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THE IMPACT OF EMERGING MARKETS ON THE PHARMACEUTICAL INDUSTRY

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Emerging markets are considered nowadays the "Promised Land" for pharmaceutical industries. Although a clear-cut definition of these markets is not yet available, *Forbes* magazine along with other economists define them as developing prosperous countries. In these countries, an investment is expected to result in higher income despite the high risks. Qualifying a market as emerging is not solely based on the country's economic status but rather on a series of criteria making the definition relative to each. Jim O'Neill, retired chairman of Goldman Sachs Asset Management, coined the names of the 2 leading economies of emerging markets into 2 acronyms. BRICS countries (Brazil, Russia, India, China, and later South Africa) emerged first and were followed years later by MIST countries (Mexico, Indonesia, South Korea, and Turkey) as the second wave of tiers countries joining emerging markets. In the last 5 years, sales of pharmaceuticals in BRICS and MIST markets doubled, reaching a share of ~20% globally. This shift stems from the huge populations of the concerned societies, an increasing prosperity, and life expectancy. In addition, companies are suffering from a flattened growth rate in developed markets, the expiration of >40% of patents leading to the up-selling of cheaper generic drugs, and the existing tight regulations. However, Big Pharma needs to be cautioned regarding these emerging markets. Pharmaceutical companies wanting to expand in these emerging opportunities have to tailor their strategies according to the developing pace of each country. These communities are in need of drugs against infectious and communicable diseases such as sexually transmitted diseases. They are ready-to-exploit territories for the innovative products of pharmaceuticals. However, with the increase in wealth and longevity, a change of lifestyle is slowly taking place accompanied by a shift in the disease trends. A disproportionately fast rise in the incidence of noncommunicable diseases such as cardiovascular illnesses, diabetes, and cancers is noticed in emerging markets, mimicking the pattern of their Western counterparts. The incidence of diabetes and oncologic diseases is expected to grow by ≥20% in the next 5 years. This could be viewed as a mixed blessing, as pharmaceutical industries will be able to sell their global products in these new markets as well. Industries face challenges to conquer emerging markets grouped into 3 categories: infrastructure development, cost-containment policies, and value-driven drug evaluation. To overcome these hurdles, new strategies need to be adopted by pharmaceutical companies. Adequate tailoring and gain in market are among the top strategies to be considered.

Key words: BRICS, emerging markets, MIST, pharmaceuticals.
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MODELING AND INTEGRATION OF INTENSIVE CARE DATA INTO AN openEHR-BASED ENTERPRISE DATA WAREHOUSE

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Background: In hospitals, clinical data are often scattered across multiple databases and application systems due to decentralized clinical information system architectures. Consequently, the reuse of once collected data for secondary purposes as data analytics and data mining is considered a challenging task.[1] Enterprise Data Warehouses (EDW) have been established at several medical centers to overcome typical obstacles to data reuse such as proprietary data models, terminologies, lack of governance, and more. However, the complexity and high rate of change of the clinical domain and medical data cause high costs for maintenance of data models and the provision of data to researchers.[2] Detailed Clinical Models might help to better manage these domain-specific challenges by introducing formal and computable methods to represent clinical content models to data warehousing.[3] One example of a Detailed Clinical Model approach is openEHR, a specification of an open, interoperable electronic health record.[4] Although the use of openEHR in the context of a health information exchange is well established, there is still a lack of evidence regarding its feasibility to represent and integrate legacy data into EDWs.

Methods: We chose the domain of intensive care medicine to investigate if openEHR can meet a diverse set of requirements to represent and help integrate clinical data that are stored in application systems. At Hannover Medical School, 2 independent patient data management systems (*COPRA* and *m.life*) are incorporated at the intensive care wards. We identified a test set of 8 clinical concepts that are commonly used in these systems: blood pressure, body temperature, pulse, heart rate, indirect oximetry, Braden Scale, Glasgow Coma Scale, and ventilation. For each of these measurements, we intended to obtain an openEHR Archetype (a formal content model of a clinical concept) or to create a new one. Subsequently, Archetypes were used to create a Template, which can be thought of as a use case-specific document. For the task of data integration and mapping, we used a combination of Microsoft SSIS, Altova MapForce 2014, and the Template Document Schema approach.[5]

Results: We obtained 7 Archetypes from the Clinical Knowledge Manager, the public content model repository of the openEHR Foundation. Because no ventilation Archetype was available at the time of this work, we created a new Archetype. We found it possible to map most types of legacy data from the given application systems to openEHR Templates. The representation and mapping of Braden Scales and Glasgow Coma Scales data were straightforward. By contrast, the mapping of continuous sensor data (eg, blood pressure measurements generated by sensors) required the arbitrary segmentation of values into multiple documents. For this purpose, we chose a 24-hour interval. When integrating ventilation data, we found a high number of corresponding variables in the source systems (~300). Because available resources were limited, we decided to create a first draft version of the ventilation Archetype that only represents data elements of the most important parameters. In coordination with a clinical expert, 30 data items were identified and then modeled in the archetype.

Conclusions: Essentially, we found it possible to use Archetypes and Templates to integrate a test set of intensive care data from 2 systems. By applying the openEHR approach for data modeling and integration, detailed clinical models can be used for tasks such as automated constraint checking, error reporting, data persistence, and querying. Although medical scores such as the Glasgow Coma Scale were a good fit for openEHR, voluminous data such as vital signs and ventilation data needed some workarounds to work properly. Especially, the demand of archetypes to be explicit about the meaning of each data element might be problematic in some data integration scenarios. On the one hand, this might be considered an advantage, as it forces EDW developers and system analysts to work thoroughly. On the other hand, this constraint might prevent pragmatic solutions when a fast integration cannot be achieved or interpretation of data can be conducted by the end-users. Although this work illustrates some of the strengths and restrictions of the openEHR approach for data integration tasks, our methodology is limited by the number of used clinical concepts. A possible next step is the investigation of the implications of openEHR-based information retrieval and the semantic interpretation of data.

Key words: clinical information systems, data warehousing, detailed clinical models, health care analytics, openEHR, secondary use.
Disclosure of Interest: None declared.

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DEVELOPMENT OF MEDICAL DEVICES

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Background: The medical devices sector helps save lives by providing innovative health care solutions regarding diagnosis, prevention, monitoring, treatment, and alleviation. Medical devices are classified into 1 of 3 categories in the order of increasing risk: Class I, Class II, and Class III.[1] Medical devices are distinguished from drugs for regulatory purposes based on mechanism of action. Unlike drugs, medical devices operate via physical or mechanical means and are not dependent on metabolism to accomplish their primary intended effect.[2,3]

Objectives: This study focused on regulations and differences in medical device and pharmaceutical drug development. It also highlighted the unique challenges faced while doing medical device development.

Methods: A US Food and Drug Administration and European Medicines Agency website search was conducted to determine current medical device regulations. A comprehensive literature search was done from Google Scholar to determine the differences in drug and medical device development.

Results: Designing well-controlled prospective clinical trials of medical devices presents unique challenges that differ from those faced in studies of pharmaceuticals. Clinical outcomes observed in medical device studies, unlike drug trials, are influenced not only by the product under evaluation and the patient but also by the skill and discretion of the health care professional. Medically appropriate alternative treatment regimens may not be available to provide randomized, concurrent controls in device trials. Because devices are often developed by small companies, financial constraints often limit the new product development and testing.

Conclusions: Medical device development is faced with unique challenges. Managing the design issues in clinical trials and complying with increasingly stringent regulatory guidelines is necessary to bring new devices faster to market with reduced cost.

Key words: clinical trials, EMA, medical devices, USFDA.
Disclosure of Interest: None declared.

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QUALITY MANAGEMENT—NEW PERSPECTIVES FOR MEDICAL DATA MANAGER

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Increasingly, hospitals and other players in the health care sector will inevitably compete in terms of quality. Interinstitutional and cross-sectoral quality assurance has been pushed forward during recent years. Institution-related outcomes are published and accessible to the public. Due to new health laws, in the near future, quality results of hospitals will not only be decisive for reimbursement increases or price reductions of the remuneration but will also be a crucial factor for a hospital's survival. Hospitals that are not able to get quality deficiencies under control may lose their public supply mandate. Thus, the outcome of hospitals should be measured on the basis of predefined quality indicators to reach the objectives described earlier. Key indicators are, on the one hand, measures of medical performance. In particular, these include, for example, the type and numbers of surgical procedures as well as surgical complications in a certain time period. Also included are structural statistics about continuous medical education such as number of passed training courses for medical doctors and nurses. Moreover, information about patient safety are key indicators for quality assurance. Patient safety indicators, for example, are the number of patient falls and side effects of medication. These parameters have to be registered in a structured form and in a fixed frequency. The method to provide these indicators is a continuous comprehensive quality management, including capturing and monitoring of all relevant data. This requires the establishment of a professional operating system gaining all necessary figures in daily clinical routine. Health information management