

Data maximisation

EphMRA Athens, 2006

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The road ahead

- A story spanning five years
 - the entire audited-pharmaceutical world
 - six core methodologies
 - primary research and multiple secondary sources
 - five informant super-sets with multiple sub-sets
 - ground-breaking fusion-data modelling

BUT

- *Not* simply a story of a long-term, big-ticket engagement
 - also an example of how consultants and researchers might strive to maximise data, its value AND their client relationships
 - and of how clients might consider maximising the value of supplier relationships

Client background

- Top-20 pharmaceutical and biotechnology company
- Research-based
 - robust pipeline with rich research stream
 - *and* strong acquisition approach
- Global
 - but with considerable US focus
- Human, animal and consumer health
- Present in all major therapy classes
- **Aiming to consolidate recent blockbuster successes**
- **Acquired rights to a novel product - aspiration to similar revenues**

Target Market

- Global
- High-volume-low-value
 - but highly specialised manufacturing, marketing and distribution
 - significant investment requirement with considerable risk
- Highly saturated
 - and already contended by client with an undifferentiated product
- Market emerging from a period of stagnation in terms of innovation
- Identified as potential growth opportunity by multiple players
- Challenges
 - select, develop and market a viable innovation
 - stimulate and expand total market by generating new patient segments
 - target specific segments and command premium price
- Imperative to be first to market

Therapeutic concept

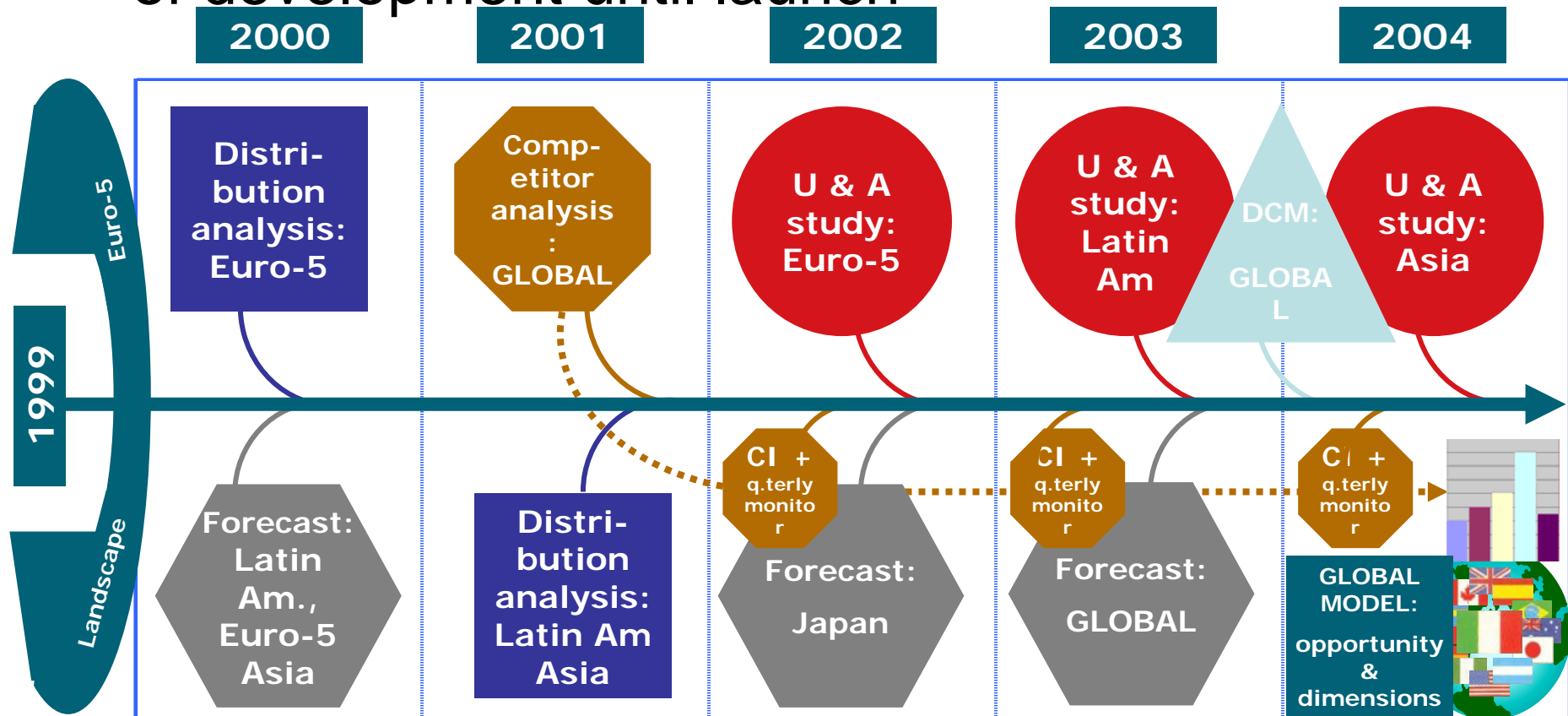
- Licensed-in product
- Novel administration
 - simpler and less invasive
 - attractive to patients
- Production benefits facilitating rapid response to market demand
- Few perceived clinical risks

Client challenges

- High cost of development and marketing
 - funding of significant licencing-in costs
 - creation of new patient segments
- Achievement of critical mass in manufacturing volume
- Relatively limited experience in ex-US markets
- Satisfy (high) senior management expectations

Our challenge - the road trodden

- navigating business intelligence through 5 years of development until launch



Situation analysis - reimbursement

- Up-to-date information gathered and analysed on key issues across 19 markets:

e.g. **CANADA: Reimbursement and funding issues**

Organisation setting Policy	Co-pay exemption recommendations	Funding	Supply for Recommended Groups	Healthy Population not covered by Recommendations	Cost or Co-pay for non-recommended Groups	Current brands
<p>National Advisory Committee publishes guidelines. Each Province has own Committee that decides on own policies. Provincial Committees follow National Guidelines as a minimum, but often go further.</p>	<p>Elderly over 65 years (may be 60 in some provinces) Chronic sick and at risk population People in Residential Care Teachers and others who work with children covered in some provinces In Ontario: universal</p>	<p>Provincial governments fully fund for those covered by recommendations</p>	<p>Various brands selected and supplied to doctors by Provincial Health Authority Doctors unable to choose brands Must use specified product presentation</p>	<p>Available to all. Some may be required to co-pay.</p>	<p>Varies between CAN\$5 and \$20</p>	<p>Alpha Beta Gamma Delta</p>

Competitor analysis (1)

- Continuous programme with quarterly CI update

CI objectives

- development history, current status, rate of progress through, development stages, likelihood of maintaining commercialisation and launch schedule
- evaluation of current clinical trial programme, patient entry criteria, centres involved in trials, outcomes, investigators involved, factors which might give insight into positioning strategy
- evaluation of competitor's product commercialisation history, handling of regulatory, average time elapsed between submissions and approvals.
likely positioning strategy for competitor offering

Primary research in CI

Depth interviews with:

- (a) opinion leaders involved in competitor-product trials
 - (b) regulatory/policy makers
- product's characteristics
clinical performance and progress
marketing strategy
positioning
outcomes

Competitor analysis (2)

- Continuous programme with quarterly CI update

Secondary research in CI

- clinical publications, analyst reports, information from conferences and symposia, published clinical trial data, company reports.
- IMS company profiles (review company's structure, direction, corporate strategy, product portfolio, product pipeline, R&D, financial status and marketing strengths)
- IMS promotional spend audits
- IMS' IDRAC regulatory affairs database

CI SWOT analysis

Competitor vs. New Concept using matched CI criteria

Why the task expanded

- Discontinuous marketing team
- Hence stable business intelligence team indispensable
 - Incoming client marketeers inexperienced and with over-ambitious expectations
 - Euphoria tempered by real-world data from assignment
 - Ongoing need for fresh evidence and validation
 - Scope and objectives subject to continuous modification
 - Reprioritisation of activities
 - Addition of new data requirements
 - Iteration of 'completed' tasks
 - Forecasts
 - Landscape
 - Competitor intelligence

Consequences

- Need to consolidate disparate pieces into a usable tool
- Reduce learning curve for incoming Clients
- Create accessible business intelligence repository
- Establish business tools for product life-cycle
 - Maximise data
 - Minimise complication

“This tool has reduced my workload by one-third.”

Incoming Product Manager

Forecast - stretching data points

Commentary from

Robert Gandolfini

Engagement Manager

Forecasting

IMS Health

DCM founded on research & CI

Commentary from

Linda Hilson

Consulting Principal

*Vaccination Therapy Area
Specialist*

IMS Health

The Modelling Process (1)

- The product choice process
 - *Who **influences** or makes the choice of product to use?*
 - *Which are the **target** population groups?*
 - *What product **attributes** are assessed in the product choice decision?*
 - **Spectrum** (2 levels)
 - **Onset** of effect (2 levels)
 - **Class** (3 levels - **physicians** *only*)
 - **Dosage** & interval (3 levels)
 - **Mode** of administration (2 levels)
 - **Side effects** & adverse reactions (2 levels)
 - **Course** (3 levels)
 - **Cost** of vaccine (4 levels)
 - **Reimbursement** (3 levels)
 - *How are these attributes and their levels **evaluated**?*
 - *Definition of existing, new and potential **competitor** products in terms of the attribute selected*

Reimbursement

Markets	First level	Second level	Third level
Canada	Free to recommended population groups: No reimbursement for other groups	No reimbursement - full cost paid by all	N/A
France	Free to recommended population groups: 30% co-payment for non-recommended groups	30% co-payment by all	No reimbursement
Germany	Free to all	Free to recommended population groups; full cost paid by all other groups	Full cost paid by all
<i>Italy:</i> <i>(For identification of surrogate)</i>	<i>Free to recommended population groups; 40% co-payment by all other groups</i>	<i>40% co-payment by all</i>	<i>Full cost paid by all</i>

The Modelling Process (2)

- Marketing factors
 - Time frame over which prediction is required
 - What are the likely take-up profiles for this type of product
 - Launch date for the new product and potential competitor products

The Modelling Process (3)

- Population
 - Estimates of the population for the country in total and for sub-groups over the prediction time frame
 - Estimates of the likely incidence of the condition for which the product is designed for each sub-group
 - Events which may influence the potential market for the product
- Revenue estimation
 - *What is the level of distribution costs?*

Functional prerequisites of the modelling tool

- Extended lifetime
- Variable modelling features
 - *new product attributes*
 - *competitor attributes*
 - *number of competitors*
 - *launch dates for each new market entrant (including NO launch)*
 - *take up profile for new products*
 - *stakeholder weight*
- Price elasticities
- Product share by country and segment
- THREE measures of market share - \$ value, units sold, patients treated
- Historical and future trends/events
- Unlimited what-if scenarios
 - *Varying any or all of the variables for except for existing products, probability, timing and impact of future events, launch dates, approval in different population groups etc*
- A single GLOBAL model

Nearing the end of the road

- the Global model
 - 9 markets (plus 3 using surrogates)
 - 12 studies (at least, covering 16 countries)
-
- the SINGLE world view

Setting variables – front end

BASE CASE click here to return to Current Selection

Preference Share Simulation

Variable launch dates (products may be 'switched' on/off)

ims		Yr 1	Yr 5
		000's	000's
VOLUME			
Leader		2463	1018
Prod 'X'		59	1901
Prod 'Y'		1198	1901
% change base case		27%	-9%
REVENUE		1,056	34,225

Share converted to forecast value & volume

X' Year 1 of launch 2006 **X'** **Set launch year**

X' Year 5 after launch 2010

Y' Year 1 of launch 2007 **Y'** **Set launch year**

Y' Year 5 after launch 2011

Weight of Paed.s' vs. PCP's views (Weighted to universe & Rx) 50% **Paed.s** **PCPs**

Variable Decider

	Current market leader	Weighted Product X'	New 'Product Y'
Spectrum	B. spectrum exc. P. aeruginosa	B. spectrum inc. P. aeruginosa	B. spectrum inc. P. aeruginosa
Onset of effect	48 hours	24 hours	36 hours
Class	3rd Gen. cephalosporin	Extended spect. penicillin	2nd Gen. macrolide
Dosage & interval	250 mg t.d.s.	350 mg b.d.	1 g u.i.d.
Mode of Administration	capsules and suspension	Oral tablet only	Oral capsule only
SEs/Adverse reactions	G.I., hypersensitivity	G.I., skin, pseudo. colitis, j	G.I., skin, anorexia, photo:
Course of acute therapy	10 days	5 days	4 days
Cost per course GBP£)	12	18	16
Reimbursement	Fully reimbursed	No reimbursement	50% co-payment

Product attributes with variable levels (Pull-down, slide or type-in value)

What if?

Country 'A' Events affecting anti-bacterial product usage

ims

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Default Event Settings

Enter a starting year for each event between 2002 and 2015.

EVENT DESCRIPTION (click here for info)	Start Year (click here for info)	Maximum Impact (click here for info)	Time to impact (years) (click here for info)	Age Group
Changes in prescribing policy	2002	0.0%	15	Neonates & babies <1yr
	2002	0.0%	15	Infants 1 - 5
	2002	0.0%	15	Children 6 - 12
	2002	0.0%	15	Children with COPD
	2002	0.0%	15	Adolescents/adults 13-64
	2002	0.0%	15	Adolescents/adults COPD
	2002	0.0%	15	Elderly 65+
	2002	0.0%	15	Elderly COPD
	2002	36.0%	15	Neonates & babies <1yr
	2002	36.0%	15	Infants 1 - 5
Increased resistance to anti-bacterial drugs	2002	36.0%	15	Children 6 - 12
	2002	29.9%	15	Children with COPD
	2002	21.5%	15	Adolescents/adults 13-64
	2002	26.2%	15	Adolescents/adults COPD
	2002	24.0%	15	Elderly 65+
	2002	24.0%	15	Elderly COPD
	2008	6.3%	5	Neonates & babies <1yr
	2008	22.7%	5	Infants 1 - 5
	2008	26.9%	5	Children 6 - 12
	2008	30.1%	5	Children with COPD
Availability of Product 'X'	2008	23.3%	5	Adolescents/adults 13-64
	2009	27.2%	5	Adolescents/adults COPD
	2009	14.3%	5	Elderly 65+
	2010	14.4%	5	Elderly COPD
	2008	0.0%	5	Neonates & babies <1yr
	2008	0.0%	5	Infants 1 - 5
	2008	0.0%	5	Children 6 - 12
	2008	0.0%	5	Children with COPD
	2008	0.0%	5	Adolescents/adults 13-64
	2008	0.0%	5	Adolescents/adults COPD

Event description
The cells below contain a description of each event. In cells marked 'new event' the user has the option to add their own events which must then be quantified in the normal way using a start year, maximum impact and time to impact.

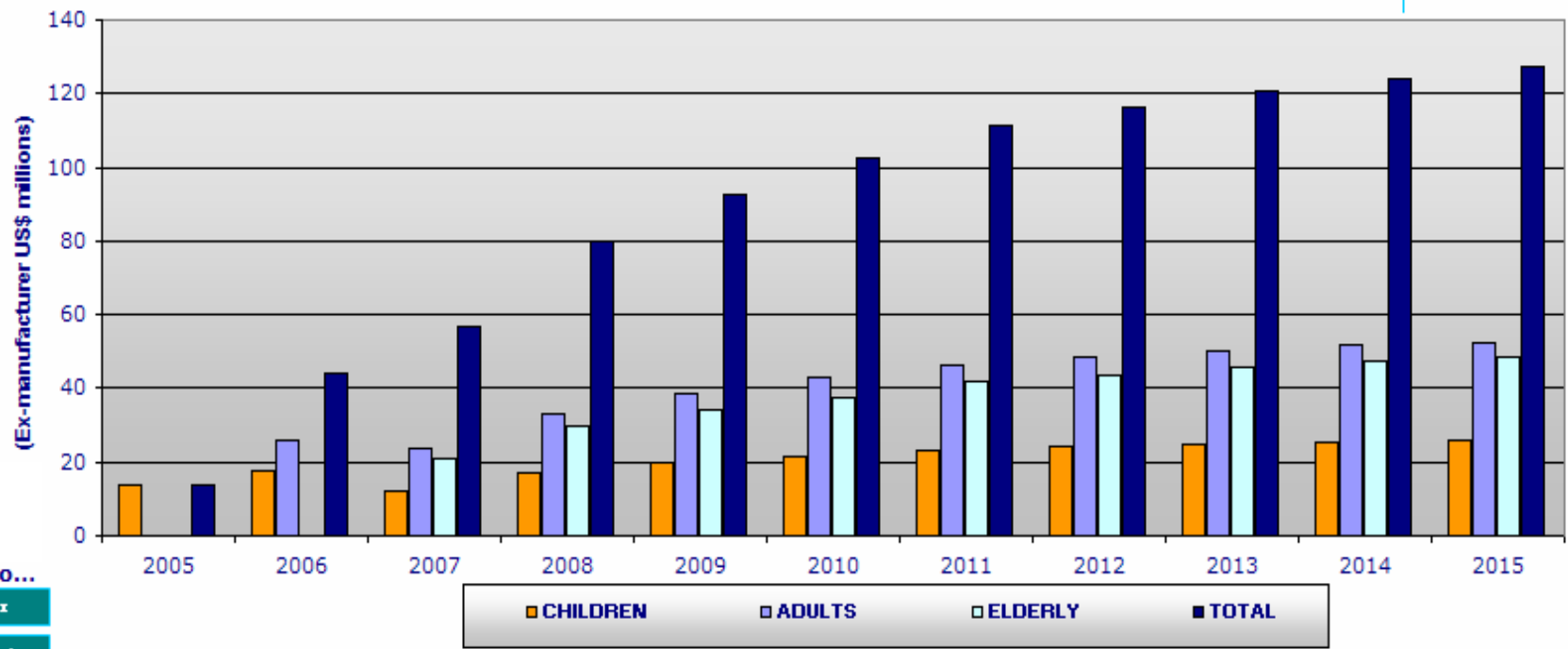
Enter the maximum impact that this particular event is expected to have in each age group. This value can be either positive, negative or zero.

Enter the time in years that you expect this event to exert its maximum impact. (This should be calculated from and include the start year).

Revenue



Country 'A' - Revenue Forecast (Ex-manufacturer US\$ millions)



Go to...
 Index
 Attribute Selection

	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	TOTAL
TOTAL	13.584	43.900	56.783	79.942	92.671	102.321	111.148	116.487	120.707	124.214	127.285	989.042
CHILDREN	13.584	17.760	12.127	17.147	19.653	21.579	22.995	24.032	24.833	25.495	26.075	225.279
ADULTS	0.000	26.139	23.735	32.806	38.624	43.243	46.421	48.684	50.342	51.576	52.517	414.088
ELDERLY	0.000	0.000	20.921	29.990	34.394	37.499	41.732	43.771	45.532	47.142	48.692	349.674

Revenue Forecast / Patient Forecasts / Volume Forecasts / Revenue Forecasts / Events / Distribution / Pi

NUM

Validation

- Peer review
 - *method*
 - *data*
 - *results*
- *A clean bill of health!*

Impact

- Tangible evidence revised management expectations
- Strategy entirely reworked across Corporation

The Product Manager's view

- **I joined the product marketing team at a late stage in the product's development:**
 - *after the pricing study had been completed and the forecasting model developed*
 - My primary responsibilities at that time were to:
 - Become familiar with this market
 - Understand and establish the framework that would maximise the product's potential
 - Initiate the preparation of the marketing teams in each country for the product launch
 - Manage the relationship with our marketing partner and licensor
 - Meet senior management requests for forecasts and information on multiple scenarios
 - Once familiar with the forecasting model, the ability to model different scenarios and meet management requests for information considerably facilitated my workload
- **I regarded the model as a very useful tool**
 - Able to model 12 markets individually and roll these into a global forecast
 - a good number of lesser markets was not modelled individually
 - while each was less important individually, **in aggregate**, they made a significant contribution to global revenue and production volume planning
 - The model was also flexible enough so that at a later stage, working with Robert, we were able to incorporate a separate worksheet in the Global Model that included the product's potential in each of these additional markets (as provided by the country managers)
 - All countries were divided by geography so that any changes to the models for the region, would impact on the figures for all the countries in the region
- **This feature made a pretty useful tool even more so. Indeed it did cut my workload by as much as 40% at times!**

Lessons & conclusions

- Maximising data is greatly amplified by the long haul
- Need for stable project teams throughout
- Assumptions must always be challenged
- Stretch people, resources and methods