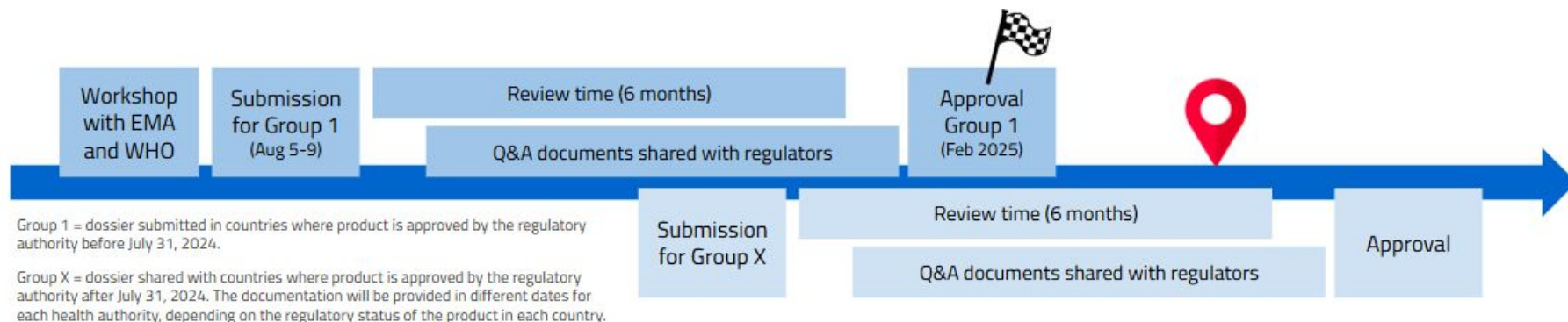


# Accelerating Global Approvals

Roche

Roche's second\* EMA WHO PAC Reliance Project

Extend the benefits of the [results of the ICMRA PQKMS PACMP collaborative assessment between FDA and EMA](#) to international markets, with the use of reliance on EMA's assessment/approval of a major PAC for a mAb



## Project characteristics



One Standard Dossier



Follow EMA submission standard



Q&A's Transparency



No Local Testing



EU Assessment Report



Maximum 6 months approval timeline

## Current status

12 approvals

5 under evaluation



\*[LINK to publication on first pilot](#)