Partnership, the Transatlantic Free Trade Area/Transatlantic Trade and Investment Partnership, and the Trade in Services Agreement has bypassed the momentum created by the WIPO Development Agenda in addressing the reformation of the dominant discourse of Patent Regime focusing sideling the "access" issues of public health.

The central issue is that of the old patent regime, which advocates that "monopoly" rights lead to "innovation" and thereby will address the public health issues versus the counterview that "monopoly" rights itself is not a linear solution to public health but needs to use it as an "appropriate intervention tool" to spur innovation. Thus, the "monopoly" question needs to be subjugated to the final question of "access" of drugs for all for a better public health.

This article aims to track and disseminate the recent developments on the question of the access versus monopoly debate from the emerging agreements outside the TRIPS and Development Agenda dialogue and its impact on the future of public health.

Disclosure of Interest: None declared.

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PUBLICATION BIAS

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Background: According to the Declaration of Helsinki, as well as the Statement on Public Disclosure of Clinical Trial Results of the World Health Organization, every researcher has the ethical obligation to publish research results on all trials with human participants in a complete and accurate way within 12 months after the end of the trial.[1,2] Nevertheless, for several reasons, not all research results are published in an accurate way in case they are released at all. This phenomenon of publication bias may not only create a false impression on the reliability of clinical research business, but it may also affect the evidence of clinical conclusions about the best treatments, which are mostly based on published data and results.

Objectives: The aim of this article was to present different types of publication bias with regard to authors, peer reviewers, and editors. Already implemented approaches for a reduction in the publication bias phenomenon will be provided to strengthen confidence in the clinical research business.

Methods: Literature on publication bias for this narrative review article was identified by searching the PubMed database using the key words "publication bias in clinical research." The search was limited to articles available as free full-text papers with publication dates later than 2010. Likewise, a Google search with the same key words was performed.

Results: Based on the reviewed literature, publication bias can be classified into 3 different types. The first type can be defined as publication bias, which occurs through the author before the submission of the manuscript to a journal in terms of nonpublication or incomplete publication of negative research results. Both other types describe publication bias after submission of the manuscript to a journal. In these cases, either the peer reviewer or the editor of a journal can cause bias during the publication process. For reducing the publication bias phenomenon in clinical research, most of the leading journals meanwhile insist on a registration of the study in public registries such as clinicaltrials.gov as a condition for successful publication.[3] Also, the implementation of a blinded peer-reviewing process, in which the peer reviewer will do the review without knowing any author details, represents an improvement in publication bias.

Conclusions: The phenomenon of publication bias not only occurs before submission of manuscripts, but it may also happen after submission to a journal.[4] It still forms an issue in discussions about evidence-based medicine. Thus, publication of trial results is required by internationally applicable guidance, and ongoing discussions are needed to keep attention by stakeholders to achieve a greater transparency in the area of clinical research.

Key words: author, editor, peer review, publication bias.

Disclosure of Interest: None declared.

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ENSURING PATIENT IDENTITY IN AN INCREASING INTEROPERABLE HEALTH CARE ECOSYSTEM

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The United States Department of Health and Human Services is charged with improving the health, safety, and well-being of all Americans. Since 2004, when former President George W. Bush set a goal for all Americans to have an electronic health record by 2014, the Office of the National Coordinator (ONC) for Health Information Technology under the Department of Health and Human Services has been steadily making progress. By moving from paper to electronic health records, many benefits can be achieved, including enhanced patient safety, improved care coordination, increased patient participation, practice efficiencies, and cost savings. The vision for 2024 as stated in an ONC report is an "interoperable health information technology (IT) ecosystem that makes the right data available to the right people at the right time across products and organizations in a way that can be relied upon and meaningfully used by recipients."[1]

At the heart of a highly functional interoperable health information technology ecosystem is accurate patient identity. Ensuring patient identity is essential for patient safety and quality of care. Accurate patient identification is the foundation for successfully linking patient records within an integrated health care delivery system and across the health care ecosystem.[2] The first of 5 building blocks in achieving ONC's vision for 2024 tackles the need for standards that address essential services for interoperability, which include methods to accurately match individuals, providers, and their information across data sources.[3] Furthermore, health care organizations need to ensure that a robust information governance program is implemented to address patient identity integrity.

Key words: electronic health record, health care, health information technology, information governance, Office of the National Coordinator, patient identity.

Disclosure of Interest: None declared.

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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.
Disclosure of Interest: None declared.

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.