Black Diamond networks

THE NEXT BIG THING

Tracking the volume and velocity of drug trends

The same consumer forces that brought us bell bottoms, Beanie Babies, and the Macarena also influence the drug development cycle. "Fashionable" drugs—and the attention they garner—generate real impacts on consumerism, regulatory priorities, and by extension, future therapy pipelines.

As demand for COVID-19 vaccines nears the peak of its natural curve, we find ourselves wondering "What comes next?" Black Diamond Networks (BDN) takes a look at why and how a drug trend unfolds to help predict regulatory shifts and prepare for resource gaps before they happen.

SPOTTING TRENDS

Drug trends may be easier to spot in hindsight. One observational study of FDA drug approvals notes "a wide variation in the number and category of approval" over two decades.[1] However, closer examination reveals periods of time—marked periodicity—where self-similar categories emerge. Think cholesterol statins in the late 80s and early 90s. Therapeutic focus areas shift over time, and they bring regulatory priorities along for the ride.

TRENDING THERAPIES

1970s
Infectious disease control

1980s
Psychiatric therapies

1990s
Oncology & immunology

2000s
Cardiovascular disease & neurology

2010s
Personalized medicine

2020s
Cell and gene therapies (CGT)

SPARKING TRENDS

Biopharmaceutical firms weigh countless factors in deciding when and where to invest in R&D. Three key considerations include:

1
Therapeutic potential
volume of evidence and positive signals

2
Maturity
how close to market the potential solutions are

3
Competitive landscape
"white space" opportunities for unmet demand[2]

The development landscape exists in a state of constant flux. Thus, any time a firm can recognize—or catalyze—a trend, the more likely they are to capitalize on it.

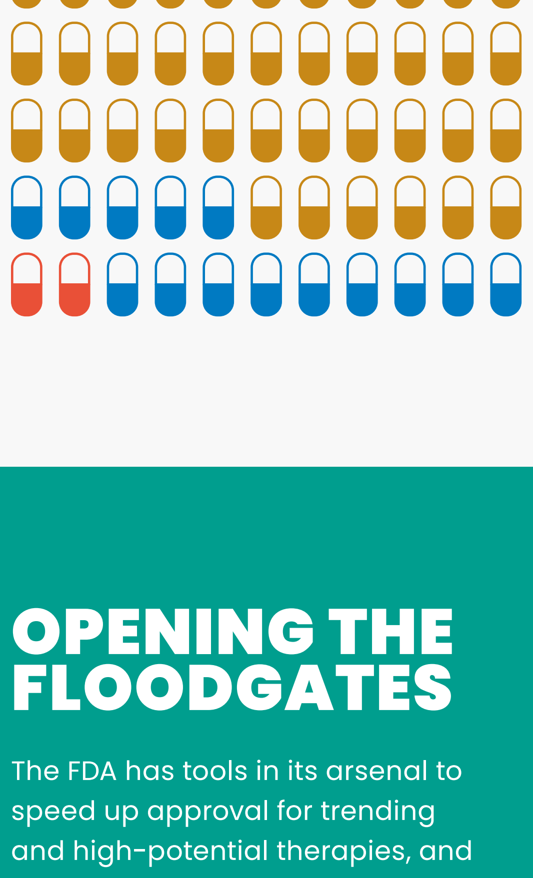
LOOKING FOR AN EDGE

Developing new drugs is expensive and risky. It's no wonder biopharmaceutical firms want to build a bandwagon for consumers to jump on. To analyze where spikes might occur, developers increasingly turn to artificial intelligence. AI is used to analyze the fundamental requirements of a drug product from a consumer's viewpoint, as well as to forecast sales and promote awareness.[3]

LOW SUCCESS RATES
Only 1 in 1000 potential drugs ever reach human testing.[4]

EXPENSIVE
R&D costs more than $1.3 billion on average per approved compound.[5]

TIME-CONSUMING
It takes an average of 12 years to bring a new medicine to market.[6]



WHAT'S HOT NOW

Right now, there's a perfect storm of factors creating buzz around cell and gene therapies, including low interest rates, intrigue around gene editing, and the lure of lucrative pricing models.[7] There are currently more than 900 active investigational new drug (IND) applications involving gene therapy products, and the size of the global biologics market is growing at close to 10%.[8] Ultimately, this investment is expected to fuel 10–20 FDA approvals by 2025.[9]

CELL AND GENE THERAPY PIPELINE
Development and Trials by Phase: 2020 [10, 11]

IND Applications **900**
Phase 1 **383** • Phase 2 **685** • Phase 3 **152**
Expected approvals **20**

OPENING THE FLOODGATES

The FDA has tools in its arsenal to speed up approval for trending and high-potential therapies, and it's prepared to use them—as was made crystal clear with COVID-19 vaccines and therapies. "The use of fast track, accelerated approval, and priority review programs have also been steadily increasing since 2000," notes Researchgate.[12]

> **"It's amazing to see the shift in investigational resources and energy that comes along with a promising new modality or mechanism of action. Developers who capitalize on all the channels available to them—from research analytics to regulatory priorities—stand to accelerate commercial success."**
>
> —**Ben Locwin**, Executive SME, Black Diamond Networks.

MARKETING SPEND FUELS THE FIRE

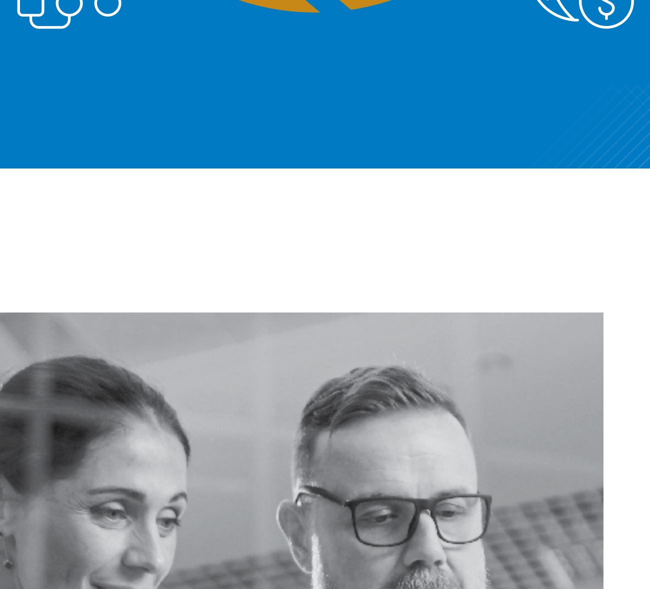
As drug trends pick up momentum, advertising dollars flow. Big pharma spends more than $20 billion each year to persuade doctors and other medical professionals of the benefits of prescription drugs. Since the first prescription drug ad for Rufen (ibuprofen) appeared on TV in 1983, consumer drug marketing has also exploded.[13]

Remember the purple pill? The bathtub silhouettes? The Nasonex bee? Jon Bon Jovi for Advil? Ars Technica reports "What's new—and why this is now a shadier situation—is the explosion of direct-to-consumer (DTC) marketing that couples with those efforts for a one-two marketing punch."[14]

DIRECT-TO-CONSUMER ADVERTISING (DTCA) GROWTH
Pharmaceutical ad spend in the U.S. in billions [15, 16, 17, 18]

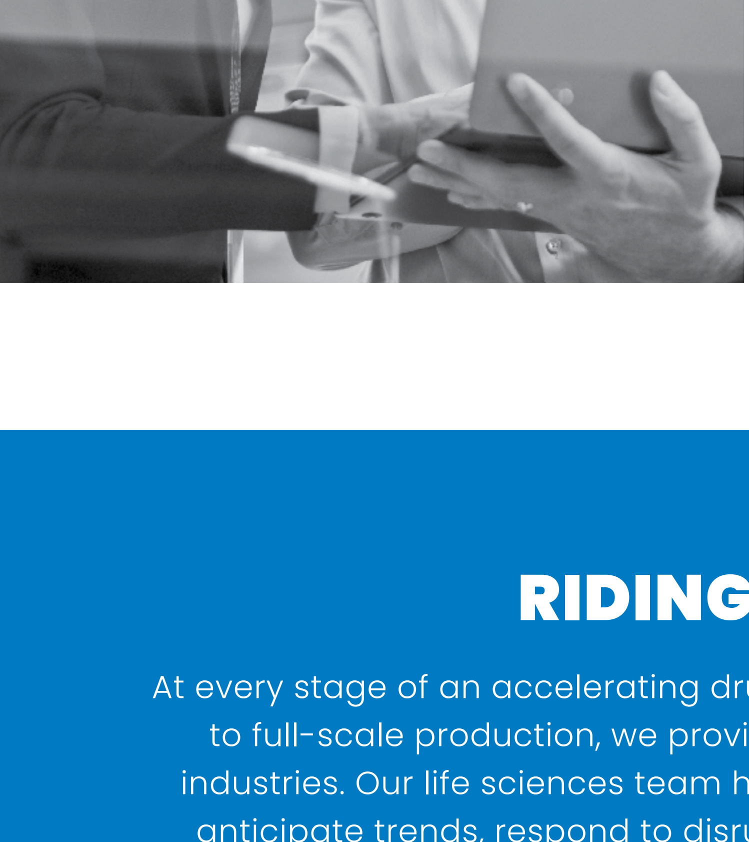
A SELF-PROPELLING CYCLE

As interest spikes and critical mass builds, investment money flows in, more firms get in the game, and more projects get funded. Follow the money to spot the rising trends. For example, regenerative medicine saw dramatic increases in funding and public interest from 2019–20.[19]



In one year in regenerative medicine:

Developers jumped **10X** to **1,100**
Global financing rose **2X** to **$19.9B**
IPOs increased from **6** to **14**
Stock performance increased **44%**



NOT SO FAST

As interest scales upward, so must capacity. Expedited approval of anticancer and biologics is seen as a recent trend in drug development, but we already see evidence of supply chain challenges and production constraints in these sectors.

According to the Alliance for Regenerative Medicine, "...the complex manufacturing process for cell and gene therapies—and the regulatory environment surrounding it—remains a key challenge for the sector." [20] It's no surprise that using outsourced CRO and CDMO services has become the norm in the industry.

When it comes to catching a trend, be careful what you wish for. The rush to market can wreak havoc on talent forecasting and leave you short of skilled talent at critical junctures.

RIDING THE WAVE

At every stage of an accelerating drug trend, BDN is there. From proof of concept to full-scale production, we provide highly skilled consultants to regulated industries. Our life sciences team helps you prepare workforce strategies that anticipate trends, respond to disruption, and reflect changing FDA priorities.

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ENDNOTES

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