Society for Clinical Data Management
DATA DRIVEN

Theme:
Capabilities | Collaboration |
Change on the way to Clinical Data Science

SCDM Live
India conference

2nd - 3rd December 2022
Radisson Blu Hotel, Bengaluru

The Evolving Landscape of Clinical Trials
3rd December 2022
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Disclosures

- Dr Al Palaniappan and Dr Noushin Brealey are both full-time employees of GSK, holding shares in the company

- The views and opinions expressed in this presentation are those of the speakers and do not reflect the views or positions of GSK

Objectives

- Drivers of healthcare costs and pharmaceutical research
- Current route of drug development
- COVID-19 vaccination development
- Accelerating drug development and how to innovate?
- Questions?

Increasing Healthcare Costs Globally

What is Healthcare?

- Organised provision of medical care
  - Prevention of disease
  - Diagnosis and treatment of disease, illness and injury
  - Treatments for long-term recovery

Global Expenditure

- Doubled from 2000 to US $8.5 trillion in 2019 (who.int)

Indian Expenditure

- US $45 billion in 2015-2016
- US $72 billion by 2020 (NITI Aayog Report March 2021)

Why are healthcare costs increasing globally?

Increasing global population

Increasing demand for healthcare

- 1950, average global life expectancy was 47 years
- 2019, average global life expectancy was 73 years (United Nations 2022)

Greater spending power

Growing proportion of global society has greater spending power

Greater availability of healthcare treatments

- Scientific breakthroughs and increase in approvals of novel treatments
- 50 FDA novel drug approvals in 2021 (FDA 2021)

Global Pharmaceutical R&D spend

Global Research & Development (R&D) spend by Pharmaceutical Industry

2012: US $137 billion (Mikulic 2022)
2021: US $238 billion

Drivers for increasing R&D spend

Increasing demand for novel innovations to treat clinical unmet need

Time-limited patent life with sales erosion through generic/biosimilar substitution

Increased understanding of biology and novel targets and new delivery modalities

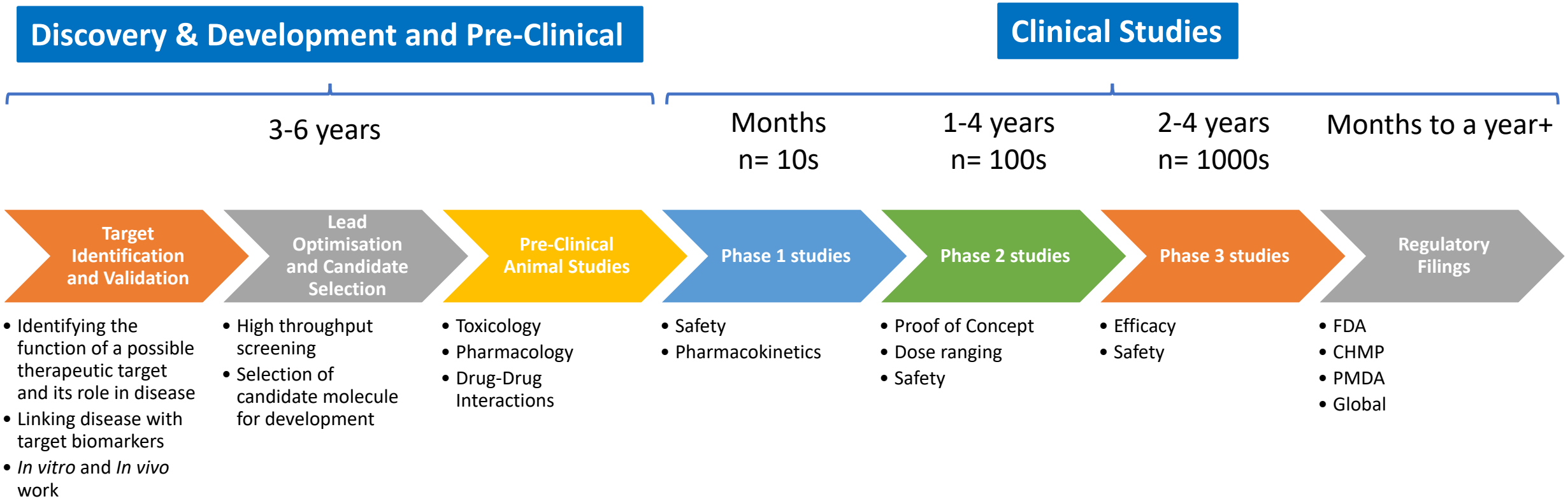
Drug development costs and timescale

Cost to bring new drug to market estimated at US $1.3 billion (JAMA 2022)

Median time to market is 11.80 years (BMJ Open 2021)

90% of clinical programmes fail

The usual route to drug development



Median time to market 11.80 years (BMJ Open 2021)


COVID-19 PANDEMIC

COVID-19 vaccines developed in under a year, without compromising safety


Courtesy of BBC 2020

SARS-CoV-2 identified in December 2019

2nd December 2020, MHRA granted first emergency-use authorisation for a COVID-19 vaccine (Pfizer and BioNTech)

Tests on more than 43,000 people showed that Pfizer vaccine was 95% effective at preventing disease (Nature 2020)	8th December 2020, Margaret Keenan (81 years) became the first person in the world to be given the Pfizer COVID-19 vaccine as part of a mass vaccination programme (BBC 2020)	By October 2022, more than 12.7 billion doses of COVID-19 delivered globally (Bloomberg 2022)

How was this achieved?

Worldwide collaboration	• Scientists and researchers sharing knowledge • Government and private sectors providing source of funding and underpinning the financial risk
Advances in genomic sequencing	• By January 2020, SARS-CoV-2 viral genome sequenced
Strategic investment	• Multiple companies and vaccine platforms, increasing the probability of success
Clinical trial design	• Rigorous standards for efficacy and safety maintained • Speeding up development, by combining phases of drug development e.g. phase 2/3
Working closely with regulators	• Rapid review of clinical trial design • Inline review of emerging efficacy and safety data • Post emergency-use authorisation safety monitoring

Accelerating drug development to reach patients faster

How to innovate and accelerate?

Using genetic and proteomic data

- Genetically validated targets are at least twice as likely to successfully become medicines
- Proteomics
  - Investigating proteins of interest to better understand disease-related mechanisms and identify biomarkers of disease
  - Paving the way for personalised medicine

Clinical trial design

- Multi-part protocols,
  - Incorporating key sub-studies to support rapid progression, e.g. food effect, drug-drug interaction cohorts
  - Incorporation of challenge models in phase 1 to de-risk early
  - Combining phases 1, 2 and 3
- Simpler study designs

Adaptive trial designs

- Ongoing data review to change the study design
  - Smaller studies which can be expanded/stopped early
  - Concentrating on specific sub-populations or dose range

How to innovate and accelerate?

Digital innovation

- Aiding recruitment and enrolment
  - Identifying potential study sites
  - Optimising clinical trial design
- Optimising the patient experience
  - Digital monitoring and wearable devices, with real time data capture and review
  - Decentralised visits and use of telemedicine
- Reducing the burdens for study sites
  - Collection of data directly from electronic health care records

Real world data

- Allowing researchers to go beyond data gathered in traditional randomised controlled trial
- Historical or contemporaneous control data to supplement or be used in lieu of comparator arms (Yap 2021)
  - Rare disease or small target population
  - Significant clinical unmet need
  - Highly predictable disease progression
  - Large expected size effect

Improving and using available regulatory frameworks

- FDA's fast track, breakthrough therapy, accelerated approval and priority review (FDA 2022)
- Can MHRA be nimbler and more efficient post-Brexit?

Can artificial intelligence (AI) accelerate drug development?

Isomorphic Laboratories

- Using AI and machine learning methods to accelerate and improve the drug discovery process

BenevolentAI

- Using AI to explore interconnected disease networks to better understand complexities of biology and derive novel insights

VERISIMLife

- Using machine learning to predict the clinical outcome of new assets before they enter clinical trials

trials.ai

- Mining massive amounts of trial-related documents to aid clinical trial design

deeplens

- Connecting trial sponsors to community oncology practices at scale for patient recruitment

Clinical One

- Platform to unify clinical data from all sources, and harmonises with patients' Electronic Health Care Records
- Collecting data after trial has ended, enabling longer term impact of treatments, collection of real-world data

A lot more investment is needed

Top 10 largest databases in the world

([Compare Business Products 2022])

1. Library of Congress

- 130 million items ranging from cook books to colonial newspapers to US government proceedings

2. Central Intelligence Agency (CIA)

- Little known about the overall size

3. Amazon

- World's biggest retail store
- Keeps extensive records on its 59 million active customers

4. YouTube

- More than 100 million clips watched per day
- Accounts for >60% of all online videos watched

5. ChoicePoint

- Background financial check service
- Contains information about American population –addresses, phone number, driving records…

6. Sprint

- World's largest telecommunication company
- Offers mobile services – keeping track of all calls placed on their network

7. Google

- 91 million searches per day
- Accounts for close to 50% internet search activity

8. AT&T

- United States' oldest telecommunications company
- Contains 1.9 trillion calling records

9. National Energy Research Scientific Computing Center (NERSC)

- Atomic energy research, high energy physics experiment, simulations of the early universe and more

10. World Data Centre for Climate

- Data for and from climate research are collected, stored and disseminated
- Information on climate research and anticipated climatic trends

Could this be the future?

Thank you!