AI in Drug Development: Opportunities and Challenges

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Overview: Challenges of current development model

- **Time**
  - Average time from test tube to market is estimated anywhere from 10 years or more (Tufts Center for the Study of Drug Development).
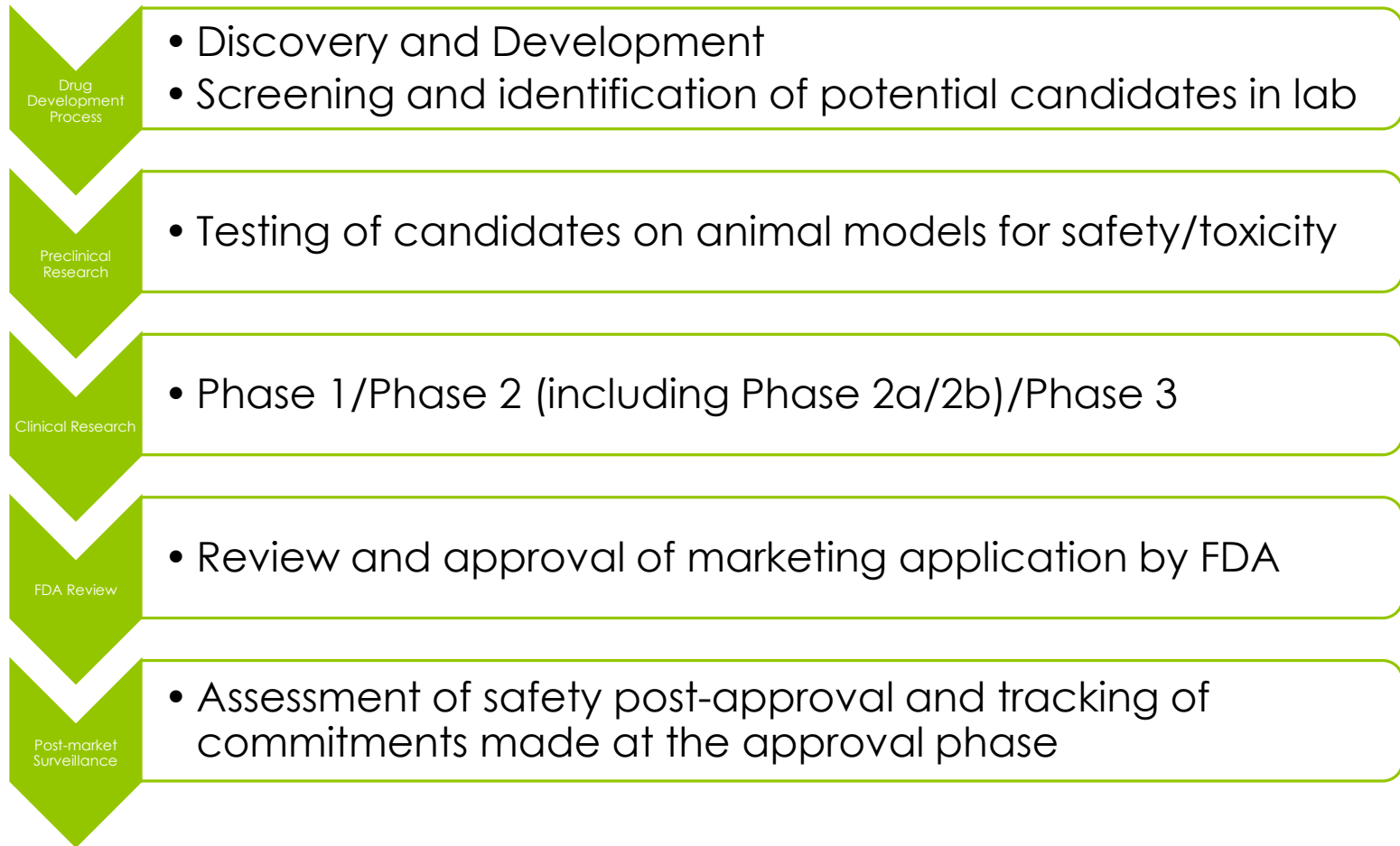- **Failure Rate**
  - 80 percent or more of potential drug candidates fail in the early phases, leading to large failure rates
- **Costs**
  - Cost of development of a product from test tube to clinic/patient is estimated to be 2.55 billion (Tufts Center for Study of Drug Development)

Traditional Model of Clinical Development (FDA)

Drug Development Process
- Discovery and Development
- Screening and identification of potential candidates in lab

Preclinical Research
- Testing of candidates on animal models for safety/toxicity

Clinical Research
- Phase 1/Phase 2 (including Phase 2a/2b)/Phase 3

FDA Review
- Review and approval of marketing application by FDA

Post-market Surveillance
- Assessment of safety post-approval and tracking of commitments made at the approval phase

Using AI to advance drug discovery

- Using AI to find insights into a disease
  - Examples
    - Machine learning and deep learning to:
      - Insights and patterns in data pools that can be used to generate hypotheses
      - Examples:
      - IBM Watson used by Pfizer in immuno-oncology research
      - Benevolent AI is using this tool to aid in determining how compounds target certain therapeutic areas

AI in Discovery and Development: Overview

- AI as a tool is not new, been in existence since the 1980's

- Tool to analyze specific data or large scale data/information to aid in the drug discovery and development process by finding specific targets for specific diseases/therapeutic areas

- AI may be more effective in areas such as immuno-oncology or auto-immune diseases (e.g., identification of the genetic cause)

Screening and Assessment

- To screen a potential new compound against similar available targets for activity
- To screen compounds in cells or animal models to predict activity
  - Examples
    - Exscientia AI platform to screen compounds in cells or animal models
    - Atomwise to identify potential drug candidates

Repurposing Existing Drugs

- Finding new uses (e.g,, indications) for previously approved drugs using AI
- Already studied or proven drug safety/toxicity profile, so less risk of failure
- Examples
  - IBM Watson and Teva Pharmaceuticals using real world data and mathematical algorithms
  - NuMedii and Astellas Pharma to identify new drug candidates using machine learning

Use in personalized or precision medicine

- Analysis of individual health data and predictive analysis to identify effective treatment on a patient specific basis
- Application easier than with large scale data and less chance of machine error
- Example
    - MIT Machine Learning Group to develop deeper understanding of disease process and design drugs

Challenges in Clinical Development

- Clinical trials fail for a variety of reasons, including failure to recruit enough participants, mid-trail patient drop out, unintended & severe side effects, and poor data collection methods. (CBI Insights, 2018)

- Naturally, trials that fail at a later stage prove more costly for both the company conducting the trial and the patients. (CBI Insights, 2018)

AI as a tool to aid Clinical Development

- Matching the right trial with the right patient
- 80 % of clinical trials fail to meet enrollment timelines
- 1/3rd of Phase 3 early terminations are due to enrollment challenges
  - Potential solution is Electronic Health Records (EHRs) and using AI as a tool to analyze this data to match patients with trials

Challenges of AI in Clinical Trials

- Concern with data confidentiality and patient privacy with EHRs and AI
- GDPR and the data protection is another concern
- HIPAA and protection of patient data
- AI may not process information in different hospital setting for example in the same way; no standadrization of the data formats etc.

Conclusion: AI and Development

- AI is potentially a tool for advancing discovery and development however there are a myriad of challenges that need to be overcome before it can be implemented across the board.

THANK YOU FOR YOUR TIME AND ATTENTION TODAY!