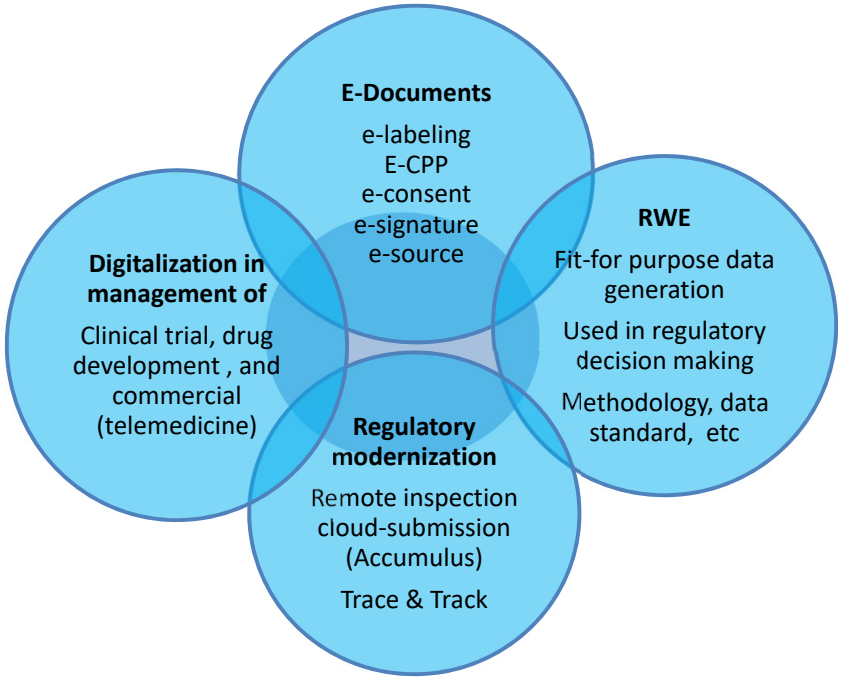
ENHANCEMENT OF DIGITALIZATION & REAL-WORLD EVIDENCE IN THE PHARMACEUTICAL AREA

Vicky Han
Senior Director
Head of Regulatory Policy & Intelligence for Asia Pacific
Global Regulatory Affairs
Janssen Pharmaceuticals, a division of Johnson & Johnson Pte. Ltd

APAC
Asia Partnership Conference of Pharmaceutical Associations

Enhancement of Digitalization & Real-World Evidence in the Pharmaceutical Area



Require clear regulation and guideline

Cross industry & region cooperation

Personal information protection, and cybersecurity

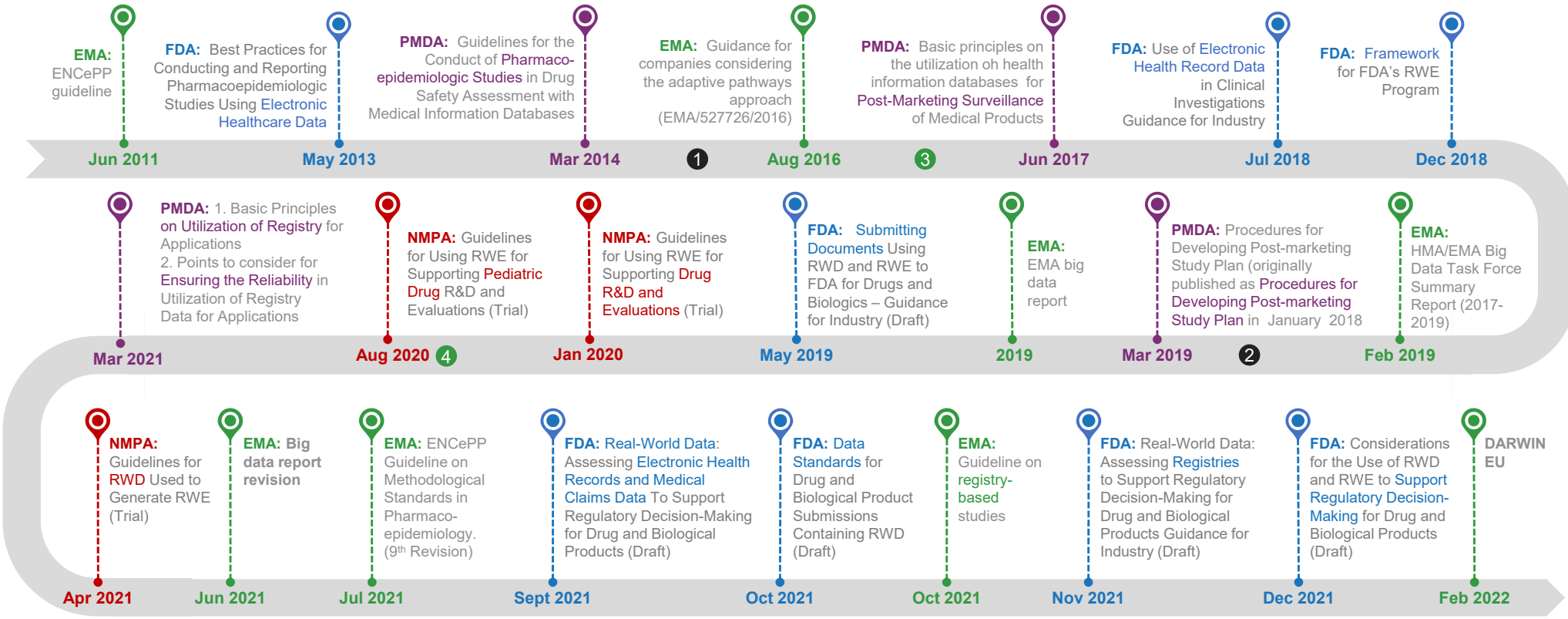
APAC
Asia Partnership Conference of Pharmaceutical Associations

RWD/RWE Supports Drug Development & Healthcare Decision

Support Product Label Change New indication New population	Extrapolation of the indication to pediatric from adult	Identify population & patient standard care for clinical trial	single arm study by using historical real world data
Supports authorising and monitoring medicines	Post marketing long term safety and effectiveness study	Patient access to new medicine via supporting reimbursement decisions	Support reducing the costs of healthcare systems

APAC
Asia Partnership Conference of Pharmaceutical Associations

Key RWD/RWE Guidelines Published by FDA, NMPA, EMA & PMDA



1. 21st Century Cures Act signed into law in Dec 2016
2. 'Rare Diseases: Natural History Studies for Drug Development' published in Mar 2019
3. Guidance on PAES by Oct 2016, https://www.ema.europa.eu/en/documents/scientific-guideline/scientific-guidance-post-authorisation-efficacy-studies-first-version_en.pdf
4. Big data report work plan published in Sep 2020

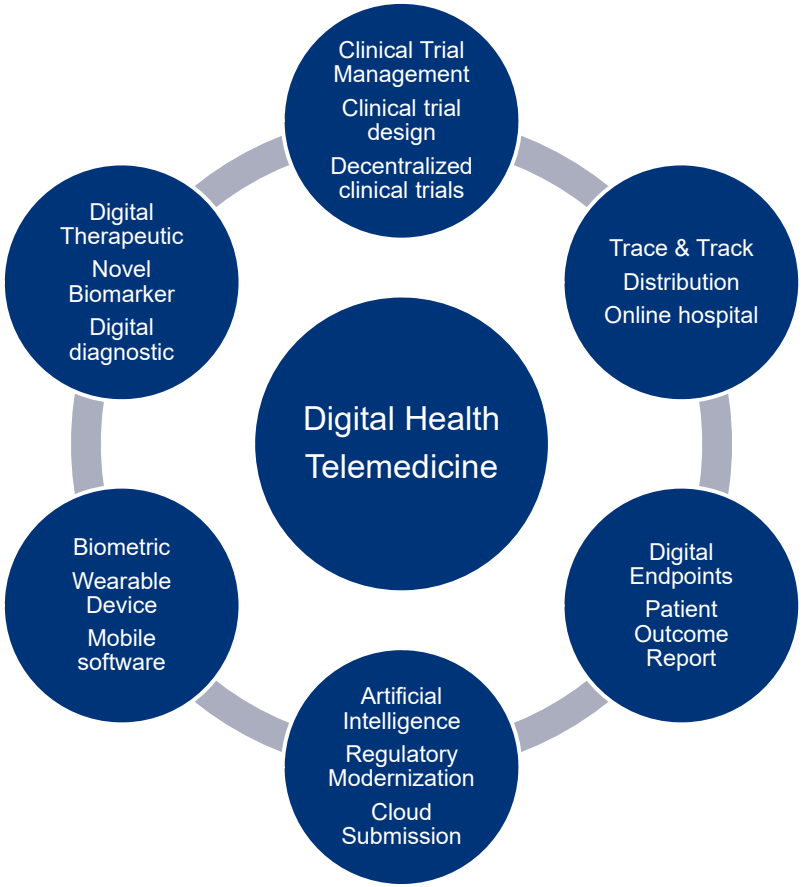
APAC
Asia Partnership Conference of Pharmaceutical Associations

Key Digital Health Guidelines

Published by FDA, EMA

APAC
Asia Partnership Conference of Pharmaceutical Associations

Digital Technology Supports Drug R&D & Telemedicine



Challenges Of Clinical Trials

Mismatched sites	Site failures	Startup delays	Slow enrollment	Poor patient retention
Unhappy Site	Unclean data	Protocol deviations	Preventable audit findings	Lack of reporting & transparency

- Actual enrollment timelines typically double planned study duration
- 18% of sites fail to enroll a patient
- Nearly 50% of Principal Investigators are 'one and done'
- 44% of sites find slow payments to be 'very' or 'extremely' burdensome
- 15% of audit findings are related to consent
- 3 of the top 5 factors in delayed recruitment are due to site startup

- Decentralized Clinical trial (DCT) is a potential solution for removing those CT challenges
- Significant developing during Covid-19 pandemic
- Gained best practices of carrying out DCT
- China CDE actively called DCT workshop
- There will be big strides in next 10 years

Data science and digitalization is rapidly changing the world

APAC
Asia Partnership Conference of Pharmaceutical Associations

Data Privacy Global Regulations to Secure digitalization

- Over 22 GDPR-like laws around the world have surfaced since GDPR
- EU: General Data protection Regulation, May 2018.
- More than eleven states in the US are creating legislation like California and/or GDPR

- In AP: majority markets have promulgated various personal data privacy regulations in the past a few years. Such as:
- China, Hongkong, Taiwan, Japan, India, Korea, Australia, New Zealand, Singapore, Malaysia, Thailand etc

APAC
Asia Partnership Conference of Pharmaceutical Associations

Thank you!

APAC
Asia Partnership Conference
of Pharmaceutical Associations