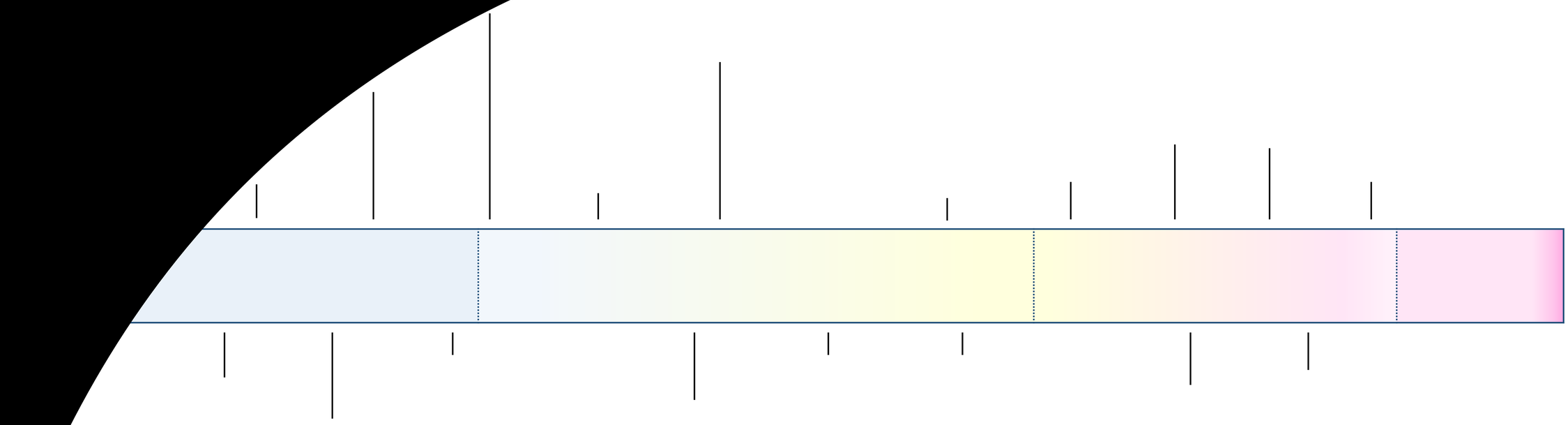
The Drug Development Process

IND Enabling Studies:
Test animals for toxicity; demonstrate potential efficacy; select dose(s) to be given in trials

FDA Review of IND Application:
FDA considers: potential risks of the drug and potential for benefit; FDA may request additional pre-clinical (animal) studies to address questions about risk and/or benefit. Sponsor proceed with clinical trials until FDA reviews & approves plan for studies in humans.

Keeping Patients Safe
Data Safety & Monitoring Board (DSMB) oversees safety & monitors data quality
IRBs oversee ethical conduct of research & protection of human subjects
Study team monitors patient safety; documents & reports any adverse events
Patients / families notify study team if there are side effects or any safety concerns

[illegible] results of animal studies, and proposed plan for clinical trials.



Select Outcome Measures
To know if a drug is effective, researchers need to measure its effects on the individual and the disease. Does the drug slow disease progression? Does the drug treat certain specific symptoms? To answer these questions, researchers select outcome measures that can tell us if the drug has a meaningful impact on how the patient