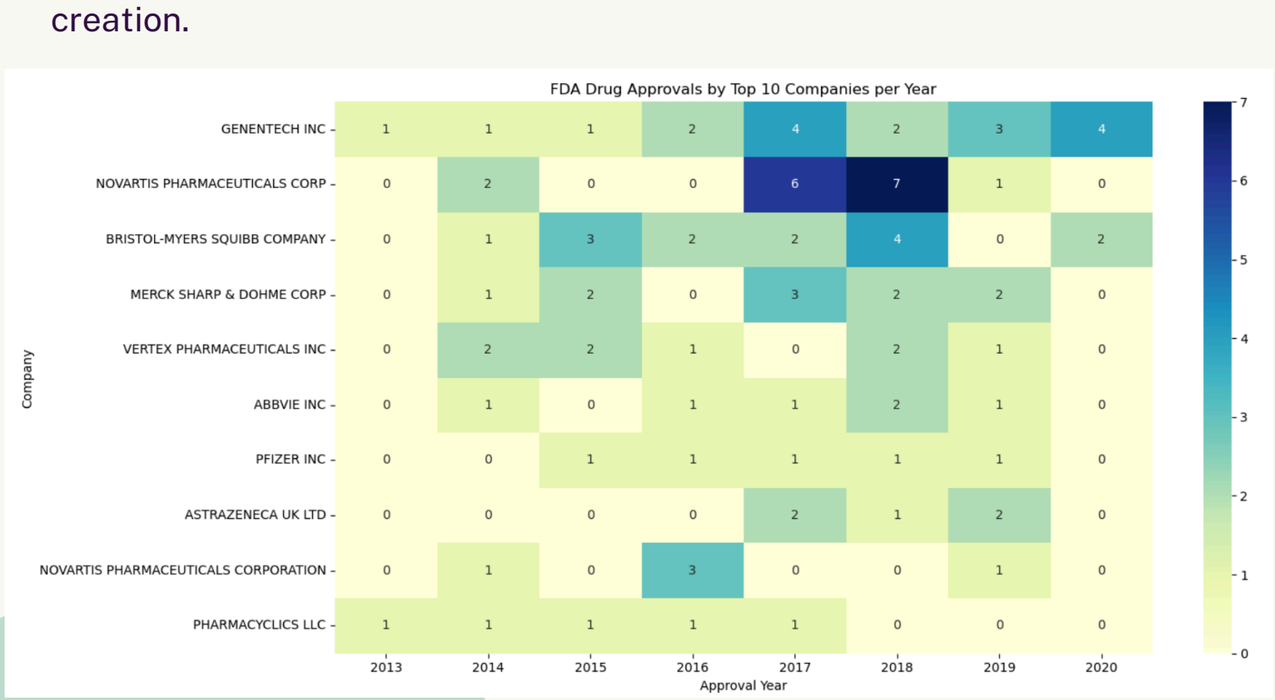
Manvi Semitha, Data Science: Methods and Context- Spring 2025, Professor Neda Heidari.

What is the Rate at which Transformative Drugs are Developed?

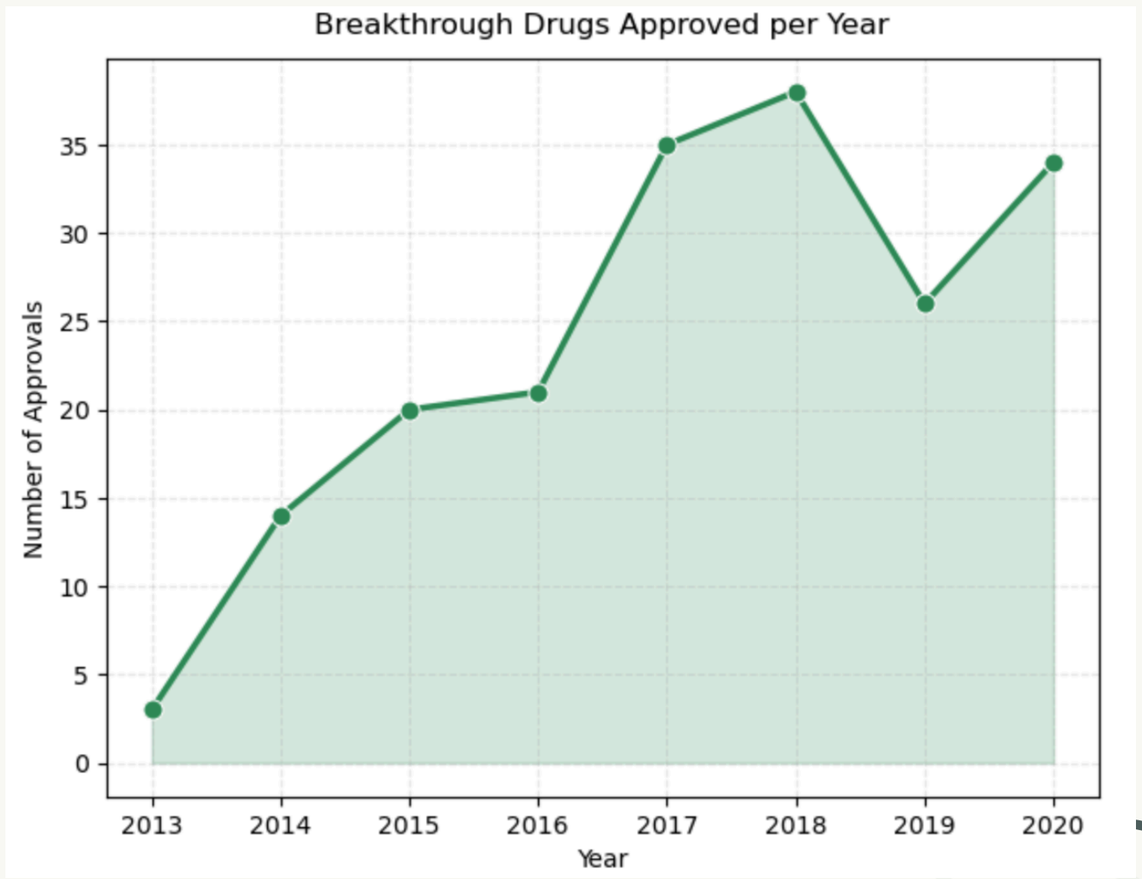
INTRODUCTION

Most treatments are incremental, a few are **“transformative”** - far better than anything else available for the condition they treat. With my research I want to quantify **how often do transformative treatments come around and how?**
I want to look into the discovery and development years of the transformative drug and see what factored into their discovery and whether there is any correlation between certain factors and the drug’s creation.



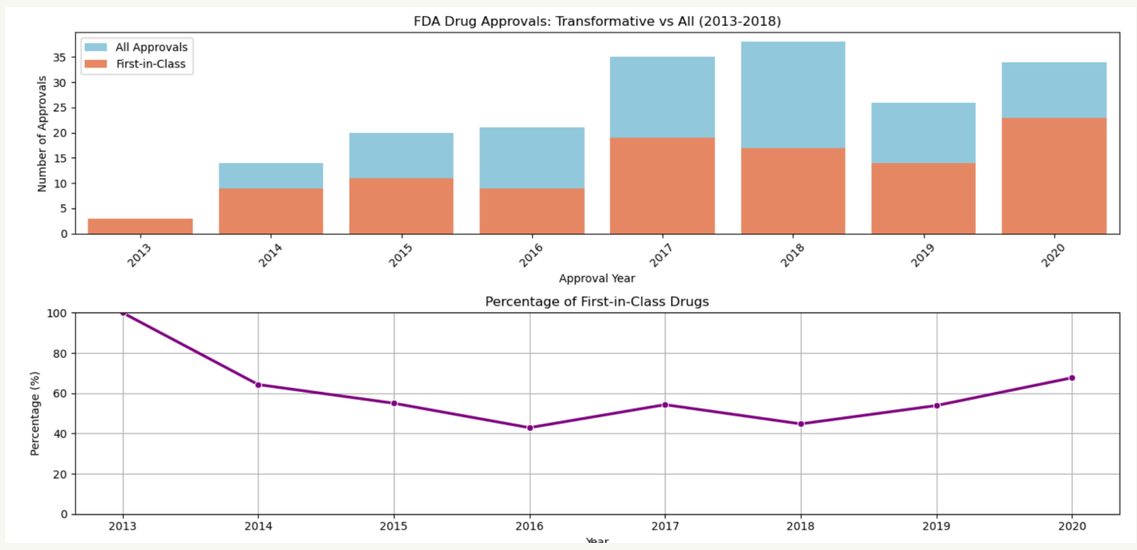
METHODOLOGY

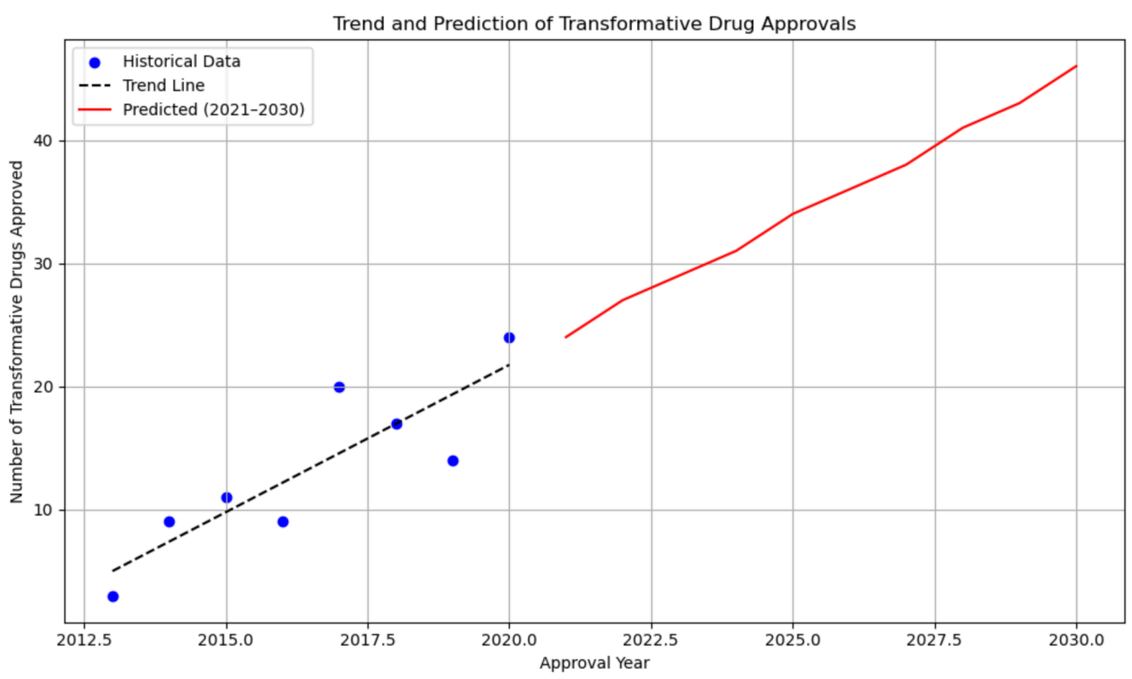
- Data was extracted from the FDA Breakthrough Drugs PDF list with a tool called Tabula.
- The resulting CSV file was coded and formatted using DeepSeek.
- Using an online CSV converter the code was then exported into a new CSV file.
- The CSV file was then imported into excel where it was delimited by “,”
- The data was cleaned- Unavailable data was removed, and cells were formatted into text and number cells.
- The datasets were in table CSV format and visualised through JupyterLab.



RESULTS, ANALYSIS AND ETHICAL IMPLICATIONS

- The analysis of FDA-approved drugs from 2012 to 2022 indicates a slight upward trend in the approval of breakthrough drugs, despite year-to-year variability.
- Predictive linear regression models, trained on historical data up to 2020, forecast a steady increase in the annual approval of transformative and FIC drugs through 2030.
- For instance, the model predicts an increase from approximately 24 transformative drugs in 2021 to around 46 by 2030.





- There is an uptick in transformative drugs approved in 2017-2018 due to discovery of CAR-T cell therapy by Novartis.
- Genentech- a research driven biotech company has been consistently contributing to breakthrough drugs since 2012.
- There is a peak in 2020 due to the FDA expediting approval processes attributed to Covid-19.

There are ethical and data limitations in this analysis-

- **Data Bias:** Reliance on FDA data excludes non-U.S. approvals, potentially overlooking global innovations and skewing results toward Western medical priorities.
- **Commercial Influence:** Pharmaceutical companies may prioritize profit-driven "transformative" drugs (e.g., high-cost therapies), limiting affordability and accessibility.

CONCLUSION

The rate at which transformative drugs are developed has been steadily rising with the number of drugs developed predicted to almost double over this decade. New technological developments, and external pressures such as covid-19 seem to be driving innovation as these situations expedite FDA approval processes. For future analysis, I would look into other contributing factors such as funding and the rate at which everyday drugs are approved.

DATASET

FDA Breakthrough Drugs list 2012-Current:
https://www.fda.gov/media/95302/download

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