

	1. Basic research	2. Development	3. NDA & Regulatory approval application	4. Production, Quality, Information Provision & Product Distribution	5. Post manufacturing and distribution
Events & key items	<p>Basic research</p> <ul style="list-style-type: none"> • Search and screening of candidates • Research on physical & scientific properties 	<p>Non-clinical studies</p> <ul style="list-style-type: none"> • Pharmacodynamics • Pharmacokinetics • Toxicity <p>Clinical studies</p> <ul style="list-style-type: none"> • Phase I • Phase II • Phase III <p>CMC</p> <ul style="list-style-type: none"> • Manufacturing procedures, specifications • Stability 	<p>New drug application (NDA)</p> <p>CMC</p> <ul style="list-style-type: none"> • Manufacturing business and other licenses <p>Regulatory approval</p>	<ul style="list-style-type: none"> • Production • Product quality management • Pursuing safe & appropriate drug use • Product information • Disease education • CME 	<ul style="list-style-type: none"> • PMS • Post-Marketing clinical trial • Partial change • Investigators Initiated Trial (IIT)
Related regulation & guidelines	<ul style="list-style-type: none"> • PAL • GLP 	<ul style="list-style-type: none"> • PAL • ICH • GLP • GCP • Investigational drug GMP 	<ul style="list-style-type: none"> • PAL • ICH 	<ul style="list-style-type: none"> • PAL • GMP, GVP • JPMA guidelines • GQP, JGSP • Fair Trade Committee • Company guideline 	<ul style="list-style-type: none"> • PAL • GPSP • GVP
Related JPMA guideline disclosing items	<ul style="list-style-type: none"> • Joint research expenses • Research commissioning expenses 	<ul style="list-style-type: none"> • Clinical study expense 	<ul style="list-style-type: none"> • Expenses for experts advices 	<ul style="list-style-type: none"> • Academic research support expenses • Manuscript/writing fees, etc. • Information provision-related expenses 	<ul style="list-style-type: none"> • PMS expenses • Post-marketing clinical study expenses • Adverse drug reaction / infection case reporting expenses