Simulating Clinical Trials: *InsilicoSource*

PRIORITY AREA: SECTION 5 (2B)

Section 5: Harness Diverse Data through Information Sciences to Improve Health Outcomes: Strategic Plan for Regulatory Science

2. Develop and apply simulation models for product life cycles, risk assessment, and other regulatory science uses:

    a. Identify opportunities and develop computer simulation and modeling to streamline data analysis and model biological systems and their responses to agents of concerns, such as toxins, pathogens, electromagnetic energy, and biomaterials;

    b. Promote novel clinical trial design using simulation, new statistical models, and novel animal models/animal model alternatives.

What is simulation?

Imitation of situation or a process

In Silico-Computational model

https://www.youtube.com/watch?v=dn8e1ffWAYg

THE CONVERSATION
Academic rigor, journalistic flair

Why computer simulations should replace animal testing for heart drugs

March 26, 2018 9.39am EDT

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Safety is imperative before new medicines are given to patients – which is why drugs are tested on millions of animals worldwide each year to detect possible risks and side effects. But research shows computer simulations of the heart have the potential to improve drug development for patients and reduce the need for animal testing.

Animal testing has, to date, been the most accurate and reliable strategy for checking new drugs, but it is expensive, time consuming and – for some – highly controversial.

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Why use simulated models?

Time

Cost

Accuracy

computational models representing human heart cells show higher accuracy (89-96%) than animal models

Safety

Lives

GLP

Human
Higher
Predic
Cardio

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Hermans[2],
Blanca Rodrigu

[1]Computational C
United Kingdom
[2]Global Safety, Ph
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[3]Oxford Compute

Early predicti
raise ethical a

U.S. Department of Health and Human Services
U.S. Food and Drug Administration

CDRH's Commitment to M&S

Medical Device Innovation Consortium
Computer Modeling and Simulation Program

The Future of Evidence

Quick and **Predictable**
access for **Patients** to **Innovative** technologies
enabled by
Computation Modeling and Simulation
Evidence of safety and performance

MDIC
MEDICAL DEVICE INNOVATION CONSORTIUM
ALIGN | ACHIEVE | ACCELERATE

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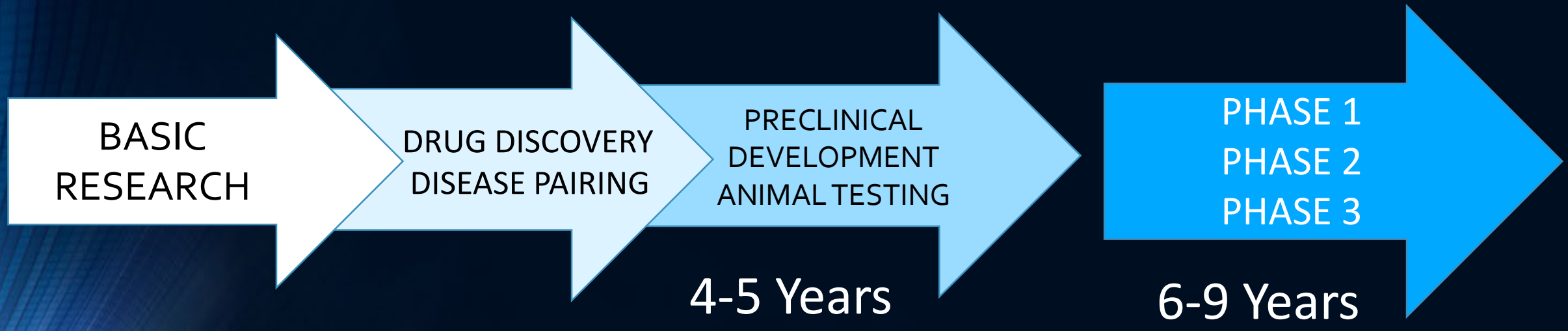
Where does simulation fit?



What would this entail?

- Proposing a centralized database that allows for data sharing of trials already using simulation. Database will include a space for clinical trails registration number, simulation upload and study info.

- https://www.powtoon.com/c/eVlX5lLrF2B/1/m