



2016 Top Markets Report **Health IT** Country Case Study

Germany

Germany has a sizable healthcare market, with Health IT applications representing more than \$280 million at present. An aging society, with significant share of chronic disease, national use of eHealth Cards, and high Internet and mobile phone penetration, potentially make Germany a strong Health IT market, particularly for telehealth and mobile health. Besides significant concerns regarding system interoperability, companies need to understand and plan for some important headwinds if they are interested in entering Germany. These include strict regulations regarding data management, security and privacy, and use of Health IT software, as well as the established presence of major international health and IT companies. Implementation of the December 2015 eHealth Law is forthcoming, and it is unknown whether the new Law will address all outstanding issues. A carefully-considered market plan and partnering with international or local companies will increase the likelihood of success for U.S. Health IT companies seeking to develop or expand their presence in Germany.

Overall Rank

7

Description of Rank and Sub-score Measurements

Germany rated highly in the Top Market Report for several reasons: one of the world's highest GDPs, above average healthcare spending per capita, a large healthcare market (more than \$300 billion in 2012)ⁱ and an aging population (behind only Japan and Italy among the countries studied). The Health IT market in Germany in 2016 stands at \$284 million, but the sector is expected to grow annually by 22 percent to reach \$631.3 million by 2020. According to the Bitkom industry association, Health IT is now the eighth most important IT segment in Germany's sector index in the first half of 2016, behind segments such as IT security, industrial Internet, big data, and the Internet of Things (IoT).ⁱⁱ As a result, the German market is sizable and offers many appealing features for increased overall use of Health IT, and for telehealth and mobile health applications in particular.

In December 2015, Germany passed an eHealth Law (hereafter "Law")ⁱⁱⁱ, which contains a number of provisions to encourage Health IT and telehealth use while incorporating financial penalties if the Law's provisions are not satisfied. The Law includes payments for creation and acceptance of different medical reports, which will be temporarily channeled through the Federal Office of Information Security until the telematics infrastructure has been fully deployed.^{iv}

In addition, the Law includes provisions for technical agreement on several telehealth applications and development of data services, along with financial penalties for medical provider non-use of the system and for government agencies failing to meet statutory deadlines; many of these provisions take effect in 2016. The Law stipulates June 30, 2016 as the beginning of the nationwide rollout. Infrastructure tests will then transit into the nationwide rollout of electronic master data

Opportunities for U.S. Companies

management, referred to as “online updates.” This is the point in time when the Law will take effect.

The Law will hopefully address some long-uncertain issues, including who will cover costs for securing the Health IT information and building the infrastructure for the in-patient and out-patient environments and the process for achieving Health IT system interoperability. Analysts have noted that patients will ultimately have to decide how much information they would like stored on the new eHealth card (eHC); like the old version, only administrative information will be mandatory.^v

In addition, as of 2018, patients have the right to have emergency data and medication plans listed on their eHCs. According to the Law, doctors and nurses can access those data in emergencies without prior patient authorization. In all other cases, patient consent must be proof-ready. By the end of 2016, *gematik*, the major federal government contractor for the telematics infrastructure, has to come up with a solution for patient access, mobile and stationary, to personal data. An option under review is wireless communications between eHC and a patient app. Infrastructure for Electronic Patient Records should be developed by 2018, according to the Law.

Demographics and population health show favorable trends for more widespread use of Health IT in Germany, especially mobile health and telehealth. Using this Report’s methodology, by 2030, Germany is expected to have the third highest percentage of people over age 60, behind Japan and Italy. In addition, chronic and long-term diseases account for roughly 80 percent of German healthcare spending.^{vi}

Germans are also familiar with and frequent users of modern technologies, which portend well for Health IT and associated subsectors. About 77 percent of the population (63 million) uses the Internet frequently, one of the highest percentages in Europe. Germany also has strong sales of smartphones (about 26 million sold in 2013, up 23 percent compared to 2012).^{vii} With Germany planning to implement 4G systems by 2018 (these systems are not yet in place), market opportunities look bright in Germany for use of faster, more innovative Health IT solutions.

There is a ready market for modern Health IT solutions and systems, with approximately 154,000 general practitioners and nearly twice as many medical specialists (296,000).^{viii} There is, however, an imbalance in the geographic distribution of doctors, with relatively few in rural areas,^{ix} which could spur further use of mobile health and telehealth solutions. Many hospitals and physicians use Health IT to store health information in digital form. The information is not readily sharable and can only be retrieved by the hospital or patient upon request.

Surveys indicate patients and physicians are interested in a range of improvements to the medical system, including electronic storage of emergency data, electronic letters of referral, and EHRs, so commercial prospects for those areas are promising. Some of these services are already being used in private clinics and rural areas with a low concentration of physicians.

Germany has also made strides in establishing a mobile health and telehealth market, primarily through pilot projects. For instance, a telematics infrastructure pilot project launched in 2015 included all 131 public sickness funds (the statutory health insurance system that covers 90 percent of the German population). A separate clinical trial on chronic heart failure, called TIM-HF II^x, includes more than 400 practitioners and 60 cardiologists, with first results expected in 2016 or 2017. In addition, an on-line portal already exists for telemedicine projects (Deutsches Telemedizinportal, or “Portal for the German Telemedicine Center”), and about 240 telemedicine projects exist in approximately 100 communities nationwide.^{xi}

Finally, Germany hosts conhIT, one of Europe’s largest annual Health IT trade shows, first held in 2008, which serves as a possible avenue for new companies to enter the market. The 2017 show will take place in Berlin from April 25 to 27. In 2016, conhIT hosted approximately 9,000 visitors and more than 450 exhibiting companies.^{xii}

Challenges in the Market

There are significant challenges and other considerations U.S. companies should keep in mind when entering or expanding their presence in Germany. Companies should give these issues careful consideration and seek consultation with

experts familiar with the sector and country, when making decisions about whether and how to enter the German Health IT market. These challenges include:

- Roughly 90 percent of Germany’s population (70 million) has public health insurance, normally using an eHealth card (eHC). These cards, however, contain no health information (only a photo, name, birth details, and an insurance ID number) due to strict data security laws, so the eHC does not function like an Electronic Health Record. Insurance funds and physician associations have accused each other of delaying tactics in connecting health information to the eHC. The new eHealth Law^{xiii} sets forth a plan for patients to allow health information to be included on an updated version of the eHC, starting in October 2016 (for patients on at least three different prescribed medicines) and July 2018 (for information such as allergies and implants), but this information can only be included with patient approval due to security concerns.^{xiv} Physicians are to receive remuneration if they are able to produce data sets from the emergency information on the new eHC, but are to be penalized if they do not comply by July 1, 2018.^{xv} The so-called “online updates” of master data are important to develop a blanket digital health infrastructure. Physicians will need to apply for an electronic pass (HBA) with a qualified electronic signature (QES) by 2017 with one of the three likely providers: Medisign (approved), T-Systems, and the Federal Government Printing Office.^{xvi}
- Health IT software is currently regulated as a medical device through the Medical Products Law, requiring certification when the software influences clinical decision making.
- Germany has strict data privacy and security laws.^{xvii}
- Roughly 9 million Germans possess private health insurance; collectively, more than 162 insurance companies exist in Germany.^{xviii} Therefore, there will be limited demand for U.S. health insurance companies to enter the German market.
- While Germany has piloted a telematics infrastructure (combining elements of telemedicine and telehealth in a single system), it has not been fully implemented, and standards, requirements and specifications have not been finalized for all possible use cases.
- Germany’s new eHealth Law does not permit all Health IT applications (such as remote treatment of a patient for their first medical diagnosis or therapy by a doctor), so developing a reimbursement case for a specific application might be difficult. Remote counseling of patients, teleconsultations between physicians, and telemonitoring of known patients, however, are allowed.
- Hospitals generally have underinvested in IT (1.5 to 2 percent of total spending)^{xix} in comparison to other European countries. According to a 2014 RWI and Accenture report, German hospitals have an investment shortfall of roughly 15 billion euros, partly due to declining patient traffic at many facilities and rising costs. The report estimated that 13 percent of German hospitals could go out of business by 2020 if no action is taken.^{xx} As a result, mobile health and telehealth services may be well suited to meet patient needs not available in the hospital environment.
- Germany has no national organization with the authority to set Health IT standards; as a result, interoperability does not exist between vendor solutions, limiting the scalability of certain Health IT products and services.
- Approximately 200 Health IT companies have established operations in Germany,^{xxi} with just over half of them targeting clinical or hospital practices. Germany has a well-established Health IT industry trade association, the German Association of Health IT Vendors (Bvitg). Bvitg has more than 50 members, including German subsidiaries of U.S.-based firms such as GE, Cisco, Cerner and 3M, and German-based companies such as Agfa, Siemens, Deutsche Telekom and SAP.^{xxii} As a result, a well-established Health IT ecosystem already exists in Germany, with a mixture of large and small companies, but one that already has significant competition for new companies looking to enter the German Health IT market.
- Alliances (such as the recent one between Royal Philips and Allianz, a major private sickness fund, to provide connected health solutions) and mergers (such as Agfa HealthCare’s recent purchase of Austrian TIP Group) are a key part of the German Health IT sector. According to Business Monitor International, cloud analytics

is a rapidly growing segment, with IBM and Dell leading the race to build huge analytics platforms.

ⁱ Ruehle, Julia. Germany Trade and Invest, “Growth Market eHealth” PowerPoint; Data from Statistisches Bundesamt 2014.

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<https://de.statista.com/outlook/312/137/ehealth/deutschland#market-revenue>; www.e-health-com.eu.

ⁱⁱⁱ E-Health Law; German Health Ministry (published in German), Federal Register 12-21-2015: http://www.bgbl.de/xaver/bgbl/text.xav?SID=&tf=xaver.component.Text_0&toctf=&qmf=&hlf=xaver.component.Hitlist_0&bk=bgbl&start=%2F%2F%5B%40node_id%3D%27946289%5D&skin=pdf&tlevel=-2&nohist=1.

^{iv} Prior to passage of the eHealth Law, there was much criticism of its provisions; for example, see Raddatz, Fabian, “E-Health-Legislation in Germany – Update,” August 12, 2015: <http://www.noerr.com/en/publications/News/e-health-legislation-in-germany.aspx>.

^v “eHealth Law” in Germany,” Taylor Wessing, March 2016; <http://united-kingdom.taylorwessing.com/synapse/ti-ehealth-law-germany.html>.

^{vi} Ruehle, Ibid., Data from DB Research 2010, Statista 2014, Statistisches Bundesamt 2014.

^{vii} Ibid., Data from Bitkom 2014, eMarketer 2013.

^{viii} Zilch, Sebastian. “German Health-IT Markets and Their Characteristics” PowerPoint, October 28, 2014.

^{ix} “eHealth Law” in Germany,” Taylor Wessing, March 2016; <http://united-kingdom.taylorwessing.com/synapse/ti-ehealth-law-germany.html>.

^x See website:

https://telemedizin.charite.de/en/research/fontane/telemedical_interventional_management_in_heart_failure_tim_hf_ii/.

^{xi} Ruehle, Ibid., Data from Deutsches Telemedizinportal; <http://telemedizin.fokus.fraunhofer.de/2014>; E-Health@Home, www.iat.eu/ehealth/2011

^{xii} <http://www.conhit.de/en/ConhIT/Review/>; more on conhIT 2016 at <http://www.conhit.com/Visitors/Events/index.jsp>.

^{xiii} See footnote 99.

^{xiv} “eHealth Law” in Germany,” Taylor Wessing, March 2016; <http://united-kingdom.taylorwessing.com/synapse/ti-ehealth-law-germany.html>.

^{xv} “Act on Secure Digital Communication and Applications in the Health Care System (E-Health Act),” German Federal Ministry of Health, July 3, 2015.

^{xvi} Ibid.

^{xvii} Zilch, Ibid.

^{xviii} Ibid., Data from Statista 2014, Statistisches Bundesamt 2014, Grunddaten der Krankenhäuser 2013, BVMED – Branchenbericht 2014, and from U.S. Commercial Service, Dusseldorf, Germany, April 2016.

^{xix} Zilch, Ibid.

^{xx} 10th Annual Hospital Rating Report by RWI, Accenture and HCB; June 26, 2014;

<http://newsroom.accenture.com/news/one-in-two-german-hospitals-unable-to-invest-in-new-initiatives-in-2012-according-to-the-tenth-annual-hospital-rating-report-by-rwi-accenture-and-hcb.htm>.

^{xxi} Zilch, Ibid.

^{xxii} Ibid.