

The Digital Health Workshop Summary

Collaborating for Digital Economy Growth,
Building a Better Intelligent World.



About the Digital Health Workshop

- **Goals and Output:**

To explore the regulation of wearable and medical devices, the formulation of mobile health standards in the field of active health, and promote the sharing and coordination of medical device policies and standards between EU and China.

- **Theme:** EU-China Discussion on Mobile Medical Health Device Policies/Application practice
- **Date:** 27th March 2022
- **Place:** Barcelona, Beijing, Online
- **Co-host:** Medical Device Industry Association(CN) / HL7 Europe



Agenda

9:30-9:40

Opening remarks

William Xu, Feng Jiang, Catherine Chronaki

9:40-10:20

Industrial environment shaping and experience sharing in innovative digital health area

- **particular understanding of the health industry on the developing road of digitalization**

Jian Chen

- **Regulatory challenges for medical software and Artificial Intelligence in Healthcare**

Annika Eberstein

10:20-11:00

Standardization practices of consumer products in the healthcare area

- **Research on Quality Evaluation of proactive Health Medical Products**

Jiage Li

- **Consumer Tech and Digital Health: Unlocking the Potential**

David Mudd

11:00-11:40

Advances in data sharing for consumer products

- **The role of HL7 FHIR in digital health ecosystems**

Giorgio Cangioli

- **From Performance Driven to Intent-Based Networking in Healthcare**

Christoph Thuemmler

11:50-12:30

- **Open Discussion**

12:30-12:40

- **Summary**

Overview of the Digital Health Workshop

- Attendees: **25** attendees from **20** organizations
 - Online: **7** guests + Onsite: **18** guests
- Main conclusions and outputs:** Digital health industry needs to strengthen industry dialogue, promote industry consensus and **form working groups**.

Industrial environment shaping and experience sharing in innovative digital health area

- The process of health digitization involves **efficiency and fairness, error and consequences, medical ethics and privacy rights, resource allocation**, etc., which need a conceptual consensus at a specialized and detailed level;
- The guidance of medical device sales is expected.

Standardization practices of consumer products in the healthcare area

- Lack of **effective, scientific and reliable evaluation methods on terminal product**;
- “Think big, start small and act now”**.

Advances in data sharing for consumer products

- EU/China and global collaboration on adoption and development HL7 FHIR artefacts** for consumer devices is hoped.
- 5G healthcare** still faces challenges such as **lack of vertical industry standards and ecosystem**.



‘It was a very good roundup of what is going on with ehealth at the moment and lots of food for thought. I do hope that you will come to our next **ETSI meeting** and tell ehealth group about it all.’

--- **Suno Wood, ETSI**

‘Excited to have met experts from different continents and discussed about innovative digital health from different perspectives. The need of continuing this conversation through a multi-stakeholder working group have been acknowledged, by following a pragmatic incremental approach based on concrete, specific and achievable objectives. It has been recognized how the nowadays digital health ecosystems are heterogenous systems of ecosystems in which medical and non-medical devices coexist, and where HL7 FHIR can play a key role for enabling the sharing of data. I’m looking forward for the next steps of this interesting journey.’

--- **Giorgio Cangioli, HL7 Europe**

Attendees of the Digital Health Workshop

25 industry leaders from 20 organizations: 9 onsite in Beijing, 9 onsite in Barcelona, 7 online.

| Role | Organization | Guest | Title |
|-----------------|---|---------------------|--|
| Chair | Huawei | William Xu | Director of the Board, President of the Institute of Strategic Research |
| Co-chairs | CAMDI, CITISA | Feng Jiang | CEO, President |
| | HL7 Europe | Catherine Chronaki | Secretary-General |
| Guest Speakers | CAMDI | Jian Chen | Senior Expert |
| | NIFDC | Jiage Li | Deputy Director |
| | BSI | David Mudd | Global Digital and Connected Product Certification Director |
| | HL7 Europe | Giorgio Cangoli | Technical Leader |
| | COCIR | Annika Eberstein | Interim Secretary-General |
| | 6GHI | Christoph Thuemmler | Scientific Director |
| | NIFDC | Jingli Li | Director of Institute for Medical Device Control |
| | NIFDC | Shu Li | Professor |
| | NIFDC | Hao Wang | Secretary-General, SDO on AIMD, China |
| | NIFDC | Xiangfeng Meng | Secretary General, Standard Development Organization on Medical Robots |
| | COCHE | Yuanting Zhang | Director |
| | Zhongguancun Xinzhiyuan Health Management Institute | Liuxin Wu | Director |
| | ITEI | Chunxia Li | Director of the medical equipment reliability research office |
| | CAMS | Zhaolian Ouyang | Director of Medical Device and Drug Strategic Intelligence Research Department of the Institute of Medical Information |
| | CAICT | Shan Xu | Senior engineer of the E-Health Department of Cloud Computing & Big Data Research Institute |
| | Artificial Intelligence Research Center for neurological diseases of Beijing Tiantan Hospital | Yunyun Xiong | Principle Researcher |
| | TM Forum | Kevin Xu | APAC Regional Director |
| | CHINA INFO 100 | Yan Zhu | Member of the Executive Committee |
| | TM Forum | Joann O'Brien | Vice-President of Digital Ecosystems |
| | Digital Europe | Michele Calabo | Senior Manager for Digital Health Policy |
| | Digital Europe | Zoey Stambolliu | Manager for Infrastructure & Security Policy |
| | UK 6GIC | Rahim Tafazolli | President |
| | BTHFT NHS | Altaf Sadique | Non-Executive Director |
| | ETSI | Suno Wood | Chair of TC eHealth |
| | ZVEI | Pia Grass | Manager for Public Affairs Medical Engineering |
| | GIO Special Advisors | 5GDNA | Zemin Yang |
| GIO Secretariat | | Martin Creaner | GIO Special Advisor |
| Moderators | CAMDI | Shang Wang | Member of the Innovation Service Professional Committee & Senior Expert |
| | 5GSA | Luigi Licciardi | Chairman and President |

Key messages – Chairs' Address



William Xu, GIO Chair, Director of the Board, President of the Institute of Strategic Research, Huawei

- Health is not only an industry but also an invariable demand of every person. With the aging society, we pursue to decode from the needs of health, and develop a series of products and solutions to help people live a happy life. Our vision of the big health is **developing a consensus**, so our products and industries will be able to enjoy more order and speedy development in a way that is truly beneficial to the elderly consumers with the happiness based solutions.



Catherine Chronaki, Secretary-General of HL7 Europe

- The HL7 vision is a world in which **everyone can securely access and use and have the right data everywhere and everytime they are needed**. For this purpose, the mission of HL7 is to **create the best and most widely used interoperability standard in healthcare**. Therefore, we at HL7 Europe, are committed to work with all actors to create these standards, to convey the right requirements so that we build these standards.



Feng Jiang, CEO of CAMDI, President of CITISA

- It is hoped that this workshop can provide us solutions and answers to the weaknesses of mobile smart medical products and wearable medical products, so as to promote the industrial development of medical devices in China and the global market. And we are hoping that **more excellent medical devices, which can reach to the CES consumer electronics manufacturers level, can enter the medical equipment area**.

Key messages —Industrial environment shaping and experience sharing in innovative digital health area



Jian Chen, Senior Expert of China Association for Medical Devices Industry

- **The Special Nature of the Digitalization of the Health Industry:**

The process of health digitization is a social project, which involves efficiency and fairness, error and consequences, medical ethics and privacy rights, resource allocation, etc. They are more complicated than the digitization of ordinary industries. We need a conceptual consensus at a specialized and detailed level.



Annika Eberstein, Interim Secretary General of COCIR

- **Regulatory challenges for medical software and Artificial Intelligence in Healthcare:**

Qualification of smart hardware has attracted attention from regulators. Qualification as a medical device or an accessory for a medical device depends on (1) the smart hardware's intended purpose and (2) how it is placed on the market. A guidance document of the Medical Device Coordination Group is currently being considered. Medical software is defined as high risk AI system in the AI Act, more requirements and obligations are proposed for provider and user of medical software. The Medical Device Coordination Group should develop detailed guidance for AI-based medical devices to support these new requirements and address any last gaps.

Key messages —Standardization practices of consumer products in the healthcare area



Jiage Li, Deputy Director of National Institutes for Food and Drug

- **Research on Quality Evaluation of proactive Health Medical Products:**

It is necessary solve four main problems of Quality evaluation : lack of effective, scientific and **reliable evaluation methods** on **terminal products performance**; lack of **mature methods for safety evaluation** of mechanical energy and electromagnetic energy; **The privacy protection** is becoming much more important for regulatory; big data and artificial intelligence bring risks in terms of data quality, algorithm performance, and human-computer interaction.



David Mudd, Global Digital and Connected Product Certification Director of BSI

- **Consumer Tech and Digital Health: Unlocking the Potential:**

Digital health is a necessity with an ever expanding and aging population. However, without trust in the digital interactions between people, organisations and things, it will never be successful. Great to see we all agreed: industry consensus with flexibility, agility, **"think big, start small and act now"**.

Key messages —Advances in data sharing for consumer products



Giorgio Cangioli, Technical Lead of HL7 Europe

- **The role of HL7 FHIR in digital health ecosystems:**

HL7 FHIR can play a key role in the sharing of health data. **EU/China and global collaboration on adoption and development HL7 FHIR artefacts for consumer devices is hoped.** Quality labeling, beyond medical device regulations, is a mean to achieve trust. A multi-stakeholder discussion on **the hybrid usage of regulated and unregulated health and wellbeing devices** should be facilitated.



Christoph Thummler, Scientific director of 6GHI

- **From Performance Driven to Intent-Based Networking in Healthcare:**

5G healthcare networks have been successfully practiced, which has verified the advantages of 5G in patient location tracking, large bandwidth, low latency, high stability, and no evidence for interference with medical devices. However, 5G healthcare still **faces challenges such as lack of vertical industry standards and ecosystem.**

Key messages —Open Discussion



Shan Xu, Senior engineer of the E-Health Department of Cloud Computing & Big Data Research Institute, CAICT

- **Digital access** has become a new social determinant of health, with connections to data, cloud and machine intelligence, but always with the focus on humans. Having it people-oriented with standardized assessment for the evaluation is the key to success.



Jingli Li, Director of Institute for Medical Device Control of NIFDC

- It is hoped that through this workshop, the outputs will be implemented as soon as possible. It is recommended **to establish a standardized research group of home or digital health medical devices**. Based on the existing research foundation of various countries, accelerate the research on the definition of terms and classification of digital health products. Jointly establish **a health database**, and conduct evaluation research on **data security, data quality, and algorithm performance**. Establish and improve the whole life cycle standard system of such products, and develop new standards, new tools and new methods. Promote the construction of a new regulatory system to meet the new needs of human beings for health under the new situation.



Liuxin Wu, Zhongguancun Xinzhiyuan Health Management Institute

- The main challenges and countermeasures of digital health: Main challenges ("**five Nos**"): unified terms and connotations; unclear boundary between active health consumption and traditional medical services; insufficient product supply of public health consumption needs and different scenarios; ineffective scientific and authoritative digital medical health index system and product technical standard system and ecological; ineffective supervision and governance system. Main countermeasures ("**four accelerations**"): To speed up the improvement of the public's digital medical health literacy; speed up the construction of a digital health care terminology system and knowledge base; speed up the establishment of a product and service standard system that can meet the needs of ordinary people's active health consumption and practical application scenarios; speed up digital health care R&D investment and technological innovation.

Key messages —Open Discussion



Rahim Tafazolli , President of UK 6GIC

- In the last 20 years, the digital transformation of digital healthcare is very limited compared with other industries, in the academic perspective, we need to **change the teaching ways**, and change the popular perceptions of Digital Healthcare from the most basic level of knowledge. Cause **the of lack of regulatory standards at national or regional level**, lots of small or medium-sized companies face the problems when developing hardware or software products. There are problems with **interconnection of data and instruments themselves**, and it is in hope that these two can be interconnected and compatible.



Shang Wang, Member of the Innovation Service Professional Committee& Senior Expert of CAMDI

- Chairman Xi has made important instructions in journal *QiuShi* that, making China's digital economy bigger, stronger, better, and digital healthcare is a very important part of digital economy. We need **make digital economy stronger and bigger but not only bigger, and simply big but not strong, or simply much but not excellent is useless**. There are as few as a dozen or as many as dozens of industries making similar products now in the market. Although China is a populous nation, its **burden of cardiovascular and cerebrovascular diseases is extremely heavy**, and China cannot absorb so many products, there must be plenty of companies eliminated in red sea.



Luigi Licciardi, Chairman and President of 5GSA

- **Trust** is essential, no matter 4G, 5G or 6G, its safety and reliability are generating around trust. **Transparency** is also very important for the consumers to use the products of medical healthcare, so the government should guarantee the data is transparent. And **cooperation** is very important, the government, consumers and medical institutions should all participate in cooperation of the whole ecosystem. **Comprehensiveness, compatibility and interoperability** are very essential for standards, we must achieve a balance between time and quality.



Thank you