

Proposal for a Provisional FDA Designation Targeting Biomedical Products Evaluated with Novel Methodologies

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Introduction and Objectives

The FDA oversees food, pharmaceuticals, and medical devices.

Recent advances in AI and bio-simulation suggest drug development lifecycle.

This proposal explores:

- A potential reduction in drug development time.
- A provisional exemption designation for innovative drugs and devices validated through new methods.

Emerging Speedups in Drug Discovery

Key factors for potential speedup:

- Automation of labor-intensive tasks.
- Scaling up of foundational models for molecule prediction and target discovery.
- Compute cost reduction.
- In-silicon flywheel effects
- In-silicon clinical trials as partial/complete substitutes for traditional trials.

Next Generation Clinical Trial Technologies (NG-CTTs)

NG-CTTs include:

- Simulation
- Digital Twins
- Organ-on-a-chip methods
- Deep-learning models for safety and efficacy evaluation

A provisional designation would apply to drugs showing promising data from NG-CTTs without fully completing clinical trials.

Proposal for NG-CTT Designation

1. Targets life-threatening conditions.
2. Shows significant improvement over existing therapies.
3. Demonstrates a good safety profile through validated data.

Implementation Approach

A scoring system*evaluates NG-CTT submissions:

- Experimental support and scientific consensus weigh into approval.
- A tailored risk assessment enables flexible, data-driven evaluations.

Conclusion

The provisional FDA designation could foster faster innovation while managing regulatory risks.

This proposal could serve as a bridge for the FDA to adopt emerging technologies, ultimately reducing drug development timelines.

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