

BMSD seeking EMA Qualification Opinion

BIG

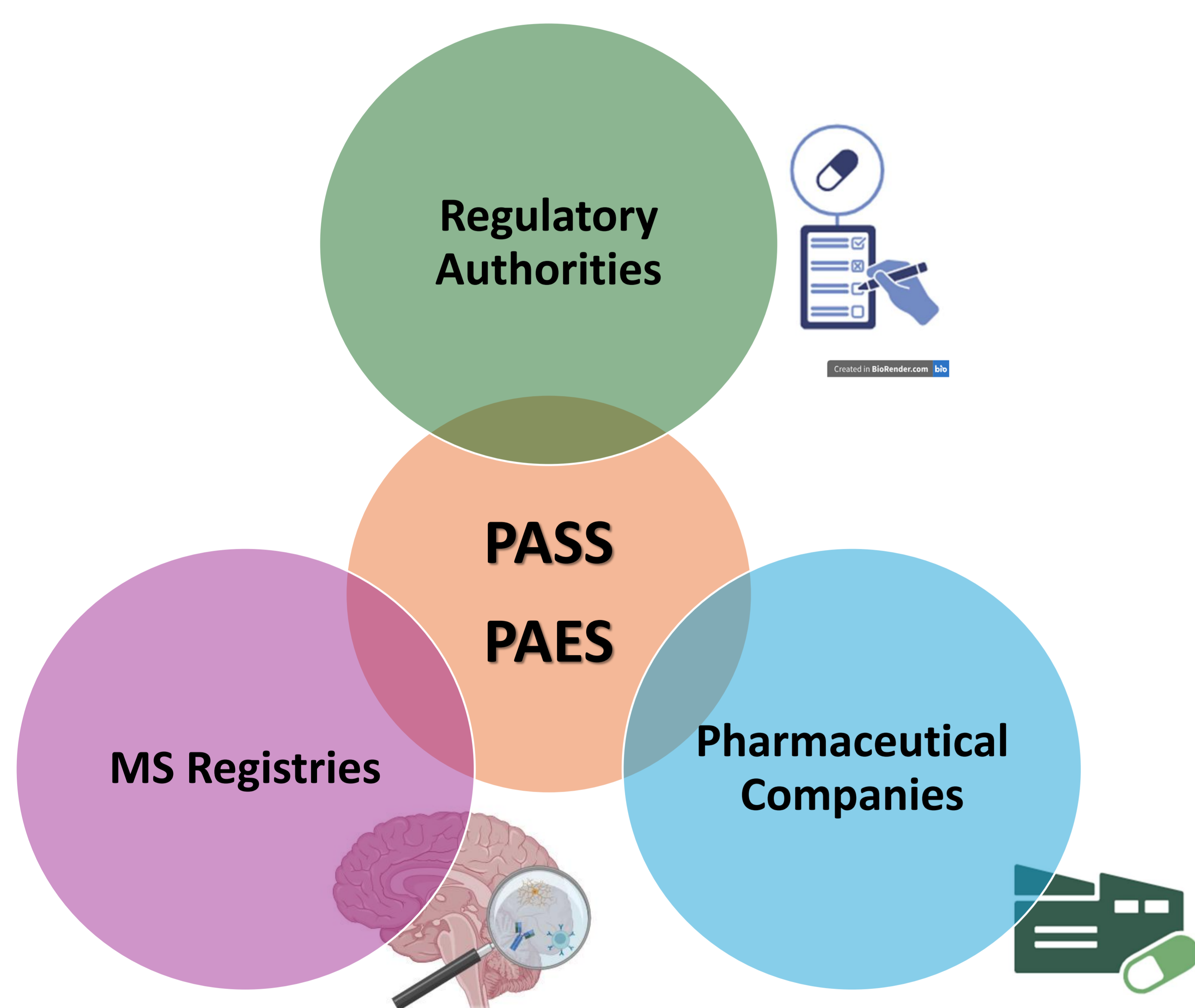


The big Multiple Sclerosis data network

Introduction

The Big MS Data (BMSD) network was initiated in 2014 and currently includes five national registries from the Czech Republic, Denmark, France, Italy and Sweden as well as the international MSBase. Together this network provides a large source of data on MS patients. With the improvement of MS treatment options, BMSD aspires to influence both post-authorisation safety studies (PASS) and efficacy studies (PAES) through participation with registry data and analytical expertise, as well as coordination.

BMSD aims to obtain an EMA Qualification Opinion (QO), primarily for PASS. Following the receipt of an EMA Letter of Support, BMSD submitted a renewed application in the summer of 2025. This EMA QO application is focused on presenting the registries and their data as well as demonstrating data quality and the ability of the registries to collect serious adverse events (SAEs) in a reliable manner as well as the registries' ability to perform PASS. The EMA QO application includes a briefing document outlining the rationale for the application, along with four additional documents that further illustrate the BMSD network, the available data, and provide additional evidence of the registries' ability to conduct PASS.



Documents of the EMA QO application

Briefing book

REQuEST tool

Core Safety Protocol

Common Data Model

Feasibility Study

Documents of the EMA QO application

Briefing book

The book outlines the BMSD registries and the reasons for applying for EMA QO.

REQuEST tool

The document details the data content and characteristics of the variables collected by the respective registries.

Core Safety Protocol (CSP)

A CSP has been jointly agreed between BMSD and Marketing authorisation holders (MAHs) and serves as a basis to provide common data requirements for PASS. MAHs will be encouraged to use the BMSD protocol for PASS, although the final decision remains with the MAH and EMA.

Common Data Model (CDM)

BMSD has been developing a general CDM to set standards for real world evidence in MS.

Feasibility Study

The study describes how SAEs are collected by the respective registries and how the rates of reported SAEs compare between the BMSD registries.

