

**Mechanisms to Decrease Total Time to Decision: Denise Hampton, Ph.D.**

Premarket Notification (510(k)):

<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm2005718.htm>

MDUFA Performance Goals and Procedures, Fiscal Years 2018 Through 2022:

<https://www.fda.gov/downloads/ForIndustry/UserFees/MedicalDeviceUserFee/UCM535548.pdf>

Guidance Documents:

Slit Lamps:

<https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080176.pdf>

Daily Wear Contact Lenses:

<https://www.fda.gov/RegulatoryInformation/Guidances/ucm080928.htm>

Contact Lens Care Products:

<https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM080218.pdf>

510(k) Database:

<https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510kClearances/ucm089319.htm>

Guidance Document Database:

<https://www.fda.gov/RegulatoryInformation/Guidances/>

Recognized Consensus Standards Database:

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

**Digital Health Functionality Initiatives to Foster Innovation in Ophthalmic Devices:  
Ron Schuchard, Ph.D.**

Software as a Medical Device (SAMd) Guidance Document:

<https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM524904.pdf>

**Science of Patient Input: Patient Reported Outcomes and Patient Preference Information:  
Michelle Tarver, M.D., Ph.D.**

21 CFR 860.7: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?FR=860.7>

Patient Preference Information Guidance Document:

<http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm446680.pdf>

MDUFA IV 2017 information:

<https://www.fda.gov/ForIndustry/UserFees/MedicalDeviceUserFee/ucm454039.htm>

Guidance on Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM193282.pdf>

Clinical Outcome Assessment (COA): Recommended Publications

<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugDevelopmentToolsQualificationProgram/ucm370220.htm>

Clinical Outcome Assessment Glossary of Terms

<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugDevelopmentToolsQualificationProgram/ucm370262.htm>

Social Research Methods

<https://www.socialresearchmethods.net/kb/measval.php>

Guidance for Industry and Food and Drug Administration Staff : Factors to Consider for Benefit Risk Determinations in Medical Device Premarket Approval and De Novo Classifications

OIS Master Class Reference List

<https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm517504.pdf>

Guidance on Patient Preference Information in Premarket Approval Applications, Humanitarian Device Exemption Applications, and De Novo Requests

(<http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm446680.pdf>)

MDIC Patient-Centered Benefit Risk Project: A Framework for Incorporating Information on Patient Preferences Regarding Benefit and Risk into Regulatory Assessments of New Medical Technology

<http://mdic.org/pcbr>

### **FDA's Early Feasibility Program: Dr. J. Angelo Green, DABT**

Early Feasibility Study Guidance

<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM279103.pdf2>

CDRH Learn Modules

<https://www.fda.gov/Training/CDRHLearn/default.htm>

Pre-Submission Guidance

<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM311176.pdf>

IDE Submission Information

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm046706.htm#regele>

E-Copy Submission Guidance

<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf>