0070 Transparency Policy

EMA Milestones & Asphalion's experience

ASPHALION
Knowledge from experience

EMA

1 January: Policy 0070 effective date for any new MAAs.

1 July: Policy 0070 effective date for extension of indication applications for centrally authorized medicinal products.

2018-2020 Policy 0070 total suspension

Policy Reactivation for COVID 19 treatments and vaccines.

Reactivation of Policy 0070

Step 1: CAPs of initial MAA for new active substances

- Initial MAA for new active substances that receive a CHMP opinion in September 2023 and onwards. Includes negative and withdrawn products.
- Covid-19 and other public health emergency clinical data publication continues.

Ongoing

Step 2: Clinical data submitted in any other applications apart from new actives substances and Covid-19 treatments.

2015 | 2016 | 2018 | 2020 | 2022 | 2023 | 2024 | 2025

ASPHALION

Asphalion's 1st project for clinical data publication Policy 0070

2018-2020 Policy stand-by period

Policy 0070 support for a COVID-19 vaccine

Support for policy 0070 relaunch

2016-2024 **Continuous support for clinical data publication projects and specialised consultancy**