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Is it Time to Adjust the Pharma PDE Sales Force Optimization Model?

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1. A Rapidly Evolving Biopharma Industry Environment Necessitating Change

The question this white paper addresses is straightforward – Is it time to adjust the long-standing pharma PDE sales force optimization model? PDE stands for primary detail equivalent. The PDE model has been the main metric biopharma companies have been using for the past 20+ years in sales response modeling, sales force optimization, and sales operations analyses. However, during the past 20 years, the US biopharma market has been undergoing dramatic changes as noted in this white paper series (see Axtria Research Hub at http://axtria.com/axtria-research-hub-pharmaceutical-industry/). Now, greater focus has turned to the development and launch of specialty medicines that necessitate altering the current metrics employed in traditional sales analytics:

- The rise of performance-based managed care contracts is requiring pharma companies to demonstrate drug value in producing health outcomes and/or health economic benefits.[1] While performance-based contracts are currently still relatively rare, even without these contracts, managed care plans are making decisions on formularies based on evidence of value. They are also looking to guidelines and the treatment pathways being adopted by providers – which are also driven by evidence of outcomes and value.
- A continued shift of pharma company drug portfolios to specialty medicines places greater pressure on pricing, market access, and affordability, requiring new data sources to demonstrate value.[2] Given the proliferation of specialty therapies, there is a need for a more nuanced understanding how these medicines perform in a real-world setting. Examples of this understanding include drug-drug interactions, broader information on side-effect profiles, performance in specific patient sub-populations, etc., that are not feasible to address in traditional patient studies.
- The previous point echoes a call from the academic research literature that challenges the current pharma commercial model. There is a need to demonstrate value across the entire project/product life-cycle given changing product and market/environmental dynamics.[3]
- This view has also been highlighted at recent PMSA (Pharmaceutical Management Science Association) annual meetings, such as a keynote address by then president and CEO of PhRMA in 2015.[4] Noted were three areas of new thinking: (a) need for companies to demonstrate value by reducing gap between what it costs to bring about new drug innovation and society's willingness/ability to pay for that innovation, (b) adopt different ways of thinking and new science, and (c) view and solve future pharma issues in an interdisciplinary fashion.
- The analysis of patient claims and EHR (electronic health records) data was also recognized in a survey of pharma industry practitioners in sales force science (from both pharma companies and consulting organizations).[5] Practitioners noted that emerging sales force strategy and big data developments must include analyzing health/economic outcomes. A different set of analytics are also needed to drive these outcomes. Lastly, new patient-level data sources, such as patient claims and EHR data, must be leveraged to generate desired patient and healthcare system outcomes.

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Significant changes have been occurring in the pharma sales force market, as highlighted in this white paper series (see Axtria Research Hub at http://axtria.com/axtria-research-hub-pharmaceutical-industry/). Such changes are but not limited to the following: (a) increasing sales rep access restrictions to physicians and especially among specialty physicians that are now the focus of new drug innovation, (b) the use of complementary technologies to deliver and record detailing messages to physicians for later analysis, (c) the use of "service" reps to provide important information to healthcare professionals beyond prescribing physicians, (d) changes in the skills required of sales reps to detail complex specialty medicines and disseminate medical information on drug value, and (e) the deployment of new selling models in light of environmental changes that are increasingly focused on patient and healthcare system outcomes. These pharma sales force market changes have significant implications on the type of sales analytics to be employed and the data required to support successful rep execution.

These preceding sales force and other numerous changes in pharma market & environmental dynamics have increased the need for companies to demonstrate measures of value that alter the focus and type of commercial analytics to support future performance-based contracts and/or drug adoption and formulary decisions. This need comes as pricing issues are becoming more common and controversial, with questions being raised about the sustainability of increasing sales revenue mainly through pricing.[6-7] Thus, commercial activities can be broken down into seven focused but increasingly interdependent areas: (1) Commercial Model Design, (2) Patient Analytics, (3) Payer Analytics, (4) Sales Analytics, (5) Marketing Analytics, (6) Commercial Analytics Innovation Center, and (7) Cloud Information Management.[8] Patient and payer analytics will drive all future commercial decisions, with activities in the other areas used to support outcomes in (2) and (3).[8]

2. Implications of Only Using PDEs in Future Sales Response Modeling

So how does the continued application of PDEs in sales analytics maintain relevance given the preceding emerging industry changes in what companies need from outcomes in sales force optimization and operations processes? The reality is industry changes are diminishing the relevance of traditional frequency-based promotion-response modeling with *sole* reliance on the PDE metric. The simple classification of weighted primary/secondary/tertiary details into a call PDE is no longer as informative as it once revealed as the nature of rep engagement becomes more complex (and supported by a wider range of auxiliary touchpoints). Before discussing

potential adjustments to the PDE model, what insights can we learn from how the PDE developed into the mainstay of sales force modeling?

The history of PDEs, as best that can be determined, dates to around the mid-1990s. From the mid-1980s through the early 1990s, the metric rep equivalents (REs) was used, which is essentially full-time equivalents (FTEs). However, the need arose for greater granularity how REs were used, and thus PDEs emerged to provide this breakdown while also enabled the brokering of detailing emphasis. Another driving force for the movement to PDEs was the introduction of physician-level prescriber data in October 1993 by IMS. This data allowed for greater granularity of segmentation, sales rep targeting, and physician-level sales response modeling. By the late 1990s, the use of REs had largely retired, except for international sales force sizing and structure work, where physician-level prescriber still does not exist.

There are distinct operational advantages to using a PDE metric approach. However, changes in the pharma environment as well as technical issues make this approach increasingly problematic. Growing disadvantages are outlined and explained below:

- Growing sales rep access restrictions over time mean that PDEs are not comparable from one period to the next since the time per call is getting shorter.[9] Thus the content that can be delivered is affected over time, all things being equal. This means biased calculations will result in measuring sales response carryover effects and strategic sales force optimization outcomes built over a multi-year period (say 3-4 years as typically done) using constant PDE weights.
- PDE weights may also vary by geography and physician specialty per time-period given dramatic differences in sales rep access restrictions.[9] So unless PDE weights vary by these cross-sectional elements, significant calculation biases will also be generated.
- The sole reliance on PDEs suggests a frequency-based transactional sales rep-physician relationship approach to detailing. This approach implies pharma commercial analytics are currently seen mainly to support tactical execution of traditional sales and marketing channels to achieve short term financial goals. Instead, commercial analytics is a strategic asset of growing importance and a key source for competitive differentiation to sustain long term industry advantage.[3]

Figure 1: Integrated Marketing Mix Evaluation Across Channel, Targeting, and Message

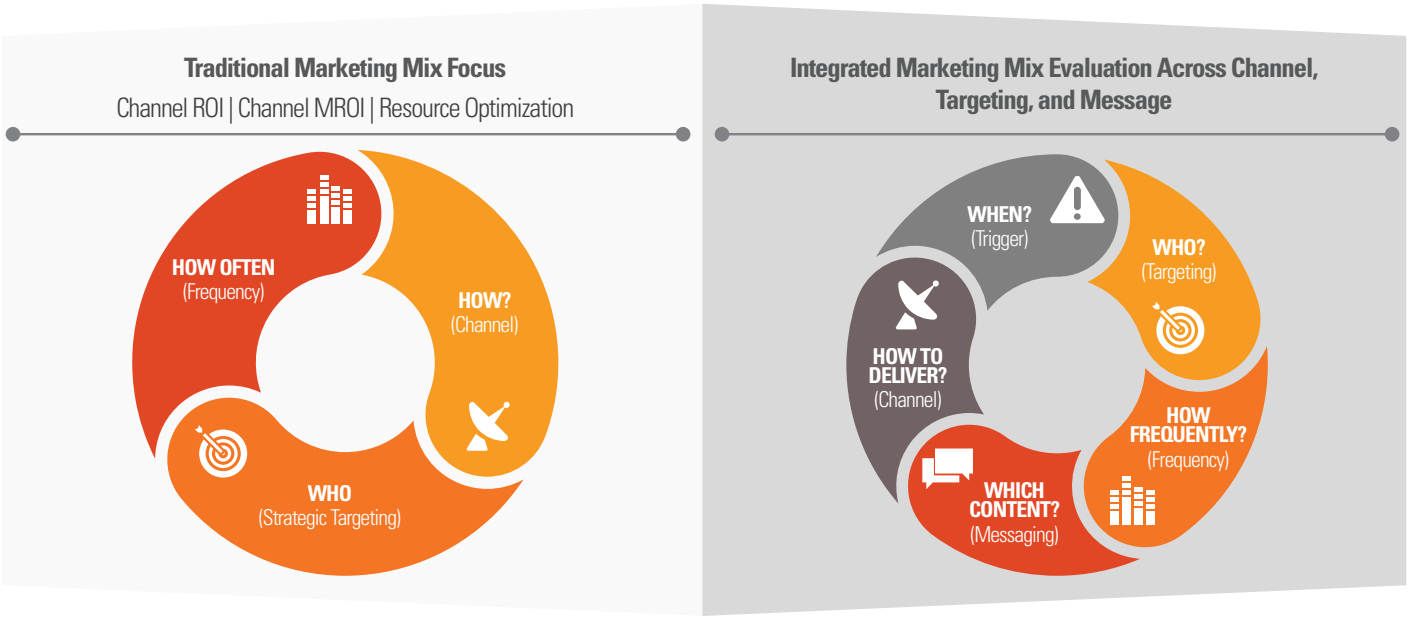


Figure 2: Growing Complexity of Marketing and Decision Pathways, and Analysis of Questions

ROI / Spend Allocation

- Are all my promotional investments working?
- Should we reallocate promotional investment across channels, segments and geographies?

Channel Interdependency and Interactions

- Impact of Rep enabled channels (Speaker programs / Emails) on call efficiency and HCP access?
- How are various digital channel working together and what is the most effective marketing pathway? E.g., TV followed by Paid Search resulting in Website visit / registration

Channel Success and Micro Conversion

- As different campaigns have different intermediate end points, how does the channel contribute in driving those micro conversions?
- Impact of unbranded campaign on disease state awareness or driving increased testing or improved diagnosis?

Real Time Insights and Issue of Low Patient Counts

- With Low patient count how can we measure conversion from Non User to trialist to Repeat user?
- How can we assess promotional effectiveness post launch using small amount of data?

Traditional time series multivariable regression models cannot handle all these ongoing questions

- The preceding point means pharma companies will be increasingly called upon to demonstrate value through significant improvements in health outcomes and reductions in treatment costs. This viewpoint is consistent with a newer perspective that research-based biopharma companies must think differently and apply tools beyond traditional boundaries. Also, companies must engage in interdisciplinary-type analyses to solve increasingly more complex business problems in the future not captured solely within a PDE metric.

- Pharma sales and marketing will be increasingly designed and executed to be "*informative*", not "persuasive".[10] This foundational approach has implications for the development of the commercial go-to-market strategy and model design, and subsequent sales & marketing strategy and operations processes that must go beyond the use of a PDE metric.

- The growth of more complex specialty medicines will mean an increasing importance placed on the effective communication of *scientific evidence* to demonstrate value to healthcare practitioners and payers for drug adoption, formulary coverage, and patient compliance, access, and adherence.[11-13] The PDE metric is void of any scientific evidence or detailing content and quality information at a time when it is becoming increasingly essential to demonstrate drug value.

- There is now much greater interaction between the sales channel and other marketing channels. Most companies now are focusing on multi-channel marketing measurements through more complex estimation methodologies to account for the following: (a) explicitly capturing the impact of channel interactions, (b) conducting pathway / exposure-sequence analysis that tie sales outcomes to the sequence of tactics to which a customer may be exposed. **Figures 1** and **2** provide illustrations of the growing complexity in marketing, decision pathways, and analysis of key questions.

- Given more specialty / rare disease products, the fundamental modeling approaches for sales force / marketing effectiveness may need to change, for example, state-space or Markov models may be more appropriate, like the modeling of conversion of a customer from non-trialist to trialist to dabbler to adopter. Also, given the natural dearth of Rx data for rare disease specialty

Figure 3: Different Approaches to Address Analysis of Marketing and Decision Pathways

Structural Equation Model

- Provides the ability to measure impact of marketing pathways as compared to channels working independently
- Best used to evaluate marketing strategy with multiple digital channels
- *For example : TV influences paid search traffic which in turns drives websites visits thus having strong interaction effect*

Multi Variable Hierarchical Model

- Allows model parameters to vary at more than one level, creating the possibility of a more granular model
- Best used to evaluate impact at nested level like HCP within account or geography
- *For example : HCPs with similar segments but affiliated to different accounts or system will have different response to promotion*

Multi State Model

- Provides the ability to model HCP transition from one state to other (non user, trialist, repeat writer)
- Best suited for Oncology / Rare Disease with low patient counts
- *For example : In a brand with low patient count, it's important to understand the channel influence in converting HCP from non user to user*

Optimization Model

Analytical / Marginal ROI

Simulation Based

Discrete Choice Model

- Discrete Choice Modeling With Monte Carlo Overcomes Low Counts, Collinearity And Risks Of False Negatives
- Best used to pprovide Insights In Early Life Stage of A Brand or with less data
- *For example : Impact of Promotional activity 3 months post product launch or impact of messaging change in call plan*

Hidden Markov Model

- Provides the ability to incorporate latent variables like awareness and perception in the model
- Best used to evaluate channels with Non Rx focus strategy
- *For example : Campaign call to action is an unbranded message to get the genetic testing done or drive registrations for the event*

Test and Control

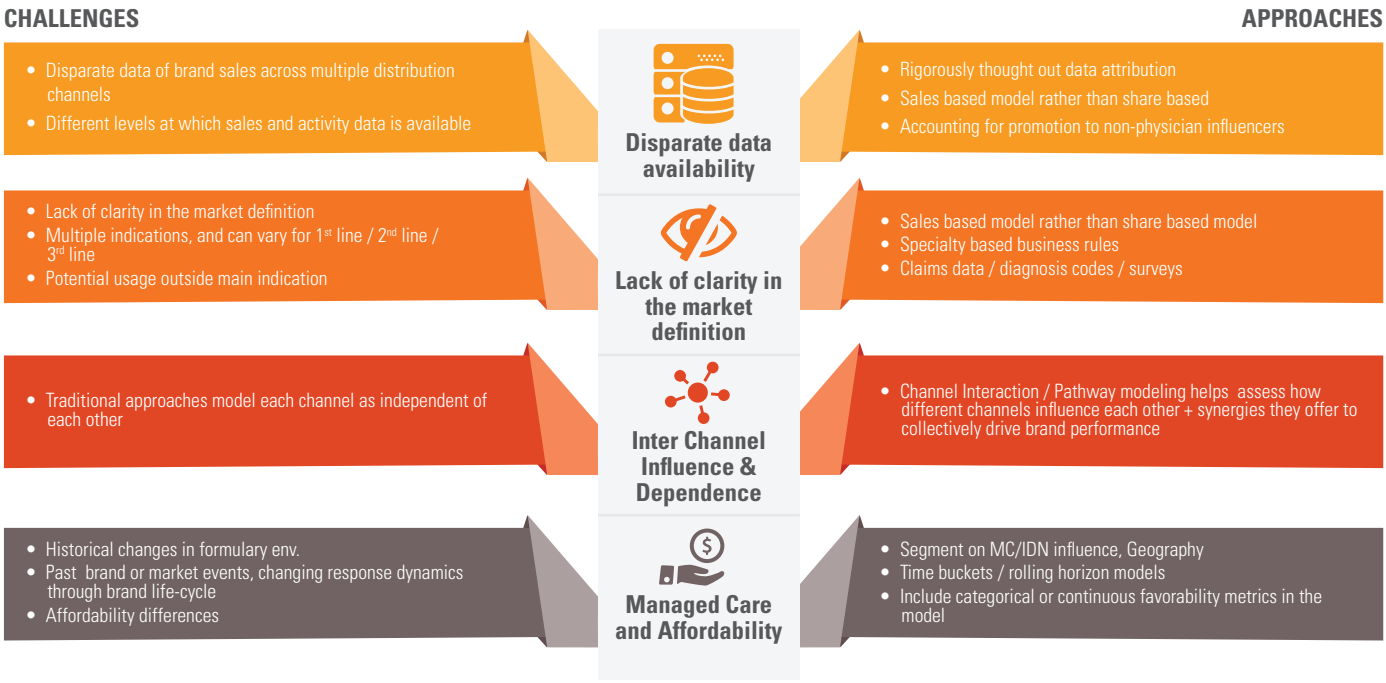
- Provides the ability to model events or one time promotional activity
- Best used to evaluate channels like speaker program or conferences
- *For example : HCP attending a speaker program is analysed by comparing with a HCP having similar characteristics but not attending the program*

products, traditional econometric methods used for measuring PDE response in the old world may no longer be feasible. **Figures 3** and **4** provide illustrations of innovative methods, and the handling of imperfect data and market complexities to solve multi-channel solutions facing pharma companies.

- Lastly, variations in the diffusion of medical information can create patterns of variable medical care use, which in turn, results in variations in health outcomes, expenditures (drug and treatment spending), and cost-effectiveness.[14] This foundation fundamentally alters the approach of commercial analytics. The current approach emphasizes promotion-response of sales & marketing on physician prescription (Rx) volume creation. The future approach must demonstrate how such channels generate changes in health/economic outcomes. This means building new analytical capabilities based more on real world evidence (RWE) and health economics outcomes research (HEOR) models. This capability will be necessary to support desired patient and healthcare system outcomes.

In summary, the preceding comments provide strong justification for adjustments in the sales force optimization model that *solely* relies on the PDE metric to drive decision-making. What the comments also provide is that adaptations have already been occurring by pharma companies to adjust to a new market reality. Companies recognize changes in the growing array of sales and marketing channels to disseminate scientific information and new analytics are needed to show the effects of those channels on key stakeholders. The next adaption will be to move away from models that focus on physicians and prescription volume generation, to those that focus on system-wide health and economic outcomes important to patients and payers. The next section provides details on the specific adjustments needed by pharma companies to adapt to a new market reality.

Figure 4: Application of Best Methods Must Contend with Data and Market Complexities



3. Adjustments Needed Now in the Pharma PDE Sales Force Optimization Model

The preceding discussion suggests a modified course from current promotion-response econometric-modeling practices for sales force optimization and strategy, operations, data development, and analytics. Current applications of commercial analytics are frequency and call emphasis-based (as captured by the PDE metric), where the endpoint is measuring drug utilization. Sales operations processes are geared to support this approach to facilitate and incentivize detailing frequency with little to no regard for the effects physician interactions have on patient outcomes, drug costs, treatment costs, and cost effectiveness. Evolving commercial analytics must be structured to see drug utilization as an intermediate outcome, especially since key physician specialties that will be associated with the focus of future new drug launches are generally the most sales rep access-restricted.[9] Focus instead must also leverage RWE data and the effects from delivering scientific medical information to specialty physicians on drug utilization and health/economic outcomes.[15] This means sales operations processes must structure the success of sales reps in their detailing efforts toward facilitating information-based and physician-engagement interactions. Sales reps should also be directed to improve a metric such as drug adherence at the physician-level as a leading indicator of their patients being more likely to achieve better health/economic, all else being equal.

Thus, while the PDE metric captures frequency and emphasis of sales calls and resource allocation from a transactional perspective, patient drug adherence at the physician level measures a qualitative perspective as an outcome of sales call quality. Here are some strategic, operational, and technical advantages of using patient drug adherence:

3.1 Strategic advantages using drug adherence

- Drug adherence is an excellent leading indicator (as supported by a plethora of academic research studies) for a patient to receive intended drug benefits as indicated on the FDA-approved label.
- Looking at adherence will shift greater company focus outward to patients, payers, and physician treatment practices and away from the current inward attention on internal sales force matters.

- The combination of metrics on PDEs and drug adherence will allow for addressing strategic sales force utilization and resource allocation questions while seeing how such allocation ultimately affects measures of health/economic value.
- This change will require companies to alter their segmentation schemes (as the underlying analytical foundation of sales force optimization) to account for matters that affect drug adherence. This will also require companies to develop sales force strategies to account changes at the healthcare system level, such as, the merging of providers and payers, the growth and impact of IDNs (integrated delivery networks), and tracking patients through these networks with a growing emphasis on delivering measures of value.

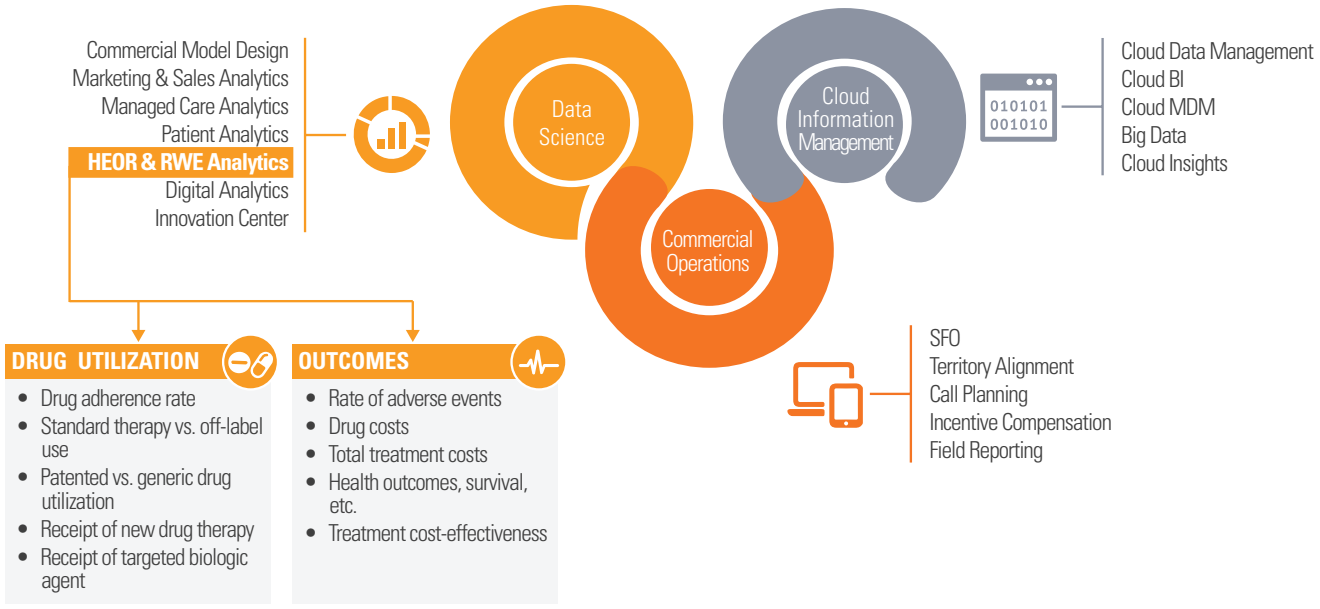
3.2 Operational advantages using drug adherence

- Using the adherence rate in operations will cause sales reps to focus on delivering scientific information and services (along with ancillary field personnel) to explain the value of costly specialty medicines.
- Territory alignment design will need to be modified to account for institutional and environmental changes noted in "section 3.1 4th bullet", while call planning of targeted physicians will be driven more by delivering patient and payer-focused measures of value.
- Management by objectives (MBOs) can be constructed as part of the objective setting and incentive compensation design processes to guide and measure sales rep activity to affect drug adherence.
- The above changes will also affect what metrics will be collected and reported for sales reporting used to gauge sales team success, performance management, and whether brand strategy (as incorporated in the sales force optimization process) is achieving value-based objectives.

3.3 Technical advantages using drug adherence

- The capture rate of drug adherence using anonymized patient-level data (APLD) for Rx claims is around 70% of all patient claims, which is what would be applied here. This rate will vary somewhat for specialty medicines and depending how open is the distribution model the product,

Figure 5: Emerging Role of Combining Commercial & HEOR/RWE Analytics



and whether the pharmacies are captured by 3rd parties that track this information. For medical claims, the capture rate is about 60% of all patient claims. These capture rates provide for a reliable estimate at the physician level that can be calculated for use in all segmentation analyses that drive the analytics behind sales force strategy and operations (territory alignment, call planning, objective setting, incentive compensation, sales reporting, and performance management) outcomes. [Note: the percent of patients for whom there exists comprehensive information, both Rx and medical claims, will be significantly lower at around 35%. Also, as best as we can determine, the coverage tracked by major 3rd parties gathering his information is very similar.]

- Statistical analyses can be conducted relating variations in sales rep MBO activities to drug adherence at the physician level.
- Patient drug adherence is linked at the individual physician-level. This means other databases at this level can be merged to conduct robust analyses on the relationship between sales, marketing, and managed markets activities on drug adherence.

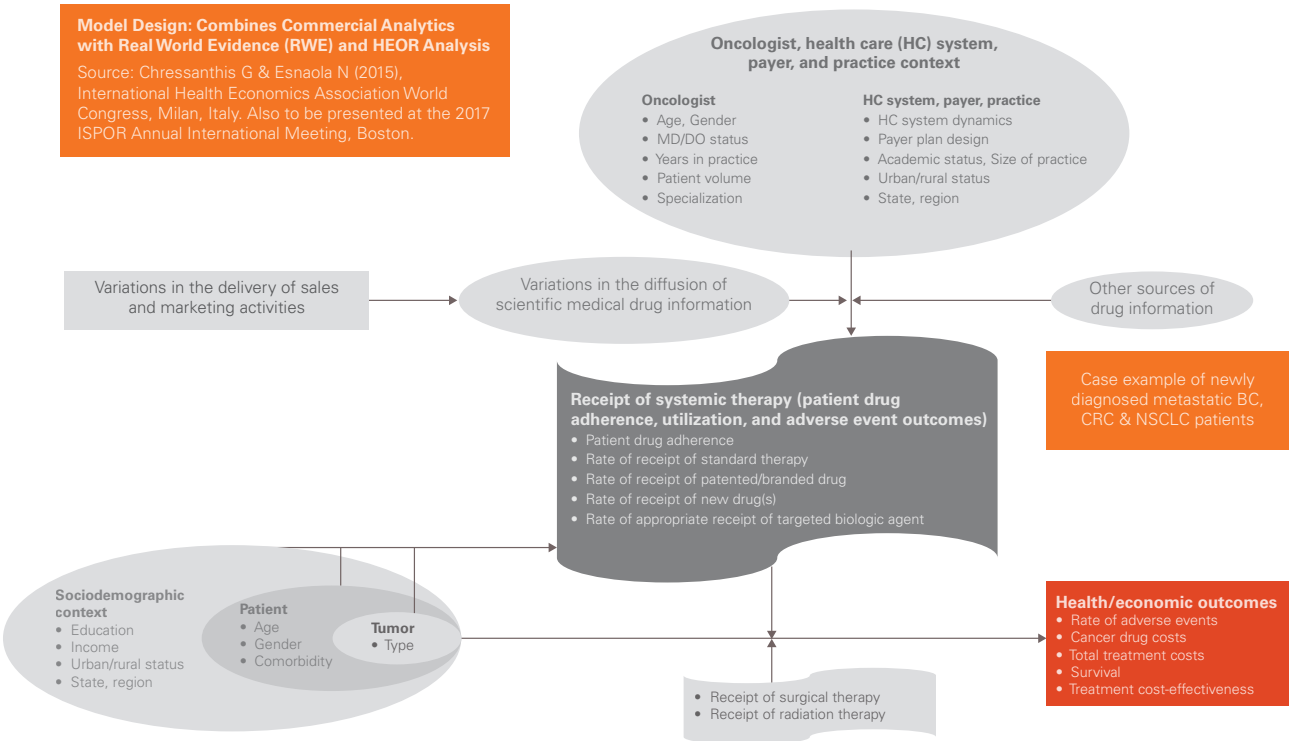
Such adjustments would be a good initial step and is reflective of perspectives by industry analytics practitioners as emerging issues in the sales force science survey conducted by the lead author.[5]

Figure 5 illustrates the emerging role of combining commercial and HEOR/RWE analytics. **Figure 6** depicts a proposed new commercial model design (CMD) in a patient and healthcare system-oriented emerging pharma environment designed for specialty medicines (the figure illustrates an example in oncology).[16-17] A list of specific implications for sales force science issues as categorized by the same survey headings and illustrated by **Figures 5** and **6** are as follows:

3.4 Sales force strategy implications

- Segmentation schemes must combine data to reflect dynamics at the following 4 levels: physicians/accounts, IDNs, payers (e.g., commercial 3rd party, Medicare, Medicaid), and patients. These segmentation schemes are not new to the industry, and are now considered state of the art / accepted practice for several years now. Multiple designs of payer/IDN influence metrics at the physician level have been devised and implemented for ensuring optimal resource allocation. The ultimate-goal

Figure 6: Proposed New Commercial Model Design (CMD)
Patient and Healthcare System-Oriented CMD for the Emerging Pharma Environment



here however is different than merely resource allocation, but to be able to follow the patient through the healthcare system to ensure both patient drug adherence and health benefits (health and economic outcomes) are derived from continued drug utilization. This segmentation scheme will drive sales force strategy and operations processes for both resource allocation and health/economic outcomes.

- Sales force size, structure, and allocation will still be physician-based but layered differently based on the above segmentation scheme and where sales force allocation efforts are implemented to cover the patient journey.

3.5 Sales force operations implications

- Territory alignment and call planning design will reflect the above-noted 4-level segmentation scheme.
- Objective setting, incentive compensation, and sales force reporting/performance management will share focus between not only Rx volume (still needed to track company objectives for financial returns and to incent sales reps) but also MBOs (management by objectives). These MBOs are designed to track activities related to the delivery of scientific information and efforts that improve patient adherence, thus helping outcomes on value delivered to physicians, health and economic benefits effects to patients, and to the healthcare system. GSK has dramatically altered their approach to sales rep-physician engagement and eliminated Rx-based objective setting and IC plan design goals.[18-19] Examples of sales rep and associated service rep activity MBOs tied to their interactions with physicians and other healthcare personnel/staff have been detailed in a previous Axtria research white paper.[20]

3.6 Sales force analytics implications

- The need to demonstrate drug value through sales force activity will require the broader use of and implications from detailing quality statistical models. As noted previously from the literature, this means measuring how the dissemination of scientific evidence affects drug utilization and patient and healthcare system outcomes. The analytics to estimate relationships outlined in **Figure 6** are more in keeping to bio-statistical models than traditional econometric methods to estimate the effects from sales and marketing.

- Rx volume will still be needed for the analytics behind promotional effectiveness and ROI. A key point here however is that the meaning of ROI, aside from return on investment, can also stand for return on information

3.7 Big data implications

- Execution on the preceding approach requires the combination of a wide array of traditional data used in sales force analytics plus newer elements utilized in HEOR/RWE models. This means leveraging claims/EHR, socio-economic, and demographic data sources. Further, the preceding suggested metrics used for objective setting, incentive compensation, and sales force reporting/performance management will also require efficient organization for analytics needed to show the effects from disseminating scientific evidence as previously described.

- Efficient data management will be required to organize a growing array of different data sources, bridge elements that allow individual data sources to be merged, and routines that allow for easy access for analysis and insight generation.

3.8 Capabilities needed to support sales force activities and drug adherence metric

Including a metric like patient drug adherence would imply changes in the capabilities of sales reps to become more "MSL-like" to deliver scientific evidence. This will also require a team of service reps to address and focus on the following matters since the time sales reps have interacting with physicians has been consistently trending downward.15 Examples of activities include disseminating information regarding:

- Payer and patient-access/affordability dynamics (given the cost of specialty medicines).

- Patient benefits of enrolling in a patient assistance program.

- Patient benefits of enrolling in a disease management program.

- Sales reps providing physicians with medical information on the latest drug indications, adverse event data, appropriate use guidelines, and black box warnings imposed by the FDA.

- Latest drug information from published medical journal studies (through approved channels).

- Connect physicians to MSLs to address scientific questions they have raised.

3.9 Technology and internal company developments

Further, attention will need to an array of developments to enable the application of analytics outlined in **Figures 5** and **6**. First is the development of technology that more efficiently and effectively delivers scientific information to healthcare professionals, and record such data for further analysis. Technologies will be needed such as the introduction of complementary devices (health diagnostic and monitoring technology) to aid in demonstrating value to payers and improve patient compliance/adherence to support performance-based payer contracts. These preceding changes mean the talents and capabilities required by people involved in commercial analytics to conduct this work will need to be upgraded to account for new modeling designs and expertise in handling different databases. Second is concomitant changes in the internal reorientation of

companies to enable this type of interdisciplinary analysis outlined in **Figures 5** and **6**. Currently, groups that need to be coordinated have little to no engagement with each other (e.g., interactions between HEOR and RWE functions with sales force strategy, operations, and analytics functions). Companies must rethink their existing culture, organizational design, talent, and processes/systems to enable the type of interdisciplinary analyses needed to solve emerging commercial problems.[21]

3.10 Data and other challenges of adopting a drug adherence metric

Challenges will need to be overcome to generate the necessary patient-level data (e.g., claims, EHR, etc.) that will enable this change in sales force science approach. Admittedly, the fragmentation of claims databases represents a significant challenge that will need to be overcome since specialized medicines increasingly cater to smaller rare disease patient populations that require national-level data to accurately study for the outcomes outlined in this paper.[22] The preceding comments acknowledge the existence of significant data gathering and aligning implications, as outlined in **Figure 5** to feed the data science, and as illustrated in more detail in the cancer example in **Figure 6**. Thus, adherence metrics may not be feasible to compute due to coverage gaps and significantly small number of patients.

Also, the approach illustrated in **Figures 5** and **6** suggests a more holistic look at sales and marketing channels (rather than a pure PDE-based model) is necessary. **Figure 5** contains a commercial operations area reserved for execution of insights generated from a newly designed cloud information management and data science areas. This middle area designed for execution can be expanded to include both sales and marketing operations, manage markets contracting and pricing, external medical affairs, public policy, etc. Increasingly, data and insight-driven decision-making using analytics will be made across the entire spectrum of operations within a pharma company.

Finally, drug adherence as a concept to predict health outcomes works for chronic disease states. What about acute therapies? Spending on drugs for acute therapies is far less than chronic conditions. Among the top 20 therapeutic classes by non-discounted spending in 2015, the highest ranked acute therapy class was antibacterials ranked at 17th, with the spending trend declining since 2011 (likely due to increased generic utilization), and the absolute level of spending far below that of the leading and higher ranked classes.[23] So continuing to use the PDE model may make sense here. However, given challenges for example in treating drug-resistant infections, it is critical in seeing promotion not only as a vehicle to advance simply frequency of messaging but also as a mechanism to transmit content of the latest development efforts and scientific medical information.

In summary, challenges in adopting a drug adherence metric to complement the current PDE model are due to the following factors: limitations in data coverage, devising robust / defensible analytical methodologies to convince sales and marketing leaders that the model provide the right guidance, culture-change challenges, and challenges in translating strategy to tactics. Some of these challenges could potentially be alleviated through greater data coverage in the future.

4. Conclusions

The pharma industry has been grappling with an array of business issues caused by changes in environmental and external trends – all this was happening all before Trump came to the presidency! Policies coming out of the Trump presidency will add to the already difficult challenges facing pharma executives. Some of the changes being proposed will be beneficial to the industry, while others, especially on drug pricing, will present significant challenges. The nomination of Dr. Scott Gottlieb by President Trump to lead the FDA, if confirmed, offers some solace to executives that radical changes may not be in the cards. However, Dr. Gottlieb's prior experiences within the FDA, understanding of the pharma industry, practice as a physician, and policy views make him someone who knows how the system works (and doesn't) to enact needed change.[24-25] One area of change relevant to a key theme in this white paper is allowing greater flexibility for pharma companies to use RWE in support of new drug applications as denoted in the 21st Century Cures Act. This means companies must begin to develop the type of combined analytical capabilities, frameworks, and internal reorientations to maximize the benefits of instituting a new commercial model design for the emerging pharma environment as outlined in this white paper. As noted at the end of the Part 1 white paper on President Trump's effect on the pharma industry, whatever your political views, he is being a change-agent or catalyst to bring about needed change. This white paper provides explicit directions and frameworks designed for long-term pharma company success.

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