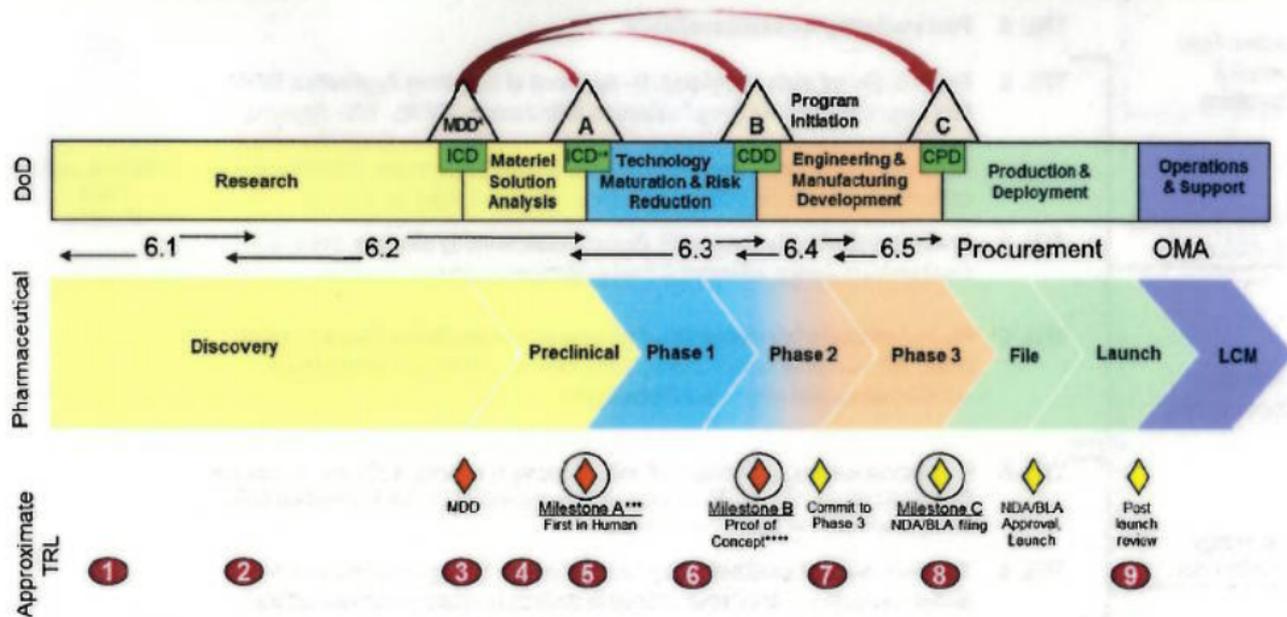


Medical Product Development Lifecycle



* Based on agreed development plan and back-up strategy multiple candidates may move through the development process.

** At a minimum, MRMC MDA requires an ICD at MS A; IPTs should develop a draft CDD for MS A if possible.*** First in Human (FIH) decision should occur after the FDA pre-Investigational New Drug Application (IND) meeting if being conducted. Not all projects will have a pre-IND meeting.

**** If FIH is a small trial, a Milestone A may occur after positive results are obtained to understand if there is a potential materiel solution to a known threat.