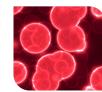
Organoid Impact on Drug Development



drugs that emerge from preclinical development go on to fail in clinical trials.

Process Overview

Start with patient-derived material or pluripotent stem cells.



Mix with an ECM. such as Corning[®] Matrigel[®] matrix.

Plate cells using desired technique or method, such as embedded, sandwich culture, or dome.

Add media, incubate, and maintain culture.

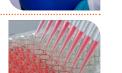
Add drugs for testing.

Obtain readout through microscopy, other imaging methods, or viability assays.









Investing in organoid cultures can improve the success rate of drug trials through more accurate preclinical testing.

In drug discovery, organoids are helping scientists improve the biological relevance and accuracy of preclinical drug development while maintaining efficiency and speed. Organoids are also advancing precision medicine, which the FDA recognizes as important to the future of therapeutics.

Organoids in Drug Testing

- Contain multiple cell types, Can capture toxicities not better recapitulating physiology and function
- Self-assemble into a 3D structure with different cell layers, capturing 3D cellcell and cell-ECM signaling not present in 2D
- Can include multiple clones from a donor, modeling the complex genetics of tumors
- predicted by 2D toxicology studies
- More accurate, predictive results may facilitate greater overall efficiency of preclinical development
- More complex setup, but many new tools, techniques, and platforms are simplifying and speeding up organoid workflows

Organoid Facts

Organs with established organoid protocols include airway, liver, intestine, heart, brain, pancreas, immune system, and others.

The FDA's Advancing Alternative Methods initiative aims to accelerate technologies that can substitute for animal testing, such as 3D cultures, enabling drug developers to seek exemptions under the FDA Modernization Act 2.0.

Organoid technology is advancing scientists' ability to personalize and predict individual response to therapy.

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