

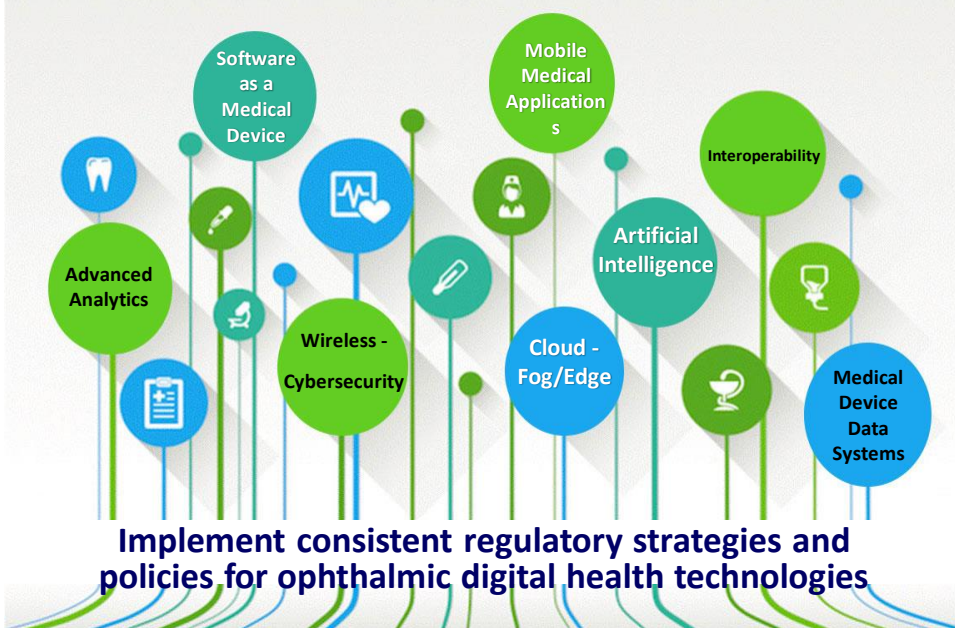


FDA Perspectives on Ophthalmic Mobile Medical Applications and Telemedicine

Ronald Schuchard
Center for Devices and Radiological Health
Office of Device Evaluation



Ophthalmic Digital Health Areas

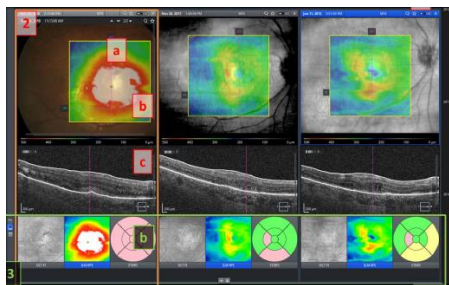


Implement consistent regulatory strategies and policies for ophthalmic digital health technologies

Digital Health

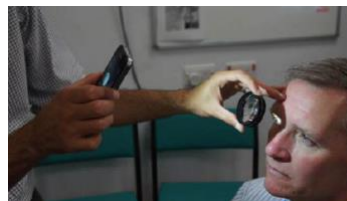
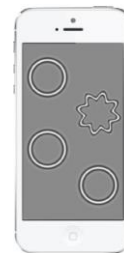
Types of Digital Health Devices

in



Software in a Medical device

as



Software as a Medical device
"SaMD"

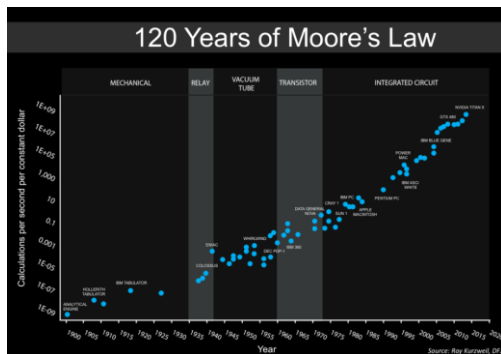


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Digital Health

Rapidly Evolving Landscape

- Many ophthalmic devices rely heavily on digital technology
- Software diagnostics (CADx) and advanced analytics (CADE) are rapidly emerging
- Greater connectivity (interoperability) of devices has lead to new/greater risks
- Software development practices are evolving rapidly
- Changes to digital technology are more frequent (including after market clearance/approval)





Telemedicine in Ophthalmic Health Care

- Telemedicine (e.g., teleophthalmology) systems
 - Telemedicine health care is part of the practice of medicine and not regulated by FDA
 - Telemedicine is likely to have Medical Device Data Systems (MDDS) functionality which transfers, stores, or displays medical device data without controlling or altering the functions or parameters of a medical device

21st Century Cures has removed the MDDS functionality from the definition of a medical device (Section 3060)



Telemedicine in Ophthalmic Digital Health

- Telemedicine systems (continued)
 - Devices used in Telemedicine are regulated by FDA (some of them are Digital Health Devices)
 - Ophthalmic Cameras
 - At Home Vision Testers (e.g., Visual Acuity & Amsler Grid)
 - Telemedicine and Digital Health Devices can be Class I or Class II 510(k) exempt devices
 - Perimeters with databases
 - Group 1 Light Source Ophthalmic Cameras vrs Group 2 Light Source Ophthalmic Cameras





FDASIA Categories of Health IT

Administrative Functionality*	Health Management Functionality*	Medical Device Functionality*
<ul style="list-style-type: none"> • Admissions; • Billing and claims processing; • Practice and inventory management; • Scheduling; • General purpose communications; • Analysis of historical claims data; • Determination of health benefit eligibility; • Reporting communicable diseases; • Reporting on quality. 	<ul style="list-style-type: none"> • Health information management; • Data capture and encounter documentation; • Electronic access to clinical results; • Most clinical decision support; • Medication management; • Electronic communication (e.g. provider-patient, provider-provider, etc.); • Provider order entry; • Knowledge management; • Patient ID and matching. 	<ul style="list-style-type: none"> • Computer aided detection software; • Remote display or notification of real-time alarms from bedside monitors; • Refractive Surgery treatment planning software; • High IOP detection.
No Additional Regulatory Oversight	Primary Focus of Proposed Health IT Framework	Primarily FDA Oversight



* Examples provided are not intended to be an exhaustive list of functionalities.



FDASIA Health IT Clinical Decision Support

Tools intended to enhance, inform, and influence health care decisions.

<p>Health Management Functionality¹</p> <ul style="list-style-type: none"> • Clinician order sets • Clinician health records access • Drug dosing calculations; • Drug formulary guidelines; • Reminders for preventative care; • Access to treatment guidelines; • Calculation of prediction rules. 	<p>Medical Device Functionality²</p> <ul style="list-style-type: none"> • Computer aided detection (CADe) • Computer aided diagnostic (CADx) • Refraction treatment planning • Robotic surgical planning and control • Electrophysiology analytical software.
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¹ If a product with health management functionality meets the statutory definition of a medical device, FDA does not intend to focus its oversight on it.

² CDS that have medical device functionality and present higher risks warrant FDA's continued focus and oversight.





FDA Perspective of Review Challenges

- Lack of experience for established device information that should be provided in applications
 - No clear/complete description of technology or device
 - Unclear indications for use / intended use
 - Eye care clinical environment
 - Non-eye care clinical environment
 - Non-clinical environment (e.g., at home or school)
- Lack of a clearly appropriate predicate
- Risk Analysis is inadequate given risk of device use
 - No or limited information provided for the software function relative to the risk of the device use



Focusing on Higher Risk Functionality



Lower Risk Functionality

May not always enforce regulatory requirements

Lower risks are not likely to exceed the limits of exemption (§886.9)



Higher Risk Functionality

Intend to assure patient safety while encouraging advances in innovative technology and product life-cycle

- De Novo
- 510(k)
- PMA





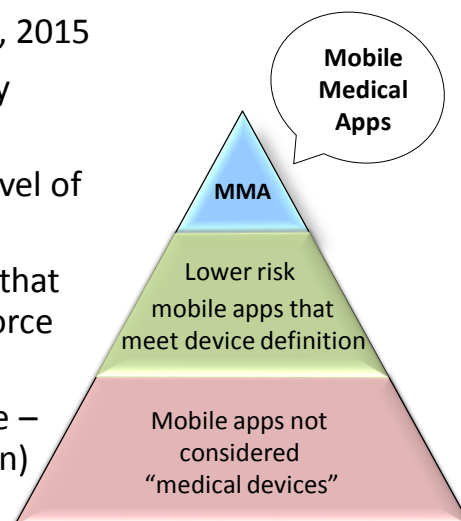
Risk Assessment is key

- **Premarket Assessments:**
 - What are the key functions of the device?
 - What are the aspects of the device that are vulnerable?
 - How are the key functions impacted by a vulnerability?
 - What protections are in place?
- **Methods of Mitigating Risks:**
 - Safeguards built into the software / hardware
 - Methods to limit the intended users
 - Labelling provided for patient use
 - Training modules and tutorials



Medical Mobile Apps (MMA)

- Final Guidance issued Feb 9, 2015
- Focuses only on traditionally regulated functionality
- Provides users with same level of assurance of patient safety
- Identifies mobile app types that FDA does not intend to enforce requirements
- Clarifies what is not a device – (Outside of FDA's Jurisdiction)



Digital Health

MMA & SaMD (Software as a Medical Device)

- Diagnostic MMAs
 - D-EYE (886.1120 / PJZ – Registered)
 - Paxos Scope (886.1120 / PJZ)
 - R&D in Tablet Video Field Assessment
 - R&D in CADx for Diabetic Retinopathy
- Therapy MMAs
 - R&D for Dichoptic Treatment of Amblyopia; Red/Green Glasses or Virtual Reality Glasses with Mobile Display
 - R&D for wayfinding and object detection/localization as assistive technology devices for visually impaired



Digital Health

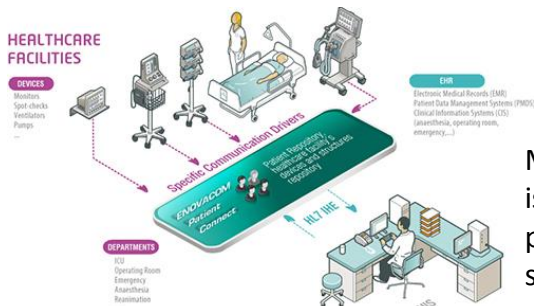
MMA & SaMD

- Disease Progression – Aids in Diagnosis/Therapy
 - MyVisionTrack (K143211) – 886.1330 Amsler Grid / HOQ
 - Saccadometer Plus (K152890) – 886.1510 Eye Movement Monitor / HLL
 - EYE-SYNC (K152915) – 882.1460 Nystagmograph / GWN
- Ophthalmic Image Management Systems - 892.2050 Picture Archiving and Communications System (PACS) / NFJ
 - Retina Workplace (K170638)
 - Huvitz Imaging System (K161829)
 - Optos Advance Software (K162039)
 - Synergy ODM (K151952)
 - IRIS Intelligent Retinal Imaging Systems (K141922)



Digital Health

Interoperability



Medical Device Interoperability is the ability of two or more products, technologies or systems to safely and effectively exchange and use information that has been exchanged

FY 2015 FDA Draft Guidance “Design Considerations and Premarket Submission Recommendations for Interoperable Medical Devices

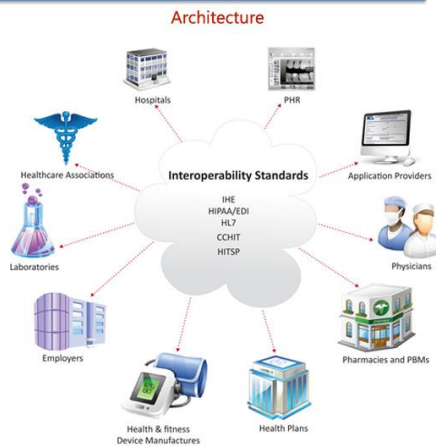
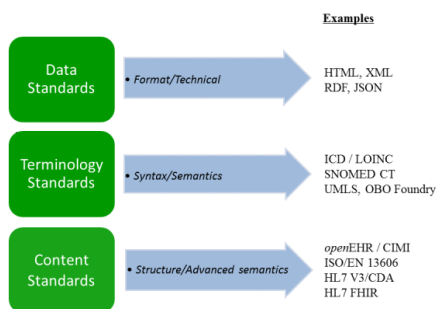


Digital Health

Interoperability Standards

August 2013 – FDA Recognized 14 standards for interoperability

- Nomenclature
- Medical device communications
- System / Software lifecycle process



Can be used for different levels of interoperability





Conclusions

- Ophthalmic Digital Health will lead to many new innovative devices that will provide diagnostic and therapeutic health care
- We hope today's workshop will foster Ophthalmic Digital Health innovation
- Right Cure for the Right Patient at the Right Time
- Thank you for your participation