The Medical Device Industry: Opportunities and Challenges of Connecting Globally

The globalization of the medical device industry has delivered significant business benefits, but it has also presented certain problems that can make the realization of those opportunities challenging. On the plus side, globalization offers opportunities to increase revenue and decrease costs. Globalization enriches the innovation that drives the industry by enabling collaboration with subject matter experts from across the globe. It also enables medical device companies to establish relationships with suppliers, manufacturing sites, distributors and customers around the world.

On the downside are the challenges of increased competition; navigating multiple complex regulatory environments; and the very real logistical challenge of connecting this new global network of employees, customers, suppliers, distributors and manufacturing sites to foster collaboration both inside and outside the organization.

Global connections

To address this global collaboration challenge, many medical device companies have begun moving key business applications to a web application delivery model. This model allows companies to leverage the Internet to connect global users. Examples of the types of applications that companies are shifting to a web-based delivery model include customer relationship management (CRM) applications; applications for collaboration; product lifecycle management (PLM) applications, support portals and business-to-business eCommerce applications.

Using web-based applications for business operations helps ensure application accessibility for remote employees, customers and business partners. However, the key to realizing the benefits of application delivery via the web hinges on the performance and reliability of the network, i.e., the public Internet.

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Limitations of the Internet for global collaboration

Medical device company end-users need fast, reliable and secure access to web-based business applications in order to connect globally and enable innovation. The Internet offers a cost-effective, global network, but business application delivery over the Internet is complicated by:

- ***The number of users.*** The total number of Internet users worldwide is estimated to have increased by 833 percent, to 3,366,260,056, between 2000 and 2015.[1]
- ***The increase in the growth and mobility of enterprise applications.*** International Data Corporation (IDC) has estimated that the number of enterprise applications optimized for mobility will quadruple between 2014 and 2016.[2]
- ***The multitude of devices accessing the Internet.*** Mobile devices, such as smartphones and tablets, have become an increasingly important means of Internet access.
- ***The variety of browsers used to access the Internet.*** Relevant browsers include Internet Explorer, Firefox, Chrome, Safari, Opera Mini and the Android Browser.[3]
- ***The fragmentation of network connections.*** Users might connect to the Internet using home Wi-Fi, a corporate-wired LAN, 3G or 4G networks, or through a tethered connection.

Data transmission over the Internet can be slow. "Due to legacy architecture and the logic of the Internet, the selection of routes between data centers and end-users is extremely inefficient," said Lord. "Once a route is selected, the transmission of data is slow, error-prone and subject to congestion and downtime."

As a result, a company's customers, employees and business partners may experience poor application-response times, inconsistent availability and data loss vulnerabilities. These Internet performance issues are particularly critical in the medical device industry.

Regulatory environment complexities

The regulatory environment in which the medical device industry operates is complex and dynamic. Health Insurance Portability and Accountability (HIPAA) regulations, Food and Drug Administration (FDA) regulations, and/or state laws may apply to information that is transmitted over the Internet, depending upon the nature and use of the information.

"Using the Internet is fine, but if it is not managed in a secure way, if it is not reliable in and of itself, those would be enforcement issues that the FDA would or could assert authority over," said Dr. Elliot Sloane, president, executive director and founder of the Center for Healthcare Information Research and Policy. "The FDA has said they're not going to try to regulate whatever network or Internet service the user is using to send their data, but they are going to hold the vendor accountable for ensuring that the data is always under appropriate privacy and reliability constraints."

In addition to performance issues, Internet connectedness introduces security concerns. "It is important to keep in mind that the Internet is open and accessible to anyone," said Lee Kim, director of Privacy and Security for HIMSS North America. "There are search engines you can query for what is connected, including mobile medical devices. There are people who use these tools for good purposes, such as testing security vulnerabilities, and there are people who use these tools for bad purposes, such as hacking."

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Why standard approaches fall short

Companies have tried a number of different approaches to connect global users and foster collaboration by addressing Internet performance, reliability and security issues. One approach is to implement physical hardware and/or a virtual appliance that lives within the walls of the company data center, such as an application delivery controller (ADC) or a WAN optimization controller (WOC).

The problem with this approach is that it does not function as a symmetrical architecture when supporting Internet users. "Organizations need symmetrical solutions that optimize both ends of application delivery – the end where the application is hosted and the other end where the end-user is located," said Lord. "Companies can't possibly implement a box or virtual appliance in every data center and in every location where their end-users are located."

A second approach is to invest in private network infrastructure. This approach addresses Internet performance and reliability issues, but it does not scale. Access to applications is limited to end-users on the private network. Moreover, it prevents companies from leveraging the cost efficiencies and global scale of the Internet to connect global users.

A third approach is to move websites and applications from a corporate data center to the public cloud. "This solves only half of the application delivery challenge," said Lord. "By moving applications to public cloud infrastructure, you realize increased scalability and cost efficiencies in managing data center infrastructure, such as servers and storage equipment. But you still need to rely on the public Internet to reach your users, which is the other half of the application delivery challenge that public cloud providers have historically not been able to effectively solve."

A comprehensive global collaboration solution

A more comprehensive approach to improving Internet performance, reliability and security in order to connect global users and foster collaboration is to use a cloud-based application delivery platform. Cloud-based application delivery platforms employ hundreds of thousands of servers, distributed across the globe, with a unifying architecture designed to ensure network speed, reliability and security. They are deployed symmetrically, meaning they optimize website and application delivery at both the origin (private data center or public cloud) and the front end (user interface). It's the Internet, but better.

A cloud-based application delivery platform optimizes application delivery using multiple strategies, including:

- ***Determining an optimal Internet route*** using intelligent route selection, instead of using the default Internet routing protocols;
- ***Facilitating connection offload.*** Inbound data requests can be served by the platform using caching, reducing the impact on data center bandwidth and infrastructure;
- ***Enabling load balancing.*** Configurable load-balancing capabilities decrease latency and increase performance;
- ***Providing real-time failover.*** Supports instant and seamless failover of traffic between data centers if there is an outage in a primary data center or cloud environment;
- ***Accelerating web performance.*** Web pages load as quickly as possible, on any device, anywhere in the world; and
- ***Optimizing for mobile and cellular users.*** An intelligent platform is able to dynamically optimize the user's experience based upon the user's device, browser and network connection.

Cloud-based application delivery platforms offer network security benefits as well. Cloud-based web application firewalls (WAFs), deployed within the platform, offer the

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advantage of intercepting malicious cyber activity at the edge of the Internet, before attack traffic reaches the company's own network or applications. Likewise, cloud-based security solutions are designed to easily scale to defend against large DDoS attacks, providing another layer of network defense at the edge of the network, away from the company's data center.

"If it is easy to break into your application, you become 'low-hanging fruit,' and you are more likely to have an intrusion," said Kim. "By prioritizing security, you decrease the chances your application will be targeted."

Making the Internet work for global medical device companies

Cloud-based application delivery platforms are designed to enable medical device companies to leverage the global reach and cost-effectiveness of the Internet without sacrificing network speed, reliability or security. In addition to being effective, this solution is easy to deploy.

"Companies are able to take advantage of cloud-based application delivery platforms by making a simple domain name system (DNS) change, versus needing to procure, provision and configure on-premise or virtual appliances in order to optimize application delivery," said Lord.

Given the complexity of the regulatory environment medical device companies operate within, network reliability and security are nonnegotiable. Cloud-based application delivery solutions offer an effective approach to Internet performance and security that is as innovative as the companies they serve.

"Medical device companies invest considerable resources in buying or building web-based applications," said Lord. "Whether it's CRM, or collaboration, or PLM, they choose these applications to support specific, critical business functions. It's important to pay attention to the performance of the network delivering those applications in order to achieve their goals in making that initial application or website investment."

[1] Miniwatts Marketing Group. (2015). Internet world stats: Usage and population statistics. Retrieved from http://www.internetworldstats.com/stats.htm
[2] International Data Corporation (IDC). (2014, December 18). IDC Reveals Worldwide Mobile Enterprise Applications and Solutions Predictions for 2015. Retrieved from https://www.idc.com/getdoc.jsp?containerId=prUS25350514
[3] Net Applications.com. (2015). Desktop browser market share & mobile/tablet market share. Retrieved from https://www.netmarketshare.com

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