

# Forecasting Capabilities

Epicenter Consulting LLC

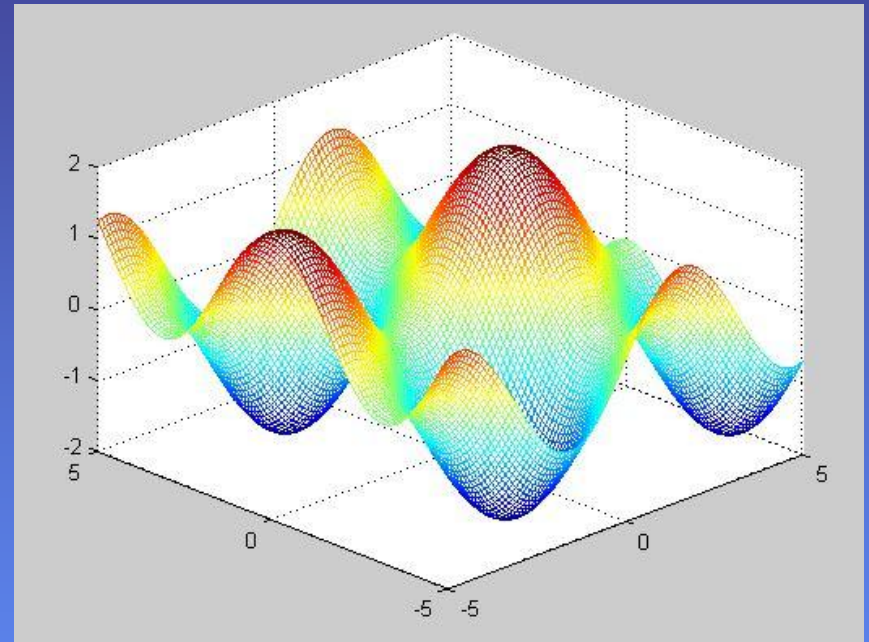
Dr. P. Mueller  
Epicenter Consulting LLC



# Forecasting Capabilities

## Table of Contents

- Mission
- The 4 Basic Forecasting Approaches
- Key Criteria for the selection of the Forecasting Approach, Methodology and Model
  - Data Availability, Triangulation
  - Forecasting Approach, Methodology
  - Analogue Product & Markets
  - The 10 Basic Forecasting Models
    - Examples of Epidemiological Models
    - Example "Source of Business" Model
    - Input and output screen shots of a Market / Product Simulation Tool
- Critical Success Factors
- The Process from Start to Finish
- Our Suite of Models



# Epicenter Consulting LLC

Our Mission is to provide World-class  
Marketing

**Forecasting**

and

Management Expertise

to our Clients in the Pharmaceutical and Biotechnology Industry

Our Forecasting expertise is based on  
23 Years of Global Experience in the  
Pharmaceutical Industry as well as  
10 years of Consulting.

Our Global Forecasting Expertise goes across  
all Therapeutic Areas and  
all phases of Product Development



# The 4 Basic Forecasting Approaches

## **Experiments, “TEST Markets”**

### Advantages:

- The Product is put into a real market environment
- The competitive reaction can be tested
- Market acceptance can be estimated

### Disadvantages:

- Time consuming and expensive
- Difficult to find true “representative market”
- No guarantee to eliminate 100 % of risk at launch
- Competition might react different at “full launch”

## **Statistical Approach** **“Surprise - free Extrapolation”**

### Advantages:

- Statistical rigor, good if solid historical data set available
- Provides historical perspective of market dynamic
- Sales responsiveness can be estimated

### Disadvantages:

- Projections are only “surprise free’ extrapolations
- New competition and changing market dynamics cannot be predicted by a statistical model
- New competition, generics etc. are not “factored in”

## **Judgmental Approach**

### Advantages:

- Fast and does not require “solid” data and statistical analysis
- Assumptions can include significant changes in the future including competitive reaction, generics, new products

### Disadvantages:

- Plain judgment without significant appreciation of market History, no statistical foundation
- Opens door for “wild speculation”
- Risk of wishful thinking becomes a substitute for facing undeniable market realities
- Completely subjective approach

## **Integrated Approach**

### Advantages:

- Statistical rigor & positive elements of judgmental approach combined (combination of two approaches)
- Allows “adjustments” to market history (out-layers)
- Allows for adjustments for market dynamics for new competition as well as generics or biosimilars

### Disadvantages:

- Relatively complex, time consuming and resource intensive
- Market simulations, but no “real test” in the market environment



# Data & Information Sources (Partial List)

## Primary Data / Information

- Ad-hoc project primary marketing research studies
- Focus Group Results
- Syndicated primary Study Results
- Telephone Interviews
- E-Market Research (internal & external)
- Trade-off Studies
- Conjoint Analysis
- Perceptual Mapping Results
- Semi-structured brain storming sessions

## Secondary Data / Information

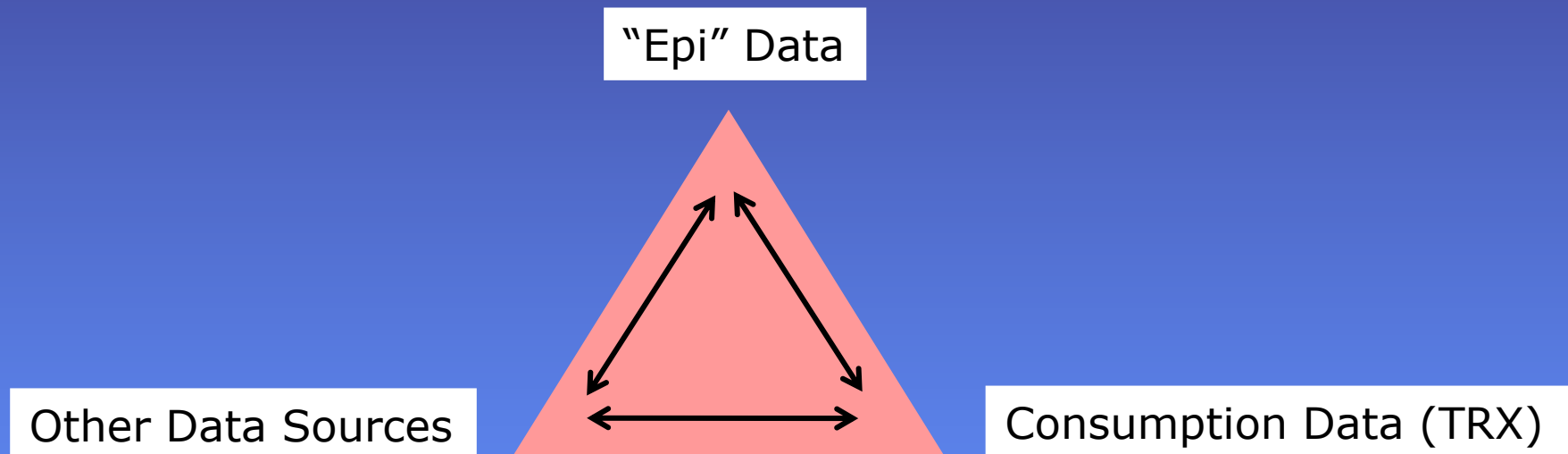
- IMS and / or other secondary data providers data sources (purchased)
  - TRX, NRX, Sales, Units, CU, Price per Tab., Daily Treatment cost
  - Sales Force Sizes, Sales Force Cost
  - A&P, Congress, Medical Phase IV etc.
- Epicenter Consulting Strategic Disease Database (proprietary Database)
  - Epi-data, Diag. and Treatment algorithms, R&D Pipelines , Strategic Disease Reviews, Healthcare Systems incl. Pricing & Reimbursement, Long Range CTY and Disease Forecasts (Epi, RX, Volume, Price, Cash)
- Internet
  - CDC, WHO, Disease Portals, Med-Scape, Edgar, Annual Reports, Pub-Med, Merck-Medicus, Published medical Journals, Dailymed, NIH, FDA Google-scholar etc.
- Other secondary providers
  - Decision Resources, Data-Monitor, others



# Data “Triangulation” for Forecast Variables Selection

Compare the robustness of various data sources and compare how consistent these data-sets are.

*Contradictions need to be resolved!*



Based on the relative “robustness” of the Data-triangulation, choose appropriate variables for the Model !



# Criteria for Analogue Product Selection

## Key criteria:

- **Expected Degree of Product Differentiation (Relative USP)**
  - Efficacy, Safety, Dosing, Convenience, Pricing, Reimbursement
- **Market Size and Dynamics**
  - Patient Population  
Patient Stratification (age, sex, ethnic etc.)
  - Target Audience  
GP, Specialist, Hospital, Managed Care
- **Market Entry**
  - First to Market
  - Second to Market
  - Me-too
  - Generic
  - Biosimilar

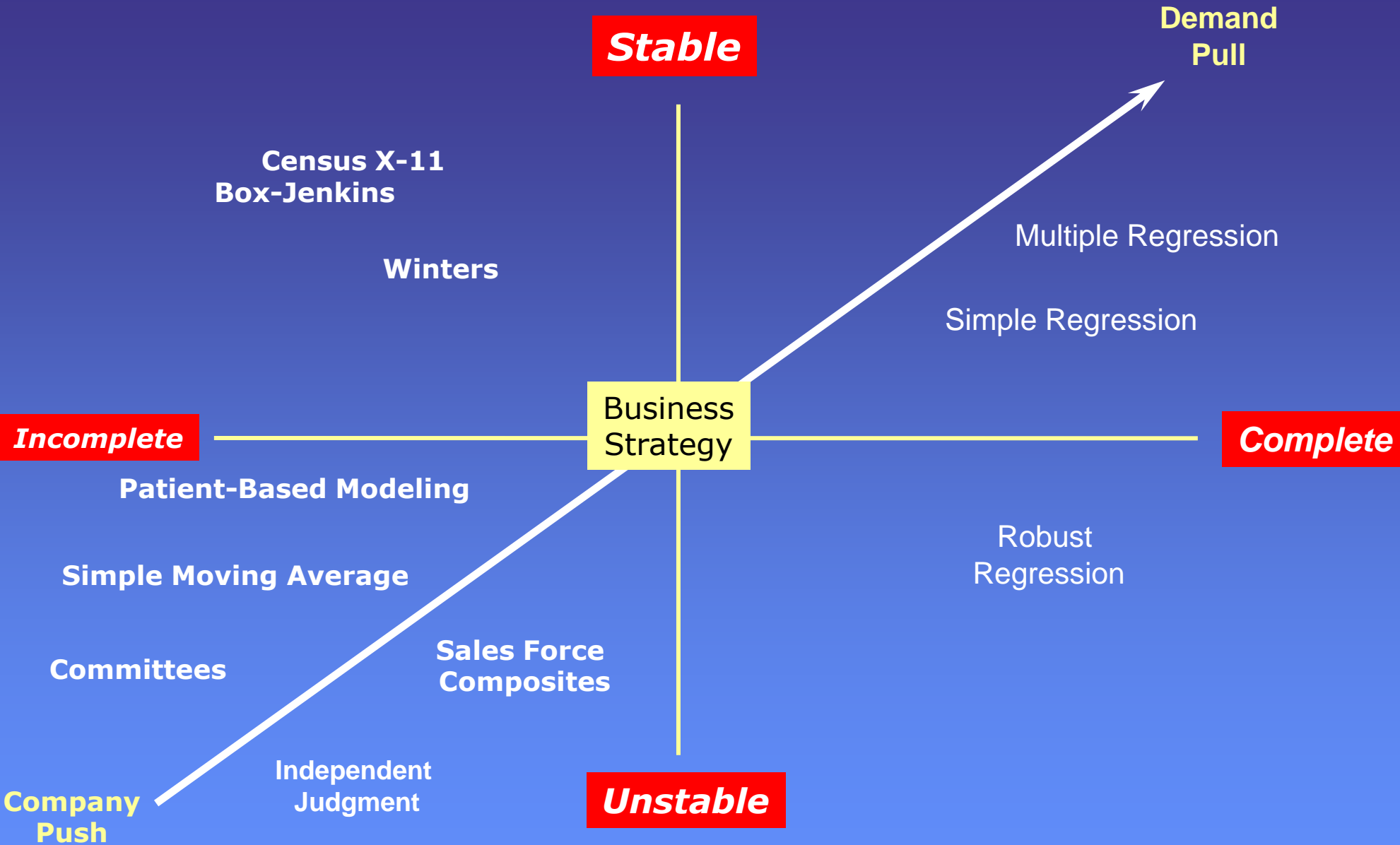
## Key criteria:

- **General Market Evolution**
  - Growing, fast growing, stagnant, decline
  - Historical trend, Future expectations
  - Volume, Patients, Cash etc.
- **Market Structure**
  - Global, non global
  - Dominant Market Leader vs. dispersed Market Leadership
  - Promotional Intensity
- **Competitive Intensity**
  - Overall quantitative Spending Pattern
  - Marketing Mix (SF, A&P, Phase IV etc.)
  - Multiple Competitors, Market Leader Promotional Strategy
  - Generics (now and at Launch)
- **Life Cycle during Forecast Period**

Analogue Products and Markets do not have to be in the same Therapeutic Area as the New Product. The most important Criteria are the market Growth, competitive Growth, and Promotional Intensity "PATTERNS" expected during the life cycle of the New Product !



# Forecasting Approach Data Quality & Quantity

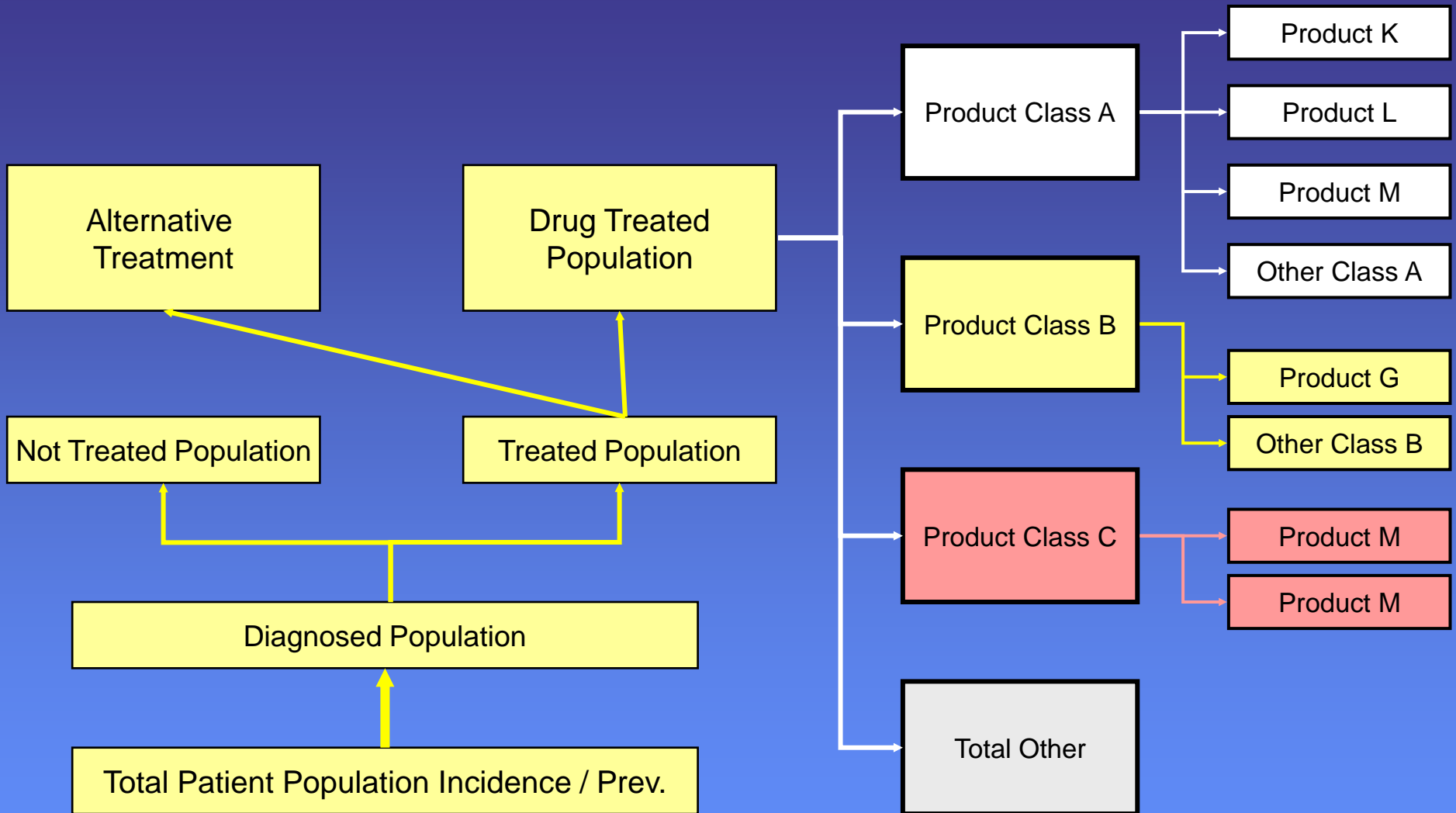


# The Top 10 Basic Forecast Models

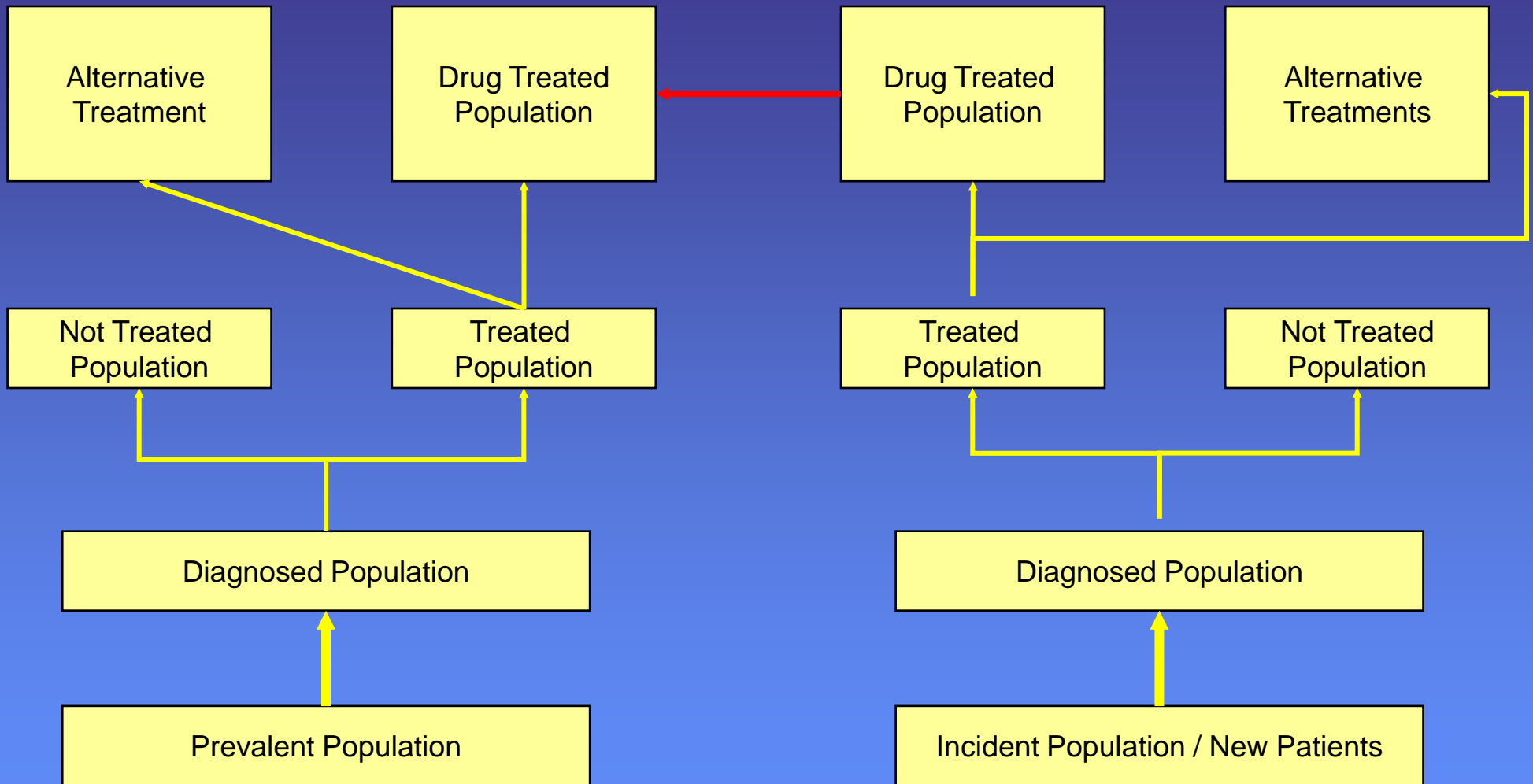
1. The basic epidemiological approach  
(incidence and prevalence based models for "acute" diseases)
2. The dynamic patient flow approach (HIV, Cancer etc)
3. The therapy class approach
4. The therapy day approach
5. The composite market model
6. "Head to head" models
7. Mixed models (Diagnosis, Therapy Days, ATC3 Class)
8. Share stealing integrated model
9. Diffusion Models (Bass diffusion model)
10. Product life cycle indexing and projection approach



# The Basic Epidemiological Approach



# The Dynamic Patient Flow Model



# Share Stealing Model

## "Source of Business Model"

Share Matrix for Volume, Sales and Promotional Investments required								
	Year -3	Year -2	Year -1	Year 1	Year 2	Year 3	Year 4	Year 5
<b>New Product</b>				4.00	7.00	12.00	15.00	18.00
<b>Competitor 1</b>	25.00	25.00	24.00	20.00	17.00	12.00	10.00	8.00
<b>Competitor 2</b>	22.00	22.00	21.00	17.00	14.00	9.00	7.00	5.00
<b>Competitor 3</b>	30.00	30.00	32.00	34.00	32.00	35.00	36.00	37.00
<b>Branded Other</b>	20.00	20.00	20.00	15.00	15.00	12.00	11.00	10.00
<b>Generic</b>	3.00	3.00	3.00	10.00	15.00	20.00	21.00	22.00
<b>Total</b>	100.00	100.00	100.00	100.00	100.00	100.00	100.00	100.00

This Model is the most comprehensive approach, since we are forecasting every single leading Product as well as the new product to be introduced over the forecast horizon.

We also project the "share of voice" for each critical component!



# Input Screen for Simulation Model

Lipid Opportunity Europe

Forecast Simulation Tool Input Screen

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## Prevalence estimates for familial Hypercholesterolemia in Europe by Country

Germany	UK	France	Italy	Spain	ROE
1 in 500	1 in 500	1 in 500	1 in 500	1 in 500	1 in 500

## Life Cycle Selection

Life Cycle 7

## Obese Population relevant for Treatment (10-20)

Germany	UK	France	Italy	Spain	ROE
800000	700000	700000	800000	500000	350000

## Daily Treatment Cost NUR per Day in USD (Euro USD 1:1.30)

Germany	UK	France	Italy	Spain	ROE
0.4 USD	0.4 USD	0.3 USD	0.3 USD	0.3 USD	0.4 USD

## Compliance, % Therapy days per calendar year

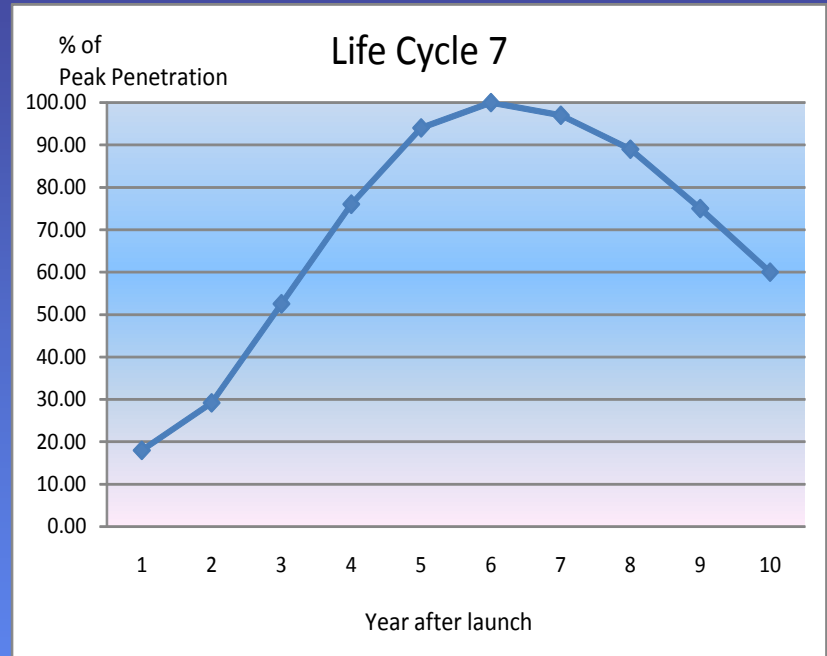
Germany	UK	France	Italy	Spain	ROE
70%	70%	70%	65%	65%	50%

## Peak Penetration in % of Patients with Familial Hypercholesterolemia

Germany	UK	France	Italy	Spain	ROE
20.0	20.0	20.0	20.0	20.0	15.0

## Peak Penetration in % of overweight / obese Patients

Germany	UK	France	Italy	Spain	ROE
10.0	10.0	10.0	8.0	8.0	5.0



# Output Screen 1 Simulation Model

Results for Forecast Simulation:

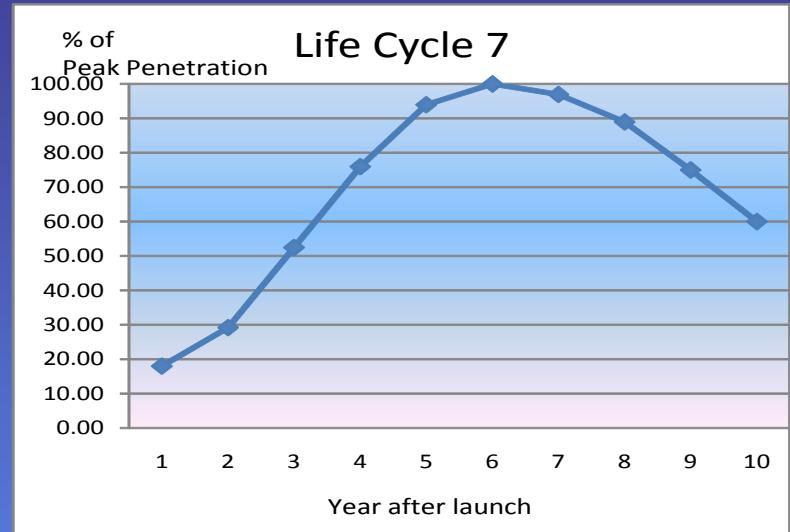
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Page 1

Prevalence familial Hypercholesterolemia and prevalent selected population

Life Cycle Selection

	Prevalence	Prevalent Popul.	"obese" Popul.	DTC in \$	Compliance %
Germany	1 in 500	12,713	800000	0.40	70%
UK	1 in 500	11,959	700000	0.40	70%
France	1 in 500	14,586	700000	0.30	70%
Italy	1 in 500	9,265	800000	0.30	65%
Spain	1 in 500	7,403	500000	0.30	65%
ROE	1 in 500	12,420	350000	0.40	50%
<b>Total Europe</b>		<b>68,346</b>	<b>3850000</b>		



Peak Market Penetration (%) in terms of prevalent selected population

	Familial Hyperchol.	Overweight Obese
Germany	20.0	10.0
UK	20.0	10.0
France	20.0	10.0
Italy	20.0	8.0
Spain	20.0	8.0
ROE	15.0	5.0

Summary of results

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Net Sales by Country in MM \$

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
<b>Germany</b>	<b>1.50</b>	<b>2.43</b>	<b>4.37</b>	<b>6.32</b>	<b>7.82</b>	<b>8.32</b>	<b>8.07</b>	<b>7.41</b>	<b>6.24</b>	<b>4.99</b>
<b>UK</b>	<b>1.31</b>	<b>2.13</b>	<b>3.83</b>	<b>5.55</b>	<b>6.86</b>	<b>7.30</b>	<b>7.08</b>	<b>6.49</b>	<b>5.47</b>	<b>4.38</b>
<b>France</b>	<b>0.99</b>	<b>1.61</b>	<b>2.89</b>	<b>4.19</b>	<b>5.18</b>	<b>5.51</b>	<b>5.35</b>	<b>4.91</b>	<b>4.13</b>	<b>3.31</b>
<b>Italy</b>	<b>0.83</b>	<b>1.35</b>	<b>2.43</b>	<b>3.51</b>	<b>4.35</b>	<b>4.62</b>	<b>4.48</b>	<b>4.11</b>	<b>3.47</b>	<b>2.77</b>
<b>Spain</b>	<b>0.52</b>	<b>0.85</b>	<b>1.53</b>	<b>2.21</b>	<b>2.74</b>	<b>2.91</b>	<b>2.82</b>	<b>2.59</b>	<b>2.18</b>	<b>1.75</b>
<b>ROE</b>	<b>0.25</b>	<b>0.41</b>	<b>0.73</b>	<b>1.06</b>	<b>1.31</b>	<b>1.39</b>	<b>1.35</b>	<b>1.24</b>	<b>1.05</b>	<b>0.84</b>
<b>Total Europe</b>	<b>5.41</b>	<b>8.78</b>	<b>15.78</b>	<b>22.84</b>	<b>28.26</b>	<b>30.06</b>	<b>29.16</b>	<b>26.75</b>	<b>22.54</b>	<b>18.04</b>



# Output Screen 2 Simulation Tool

Results for Forecast Simulation:

Page 2

10/7/2011 8:02

## Market Share for familial hypercholseterinemia

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
Germany	3.60	5.84	10.50	15.20	18.80	20.00	19.40	17.80	15.00	12.00
UK	3.60	5.84	10.50	15.20	18.80	20.00	19.40	17.80	15.00	12.00
France	3.60	5.84	10.50	15.20	18.80	20.00	19.40	17.80	15.00	12.00
Italy	3.60	5.84	10.50	15.20	18.80	20.00	19.40	17.80	15.00	12.00
Spain	3.60	5.84	10.50	15.20	18.80	20.00	19.40	17.80	15.00	12.00
ROE	2.70	4.38	7.88	11.40	14.10	15.00	14.55	13.35	11.25	9.00

## Market Share for obese / overweight population

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
Germany	1.80	2.92	5.25	7.60	9.40	10.00	9.70	8.90	7.50	6.00
UK	1.80	2.92	5.25	7.60	9.40	10.00	9.70	8.90	7.50	6.00
France	1.80	2.92	5.25	7.60	9.40	10.00	9.70	8.90	7.50	6.00
Italy	1.44	2.34	4.20	6.08	7.52	8.00	7.76	7.12	6.00	4.80
Spain	1.44	2.34	4.20	6.08	7.52	8.00	7.76	7.12	6.00	4.80
ROE	0.90	1.46	2.63	3.80	4.70	5.00	4.85	4.45	3.75	3.00

## Treated selected Patients genetic and obese / overweight combined

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
Germany	14858	24102	43335	62732	77590	82543	80066	73463	61907	49526
UK	13031	21138	38006	55018	68048	72392	70220	64429	54294	43435
France	13125	21292	38282	55417	68542	72917	70730	64896	54688	43750
Italy	11854	19229	34573	50048	61902	65853	63877	58609	49390	39512
Spain	7466	12112	21777	31525	38992	41481	40236	36918	31110	24888
ROE	3485	5654	10166	14716	18201	19363	18782	17233	14522	11618
<b>Total Europe</b>	<b>63819</b>	<b>103528</b>	<b>186138</b>	<b>269457</b>	<b>333275</b>	<b>354548</b>	<b>343912</b>	<b>315548</b>	<b>265911</b>	<b>212729</b>

## Net Sales total Europe by Market Segment

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
	000 \$	000 \$	000 \$	000 \$	000 \$	000 \$	000 \$	000 \$	000 \$	000 \$
Genetic Segment	195	317	570	825	1021	1086	1054	967	815	652
Obesity Segment	5215	8460	15211	22019	27234	28973	28104	25786	21730	17384
<b>Grand Total</b>	<b>5411</b>	<b>8777</b>	<b>15781</b>	<b>22845</b>	<b>28255</b>	<b>30059</b>	<b>29157</b>	<b>26752</b>	<b>22544</b>	<b>18035</b>



# The Net Present Value

Today

Launch

Y-3

Y-1

Y 1

Y 5

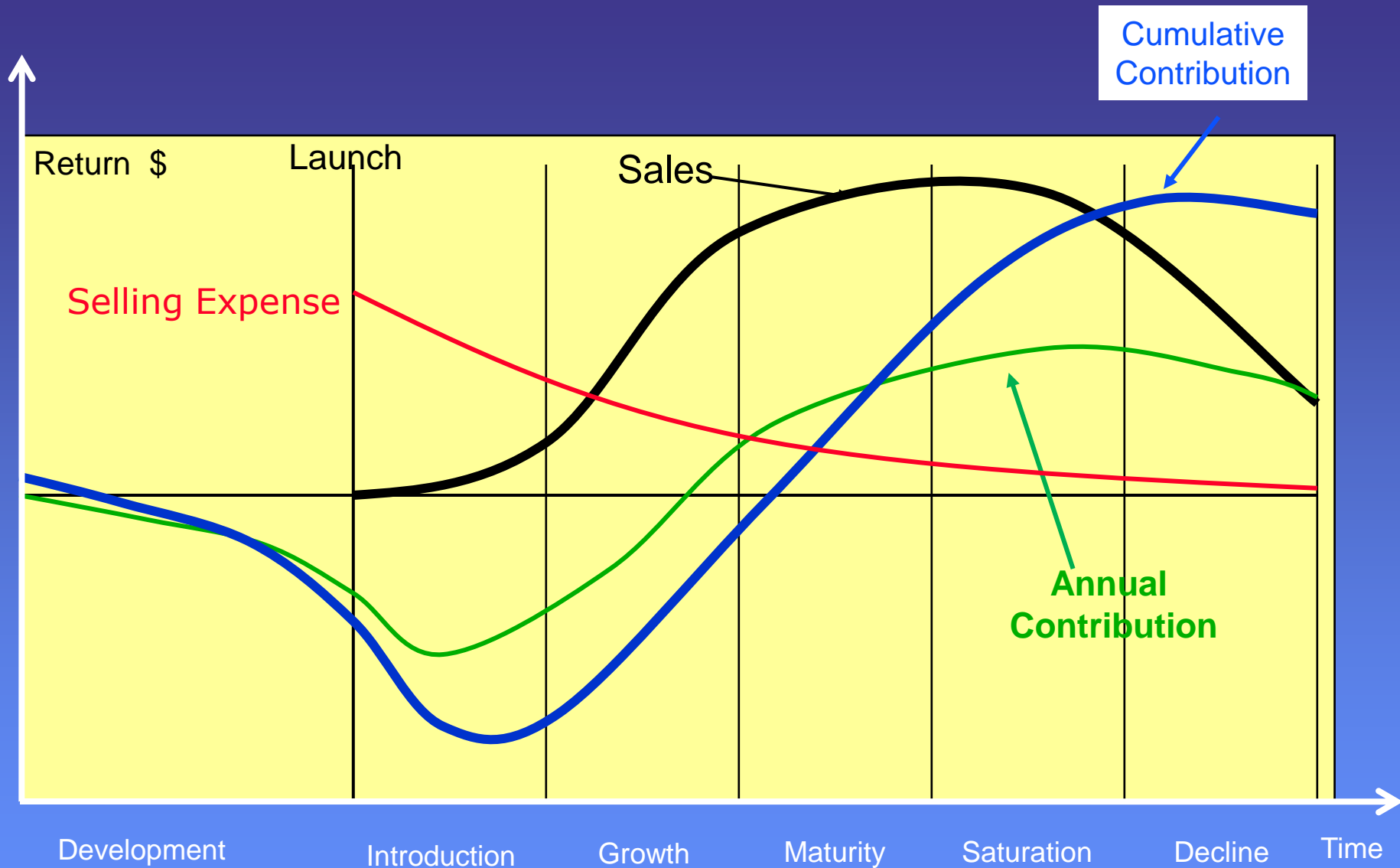
Y 10

Q I Development Cost PH III Pre Marketing Cost	Q2 The Driver of NPV Sales COGs Selling Expense <i>Product Contribution</i>
Q3 Capital Investments etc.	Q4 Working Capital Taxes Financial Calculations

NPV



# Phases of the Product Life Cycle



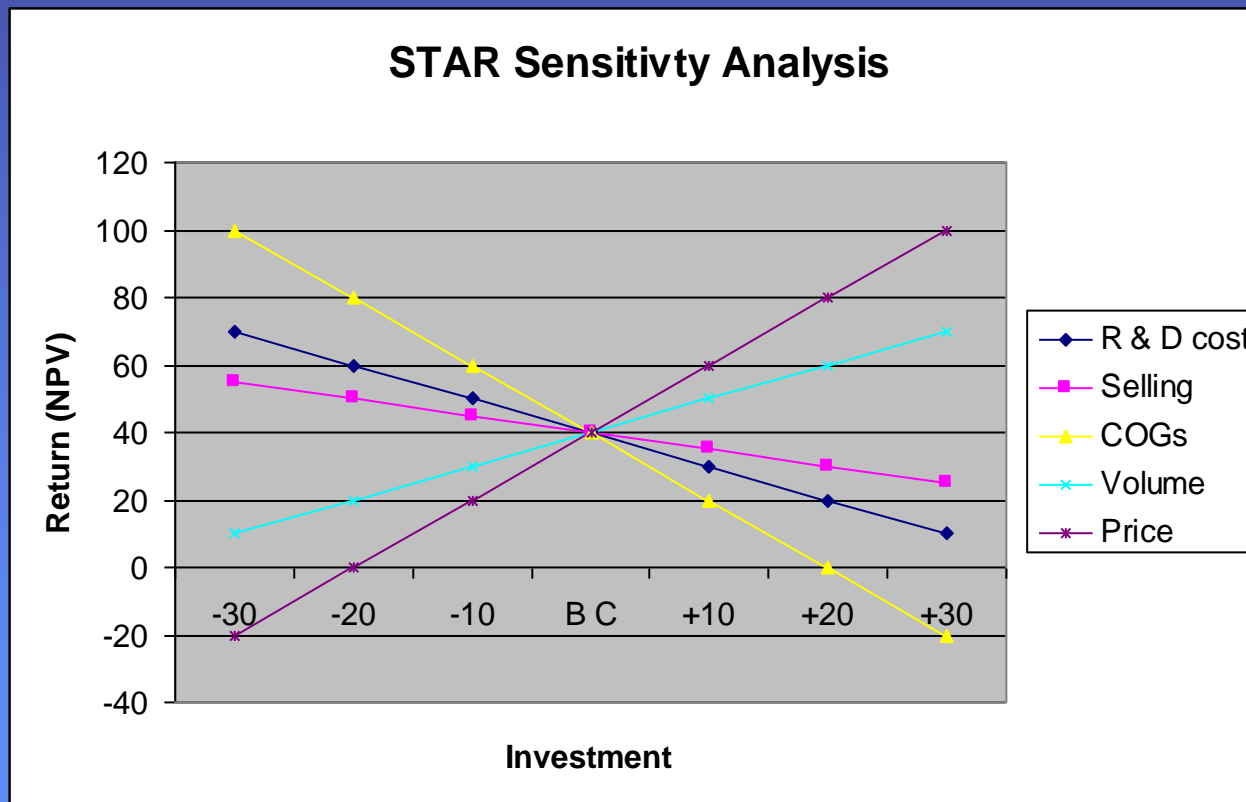
# Product P & L

Product P & L	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
Illustration	MM \$	MM \$	MM \$	MM \$	MM \$	MM \$	MM \$
Sales	44.0	90.0	129.0	157.0	178.0	180.0	175.0
COGs	8.8	18.0	25.8	31.4	35.6	36.0	35.0
% of Sales	20%	20%	20%	20%	20%	20%	20%
Gross Margin	35.2	72.0	103.2	125.6	142.4	144.0	140.0
% of Sales	80%	80%	80%	80%	80%	80%	80%
Sales Force Cost	65.0	56.7	45.2	33.0	31.2	25.2	24.5
Advertising & Promotion	25.0	20.3	16.1	11.8	11.1	9.0	8.8
Medical Expense	5.0	4.1	3.2	2.4	2.2	1.8	1.8
Total Selling Expense	95.0	81.0	64.5	47.1	44.5	36.0	35.0
% of Sales	216%	90%	50%	30%	25%	20%	20%
Product Contribution Margin	-59.8	-9.0	38.7	78.5	97.9	108.0	105.0
% of Sales	-136%	-10%	30%	50%	55%	60%	60%
Cumulative Contribution	-59.8	-68.8	-30.1	48.4	146.3	254.3	359.3



# NPV Sensitivity Analysis

	-30	-20	-10	B C	+10	+20	+30
R & D cost	70	60	50	40	30	20	10
Selling	55	50	45	40	35	30	25
COGs	100	80	60	40	20	0	-20
Volume	10	20	30	40	50	60	70
Price	-20	0	20	40	60	80	100



# Critical Success Factors for our unique Forecasting Process

## 1. **Quality and reliability of historical data**

We validate individual data sources and cross validate different data sources for maximum data integrity.

## 2. **Tools to perform data analysis**

We use “state of the art” statistical tools and Forecasting Software to perform historical analysis and for “surprise free” extrapolations. Tools for time series analysis, cross sectional analysis, simulation software.

## 3. **Market / Product History: Statistical Analysis**

Our historical data analysis includes time series as well as cross-sectional analysis, simulations, sales response estimates, promotional sensitivity analysis

We use consumption data (number of tablets, daily doses etc.),

RX-data, promotional as well as epidemiological data from various sources to generate a comprehensive review of the market history and provide insight into market dynamics (Historical growth rates, seasonal patterns, cyclical patterns, new product adoption curves, sales responsiveness, competitive intensity).

## 4. **Experience in Judgment**

Our experience in new product forecasting is based on hundreds of forecasts across all therapeutic areas, diseases and geographies. We have up-to-date information on healthcare systems, pricing and reimbursement information. We have a database comparing forecasts (including revisions over time) with real world experience / data after launch.

## 5. **Process to integrate statistical and judgmental approaches**

Our time tested process for integration of historical data analysis, projections and integration of judgmental input is an iterative process, by which we are in a continuous feed-back loop with the client to ensure total integrity in the model.

## 6. **Continuous communication with our clients during the entire process**

During the entire process we regularly communicate with our client to ensure that all findings are appropriately integrated into the model and that there are no “late surprises”. This process guarantees also that everybody is informed and “conditioned” for the final meeting and results.

## 7. **Clear and unbiased communication of recommendations**

Our client receives a presentation with the results of various simulations and our recommendations. We provide a “SIMULATION TOOL” which enables the client to perform it’s own simulations and scenario analysis.



# The Process from Start to Finish

## 1. **Get clarity and agreement on forecasting objective**

During our initial briefing meeting (TCON or face-to-face meeting) with our clients we get a full understanding of the situation at hand. We agree with our client on the objective of the forecast, expected deliverables, the process, timing and cost.

## 2. **Get agreement on process, methodologies, tools, deliverables, timing and cost**

Before starting the forecasting process, we propose to the client a detailed T&E schedule and contract

## 3. **Data collection, analysis, synthesis, market system drivers and dynamics**

At this stage we go through the complete statistical “routine” of data collection, analysis, sales response estimation, promotional sensitivity analysis, analysis of market / system dynamics and surprise free market projection

## 4. **Creating market / product simulation model**

The market simulation tool is driven by the key variables identified during the statistical analysis. Volume, price, market growth rates in volume terms, peak penetration and indexed life cycle curves are always an integral part of each model. Depending on the disease, geography, stage of development additional variables are integrated into the simulation tool. Each simulation tool is customized to the product, technology, market, competitive environment, geography and other relevant market drivers.

## 5. **Forecast simulation session (testing and fine tuning of the simulation tool)**

At this stage we test the simulation tool and the sensitivity of the system for each variable and combinations of variables to understand the systems dynamic. “Realistic ranges” for each variable are tested to understand all dimensions of the model.

## 6. **Agreement on selected scenarios and outcomes**

Based on the understanding gained in step 5 we then simulate a set of “realistic scenarios” where each scenario simulates a set of assumption / variables. (i.e. Peak penetration, life cycle curve, price, market growth rates, launch date, level of investment Sales Force cost, A&P etc.)

## 7. **Communication of forecasting results to Client**

Key deliverables of each project is a Power-point presentation explaining the simulation tool, key variables and system dynamics as well a set of selected scenarios and recommendations. Based on client need this meeting can be face-to-face, via T-CON, Skype or other electronic communication.



# Our Suite of Model Options

- **Sales Forecast**  
(Basic Simulation Tool)  
Volume, price & sales forecast assuming  
"competitive share of voice"
- **Profit Forecast Model**  
(Advanced Simulation Tool)  
Complete Profit & Loss Statement of the new  
product including basic Sensitivity Analysis  
(Quadrant II of NPV Model)
- **Dynamic Market Simulation Model**  
(Complete Simulation Tool including Commercial  
NPV Sensitivity Analysis)  
STAR Analysis, Maximizing Commercial NPV

