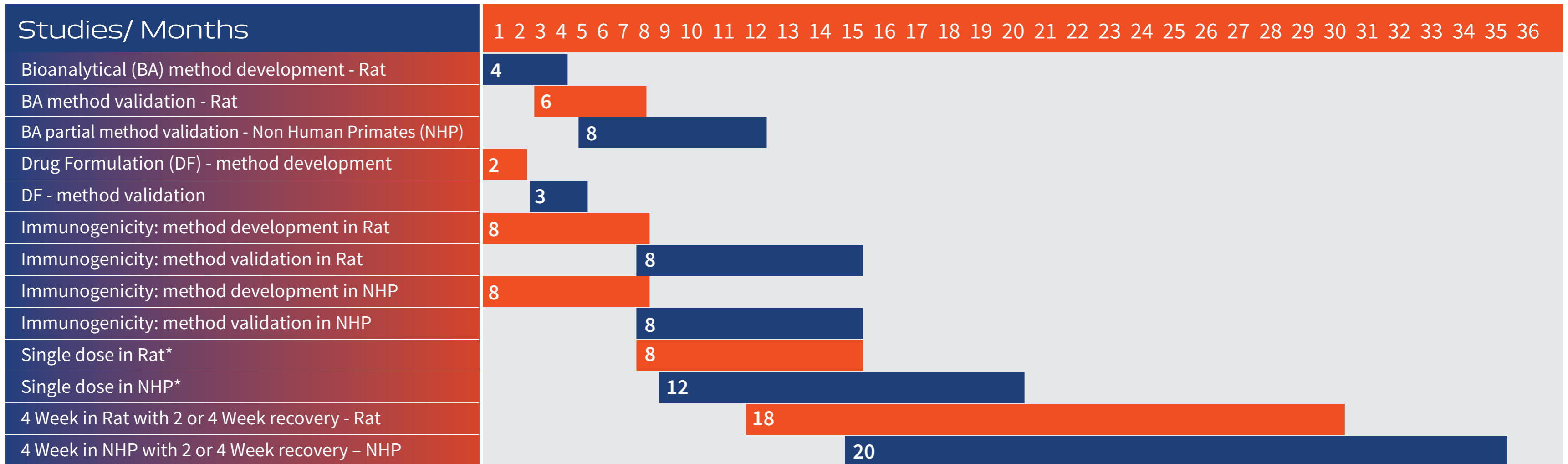


Nonclinical Safety Assessment of New Biological Entities (NBEs)

IND in 9 Months



*Study duration based on PK

Species Selection:

Pharmacology as a primary factor; may be one or two species

Dose Selection:

Based on pharmacology or maximum feasible dose

Pivotal Toxicology:

One species - up to six months in duration

Safety Pharmacology:

Part/all may be in toxicology studies

Genetic Toxicology:

May not be required

The timeline can be optimized upon an understanding of the molecule and regulatory pathway