases of clinical (human) trials to gain approval for a new drug

See "Drug Development: Regulatory Pathway" resource for further information

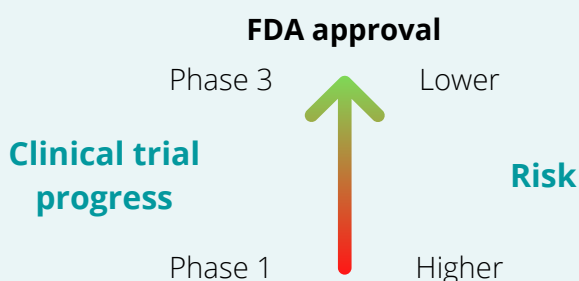
FDA drug development and approval pathway



FDA medical device development and approval pathway



Business risk at different stages of the clinical trial process



Red biotechnology - reasons to invest:

- High growth potential
- Beneficial to the community (medical advances)
- Less affected by broader economic conditions than other equity sectors
- Diversification

Investor considerations

Important points to consider:

- Drug candidate phase of development - the later the phase, the lower the risk (usually)
- Drug candidate's peak annual projected sales - the higher the better
- Number of drug candidates/products in a company's pipeline - more candidates may signal less risk
- Intellectual Property (IP) assets (i.e. patents - see IP asset resource) and IP strategy
- Company financial position and funding channels - expensive to fund operations prior to gaining approval and launching products to market
- Government policies - i.e. related to approval, reimbursement, procurement, tax and IP laws

References and further details

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