

MIETULIS ARTURS

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PLAYING A FORTUNE-TELLER AND GETTING READY FOR THE BIG GAME: BEING READY FOR EMA TO BUILD A BRIDGE BETWEEN CODED AND SEMI-STRUCTURED DATA BY VIRTUE OF A DIGITAL FIT STRATEGY

The article deals with digital solutions in the field of healthcare. The author outlines pros and cons of new modern technologies, including big data and its analysis techniques in the said field. The activity of the European Medicines Agency as a model for developing promising data strategies for internal reuse of standardized data has been analyzed. The importance of investing in pharmacological examination has been substantiated.

Key words: European Medicines Agency (EMA), common standards for data, data silo, reuse of standardised data, pharmacovigilance.

Introduction

Purposefully implemented digital solutions for health and care positively affect millions of individuals [5]. New modern technologies, including big data and its analysis techniques, promise us scientifically perfect future [14]. When unsorted or when generated at different places of origin, data may become unobjective [9]. Apart from that, since data comes from various information sources, big amounts of data may be characterised not only with the great variability but are indeed also constantly changing [28]. Data is the key ingredient of digital transformation, but it is often dependent on technologies that are non-interoperable [5]. Interpretability, portability, interoperability, and reusability may be reached by setting common standards for data [26]. When speaking about data related to public health policies, introduction of such standardisation could be seen as a path to development of integrated

solutions, which is superior to approaches connected to attempts to improve isolated solutions on a one-by-one basis [23]. Apart from that, shared services based on such standards brake the data silo and may generate cost savings of more than 40 percent in terms of support service spending [32]. For this reason, author would like to draw the attention on standardisation of data, and its internal reuse. In the current paper, European Medicines Agency (EMA) will function as a model for the development of a prospective data strategy for the internal reuse of standardised data. Materials observed and strategies proposed may become reality in the near future. Especially since EMA is already actively working on re-shaping its master data [18]. Being prepared for the development of scenario described below may give strategic advantage to those planning to apply for the marketing authorisation through Common European Single Submission Portal (CESSP), or, in case the practical implementation takes long enough, will give stakeholders opportunity to participate in the promotion of below mentioned strategy in collaboration with a consultancy agency knowledgeable in the area.

Background

Pharmacovigilance is a subbranch of pharmaceutical science with an ultimate goal of protecting public health by virtue of preventing, detecting and assessing adverse reactions that individuals may develop after intake of a medicinal product [11]. It is hard to underestimate the importance of pharmacovigilance remembering that its purpose is to avoid harm similar to that caused by the thalidomide, when thousands of infants were born with limb deformation caused by the intake of that medicinal product by their mothers in the course of their pregnancy [22]. For this reason, full safety profile of each medicinal product is sustained by certain competent authorities. In the European Union (EU), authorisation, supervision and pharmacovigilance of medicinal products is a prerogative and duty of EMA [31]. In order to maintain information on adverse events at disposal at a single point of access, already back in 2001 a European database called EudraVigilance Clinical Trials Module database appeared, where pharmaceutical companies were obliged to submit information on SUSARs* [1]. Out of this service, a EudraVigilance** information network and management system has emerged. EudraVigilance, based on the gathered data from pharmaceutical industry, developed an EVMPD***, that since 2012 has been substituted by an xEVMPD**** [6]. The xEVMPD is populated by means of xEVPRM*****, which is in process of being substituted by

* suspected unexpected serious adverse reaction

** European Union Drug Regulating Authorities Pharmacovigilance

*** EudraVigilance Medicinal Product Dictionary

**** Extended EudraVigilance Medicinal Product Dictionary

***** Extended EudraVigilance Product Report Message

ISO IDMP* standard [15]. As time passed, EMA roadmap defined that for sake of data harmonisation and interoperability, ISO IDMP standards are to be implemented with the common EU IDMP/SPOR** strategy. The result of this strategy was endorsement of data submission in ISO IDMP standard suit [15].

Analysis of the current state of play

Since more European nowadays have access to information technologies, in parallel to introduction of ISO IDMP that is to be used for populating xEVMPD, where SUSARs reports end-up, EMA in its action plan has introduced some novelties to other elements of product information (PI) [4] – summary of product characteristics (SmPCs) [34] and package leaflet (PLs)***. Medicinal product information in the EU includes SmPC, which is mostly intended for health-care professional, and PL, which is primarily consumer-oriented. These two documents represent a source of information vital for prescription and usage, including information on safety of use [13]. Novelties include alignment of key information sections in SmPCs and PLs, including data on safety, in order to ensure rapid access to key safety messages from consumer's or health care professional's side. It is envisaged that application of electronic formats will bring new opportunities for those summaries and leaflets. Nevertheless, key principles for the use of those undefined formats have not yet been developed [19]. It is worth mentioning, that SmPCs and PLs can only be edited by EMA, which receives data ISO IDMP-encoded. Nevertheless, the transfer of data into SmPC and PL is performed manually and the text itself semi-structured and at least partially consists of free text [4]. While the question of developing a common electronic standard is still a matter of negotiation, it could be considered quite straight-forward that data on pharmacovigilance gathered for the inclusion into ISO IDMP-encoded database (xEVMPD) in form of controlled vocabulary could be also integrated into semi-structured text of SmPCs and PL. In the current situation, the data is preserved within the same organisation, while it is not being fully utilised and re-used. Automated system, e.g. currently existing Common European Single Submission Portal (CESSP) [25], could simultaneously change the data in both repositories – xEVMPD and product information repository [13].

ISO IDMP is preferable to stick with, since it is suitable not only for pharmacovigilance, but may also be utilised for other use-cases, such as regulatory affairs, good manufacturing practice tracking, clinical trials etc. Apart from the codinf standard itself, the messaging system is also present

* International Organization for Standardization – IDentification of Medicinal Products

** European Union's Identification of Medicinal Products – Substances, Products, Organisations and Referentials

*** The content of Package leaflet is described in Article 59 of Directive 2001/83/EC

and agreed on – HL7* Common Product Model standard based on XML** will be used to exchange IDMP coded data [20]. Based on the current information and communication information infrastructure of EMA, data management services employed for the centralised management of IDMP master data could be employed for the management of PI, transforming it into an ePI***. It should be noted that the mere idea of digitising the PI into ePI is not new by itself and has been vocalised by common vision of European Medicines Agency, Heads of Medicines Agencies, and the European Commission. Such approach aiming at robust inter-linkage of different parts of a single infrastructure may be seen not only bringing positive changes for the end-users, but also as a mean to solve long-standing and often non-resolvable problem of resource saving by data reuse [8].

Vision

The overall vision is that in the current situation where the legal framework has already been shaped and means to be implemented for the digital transformation are present, it is feasible and promising to develop a data strategy for EMA to inter-connect fragmented segments of data management system.

Presence of following criteria allows to judge that the overall vision is based on sound arguments:

- Legal obligation exists to further digitalize the master data management system;
- There is developed path within the organisation for incoming data to populate xEVMPD with IDMP coded data fluxing in using HL7 messaging system;
- EMA is already running digital infrastructure to sustain xEVMPD, which means that the ICT infrastructure is present;
- No need to develop a new standard, since the data previously incoming for a certain use-case will be reused for a different purpose remaining in the same coding system; thus, no application programming interfaces needed;
- Recirculation of data within the same organisation ensures sustainable data use;
- Automatic transfer of information diminishes error-prone manual editing;
- Internally transferred and reused data speeds-up the information appearance in SmPC and PL;
- Thorough data management based on data reuse optimises costs;

* Health Level Seven

** eXtensible Markup Language

*** Electronic product information

- Data reliability ensures efficient decision-making; helps avoiding data silo and ensures interoperability [25].

From the human capital perspective, the ultimate goal of a new data strategy for EMA would be to protect individual by providing data on adverse events as fast as possible, while from technical perspective the goal would be to maximise utilisation of current capacities to improve quality, reduce costs, and avoid errors.

Model and methods

In order to diminish the possibility of becoming dependent on technologies coming from the outside of the EU, EMA should focus on advancing own available data technologies, especially since there is an already existing interwind between a policy, legal and societal aspects bound around technical activities [3, p. 4] in the sphere of pharmacovigilance data. In such a manner, one may insist that the future strategy shall deploy currently available xEVMPD ISO IDMP-enhanced model and methods of digital data management. It is worth describing the data value chain of current model. A brief analysis will cover data acquisition, data analysis, data curation, data storage, and data usage [3, p. 32].

Data acquisition: properly coded information on adverse events may be gathered either from medicinal product's marketing authorisation holder (e.g. pharma producer) in a form of SUSARs, or from competent authority in a form of ICSR* that the authority gathers from health care professional / individual users [20].

Data curation: data can be submitted only by a qualified person for pharmacovigilance/responsible person for EudraVigilance. Submission happens through the EMA account management portal [17]. Further active management is happening in-house.

Data storage: EMA applied (and possibly still applies) multiple data storage methods, such as clustered object-rational databases implemented on separate database server levels, Lightweight Directory Access Protocol directory, and Java embedded directories [16].

Data usage: the end-user of data is EMA that uses information obtained for decision-making (operations with marketing authorisation), and public health concern minimisation (through information provision to end beneficiaries). End beneficiaries are individual consumers and healthcare professionals, who do not have access to the master data databases, while having the possibility to freely access SmPCs and PLs. Current political agenda is addressing the need of re-use of EMA ISO IDMP-encoded master data to become intertwined with ePrescriptions, Electronic Healthcare Records, Patient Summaries and other elements of EU eHealth Digital Single Infrastructure [12], that are out of the scope of the current strategy.

* Individual Case Safety Report

In terms of methods used for sustaining data flow at EMA it should be observed, that data managed by EMA can be considered shared [29] dark [10] data, shared within networks of machines within same organisation, and curated by virtue of mixing crowdsourcing (where previously encoded information is being gathered) and master data management that happens in-house and focuses on master data coordination and compliance with pre-set requirements [3, p. 94]. Nevertheless, synchronisation of master data across different structures of the agency is somewhat weak, thus the following strategy is proposed.

Strategy

Currently European pharmacopeia of the European Directorate for the Quality of Medicines of the Council of Europe, that is binding for all EU, has collected information on more than 2400 monographs on substances and around 2800 descriptions of reagents [24]. Taking into account the fact, that most of active substances are sold EU-wide with different brand names, the amount of medicinal products in the EU market may reach several hundreds of thousands. Such amount may be easily considered being big data and needs a specific data strategy to be managed.

Current model is described in Illustration 1.

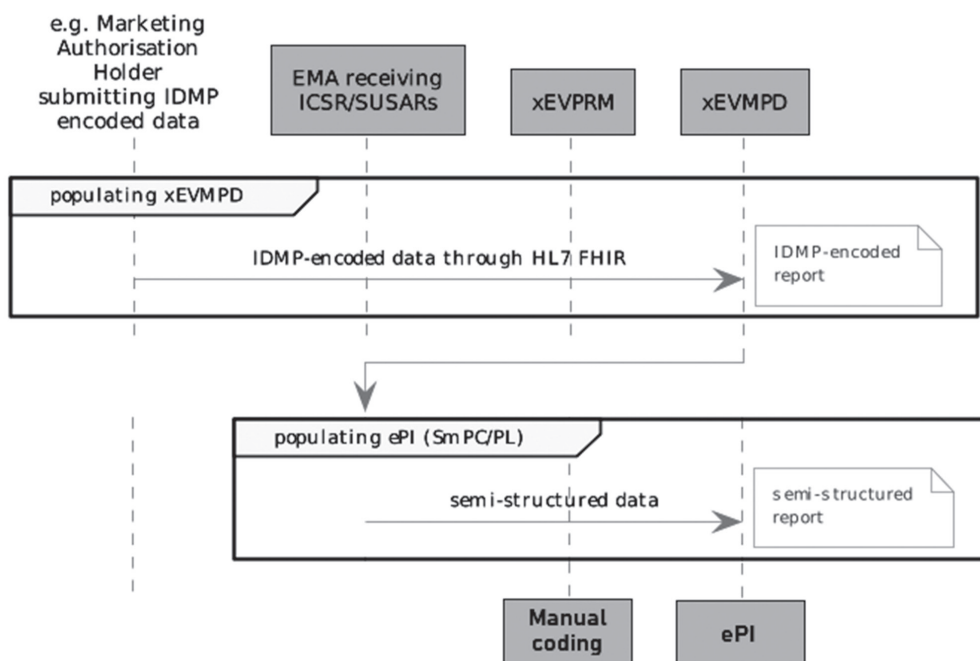


Illustration 1. Current mode, subject to refurbishing in accordance with the new data strategy

The new model of data strategy will try to embody variables of interest concerning both pharmacovigilance, and product information. Even though such model would be highly sensitive to underlying assumptions [30], it should not hamper its utility, since internally it focuses only on one specific organisation, while externally it will be intertwined with other models applying same standards.

In order to develop a rigorous strategy model, data use cases should be defined first. Two internal use cases identified (pharmacovigilance, regulatory intelligence, and master data management) are based on a single external use case (regulatory review and approach). Data use case analysis of those three internal use cases looks as follows [2].

Pharmacovigilance

- 1) Link to strategic goal – public health threat prevention;
- 2) Objective questions – passive surveillance over adverse events through encoded data;
- 3) Measures of success (KPIs) – reduced amount of time to react on incoming reports;
- 4) Use case owner – EMA;
- 5) User and data customers – EMA;
- 6) Required data – new external structured IDMP-encoded data;
- 7) Data governance – defined by legislation and internal acts; no external risks;
- 8) Data analysis and analytics – IDMP-encoded data;
- 9) Technology – IDMP-encoded data flowing by means HL7 FHIR messaging system;
- 10) Skills and capacity – data generated and coded by counterparts, analysed inhouse by means of present capacities;
- 11) Implementation and change management – currently available facilities satisfy needs.

Regulatory intelligence

- 1) Link to strategic goal – gathering and analysing information and integrating result of the analysis into evidence-based decision-making on product marketing authorisation through pharmacovigilance activities;
- 2) Objective questions – turning surveillance process results into policy;
- 3) Measures of success (KPIs) – reduced amount of time to react on identified serious adverse events by introducing changes in policy (e.g. marketing authorisation);
- 4) Use case owner – EMA;
- 5) User and data customers – EMA;
- 6) Required data – new external structured IDMP-encoded data;
- 7) Data governance – defined by legislation and internal acts; no external risks;
- 8) Data analysis and analytics – IDMP-encoded data;

9) Technology – redesigned internal communication able to facilitate IDMP-encoded data flowing by means HL7 FHIR messaging system;

10) Skills and capacity – data generated and coded by counterparts, analysed inhouse by means of present capacities;

11) Implementation and change management – currently available facilities satisfy needs.

Master data management

1) Link to strategic goal – gathering and analysing information and integrating result of the analysis into evidence-based decision-making on product marketing authorisation through pharmacovigilance activities;

2) Objective questions – bridging regulatory intelligence with ePI repository;

3) Measures of success (KPIs) – reduced amount of time between appearance of data in xEVMPD and ePI;

4) Use case owner;

5) User and data customers – EMA;

6) Required data – new external structured IDMP-encoded data;

7) Data governance – introducing data flow principles relevant for xEVMPD to ePI data flow;

8) Data analysis and analytics – IDMP-encoded data;

9) Technology – redesigned internal communication able to facilitate IDMP-encoded data flowing by means HL7 FHIR messaging system;

10) Skills and capacity – need to integrate HL7 FHIR enhanced IDMP-data flow into internal communication flow between xEVMPD repository and ePI repository;

11) Implementation and change management – bureaucratic hindrances.

Is it apparent from the description of the current model, there is no need to digitise/digitalise the workflow, neither is there a need to introduce big data into the model, since EMA is already managing big data *per se*. The new strategy is rather built on the concept of digital fit, where the pre-existing model is not to be dismantled, but rather reshaped [7, p. 16-18]. The digital fit is ensured by building an omnichain at EMA. Currently, the xEVMPD module digests IDMP-coded data that it receives through HL7 FHIR messaging paths, while ePI module produces SmPC/PL based on IDMP data from xEVMPD, but “lacks ferments” to digest this IDMP data, thus the data needs to be decoded, manually transformed and integrated into a semi-structured body of SmPC/PL. To avoid errors and reduce costs arising from utilisation of not interoperable, not semantically coded information by ePI module, it needs to adopt the same path of data transfer and the same coding system as applied xEVMPD module. Illustration 2 demonstrates how those two insular modules into a functional omnichain.

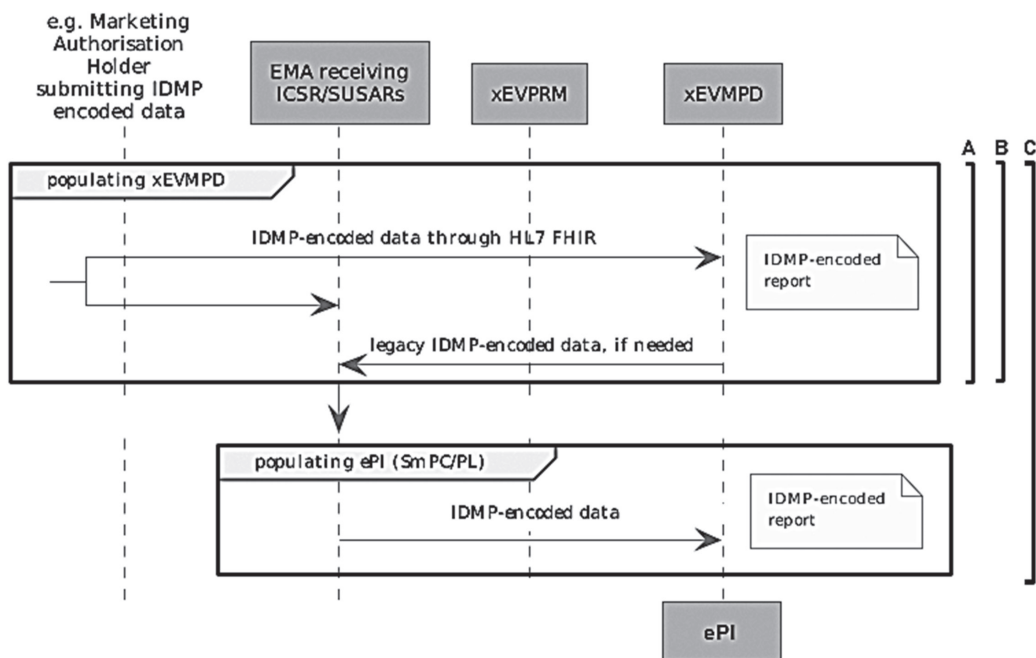


Illustration 2. A model representing a digital fit strategy employing omnichain in data flow, and depicting three use cases: pharmacovigilance (A), regulatory intelligence (B), and master data management (C)

Evaluation

Even though EMA represents a closed ecosystem, omnichain approach is still valid for it. Instead of enhancing interaction between different players, focus is shifted to the inside world of the organisation, improving interaction within it [7, p. 69, 73]. In a case scenario where an omnichain is employed, the value chain is adapted to work more effective and efficient, avoiding break of flow of data and enhancing seamless data processing. New strategy based on digital fit approach demonstrates extended use cases for current IDMP-coded data. Different modules of the chain (xEVMPD vs SmPC/PL) remain independent while becoming intertwined by the standardised data flow [7, p. 16]. In such case scenario, where the data stream junction is facilitated at the xEVPRM level, it is possible to utilise both legacy data from Lightweight Directory Access Protocol directories and the field level incoming data applying same bus systems. Even though literature suggests traditional relational databases as an example, such data flow architecture should also be applicable to Lightweight Directory Access Protocol directories applied at EMA [27].

The data, that is encoded in IDMP, does represent a structured summary or certain identifiers, such as medicinal product name, ingredient substances, route of administration etc., as well as identifiers for the description of adverse

event itself, as presented in medical dictionary for regulatory affairs (MedDRA). None of the data, submitted by marketing authorisation holder to EMA for the evaluation, contains personal data, thus cannot be considered sensitive and raises no concerns regarding personal data protection.

Protocols and standards, described in the strategy, are the ones prescribed by the current legislation, thus do not require any changes in the current state of play from legal point of view. The only concern would be lengthy bureaucratic procedures required to be fulfilled in order to ensure the switch from manual coding to omnichain data flow.

It should be noted, that EMA needs to be at the avant-garde of technological transformation in order to be competitive on the international arena with other major players, such as Food and Drug Administration of the United States of America (FDA) and the Japanese Pharmaceutical and Medical Devices Agency (PDMA) [21].

Conclusions

As estimates from the United States of America show, 44 to 98 thousand people in United States alone die due to preventable medical errors [33]. Since adverse event are part of a greater medical error family, it is absolutely worth investing in pharmacovigilance. As mentioned above, apart from obvious benefits from preserving lives, wise digital transformation and application of advanced data management strategies may significantly reduce costs, accelerate the reporting and subsequent policy actions, as well ensure competitiveness of EMA on the global arena.

This is exactly the strategy that EMA is likely to adopt. Being prepared for the development of scenario described below may give strategic advantage to those planning to apply for the marketing authorisation through Common European Single Submission Portal (CESSP), or, in case the practical implementation takes long enough, will give stakeholders opportunity to participate in the promotion of below mentioned strategy in collaboration with a consultancy agency knowledgeable in the area.

There is an even greater potential of spreading of ISO IDMP standard to fields of ePrescriptions, Electronic Healthcare Records, Patient Summaries etc. Nevertheless, those use-cases were left outside of the scope since they go beyond activities of EMA. Future research on the topic needs to be performed.

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Вдавати ворожок і готуватися до великої гри: підготовка до того, щоб ЄАЛЗ побудувало місток між кодованими та напівструктурованими даними на основі стратегії цифрової підгонки

Висвітлено ефективність використання цифрових технологій у галузі охорони здоров'я, їх переваги і недоліки, зосереджено увагу на великих даних (big data) і методах їх аналізу, оскільки стандартні способи обробки інформації не придатні для роботи з великими обсягами даних, які надходять з різних джерел і характеризуються не лише розмаїттям, а й мінливістю. Інтерпретабельності, портативності, сумісності і повторного використання інформації можна досягти запровадженням загальних стандартів даних. Стандартизацію даних, пов'язаних з громадським здоров'ям, варто розглядати як шлях до розробки інтегрованих рішень у цій площині. Саме тому автор привертає увагу до проблеми стандартизації даних та їх повторного внутрішнього використання й описує основні аспекти діяльності Європейського агентства з лікарських засобів як організації, що спроможна забезпечити розробку перспективних стратегій для внутрішнього повторного використання стандартизованих даних.

Ключові слова: Європейське агентство з лікарських засобів (ЄАЛЗ), загальні стандарти даних, «бункер» даних, повторне використання стандартизованих даних, фармаконагляд.

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