Data Disclosure

Regulatory Requirements & Asphalion's experience

ASPHALION
Knowledge from experience

REGULATORY REQUIREMENTS

2007
- Enactment of FDAAA 801

2010
- Introduction of EMA policy 0043 on access to documents

2014
- EU CTR entry into force

2015
- EMA Policy 0070 becomes effective for any new centralised MAA
- EMA Policy 0070 becomes effective for extension of indication and line-extension applications

2016

2017
- FDAAA 801 and Final Rule (42 CFR Part 11) for the registration of applicable clinical trials on ClinicalTrials.gov and the submission of results, including Study Protocols and SAP

2018
- Revision of EMA policy 0043 on access to documents
- EMA Policy 0070 total suspension

2018-2020
- Health Canada's PRCI comes into force. Applicable to all New Drugs Submissions (NDS), Supplemental NDS (SNDS), Abbreviated NDS (ANDS), Supplemental Abbreviated NDS (SANDS), and Class III and IV devices

2019

2020
- EMA Policy 0070 Reactivation for COVID-19 treatments and vaccines

2021

2022
- EU CTR implementation
- CTIS Launch

2023
- Reactivation of EMA Policy 0070

  Step 1: CAPs of initial MAA for new active substances
  - Initial MAA for new active substances that receive a CHMP opinion. Includes negative and withdrawn products from September 2023 onwards.
  - Covid-19 and other public health emergency clinical data publication
- EMA Policy 0070
  Step 2: Pending.
  Clinical data submitted in any other applications apart from new actives substances and COVID-19 treatments.

ASPHALION

- Asphalion's 1st project for clinical data publication EMA Policy 0070
- Asphalion's 1st project for Access to documents – EMA Policy 0043
- Asphalion's 1st project for Clinical Trials Gov. management
- CTIS Master Trainer accreditation
- EMA Policy 0070 support for a COVID-19 vaccine
- Asphalion´s 1st project for Health Canada PRCI
- CTIS Services
- EMA Policy 0070 Support for CAPs in scope of re-launch Step 1
- CTIS Subject Matter Expert
- 2018-2024 Asphalion participation in CTIS Stakeholders meetings
- 2016-2024 Continuous support for clinical data publication projects and specialised consultancy

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