IMDRF /DITTA joint workshop on

Artificial Intelligence in Healthcare

Opportunities and Challenges

Monday 16 September 2019

Venue: Hyatt Regency, 8, Ulitsa Borisa Yel'tsina, St, Yekaterinburg

Artificial Intelligence (AI) in Healthcare is receiving more and more attention. For example, healthcare providers are embedding the technology into their workflows and the decision-making processes. AI is aimed at improving outcomes for patients and other healthcare stakeholders. Uncertainty about regulatory appreciation of AI in Healthcare is leading to a variety of national legislative initiatives, risking serious fragmentation and limitation of exploiting what AI has to offer. We will only get the full benefits of Artificial Intelligence in Healthcare if we appropriately identify and address the key regulatory challenges which will be discussed during the workshop.
This workshop provides a unique opportunity to gain a status overview of regulatory and standardization initiatives across the world and to openly discuss possibilities to converge on future regulatory obligations. Still AI is not something to automatically regulate, thus participants will discuss what is applicable, how to apply, or whether we need to adapt existing regulatory frameworks and IMDRF guidance documents. This event will also include a discussion on possibilities of global convergence in the IMDRF context.

Morning moderators: Vladimir Kutichev, Head of medical device software lab, Roszdravnadzor, Russia; Aysylu Valeeva, Deputy Head of Division of organization of state control and registration of medical devices, Roszdravnadzor, Russia
Afternoon moderator: Peter Linders, Philips

DRAFT AGENDA*

* The IMDRF Secretariat reserves the rights to make changes to the workshop program

No	Topic	Speaker	Scheduled Time
Welcome coffee and registration			8:30 – 9:00
Section 1: Opening Remarks			
1a	Welcome from IMDRF Chair	Elena Astapenko, Head of Division of organization of state control and registration of medical devices, Roszdravnadzor, Russia	9:00 – 9:10
1b	Welcome from DITTA	Nicole Denjoy, DITTA Chair	9:10 – 09:20
Section 2: AI in Healthcare and regulatory developments (industry and healthcare professionals view) • Introduction into AI; • Concrete examples by industry of AI software in different application areas; • What does AI bring to healthcare from a clinician's perspective; • Development of AI based software causes both new opportunities as well as new challenges			
2a	Introduction into AI and its unique characteristics	Robert Phillips, Siemens Healthineers	9:20 – 9:35

2b	What does AI bring to healthcare and AI examples including application in Oncology	Olga Bakhvalova, Philips, Russia	9:35 – 9:50
2c	Prospects for the use of artificial intelligence technologies in the Russian healthcare system	Alexander Gusev, Expert at K-MIS, Member of the Expert Council of the Ministry of Health of the Russian Federation on the use of information and communication technologies in the healthcare system	9:50 – 10:05
2d	Creating an Artificial Intelligence Market for Health service	Andrey Almazov, Member of the supervisory board of the association of developers and users of artificial intelligence in medicine "National Medical Knowledge Base", Russia	10:05 - 10:20
2e	The participation of the Skolkovo Foundation in the development of medical artificial intelligence in Russia. Features of the launch of a Russia-based startup on the global market	Vladimir Egorov, Skolkovo Foundation, Senior Project Manager, Biological and medical technology cluster, Russia	10:20 – 10:35
2f	Panel discussion	Panelists	10:35 - 10:55
Coffee / tee break			10:55 - 11:15
Section 3: AI in Healthcare and regulatory developments: possibility and challenges (regulatory view) • Current regulatory practice and Overview of regulatory developments on AI			
3a	Perspectives and Regulatory Considerations for AI and Big Data in Medical Devices	Seungho Son, Ministry of food and drug safety (MFDS), South Korea	11:15 - 11:30
3b	WHO view for AI	Adriana Velasquez, Senior Advisor of medical devices, World Health Organisation	11:30 – 11:45
3c	Regulatory framework on medical devices using AI technology in Russia	Vladimir Kutichev, Head of medical device software lab, Roszdravnadzor, Russia	12:00 – 12:15
3d	The development of policy measures on medical devices using AI technology in Japan	Fumihito Takanashi, Deputy Director Medical Device Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare (MHLW), Japan	12:15 – 12:30
3e	Panel discussion	Panelists	12:30 - 13:00
Lunch break			13:00 – 14:00

Section 4: Overview of AI standardization activities • State-of-play of existing initiatives			
4	Overview of AI standardization activities. *Multiple international standard initiatives regarding AI in healthcare incl. at ISO, IEC and WHO levels.*	Pat Baird, Philips *via Webex	14:00 – 14:30
Section 5: Challenges for Healthcare Professionals and patients • Questions of clinical evaluation/evidence/investigation of AI based software • Data quality and availability, protection, interoperability, cybersecurity • Liability • The problem of responsible party determination in the sphere of AI application. Concerns of healthcare professionals as well as software manufacturers			
5a	Experience of introducing products based on artificial intelligence in the health care of Yamal	Olga Belorus, Director of Medical Information and Analytical Center, YNAO, Salekhard, Russia	14:30 – 14:45
5b	Experience in testing and comparing different solutions based on artificial intelligence for the Moscow health service	Sergey Morozov, Chief Freelance Specialist in Radiation and Instrumental Diagnostics, Director of the Scientific-Practical Clinical Center for Diagnostics and Telemedicine Technologies of the Moscow Health Department, Russia	14:45 – 15:00
5c	Preparation and conduct of clinical trials of the support system for making medical decisions based on artificial intelligence.	Denis Gavrilov, Chairman of the Karelian Republican Branch of the Russian Society of Cardiology, Russia	15:00 – 15:15
5d	How industry can cope with challenges?	Philippe Lartigue, GE Healthcare	15:15 - 15:30
5e	Industry responsibility and liability	Pat Baird, Philips *via Webex	15:30 – 15:45
5f	Panel discussion	Panelists	15:45 – 16:05
Coffee / tea break			16:05 – 16:35
Section 6: Regulatory challenges - what applies to AI? • Conformity assessment • Change control • Feasibility of creating AI adaptation rules and algorithm change protocol (ACP) • Cybersecurity			
6a	Introduction to review points for decision-making medical device software using deep learning technology	Peng Liang, Deputy director of division I of Center for Medical Device Evaluation (CMDE), National	16:35 – 16:50

		Medical Products Administration (NMPA), China* **via Webex*	
6b	Regulatory challenges for AI – a European RA perspective	Matthias Neumann, Federal Ministry of Health Germany, EU	16:50 – 17:05
6c	Industry overview on regulatory challenges	Naoki Morooka, Shimadzu	17:05 – 17:20
6d	Applying Advanced Technology in Clinical Practice: Regulatory Approval Cases of AI Software	Jungin Lee, Lunit	17:20 – 17:35
6e	Panel discussion	Panelists	17:35 – 17:50
Section 7: Concluding Remarks & Next Steps			
7	Conclusions	Moderators	17:50 – 18:00