



Day 2: IMDRF Stakeholder Forum
Wednesday 21 March 2018 – 9:00am to 17:35pm
Venue: Grand Ballroom, Shanghai Hyatt on the Bund
No. 199 Huangpu Road

(500 meters walking distance from the MC meeting venue- Broadway Mansions Hotel)

AM Session 9:00am – 12:35pm

	TIME	ITEM	Material
1	9:00 – 9:15	Welcome speeches by Madam JIAO Hong, CFDA Vice Minister, and Mr. XU Kunlin, Deputy Mayor of Shanghai	
2	9:15– 10:55	Management Committee Member Regulatory Updates (10 min each)	
	9:15 – 9:25	a. Australia (Adriana Platona)	
	9:25 – 9:35	b. Brazil	
	9:35 – 9:45	c. Canada (David Boudreau)	
	9:45 – 9:55	d. China (WANG Zhexiong)	
	9:55 – 10:05	e. European Union	
	10:05 – 10:15	f. Japan	
	10:15 – 10:25	g. Russia	
	10:25 – 10:35	h. Singapore (Wong Woei Jjuang)	
	10:35 – 10:45	i. South Korea (Chun-su Shin)	
	10:45 – 10:55	j. United States (Jeff Shuren)	
3	10:55–11:05	Questions and Answers	
	11:05 – 11:15	Coffee/tea break	
4	11:15 – 12:25	Overview of progress to date on work items (10 min each)	
	11:15 – 11:25	a. Regulated Product Submission (RPS) (Canada, Nancy Shadeed)	
	11:25 – 11:35	b. Patient Registry (USA)	
	11:35 – 11:45	c. Medical Device Adverse Event Terminology (Japan, H. Ishikawa)	
	11:45 – 11:55	d. Good Regulatory Review Practices (USA, Melissa Torres)	
	11:55– 12:05	e. Standards (USA)	
	12:05 – 12:15	f. Personalized Medical Devices(Australia, Elizabeth McGrath)	
	12:15 – 12:25	g. Unique Device Identification (EU)	
5	12:25– 12:35	Questions and Answers	

12:35 – 13:30 Lunch break

PM Session 13:30 – 17:35

	TIME	ITEM	Material
6	13:30 – 15:00	Forum Session: Artificial Intelligence Medical Device Moderator: Director YUAN Peng, CFDA Panellists: Dr. PENG Liang, CFDA’s Centre for Medical Device Evaluation; Dr. ZHANG Xin, Chinese Academy of Sciences; Dr. HE Xiaoxu, Tencent Internet; Prof. YU Weihong, Peking Union Medical College Hospital; Director REN Haiping, National Institute for Food and Drug Control	
	13:30-13:45	PENG Liang, Considerations on the premarket review of AI medical devices	
	13:45-14:00	ZHANG Xin, Key points of artificial intelligence applications to brain diseases	
	14:00-14:15	HE Xiaoxu, Introduction of Tencent AIMIS and Advice on the quality supervision of AI-aided Medical Product	
	14:15-14:30	YU Weihong, AI: from concept to clinical-challenges and Opportunities	
	14:30 – 14:45	REN Haiping, Testing of Medical AI: efforts and challenges in China	
	14:45-15:00	Discussion	
	15:00 – 15:15	<i>Coffee/tea break</i>	
7	15:15 – 17:15	Stakeholder Sessions	
	15:15 – 15:30	a. China Association for Medical Devices Industry(CAMDI, XU Shan)	
	15:30 – 15:45	b. DITTA (Patrick Hope)	
	15:45 – 16:00	c. GMTA(Zach Rothstein)	
	16:00 – 16:15	d. WHO (Irena Prat)	
	16:15 – 16:30	e. APEC	
	16:30 – 16:45	f. AHWP(Ali Aldalaan)	
	16:45 – 17:00	g. PAHO	
	17:00 – 17:15	h. Saudi Arabia (Ali Aldalaan)	
8	17:15 – 17:30	Questions and Answers	
9	17:30 – 17:35	Concluding remarks by IMDRF Chair	