Throughout a product’s lifecycle, health economics and outcomes research (HEOR) teams take on a number of activities to support a company’s broader market access efforts. In addition to supporting brands nearing regulatory approval, HEOR groups must be able to support teams negotiating pricing and reimbursement. To best advocate for evolving brand goals, health economics efforts also shift focus as products move through the lifecycle. HEOR groups must anticipate payer needs pre-launch and then shift to support marketplace and packaging changes as the brand matures. To best showcase a product’s value, companies may leverage multiple internal functions — ranging from medical personnel to managed care liaisons (MCLs) — to support health economics strategy.

For example, Company A* begins preparing a brand’s health economics strategy early in development — a minimum of 18 months before product launch — as part of a launch readiness process. During this process, managed care support and medical groups work together to prepare brand materials for payers. All materials go through an internal review process to ensure that they can be distributed compliantly to payers prior to these organisations asking their own questions. These groups also consider the kinds of questions to anticipate from payers so that they can prepare answers and determine which accounts are priorities.

However, the work does not end with launch readiness. An executive at Company A noted that HEOR information development and distribution are ongoing. The group assesses account-level payer needs, and the HEOR team equips Company A’s MCLs with the appropriate information. As products move through development and field liaisons prepare to meet with payers, HEOR teams must consider the best ways to support their products. Innovative teams look beyond traditional models to demonstrate brand value. A Company C director explained, “As products move to launch, our HEOR team really shifts toward looking at ways to collect real-world evidence and the real-world benefit of the product — whether it’s observational or non-interventional studies, post-approval or claims database analysis — to get a sense of how the product is actually performing.” This outlook is increasingly important as brands are priced closer to their value threshold. Companies must be able to demonstrate brand impact in both efficacy and cost-effectiveness to maintain profits.

**Embrace Multiple Strategies to Disseminate Key HEOR Data to Payers**

While piecing together meaningful health economics information is the first part of the battle, delivering it to stakeholders in the healthcare community can be a real challenge. HEOR teams often look to a combination of publications and payer presentations to support brands — presenting both a broad look at a brand’s health economics and outcomes performance and a tailored view for individual stakeholders. Field forces including health outcomes liaisons (HOLs), medical science liaisons (MSLs) and MCLs then reach out to payers and other HEOR stakeholders to deliver this information.

Company E uses publications to spread its health economics data throughout the scientific community. This company’s published data combine high-quality research, on-label clinical outcomes and strict adherence to industry publication guidelines. However, outside of publishing articles, Company E often has difficulty distributing this information and is resigned to hoping that the right stakeholders — pricing and contracting committees and managed markets groups — see it. “Our company has a system in place to approve materials for our sales force’s promotions, but they throw their hands up when dealing with our health economics materials,” explained a Company E executive. “All health economics analysis is off-label. Nobody has a comparative or cost-effectiveness claim on the label — and that scares people.”

This director is aware of distribution tactics at other companies; these include leaving HEOR-related flyers and other materials behind in doctors’ offices and other venues, as well as distributing scientific posters or giving conference presentations. But the director and other Company E executives are very concerned about remaining compliant while disseminating their findings. “The FDA doesn’t want to see health economics as a backdoor for off-label promotions, but at the same time decision-makers need to know this information,” said the Company E director. “It’s a hard balance and we’re still trying to find it.”

At Company A, the managed care support group plays a large role in disseminating HEOR information. During a brand’s launch readiness programme, internal stakeholders compile a number of different materials focusing on key HEOR data. Right now, these materials are evolving to look at real-world data in addition to budget impact studies and cost-effectiveness data. The company’s medical and health economics-focused groups feel that real-world data — how the treatments are performing in real patients and how they are impacting healthcare savings — are the most useful and most persuasive information for their customers.

To maximise their resources, Company A’s field force prioritises customers — by labelling them as either Tier 1, Tier 2 or Tier 3 — and tailors health economics presentations accordingly. These priorities are based on how a product’s therapeutic area has been met in the past by that account. The managed care support director at Company A explained, “If a company has a pretty open application, there’s a different level of information we might present. If the therapeutic area has been tightly managed, we might be more aggressive. The last consideration is based on [pure size] — a very large entity with a lot of coverage will be assessed early on. Last would also be referred to as malignancy: If you have someone regardless of size, if they have influence in a particular area,
then you may want to highlight them early on for what you do.”

**Coordinate Payer and Stakeholder Visits with Commercial Representatives**

Company E, which does not maintain HOLs, looks to MSLs to disseminate health economics information. These field agents often accompany sales representatives and managed markets account managers to meet with stakeholders. Because health economics data are typically considered off-label, commercial reps will leave during these presentations to maintain compliance.

Like Company E, top 10 biotech Company A’s internal HEOR stakeholders also collaborate with commercial reps to distribute information to payers and other external targets. Often, the MCLs — a key force in payers’ health economics education — have schedules and visits that overlap with managed markets account managers’ efforts. In these cases, the two representatives may be present at the same meeting. However, as noted before, the commercial representative must leave before the MCL can present health economics and outcomes data. If the MCL is sharing information approved for a proactive setting, the managed markets account manager may be present. However, if the stakeholder has questions that are beyond the label — beyond what has been approved for these proactive discussions — the MCL will address those concerns at the end of the meeting, after the account manager has left the room.

**Tailor HEOR Presentations to Specific Payer Expectations**

Company B’s EU-based team splits HEOR responsibilities between an in-office group and a field force. The health outcomes team in the office is responsible for generating data and compiling them into presentations and health economics models. Often these data originate in regulatory documents — either the National Institute for Health and Care Excellence (NICE) or Scottish Medicines Consortium (SMC) submissions. While these documents may be 200 or more pages of brand data, the EU-based HEOR team condenses this information to around 20 PowerPoint slides. “There’s an element of simplification and summarisation when presenting our key HEOR data to our customers,” explained a Company B executive.

Company B’s team also tailors information so that it is region-specific as the field HEOR team visits payers. “We take national data that’s associated with regulatory submissions and refine it,” said one interviewed health outcomes consultant. “Our data is focused and relevant to the key customer we’re speaking to on a face-to-face basis.” The field team is responsible for delivering this information to stakeholders, as well as informing the in-office team of HEOR needs in the scientific community — letting them know which data would be most helpful in supporting clear conversations with customers.

This tailored approach aids the HEOR team and the company’s field force as they work through the multiple levels of market access. For example, in the UK, there are tiers at the national, regional, local and sublocal levels. Because each tier has its own evaluations, a medicine recommended at the national level — by NICE, for example — may not make it through a formulary committee at the regional level. Each tier must recommend the brand for patients to get access to the medicine. Tailoring HEOR data to specific expectations helps to ensure that brands are proactively prescribed post-approval.
Stay Vigilant to Respond to Newly Released Comparative Effectiveness Research

Comparative effectiveness research plays a key role as companies carve out brand positions in the commercial space. Proving a product’s superior efficacy or safety can be an engaging argument as health economics groups prepare value propositions for payers. However, teams must also be vigilant in reviewing competitor publications — making sure that they are not the competitor in question.

Company E’s brand was recently used in a competitor’s comparative effectiveness study. The competitor’s product is a much cheaper medical device — costing $50 per device versus Company E’s $200 device. “Our competitor has no efficacy, but they’re saying that they perform just as well as our product. That’s very attractive to someone working under budget constraints,” said an interviewed Company E director. In response, the health economics team pulled together a study to demonstrate the brand’s value. This study is a direct contradiction to the findings shown in their competitor’s retrospective study. “Responding to these situations is a high priority,” explained the director. “We have to look for ways to do high-quality comparative effectiveness work to either negate or discredit those claims.”

Prioritise HEOR Team Activities Based on Team Scope: Central Global Groups Focus on Preparing Information for Government and Private Payers

Health economics and outcomes research teams must take on a wide range of responsibilities to support brands throughout their lifecycle. However, not all HEOR activities command the same percentage of a team’s time and focus. Surveyed HEOR teams were asked to consider their regular responsibilities and the allocation of their time. They then ranked specific HEOR activities as one of four categories:

- **Core activities**: Responsibilities that consume more than 20% of a team’s time
- **Supplemental activities**: Responsibilities that consume between 5% and 20% of a team’s time
- **Minor activities**: Responsibilities that consume between 0% and 5% of a team’s time
- **Not performed**: Responsibilities that are covered by other internal teams or are not regularly performed by HEOR teams

Data show HEOR team priorities across multiple group types and geographies. Data also examine the range of time allocated to surveyed teams’ major activities.

Figures 1.1 and 1.2 examine key HEOR activities performed by central global groups. These groups are headquarters-level teams that provide HEOR information and support to country-level teams worldwide. At small companies, these central global groups may also have contact with external stakeholders; for larger firms, these groups will primarily support country-level HEOR.

Sartoclear Dynamics®:
Sartorius Stedim Biotech launches a new single-use harvesting technology for high cell density cultures up to 2,000 L

- Single-use clarification system eliminates centrifuges
- High cell density harvesting performed in a single step
- Process robustness and predictability ensured

Goettingen, Germany, April 14, 2015 - Sartorius Stedim Biotech (SSB), a leading international supplier for the biopharmaceutical industry, has introduced Sartoclear Dynamics®, a clarification system featuring new single-use technology for harvesting mammalian cell cultures with high cell densities.

Continuous improvements in growth media and cell lines have elevated biomass concentrations in bioprocesses. Therefore, these increasingly higher concentrations place growing challenges on the purification process. As body feed filtration has proved to be the best solution to solve similar challenges in related industries, Sartorius Stedim Biotech has now developed this robust technology for biotech applications.

Specially designed for cGMP processing, Sartoclear Dynamics® consists of prefilled single-use bags containing ultrapure diatomaceous earth (DE) in a choice of 0.5 kg to 10 kg. With a new quick-connect adapter for dust-free powder transfer, DE can be directly mixed into the cell culture fluid. This porous filter aid prevents blockage of the Sartoclear Dynamics® filters. As the system maintains a constant ratio of biomass and filter aid, users will benefit from continuous maximum filter performance.

Consistent results, ease of use, tremendous speed and linear scalability are the key characteristics of the Sartoclear Dynamics® technology. Used in combination with precipitation, this technology transforms harvesting from a two-stage process into a single-stage operation, saving valuable footprint and time.

Stefan Schlack, the Senior Vice President of Marketing at SSB, comments: “With Sartoclear Dynamics®, we are closing one of the biggest gaps in the single-use product offering.

Nowadays, 2,000 L is a standard size for single-use bioreactors, but a centrifuge is still required for removing cells from such volumes. This technology now enables a fully single-use process, which brings enormous flexibility to our customers’ facilities. It also eliminates considerable capital investments, which is attractive for newcomers from emerging biotech markets.”

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teams. Among surveyed groups, five identified major HEOR activities are developing information for government and private payers, conducting internal health economics analyses, valuating products for marketing messages, and managing vendors (Figure 1.2):

- The highest percentage of surveyed teams (33%) consider developing information for government payers a core activity. Teams spend an average 16% of time on this activity, ranging between 5% and 42%.
- Developing information for private payers — which averages 12% of global teams’ time — follows a similar trend; surveyed groups allocate up to 40% of their time on this task.
- The remaining major activities claim between an average 9% and 11% of teams’ time.

Though only five major activities are identified, an equal percentage (17%) report prioritising eight different activities as well as the 33% which prioritise developing information for government payers (Figure 1.1). These additional core activities include aiding trial design, meeting with payers, supporting pricing decisions and preparing content for regulatory submissions. While teams note a number of core activities, larger percentages report each activity as either supplemental or minor activities.

With the exception of working with government payers and organising or presenting data, some percentages of groups report not performing activities. There is significant overlap in certain activities — such as managing vendors and marketing valuations — that some companies consider core while others do not perform at all. Two-thirds of teams (67%) do not train sales reps, MSLs or account managers.

Conclusion
Despite a wide range of activities, HEOR groups must be able to prioritise responsibilities to best reach their target audiences. Though some activities require more attention and time than others, each one is necessary in developing thorough health economics support for emerging and existing brands across multiple payers and HEOR stakeholders. Stakeholders may have different expectations depending on their region of operation, government versus private oversight and their own resources and priorities. As companies prepare brands for launch, pricing and reimbursement discussions and beyond, health economics strategies must account for distributing best-fit data to address individual payer needs.

*The data for this article come from primary survey data collected by research analysts at Cutting Edge Information. Study participants included vice presidents, directors of global and regional HEOR departments, market access managers, and other related personnel from more than 30 companies of all sizes and geographic locations. Company, product and participant names are blinded to ensure that the identities and privacy of all participants are protected. Blinding allows survey respondents to comfortably provide accurate data for all Cutting Edge Information studies.

Reference

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