

Improving the accuracy and flexibility of MR models to address evolving management needs

Prepared for *Eph*MRA Annual meeting

June 2007

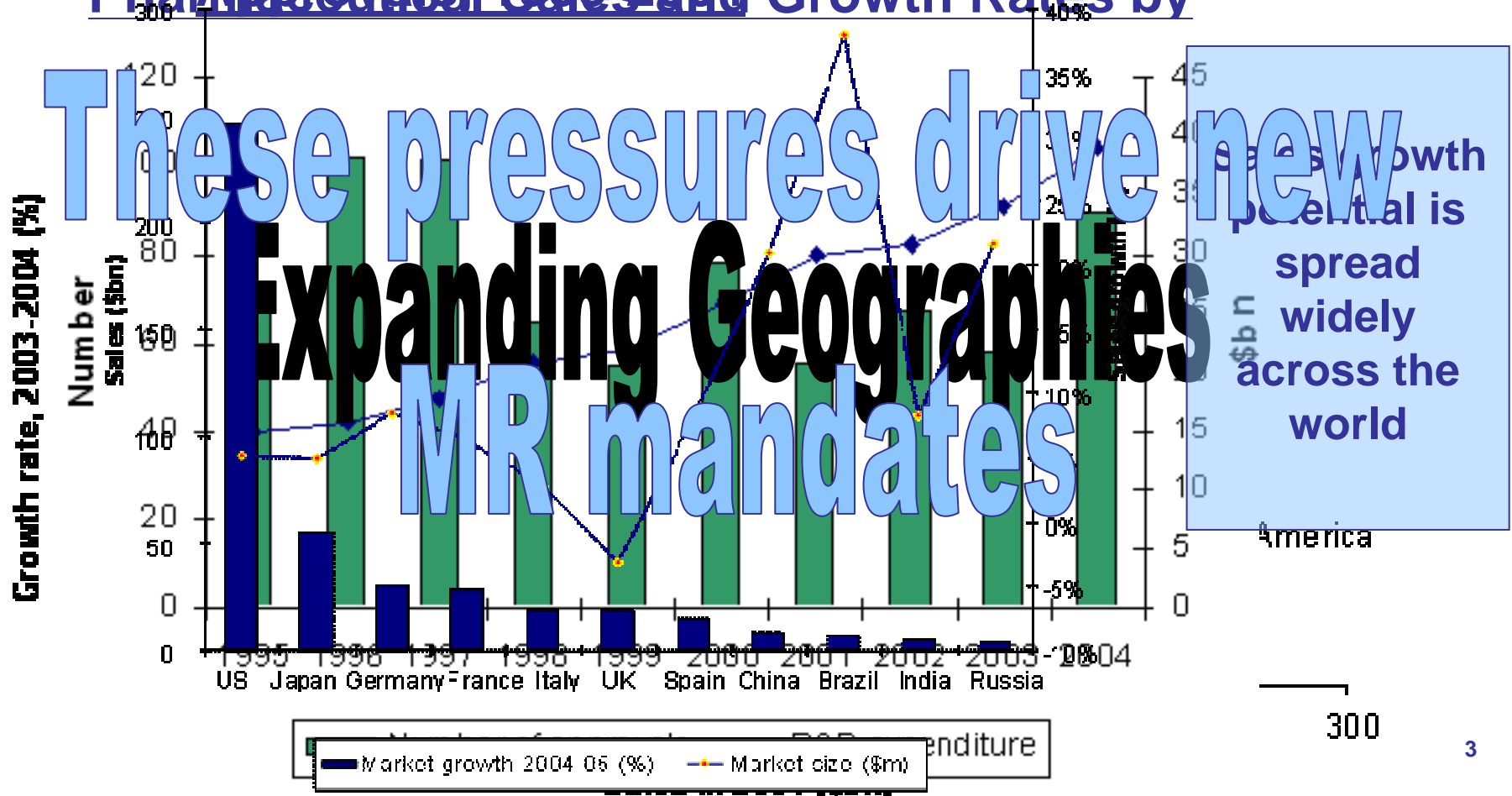
Portomaso, Malta

Agenda

- Background
 - New product testing brings new pressures on MR
 - Specific case
- How we approached it
- What we learned

Pharma companies operate within an increasingly pressure-packed environment

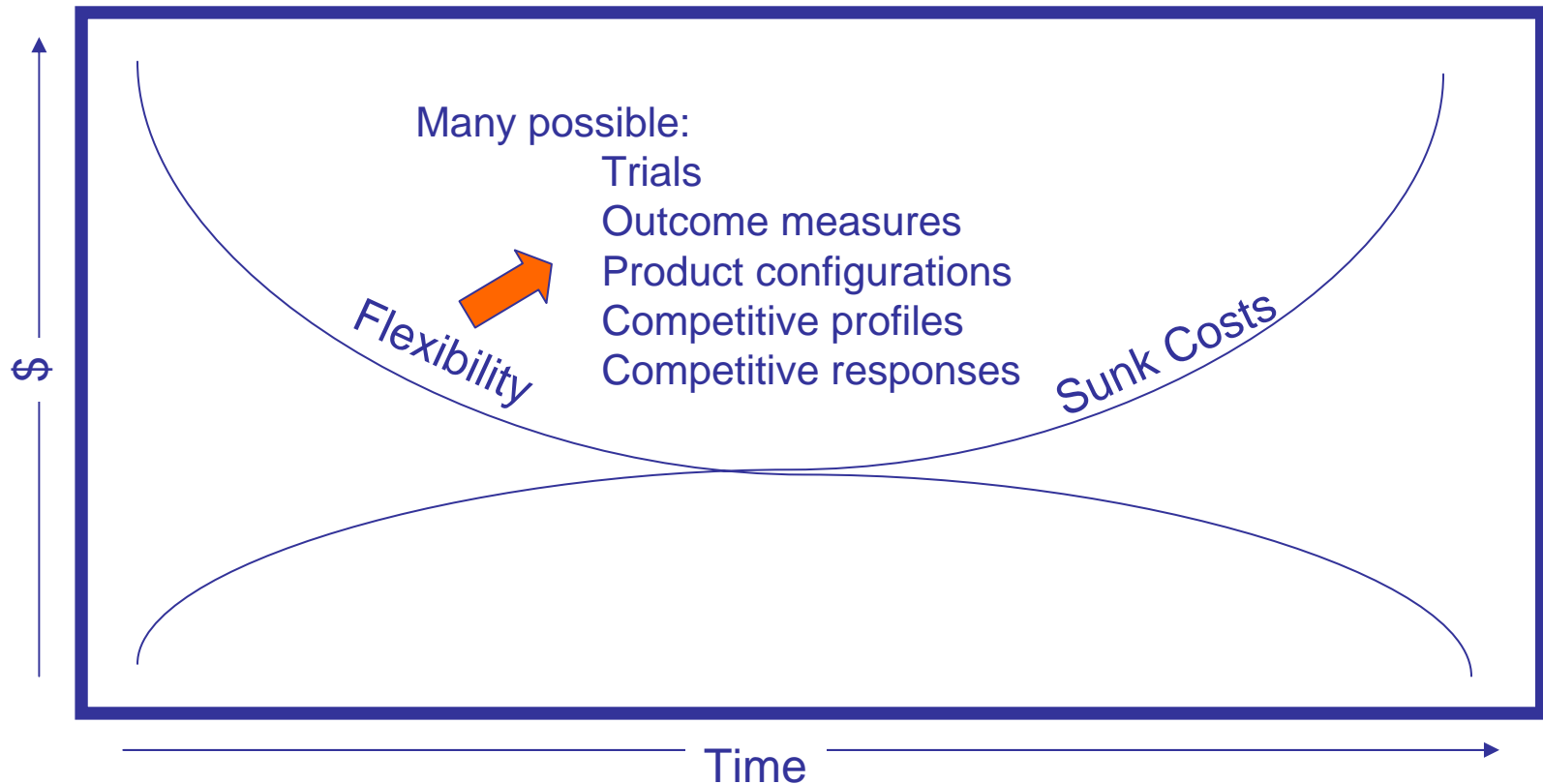
US R&D Spending v. New Drug Approvals, 1995-2004
 Pharmaceutical Sales by Country, 2005
 Pharmaceutical Sales Growth Rates by Country, 2003-2004



300

These pressures drive a substantial need for earlier, more flexible insight into market potential

Impact of Time on Flexibility in New Product Development



A specific case study . . . The background

- Novo Nordisk offers a complete range of modern (analogue) insulins: NovoRapid®, NovoMix 30®, Levemir®
- In addition, Novo Nordisk also has a strong development pipeline including Liraglutide (GLP-1 analogue) and pulmonary insulin (AERx).
- Key competitors have strong products currently in the market or in development:
 - pre-mixed and rapid-acting modern insulins (Lilly)
 - rapid and long-acting modern insulins (Sanofi-Aventis)
 - Exenatide (Lilly)
 - Exubera (Pfizer)
 - DPP-IVs

A specific case study . . . The planning needs

- Understand the drivers of prescription in the type 2 diabetes market
 - amongst both specialists and GPs
 - across the US, EU, and Japan
- Assess relative contribution of current and future brands at different levels of attributes to guide development of clinical trials.
- Forecast true ***commercial potential*** for each of Novo Nordisk's compounds. (Market Size)

A specific case study . . . The complications

It's a big, big, big, big question:



56 attributes tested!
~200 levels assessed!
3 new products
evaluated!
6 patient types!
6 countries!

Agenda

- Background
- How we approached it
 - Modeling design: Benchmark Discrete Choice
 - Collaborative, interactive, forgiving approach
 - Sample design
 - Getting the study running
- What we learned

The study specifications . . .

- A 45 minute Internet facilitated study using the Ziment WebSurveyMD panel of physicians.
- 6 countries
- PCPs and Specialists in each country
- Total of 2,439 respondents enabling analysis by respondent type within each country
- Respondents were screened for specialty, years in training and number of Type 2 diabetes patients seen for management of diabetes

Our basic approach fused two well-established research methods

The philosophy:

1. Respondents are able to provide accurate preference share evaluations of even complex profiles ONCE
 - Monadic measures are believable
2. Trade-offs between attribute levels can best be made when the task is simple and direct
 - Partial-profile approaches simplify complexity
 - Paired-comparison conjoint approaches measure direct trade-offs

Data for Benchmark Discrete Choice is gathered in two steps

Step One

- **Obtain preference share on benchmark scenarios**
 - Split sample within countries
 - Measure best, base, worst case
- **Market baskets should be realistic**
 - All products in market or a subset
 - Account for combination usage by measuring patients not Rx
- **Evaluations should be based upon full profiles**
 - 'Product profiles,' not scenario cards

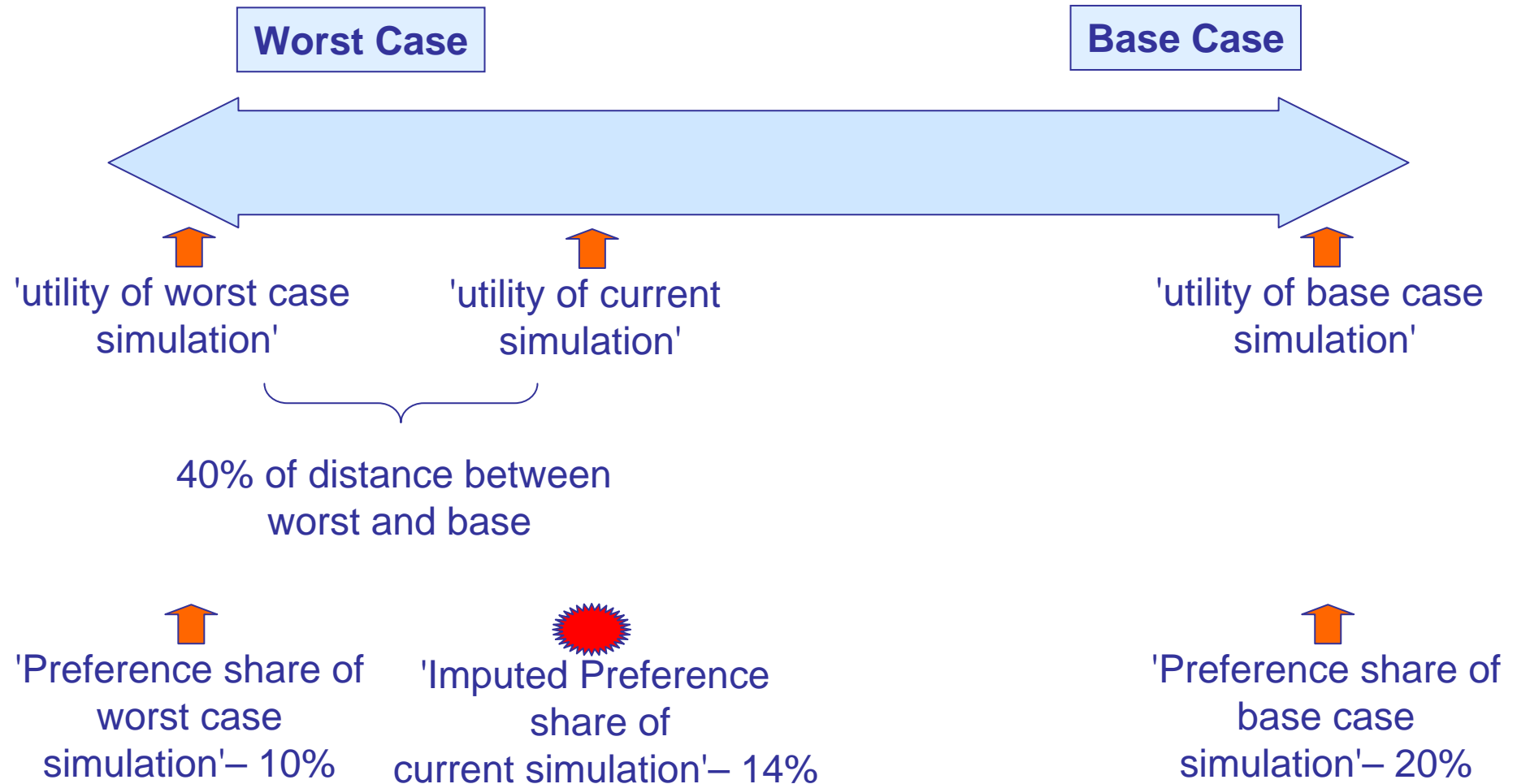
Step Two

- **Obtain trade-off information**
 - Blocked design splits sample
 - Number of blocks TBD based upon final list of attributes and levels
 - ~ 12 – 15 scenarios evaluated
- **Use partial-profile design to account for complexity**
 - Each respondent evaluates scenarios trading off 5 attributes
 - Assumes concepts are identical in all ways not contrasted in scenarios
- **Measure should tap 'pure preference'**
 - Strength of preference for Concept A v. Concept B

Data from monadic evaluations and trade-offs are combined into a market simulator

- Benchmarks provide preference share 'sign-posts'
- Partial-profile evaluations provide attribute-level sensitivities
 - Strength of each driver
 - 'Shape' of effect– relative impact of each level
- In simulator, preference share is imputed from benchmarks

To impute preference share, we measure the distance between benchmarks using trade-off data



This complex methodology coupled with a very complex problem meant true collaboration was key

- A team approach
 - Many in-person meetings
 - Substantial back and forth to insure correct stimuli & expectations
- A sophisticated team (both sides)
 - Keep category knowledge
 - Understanding of key methodologies
 - Flexibility in limiting scope where needed
- Unusually low walls between consultant and client required
 - Nip confusion/errors early
 - Flexibility in finding creative solutions

Agenda

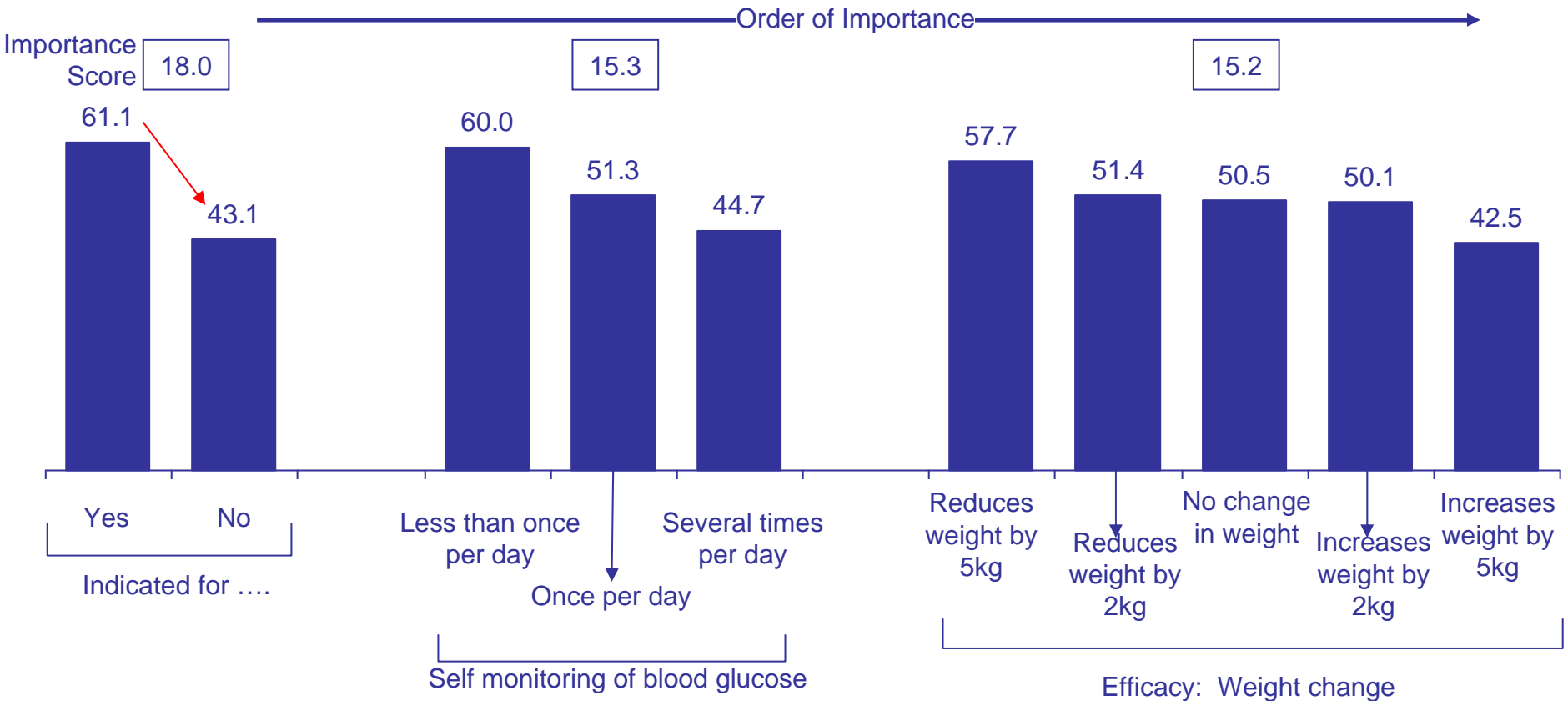
- Background
- How we approached it
- What we learned
 - Findings and example output
 - Best practice recommendations

Overview of findings

- Two of the top four key prescription drivers were not predicted
 - Generating the ‘Aha’ moment when something that is ‘not obvious’ becomes, well, ‘obvious’ – an unstated prerequisite
- Product A gained 11.9% share amongst specialists and 10.6% amongst GPs, but significantly more in Europe than USA or Japan – needing specific decisions in Japan.
 - One particular development scenario was identified as superior
- Product B gained 15.0% share amongst PCPs but only 10.0% amongst specialists
 - And was very much favoured in both Japan and Europe, but less in the USA
 - One development scenario will cause a DECREASE in share

Attributes of greatest importance

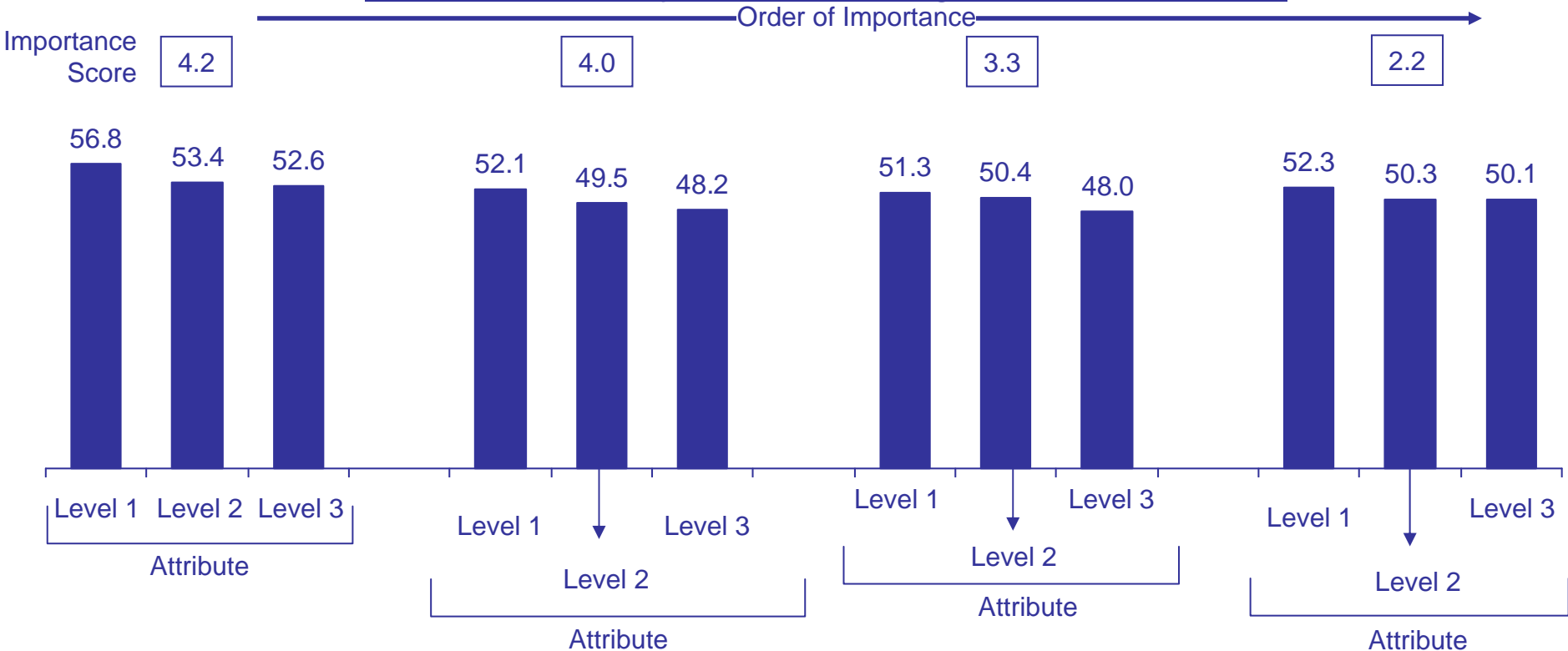
Total Utility – 1-3 of 56 Attributes Global Total Physicians – Weighted Total Patients



Among Global Total Physicians (n=2439); Derived From Model Output
N.B. Examples only: Attributes and figures have been switched

Attributes of least importance

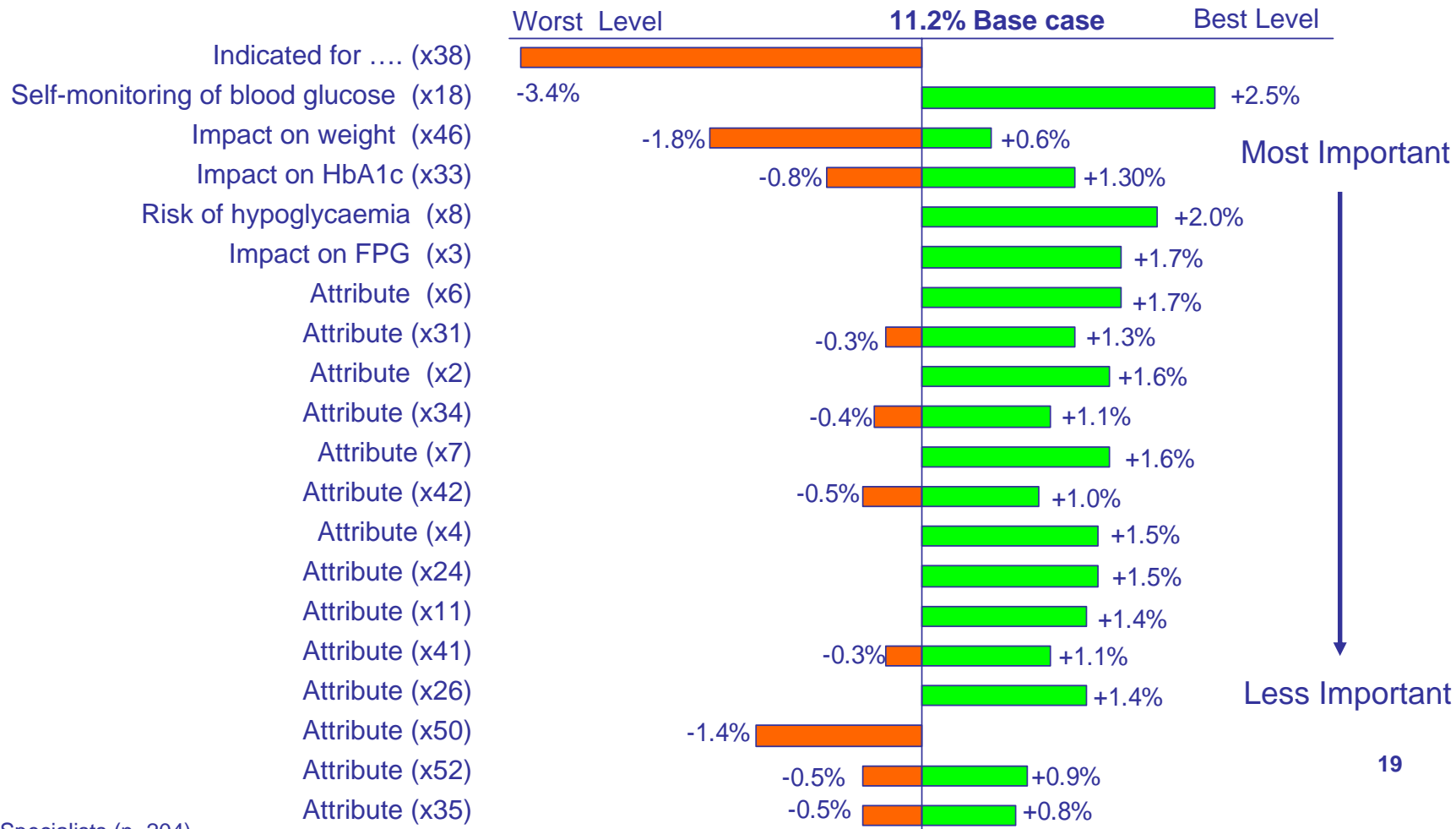
Total Utility – 53-56 Attributes Global Total Physicians – Weighted Total Patients



Among Global Total Physicians (n=2439); Derived From Model Output
N.B. Examples only: Attributes and figures have been switched

Each change in level of attribute impacts preference share positively or negatively from the 'base case'

Derived Importance of Attributes* in a Base Case Market^ Among **Global Total Specialists** Weighted Total Patients

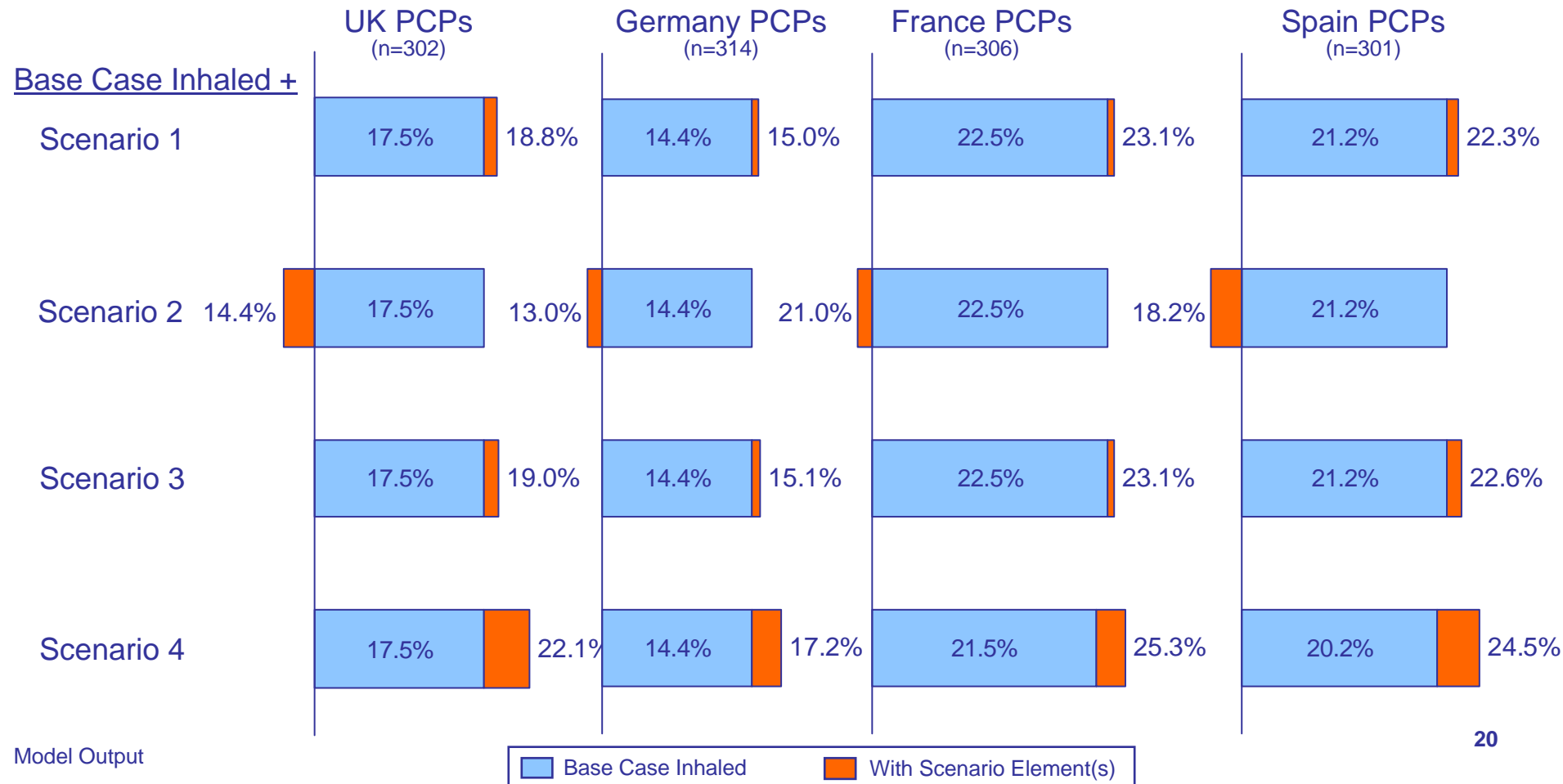


Among US Specialists (n=204).

*Top 20 attributes with most impact on preference share shown

The simulator allowed Novo Nordisk to establish preference share levels for any scenario modeled

Preference Share Change from Base Case Inhaled Insulin for Scenarios
(Weighted Total Patients)



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- [CLICK HERE TO DEMONSTRATE THE SIMULATOR](#)

How Novo Nordisk used the results

- Competitive assessment
 - Looked at the competitors' clinical trials and evaluated the impact of their potential claims
- Resource allocation
 - A clinical trial was prioritized because it would lead to a very valuable claim
- Marketing decision making
 - On one of our products in development, we are able to work on the evolution of positioning post launch

Challenges encountered

- Even with careful collaboration and review, some things nearly slipped through the cracks:
 - Best, base, worst-cases that weren't
 - Translations that weren't
- Even with careful, honest communication, there were misunderstandings
- Even with careful QC, fine tuning the simulator was a challenge
 - It was so big, with so many nuances, it took time to debug together

Best practices for studies like this

- Create a true team
- Have realistic expectations
- Create buy-in broadly and early
- Go overboard on QC, both consultant and client
- Expect some mistakes
- Be creative and flexible