Personalized Healthcare Brand Index Surveillance;
Pharma Communication Trends for Companion Testing

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Our Focus

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Our Focus

- As Pharma pipelines depend ever more on diagnostics as a gatekeeper to physician prescribing and, as we enter highly competitive full personalized healthcare markets like PD-L1, WHO is communicating WHAT around testing will become a critical success factor.

- Our goal in exploring the *Pharma Communication Trends for Companion Testing* was therefore to determine WHO is educating about personalized healthcare (PHC) in connection with therapy branding (initially in oncology) and to understand HOW the testing narrative around a brand is shaping current and evolving brand strategies.

- Our testing narrative is not about right versus wrong, but rather about understanding a range of market activities. In this way we hope to understand HOW and WHERE investments in test communication are relevant, and WHEN and WHERE they impact brand differentiation.

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Our Focus: Oncology Brands

We analysed 16 oncology brands launched between 2004 and 2014.*

PM therapy	Launch date	Company	Primary indication	Primary biomarker	Biomarker type	Approved CDx?
Bosulif (bosutinib)	2012	Pfizer	Chronic myeloid leukemia (CML)	BCR/ABL	diagnosis/monitoring	no
Erbitux (cetuximab)	2004	BMS/Lilly/Merck Serono	Metastatic colorectal cancer (mCRC)	KRAS	predictive	yes
Gilotrif (afatinib)	2013	Boehringer Ingelheim	Non-small cell lung carcinoma (NSCLC)	EGFR	predictive	yes
Iclusig (ponatinib)	2013	Ariad Pharmaceuticals	CML	BCR/ABL	diagnosis/monitoring	no
Imbruvica (ibrutinib)	2014	Janssen	Chronic lymphosytic leukemia (CLL)	del 17p	predictive	no, nucleic acid based test
Iressa (gefitinib)	2003	AstraZeneca	NSCLC	EGFR	predictive	no
Mekinist (trametinib)	2013	GSK	melanoma	BRAF	predictive	yes
Perjeta (pertuzumab)	2012	Roche	breast cancer	HER2	predictive	yes
Sprycel (dasatinib)	2006	BMS	CML	BCR/ABL	diagnosis/monitoring	no
Tafinlar (dabrafenib)	2013	GSK	melanoma	BRAF	predictive	yes
Tarceva (erlotinib)	2004	Roche	NSCLC	EGFR	predictive	yes
Tasigna (nilosinib)	2007	Novartis	CML	BCR/ABL	diagnosis/monitoring	no
Vectibix (panitumumab)	2006	Amgen	mCRC	KRAS	predictive	yes
Xalkori (crizotinib)	2011	Pfizer	NSCLC	ALK	predictive	yes
Zelboraf (vemurafenib)	2011	Roche	melanoma	BRAF	predictive	yes
Zytiga (abiretarone)	2011	Janssen	prostate cancer	Circulating tumor cells (CTC)	monitoring	no

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*Brand communication materials were accessed during Q1 2015.

Our Method

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Our Method: Analysis of push and pull factors

We looked at a number of push and pull communication factors which have directly or indirectly shaped the degree of integration between testing and treatment within targeted therapy branding.

Push factors are those shaped by brand teams directly.

Pull factors are those external to the Pharma company or indirectly influenced by competitive Pharma activity.

push

1. Online marketing footprint in support of the asset/testing
2. Strength of 'full personalized healthcare focus' and 'call to action' within online media
3. Asset-related news flow around the biomarker
4. Positioning of testing in therapy communications

pull

1. Footprint of biomarker-related publications across the clinical-research community
2. 'First in proprietary class' status: first to market equals first to drive the need to test
3. The type of test used with the therapy – companion versus complementary
4. Location of testing in the FDA drug label, e.g., testing 'required' by the FDA label

Our Method: Weightings applied to factors

Using trade-off and sensitivity analysis alongside expert discussion, we identified a number of the push and pull factors that had a higher impact than others.

Push and pull factors have been weighted based on expert assessment and analysis. Weightings have been subjected to various sensitivity analyses discussed in this deck.

Higher impact push

1. Online marketing footprint in support of the asset/testing
2. **Strength of 'full personalized healthcare focus' and 'call to action' within online media**
3. Asset-related news flow around the biomarker
4. **Positioning of testing in therapy communications**

Higher impact pull

1. **Footprint of biomarker-related publications across the clinical-research community**
2. 'First in proprietary class' status: first to market equals first to drive the need to test
3. The type of test used with the therapy – companion versus complementary
4. **Location of testing in the FDA drug label, e.g., testing 'required' by the FDA label**

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Testing narrative modalities

In-depth analysis of the impact of push and pull factors suggests four modalities of test communication. We have called these our testing narrative modalities.

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4 testing narrative modalities

Analysis of the Index suggests there are four communication modalities resulting from investments in marketing push and external market pull.

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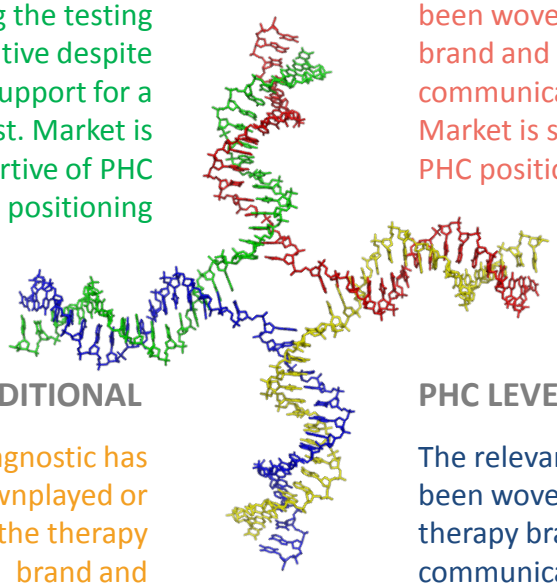
DISCORDANT

Little investment in promoting the testing narrative despite positive support for a need to test. Market is supportive of PHC positioning

PHC INTEGRATED

The relevant diagnostic has been woven into the brand and communications strategy. Market is supportive of PHC positioning



TRADITIONAL

The relevant diagnostic has been downplayed or absent in the therapy brand and communications strategy. Market is neutral or unaware of PHC positioning

PHC LEVERAGED

The relevant diagnostic has been woven into the therapy brand and communications strategy. Market is neutral or unaware of PHC positioning

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Our Findings

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The majority of current oncology therapies fall into 3 of the 4 modalities

More PULL

DISCORDANT

Little investment in promoting the testing narrative despite positive support for a need to test. Market is supportive of PHC positioning

TRADITIONAL

The relevant diagnostic has been downplayed or absent in the therapy brand and communications strategy. Market is neutral or unaware of PHC positioning

Less PULL

PHC INTEGRATED

The relevant diagnostic has been woven into the brand and communications strategy. Market is supportive of PHC positioning

PHC LEVERAGED

The relevant diagnostic has been woven into the therapy brand and communications strategy. Market is neutral or unaware of PHC positioning

Source: Bioceutics Brand Index 2015

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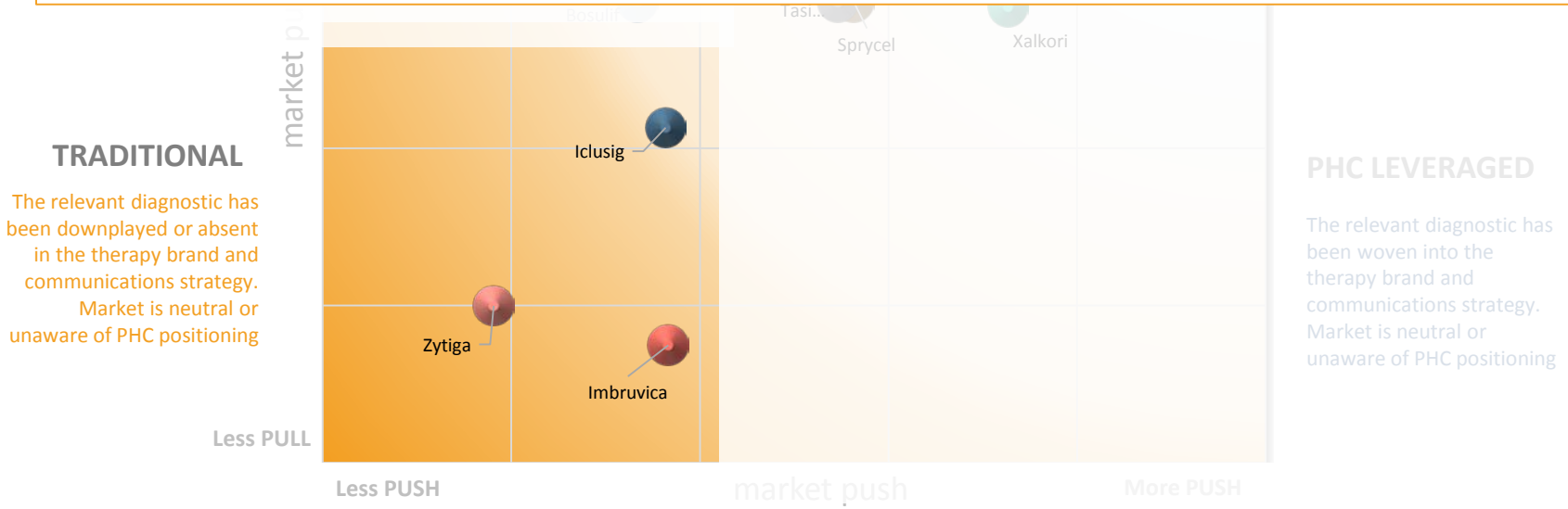
Some therapies are marketed within the traditional modality

Examples:

Iclusig: not first in class and has competition from older drugs; also, the biomarker is not predictive but diagnostic/monitoring, but is well established and widely used so there is less motivation to promote it.

Zytiga: not yet fully established as personalized medicine; biomarker utility is still being investigated and used for monitoring rather than prediction; also, CTC are not specific for Zytiga or even prostate cancer so there is no motivation to promote it.

Imbruvica: similar to Zytiga in that the biomarker is not yet fully embraced by the FDA so co-promotion of the test is potentially a risky strategy.



Source: Bioceutics Brand Index 2015

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Some therapies are marketed within the discordant modality

More PULL

DISCORDANT

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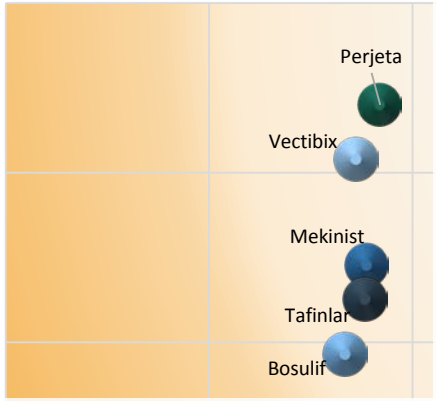

Examples:

Several ‘second in class’ therapies fall into this category.

Mekinist: BRAF crucial for therapy, a de facto 'first in class' MEK inhibitor, but related to the same biomarker as Zelboraf and bundled together with Tafinlar so less effort made on biomarker promotion. In terms of FDA communications it is definitely considered a personalized therapy, and the relatively new biomarker has generated substantial interest from the scientific community in the last decade.

Perjeta: as a ‘sister drug’ to the 1998 Roche launch Herceptin, it benefits from the awareness of HER2 testing already present and may not need to push the testing as hard as other therapies.

Source: Bioceutics Brand Index 2015

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Some therapies are marketed within the PHC integrated modality

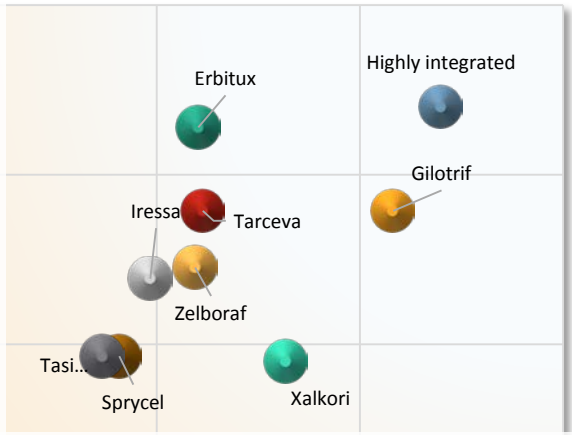
Examples:

Several new and established oncology therapies fall into this category.

Gilotrif (2013): very good campaigns make it the best on market push despite fierce competition as 3rd line EGFR NSCLC, and substantial personalized medicine awareness with Iressa and Tarceva on the market for a long time.

Zelboraf, Xalkori, Erbitux: all are 'first in class' so have more motivation to promote biomarkers and quickly claim their niche in the market.

Sprycel and Tasigna: recently started pushing a personalized medicine strategy with more PM-focused branding but still not as strong as Gilotrif or Xalkori.



PHC INTEGRATED

The relevant diagnostic has been woven into the brand and communications strategy. Market is supportive of PHC positioning

PHC LEVERAGED

The relevant diagnostic has been woven into the therapy brand and communications strategy. Market is neutral or unaware of PHC positioning

Source: Bioceutics Brand Index 2015

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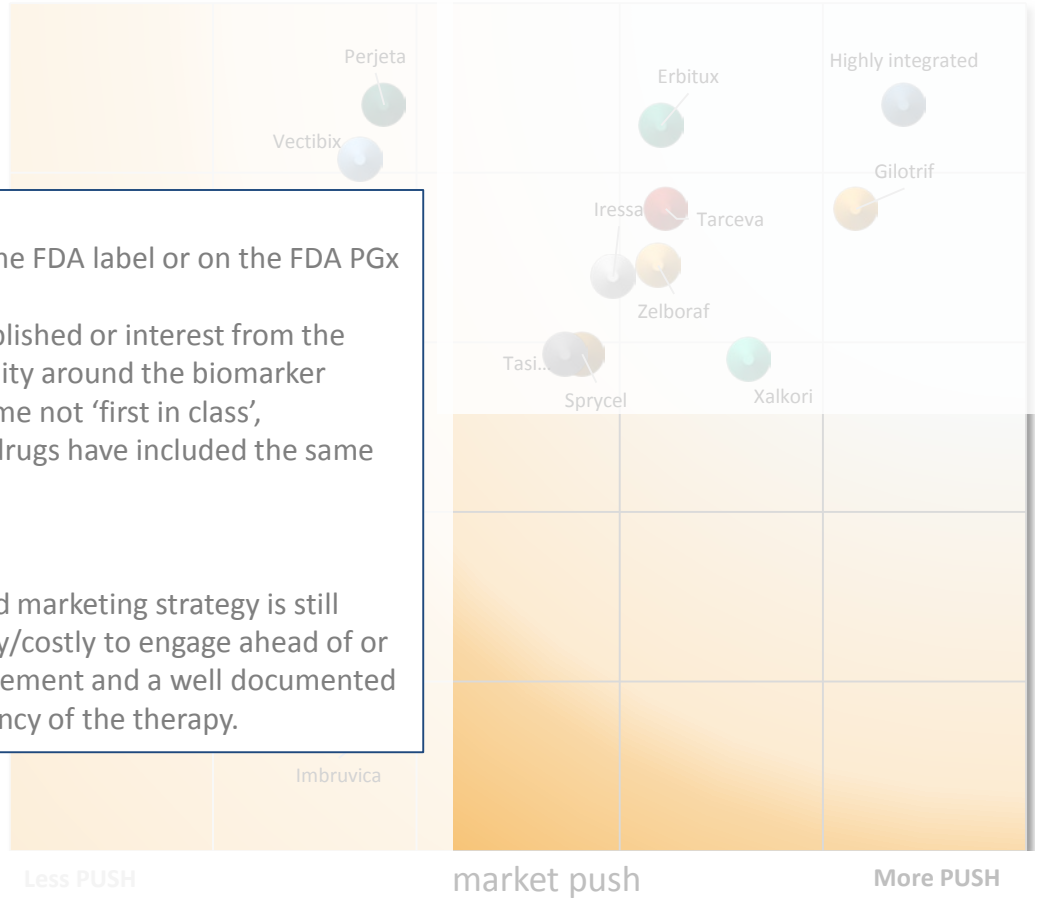
None of the therapies fall within the PHC leveraged modality



Low on PULL factors:

- No biomarker in the FDA label or on the FDA PGx list
- Little research published or interest from the scientific community around the biomarker
- Yet at the same time not 'first in class', suggesting other drugs have included the same biomarker before.

High on PUSH factors:

- A biomarker-centred marketing strategy is still considered too risky/costly to engage ahead of or without FDA endorsement and a well documented biomarker dependency of the therapy.

PHC INTEGRATED

The relevant diagnostic has been woven into the brand and communications strategy. Market is supportive of PHC positioning

PHC LEVERAGED

The relevant diagnostic has been woven into the therapy brand and communications strategy. Market is neutral or unaware of PHC positioning

Source: Bioceutics Brand Index 2015

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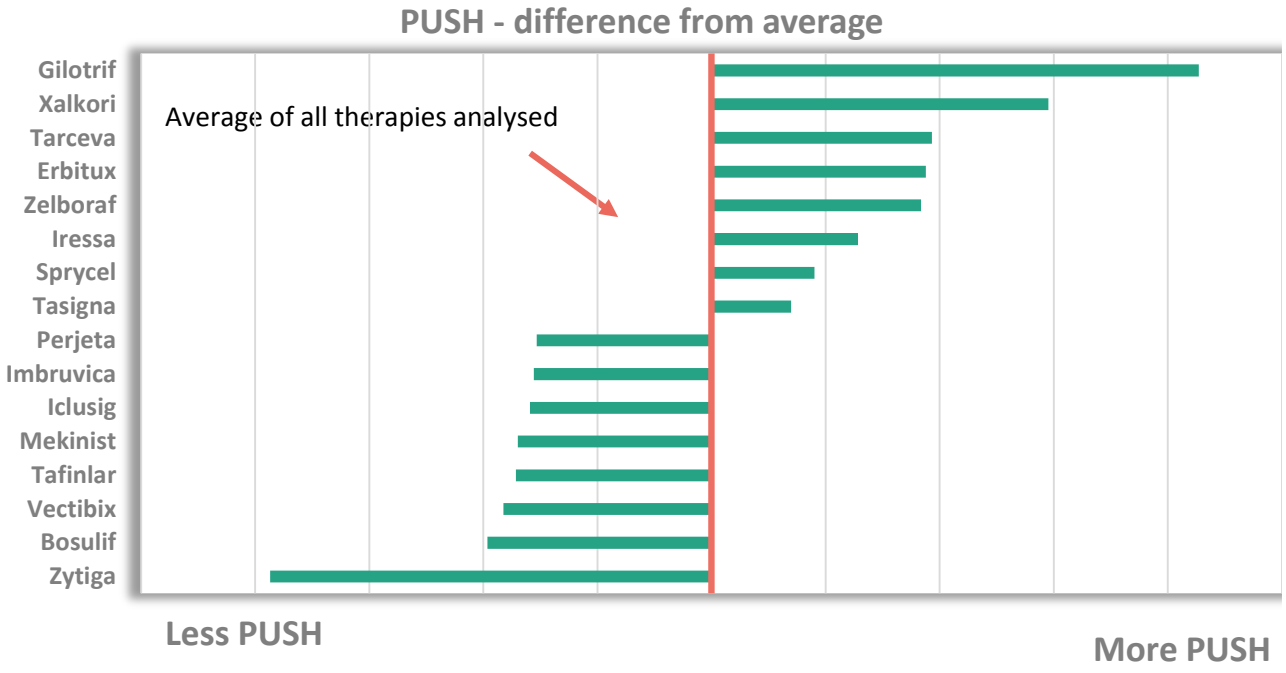
Therapies split on their degree of marketing PUSH factors

There are great differences between the brands in terms of their emphasis on push factors, so not everyone is doing the same.



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Do older therapies lean towards a deeper testing narrative?

Older therapies have an above average push while newer therapies trend below average.

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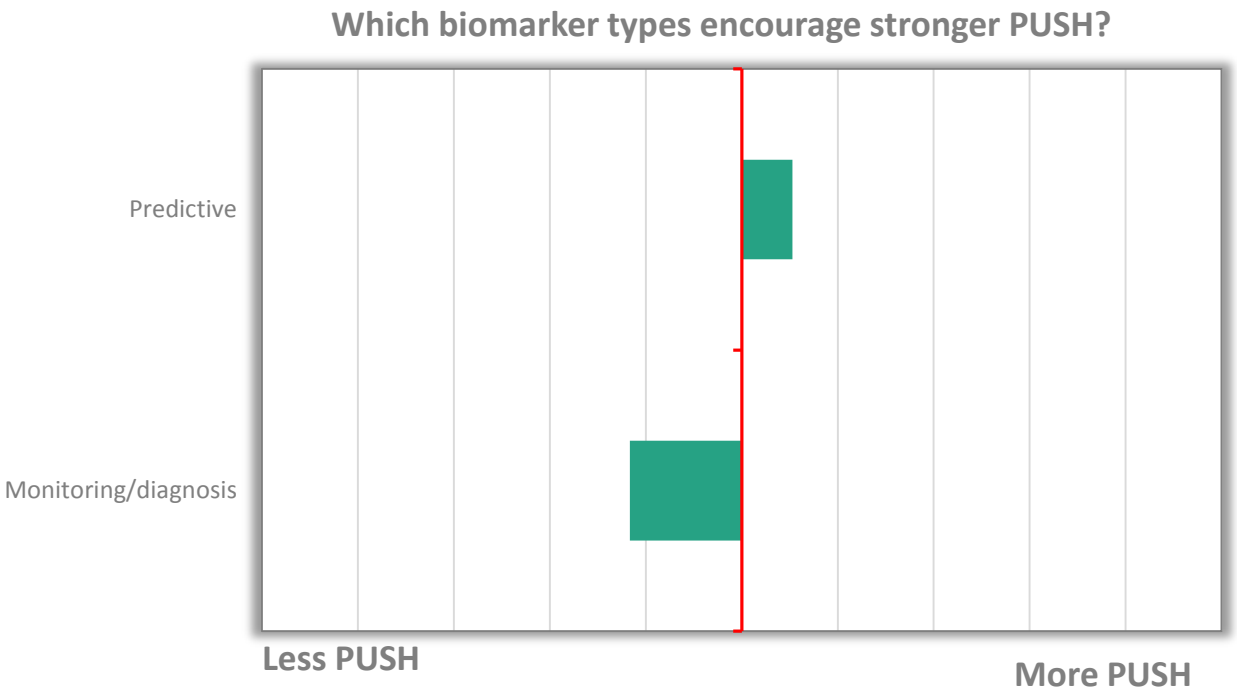
Is the perceived need to communicate on predictive testing greater than for other test types?

Predictive tests tend to receive a deeper testing narrative despite the role other tests might play in channelling or managing patients towards the right drug.



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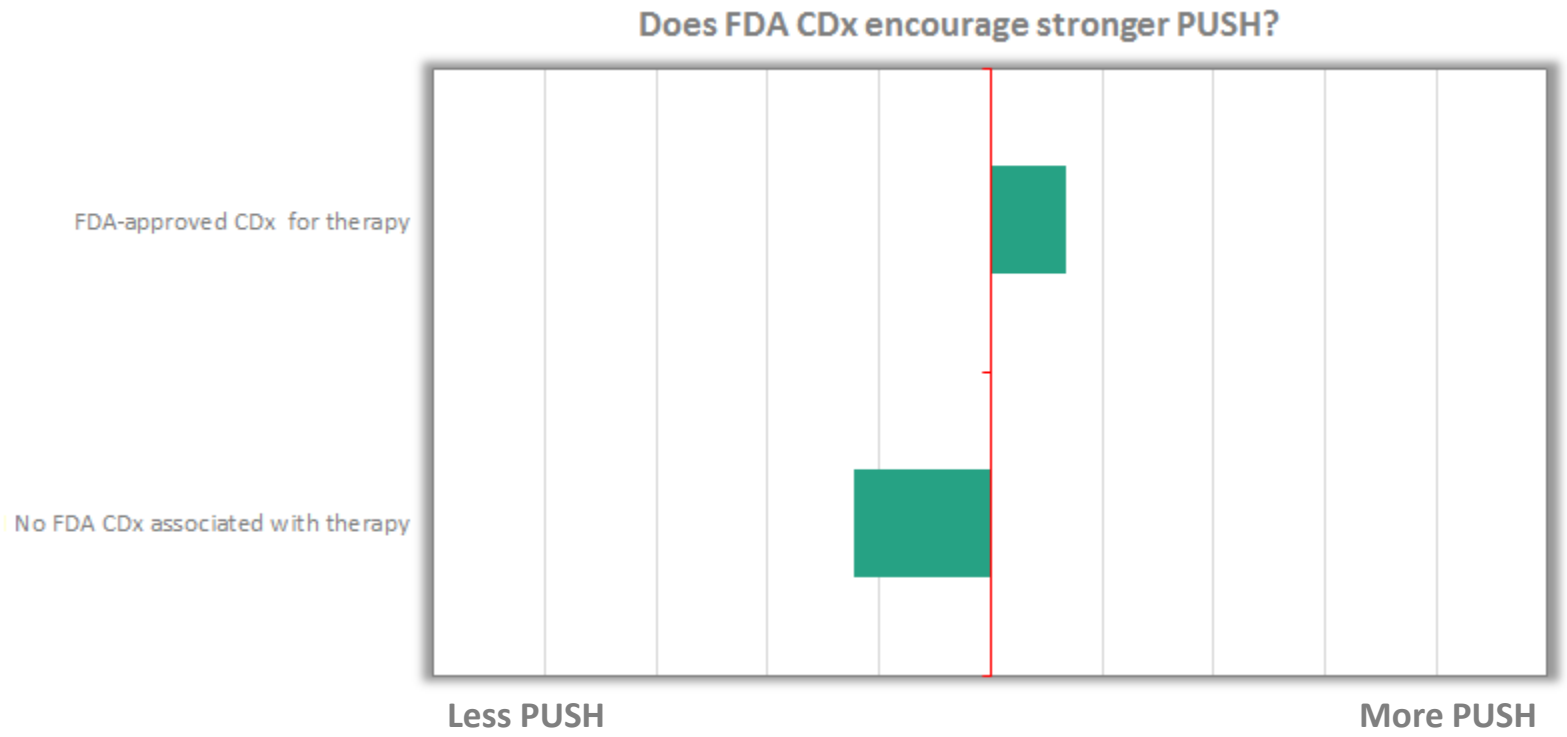
Why would the perceived need to communicate on predictive testing be greater than for other test types?

One reason may lie with the interdependence of therapy and diagnostic in the FDA therapy label.



CDx = Companion Diagnostic

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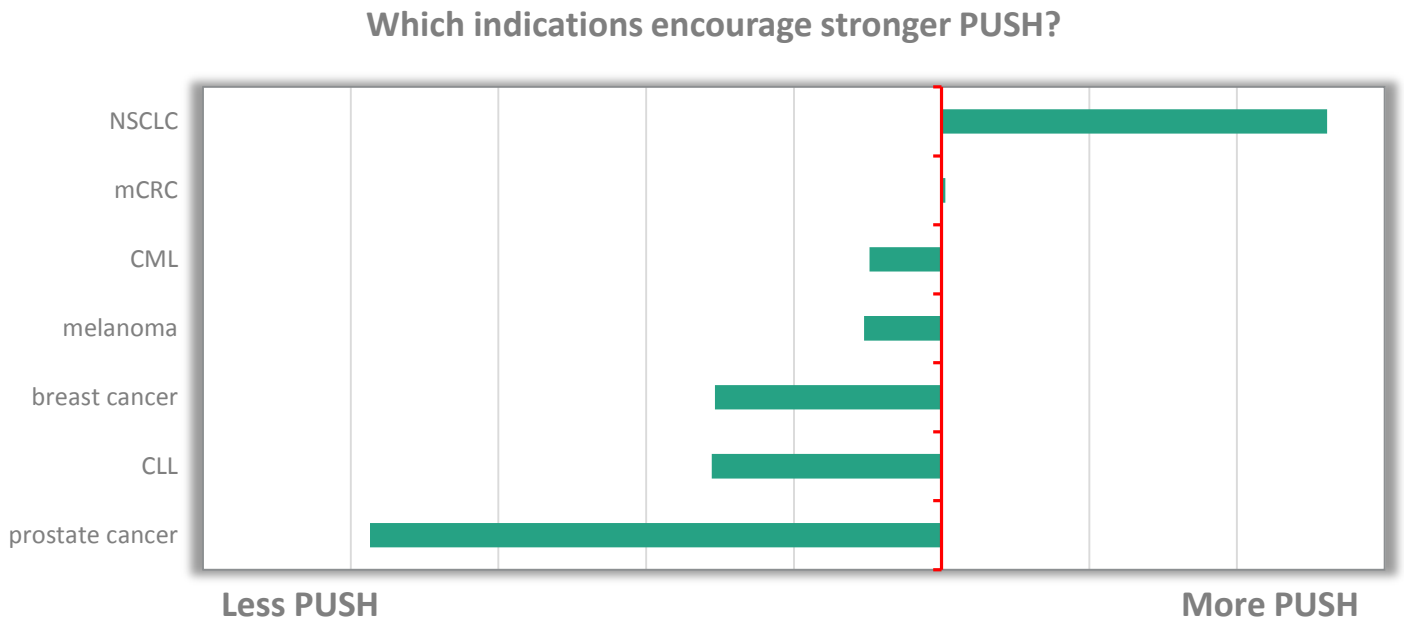
Does competition in an indication where predictive biomarkers are required trigger deeper testing narrative?

Lung cancer therapies appear most associated with marketing push and less competitive classes associated with a traditional approach.



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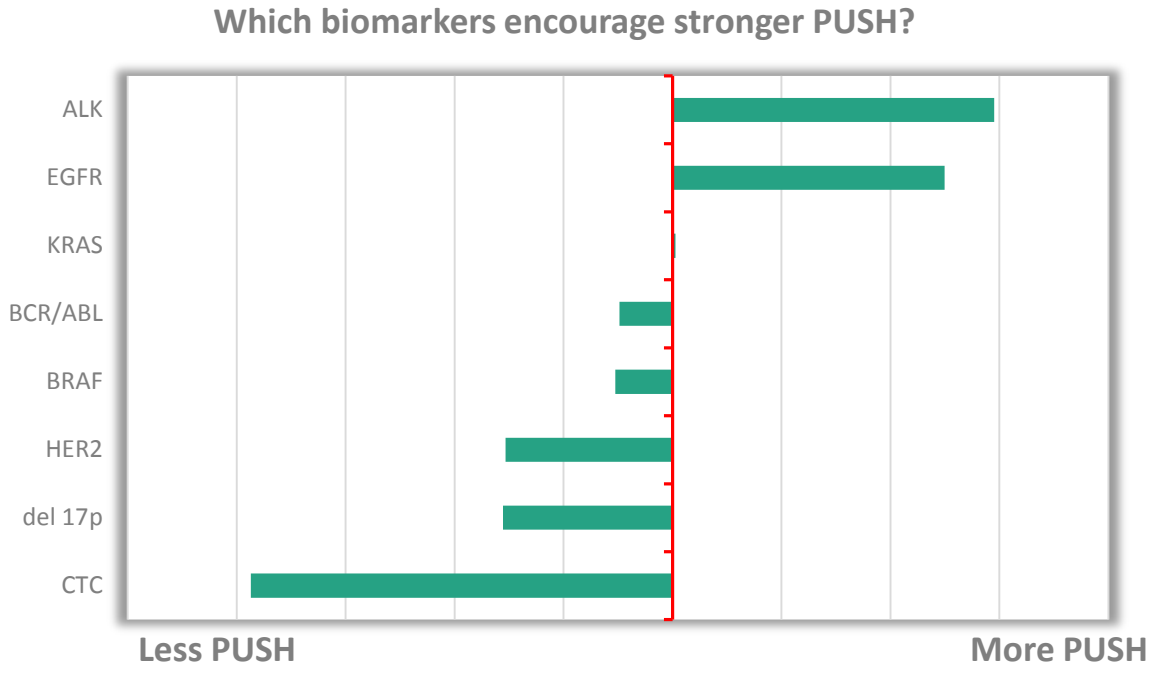
Biomarkers most associated with lung cancer have therefore benefited from the greater investment in PHC communication

Examples:

BCR/ABL and CTC are not used to predict patients' response but rather to diagnose and monitor disease progression, so there is less incentive to test.

Despite being a potential predictive biomarker del17p has not yet been fully endorsed by the FDA in terms of the label and Pharmacogenomics list.



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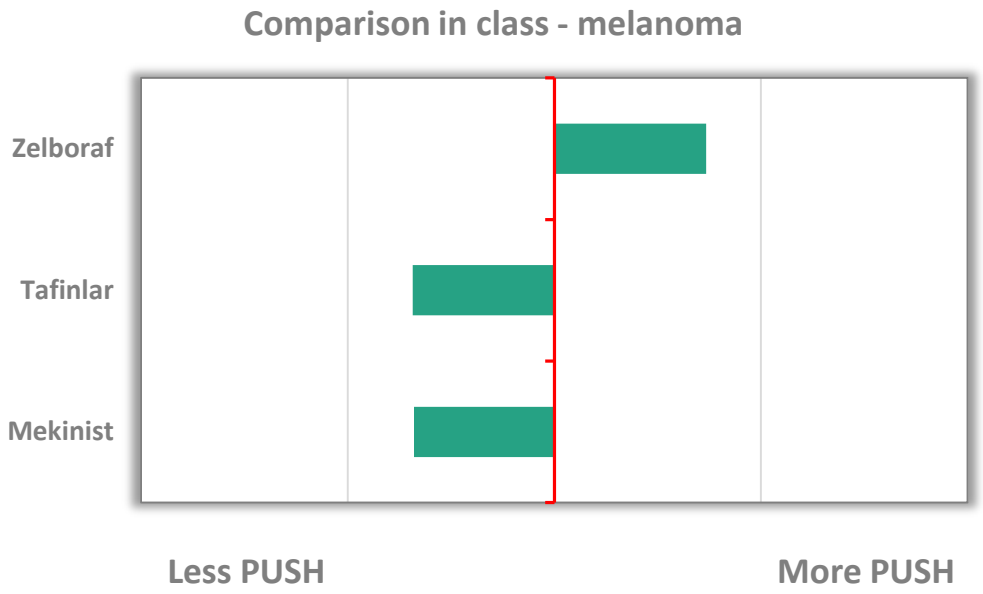
How will the competitive pressures of today impact PHC communication tomorrow?

The competitive pressure to increase PHC communication in melanoma does not always translate into other competitive classes.



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Key Takeaways and Areas to Monitor

Key takeaways

The testing narrative as an analysis helps us to better understand **how the market is responding** to the challenges of PHC.

A number of brands **do successfully embrace the testing narrative** with physicians and patients without distracting from other brand priorities.

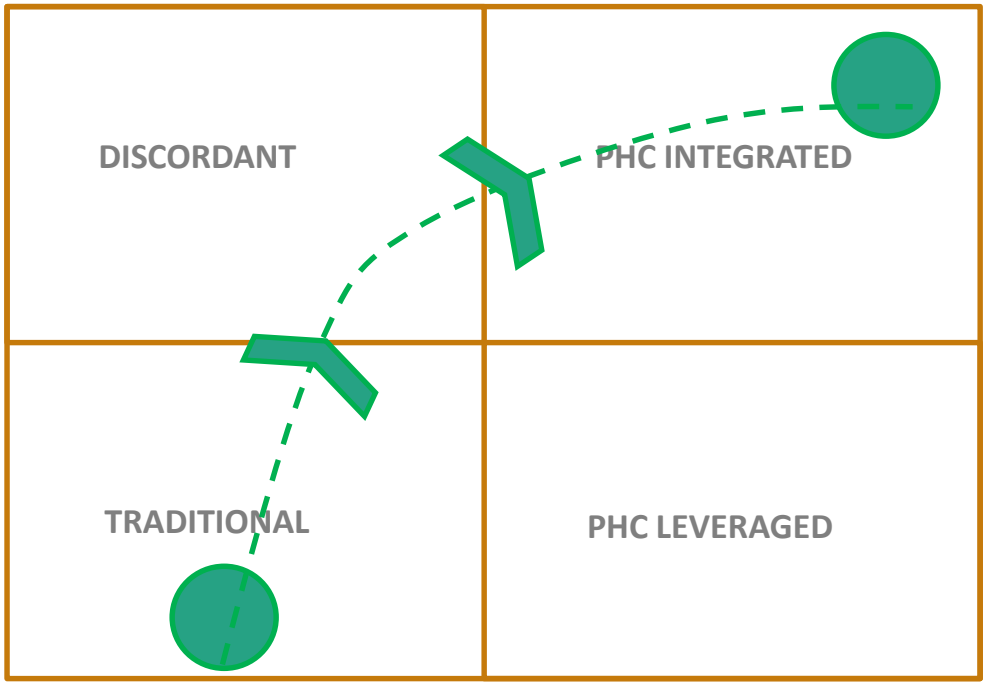
For other brands the **testing narrative is likely to be a journey**, starting in one place and augmenting the push factors over time to become more PHC integrated.

Competitive and regulatory factors all play a key role in persuading brand teams towards the level of investment they wish to make in PHC versus traditional therapy brand marketing.

What (if any) is a common path for ‘migration’?

Do brands ‘migrate’ among quadrants? What prompts a specific brand to move?

The analysis suggests there may be a migration for brands that start out with little test communication but which, over time, are pulled towards a deeper narrative on testing.



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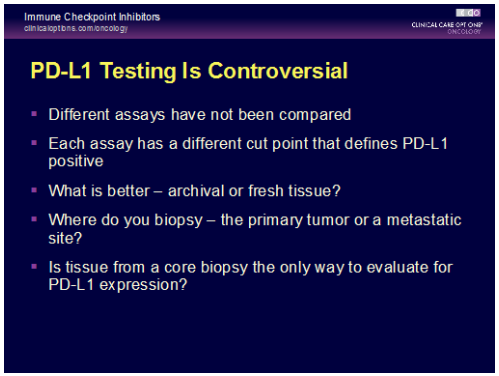
What does the entry point look like? Should the validity of the test be under discussion?

Example: PD-L1

DISCORDANT	PHC INTEGRATED
TRADITIONAL	PHC LEVERAGED



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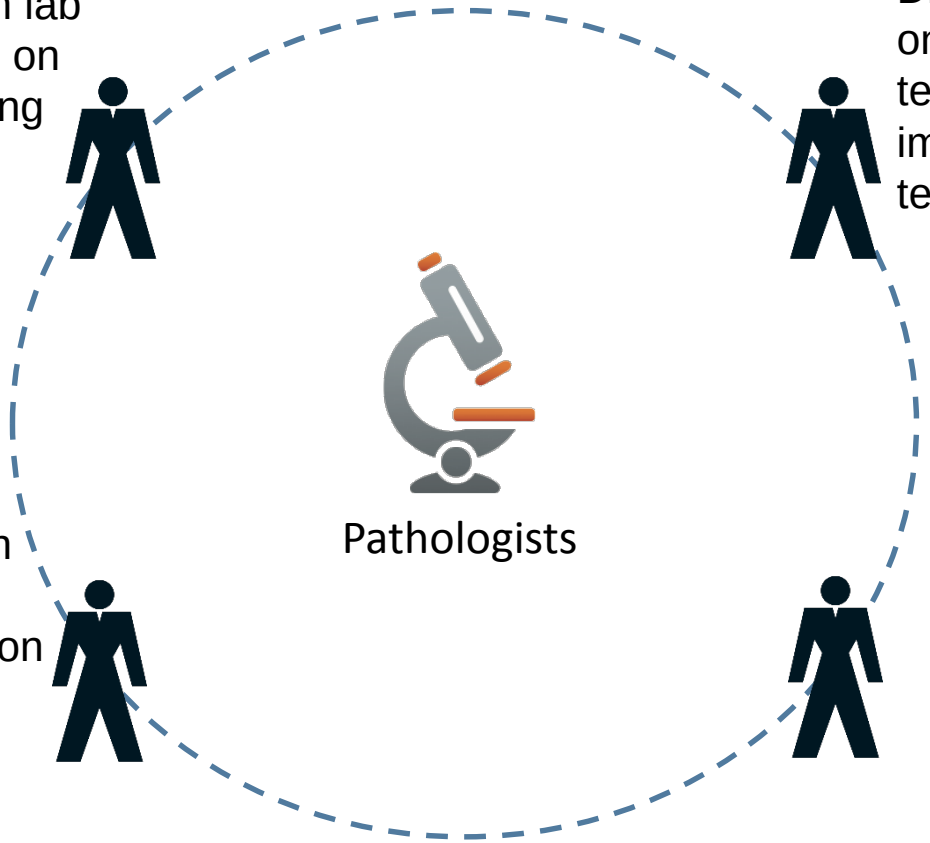
Could pathologists be the new champions of education?



Discussion with lab staff/managers on the best handling of the tissue

Discussion with oncologists on the tests available, impact of additional tests, etc.

Discussion with hospital administration on the need for additional funding

Educate nursing staff on what results mean, timelines for results, etc.

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How will the patient shape demand and the narrative?

For more information

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