

Mission Critical 505 (b)(1) or (2) Product Launch Excellence & Value Proposition Workflow (continuum)

Product Development & Market Alignment Integration Starts at TPP (Timelines & Benchmarks)

TPP–Target Product Profile

CMC–Chemistry, Manufacturing, Control

HTA–Health Technology Assessments

PoC–Proof of Concept

PRO–Patient reported outcomes

RoA–Route of Administration

RWE–Real-World Evidence

- TPP**
- R&D
 - Legal
 - Regulatory
 - Management Team
 - Medical Affairs
 - Brand Marketing
 - Compliance
 - Market Access
 - Supply Chain
 - Distribution

- CMC**
- Knowledge Transfer
 - Batch Production
 - Scale-up
 - Packaging
 - Temp specs

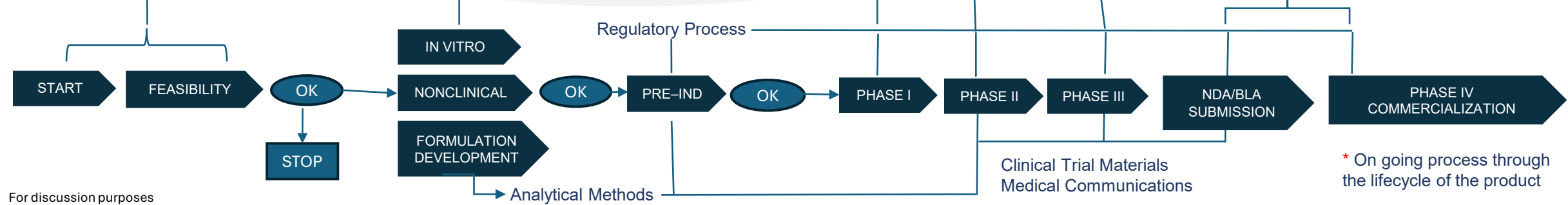
- Nonclinical**
- PoC
 - Pharmacology
 - Biodistribution (ADME)
 - PK studies
 - Toxicology

- Packaging, Formulation, Supply

- Clinical**
- Cost of Treatment
 - Specifications
 - Methods
 - Validation
 - Safety
 - Indication
 - RoA

- Physician Acceptance
- KOL- Advisory Meeting
- Product Positioning
- Value Proposition Development
- Pharmacy Assessment
- Pricing Assessment
- AMCP Dossier
- PRO
- Health economics/HTA
- Care pathway/guidelines
- Long term outcomes

- Market Access***
- Reimbursement
 - Payer Liaison
 - Value Proposition
 - Messaging
 - Publication Strategy
 - Dossier Strategy Development
 - Real World Evidence and Data
 - Competitive Claims Data
 - Indication Differential
 - HUB Strategies
 - Patient Assistance Programs
 - Copay programs
 - Free meds programs
 - Temp coverage
 - Adherence programs
 - Disease specific tools



* On going process through the lifecycle of the product