

NDA Review Process

Application submitted to TFDA

Documentation Evaluation

Center for Drug Evaluation (CDE)



Project
Manager

Review Team

CMC

Pharm/Tox

PK/PD

Clinical

Statistics

Assessment Report

Advisory
Committee

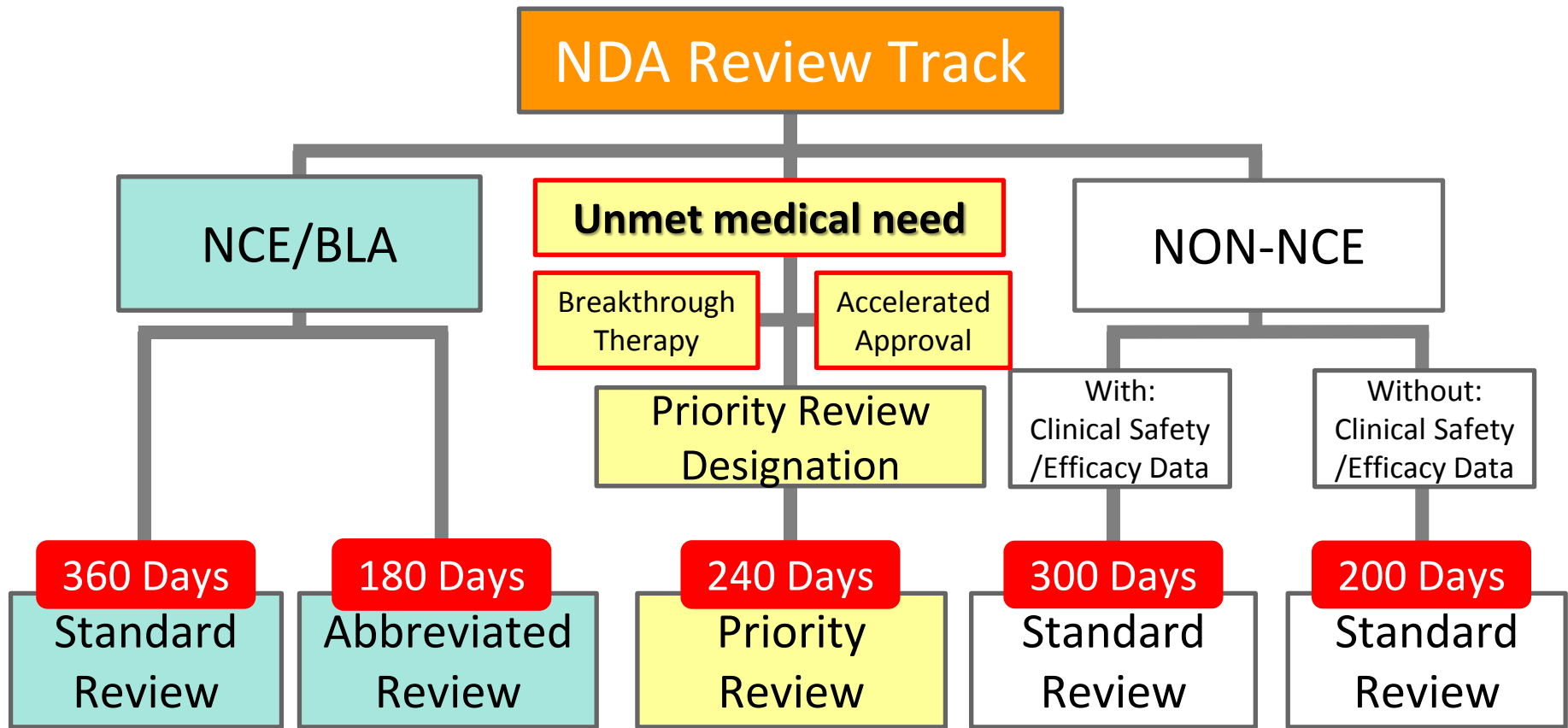
Asking for suggestion

When necessary

Providing opinion

Final Decision made by TFDA

NDA Review Pathway



***Priority Review (meet 2 of the following criteria):**

- new drug
- serious disease + unmet medical needs
- priority counseling + R&D grants + unmet medical need

***Abbreviated Review: NCE + US FDA, EMA, MHLW approved (2 out of 3)**