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Development Strategy for the production of Novel Drugs

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- What are Novel Drugs?
- What is the need of having a strategy for development of novel drugs?
- Unknown mechanism of action.
- Lack of appropriate animal models.
- Long clinical development timelines.
- Safety issues observed in clinical Development.
- Lack of appropriate regulatory pathways and guidance documents.
- High cost of development.
- Lack of government support.
- Inadequate collaboration between Industry, academia & govt.

- Alternative Solutions to animal testing

 - Organ on chip,

 - Computational and mathematical models etc.

- In silico drug design

- AI Tools

- Identification of molecular targets

- Well defined regulatory pathway for drug development

- Novel clinical development methodologies

 - Adaptive clinical trial design,

 - Umbrella trials, basket trials & platform trials etc.

Strategies to tackle challenges



- Multi disciplinary expert collaboration
- Robust models of industry, academia and government collaboration
- Novel excipient/adjuvant development
- Novel drug delivery systems
- Repurposing of drugs
- Development of CRAMS Services

- Drug development is becoming increasingly challenging.
- Robust Industry, academia & govt collaboration.
- Multi disciplinary expert involvement from the conceptual stage.
- Well defined regulatory pathway.
- Novel clinical development pathways.
- Totality of evidence.
- Fast track or expedient review.



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