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Data Sharing Policies for Digital Health Innovations in South Korea

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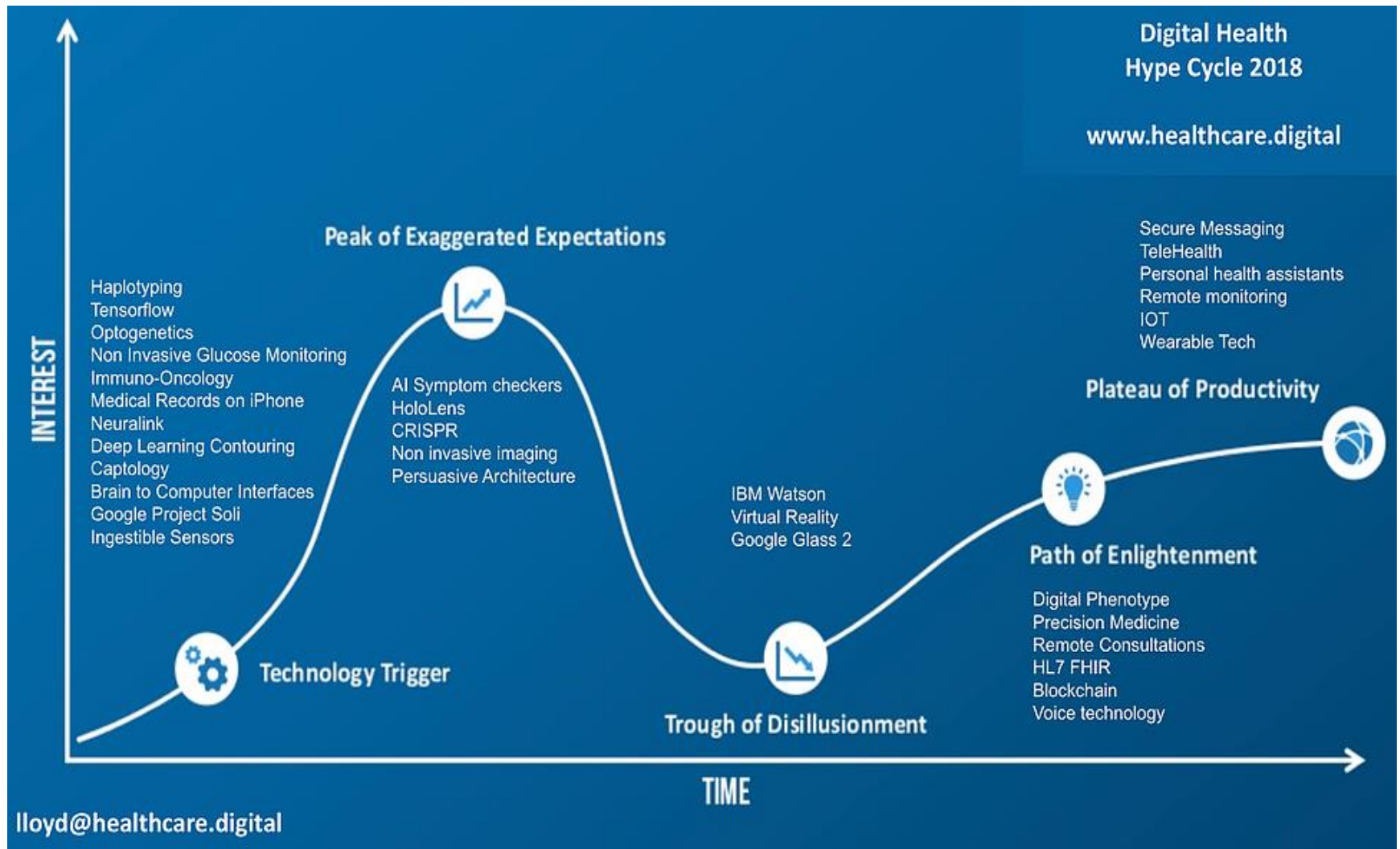
Challenges and Recent Changes



Current Status of Digital Health in Korea



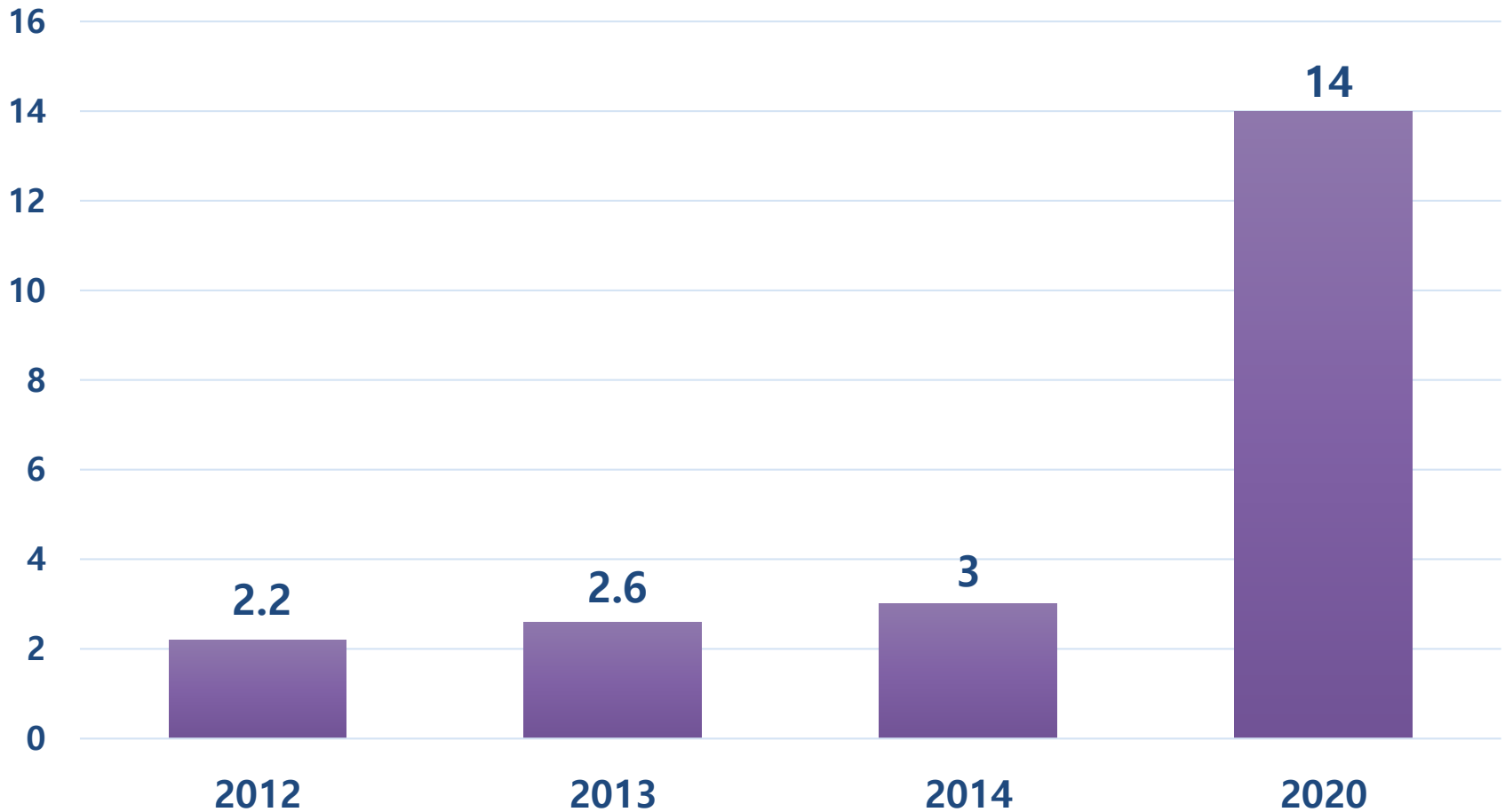
Where is Korea?





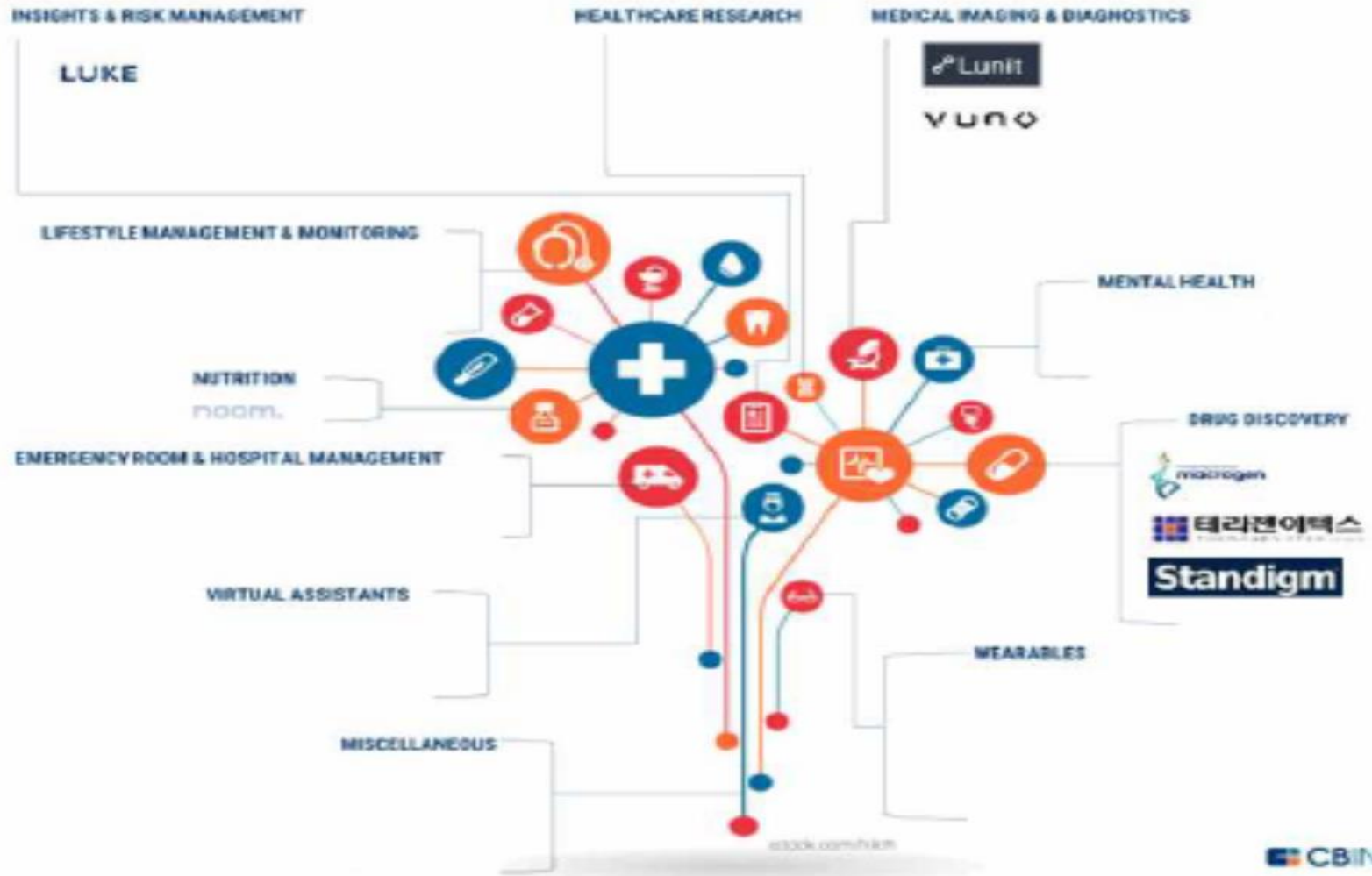
Digital Health Market in Korea

Unit : Billion US Dollar

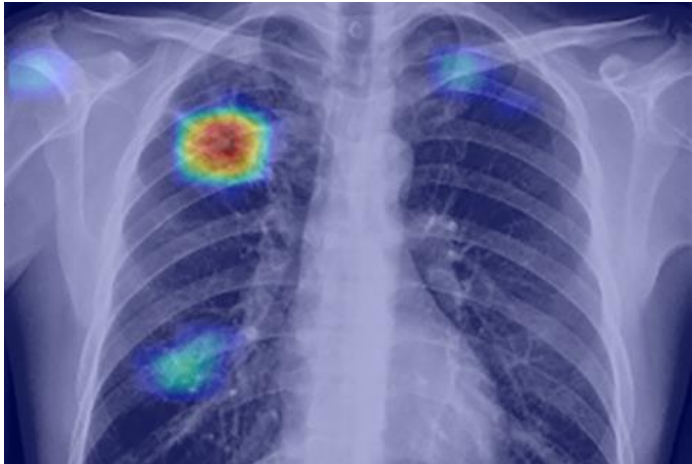


Source: MFDA & Hyundai Research Institute (2017)

AI-Healthcare Companies in Korea



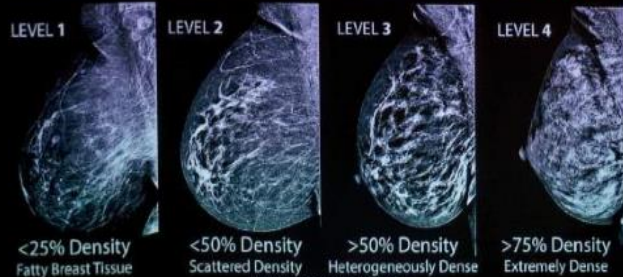
Imaging & Diagnostics Start-ups



Problem: dense breast

False-negative (missing) rates according to breast density

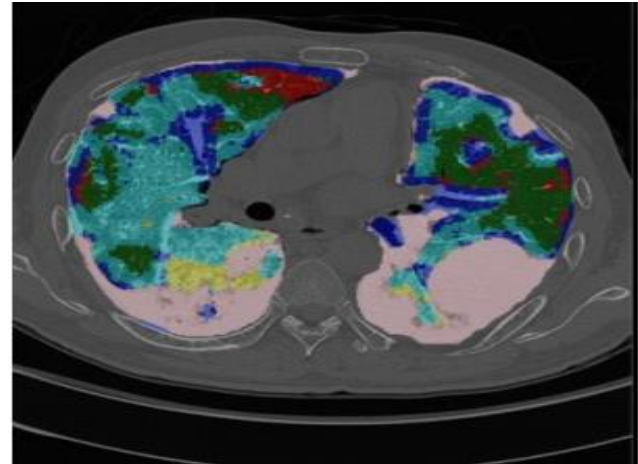
11.1% 13.9% 21.2% 31.8%



<http://www.bccrcresearch.org/>



PUTTING THE WORLD'S MEDICAL DATA TO WORK

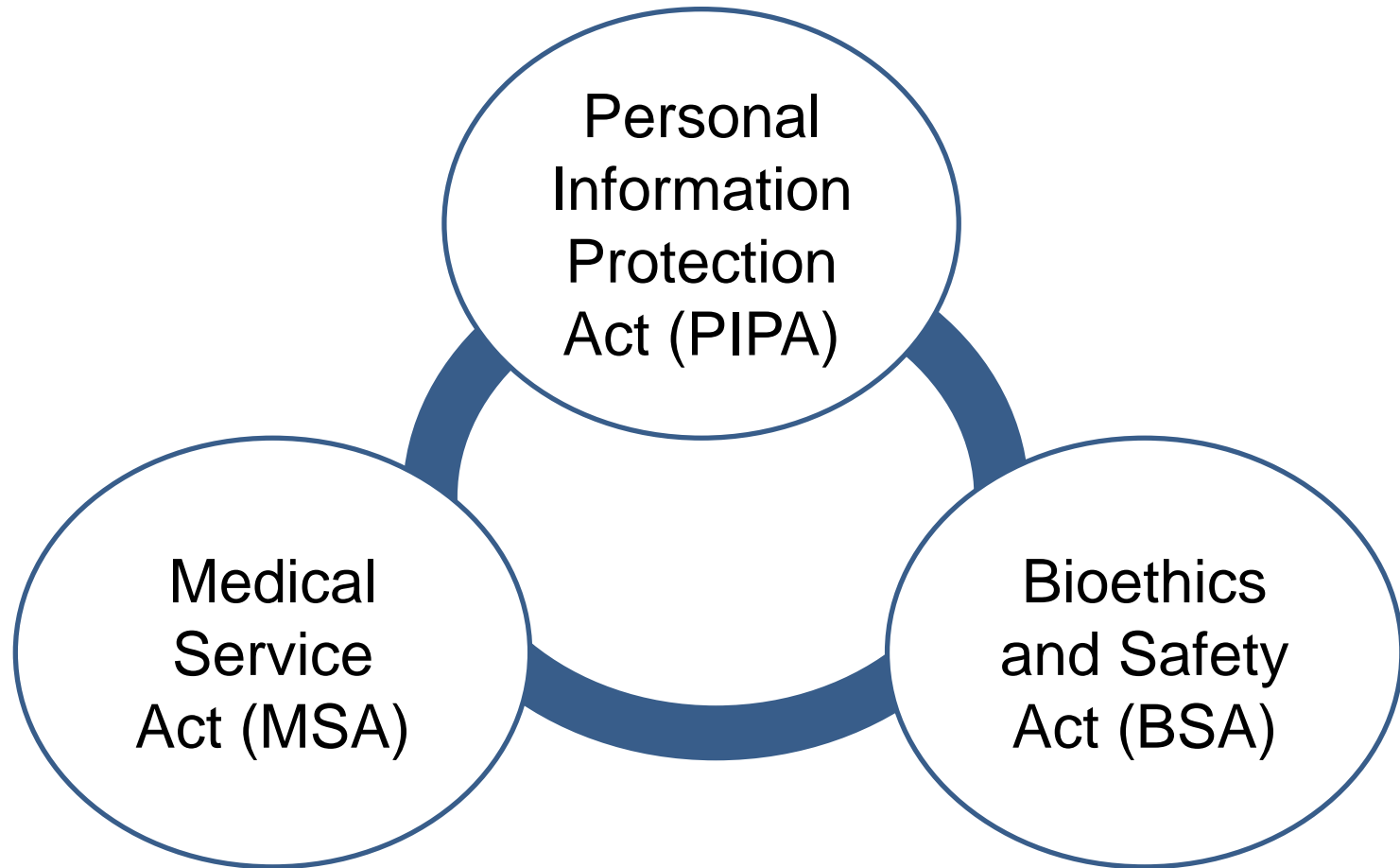




Major legislation Regarding Data Sharing



Three Major Laws



Personal Information Protection Act (PIPA)

- Enacted in 2011
- The purpose of this Act is [...] to protect the rights and interests of all citizens and further realize the dignity and value of each individual by protecting personal privacy, etc. from collection, leakage, misuse and abuse of individual information.
- It includes provisions regarding Purpose, Definitions, Principles, Rights of Data Subjects, Personal Information Protection Commission, Personal Information Protection Guidelines, Collection/Use/Provision, etc of Personal information, Methods of Obtaining Consent, Limitation to Processing of Sensitive Information, etc



Sensitive Information including Health is limited to processing (PIPA)

- Article 23 (Limitation to Processing of Sensitive Information) (1) A personal information controller **shall not process any information** prescribed by Presidential Decree (hereinafter referred to as "sensitive information"), including **ideology, belief, admission to or withdrawal from a trade union or political party, political opinions, health, sexual life, and other personal information** that is likely to threaten the privacy of any data subject noticeably: Provided, That this shall not apply in any of the following circumstances:
 - 1. Where the personal information controller informs the data subject of the matters provided for in Article 15 (2) or 17 (2), and obtains the consent of the data subject apart from the consent to the processing of other personal information;
 - 2. Where other statutes require or permit the processing of sensitive information.
 - (2) Where a personal information controller processes sensitive information pursuant to paragraph (1), the personal information controller shall take measures necessary to ensure safety pursuant to Article 29 so that the sensitive information may not be lost, stolen, divulged, forged, altered, or damaged. <Newly Inserted by Act No. 14107, Mar. 29, 2016>



Medical Service Act (MSA)

- Enacted in 1951
- Purpose - to ensure that all citizens can enjoy benefits of high-quality medical treatment and thereby to protect and improve public health
- It includes provisions regarding duties of medical person, medical institution, hospitals, licenses, verification of drug info. Confidential info., patients' records, etc



Patient's Records are limited to be released in MSA

- Article 21 (Inspection of Records, etc.) (1) Neither medical personnel nor any person working for a medical institution may release the details of a patient's record or allow the inspection thereof, such as providing a transcript thereof, to a third party, other than the relevant patient.
- (2) Notwithstanding paragraph (1), each medical personnel or any person working for a medical institution shall release the details of a patient's record or make them accessible, such as providing a copy thereof, in any of the following cases:

Bioethics and Safety Act (BSA)

- Enacted in 2004
- The purpose of this Act is to ensure bioethics and biosafety, [...] by preventing the violation of human dignity and values or the infliction of harm on human body in the course of researching on human beings and human materials or of handling embryos, genes, etc.



Bioethics and Safety Act (BSA)

- It includes provision regarding bioethics policy research centers, National Bioethics Committee, institutional bioethics committees, research on human subjects, personal information, human cloning, embryo research, donors of ova, human materials, genetic information, consent, etc.



Personal Information may be provided to a third party with written consent (BSA)

- Article 18 (Provision of Personal Information) (1) When a human subject of research gives written consents to providing his/her personal information to a third party pursuant to Article 16 (1), the relevant human subjects researcher may provide his/her personal information to a third party, subject to examination thereof by the competent institutional committee.
- (2) When a human subjects researcher intends to provide personal information about a human subject of research to a third party under paragraph (1), he/she shall anonymize such personal information: Provided, That the foregoing shall not apply where a human subject of research consents to leaving his/her personally identifiable information therein.



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Challenges and Recent Changes



Current Challenges

- How to integrate more personal health data while reducing privacy concerns? (De-identification)
- How to make patient data from different EMR systems more transferrable? (standardisation)

The Guidelines for De-Identification of Personal Information

- Effective as of July 1, 2016
- Several government agencies are involved, including the Korea Communications Commission, the Financial Services Commission, the Ministry of the Interior, the Ministry of Health and Welfare, and the Ministry of Science, ICT and Future Planning



Major Steps in The Guidelines

Pre- Review

To determine whether the data falls within the legal definition of "Personal Information" or not. If it does not, such data may be utilized without de-identification.

De-Identification

De-identification methods including pseudonymization, aggregation, data reduction, data suppression, data masking and more.

Appropriateness Evaluation

An outside evaluator should objectively evaluate whether such de-identification has been appropriately completed or not, based on the "K-anonymity" model.

Follow-up

To ensure that the de-identified data is not abused or misused, and is securely protected with proper managerial and technical security measures.



Health Data Standardisation

- 92.1% of hospitals in Korea have EMR systems
- BUT only 4 % of EMR systems can be data-transferrable (DailyMedi, 2016)
- A new article regarding the standardisation of EMR was inserted into the Medical Service Act in December 2016
- Several projects have been initiated for data standardisation



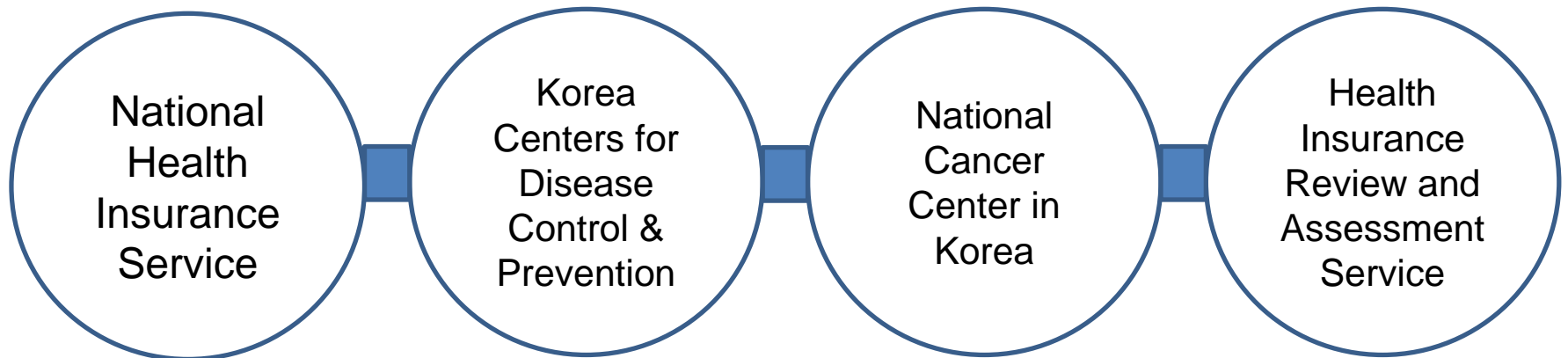
New Governance

- Oct. 2017. Launching Presidential Fourth Industrial Evolution Commission (PFIEC)
- Nov. 2017. Establishing a National Plan for Fourth Industrial Evolution
- Dec. 2017. Launching Healthcare Special Committee under PFIEC



A Case of Health Big-Data Platform

- A Project of Health Bio-Data Platform is expected to start as a pilot study in 2018
- The purpose of this plan is to connect data from four major public institutions as follows;



Thank you