The Devil's Advocate Tool – a calculated approach to peak patient share and competitor analysis

groupH Paper for ephmra 2022 Annual Conference

June 2022

Why the need for a new tool?

Estimating patient shares is critical to forecasting

PMR Approach to Patient Share

Calculated Approach

Overall educational aspect ✓
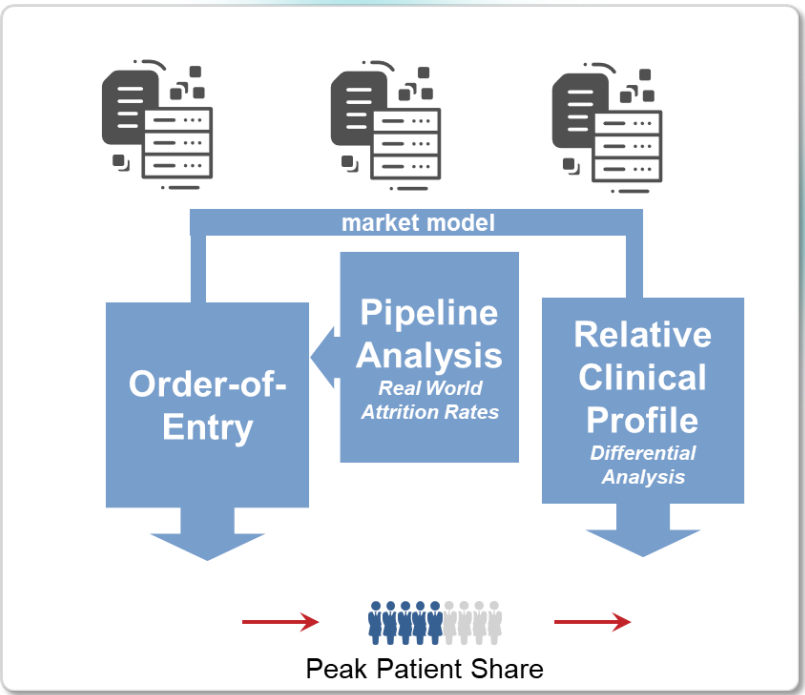
Physician bias and potential adjustments ✗

Physician fatigue ✗

Peak patient share estimates require combining two different sources – not ideal ✗
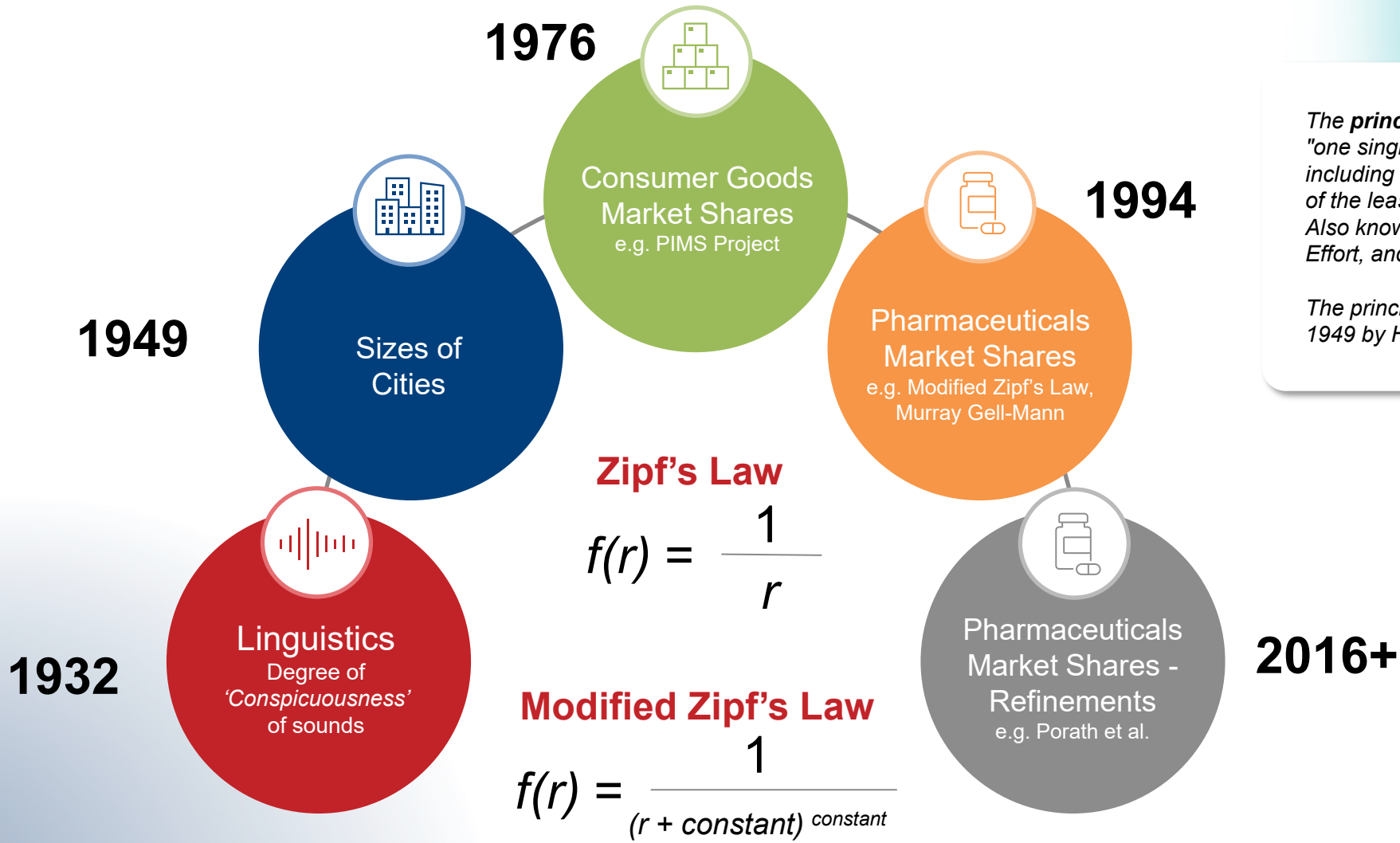
Cost and timing implications ✗

market model

| Order-of-Entry | Pipeline Analysis *Real World Attrition Rates* | Relative Clinical Profile *Differential Analysis* |

Peak Patient Share

Source: groupH research and analysis

The evidence behind the tool

Many natural phenomena obey Zipf's law - from linguistics to prescribing behaviour

1976

Consumer Goods
Market Shares
e.g. PIMS Project

1994

Pharmaceuticals
Market Shares
e.g. Modified Zipf's Law,
Murray Gell-Mann

1949

Sizes of
Cities

1932

Linguistics
Degree of
'Conspicuousness'
of sounds

2016+

Pharmaceuticals
Market Shares -
Refinements
e.g. Porath et al.

Zipf's Law

$$f(r) = \frac{1}{r}$$

Modified Zipf's Law

$$f(r) = \frac{1}{(r + constant)^{\,constant}}$$

*The **principle of least effort** is the theory that the "one single primary principle" in any human action, including verbal communication, is the expenditure of the least amount of effort to accomplish a task. Also known as Zipf's Law, Zipf's Principle of Least Effort, and the path of least resistance.*

The principle of least effort (PLE) was proposed in 1949 by Harvard linguist George Kingsley Zipf

DEVIL'S
ADVOCATE

Source: groupH research and analysis

5

Empirical theories such as Order-of-Entry have a long history >300 related articles have been published since 1985

DEVIL'S ADVOCATE

Selection

30ies   40ies   50ies   60ies   70ies   80ies   90ies   00ies   10ies   20ies

Selected Studies of the Principle of Relative Frequency in Language
George Kingsley Zipf
1932

PIMS Project – Entry Strategy and Performance (40 Industrial Products)
R. E. Biggadike
1976

Market Share Rewards to Pioneering Brands: An Empirical Analysis and Strategic Implications
Glen L. Urban et al.   **1986**

Human behavior and the principle of least effort: An introduction to human ecology
George Kingsley Zipf
1949

PIMS Project - The Sources of Market Pioneer Advantages in Consumer Goods Industries (371 Industrial Products)
W. T. Robinson and C. Fornell   **1985**

The Profit Impact of Marketing Strategy Project: Retrospect and Prospects
Paul W. Farris and Michael J. Moore
2004

The Quark and the Jaguar – Adventures in the Simple and the Complex
Murray Gell-Mann
1994

Size and Dynamics of Order-of-Entry Effects in Pharmaceutical Markets
D. Porath et al.
2016

Legend:
Non-pharmaceutical dataset
Pharmaceutical market dataset

Source: groupH research and analysis

| Bond and Lean, 1977 | Gorecki, 1986 | Berndt et al, 1995 | Shankar et al. 1998 | Coscelli, 2000 | Fischer et al., 2010 |

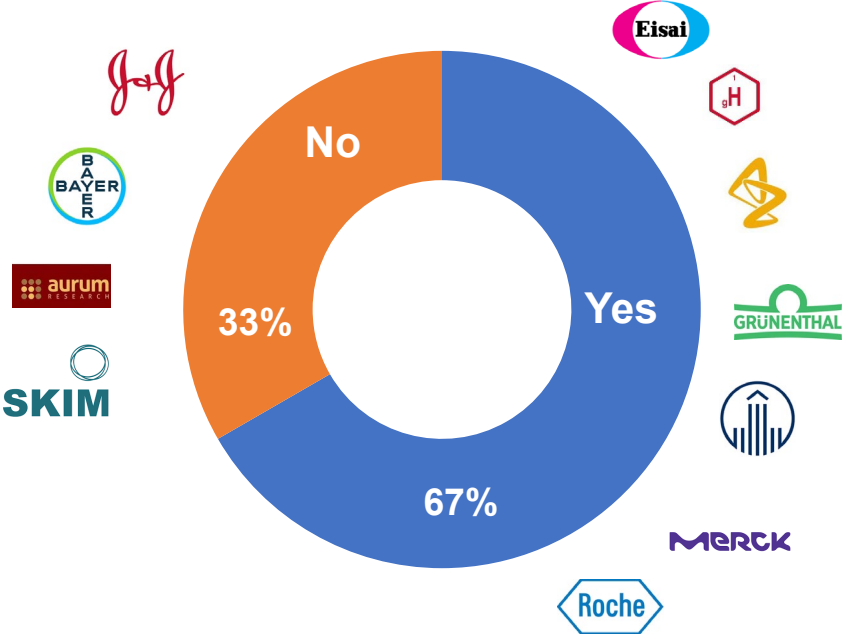| Bain, 1956 | Robinson & Fornell, 1985 | Lieberman & Montgomery, 1988 | Fischer et al, 2005 | Kalyanaram, 2008 | Wilkie et al, 2012 |

| Carpenter and Nakamoto, 1989 | Kardes and Kalyanaram, 1992 | Robinson et al, 1994 | Lieberman & Montgomery, 1998 and 2013 |

Q1: Do you use the Order-of-Entry model as a basis for your product forecasts?

No **33%**

Yes **67%**

Order-of-Entry is widely used

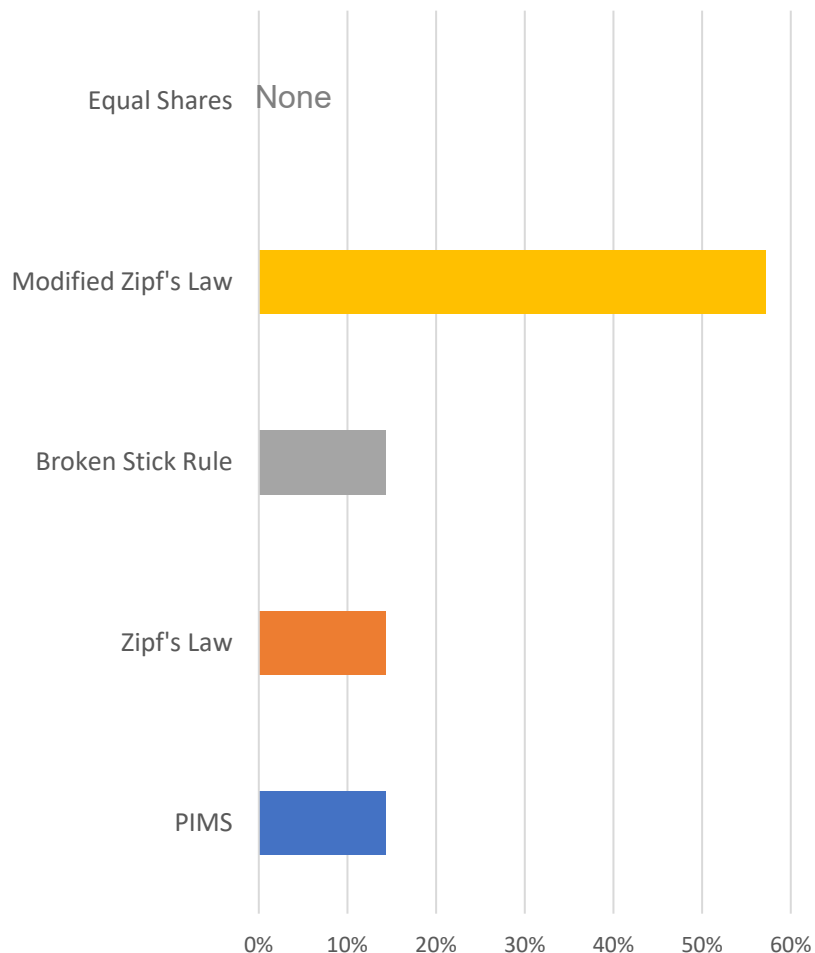**If used, OoE is seen as more suitable for predicting product shares [in class] than for class shares in an indication**

Source: groupH research & analysis, n = 12

Q2: Rate the suitability of an Order-of-Entry model (among other criteria) for the following uses from 1 (not suitable) - 5 (very suitable)?

	Product Shares in Class	Class Shares in Target Population
Very suitable	40%	40%
	30%	30%
	30%	20%
Not suitable		10%

LEGEND
- Very suitable
- Not suitable

DEVIL'S ADVOCATE

7
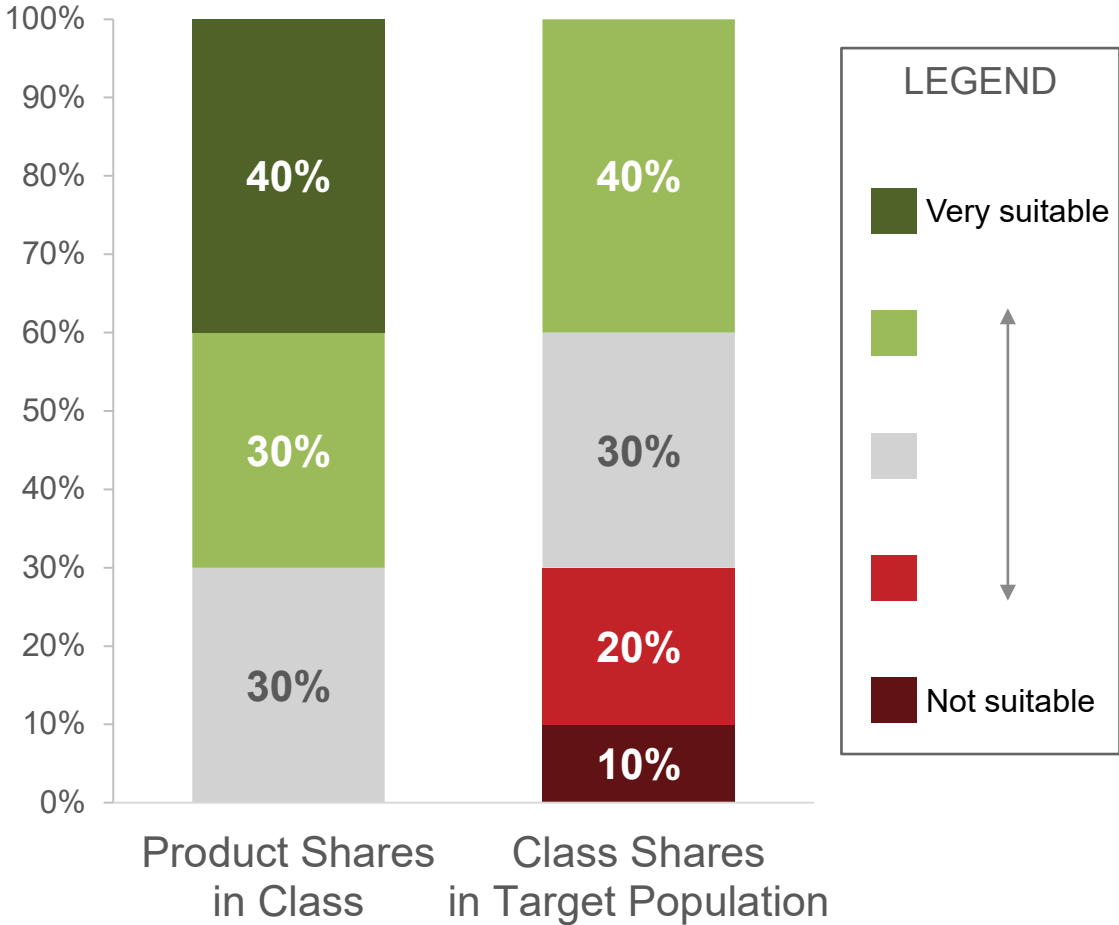
Modified Zipf's Law is the most widely used Order of Entry method

ephmra
excellence · community · standards

DEVIL'S ADVOCATE

Q3: Which Order-of-Entry model do you most commonly use in your organisation for your forecasts?

Rationale

Chart categories (top to bottom):
- Equal Shares — None
- Modified Zipf's Law
- Broken Stick Rule
- Zipf's Law
- PIMS

X-axis: 0%, 10%, 20%, 30%, 40%, 50%, 60%

Evidence, simplicity, established, 'reasonable basis', 'good for the early stages when not much information is available about the molecule', 'approximately right and not precisely wrong', 'allows to move away from OoE the better one understands the market'. 'OoE can be overcome'

'fast, [good in situations when…] lack of deeper knowledge on comparative TPPs'

'Easy to implement', adjustments can be made based on market conditions (e.g. very early, product differentiation, company size)

'Analogue comparability'

Source: groupH research & analysis, n = 12

Order-of-entry relies on robust pipeline analysis

Illustrative Example

Brick Wall

Overall Pipeline
For an 'Autoimmune Indication'

Phase 1		Phase 2		Phase 3	Filed	Recently Approved
Drug AA SC	Drug BE Oral	Drug AC SC	Drug FA Topical	Drug AF SC	Drug NA Topical	Drug MB SC
Drug AB SC	Drug CA Oral	Drug AD SC	Drug FB Topical	Drug AG SC	Drug OA Topical	
Drug BA Oral	Drug CB Oral	Drug AE SC	Drug FA Oral	Drug DC Oral		
Drug BB Oral	Drug DA Oral	Drug BF Oral	Drug FB Oral	Drug LA Oral		
Drug BC Oral	Drug EA Oral	Drug CC Oral	Drug DB Oral	Drug MB SC		
Drug BD Oral		Drug UA Topical	Drug PA Oral			
		Drug GA Oral	Drug IA Topical			
		Drug HA Oral	Drug KA SC/IV			

① **'filter' for relevant trials and add current options**

- Only for **target patient segment** and **target geography**
- Exclude otherwise non-relevant trials

'Filtered Brickwall'
'Autoimmune Indication', moderate-severe, US only

Phase 1	Phase 2		Phase 3	Filed	Approved	
Drug DA Oral	Drug AC SC	Drug CC Oral	Drug AG SC		Drug MB SC	Drug AH SC
	Drug AD SC	Drug FA Oral	Drug DC Oral		Drug MC SC	Drug AI SC
	Drug AE SC	Drug DB Oral	Drug LA Oral		Drug MD SC	Drug AK SC
	Drug BF Oral	Drug PA Oral			Drug PA SC	Drug QB SC
					Drug QA SC	Drug QC SC

Current options only **SC biologics** (4 different classes)

② **data sets for pipeline products and current classes fed into tool**

1. **Pipeline analysis: How will the future treatment landscape for a Product X look like?**

2. **Market model: What does that mean for the peak share potential of Product X?**

Source: groupH research and analysis

How the tool works

The tool combines a probability-adjusted pipeline analysis with a simple market model

Source: groupH research and analysis
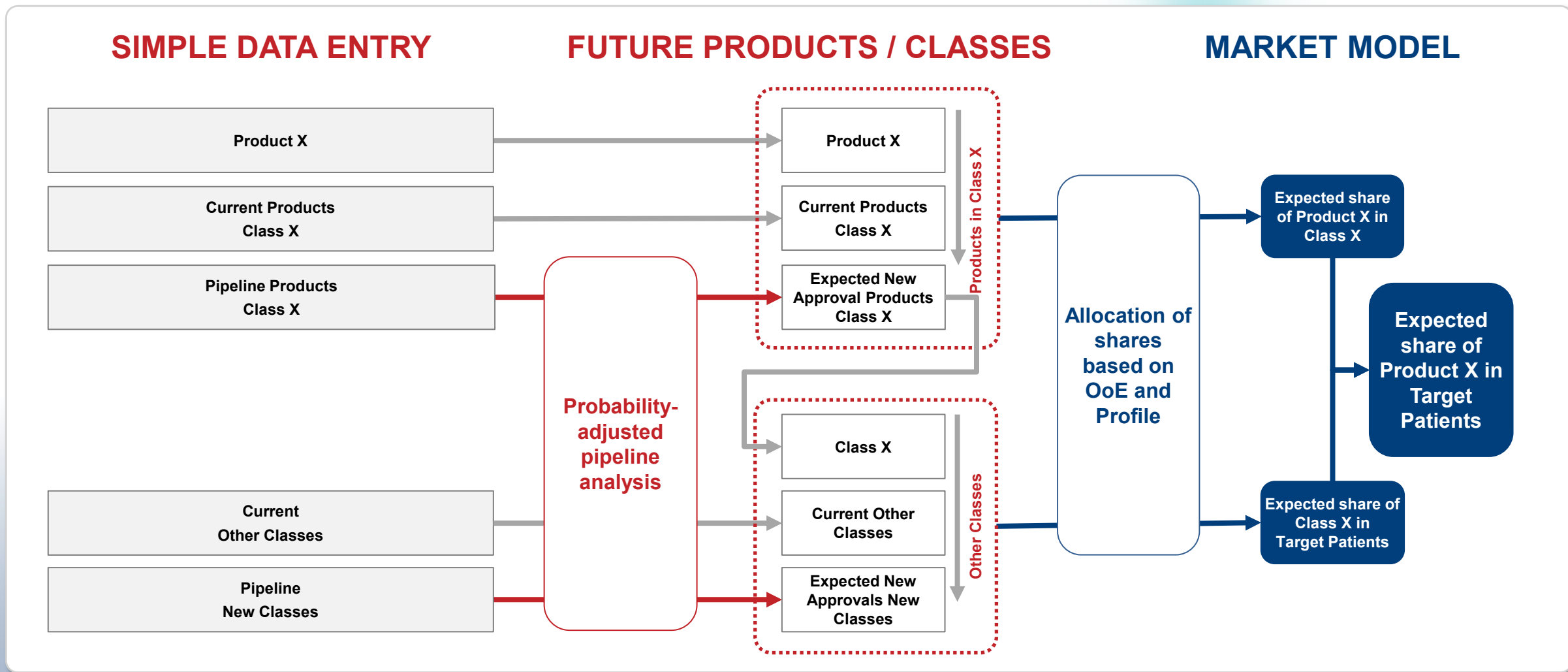
The tool calculates likely approval dates for pipeline products, includes existing products and projects forward a future treatment landscape and order-of-entry

Illustrative

Data Entry Template x No. of Competitors

NEW CLASS PRODUCT - PHASE 2 ×

PRODUCT DETAILS

Product name
[   ]

Manufacturer (optional)
[   ]

Class name
[   ]

Product type
[Select...   ⌄]

IN TARGET INDICATION

Development phase
[Phase 2   ⌄]

Start of development phase
[dd/mm/yyyy   📅]

Expected overall profile vs. current SoC
[Select...   ⌄]

ADD

Future Treatment Landscape

Competitor	# Products	OoE	Average Profile
Product X	1	5th of 5	4
Current before	3	1st-3rd of 5	3
Current after	0	-	-
Pipeline before	1	4th of 5	4
Pipeline after	0	-	-

Source: groupH research and analysis

12

Case study

Case study - recent project on a follow-on biologic for a later line segment in an immunology disease

simplified

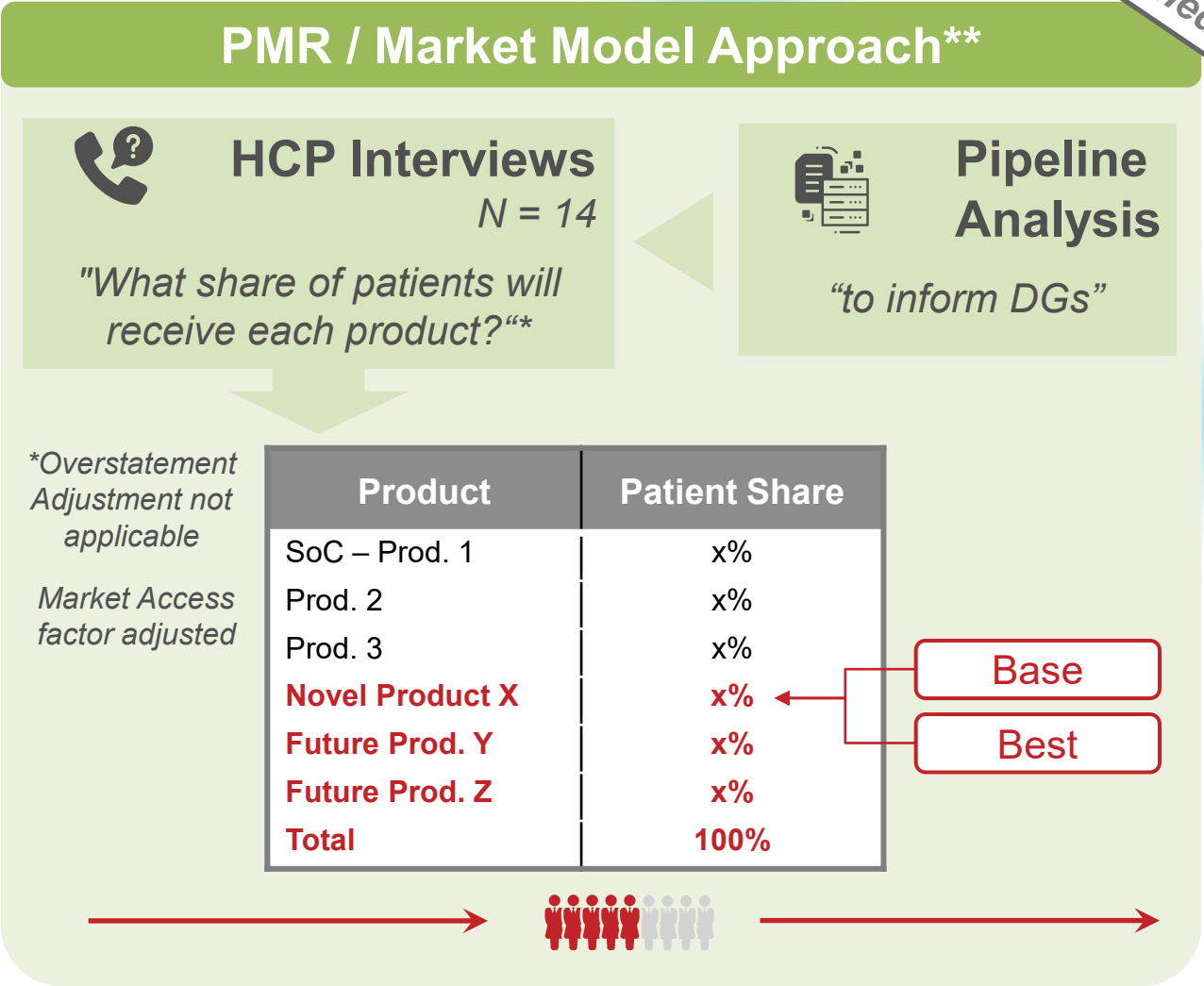|	
Project Type	Commercial Assessment for a novel Ph. 2 immunology biologic
Project Scope	+ RoW
Project Work Streams	▪ Epidemiology ▪ Competitor and Pipeline Analysis ▪ TPP Base Case/Best Case ▪ PMR with 14 TAEs Focused on Biologics Treated Population ▪ Market Access PMR with 12 Senior Payers ▪ Commercial Analysis and Forecasting

PMR / Market Model Approach**

HCP Interviews
N = 14

"What share of patients will receive each product?" *

Pipeline Analysis

"to inform DGs"

*Overstatement Adjustment not applicable

Market Access factor adjusted

Product	Patient Share
SoC – Prod. 1	x%
Prod. 2	x%
Prod. 3	x%
Novel Product X	**x%**
Future Prod. Y	**x%**
Future Prod. Z	**x%**
Total	**100%**

Base

Best

Sources: groupH research and analysis (anonymized client project), **Epi based diagnosed prevalence based, steady state market model

We fed pipeline and existing market data into our Devil's Advocate Tool
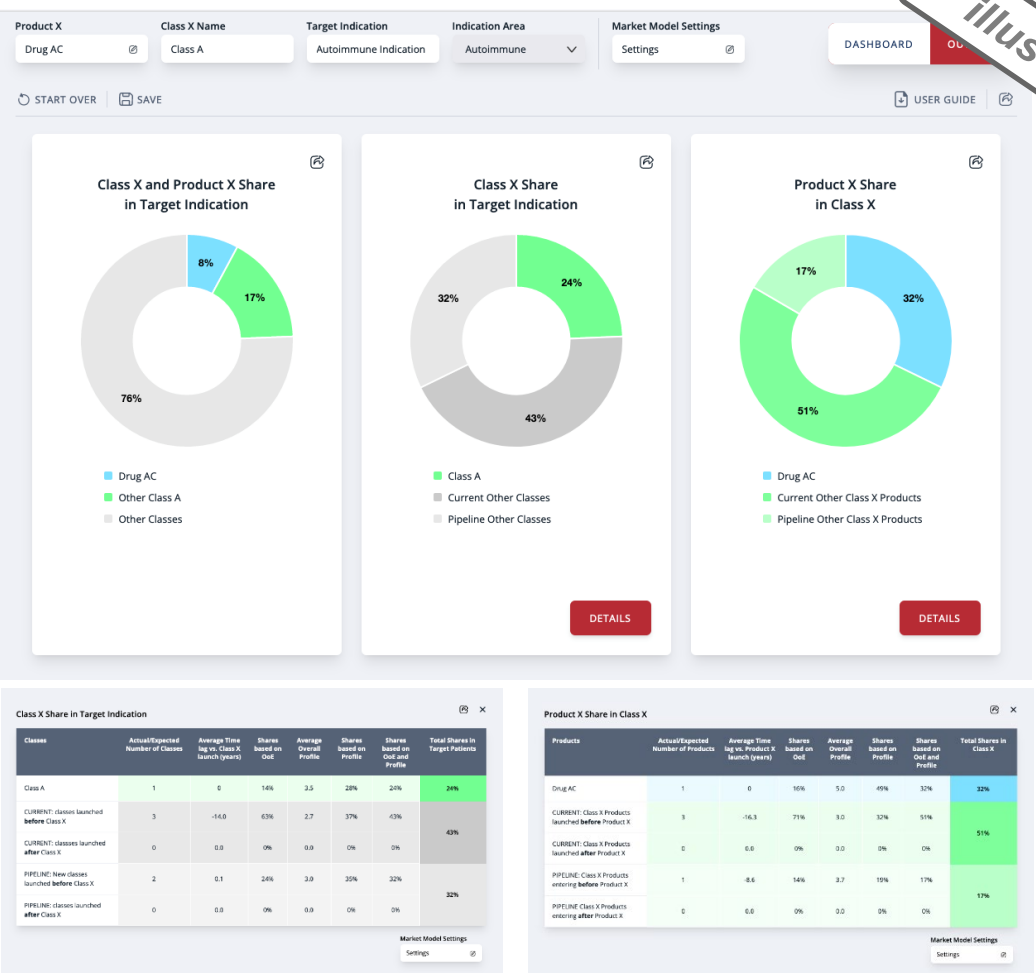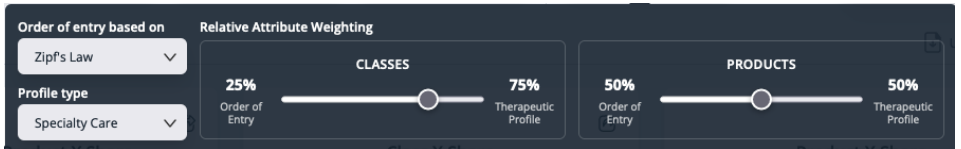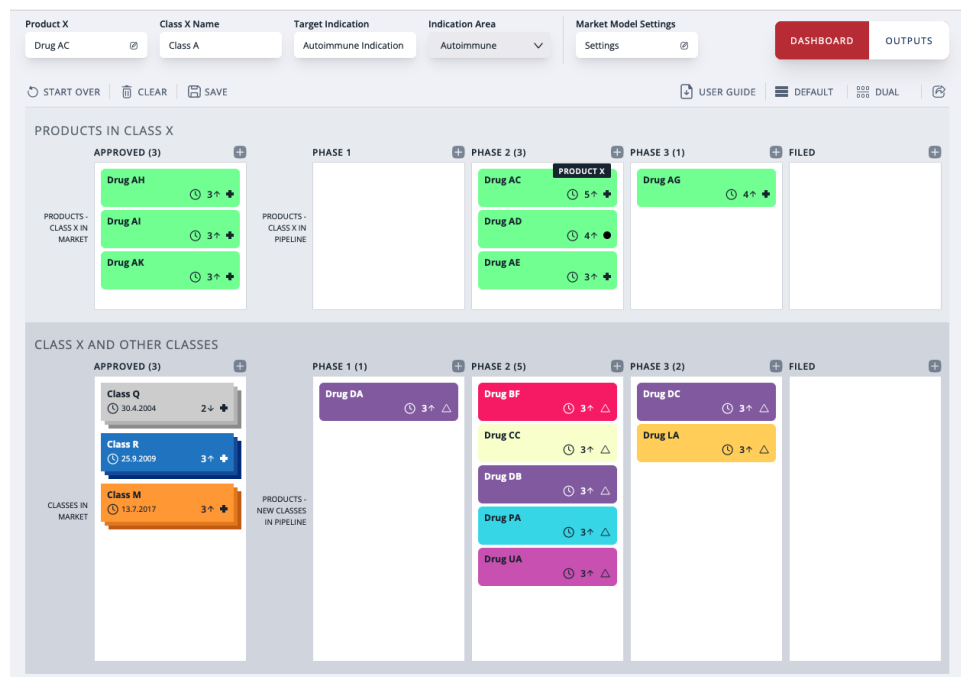
Discussion - PMR-only vs. *Devil's Advocate Tool*

		PMR Assessment Base Case	Devil's Advocate Tool Online Competitor & Pipeline Tool	
			Base Case	Market – Scenario 1
Market Assumptions	New Approvals – Same Class	Yes – 1 expected	Yes – 1 expected	Yes – 1 expected
	New Oral Classes	No – not expected	No – not expected	Yes – 2 expected
Product X US Peak Share	Base Case	8%	8%	5%
	Best Case	17%	12%	8%

Source: groupH research and analysis (anonymized client project)

Key Take Aways

Conclusions

1. **Creates a second leg to stand on for patient share using a different methodology**

2. **Helps to minimize subjectivity or biases introduced by PMR or the project team**

3. **Evidence based and no black box**

4. **Not about *right or wrong* but about challenging assumptions**

5. **Helps to calculate additional *What-If* Market Scenarios without new PMR**

6. **Can be used as Stand-alone forecast option for pre-clinical / Phase 1 assets**

7. **Experts already using this approach may find the tool time saving and simpler**

8. **Free Tool – available on *grouph.com/tools/devils-advocate-tool/***

Source: groupH research and analysis

Questions

Erik Holzinger
erik.holzinger@groupH.com
m +44 7718 967 633

Moritz Hillgenberg
Moritz.hillgenberg@groupH.com
m +49 175 176 6382

DEVIL'S ADVOCATE

COMMERCIAL ASSESSMENTS

STRATEGY SUPPORT

gH^1

MARKET ACCESS

LONDON   SAN FRANCISCO