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What does patient-centric, outcomes-driven R&D mean to you?

The shift to a patient-centric, outcomes-based business model in life sciences has a fundamental impact on R&D. EY can help you adapt your R&D model today so you remain relevant in the future.

The better the question. The better the answer. The better the world works.
Moving from pills to digitally enabled outcomes

The change in focus will be uncomfortable for many as it goes against decades of learned practice and the organizational “norms”.

<table>
<thead>
<tr>
<th>Pills – now</th>
<th>Outcome – future</th>
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<tbody>
<tr>
<td>Indication driven</td>
<td>Outcome driven</td>
</tr>
<tr>
<td>Rep push based on features</td>
<td>Patient, provider, payer pull based on outcomes</td>
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<tr>
<td>Pill/treatment focus</td>
<td>Focus on prevention, treatment and management</td>
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<tr>
<td>Volume and revenue</td>
<td>Value driven</td>
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<tr>
<td>Limited patient engagement, low data risk</td>
<td>Greater openness and greater data risk</td>
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<tr>
<td>Trials data</td>
<td>Trials data and real world evidence</td>
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New R&D model
Client must transform to a new R&D model to drive towards accelerated clinical outcomes
1 Who we are
Key challenges
EY’s network of 6,000 life sciences-focused practitioners help clients address their key challenges

Grow
• Are we ready to take advantage of opportunities presented by the growth of genomics and personalized medicine?
• How do we leverage new technologies to improve patient adherence?
• Where are the greatest opportunities for drug discovery partnerships?
• How can we leverage collaboration with various health care stakeholders (payors, providers, integrated delivery network (IDN), advocacy groups) to promote patient wellness across the continuum of care?

Protect
• What can we do to maintain market share following patent loss and introduction of generics and biosimilars into the market?
• How do we provide for the safety of patients while upholding the brand and satisfying the shareholders?

Optimize
• Are we effectively transitioning from a product-efficacy approach (to an outcome-based approach)?
• Where can we improve drug launch effectiveness?
• How can we reduce our costs and accelerate value throughout the value chain?
• How can we develop the necessary information technology (IT) infrastructure/architecture to enable use of big data to increase R&D efficiency, analyze sales and marketing activities across channels, control risk and manage our supply chain?
• How can we position ourselves to better adapt to the various changes resulting from the Affordable Care Act/integrated delivery network (IDN) and IDPM regulations (for example)?

How do organizations react to these ever-present forces and transform their businesses to succeed in spite or because of them?
2 R&D solutions and services
Our industry is changing

Our industry is changing as a result of significant challenges that require new responses and capabilities

Pharmacos are facing pressures from all sides ...  
... and this is leading to evolutionary responses ...  
... that require new capabilities

<table>
<thead>
<tr>
<th>Challenges</th>
<th>Responses</th>
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<tbody>
<tr>
<td>Falling innovation</td>
<td>No longer have all you need within your four walls — <strong>collaboration, relationship and influence</strong> is key</td>
</tr>
<tr>
<td>Spending more, getting less</td>
<td>Lines between R&amp;D and Commercial are increasingly <strong>blurred</strong> — more post-marketing R&amp;D activity</td>
</tr>
<tr>
<td>Payer budgetary pressure</td>
<td><strong>Patient centricity and patient support</strong> programs key to driving better outcomes</td>
</tr>
<tr>
<td>Drug budget squeeze</td>
<td>Need to capture, manage and consume new types of data from <strong>new data sources</strong></td>
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<tr>
<td>Innovation bar raised</td>
<td>More <strong>iterative interaction</strong> with HAs with shorter cycle times</td>
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<tr>
<td>One size does not fit all, personalized treatments</td>
<td>Increased time and resource spent on achieving, demonstrating, and maintaining <strong>compliance and reputation</strong></td>
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<tr>
<td>Evidence bar raised</td>
<td><strong>Portfolio and resource management, earlier failures</strong></td>
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<tr>
<td>Continually capturing data and building body of proof</td>
<td>Manage bets better</td>
</tr>
<tr>
<td>Competition bar raised</td>
<td><strong>Alliance and contract management</strong></td>
</tr>
<tr>
<td>Disruptive innovation from new players outside of industry</td>
<td>Manage alliances better</td>
</tr>
<tr>
<td>Reputation bar raised</td>
<td><strong>Real world evidence</strong></td>
</tr>
<tr>
<td>Increase in fines, warning letters and withdrawals</td>
<td>Manage data better</td>
</tr>
<tr>
<td><strong>Evidence bar raised</strong></td>
<td><strong>Patient outreach programs</strong></td>
</tr>
<tr>
<td>Continually capturing data and building body of proof</td>
<td>Manage outcomes better</td>
</tr>
<tr>
<td>Regulatory bar raised</td>
<td><strong>Product and information standards — IDMP</strong></td>
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<tr>
<td>Increasingly complex, drive to transparency and compliance</td>
<td>Manage standards better</td>
</tr>
<tr>
<td><strong>Competition bar raised</strong></td>
<td><strong>Risk and reputation compliance management</strong></td>
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<tr>
<td>Disruptive innovation from new players outside of industry</td>
<td>Manage risk better</td>
</tr>
<tr>
<td><strong>End-point bar raised</strong></td>
<td><strong>Dashboards and continuous improvement</strong></td>
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<tr>
<td>Focus on outcomes and disease understanding</td>
<td>Manage performance better</td>
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<tr>
<td></td>
<td><strong>Outsourcing, financial management</strong></td>
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<td></td>
<td>Manage costs better</td>
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What we do
Supporting market access

Analysis of real-world evidence will provide deeper insights to support market access

Outcomes-driven, patient-centric design

- We can help to bring a Market Access lens to portfolio investment decisions and provide additional insight on prioritization and value.
- We can help to design real world data capture into the clinical trials to maximize the benefit and evidence generation.
- We can help to source and analyse real world data to support hypothesis testing and decisions.
- We can help to develop partnerships with the health care ecosystems to engage in the data stream, analyze and develop new insights into unmet needs, product and services opportunities.
Proactive management of risk
Companies need to leverage analytics to allow proactive management of risk and to identify and mitigate fraud

Risk-optimized approach

Risk-based management

- We use commercially valuable risk insight from multiple sectors to help our clients make better decisions when managing both tangible and intangible R&D assets. We use leading risk indicators to make those decisions more forward looking, more timely and more reliable.
- We integrate cost-effective risk management into the day-to-day rhythm of the business, driving effective governance, accountability and performance improvement as a result.

Fraud forensics

- Our Fraud Forensics practice has experience in using analytics to identify potential fraudulent behaviour. This includes clinical data fraud and financial malpractice.
Remain compliant and drive quality

New areas of regulation will require innovative analytics techniques to remain compliant and drive quality.

Compliant, auditable processes

- With ever-increasing regulations the cost to maintain compliance and the inherent risk of non-compliance is on an upward trend.
- In recent years, there has been increasing scrutiny on the use of social media, in particular around marketing messages and, highly relevant to R&D, pharmacovigilance.
- We support clients to inventory their web presence and current mechanism to monitor, capture and analyse adverse events.
- Advanced analytical techniques, such as Natural Language Processing for unstructured text data, are key to success.
Transformation opportunities

Transparency of performance, not just internally but also against industry peers, will identify transformation opportunities. In additional, Robotic Process Automation (RPA) will automate manual steps, increasing quality and compliance, increasing speed, and reducing cost leading to a lean end-to-end Development process.

Performance-optimized operations

- We help clients to define a balanced set of performance metrics that reflects their strategic business goals and objectives.
- We leverage industry benchmark data to put that performance into context to support and enable data-driven decision-making and business management.
- In addition this data is then able to support key change initiatives, such as CRO cost benchmarking and optimization, and data-driven diagnostics for transformation.
- EY works with clients to define, design and implement RPA to create a lean end-to-end Development process.
This transformation will have an impact right across the whole value chain ...  ... and EY has the skills and experience to support clients every step of the way.

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<tbody>
<tr>
<td>Research</td>
<td>Exploratory development</td>
<td>Full development</td>
<td>Launch and commercialization</td>
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- Clinical (clinical pathology, clinical science, clinical operations, medical affairs)
- Pharmacovigilance (trial based, case based, processing, spontaneous)
- Regulatory (regulatory affairs, regulatory operations)
- Biometrics (statistics, data management)
- Pharmaceutical development (process, scale-up, technical transfer)
- Support functions (IT, finance, procurement, HR, legal)

- Portfolio and life cycle management
- Performance, project and resource management
- Alliance and partnership management
- Compliance, risk and quality management
Recent examples and client work
EY is delivering projects and programs across the R&D value chain
Here’s an example of what we are doing for clients

**Regulatory IT strategy and road map**
- Develop a five-year IT strategy and road map aligned to the business vision and goals
- Create better alignment between the IT spend and business need giving increased ROI

**Quality systems documentation**
- Create an end-to-end R&D QSD documents value chain with role-based format. Re-write the QSDs in alignment with external regulation to increase user-friendliness, efficiency, compliance and simplicity. Develop governance model, document hierarchy and document format.

**Regulatory eCDMS and RIMS**
- The project seeks to update the regulatory submission creation, publishing and tracking environment.
- EY supported the client in developing the country-specific rollout and data migration plan.

**Patient centricity**
- Assisted the client to understand how to “put patients first” by developing a patient-centric proposition that adds value and reduces inefficiencies
- Develop stakeholder perspectives, including patient, payer, health care professionals and employees, including legal and regulatory considerations

*RIMS stands for Regulatory Information Management System
*eCDMS stands for Electronic Clinical Data Management System
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We are independent but understand the solutions on the market.

We make strategy real. We implement people, process and technology and make it work.

We bring deep industry experience. We have life science R&D-specific solutions.

We can leverage EY’s brand and capabilities globally
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