KOSMI, Daegu, Korea, 8 Nov 19, Presentation

Bron Kisler (Chair, ISO Genomics SC, NIH/NCI, USA)

ISO Genomics Sub-Committee: Overview and Future Direction

The field of Genomics Research is expanding rapidly, generating large amounts of data never before seen on this scale within translational research. In order to effectively manage and share this data as well as pool and analyze the data, international data standards are pivotal. To address this need ISO/TC215 member nations unanimously approved formation of the new ISO Genomics Sub-Committee. The inaugural meeting of the Genomics Sub-Committee will be held November 4-8 in Daegu, Korea.

This presentation will provide an overview of…

- ISO/TC 215 for Health Informatics
- ISO Genomics Sub-Committee
- Genomics Standards Projects from Korea and Japan
- Implementations in Korea
- Future Direction for International Genomics Standards

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Manufacturing medical knowledge on an industrial scale: Data quality

Abstract of main presentation points

Digitization may be the greatest medical advance of all time. It provides both the possibility of producing medical knowledge on an industrial scale and its effective application for personalized care. Realizing these benefits requires a paradigm shift in generating medical knowledge and evaluating health care delivery to create a virtuous spiral of continuous evaluation, improvement, and innovation; exemplified here by tightly coupling clinical decision support systems with health information factories (HIF). A HIF transforms data into pre-specified information products using predefined manufacturing processes: data are its raw material; information, its finished product. Such manufacturing system consists of 1) production system and 2) associated quality management system (QMS). Its many production processes encompass 1) data procurement, 2) data processing, 3) data analysis, 4) interpretation, and 5) information display and distribution. An ecosystem of HIF, spanning the entire medical product life-cycle, could manufacture medical knowledge on an industrial scale. Regulators and payors could promote the growth of HIF; permitting patients and others stakeholders to know medical products' true value. An international QMS standard would permit third-party certification of HIF; encompassing data sources. Multiple dimensions are useful for assessing data quality, which 1) is defined by users and 2) is key to producing fit-for-purpose information. Once data leave their source, context may be lost. International

standards are needed for assessing, assuring, and documenting data quality. Promoting HIF is an important policy priority and promises significant improvements in the quality of health care and people's health.

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Todd Cooper (Trusted Solution Foundry, USA)

Future Health Navigation: Are we on the right path from precision medicine to personalized health?

The intensity of activity around health informatics around the world seems to increase almost daily, especially with healthcare providers, technology industry and governments working hard to leverage the promise of AI/machine learning, big data analytics and real-world evidence, care coordination and clinical decision support, and yes precision medicine with genomics informatics. But in the midst of this hyperactivity running toward "future health", one has to ask: Are we on the right path to enable true health navigation that not only supports improved healthcare and medical care quality, but also provides the foundation for impacting the quality of life for individuals, 24/7, regardless of their socio-economic, geographic or even genetic situation? Precision medicine is great ... but will it scale? And will it help people, around the world, navigate back to a life that advances health, wellness and fitness? In this presentation, Mr. Cooper provides some perspectives that have emerged over the last few years starting with the proposal for revising the IEC 80001-1:2010 standard to considering a digital health legacy for the southern California Olympics in 2028 to the creation of the ISO/TC 215 SC1 Genomics Informatics, and now the Ageing in Community & Personalized Digital Health Informatics discussions, beg the question: What's next after SC1? As a Korean and global health informatics community, are we on the right path to help impact the daily lives of people around the world?

Ock Hee, Oh (FirstDIS Ltd., Korea)

“Korean IDMP Model: Preparing for Compliance with ISO IDMP Standards”.

[Summary]

전 세계적으로 의약품의 오남용, 부작용 그리고 잘못된 라벨 작성에 의한 약화사고 발생 통계는 새로운 의약품 관리기준의 필요성을 강력히 시사하고 있다.

의약품은 비슷한 이름과 모양이 유사해 보이지만 완전히 다른 속성을 갖는다. 오늘날 처방의약품 성분의 규모는 1 만 건 이상(국내 의약품은 성분기준으로 약 6700 건, 제품명 기준으로 약 35,000 건)으로, 약물의 기전 또는 사용법이 복잡하기

때문에 약을 처방하고 조제·투약하는 전문가들에게 안전한 의약품의 처방과 유통이 큰 과제가 되고 있다.

위와 같이 의약품 사용과오의 규모와 심각성을 고려할 때 국제적으로 일치된 의약품 속성의 식별(identification of medicinal product, IDMP) 표준의 필요성이 대두되었다.

IDMP 표준이 국내에 적용된다면 국내 의료기관, 의료정보시스템 개발 기업 등 관련기관 및 기업들이 동일한 용어와 코드 체계를 활용함으로써 시간과 비용이 절감되고 결국 안전한 처방 발행으로 의약품 코드 오류에 의한 DUR 점검을 놓치거나 적절한 코드가 없어 지식데이터베이스 구축의 어려움은 해소 할 수 있을 것이다. 뿐만 아니라 다양한 의약품 관련 통계의 생성과 데이터 질 관리를 효과적으로 이용할 수 있으며 또한 IDMP 표준시리즈의 활용으로 국내 기업의 국외 진출을 위한 국제표준 규격준수가 가능해져서 미래의 제약 산업의 경쟁력을 높일 수 있을 것으로 기대한다. 그러나 국제표준 IDMP 식별 체계를 준수하기 위해서는 규제기관의 정보 수집 및 관리방법의 변화가 절실히 필요하며 기존의 데이터를 IDMP 속성과 연결해야 하는 것은 극복해야 할 큰 장애물이다.

이에 본 발표자는 국가표준기술력향상사업 연구로 국제 표준을 준수하는 한국형 의약품 속성 식별체계를 연구 중이며 연구 성과 중 국제표준 체계 기반 의약품 DB 모델 및 의약품 지식베이스 연동사례를 공유 하고자 한다.