Before You Invest:

Lessons From What Patient Data Reveals About Drug Programs

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Solo driver vs a “team player”

FGFR2 case study

$1.9B+

Paid by Amgen for the FGFR2 asset

A Costly Failure

Gastric cancer is a high unmet need. And FGFR2 showed strong preclinical data supported by an early clinical signal. What was there not to like?

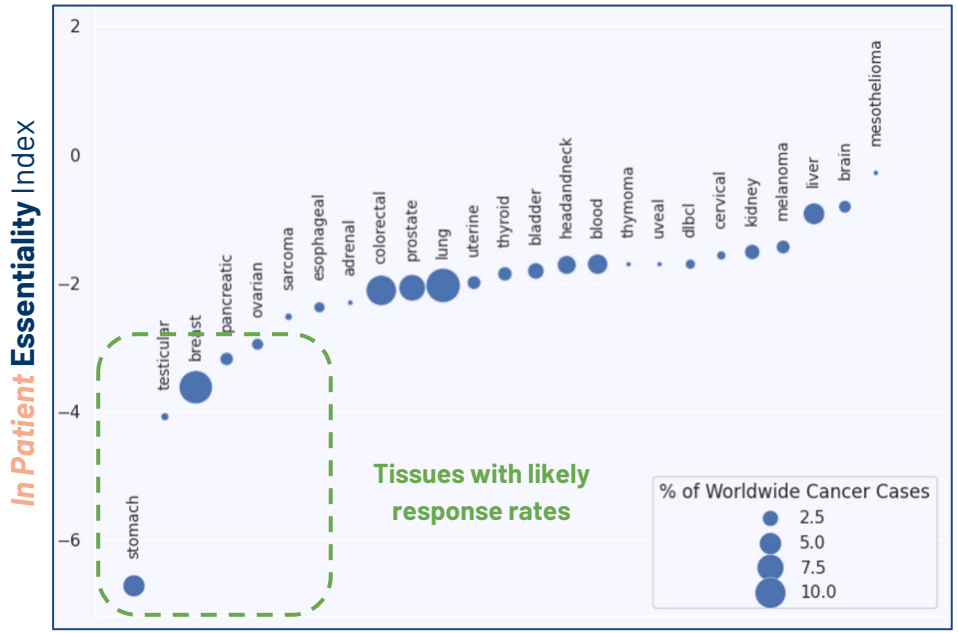
Later phases of clinical development did not recapitulate the early efficacy signal. So what went wrong?

What the Patient Data Revealed

Patient data uncovered that FGFR2 is not a solo driver; instead, it is part of a “team” driving gastric cancer.

- Inhibiting sole drivers like HER2 or EGFR translates into high clinical response rates.
- FGFR2 is part of a “team” driving gastric cancer. Therefore, despite overexpression of FGFR2, its inhibition is necessary but insufficient to achieve high clinical response rates.
- Hence, the combination approach or a bispecific antibody targeting this “team” of drivers is required for clinical success.

Gastric cancer is indeed the strongest indication for FGFR2



Consistent with preclinical and clinical results, data from patients show that Gastric cancer is the best tissue for the FGFR2 program.

The Take-Home Message:

Correlation is not causation

Cancer biology is complex

When you observe a drug target being overexpressed, do not jump to the conclusion that its inhibition will translate into clinical efficacy. Gleevec, Herceptin and Tagrisso succeed because they inhibit solo drivers.

Patient data opportunity

Data from patients can reveal the complexity of tumor biology. Ask a good question: is my target a solo driver or part of a “team” and you will save years of clinical development and avoid painful surprises like FGFR2.

Strategic Recommendations

From Insight to Action

Consult Patient Data for Reliable Outcomes:

Preclinical models are valuable but inherently limited.

The models are important, but remember, they are constructed to test a single dependency, not to assess the complexity of real tumors.

Solo vs team player.

Use patient data to determine whether your target is an independent driver or is supported by another player.

Patient data should be used before your trial begins.

There's a common misconception that clinical trials are required to assess response rates. Treatment-naive patient data can actually identify factors that limit clinical response before any patients are dosed.

Medicines intended to work in patients should be developed with patient data in mind.

For inspirations check:

https://www.gordion.bio/before-you-invest