SOLUTION

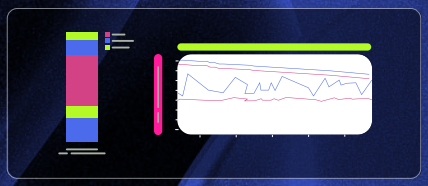
FORMsight^{AI}

Predict and Optimize Cell and Gene Therapy Manufacturing

Two breakthrough AI-powered solutions for addressing the top issues that make biomanufacturing difficult, time-consuming and expensive.

FORMsight^{AI} SIMULATE

Predict your construct's manufacturing output before spending up to millions of dollars on bioreactor test runs.



With **FORMsight^{AI} SIMULATE** you can:

- Predict capsid fill rates and easily identify the proportion of full, truncated and chimeric species
- Predict truncation propensities
- Breakdown truncation contribution proportions by region

FORMsight^{AI} OPTIMIZE

Generate new construct derivatives with the greatest predicted likelihood of manufacturing success and cost efficiency.

With **FORMsight^{AI} OPTIMIZE** you can:

- Identify the ideal combination of construct parameters for maximized predicted full reads, minimized predicted truncation propensity and other key factors
- Generate a new construct design blueprint

Broad Cell & Gene Therapy Use Cases

EXAMPLE NUCLEIC ACIDS

- DNA
- siRNA
- mRNA
- miRNA
- CRISPR Constructs

EXAMPLE VECTORS

- AAV
- Adenovirus
- Lentivirus
- HSV
- LNP

Benefits by the Billions

Replication and packaging issues in cell and gene therapy development represent a multi-billion dollar problem. With FORMsight[AI] you can simulate and optimize therapy candidates for manufacturing from the get-go.

Predicted improvements to a publicly traded gene therapy company's pre-clinical construct design.

UP TO
18%
INCREASE IN FULL READS

UP TO
70%
DECREASE IN TRUNCATIONS

REDUCE MANUFACTURING COSTS
Simulate the therapeutic output of a construct before spending millions of dollars on bioreactor runs.

SHORTEN TIME-TO-MARKET
Minimize manufacturing trial-and-error relating to identifiable construct contamination propensities.

IMPROVE SAFETY
Predict and optimize capsid fill rates before spending time and resources on test production.

EXTEND IP PROTECTION
File fresh patents on newly optimized constructs generated by FORMsight[AI].

Powerful AI Tailored for Cell and Gene Therapy

- Turnkey path to adopt AI, get up in running in weeks not months
- Proven AI models trained to predict truncations and other key contributors to manufacturing contaminations
- Analysis of datasets with >80 million parameters

Stay Safe, Stay Compliant

FDA Draft Guidance on AAV-Based Gene Therapies

In 2021, the FDA's Cellular, Tissue, and Gene Therapies Advisory Committee (CTGTAC) shared a report and draft guidance* on safety issues for AAV-based gene therapies. In its report the FDA singled out the importance of screening AAV-based gene therapies for empty capsids.

*SOURCE: PROPOSED DRAFT GUIDANCE FOR FDA CONSIDERATION: TESTING OF ADENO-AS SOCIATED VIRAL (AAV) VECTOR-BASED HUMAN GENE THERAPY PRODUCTS FOR EMPTY CAPSIDS DURING PRODUCT MANUFACTURE. 2021

How FORMsight[AI] Helps You Stay Safe

HIGHER CAPSID FILL RATES
Avoid the truncations that frequently lead to empty capsids.

PRE-EMPTIVE FDA COMPLIANCE
Meet or beat FDA draft guidance on AAV capsid fill rates.

FULLER CAPSIDS, BIGGER YIELDS
Increase the number of viable doses per manufacturing run.

SAVE MONTHS AND MILLIONS
Reduce FDA approval cycles, CMC iterations and costs to reach clinical trial stages.

Ready to accelerate your cell and gene therapy development?

Connect with our team today learn how Form Bio can help you go further and faster.

Learn more

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