ÖNEMLİ MEVZUAT VE KILAVUZLAR

- **Tıbbi Ürünlere Yönelik Mevzuat**
  https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-1_en

- **Tıbbı Cihazlara Yönelik Düzenlemeler (Medical Devices - Topics of Interest (europa.eu))**
  - Harmonised standards
  - Combined studies
  - Guidance documents endorsed by the Medical Device Coordination Group (MDCG)

- **Avrupa İlaç Ajansı (EMA) Önemli Kılavuzlar**
  - Qualification of novel methodology for drug development: guidance to applicants
  - Essential considerations for successful qualification of novel methodologies.
  - Questions and answers: Qualification of digital technology-based methodologies to supportapproval of medicinal products.

- **Amerika Birleşik Devletleri Gıda Ve İlaç Dairesi (FDA) Önemli Kılavuzlar**
  - Biomarker Qualification: Evidentiary Framework
  - BEST (Biomarkers, EndpointS, and other Tools) Resource
  - Qualification Process for Drug Development Tools – Guidance for Industry and FDA Staff
  - Drug Development Tool (DDT) Qualification Programs
  - Innovative Science and Technology Approaches for New Drugs (ISTAND) Pilot Program
  - Medical Device Development Tools (MDDT) Qualification webpage

- **Desteklenen Projelerin Çıktısı Olarak Önemli Kılavuzlar**
  - **BEAT-DKD**: Biomarker qualification at the European Medicines Agency: A review of Biomarker Qualification Procedures from 2008 to 2020 https://doi.org/10.1002/cpt.2554
  - **IDEA-FAST**: Regulatory Qualification of a Cross-Disease Digital Measure: Benefits and Challenges from the Perspective of IMI Consortium IDEA-FAST https://doi.org/10.1159/000533189
  - **LITMUS:** NAFLD and NASH biomarker qualification in the LITMUS consortium-Lessons learned https://doi.org/10.1016/j.jhep.2022.11.028
  - **MOBILISE-D**: Toward a Regulatory Qualification of Real-World Mobility Performance Biomarkers in Parkinson's Patients Using Digital Mobility Outcomes https://doi.org/10.3390/s20205920
  - **RADAR-AD**: The Use of Remote Monitoring Technologies: A Review of Recent Regulatory_Scientific Advices, Qualification Opinions, and Qualification Advices Issued by the EuropeanMedicines Agency https://doi.org/10.3389/fmed.2021.619513
  - **HARMONY** deliverable "Qualification for novel methodologies' stakeholders guide"https://cordis.europa.eu/project/id/116026/results
  - **NEURONET**: regulatory and HTA decision tool that outlines key processes and procedures forengaging with regulatory, HTA bodies, and payers, and may help IMI/IHI projects identify relevant procedures, based on the project's stage of research and asset developed

- **Veri Yönetimine İlişkin Standartlar:**
  - CDISC standards in the clinical research process
  - HL7® FHIR® standard that allows the sharing and reuse of scientific data
  - The International Council for Harmonisation of Technical Requirements guidelines - for instance multidisciplinary guidelines M11 (Clinical electronic Structures Harmonised Protocol - ceSHarP) and M14 (Guideline on General Principles on Plan, Design, and Analysis of Pharmacoepidemiological Studies that Utilize Real-World Data for Safety Assessment of Medicines).
  - HMA-EMA Catalogues of real-world data sources and studies
  - List of metadata for the HMA-EMA Catalogues of real-world data sources and studies
  - EMA Good Practice Guide for the use of the Metadata Catalogue of Real-World Data Sources
  - EMA Data quality framework for EU medicines regulation
  - EMA Reflection paper on the use of artificial intelligence in the lifecycle of medicines

- FDA Using Artificial Intelligence and Machine Learning in the Development of Drug and Biological Products
- International Medical Devices Regulators Forum: Machine Learning-enabled Medical Devices: Key Terms and Definitions (IMDRF/AIMD WG/N67)