Comparison of EU and USA licensing flexibilities

EMA	FDA
Conditional approval Allows approval of a drug for serious or life threatening conditions based on less complete data than is normally required, subject to certain specific obligations to be reviewed annually	**Accelerated approval** Allows approval of a drug for serious or life threatening conditions based on an effect observed on a surrogate endpoint that is reasonably likely to predict clinical benefit
Approval under exceptional circumstances Applicants must demonstrate that they are unable to provide comprehensive data on the efficacy and safety under normal conditions of use (e.g. rare conditions)	No direct equivalent procedure
Accelerated assessment CHMP opinion given within 150 days as opposed to 210 days	**Priority review** Regulatory review period shortened from standard 10 months to 6 months
Similar supportive mechanisms to Fast track designation Innovation task force/ SME office/ CHMP scientific advice & protocol assistance/ Qualification of novel methodologies for medicine development	**Fast track designation** Facilitate development and expedite review of drugs through more frequent FDA interaction and rolling review of data
Similar supportive mechanisms to breakthrough designation Innovation task force/ SME office/ CHMP scientific advice & protocol assistance/ Qualification of novel methodologies for medicine development	**Breakthrough designation** Expedite the development and review of drugs through more intensive FDA guidance and commitment to involve senior management
Orphan Designation A supportive legislative framework for medicines for rare diseases was adopted in Europe in 2000 (Regulation (EC) 141/2000). Although similarities exist, the criteria and processes for designation are not internationally harmonised. However, a common joint EMA/FDA orphan designation application form is available	**Orphan Designation** A supportive legislative framework for medicines for rare diseases was adopted in the USA in 1983 (the Orphan Drug Act).