Digital Animal Replacement Technology
Shift from traditional animal testing and adopt viable, ethical and sustainable alternate approaches

Current safety and efficacy testing approaches rely on animal testing and require skilled manpower, time-consuming protocols, and high cost. DART aims to utilize next-generation intelligent technologies that apply deep-learning neural network algorithms to generate highly accurate readings in reduced time and cost while eliminating the need to use animal models.

The replacement of an animal test is not just a scientific but also a bureaucratic process. However, with the FDA Modernization Act 2.0 passed in December 2022, researchers are now allowed to use scientifically proven, non-animal testing methods, such as cell-based assays, microfluidic chips, tissue models, computer models, and human volunteers, when possible in support of more ethical and sustainable approaches. The European Parliament in September 2022 has also adopted a resolution to phase out animal testing.

The current gold standard for safety assessments in the Pharma/Biotechnology industry involves conducting animal studies, which have challenges associated with it.

Industry Challenges

Loss of animal life:
Every year, over 110 million animals are killed due to scientific experiments in the U.S. alone.

Higher costs:
Maintenance of animal subjects, and utilization of skilled manpower over multiple years increase the costs associated with drug development.

Low translational data:
96% of drugs that pass animal tests fail in human clinical trials. When extrapolated to humans, many animal models have low predictive value on how a drug will behave.

Time-consuming:
The process to get the closest predictive rate is extremely time-consuming, and is riddled with false positives or false negatives, which delay the development process or provide misleading or ambiguous results.
Our offering, DART (Digital Animal Replacement Technology) offers a single non-animal biobank-enabled workstation that can be applied to safety and efficacy assessments to yield human-relevant data points.

DART is an AI-based solution that can be used to predict neurovirulence, neurotoxicity, and sterility-like safety concerns in the workflow during the R&D, clinical trials, and production phases.

An in-vitro platform that comprises of human micro-physiological systems created by utilizing ethically sourced biobank biologics

A Digital Workstation leverages machine learning algorithms and advanced intelligence capabilities to predict safety concerns from microscopic images generated from the biologic reaction and responses of the in-vitro platform treated with aliquot samples of the sample drugs or agents

The annotated and processed images are then analyzed against benchmark patterns that have been derived through segmentation model training to provide accurate predictions.

**Business Impact**

**Obviate the ethical dilemma** as DART does not require experimenting on animals or biopsies, and is in accordance with the 3Rs (Replacement, Reduction, and Refinement) of animal testing

**More relevant to human physiology** since the test is based on healthy human biobank-sourced stem cells

**Reduce testing time** from 28 days to a few hours and enables massive throughput; such agility is conducive to developing and testing vaccines and other biologics and drugs faster

**Integrate seamlessly with** the existing quality check workflow/standard operating protocols

**Reduce technical variability** between measurements due to the quantitative nature of the test

**Customize to any phenotypic distinct population** that the vaccine is intended for, or check for any genetic basis/susceptibility for neurovirulence while being agnostic to mutations occurring in the pathogen

**Reduce high costs** involved with traditional processes and failure rates

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