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Evidence maps guides drugmakers to gold

Steve Clark, Nic Gwatkin and Chantal Hinds of Optum discuss the benefits of evidence maps to view data in disease areas.

If you showed Google Earth and Google Maps to your great-grandfather, his white-bearded jaw would drop. He'd marvel at the effortless zoom from a satellite view of planet earth to a roadmap of his hometown to a street view of his house.

Similar advances in data assembly are changing the way pharma companies look at information on products moving from the research pipeline into the commercial sphere.
The breakthrough is called an evidence map. At first glance, it resembles a standard information grid constructed in Microsoft Excel. But what it delivers is a unique, interlinked and concentric view of every domain a medication touches en route from design and synthesis to clinical testing and review, to the insurance formulary, the pharmacy shelf, and the patient's home.

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Five reasons to create an evidence map:

1. To provide a single, integrated window onto current standards of treatment for a disease, segmented by patient population and showing the gaps in care
2. To understand the value components of a therapy, including what kind of investment is required to overcome a value threshold
3. To compile relevant input from clinicians, academic scientists, patient groups, regulators and everyone involved in health technology assessment
4. To learn which stakeholders and key opinion leaders have the greatest influence on payer decisions
5. To see how the media is treating reimbursement decisions by payers and public statements by thought leaders who influence the guidelines.

Much of the information I'm describing is available from various sources. You can study trial results in peer-reviewed journals, scan blogs that track every move of the Food & Drug Administration (FDA), attend academic meetings, pore over the message boards of patient support groups and analyze prescription claims data.

The trouble is doing all of that would become a full-time job. And there would be no easy way to format or update what you learned. An evidence map answers the need, with categories on the grid that are tailored to each species of data you're trying to track.

Gathering the data

Data collection remains a priority, of course. The map's creator must track down all the information on drugs – approved and in the pipeline – that treat a condition. He or she must identify direct and indirect comparators, as well as current and future "key attributes" that describe the clinical and economic impact of managing the disease. These attributes are a set of comparable characteristics and performance value thresholds of competing therapies, based on a range of clinical and patient-reported outcomes.

Once the structure is in place, the map incorporates both linear and weighted rating scales that help track the importance of key attributes and predict the performance of therapy / drug comparators. Reading across one axis, you see relevant performance data on your drug and each competing product in the same category. Scroll up or down, and you might find published statements from all key opinion leaders, panels or committees whose pronouncements affect value and value thresholds.

Who's on the expert panel to choose key attributes:

- Clinicians
- Academic authorities
- Members of patient advocacy groups
- Insurance executives
- Staff at health technology assessment organizations
- FDA Advisors

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Building expert opinion into the grid is important, for example, if a development program promises patient benefits only at the margin. Take a disease like diabetes, where many new treatments offer just 0.2 or 0.3 percent improvement on a hemoglobin A1c test. How would an FDA panel look at that number, or something a little higher? What about the Centers for Medicare and Medicaid Services (CMS), or a major hospital chain? By drilling down in the grid, a drug developer can learn about the value thresholds for each stakeholder.

Or consider a complex illness such as osteoporosis, where there are at least five approved medicines on the market and three distinct categories of drugs in the pipeline. Clinicians may be looking at baselines for bone mineral density in the lumbar spine, the hip or the femoral neck, while contemplating adverse events that could be cardiovascular, gastrointestinal, skeletal, microbial / infectious or oncological.

With an evidence map, a drug developer can impose order on this complexity, judging costs, risks and benefits from the perspective of the patient, the clinician, the regulator or the payer. The developer is like an avatar in an online multiplayer game, assuming different guises while traversing a data-rich landscape.

Bird's eye view

Like Google Earth and Google Maps, the evidence map provides different insights depending on your "distance" from the viewed surface. From a bird's eye view, colors of different boxes may alert the analyst to disease pathologies that aren't addressed by any current medicine. Another colour might signal the deadliest side effects.

As you draw closer to the grid, the granularity increases, just like on Google Maps. Now you are following links to papers in science journals, accessing the prescription data, reading press coverage of an FDA panel, or following the twitter stream of an advocacy group.

In short, the evidence map embraces a whole new paradigm – that of a digital geographic map in a world brimming with online databases and social media. It's a tool your development team would be eager to exploit. Your great grandfather would be shaking his head in wonder.

Closing thought: Does the evidence map embrace a whole new paradigm?

About the authors:

About Steve Clark

Steve Clark is Vice President, Product Value Strategy at Optum, in Eden Prairie, Minn. Previously of The Lewin Group, Steve has more than 20 years of experience in the medical device field with extensive experience helping pharmaceutical and medical device companies in marketing, clinical and reimbursement areas. Mr. Clark has worked with numerous early stage technologies to assess reimbursement issues and develop strategies to assess market differentiation opportunities.

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